Fifth Circuit rules USDA without authority to shut down Texas packing plant for salmonella *contamination*

In mid-December 2001, the Fifth Circuit Court of Appeals held that the United States Department of Agriculture ("USDA") exceeded its authority when it shut down a Supreme Beef Processors plant in Dallas after the processor failed three rounds of tests for *Salmonella* contamination. *Supreme Beef Processors, Inc. v. Dept. of Agriculture*, 2001 U.S. App. Lexis 26205 (5th Cir. 2001). This ruling is significant in that it calls into question the enforceability of certain microbial performance standards set for meat and poultry plants in USDA's new system of food safety inspection known as the Hazard Analysis and Critical Control Point ("HACCP") rule.

The purpose of this article is to give a brief overview of the HACCP rule and the controversy stemming from its adoption, to detail the court's analysis, and to describe reaction to the decision from various interests.

Background on the HACCP rule

Deemed a "state-of-the-art approach to food safety," HACCP is a food safety program that was developed by private industry over forty years ago to produce food for the space program. Traditionally, industry and regulators have used spot-checks of manufacturing conditions and sampling of final products for contamination to ensure a safe food supply. HACCP is a food process control system layered over that regime that is designed to mitigate risk in food safety by instituting specified procedures at critical points in the production process. As such, the HACCP approach is preventive rather than reactive because it prevents problems from happening in the first place instead of detecting problems after they have occurred.

During the 1980s, there was widespread adoption of HACCP by industry due to concerns over high-profile outbreaks of deadly pathogens such as *Listeria monocytogenes*. Allison Beers, Paul Shread, *HAACP Under Siege: Legal Challenges, Enforcement Consequences*, p. 7, Food And Chemical News (Mar. 2000). In 1985, the National Academy of Sciences issued a report recommending that the federal government adopt HACCP for regulation of meat, poultry, seafood, and other food products. *Id.* However, this recommendation took over a decade to implement.

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Forum selection clause in Monsanto technology agreement ruled enforceable

In an appeal involving several damages actions brought by Alabama farmers who had purchased and planted transgenic Monsanto cottonseed, the Alabama Supreme Court has held that the forum selection clause in the Monsanto technology agreement signed by the farmers was enforceable. *See Ex parte Monsanto Co.*, Nos. 1001766, 1001916, 1001917 & 10011767, 2002 WL 64734, at *1 (Ala. Jan. 18, 2002) (not yet released for publication). The farmers had commenced their damage actions against Monsanto and other defendants in Alabama. The forum selection clause, however, recited that the parties to the technology agreement had consented to the exclusive jurisdiction of the federal and state courts in St. Louis, Missouri, Monsanto's principal place of business. Over Monsanto's objection, the trial court refused to enforce the forum selection clause on the grounds that it was unfair and unreasonable and therefore unenforceable. On appeal, the Alabama Supreme Court overturned the trial court's decision, holding that the trial court had abused its

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- Farm Bill

With respect to meat inspection, it was the outbreak of foodborne illness caused by *E. coli 0157:H7* in Jack-in-the-Box hamburgers that focused the attention of the public, Congress, and USDA on the shortcomings of traditional methods of inspection for meat products. *Id.* Meat and poultry inspections based on organoleptic evaluation alone did not address microscopic pathogens like *E. coli 0157:H7,* which are the major cause of foodborne illness. Beyond the Jack-in-the-Box incident, modernization of the meat and poultry inspection system was also prompted by the development of new and highly consolidated meat and poultry production methods, widespread transportation, scientific advances, mutation and emergence of new pathogens, research, and new ways of detecting and tracing foodborne illnesses. *Food Safety and Inspection Service, Questions and Answers/Hazard Analysis and Critical Control Point (HACCP) Systems*, http://www.fsis.usda.gov/oa/haccp.

In 1996, after informal notice and comment rulemaking, the Food Safety and Inspection Service ("FSIS"), the agency within USDA responsible for food safety inspection, published regulations requiring all meat and poultry processors to adopt a HACCP system. *Pathogen Reduction; Hazard Analysis and Critical Control Point (HACCP) Systems*; Final Rule, 61 Fed. Reg. 38806 (July 25, 1996). In order to enforce HACCP, FSIS established pathogen reduction performance standards for *Salmonella* that slaughter establishments and establishments producing raw ground products must meet. *Id.* Under that regime, raw meat products may not test positive for *Salmonella* at a rate that exceeds a performance standard, or "passing mark," which is determined based on FSIS' "calculation of the national prevalence of *Salmonella* on the indicated raw product." 9 C.F.R. § 310.25(b)(1). If an establishment fails to meet the standard on at least three consecutive series of tests, FSIS will deny inspection services to that entity. 9 C.F.R. § 310.25(b)(3). Specifically, the regulations provide that the third failure to meet the performance standard "constitutes failure to maintain sanitary conditions and failure to maintain an adequate HACCP plan...for that product, and will cause FSIS to deny inspection services." *Id.* In effect, denial of inspection services is fatal to an establishment's business as all meat products must pass USDA inspection in order to be legally sold to consumers.

