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Transgenic Plants and Substantial Success

This Article discusses the validity of issuing patents for genetically engineered (GE) traits for plants. These patent applications present the USPTO with the issue of authorizing patents that have an ability to create significant detrimental effects on the environment and uncharted risks to health. The patents allow control over enormous segments of world agriculture. Invalidity arises from the utility standard in the Patent Statute.

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I
THE WARNINGS OF HARMS ARISING FROM ISSUING PATENTS FOR GENES ON FORMS OF LIFE RAISED BY THE PATENT OFFICE IN THE *CHAKRABARTY* CASE HAVE BECOME PROPHETIC

A. The Failures

Three postpatent failures of GE plant traits bring to the forefront the allowance of patents for them. These patents ignore environmental consequences that arise when working with genes to be inserted into the plant nucleus.[1] The example trait involved here, increased tolerance to glyphosate, is engineered from a gene contained in a bacterium and forced into the host plant. The inserted gene encodes a special enzyme (Class II EPSPS). The enzyme makes plants resistant to herbicides. It allows the patent holder, Monsanto, to profit from the purchase of two of its commercial products—Roundup, for use with the patented plant, and patented seeds. The asserted benefit from the purchase of Roundup is the elimination of a number of weed species without injury to the patented crop. Roundup contains approximately forty-one percent glyphosate and inert chemicals, including surfactants (discussed below).

Transgenic patents seek approval of claims to intellectual property that oversee vast environmental and social changes. Warnings of hazards from genetic engineering appeared in the briefs of the petitioner, Commissioner of Trademarks and Patents, and amicus curiae in *Diamond v. Chakrabarty*.[2]

The first failure was the appearance of a variety of superweeds on U.S. farmlands following a dramatic rise in the use of Monsanto's Roundup. It became by far the leading herbicide; glyphosate usage in

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1 Second Declaration of Paulette Pierson, Ph.D., In Support of Memorandum at ¶ 35, Geertson Seed Farms v. Mike Johanns, No. C-06-1075 CRB (N.D. Cal. 2007) (222a) [hereinafter Second Declaration].

> Herbicide tolerant weeds are neither a new phenomenon nor exclusively restricted to glyphosate. In 1957, the first herbicide resistant weed was identified in the U.S.—spreading dayflower resistant to 2, 4-D, a synthetic auxin, identified in Hawaii. There are currently 119 weed biotypes in the United States that are resistant to one or more herbicides. Of the herbicide resistant biotypes in the United States, thirty-eight weeds have biotypes that are resistant to ALS herbicides, twenty-three weeds are resistant to triazine herbicides, while only seven weeds have developed biotypes resistant to glyphosate in the United States. This low risk for weed resistance is based on several factors.

Compare her limited tolerant numbers with the references in Barrie, *infra* note 4.

2 447 U.S. 303 (1980).

the United States rose from 7,933,189 pounds for soybeans, corn, and cotton in 1994 to 119,071,000 pounds in 2005.[3]

Monsanto introduced the patented glyphosate tolerant (GT) soybean seed and plant for full utilization in 1996. Monsanto adopted various marketing strategies to enhance its sales of Roundup for use with its patented seeds. A lawsuit filed by organic farmers and seed companies asserts that Monsanto genes are in eighty-five to ninety percent of the country's soybean, sugar beet, corn, cotton, and canola plants.[4] It is estimated that superweeds will appear on forty percent of domestic farmlands planted for corn and soybeans by the middle of the decade.[5] Farmer groups report that 103 biotypes of weeds within sixty-three weed species have herbicide resistance.[6] Superweeds have spread to more than twenty-two states in which corn, cotton, and soybean are raised.[7] One of the weeds, pigweed, is so tough that farmers complain that it damages parts of cotton picking equipment. Monsanto has granted corn farmers who purchased its GT seeds twelve dollars per acre payment to compensate for the cost of other herbicides.[8]

The second failure involves the controversy of gene flow from GE plants. Organic farmers claim that Roundup Ready Alfalfa (RRA) gene flow will make their crops ineligible as organic product. In *Monsanto Co. v. Geertson*, organic farmers brought a case involving alleged contamination from Monsanto's patented RRA.[9] This case is addressed in the section immediately below. A similar action has also been filed in

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3 CENTER FOR FOOD SAFETY, GENETICALLY MODIFIED (GM) CROPS AND PESTICIDE USE (Jan. 2008). The 2006 poundage for soybean alone was 96,725,000 pounds.

4 F.W. Barrie, *A Band of 60 Davids Challenges Monsanto, the Goliath, in Federal Court*, OSGATA.ORG (May 27, 2011), http://knowwhereyourfoodcomesfrom.com/2011/05/27/a-band-of-60-davids-challenges-monsanto-the-goliath-in-federal-court/.

5 Scott Kilman, *Superweed Outbreak Triggers Arms Race*, WALL ST. J., June 4, 2010, at A16.

6 Roy Roberson, *Glyphosate Resistant Weeds a Reality for Cotton Growers*, SOUTHEAST FARM PRESS (Feb. 10, 2006, 9:50 AM), http://southeastfarmpress.com/glyphosate-resistant-weeds-reality-cotton-growers.

7 William Newman & Andrew Pollack, *Farmers Cope With Roundup-Resistant Weeds*, N.Y. TIMES, May 3, 2010, at B1.

8 *Id.*; Vandana Shiva, *Superweeds, Super Pests, and Super Profits*, INFOCHANGE NEWS & FEATURES (Sept. 2011), http://infochangeindia.org/environment/analysis/superweeds-superpests-and-superprofits.html.

9 Geertson Seed Farms v. Johanns, et al., No.C-06-1075 (N.D.Cal.2006), *aff'd*, Monsanto Co. v. Geertson Seed Farms, et al., 570 F.3d 1130 (9th Cir. 2009), *rev'd*, 130 S. Ct. 2743 (2010).

federal court over the genetic engineering consequences of sugar beets.[10] Sugar beet planting has recently been subject to deregulation.

A third failure results from the inability to detect RRA seed in seed lots. A study from the Union of Concerned Scientists demonstrates the concern over contamination.[11] Any plant subject to widespread acreage places thousands of tons of RRA seeds on the market even at a one-half to one percent rate of contamination.[12] The study concluded that traditional varieties of "corn, soybeans, and canola are pervasively contaminated with low levels of DNA sequences derived from transgenic varieties."[13]

B. The *Geertson* Case

The *Geertson* case involved genetically engineered alfalfa. It considered the application of the National Environmental Policy Act, 42 U.S.C. §§ 4331–4335 (1970) (NEPA) over the regulation of GE plant traits by federal agencies. NEPA places duties on the federal government to use all practical means consistent with other essential considerations of national policy to safeguard the environment.

