

ARE CURRENT PATENT LAWS DISCOURAGING CRITICAL RESEARCH AND DEVELOPMENT ON CHEMICAL ALTERNATIVES TO METHYL BROMIDE?

I. INTRODUCTION

Pesticide use allows for tremendous increases in the productivity of food and fiber.¹ Methyl bromide is world renowned as “an invaluable crop protection tool used to combat a wide spectrum of pests on some 100 different crops worldwide.”² There is scientific evidence indicating that methyl bromide destroys the ozone.³ Ozone depletion has been discussed by the global community for over two decades⁴ as evidenced by the activity of the Montreal Protocol⁵ in attempting to regulate the phase-out of this extremely effective biocide.⁶ The United States is

¹ Kyle W. Lathrop & Cindy K. Bushur-Hallman, *Sixteenth Annual American Agricultural Law Association Educational Conference Symposium: U.S. and Mexican Regulation of Methyl Bromide: Comparing Pesticide Regulation after NAFTA*, 48 OKLA. L. REV. 289, 289 (1995).

² David Riggs, *Next Few Months Critical for Methyl Bromide*, WINES & VINES, Apr. 1996, at 46.

³ See R. W. D. Taylor, *Methyl Bromide-Is There Any Future for This Noteworthy Fumigant?*, 30 J. STORED PROD. RES. 253, 255 (1994).

⁴ Lee Anne Duval, Note, *The Future of the Montreal Protocol: Money and Methyl Bromide*, 18 VA. ENVTL. L.J. 609, 609 (1999).

⁵ *The Montreal Protocol on Substances That Deplete the Ozone Layer*, CIESIN Thematic Guides *Provisional Release*, at <http://www.ciesin.org/TG/PI/POLICY/montpro.html> (last visited Apr. 19, 2002) (defining the Montreal Protocol as an international treaty designed to protect the stratospheric ozone layer). Janet Carpenter, Lori Lynch & Tom Trout, *Township Limits on 1,3-D Will Impact Adjustment to Methyl Bromide Phase-out*, CAL. AGRIC., May-June 2001, at 12.

⁶ Catherine Jacobson, Maya Komanovsky, Susan McCarthy, Phillip Nguyen & William Phillips, *Issues Surrounding Methyl Bromide*, COOPERATIVE EXTENSION U. OF CAL. ENVTL. TOXICOLOGY NEWSL., at http://www.ace.orst.edu/cgi-bin/mfs/01/newsletters/n162_96.htm?915, (April, 1996). See generally SHIRLEY A. BRIGGS, BASIC GUIDE TO PESTICIDES: THEIR CHARACTERISTICS AND HAZARDS 164 (Hemisphere Publishing

planning to ban the production and importation of methyl bromide by the year 2005 through provisions of the U.S. Clean Air Act.⁷ The American agricultural community is extremely concerned over the impending prohibition of this valuable pesticide that has for sixty years⁸ been a crucial tool in the growers' arsenal in their quest for pest-free and economically valuable crops. According to the United States Department of Agriculture (USDA), the estimated potential damage to U.S. agriculture from methyl bromide loss exceeds \$1.3 billion annually.⁹ As this pesticide is gradually abandoned, and forgotten pests reassert their former dominance, the need for alternatives becomes supremely paramount.

The search for chemical alternatives to methyl bromide requires long term investments in research and development (R&D). The importance of this scientific exploration is partially evidenced in the increased federal funding made available to the USDA, Agricultural Research Service from \$7 million in 1993 to \$13.7 million in 1996.¹⁰ "President Clinton [asked] Congress for a \$14.7 million increase to the 2001 budget for [methyl bromide] alternatives research."¹¹ Historically, successful scientific breakthroughs and greater innovation overall have been generated from private sector R&D efforts.¹² However, the amount of increased federal funding devoted toward a perceived crisis is an indication of government/industry interest in discovering alternatives to methyl bromide. "Methyl bromide producers . . . say they are working on chemical replacements, but administration officials say companies are unwilling to risk R&D investments to develop products that may also be subject to regulation."¹³ "Pesticides companies see too many environmental and health problems or patent hurdles . . ." according to Ken Vick, coordinator/methyl bromide alternatives research at the USDA.¹⁴ Vick believes the main barrier to finding a

Corp.) (1992) (listing further characteristics and hazards of the fumigant methyl bromide).