In implementing the *Salmonella* performance standard, FSIS explained the purpose of the standard and its relation to HACCP as follows: "The likelihood of product contamination by *Salmonella* is affected by factors in addition to the incidence or degree of fecal contamination, including the condition of incoming animals and cross contamination among carcasses during the slaughter process and further processing. Under HACCP, establishments will be expected to establish controls wherever practicable to address and reduce the risk of contamination with harmful bacteria. The pathogen reduction performance standards FSIS is establishing for *Salmonella* are an important step toward enabling FSIS and the establishment to verify the aggregate effectiveness of an establishment's HACCP controls in reducing harmful bacteria." 61 Fed. Reg. 38846.

Industry was vocally opposed to the *Salmonella* testing standards when they appeared in the final HACCP rule. 61 Fed. Reg. 38851. A central point of opposition centered on the question of whether FSIS has the legal authority to withhold the mark of inspection or to suspend inspection privileges for failure to meet established standards of performance. *Id.*

Notwithstanding this uncertainty, the HACCP rule held together during the initial years of its implementation. Several factors may account for this stability. First, FSIS readily put suspensions in abeyance, which made plants less likely to challenge the legality of the HACCP rule. Beers and Shread at 11. Second, the agency sought enforcement actions under the HACCP system only against plants with egregious problems. *Id.* If such a plant were to take the agency to court to fight enforcement under any aspect of HACCP, the entity could endure substantial negative publicity. Further, if the conditions were particularly reprehensible, the court would be reluctant to allow it to keep operating. *Id.*

Enforcement against Supreme Beef processors

During the two years following USDA's implementation of the HACCP regulation, several plants failed the *Salmonella* performance standard one and two times. Beers and Shread at 17. But, no plant failed all three sample sets so as to bring about denial of inspection services. *Id*.

In October 1999, Supreme Beef Processors, Inc. ("Supreme Beef"), a meat processor and grinder, became the first plant to fail the third set of tests. 2001 U.S. App. Lexis 26205 at 7. When FSIS decided to suspend inspection of Supreme Beef's plant, Supreme Beef brought suit against USDA alleging that FSIS, in creating the *Salmonella* standard, had overstepped the authority given to it by Congress in the Federal Meat Inspection Act ("FMIA"). *Id.* In addition to the complaint, Supreme Beef moved for a temporary restraining order to prevent USDA from withdrawing its inspectors. *Id.* at 8.

At the district court level, the U.S. District Court for the Northern District of Texas granted Supreme Beef's motion as well as a request for a preliminary injunction. *Id*. On cross motions for summary judgment, the court ruled in favor of Supreme Beef, finding that the *Salmonella* performance standard exceeded USDA's statutory authority. *Id.* The court then entered a permanent injunction to stop enforcement of that standard against Supreme. *Id.*

On appeal, the Fifth Circuit affirmed the district court. In reaching this decision, the court began its analysis by enunciating the Supreme Court's rule in *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc. Id*. at 14. Under that approach, the court's inquiry consists of two steps. First, the court looks to the plain language of the statute and determines whether the agency construction conflicts with the text. *Id*. Second, if the agency's interpretation is not in direct conflict with the plain language of

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VOL. 20, NO. 2, WHOLE NO. 219 January 2002

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Agricultural Law Update is published by the American Agricultural Law Association, Publication office: Maynard Printing, Inc., 219 New York Ave., Des Moines, IA 50313. First class postage paid at Des Moines, IA 50313.

Letters and editorial contributions are welcome and should be directed to Linda Grim McCormick, Editor, 2816 C.R. 163, Alvin, TX 77511.

the statute, the court gives deference to the agency. *Id*. Here, the district court held that USDA had exceeded its authority in developing the *Salmonella* performance standard under the first step of *Chevron*. *Id*.

On review, the appellate court first examined the text of the statute that USDA relied on for its authority to impose the standards. *Id*. at 15. Under the FMIA, the Secretary of Agriculture is commanded to: "where the sanitary conditions of any such establishment are such that the meat or meat food products are rendered adulterated,...refuse to allow said meat or meat food products to be labeled, marked, stamped or tagged as 'inspected and passed.'" 21 U.S.C. § 608. The FMIA contains several definitions of "adulterated." Section 601(m)(4) of Title 21 classifies a meat product as adulterated if "it has been prepared, packed, or held under unsanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health." This definition is broader than that found in 21 U.S.C. § 601(m)(1), which defines a meat product as adulterated if: "it bears or contains any poisonous or deleterious substance which may render it injurious to health; but in case the substance is not an added substance, such article shall not be considered adulterated under this clause if the quantity of such substance in or on such article does not ordinarily render it injurious to health."