42 U.S.C. § 4331 provides, in part:

> (b) In order to carry out the policy set forth in this chapter, it is the continuing responsibility of the Federal Government to use all practicable means, consistent with other essential considerations of national policy, to improve and coordinate Federal plans, functions, programs, and resources to the end that the Nation may—
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> (1) fulfill the responsibilities of each generation as trustee of the environment for succeeding generations;
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> (2) assure for all Americans safe, healthful, productive, and esthetically and culturally pleasing surroundings;
>
> (3) attain the widest range of beneficial uses of the environment without degradation, risk to health or safety, or other undesirable and unintended consequences;
>
> (4) preserve important historic, cultural, and natural aspects of our national heritage, and maintain, wherever possible, an environment which supports diversity and variety of individual choice;

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10 Ctr. for Food Safety v. Connor, No C08-00484 (N.D. Cal. Dec. 2, 2009).

11 MARGARET MELLON AND JANE RUSSLER, GONE TO SEED, TRANSGENIC CONTAMINANTS IN THE TRADITIONAL SEED SUPPLY (Union of Concerned Scientists 2004), *available at* www.ucsusa.org/assets/documents/food_and_agriculture/seedreport_fullreport.pdf.

12 *Id.* at 2.

13 *Id.* at 1.

> (5) achieve a balance between population and resource use which will permit high standards of living and wide sharing of life's amenities; and
>
> (6) enhance the quality of renewable resources and approach the maximum attainable recycling of depletable resources.
>
> (c) The Congress recognizes that each person should enjoy a healthful environment and that each person has a responsibility to contribute to the preservation and enhancement of the environment.

Until 1986, all federal agencies applied a "worst case analysis."[14] This analysis required an evaluation of the probability of worst-case occurrences that could result from the major action.[15] The 1986 amendment requires an evaluation of the reasonably foreseeable significant adverse impacts of a proposed action on the human environment.

In 1981, the Animal and Plant Health Inspection Service (APHIS) became the federal agency involved with regulating genetically engineered plants. Its powers included the regulation of substances that create plant pests under the Plant Protection Act.[16] APHIS failed to prepare an Environmental Impact Statement (EIS) before allowing the deregulation of Roundup Ready Alfalfa (RRA), the genetically engineered plant tolerant to glyphosate.[17] Alfalfa is not thought to have a problem with windblown pollen. However, bees and insects can carry RRA pollen, distributing it onto other fields and causing contamination. Nationwide planting of RRA was halted by the district court until APHIS prepared an EIS under NEPA, subject to the grandfather inclusion.[18] The district court found that there was a sufficient showing of immediate harm to support an injunction.[19] The district court also concluded that the problem of resistant weeds needed to be addressed.[20]

The Supreme Court, over the dissent of Justice Stevens, remanded and dissolved the injunction to allow APHIS to consider partial deregulation.[21] The Court ruled that an injunction does not automatically follow from the failure to have prepared an EIS.[22] It held that a court of

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14 40 C.F.R. § 1502.22 (1985) (amended 1986).

15 Robertson v. Methow Valley Citizens Council, 490 U.S. 332, 347 (1989).

16 7 U.S.C. § 7711(a) (2006).

17 *Monsanto*, 130 S. Ct. at 2749–50.

18 *Id.* at 2749.

19 *Id.* at 2751.

20 *Id.* at 2763 (Stevens, J., dissenting).

21 *Id.* at 2761–62.

22 *Id.* at 2758.

equity may not act before the details of the specific partial deregulation are before it.[23] The Court thus bypassed the impact of the district court's findings.

Justice Stevens's dissent urged that the majority opinion should not ignore the factual findings of the district court. The dissent begins as follows:

> The Court does not dispute the District Court's critical findings of fact: First, Roundup Ready Alfalfa (RRA) can contaminate other plants. Second, even planting in a controlled setting had led to contamination in some instances. Third, the Animal and Plant Health Inspection Service (APHIS) has limited ability to monitor or enforce limitation on planting. And fourth, genetic contamination from RRA could decimate farmers' livelihoods and the American alfalfa market for years to come.[24]

The dissent asserted that, in light of the findings of fact by the district court, the injunction against partial deregulation should stand.[25] It should have been viewed as consistent with the broad environmental objectives of NEPA.[26] The Court cited *Marsh v. Oregon Natural Resources Council*[27] for the principle that NEPA requires an agency not to act upon "incomplete information, only to regret its decision after it is too late to correct."[28] Justice Stevens urged that any deregulation affecting gene transference requires an EIS.[29] He viewed the guardianship of the public good as residing in the federal courts with their broad powers as courts of equity, in contrast to the exercise of power by the federal agency. Justice Stevens noted:

> While a court may not presume that a NEPA violation requires an injunction, it may take into account the principles embodied in the statute in considering whether an injunction would be appropriate. This District Court had before it strong evidence that gene transmission was likely to occur and that limits on growing could not be enforced. It also had a large amount of highly detailed evidence about whether growing restrictions, even if enforced, can prevent transmission. That evidence called into question the agency's own claims regarding the risks posed by partial deregulation. In enjoining partial deregulation until it had the

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23 *Monsanto*, 130 S. Ct. at 2754.

24 *Id.* at 2762.

25 *Id.* at 2769.

26 *Id.* at 2768.

27 490 U.S. 360, 371 (1989).

28 *Monsanto*, 130 S. Ct. at 2768 (Stevens, J., dissenting).

29 *Id.* (citing 40 C.F.R. §§ 1508.8, 1508.27(b)(4), (5)).

> benefit of an EIS to help parse the evidence, the court acted with exactly the sort of caution that Congress endorsed in NEPA.[30]

Chances are that Justice Breyer, who recused himself, would have joined Justice Stevens.[31]

APHIS's GE approvals are often attacked for their the lack of scientific research.[32] The organic community argues that partial deregulation of present GE traits cannot prevent contamination. The community is highly vocal in its concerns. Mr. Geertson stated:

> The arrogance of Monsanto, Forage Genetics and the USDA authorities supporting Monsanto is unbelievable! It is unjust and improper for them to suggest that conventional seed growers should move their farming operation to another location so Forage Genetics and Monsanto can raise RR alfalfa anywhere they want. Rather, if they want to commercialize this crop they need to require it be done in a manner that allows all farmers can continue to grow crops of their choice, without risk of contamination. The EIS refuses to even consider any such scenarios where such measures are required, let alone recommend they be required.[33]

C. Monsanto Patents

The application for the patent allowing plants to withstand the herbicide glyphosate embraces DNA molecules, which encode an EPSPS enzyme. The EPSPS enzyme has the following described sequences: a recombinant, double-stranded DNA molecule comprising a promoter, which causes the production of RNA sequences that encode the EPSPS enzyme. The application claims methods of producing genetically transformed plants tolerant to glyphosate, the tolerant plant cells, seeds and plants, and the tolerant soybean and seed.[34]

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30 *Id.* at 2771–72.