⁷ U.S. Clean Air Act of 1955, 42 U.S.C.S. § 7401 (2002); Environmental Protection Agency, 40 C.F.R. § 82.5, 82.7 (2002); Doris Stanley Lowe, *Natural Plant Extracts Might Sub for Methyl Bromide*, AGRIC. RES., Mar. 1999, at 14.

⁸ Taylor, *supra* note 3, at 253.

⁹ Riggs, *supra* note 2, at 46.

¹⁰ Jim De Quattro, *Gas 'N' Go Grapefruit*, AGRIC. RES., Nov. 1996, at 16.

¹¹ Neil Franz, *Methyl Bromide Users Clamor for Alternatives; Regulation*, CHEM. WK., Feb. 16, 2000, at 55.

¹² See Stephen Cox, *The Evolution of Ayn Rand*, LIBERTY, July, 1998, at 49, 56 (discussing environments conducive to scientific discovery).

¹³ Franz, *supra* note 11, at 55.

¹⁴ *Id.*

chemical alternative is “the lack of a profit motive.”¹⁵

II. AGRICULTURAL RESEARCH AND DEVELOPMENT CONCERNS

The most promising chemical alternatives to methyl bromide would appear to be those that fall into the same genus of structurally related chemicals with fumigant properties similar to methyl bromide. These chemical fumigants are quite often disclosed in prior publications describing their properties and known uses.¹⁶ The prohibitive cost of researching, developing, and registering a potentially unpatentable chemical destroys the incentive for the research industry to invest the time, money and energy without the protection a patent provides.

Some compounds “have the potential to be mixed to make an effective insecticidal and nematicidal formulation that performs as well as methyl bromide against insects and nematodes.”¹⁷ These potential chemical alternatives to methyl bromide will require major investments and the incentive for these investments quite often are traced to patent protection. A patent provides a twenty-year exclusive right to control the manufacture and distribution of the patented item or process, measured from the filing date of the application for the patent.¹⁸ Auburn University professor and researcher, Rodrigo Rodriguez-Kabana, believes there are many potential chemical alternatives to methyl bromide that are not being investigated because they are unpatentable.¹⁹ Unpatentable, because they have known properties and were synthesized long ago, many of which could “outperform methyl bromide in the fumigation of soils.”²⁰ He feels the crisis situation in finding methyl bromide alternatives suggests a “need for Congress to enact legislation permitting ‘rights of exploitation’ to anyone or any organization that wishes to develop chemicals that are not patentable”²¹ “[A]ppropriate legislation [would] make it attractive for investors to

¹⁵ *Id.*

¹⁶ Russell S. Lehman, *Laboratory Tests of Organic Fumigants for Wireworms*, 35 J. OF ECON. ENTOMOLOGY 659, 659 (1942).

¹⁷ A.G. Appel & R. Rodriguez-Kabana, *Nematicidal Properties of Iodinated Hydrocarbons*, METHYL BROMIDE ALTERNATIVES, July 2000, at 7.

¹⁸ 35 U.S.C.S. § 154 (2002).

¹⁹ E-mail Interview with Rodrigo Rodriguez-Kabana, Distinguished Professor, Auburn University (July 7, 2000) (recipient of the U.S. Environmental Protection Agency’s Stratospheric Ozone Protection Award for outstanding leadership and innovation in protecting the Earth’s stratospheric ozone layer in 1997) (on file with the San Joaquin Agricultural Law Review).