In defending the *Salmonella* standard, USDA cited § 601(m)(4) as its authority for the regulation. 2001 U.S. App. Lexis 26205 at 15. After reviewing this provision, the court concluded that the use of the word "rendered" in the statute indicates that a deleterious change must occur while the meat product is being "prepared, packed or held." *Id.* at 20. Therefore, a characteristic of the raw material like *Salmonella* that exists before the product is "prepared, packed or held" in a processing establishment cannot be regulated by USDA under § 601(m)(4). Id.

In response, USDA countered that the *Salmonella* performance standard at issue in this case serves as a proxy for the presence or absence of pathogen controls. Id. at 21. As such, a high level of *Salmonella* indicates adulteration under § 601(m)(4). *Id*. The court rejected this argument, however, on the basis that Supreme Beef has maintained throughout this litigation that it failed to meet the performance standard not because of any condition of its facility, but because it purchased beef trimmings that had higher levels of *Salmonella* than other cuts of meat. *Id*. at 23. When USDA failed to dispute this assertion, the court held that the performance standard was invalid because it regulates the procurement of raw materials, not the implementation of pathogen controls in the plant. *Id.*

Notwithstanding this holding, USDA and its amicus supporters argued that there is no meaningful distinction between contamination that arrives in raw materials and contamination that arises from other conditions in the plant because Salmonella can be transferred from infected meat to non-infected meat through the grinding process. *Id*. at 26. But, the court noted that the *Salmonella* standard does not measure the differential between incoming and outcoming meat products in terms of the Salmonella infection rate. *Id*. at 27. Rather, it measures the final meat product for *Salmonella* infection. *Id*. Because there is no corresponding determination of the incoming *Salmonella* baseline, the performance standard cannot serve as a proxy for cross-contamination. *Id*.

Interestingly, USDA never asserted authority for the *Salmonella* performance standard under § 601(m)(1). However, the court stated that the presence of *Salmonella* would not render a meat product "injurious to health" under this subsection because normal cooking practices for meat and poultry destroy the organism. *Id*. at 16. In fact, beef infected with *Salmonella* is routinely labeled "inspected and passed" by USDA inspectors and is legal to sell to the consumer. *Id*.

Reaction to the *Supreme Beef* decision

Prior to the Fifth Circuit's decision, the Supreme Beef situation had garnered substantial attention from a variety of interests. This may be due in part to the fact that Supreme Beef was a large supplier of ground beef for the national school lunch program. See *Beef Plant That Failed Test Challenges Screening System*, The Dallas Morning News, Dec. 10, 1999 ("Before losing the contracts, Supreme Beef had supplied 14 million of the 90 million pounds of ground beef purchased since July 1 for the national school-lunch program, according to the government."). In addition, Supreme Beef was the first plant to feel the true impact of the new *Salmonella* standards.

Following the appellate court's review, the debate continues. On December 18, 2001, Secretary of Agriculture Veneman released the following statement on behalf of the Administration: "This ruling does not impair our ability to close plants that do not meet the statutory and regulatory requirements of the law for processing meat and poultry. We can and will shut down plants that do not meet that responsibility. We will increase our vigilance in meat plants to ensure compliance and the safety of our food supply." *USDA to Continue Testing for Salmonella in Meat Plants*, U.S. Dept. of Agriculture, News Release No. 0267.01 (Dec. 18, 2001).

To carry out this plan, Veneman indicated that USDA will continue to test for *Salmonella* in grinding plants to verify that the plant's food safety systems are meeting required specifications. *Id*. If a plant fails two sample sets, USDA will immediately conduct an in-depth review of the plant's food safety systems and identify corrective actions to be taken. *Id*. Failure by the plant to address any deficiencies will result in suspension or withdrawal of inspection. *Id*. Further, the agency will take the following actions: (1) conduct a comprehensive review of current food safety regulations and work with interested parties to determine if science-based changes are necessary to strengthen the HACCP system, (2) expedite the placement of 75 new consumer safety officers with the primary responsibility of conducting in-depth reviews of plant HACCP plans throughout the country, with particular emphasis on facilities that fail a second sample set or do not meet HACCP requirements, (3) review training procedures for USDA plant inspectors and enhance HACCP training to ensure inspectors clearly understand their responsibilities in the wake of the court decision, and (4) conduct a series of public meetings to gain input from interested parties about how to strengthen food safety programs. *Id*.