31 *See* Massachusetts v. Watt, 716 F.2d 946 (1st Cir. 1983).

32 Carey Gillam, *Patents Trump Public Interest in Monsanto's Ag Empire*, REUTERS (Apr. 13, 2010), www.reuters.com/article/2010/04/13/us-usa-gmos-regulators-idustr56e63c2aj 200100413.

33 *Flaws in the Draft Environmental Impact Statement for Roundup Ready Alfalfa*, FARMWARS 5, http://farmwars.info/wp-content/uploads/2011/02/eis_problems.pdf (last visited Nov. 15, 2011).

34 *See* U.S. Patent No. RE39247 (filed July 18, 2003).

D. The U.S. Supreme Court's Ruling on Patents from Forms of Life

Diamond v. Chakrabarty was concerned with the allowance of patents for the engineering of oil-eating bacteria unknown to natural selection.[35] The decision struck down two assertions: (1) modifications of life-forms are not allowable as patentable statutory subject matter and (2) Congress is the only branch equipped with the capacity to determine whether patents can be issued on altering forms of life.[36] The Court, in a five to four opinion, held that the first issue was a narrow one of statutory interpretation.[37] The Court held that there had never been a fixed rule precluding patents on living matter.[38] As a matter of statutory construction, the congressional purpose of rewarding "invention" prevailed over the interpretation of the statute that did not recognize living matter as patentable subject matter.

The Commissioner of Patents urged that congressional purpose is shown by the subsequent enactments of specific statutes covering the patenting of living plants (Plant Variety Protection Act (PVPA)[39] and Plant Patent Act (PPA)).[40] The Commissioner urged there would have been no need for such specific authorizations for patents if the utility statute, 35 U.S.C. § 101, embraced living plants. The Court disagreed, determining that Congress passed the plant statutes for the narrow purpose of making certain that plant breeders had special patent protection.[41]

The Court then went on to reject urgings by the Commissioner of Patents that the Court should defer to Congress. The Court ruled it had a constitutional duty to determine the scope of the general patent statute (35 U.S.C. § 101). The brief of the Solicitor General urged:

> Even if Congress were to limit its consideration of the desirability of extending patent protection to microorganisms, it would have to make difficult policy decisions with far-reaching effects. Chakrabarty's discovery is closely related to recombinant DNA research and like that research involves "genetic engineering.". . .

35 447 U.S. 303, 305 (1980).

36 *Id.* at 314, 317–18.

37 *Id.* at 307.

38 *See id.* at 303.

39 7 U.S.C. § 2321 (2006).

40 35 U.S.C. §§ 161–164(2006).

41 *See Diamond*, 447 U.S. at 303.

> Research in this area is already highly controversial, in part because of the potential hazards involved. Microorganisms with transplanted genes, if allowed to escape into the environment or to infect laboratory workers and others, could be hazardous to man or to other life forms. It was for this reason that the Director of the National Institutes of Health in 1976 released guidelines for NIH-sponsored research on recombinant DNA that established controlled conditions under which such research was to be performed. Continuing controversy over the degree of governmental control of recombinant DNA research has resulted in revisions of these guidelines.
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> One aspect of this controversy is the extent, if any, to which patent grants should be afforded on organisms that result from genetic engineering. Some persons believe that the ethical problems raised by creating the genetic material of life including human life-should not be compounded by providing that such life can be "owned" by patent holders. Others favor exploitation of this research under the patent system and suggest that the patent system might control public health risks. Yet others are skeptical of this claim and see the need for far more consideration of the relationship between patent law and genetic engineering. Resolution of such disputes is precisely the type of task for which Congress, and not the judiciary, is equipped.[42]

II
THE RAPID RACE TO PATENTABILITY

A. The White House

Genetic engineering is said to have begun in 1972 upon the success of recombinant DNA technology, for which Herbert Boyer and Stanley Cohen ultimately received patents in 1980.[43] By 1973, the prospect for a better world through biotechnology, including cures for illnesses and control of nature, was on the table.[44] The desire to jump-start projected successes collided with the need for a long-term scientific analysis of all the benefits and detriments. Paoletti and Pimental discuss this dilemma and have brought into focus proposed hurdles:

> Whitten (1992) proposes several essential characteristics that genetically engineered organisms must have if they are to be suitable for release in agriculture and the environment: They should

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42 Brief for the Petitioner at 18–20, Diamond v. Chakrabarty, 447 U.S. 303 (1980) (No. 79-136) (internal citations omitted) (footnotes omitted).

43 *See* Emily Marden, *Risk and Regulation: U.S. Regulatory Policy on Genetically Modified Food and Agriculture*, 44 B.C. L. REV. 733 (2003).

44 *Id.*

> be environmentally safe, have limited impact on nontarget organisms, not be present in human food, not cause pest resistance, and be able to be withdrawn from the environment if ultimately required.[45]

A major issue would be an allowance of patents for the jump-start.

The executive branch in the mid-1980s initiated a push to develop standards to encourage the expenditure of significant funds for biotechnology, whether for plants or cures for humans. The Reagan administration created an interagency working group within the White House Office of Science and Technology Policy (OSTP), which began drafting an overall federal framework for biotechnology.[46] In 1984, the OSTP published the Coordinated Framework for Regulation of Biotechnology (Coordinated Framework).

The 1984 publication of the Coordinated Framework set forth the view that biotechnology products should be regulated the same way as other products—these GE products would fall within existing federal statutory authority. After soliciting comments from the public, the final version of the OSTP Framework was issued in 1986.[47] It followed the outlines set forth in 1984 and established assignments based on them. The FDA became responsible for the safety of food, feed, food additives, and veterinary drugs; the USDA was responsible for safety of plants, pests, and veterinary biologic; and the EPA was given authority over microbial/plant pesticides, new uses of existing pesticides, and novel microorganisms.[48] The EPA was to review these subjects as safe for the environment and safe for new use of a companion herbicide.

Following the publication of the Coordinated Framework, the federal agencies and the White House continued to work together to devise a common strategy for discretionary authority allowed under the various statutes. An interagency committee responsible for coordination of science policy, the Biotechnology Science Coordinating Committee (BSCC), started to work with the agencies and the OSTP. A consensus was not reached and the working papers of the BSCC were sent to the

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45 Maurizio G. Paoletti & David Pimentel, *Genetic Engineering in Agriculture and the Environment*, 46 BIOSCIENCE 665, 668 (Univ. of Cal. Press Oct. 1996) (citing Max J. Whitten, *An International Perspective for the Release of Genetically Engineered Organisms for Biological Control*, BIOLOGICAL CONTROL BENEFITS AND RISKS 253 (Heikki M.T. Hokkanen & James M. Lynch eds., Cambridge Univ. Press 2003)).