²⁰ *Id.*

²¹ *Id.*

develop old but highly effective chemicals for practical use by producers instead of methyl bromide."²²

Greg Burger is a member of the private sector agricultural industry and responsible for new product development at Illovo Sugar, LTD. in Merebank, Durban, South Africa. He is actively pursuing chemical alternatives to methyl bromide and feels "[t]he patent situation is a critical factor in the development of an agricultural product."²³ Without some form of "competitive edge, few companies would be prepared to spend the necessary funds on development and registration."²⁴ Burger agrees with Rodriguez-Kabana that "rights of exploitation" legislation would probably greatly enhance finding chemical alternatives to methyl bromide, but he believes the process "needs to be applicable and reviewed with respect to a particular situation."²⁵ Burger also expressed concern over excessive regulatory requirements, "especially where relatively user friendly products are to be reviewed [in a] regulatory system designed for review of toxic agricultural chemicals"²⁶

III. PATENT LAW DEFINITION AND PURPOSE

The power of Congress to enact the patent laws originates in Article I, Section 8, Clause 8 of the United States Constitution which states, "The Congress shall have Power . . . To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries;"²⁷ The Framers of the Constitution must have thought that promoting the "useful Arts" would benefit society and this fundamental purpose provides the ultimate standard for evaluating the patent laws enacted by Congress.²⁸ This purpose can be served "by providing an incentive for invention, disclosure, innovation, and by allowing patent owners to coordinate research and development of the new tech-

²² *Id.*

²³ E-mail Interview with Greg J. Burger, New Product Development, Illovo Sugar, LTD (Feb. 2, 2001) (on file with the San Joaquin Agricultural Law Review).

²⁴ *Id.*

²⁵ *Id.*

²⁶ *Id.*; see also Henry I. Miller, *No Kernel of Truth*, FOOD TECH., Dec. 2000, at 120 (describing the United States government's wrong-based regulatory approach to gene-spliced plants).

²⁷ U.S. CONST. art. I, § 8, cl. 8.

²⁸ Paul Blunt, Note, *Selective Breeding and the Patenting of Living Organisms*, 48 SYRACUSE L. REV. 1365, 1371 (1998).

nology.”²⁹ A. Samuel Oddi suggests “that the present patent system does not provide adequate incentives for creation of . . . inventions [to] sustain and advance the United States economy in the twenty-first century.”³⁰ “[W]hether the patent system provides a net social benefit has not been empirically resolved . . . [despite] a widely held perception . . . that it does . . . [i]t is a most propitious time for a re-evaluation of how best to achieve the promise of article 1, section 8, clause 8 of the Constitution.”³¹

“The difficulty of formulating conditions for patentability was heightened by the generality of the constitutional grant and the statutes implementing it”³² “The inherent problem was to develop some means of weeding out those inventions which would not be disclosed or devised but for the inducement of a patent.”³³ Congress defines patentable inventions as “[w]hoever 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 therefor, subject to the conditions and requirements of this title.”³⁴

The 1952 codification of the patent laws introduced some new provisions in replacing the word “art” with the word “process.”³⁵ Process is defined as “process, art or method, and includes a new use of a known process, machine, manufacture, composition of matter, or material.”³⁶ The court in *Joseph Bancroft & Sons Co. v. Robert C. Watson, Commissioner of Patents* declared that this new provision provides that “a new use of a previously known invention is no longer a bar to a patent [as long as] all the other requisites of patentability are met.”³⁷ Congress defines those requisites of patentability as an invention that has the “qualities of novelty, utility, and non-obviousness.”³⁸ The court in *Bancroft* reasons, “the fact . . . that the industry had been searching for a solution to a difficult problem, [and the applicants’ so-

²⁹ *Id.* at 1373.

³⁰ A. Samuel Oddi, *Beyond Obviousness: Invention Protection in the Twenty-first Century*, 38 AM. U.L. REV. 1097, 1147 (1989).

³¹ *Id.* at 1148.