On Capitol Hill, several members of Congress have expressed their concern about the court's decision and their intent to introduce legislation to explicitly empower USDA to close down facilities that repeatedly fail to meet minimum food quality standards. In a recent "Dear Colleague" communication, Senators Harkin, Durbin, and Schumer along with Congresswomen Eshoo, DeLauro, and Lowey wrote: "We believe that the court's ruling was erroneous and dangerous to public health." In making the case for legislation to their peers, the members cited a recent New York Times editorial where the press stated: "The decision's practical impact was to gut the government's power to rely on new scientific methods of policing meat safety that make it easier to detect and significantly limit the invisible hazard of bacterial contamination." *A Threat to Meat Inspection*, The New York Times (Dec. 26, 2001).

From the other side, the National Meat Association, an intervenor at the appellate level, praised the court's ruling.In a news release dated December 11, 2001,

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Supreme Court holds utility patents may be issued for plants

By Anne Hazlett

On December 10th, the Supreme Court issued a long-awaited opinion in *J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred International, Inc.*, 2001 U.S. Lexis 10949. This case addressed the question of whether utility patents may be issued for plants under 35 U.S.C. § 101 or whether the Plant Variety Protection Act, 7 U.S.C. § 2321 et seq., and the Plant Patent Act of 1930, 35 U.S.C. §§ 161-164, are the exclusive means of obtaining a federal right to exclude others from reproducing, selling, or using plants or plant varieties. In a 6-2 decision, a majority of the Court held that utility patents issued under 35 U.S.C. § 101 to Pioneer Hi-Bred International ("Pioneer") for the manufacture, use, sale, and offer for sale of its corn plants and corn seed products were valid.

Background

Pursuant to 35 U.S.C. § 101, the United States Patent and Trademark Office has issued over 1,800 utility patents for plants, plant parts, and seeds. *Id*. at 7. Pioneer holds seventeen of these patents for its inbred and hybrid corn plants and corn seed products. *Id*. Such patents cover the manufacture, use, sale, and offer for sale of the company's products. *Id.*

With respect to its patented hybrid seeds, Pioneer has a limited label license, which provides: "License is granted solely to produce grain and/or forage." *Id*. at 9. The license "does not extend to the use of seed from such crop or the progeny thereof for propagation or seed multiplication." *Id*. It then prohibits "the use of such seed or the progeny thereof for propagation or seed multiplication or for production or development of a hybrid or different variety of seed." *Id*.

Petitioner J.E.M. Ag Supply, Inc., doing business as Farm Advantage, Inc. ("Farm Advantage"), purchased patented hybrid seeds from Pioneer. *Id.* Although Farm Advantage is not a licensed sales representative of Pioneer, it resold bags of this seed bearing the license agreement described above. *Id*. Pioneer brought a patent infringement action against Farm Advantage as well as several of its distributors and customers. *Id*. There, Pioneer alleged that Farm Advantage was infringing one or more of its patents by "making, using, selling or offering for sale" corn seed of the protected hybrids. *Id*. at 10.

Farm Advantage answered with a general denial of patent infringement. *Id*. More importantly, however, Farm Advantage entered a counterclaim of patent invalidity in which it argued that patents that purport to confer protection for corn plants are invalid because sexually reproducing plants are not patentable subject matter within the scope of 35 U.S.C. § 101. Farm Advantage maintained that the Plant Patent Act of 1930 ("PPA") and the Plant Variety Protection Act ("PVPA") are the exclusive statutory means for the protection of plant life because these provisions are more specific than § 101. *Id*.

A district court in the Northern District of Iowa granted summary judgment in favor of Pioneer. *Id*. at 11. In so doing, it relied on the Supreme Court's broad construction of § 101 in *Diamond v. Chakrabarty*, 447 U.S. 303 (1980). *Id*. Further, the district court reasoned that in enacting the PPA and the PVPA. Congress neither expressly nor implicitly removed plants from the coverage of § 101. *Id*. Specifically, the court noted that Congress did not repeal § 101 by implication when it passed the more specific PVPA because there was no irreconcilable conflict between the two statutes. *Id*. The United States Court of Appeals for the Federal Circuit affirmed this judgment and reasoning. *Id*.

After granting certiorari, the Supreme Court affirmed. Justice Thomas delivered the opinion of the Court in which Chief Justice Rehnquist and Justices Scalia, Kennedy, Souter and Ginsburg joined. Justice Scalia filed a concurring opinion. Justice Breyer filed a dissenting opinion in which Justice Stevens joined. Justice O'Connor did not take part in the decision of the case.