46 *See* Marden, *supra* note 43.

47 Coordinated Framework for Regulation of Biotechnology, 51 Fed. Reg. 23,302 (June 26, 1986).

48 *Id.*

President's Council on Competitiveness, a group formed under the Bush administration.[49]

The Council then established an Ad Hoc Committee on Scope which published Principles for Federal Oversight of Biotechnology: Planned Introduction Into the Environment of Organisms with Modified Hereditary Traits, 55 Fed. Reg. 31,118 (proposed July 31, 1990). The Ad Hoc Committee included representatives of the federal agencies as well as other individuals. The draft policy statement devised a common statement of the basis for exercising oversight within the scope of discretionary authority under the statutes. The proposal placed the burden of proving the existence of hazards upon those who raised the complaint about hazards. The complainant had to show, based on scientific evidence, that the existence of the hazards outweighed the benefits of the biotechnology.

In August 1990, the Bush administration published Four Principles of Regulatory Review for Technology, an approval of principles to guide the use of oversight. The first part of this Declaration read:

> (1) Federal government regulatory oversight should focus on the characteristics and risks of the biotechnology product—not the process by which it is created. . . .
>
> (2) For biotechnology products that require review, regulatory review should be designed to minimize regulatory burden while assuring protection of public health and welfare. . . .
>
> (3) Regulatory programs should be designed to accommodate the rapid advances in biotechnology. . . .
>
> (4) In order to create opportunities for the application of innovative new biotechnology products, all regulation in environmental and health areas—whether or not they address biotechnology—should use performance standards rather than specifying rigid controls or specific designs for compliance.[50]

The evaluation of hazards became one of burden of proof. The principle of a precautionary approach ("precautionary principle")[51] was

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49 Marden, *supra* note 43.

50 Restated in Exercise of Federal Oversight Within Scope of Statutory Authority: Planned Introductions of Biotechnology Products into the Environment, 57 Fed. Reg. 6753-01, 6760 (Feb. 27, 1992). How engineered genes affect the genome is largely unknown. The process includes the use of vectors, promoters, and bacterial genes. *See generally*, CLAIRE HOPE CUMMINGS, UNCERTAIN PERIL: GENETIC ENGINEERING AND THE FUTURE OF SEEDS 12–17 (2008).

51 In January 2000, the Cartagena Protocol on Biosafety was approved at the Montreal negotiating round of the Convention on Biological Diversity (CBD). The language of the protocol endorsed the precautionary principle. Frederick H. Buttel, *The Global Politics of*

rejected. The precautionary principle has two major components. The first is a "shift in the burden of proof from governmental regulatory agencies to private firms . . ."; the private firms are obligated to prove that the new product is safe.[52] The second is that "products or practices can be rejected if there is evidence of any harm or if there is a plausible scientific rationale that approval could lead to negative health or environmental effects."[53]

In February 1991, the Council of Competitiveness published its Report on National Biotechnology Policy.[54] The Report specified that in order to not inhibit growth, the government should presume that a product poses a minimal risk in the absence of any evidence to the contrary. On this basis, the administration would seek to eliminate unneeded regulatory burdens on all phases of the development of new biotechnology products, experiments, product development, sales, and use.[55]

The Final Statement of Scope stated that federal oversight should be limited to science-based risk assessment to "ensure the safety of planned introductions of biotechnology products into the environment while not unduly inhibiting the benefits of such introductions."[56]

The stated rationale for this approach was that "[p]roducts developed through biotechnology processes do not *per se* pose risks to human health and the environment; risk depends instead on the characteristics and use of individual products."[57] Further, the policy stated that when review is deemed necessary it "should be designed to minimize regulatory burden while assuring protection of public health and welfare."[58] Agencies' regulation should be designed "to accommodate the rapid advances in biotechnology."[59]

GEOs, *in* ENGINEERING TROUBLE: BIOTECHNOLOGY AND ITS DISCONTENTS 152, 163 (Rachel A. Schurman & Dennis Doyle Takahashi Kelso eds., 2003).

52 *Id.*

53 *Id.*

54 PRESIDENT'S COUNCIL ON COMPETITIVENESS. REPORT ON NATIONAL BIOTECHNOLOGY POLICY 11 (1991), *available at* http://babel.hathitrust.org/cgi/pt?id=umn.31951003088116i [hereinafter BIOTECHNOLOGY REPORT].

55 *Id.*

56 Exercise of Fed. Oversight Within the Scope of Statutory Authority: Planned Introductions of Biotechnology Prods. Into the Env't, 57 Fed. Reg. 6753, 6755 (Feb. 27, 1992).

57 *Id.* at 6756.

58 *Id.* at 6760 (citing the August 1990 Four Principles of Regulatory Review for Biotechnology).

59 *Id.*

This approach to risk was chosen because it "is scientifically sound, properly protects public health and the environment against risk, and avoids hindering safe innovations."[60] It relied on five conclusions from The National Research Council's review:

> 1. The same physical and biological laws govern the response of organisms modified by modern molecular and cellular methods and those produced by classical methods.
> 2. Information about the process used to produce a genetically modified organism is . . . not a useful criterion for determining whether the product requires less or more oversight.
> 3. No conceptual distinction exists between genetic modification of plants and microorganisms by classical methods or by molecular techniques . . . .
> 4. Crops modified by molecular and cellular methods should pose risks no different from those modified by classical methods for similar traits . . . .
> 5. In many respects, molecular methods resemble the classical methods for modifying particular strains of microorganisms, but . . . [are] even more useful than the classical methods.[61]

The final Scope principles announced are:

> 1. A determination to exercise oversight within the scope of discretion afforded by statute should not turn on the fact that an organism has been modified or modified by a particular process or technique, because such fact is not alone a sufficient indication of risk.
> 2. A determination to exercise oversight in the [s]cope of discretion afforded by statute should be based on evidence that the risk presented by introduction of an organism in a particular environment used for a particular type of application is unreasonable.
> 3. Organisms with new phenotypic trait(s) conferring no greater risk to the target environment than the parental organisms should be subject to a level of oversight no greater than that associated with the unmodified organisms.[62]

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60 *Id.* at 6755.

61 *Id.* at 6756.