³² *Graham v. John Deere Co.*, 383 U.S. 1, 10 (1966).

³³ *Id.* at 11.

³⁴ 35 U.S.C.S. § 101 (2000).

³⁵ 35 U.S.C.S. § 101 (2000) (based on 35 U.S.C. § 31 (1946)).

³⁶ 35 U.S.C.S. § 100(b) (2000).

³⁷ *Joseph Bancroft & Sons Co. v. Robert C. Watson*, 170 F. Supp. 78, 80 (D.D.C. 1959).

³⁸ *Raymond M. Carson and Louis A. Rosproy v. Charles Bland and B & D Distrib. Co.*, 398 F.2d 423, 426 (10th Cir. 1968); *see* 35 U.S.C.S. §§ 101-103 (2000).

lution] . . . met with commercial success, is evidence of the fact the solution was not obvious to a person reasonably skilled in the art, but involved the exercise of the inventive faculty.”³⁹

A. *Statutory Requirements for Obtaining a Patent*

The standard Congress chose to implement the stated Constitutional purpose of promoting “the Progress of Science and useful Arts”⁴⁰ includes issuing patents upon which the subject matter fulfills the requirements of useful process, novelty, and non-obviousness.⁴¹

1. Useful Process

“Whoever invents or discovers any new and useful process . . . or composition of matter, or any new and useful improvement thereof,”⁴² Again, “the term ‘process’ means process, art or method, and includes a new use of a known process, machine, manufacture, composition of matter, or material.”⁴³

2. Novelty

A person shall be entitled to a patent unless – (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent, or (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States⁴⁴

3. Nonobvious

A patent may not be obtained . . . if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.⁴⁵

³⁹ *Joseph Bancroft & Sons Co.*, 170 F. Supp. at 81.

⁴⁰ U.S. CONST. art. I, § 8, cl. 8.

⁴¹ 35 U.S.C.S. § 101-103 (2000).

⁴² 35 U.S.C.S. § 101 (2000).

⁴³ 35 U.S.C.S. § 100(b) (2000).

⁴⁴ 35 U.S.C.S. § 102(a)-(b) (2000).

⁴⁵ 35 U.S.C.S. § 103(a) (2000).

B. Judicial Interpretation of Statutory Requirements for Chemical Patentability

Predictability is an important policy in patent law.⁴⁶ This policy is sometimes undermined by ambiguous tests used by the judiciary in interpreting statutory requirements.⁴⁷ The following discussion elucidates this observation in relation to the determination of patentability requirements.

1. Useful process

“Chemistry . . . is predominately an unpredictable art.”⁴⁸ This unpredictability makes it “difficult for courts and the PTO [Patent and Trademark Office] to apply already ambiguous statutory language.”⁴⁹ The Supreme Court clarified the utility requirement as it pertained to chemical processes, as opposed to a chemical product or composition,⁵⁰ by reversing a United States Court of Customs and Patent Appeals decision. The Supreme Court held that a chemical process must meet the same requirement of utility as the chemical product, which requires a showing of utility greater than that of an object of scientific research or use-testing.⁵¹

Any chemical shown to be as effective and versatile as the powerful biocide methyl bromide would most certainly be considered useful beyond simple use-testing. For instance, public use chemicals, which were synthesized long ago, present in the literature as fumigants with known properties,⁵² have a potentially tremendous utility as alternatives to methyl bromide.⁵³ “The basic quid pro quo contemplated by

⁴⁶ Paul R. Michel, *The Challenge Ahead: Increasing Predictability in Federal Circuit Jurisprudence for the New Century*, 43 AM. U. L. REV. 1231, 1233-34 (1994) (discussing the importance of predictability in matters of entitlement within the national, semispecialized court, the United States Court of Appeals for the Federal Circuit).

⁴⁷ Timothy R. Holbrook, *The More Things Change, The More They Stay The Same: Implications of Pfaff v. Wells Electronics, Inc. and the Quest for Predictability in the On-Sale Bar*, 15 BERKELEY TECH. L.J. 933, 939 (2000).