Analysis

Majority opinion

In approaching the question presented in this case, the Court first noted that it has already interpreted the language of 35 U.S.C. § 101 as being extremely broad. *Id*. at 12. The text of § 101 reads: "Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title." *Id*. In *Diamond v. Chakrabarty*, 447 U.S. at 308, the Court held that in using such expansive terms as "manufacture" and "composition of matter," Congress contemplated that patent laws would be given wide scope. Thus, the Court concluded that living things, specifically man-made microorganisms, were patentable under § 101. *Id*. It explained that "the relevant distinction was not between living and inanimate things, but between products of nature, whether living or not, and human-made inventions." *Id*. (quoting *Chakrabarty*, 447 U.S. at 313).

With this precedent in mind, the Court turned to the question of whether either plant specific statute, the PPA or PVPA, forecloses utility patent coverage for plants by providing the exclusive means of protecting new varieties of plants. 2001 U.S. Lexis 10949 at 14. In considering the PPA, which confers patent protection to asexually reproduced plants, the Court held that nothing in either the original 1930 text of the statute or its 1952 amendment indicates that its protection was intended to be exclusive. *Id*. at 15. The 1930 Act amended the general utility patent provision to provide protection only to the asexual reproduction of a plant. *Id*. And, the 1952 amendment, which moved plant patents into a separate chapter of Title 35 entitled "Patents for Plants," was merely a "housekeeping measure" that did not change the substantive rights or requirements for obtaining a plant patent. *Id*. at 16. A plant patent issued under 35 U.S.C. § 161 as distinguished from a § 101 utility patent, continued to provide only the exclusive right to asexually reproduce a protected plant. *Id*. at 17. Further, plant patents required a less stringent description requirement than § 101 utility patents. *Id*.

After determining that the plant patent protection chapter states nowhere that plant patents are the exclusive means of granting intellectual property protection to plants, the Court rejected three arguments why the PPA should preclude issuing utility patents for plants. *Id*. at 18. First, Farm Advantage argued that plants were not covered by the general utility patent statute prior to 1930 because if they were covered then there would have been no reason for Congress to have passed the 1930 PPA. *Id*. In response, the Court stated that Congress' actions in enacting the 1930 PPA merely illustrate that Congress may have believed that plants were not patentable under § 101—not that they actually were not patentable. *Id*. at 19. Congress may have thought that plants were not patentable because they were living things and because they could not meet the stringent description requirement contained in § 101. *Id*. But, these shortcomings were disproved over time. *Id*. In fact, plants have always had the potential to fall within the general subject matter of § 101, which is a dynamic provision designed to accommodate new types of inventions that are often unforeseeable. *Id*. at 20.

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Second, Farm Advantage contended that the PPA's limitation to asexually reproduced plants would make no sense if Congress intended § 101 to authorize patents on plant varieties that were sexually reproduced. *Id*. at 21. The Court disagreed, stating that this limitation merely reflects the reality of plant breeding in 1930 when the PPA was enacted. *Id*. At that time, the primary means of reproducing plants true-to-type was through asexual reproduction. *Id*. Further, at the time Congress passed the PPA, there was no significant need to protect seed breeding because most farmers were receiving seed from the government's free seed program. *Id*. at 22. In addition, seed companies lacked the scientific knowledge to engage in formal breeding that would increase agricultural productivity. *Id*. at 23.

Third, Farm Advantage maintained that Congress would not have moved plants out of the utility patent provision and into a separate plant patent chapter in 1952 if it had intended § 101 to allow for protection of plants. *Id*. at 25. In rejecting this contention, the Court stated that this negative inference does not support carving out subject matter from the expansive language of § 101 because § 101 protects different attributes and has more stringent requirements than the plant patent chapter. *Id*.

Looking at the PVPA, which provides plant variety protection for sexually reproduced plants, the Court found no evidence of Congressional intent to deny § 101 protection to plants. The PVPA contains no statement of exclusivity. *Id*. at 30. Further, at the time the PVPA was enacted, the PTO had already issued numerous utility patents for hybrid plant processes so as to affirm that such material was within the scope of § 101. *Id*.

In addition, the Court rejected an argument that the PVPA altered the coverage of § 101 by implication on the basis that the statutes are not irreconcilable. *Id*. at 31. There are differences in the requirements for, and coverage of, utility patents and plant variety certificates issued under the PVPA. *Id*. In order to obtain a utility patent, a breeder must show that the plant is new, useful and non-obvious. *Id*. at 32. Further, the breeder must describe the plant with sufficient specificity to enable others to make and use the invention once the patent term expires. *Id*. This description requirement includes a deposit of biological material such as seeds that is accessible to the public. *Id*. By contrast, a breeder can receive a plant variety protection certificate without a showing of usefulness or non-obviousness. *Id*. The statute requires only that the variety be new, distinct, uniform, and stable. *Id*. In addition, the PVPA requires less description and disclosure than § 101. *Id*.