62 *Id.*

B. Developments in the Office of Trademarks and Patents After *Chakrabarty*

Immediately following *Chakrabarty*, the Patent and Trademark Office (PTO) would not allow general utility patents on plants, assuming a congressional intent in the enactment of the two plant statutes to preclude subject matter validity.[63] Challenges to this policy were brought. In *Ex Parte Hibberd*, the Board of Patent Appeals overruled the rejection and refused to accept the PTO's interpretation of congressional intent.[64] The PTO began issuing patents upon plants under 35 U.S.C. 101 after *Hibberd*.[65]

In 1984, the PTO granted a patent on a mouse that was particularly prone to cancer, the "oncomouse."[66] In 1987, the PTO announced it would accept applications for "nonnaturally occurring" organisms as long as the "invention" had a "new form, quality, properties or combination not present in the original article existing in nature in accordance with existing law."[67]

"[T]he PTO began issuing patents on human genes and gene fragments, transgenic bacteria that express human genes, and human cell lines that express DNA sequences producing pharmacologically important proteins and that perform other important biological functions."[68] The PTO allowed "the patenting of (1) the genomes and DNA sequences of plants; (2) the genomes and DNA sequences of bacteria, animals, and other living organisms; and (3) the DNA sequences of human beings, but not the entire genome of [human] or human-like being[s]."[69]

In 1994, the PTO began rejecting patents for small gene fragments known as express gene sequence tags (ESTs). In 1995, the PTO announced a new "credible" utility standard, as opposed to the

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63 Linda J. Demaine & Aaron Xavier Hellmeth, *Reinventing the Double Helix: A Novel and Nonobvious Reconceptualization of the Biotechnology Patent*, 55 STAN. L. REV. 303, 319 (2002).

64 227 U.S.P.Q. 443 (C.C.P.A. 1985).

65 Demaine & Hellmeth, *supra* note 63.

66 U.S. Patent No. 4,736,866 (filed June 22, 1984); Demaine & Hellmeth, *supra* note 63, at 318.

67 1077 Off. Gaz. Pat. & Trademark Office 24 (Apr. 7, 1987).

68 Demaine & Hellmeth, *supra* note 63.

69 *Id*.

substantial utility standard.[70] A few years later, the PTO announced it would allow patents on ESTs based on their capability to act as probes.

On December 21, 1999, the PTO issued new utility examination guidelines.[71] Under the new guidelines, one specific utility shown in the application would be sufficient.[72]

III
THE COURT'S DECISION IN *J.E.M. AG SUPPLY*

The developments discussed above preceded the Court's life-form ruling, which has allowed utility patents to be granted for hybridized plants. *J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred International, Inc.* resolved the question of whether there was a distinction between microbes and plants for subject matter approval in the light of the two special plant statute enactments.[73] The majority decision followed *Chakrabarty* in rejecting the doctrine that patents from forms of life are repugnant to access to the commons.[74]

The ability to patent sequences of DNA for specific functions in forms of life is an open matter. A district court has ruled that the product-of-life exception precludes patents for gene purification and isolation of natural sequences with detriment to upstream research.[75] The Department of Justice filed its amicus curiae brief in *Ass'n for Molecular Pathology*, urging that the copying of the DNA of genes is ineligible subject matter.[76] It used a "magic microscope" test: if the isolated DNA could be seen from a supposed microscope after it is isolated, it still remains a form of nature.[77] The Report addresses the undesirable impacts of allowing patents for genetic testing. It promotes a change in the patent statute to exclude patents from

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70 PTO Examination Guidelines on Utility Requirement, 50 Pat. Trademark & Copyright J. (BNA) 295, 303 (July 20, 1995).

71 Revised Utility Examination Guidelines; Request for Comments, 64 Fed. Reg. 71440 (Dec. 21, 1999).

72 *See* Part IV B, *infra.*

73 534 U.S. 124 (2001).

74 *Id.*

75 *See* Ass'n for Molecular Pathology, v. U.S. PTO, 669 F. Supp. 2d 365 (S.D.N.Y. 2010), *rev'd, in part*, 99 U.S.P.Q.2d 1398 (2011); Bilski v. Kappos, 130 S. Ct. 3218 (2010) (recognizing phenomena of nature as unpatentable subject matter, rejecting the patenting of algorithms, requiring the narrowing of claims which would otherwise preempt wide swaths of technological development).

76 Ass'n for Molecular Pathology, 99 U.S.P.Q.2d 1398.

77 *Id.*

infringement research and the sale of tests when allied to health care.[78]

In *J.E.M.*, the Patent Office supported the patent holder.[79] The facts of the case do not necessarily involve the fundamental public good issue of irremediable impact on the environment by privately held patents. The development of hybrids through selective breeding, which accepts entire genomes, allows nature to be the force determining the acceptability of the new hybrid. Genetic engineering, in contrast, forces the entry of the chosen gene or genes into the genome. This forced entry immediately raises the requirement for long-term scientific analysis of the effects of genetic engineering on the environment and human health. Patents allow control of the effects by multinational corporations who possess enormous capital. As seen herein, control of the seed by patent changes the farmer from a breeder to a consumer. The Court framed the decision on the arguments advanced by the infringer of a plant utility patent.[80] The central claim was the proof of congressional intent based on the two special plant statutes. The issues of control of seeds and life-forms were decided under the separation of powers approach. A specific provision of the Plant Variety Protection Act allows the farmer control over the seeds and allows for research on the plant form under patent protection.[81] The defendant was accused of infringement in the sale of hybrid corn seeds that had been patented as a general utility invention.[82] Since Congress had the power to allow patents for living matter and had never excepted any form of matter, the Court ascribed to Congress the intent to allow patents for products from nature.

The Court noted that the PTO had issued utility patents for hybridizing plants and that there had been 1800 of such patents issued since 1985. Most of these patents, then, were issued following White House action and pursuant to the PTO guidelines previously discussed. Most of these patents involved transgenic seeds or plants. However, the Court did not consider the utility requirement for transgenic plants. That matter must await decision. The Court did notice the lack of argument under the utility standard in the pending case.

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78 *Id.*

79 *J.E.M. Ag Supply, Inc.*, 534 U.S. 124.

80 *Id.*

81 7 U.S.C. §§ 2543, 2544.

82 *J.E.M. Ag Supply, Inc.*, 534 U.S. 124.

IV
PLANT GMOS SHOULD BE PROCESSED BY THE PATENT OFFICE UNDER THE PRECAUTIONARY PRINCIPLE

A. Hazards

Since "utility" was not involved in *J.E.M.*, it becomes another important area of attention. There is no doubt that utility is embedded in 35 U.S.C. § 101, which requires that a patentable invention be "new and useful."