In light of these differences, the Court concluded that holders of a utility patent receive greater rights of exclusion than holders of a plant variety protection certificate. *Id*. at 33. There are no exemptions under a utility patent for research or saving seed. *Id*. Moreover, a plant variety protection certificate does not grant the full range of protection afforded by a utility patent. *Id*. For example, a utility patent on an inbred plant line protects that line as well as any hybrids produced by crossing that inbred into another plant line. *Id*. Under the PVPA, however, a breeder can use a plant that is protected by a plant variety protection certificate to "develop" a new inbred line. *Id*.

Finally, the Court noted that the PTO has assigned utility patents for plants for at least sixteen years with no indication from Congress or any relevant agencies that such coverage is inconsistent with the PPA or the PVPA. *Id*. at 36. In fact, Congress has even recognized the availability of utility patents for plants. *Id*. at 37. In a 1999 amendment to 35 U.S.C. § 119, which concerns the right of priority for patent rights, Congress provided that applications for plant breeder's rights filed in a World Trade Organization member country shall have the same effect for the purpose of the right of priority as applications for patents. *Id*. The fact that this amendment was part of the general provisions of Title 35 rather than the plant specific chapter suggests a recognition by Congress that plants are patentable under § 101. *Id*.

Concurring opinion

Justice Scalia wrote a concurring opinion in which he maintained that the only ambiguity in § 101 that could have been clarified by the PPA is whether the term "composition of matter" included living things. *Id*. at 38. Scalia argued that the PPA, as a newly enacted provision for plants, certainly invited the conclusion that this term did not include living things. *Id*. at 39. The term "matter," after all, is sometimes used in a sense that excludes living things. *Id*.

Nevertheless, Scalia agreed that the Court's previous opinion in *Chakrabarty* prevents the Court from reading the term "composition of matter" as ambiguous on the question of whether it includes living things. *Id*. In this posture, therefore, the PPA should be deemed to amend, not clarify, § 101 if it is to have any effect on the outcome. *Id*.

Dissenting opinion

Justice Breyer, joined with Justice Stevens, wrote a dissenting opinion in which he argued that the Court's decision in *Chakrabarty* should not control the outcome of this case. *Id*. at 41. Breyer disputed the majority's reliance on *Chakrabarty* because that decision said nothing about the specific issue before the Court in this case. *Id*. In considering the scope of the utility patent statute's language "manufacture, or composition of matter," *Chakrabarty* asked whether those words included such living things as bacteria—not plants which are the subject of the specific statutes at issue in this case. Id. at 42.

Putting the Court's holding in *Chakrabarty* aside, the dissent then stated that the words "manufacture" and "composition of matter" in § 101 do not cover plants. That is because Congress intended the two more specific statutes, the PPA and PVPA, to exclude patent protection under the utility patent statute for the plants to which the more specific statutes directly refer. *Id*. at 40. To read the PPA as compatible with the claim that the utility patent statute also covers plants would virtually nullify the PPA's primary requirement that the breeder have reproduced the new characteristic through a graft. *Id*. at 49. Moreover, since the utility patent statute would forbid reproduction by seed, such a holding would read out of the statute the PPA's more limited list of exclusive rights. *Id*. Similarly, with respect to the PVPA, nothing in the history, language, or purpose of the 1970 statute suggests an intent to reintroduce plants, the subject matter that the PPA removed, into the scope of the general words "manufacture, or composition of matter." To the contrary, any such reintroduction would make the PVPA's exceptions for planting and research meaningless. *Id*. at 52.

Conclusion

The Court's decision in *J.E.M. Ag Supply* brings a sharp focus to an important policy debate in production agriculture. On one hand, companies such as Pioneer who engage in costly seed development argue that they deserve patent protection that will ensure that they receive compensation for up to twenty years once their seeds are used. Without patent rights, industry will be unable to protect new developments from copycats. And, without such protection, many compa-

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nies simply will not invest in creating new technology.

On the other hand, however, issuing utility patents on seed may have serious consequences for farmers and future research. Most notably, the Court's ruling affirms the ability of seed companies to sue those who try to save or reuse protected seed in violation of a patent. The decision may also increase seed costs as companies pass the costs of obtaining patent protection through to their farmer customers. In this light, the ruling may be viewed as punishing farmers by driving up the costs of production. But, industry can also counter that by protecting the profits of agribusiness firms, the ruling ensures that new, more efficient varieties of plants will keep coming to market.

Beyond the economic impact on farmers, the *J.E.M. Ag Supply* decision raises additional concern with respect to research. Some critics contend that the ruling will perpetuate a system that slows the pace and diversity of research. Melinda Fulmer, *Patent Ruling Aids Seed Biotech Firms*, L.A. Times, Dec. 11, 2001. Public research institutions will be encouraged to patent more of their research efforts. They may also redirect the focus of their work from the needs and wants of farmers and consumers towards big business who is willing to buy the rights to patents or otherwise support public research projects. See David Dechant, *Pioneer v. J.E.M. Ag Supply May Sprout Rude Awakening*, http://www.cropchoice.com. In addition, the decision could impact public plant breeding in that there will be less sharing of information and germplasm.

Finally, there is concern that the Court's ruling could further accelerate an already rapidly consolidating agribusiness industry. To the extent that small seed companies are now prevented from finding new breeding material because of patent protection, the seed market will become even more concentrated.

Notwithstanding this difficult policy debate, the Court's decision in *J.E.M. Ag Supply* sends a strong signal that the high court is taking a tough stance on intellectual property rights. Should seed companies respond to this decision with increased litigation against farmers, look for the farm community to seek relief from Congress in order to keep plants in the public hands.

MonsantoCont. from page 1
discretion by refusing to enforce the forum selection clause in the technology agreement. *See id*. at *7.

Farmers who purchase Monsanto transgenic cottonseed, such as Bollgard™, are required to pay a licensing fee and sign a "Technology Agreement." *Id*. at 1. The technology agreement sets forth certain conditions and restrictions regarding the use of the transgenic cottonseed. It also includes a forum selection clause. This clause, which appears in the agreement entirely in capital letters, recites that the terms and conditions of the agreement are governed by federal and Missouri law and that the parties consent to the exclusive jurisdiction of the federal and state courts having geographical jurisdiction over St. Louis County, Missouri. *See id*. at *2. Monsanto has its headquarters in St. Louis, Missouri.

Notwithstanding the forum selection clause, the Alabama cotton farmers involved in *Ex Parte Monsanto* brought their respective damages actions against Monsanto and the Alabama sellers of the Monsanto cottonseed in the state circuit courts for Wilcox and Dallas counties, Alabama. They resisted Monsanto's attempt to dismiss their actions based on the forum selection clause on three grounds, only one of which was reached by either the trial court or the Alabama Supreme Court. More specifically, the farmers' contentions that their tort claims were not covered by the terms of the technology agreement and that the forum selection clause was an enforceable attempt to limit the jurisdiction of Alabama courts were left unresolved. *See id*. at *4. Instead, the trial court ruled that the forum selection clause was unenforceable under the circumstances because the farmers had shown that the forum selection clause was unfair and unreasonable. *See id*. On appeal to the Alabama Supreme Court through Monsanto's petition for writ of mandamus, the sole issue was the propriety of this ruling.

Because the Alabama Supreme Court had never reviewed a case involving a dismissal based on a forum selection clause, the court first had to determine the proper standard of review. *See id*. at *2. Its analysis of this issue began with the observation that there was no consensus of the standard of review in similar cases in other jurisdictions. *See id*. Some courts applied an abuse of discretion standard while other courts used the de novo standard. *See id*. at *2-3. The court concluded that the better reasoned rule, the one followed by the majority of state appellate courts, was the abuse of discretion standard. *See id*. at *3.

Having accepted this standard as governing the dispute at issue, the court turned to Monsanto's claim that the forum selection clause was neither unfair nor unreasonable. As to the farmers' arguments to the contrary, the court first considered the cotton farmers' contention that the clause was unenforceable because they had no choice but to purchase Monsanto's technology and therefore had not freely entered into the technology agreement. *See id*. at *5. Monsanto countered this argument by pointing out that it did not control 100% of the cottonseed market; there were conventional cottonseed varieties available for purchase; and, in fact, some of the farmers had purchased conventional cottonseed in previous years. *See id*.

Characterizing the farmers' argument as an implicit invitation to disregard the clause because of their lack of bargaining power, the court declined to do so. Instead, the court noted its earlier decision in another case where it had ruled that disparities in the size of the corporate parties to such a contractual clause and the inability of one party to negotiate changes to the contract is not sufficient, standing alone, to establish "'overweening bargaining power.'" *Id*. (relying on and quoting *Ex parte D.M. White Construction Co.*, No. 1000199 (Ala. June 15, 2001)).

The court then considered cotton farmers' "basic argument" that it would be inconvenient for them and the defendants other than Monsanto to have the trial in St. Louis, Missouri. The farmers argued that they are full-time farmers and need to be present on their Alabama farms "virtually every day." *Id*. at *5. The court dismissed this argument by noting that the farmers did not claim the necessity of being on their respective farms every day, only "virtually every day," which revealed that there will be days when they could be in St. Louis for the trial. *See id*.