Scientists, organic farmers, nonprofit organizations, and environmentalists have raised the question of possible adverse consequences involved in the genetic engineering of plants.[83] Negative warnings from these sources include (1) gene flow allowing invasions of organic fields;[84] (2) the reaction to the genetically engineered gene(s) and developments by weeds or insects to attain tolerance, allowing ever resistant weeds or insects;[85] (3) decreased biodiversity from the introduction of genetically engineered seeds or plants, which, directly or through wild relatives, may cause a substantial displacement of either flora or fauna with the resulting destruction of land races developed over millennia;[86] (4) the contamination of all seed supplies in significant amounts;[87] and (5) decreased yields.[88] Determining the validity and

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83 *See, e.g.*, MARC LAPPE & BRITT BAILEY, AGAINST THE GRAIN (1998); Ronnie Cummins, *Hazards of Genetically Engineered Food and Crops: Why We Need A Global Moratorium*, IN MOTION MAGAZINE (Aug. 29, 1999), http://www.inmotionmagazine.com/geff4.html; PAUL LURQUIN, HIGH TECH HARVEST (2002); William Boyd, *Wonderful Potencies*, *in* ENGINEERING TROUBLE 24 (2003); Allison Wilson, *Genome Scrambling—Myth or Reality?*, ECONEXUS (Oct. 2004), http://www.econexus.info/publication/genome-scrambling---myth-or-reality; *Transformation-induced mutations in transgenic crop plants*, ECONEXUS, www.econexus.info (2004); Gillam, *supra* note 32; Keith Aoki, *Seed Wars* (Carolina Academic Press 2008); CUMMINGS, *supra* note 50; UNION OF CONCERNED SCIENTISTS, Gone to Seed (2004), www.ucsusa.org/food_and_agriculture/science_and_impacts/impacts_genetic_engineering/gone-to-seed.html. *See* discussion of letter of Dr. Don Huber, plant scientist, formerly at Purdue University to the USDA, January 2011, asserting the discovery of disease causing microorganisms in GE corn and soybeans; entry allowed by glyphosate. Dr. Huber claims that the mysterious organism and weakened defense caused by glyphosate accounts for unexplained epidemics of disease, the sudden death syndrome of soybean crops and Goss' wilt on corn. Dr. Huber's findings have not been verified by outside scientists nor published in a peer reviewed journal. *See* Melanie Warner, *Mystery Science: More Details On The Strange Organism That Could Destroy Monsanto*, (May 5, 2011), www.cbsnews.com/8301-505123_162-44043052/mystery-science-more-details-on-the-strange-organism-that-could-destroy-monsanto/ (last visited Dec. 7, 2011).

84 *See Geertson*, 570 F.3d 1130.

85 *See* LAPPE & BAILEY, *supra* note 83; CUMMINGS, *supra* note 50, pp. 445-46.

86 LAPPE & BAILEY, *supra* note 83 at 97–98, 101–03.

87 GONE TO SEED, *supra* note 11.

extent of these risks is difficult because patent holders have the right to (and do) protect knowledge of their tests and prevent research.

The use of glyphosate, as asserted above, produces other alleged hazards. These hazards include (1) harms to exposed nontarget organisms, especially aquatic forms;[89] (2) interference with estrogen biosynthesis enzymes in human placental cells;[90] (3) increased susceptibility of plants to disease;[91] (4) increased appearance of root fungal disease;[92] (5) the development of neural defects and craniofacial malformations in amphibians;[93] (6) microbial ecosystem disturbance with subsequent unwanted effects upon beneficial microbes;[94] (7) an increase in bile acids, which suggests toxicity in the liver and its detoxifying system;[95] (8) the introduction of "inert" toxic surfactants, including polyethyloxylated tallow amine, which constitute fifty-nine percent of the Roundup compound;[96] (9) the inhibition of monooxygenases that mammals need to detoxify other chemicals that

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88 LAPPE, *supra* note 83 at 81.

89 *See, e.g.*, Bette Hileman, *Common Herbicide Kills Tadpoles*, CHEMICAL & ENGINEERING NEWS, Apr. 11, 2005, at 11, *available at* http://pubs.acs.org/cen/news/83/i15 /8315notw8.html.

90 Sophie Richard et. al., *Differential Effects of Glyphosate and Roundup on Human Placental Cells and Aromatase*, 113 ENVTL. HEALTH PERSPECTIVES 716, 720 (2005) ("Roundup may be thus considered as a potential endocrine disruptor. Moreover, at higher doses still below the classical agricultural dilutions, its toxicity on placental cells could induce some reproduction problems.").

91 Gillam, *supra* note 32.

92 *Id. See also* Stephen O. Duke et al., *Herbicide Effects on Plant Disease*, 18 PEST MGMT. SCI. 36 (2007).

> Herbicides have the potential to affect plant disease by several Mechanisms. These secondary effects of herbicides have not been sufficiently studied to fully understand their environmental toxicology implications or for an adequate knowledge of them to enhance integrated past management. This information is especially important in the context of biocontrol of weeds with plant pathogens.

93 *See also* R.A. Relyea, *The Lethal Impacts of Roundup and Predatory Stress on Six Species of North American Tadpoles*, 48 ENV'T CONTAMINATION AND TOXICOLOGY 351, 355 (2004).

> Roundup with the POEA surfactant has the potential to play a major role in amphibian declines. However, it is worthy to note that the manufacturer of Roundup (Monsanto Corp.) has recently released an additional formulation of glyphosate (Roundup Biactive) which contains a different (but unspecified) surfactant that is reported to be less toxic Tsui and Chu 2003.

94 LAPPE & BAILEY, *supra* note 83, at 60.

95 *Id.* at 54.

96 *Id.*

may be attributed to the possible disruption of the cellular membrane;[97] (10) indications of manganese deficiencies in (GT) soybeans;[98] (11) concerns that heavy meat eaters may be exposed to Roundup Ready soybean hulls digested by livestock, which allow bacteria to metabolize glyphosate into a more fat soluble and toxic amine that could, in theory, accumulate in body tissues;[99] and (12) the lack of knowledge of the formation of neo-allergens harmful to humans.[100] In fact, statistics from the California Environmental Protection Agency's Pesticide Illness Surveillance Program indicate that glyphosate has the highest number of all pesticides for health-related incidents.[101] All of these hazards raise a considerable demand that the FDA require the labeling of GE foods.[102]Monsanto offers a website to counter many of these claims.[103]

Pleas have been made to the EPA that human exposure to glyphosate poses unreasonable risks and has led to crop resistance. These organizations requested that the EPA disallow glyphosate and Roundup registration.[104]

Another area of concern involves the use of university research by corporations for agricultural projects. Bioengineering patents further the development of an industrial-university nexus allowing for penetration of university research by corporations with conflicting objectives.[105] Patents raise a conflict of interest between the search for knowledge and the overseeing of large agricultural projects for commercial objectives.