The proper question, according to the court, was not whether the farmers would be inconvenienced. Instead, the proper question was whether the chosen forum was convenient for the trial of the actions involved. *Id*. Finding that the farmers' damages actions were based upon their allegations that Monsanto's technology had resulted in their crop losses, the court pointed out that most of the wit-

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Salmonella/Cont. from p.3

NMA wrote: "This decision will serve food safety by focusing USDA on regulatory activities that are relevant to sanitation, as the law requires. The *Salmonella* standard was both arbitrarily enforced and unscientific. It really made no sense at all." *Appeal Court Affirms Supreme Beef Decision*, National Meat Assn., http://www.nmaonline.org. Further, NMA explained: "Despite the fact that this standard was fatally flawed from the beginning, NMA believes that microbial standards do have a place in HACCP. The appropriate 'next step' for USDA would be to initiate rulemaking to develop scientifically sound microbial performance standards." *Id*.

Similarly, the American Meat Institute, which helped fund the appeal, praised the ruling. In a December 12, 2001 news release, AMI wrote: "We are gratified— but not surprised—that the court has affirmed that the *Salmonella* performance standard is scientifically unsupportable as a measure of plant sanitation. It is our hope that USDA will withdraw the standard and rely upon the advice of its National Advisory Committee for Microbiological Criteria for Foods in developing a new, meaningful, scientific standard." *Appeals Court Upholds Lower Court Ruling that USDA Salmonella Performance Standard is Invalid*, American Meat Institute, http://www.meatami.com.

Amidst this dialogue, the National Research Council of the National Academies of Sciences is completing a fourteen-month study that will review the scientific basis for criteria for food and food ingredients. As part of this study, an oversight committee will define the relationship between public health objectives and a HACCP-based approach to food safety; define the terms "performance standards" and "criteria" as related to food products and processes; and recommend guidelines for determining the type of data that should be used in developing food safety criteria, including microbiological performance standards. Perhaps the conclusions reached in the NAS study and its corresponding report to Congress will remove this important food safety issue from on-going litigation.

—Anne Hazlett, Washington, D.C.

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nesses and documents referring to the transgenic technology are located in Monsanto's headquarters in St. Louis. Thus, when measured by convenience to the trial of the damages actions, St. Louis was not inconvenient. *See id*.

The court also addressed the farmers' contention that the forum selection clause should not be enforced because their businesses do not deal on equal terms with Monsanto and their level of sophistication is not equal to Monsanto's. *Id*. at *6. The court rejected this argument by stating that it has never required equal levels of sophistication between the parties as a prerequisite for enforcing a forum selection clause. *See id*. Moreover, reasoned the court, the evidence contradicted the farmers' argument that they were unsophisticated. In this regard, the court noted that some of the farmers were corporate entities engaged in commercial agriculture, with operations in multiple counties, and one had been in the farming business for 75 years. *Id*. The critical question, according to the court, was not the relative levels of sophistication between or among the parties, but rather the proper question was whether the parties signing the forum selection clause were "business-oriented." *Id.*

Finally, the court considered the farmers' argument that Monsanto's use of Alabama courts was inconsistent because Monsanto brought suits in Alabama to collect debts, yet was seeking enforcement of the forum selection clause here. *Id*. The court found little weight in this argument, observing that there was a vast difference between debt collection cases and the tort claims being made under the technology agreement here. *Id*.

In granting Monsanto's petition for mandamus and thus permitting enforcement of the forum selection clause, the Alabama Supreme Court ultimately concluded that Monsanto's technology was at issue in the farmers' damages actions. This, in turn, meant that Monsanto would need to rely on witnesses and documents located at its headquarters in St. Louis, Missouri. St. Louis, therefore, was not an unreasonable forum in this case; the farmers had failed to carry their burden of showing that the forum selection clause was unfair or unreasonable; and the trial court had abused its discretion in ruling that the farmers had met their burden. *Id*. at *6-7.

—Beth Crocker, NCALRI Graduate Fellow

This material is based on work supported by the U.S. Department of Agriculture under Agreement No. 59-8201-9-115. Any opinions, findings, conclusions, recommendations expressed in this article are those of the author and do not necessarily reflect the view of the U.S. Department of Agriculture.

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Law: Professor, Agricultural Law (rank open), Department of Agricultural and Consumer Economics, University of Illinois at Urbana-Champaign. Business organizations, commercial law, taxation and tax policy, natural resources, land use, or other area of agricultural law. Qualifications: JD, superior law school record, excellent research and writing skills, legal research experience, and enthusiasm for educating attorneys and the public on legal issues affecting farmers, agri-businesses, and rural communities. The full announcement is at http://www.ace.uiuc.edu. UIUC is an AA-EOE.