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97 *Id.*

98 Gillam, *supra* note 32.

99 LAPPE & BAILEY, *supra* note 83, at 55.

100 Lurquin, *supra* note 83 (Studies show that allergens are not present in corn and canola due to their genetically altered status. He advocates labeling to assist persons with allergy problems.); LAPPE & BAILEY, *supra* note 83, at 136.

101 *See* Daniel A. Goldstein, et. al., *An Analysis of Glyphosate Data from the California Environmental Protection Agency Pesticide Illness Surveillance Program*, 40 J. TOXICOLOGY, CLINICAL TOXICOLOGY, 885, 885–92 (2002).

102 Rachel A. Schurman & William A. Munro, *Making Biotech History: Social Resistance to Agricultural Biotechnology and the Future of the Biotechnology Industry*, *in* ENGINEERING TROUBLE: BIOTECHNOLOGY AND ITS DISCONTENTS 111, 120 (Rachel A. Schurman & Dennis Doyle Takahasha Kelso eds., 2003).

103 *Roundup/Glyphosate Background Materials*, MONSANTO.COM, (last visited Sept. 26, 2011), http://www.Monsanto.com/products/Pages/roundup-safety-background-materials.aspx.

104 *See, e.g.*, Letter from Beyond Pesticides et. al., to Office of Pesticide Programs, Environmental Protection Agency (Sept. 21, 2009), *available at* http://www.beyondpesticides.org/documents/glyphosate-final9-21-1.pdf.

105 *See*, *e.g.*, Patent and Trademark Law Amendments (Bayh-Dole) Act, 35 U.S.C. §§ 200–212 (2006).

As seen above, there exists a lack of knowledge concerning the effect of GMO foods on human health. In the distinct area of social effects, GE patents raise the need for strict control by the patent owner of the seeds licensed to farmers and allow monopoly control.[106]

B. The Requirement of Successful Conclusion

Courts were concerned with "utility" prior to the mid-1980s. The Court of Patent Appeals faced applications upon the newly discovered release of energy from splitting atoms in *In re Chilowsky*.[107] The court laid down a three part test for proof of operability: (1) where operation is readily understood and conforms to known laws of science, operativeness may be presumed; (2) where there appears to be a conflict with scientific principles, very clear evidence is required to overcome the possibility; and (3) where testing is not available, it is incumbent on the applicant to demonstrate the workability and utility of the device and make clear the principles on which it operates.[108]

Applying the tests of *Chilowsky* to GE plants, proponents would be required to respond to concerns about the ability of plants to naturally adapt to new environments and the principles of outcrossing, backcrossing, and pollination.[109] It was predictable that implanted transgenic genes would have impacts on the environment; *Chilowsky* now requires patent seekers to discuss this impact.

Then came *Brenner v. Manson*.[110] In *Brenner*, the Court held that a patent is not a reward for the search but compensation for only a *substantial utility*.[111] The Court directed its statement to the ruling of the Court of Custom and Patent Appeals (CCPA), below, that any chemical process resulting in a product dispensed with a showing of utility. Starting from the premise that patents can only issue if not injurious to the public good, the Court stated that the rewards for an invention can

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106 *See, e.g.*, Monsanto Co. v. McFarling, 302 F.3d 1291 (Fed. Cir. 2002); Monsanto Co. V. Scrubbs, 342 F. Supp. 2d 854 (N.D. Miss. 2004); Monsanto Co. v. Trantham, 156 F. Supp. 2d 855 (W.D. Tenn. 2001) (holding that seeds may not be saved by farmers nor can the seeds be used for research).

107 229 F.2d 457 (C.C.P.A. 1956).

108 *Id.*

109 Cummings, *supra* note 50. The USDA expressed surprise when genes from Roundup Ready creeping bentgrass at an experimental test site in Oregon had pollinated plants thirteen miles away.

110 383 U.S. 519 (1966).

111 *Id.* at 535–37.

only be granted for a "successful conclusion."[112] *Brenner* does not allow patents for experiments that tolerate harmful and unreliable results. The Court stated that "[t]he basic quid pro quo contemplated by the Constitution and Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility."[113] Unless benefits are derived by the public from the invention with substantial certainty, the statute disallows the patent.[114] "[A patent] is not a reward for the search, but compensation for its successful conclusion."[115]

The benefits advanced by seekers of GE seed patents are countered by studies that claim that failures limit the benefits only to the very short-term. First, those that claim that the glyphosate resistant trait reduces use of other more toxic herbicides must acknowledge the arrival of superweeds, which arise from the extended and substantial use of glyphosate. Currently, chemical companies advocate the use of more toxic chemicals to combat superweeds. The *Wall Street Journal* interviewed representatives of chemical companies who speak of the need for and development of new chemicals and GE traits to protect crops from superweeds. Dow AgroSciences sells such a chemical, 2,4-D, and genetically engineers specific tolerance. However, in 2008, the Natural Resources Defense Council petitioned the EPA to ban 2,4-D alleging the chemical is an endocrine disruptor with predicted human health risks, including changes in estrogen and testosterone levels, thyroid problems, prostate cancer, and reproductive abnormalities.[116] 2,4-D has been banned in Norway as an impairment to human health and the environment.[117] Monsanto recommends this herbicide as a mix with Roundup when resistance to glyphosate is suspected.[118] Second, as to Monsanto's claim that GT plants allow a decrease of undesirable land tillage, studies have shown that superweeds create the need for greater

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112 *Id.* at 534–37.

113 *Id.* at 534.

114 *See generally*, *id.* at 534–35.

115 *Id.* at 536.

116 Jennifer Sass, *NRDC Petitions EPA to Ban 2,4-D: An Agent Orange Chemical Doesn't Belong on Lawns*, JENNIFER SASS'S BLOG (Nov. 6, 2008), http://switchboard.nrdc.org/blogs/jsass/nrdc_files_a_legal_petition_to.html (last visited Dec. 7, 2011).

117 Declaration of William Freese, *Geertson Seed Farms v. Mike Johanns*, et al., (N.D. Cal. 2006) No. C-06-1075 CRB, ¶ 10.

118 *See* Technology Development, by Monsanto, *Roundup Ready Plus Weed Management Solutions, Management Options for Common Groundsel and Yellow Rocket at Z*, FIELDER'S CHOICE DIRECT (2011), http://www.fielderschoicedirect.com/wp-content/uploads/2011/04/RRPLUS%E2%84%A2-Common-Groundsel-and-Yellow-Rocket.pdf.

efforts for elimination, including tillage.[119] Third, the claim that GT plants allow for an effective increase in profits to farmers and substantial decrease in labor required for chemical use is in dispute. Organic farmers, including the plaintiffs in *Geertson*, have urged that the record regarding GT alfalfa disproves profitability. The *Wall Street Journal* article reports a backlash by farmers against the steep prices charged by Monsanto for GT seeds.[120] Monsanto's profits on the sale of its GT seeds have recently risen after a policy of price-cutting and a focus on volume.[121]

The PTO's practice of allowing a patent on the showing of one specific, substantial, and credible utility, without balance, needs reassessment.[122] The continual granting of plant patents by the PTO following *Hibberd*, as emphasized in *J.E.M.*, would not necessarily have required "successful conclusion."[123] The guidelines do not demand tests alleviating the hazards raised here.

Analogous issues have been decided on rulings requiring a showing of *de minimis* hazards or the ability to prevent them.[124] *Application of Sichert* states that the test is one of balancing risks.[125] Patents are not to be issued if they present hazards. If the contingency of harm is minimal, however, and can be alleviated by proper application from those skilled in the art, there would be a showing of sufficient safeguards to justify acceptance.

The admissions in *Geertson* that the use of RRA requires special conditions, special barriers, special recommendations for tillage, special use of glyphosate, and special seed cleaning acknowledge dangers from GE seeds. Patent policy under these patents deputizes the patent holder to enforce the patent and requires the organic farmer to cooperate with those policies. Such a principle seems foreign to Anglo-Saxon tort law, which raises liability for negligence, trespass, and nuisance from those who allow drift upon another's land.[126]

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119 *Id.;* Second Declaration, *supra* note 1.

120 Kilman, *supra* note 5.

121 Ian Berry, *Monsanto's Seeds Sow a Profit*, WALL ST. J., Jan. 7, 2011, at B3.

122 *See* Utility Examination Guidelines, 66 Fed. Reg. 1092-02 (Jan. 5, 2001).

123 *See generally J.E.M. Ag Supply, Inc.*, 534 U.S. 124.

124 Application of Sichert, 566 F.2d 1154, 1159–60 (C.C.P.A. 1977), citing *In re* Anthony, 414 F.2d 1383, 1394–95 (C.C.P.A. 1969) and *In re* Hartop, 311 F.2d 249 (C.C.P.A. 1962).

125 *Id.*

126 Jacobs Farm v. Western Farm Serv. Inc., 190 Cal. App. 4th 1502, 1524–25 (Cal. App. 2010).

It is often asserted, as in *Application of Sichert*, that concern for the potentially injured is not placed on the PTO but on agencies specifically granted jurisdiction over harmful products. "Utility" includes nonhazardous process or product and substantial benefit for the public good. The Patent Statute places responsibility for public good on the PTO.[127] Reward for innovation can only occur when each and every requirement of the Statute is met. *Graham v. John Deere Co.* states that:

> The Congress in the exercise of the patent power may not overreach the restraints imposed by the stated constitutional purpose. Nor may it enlarge the patent monopoly without regard to the innovation, advancement or social benefit gained thereby. Moreover, Congress may not authorize the issuance of patents, whose effects are to remove existent knowledge from the public domain, or to restrict free access to materials already available. Innovation, advancement, and the things which add to the sum of useful knowledge are inherent requisites in a patent system which by constitutional command must "promote the Progress of . . . useful Arts." This is the *standard* expressed in the Constitution and it may not be ignored. And it is in this light that patent validity "requires reference to a standard written into the Constitution."[128]

There is manifest conflict between a standard calling for reward for only successful conclusion and a standard allowing reward for the showing of a single utility without consideration of the detriments.

C. The Study by the National Research Council

The National Research Council has published *The Impact of Genetically Engineered Crops on Farm Sustainability in the United States*.[129] Its summary findings would not support the contention that GE patents meet the utility standard of successful conclusion. The key findings show that all the preliminary successes are qualified. Finding No. 1 states that glyphosate is less toxic than other herbicides, but warns that its predominance reduces its effectiveness as a weed management tool.[130] Finding No. 2 allows for conservation tillage, but finds that farmers who use GE seeds are bent to such practice.[131]

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127 *See* Application of Hartop, 311 F.2d 249, 263–66 (C.C.P.A 1962) (Worley, J. dissenting).

128 383 U.S. 1, 5–6 (1966) (quoting A&P Tea Co. v. Supermarket Corp., 340 U.S. 147, 154 (MSG) (Douglas, J., concurring).

129 NATIONAL RESEARCH COUNCIL NAT'L ACAD. PRESS, THE IMPACT OF GENETICALLY ENGINEERED CROPS ON FARM SUSTAINABILITY IN THE UNITED STATES (2010).

130 *Graham*, 383 U.S. at 4.2(a).

131 *Id.* at 5.

Finding No. 4 is concerned with gene flow to organic farmers, and it warns of the problems of further gene flow upon the use of more GE traits.[132] Finding No. 7 indicates that the effect of GE crops on prices is not understood.[133] Finding No. 8 finds that the economic effect of GE crops has not received adequate research.[134] Finding No. 8 also finds both favorable and unfavorable social impacts and again states that GE crops need further study.[135] Finding No. 10 states that there has been little research on how increasing market concentration of seed suppliers affects overall yield benefits, crop genetic diversity, seed prices, and farmers' planting decisions and options.[136]

In its conclusions, the report states that weed problems will become more common as weeds develop resistance to herbicides.[137] The infrastructure to track environmental benefits is not in place; studies are needed to evaluate environmental and economic effects. As more genetic engineering develops, such studies are ever more important. The report's final summary conclusion accords benefits to farmers when GE traits are used properly, but suggests a "targeted and tailored regulatory approach to GE-trait development and commercialization that meets human and environmental safety standards while minimizing unnecessary expenses . . . ."[138]

The justification for monopoly by patent is the ability of scientists or inventors to have knowledge of the art to allow for beneficial post expiration uses. The failures, shown by field use of the GT patents, create heavy concerns regarding the impact of GE plants on agriculture.

CONCLUSION

Real world developments show that genetic engineering of agricultural products is experimental. Such patent applications tinker with life forces, thus requiring long-term analysis for all environmental and human health risks. Impact levels as set forth by Whitten should be considered. The precautionary principle should be adopted. Control of agriculture by patents is a fundamental issue,

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132 *Id.* at 8.

133 *Id.* at 10.

134 *Id.* at 11.

135 *Graham*, 383 U.S. 11.

136 *Id.* at 12.

137 *See* Biotechnology Report, *supra* note 53.

138 NAT'L ACAD. PRESS, *supra* note 128, at 15.

which should rank very high on the matters for the concern of Congress.