⁴⁸ William D. Marsillo, *How Chemical Nomenclature Confused the Courts*, 6 U. BALT. INTEL. PROP. J. 29, 37 (1997).

⁴⁹ *Id.* at 38.

⁵⁰ See *Brenner, Comm’r of Patents v. Manson*, 383 U.S. 519, 530 (1966) (acknowledging that differences arise as to how the test of usefulness is to be applied to chemical processes).

⁵¹ *Brenner*, 383 U.S. at 535.

⁵² Lehman, *supra* note 16, at 659.

⁵³ See W. D. Kelley and R. Rodriguez-Kabana, *Effects of Annual Applications of Sodium Azide on Soil Fungal Population with Emphasis on Trichoderma Species*, 12

the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility.”⁵⁴ Newly synthesized chemicals as well as public use chemicals, which have the potential to outperform methyl bromide, therefore, qualify as useful under the constitutional and statutory requirements.

2. Novelty

“It is well settled that prior art . . . must sufficiently describe the claimed invention to have placed the public in possession of it.”⁵⁵ The prior art must be enabling, in that “one of ordinary skill in the art could have combined the publication’s description of the invention with his own knowledge to make the claimed invention.”⁵⁶ There appears to be a lack of predictability for determining when a particular chemical will be considered anticipated from a prior art publication. This is no doubt related to the unpredictability of properties of similar chemical structures. A chemical with the same or similar structure to one in public use, which after extensive research, was determined to outperform methyl bromide, may be considered anticipated and therefore, unpatentable. This is the predicted result even though the resultant chemical product could resolve an ongoing international search for a non-ozone depleting alternative to methyl bromide.

It is also appropriate to analyze the requirements of a “prior publication,” as stated in *In re Edward Burton Le Grice*, quoting Robinson on Patents, Sec. 325.⁵⁷

To have this effect, the publication must be: (1) a work of public character, intended for general use; (2) within reach of the public; (3) published before the date of the later invention; (4) a description of the same complete and operative art or instrument; and (5) so precise and so particular that any person skilled in the art to which the invention belongs can construct and operate it without experiments and without further exercise of inventive skill. Unless a publication possesses all these characteristics it does not place the invention in the possession of the public, nor defeat the claim of its re-inventor to a patent.⁵⁸

PESTICIDE SCI. 235, 235 (1981).

⁵⁴ Brenner, 383 U.S. at 534.

⁵⁵ *In re John A. Donohue*, 766 F.2d 531, 533 (Fed. Cir. 1985); 35 U.S.C.S. § 102(b) (2000).

⁵⁶ *Id.*

⁵⁷ *In re Edward Burton Le Grice*, 301 F.2d 929, 933 (C.C.P.A. 1961).

⁵⁸ *Id.*

Under this summary of “prior publication” requirements, after extensive research, a previously published chemical composition found to be an alternative to methyl bromide may be deemed patentable.

3. Nonobvious

The most difficult patent hurdle to overcome for many inventions, including chemical composition inventions, is the requirement for non-obviousness. *Graham v. John Deere Co.*⁵⁹ is the first Supreme Court decision on patent validity which provides insight on the interpretation of the test of obviousness codified in the Patent Act of 1952.⁶⁰ The court in *Graham* suggests that “secondary considerations as commercial success, long felt but unsolved needs, failure of others [to solve the problem], might be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented.”⁶¹ The issue of chemical nonobviousness presents a unique difficulty for the courts. The courts have been unable to consistently maintain the distinction between “the list of chemicals generated by rules of nomenclature and the actual purpose for producing particular compositions.”⁶² Recent cases decided by the Federal Circuit in the early 1990’s broadened the interpretation of the previously used generalized bright line per se rule⁶³ where “a claimed species is obvious if a prior art discloses a genus that encompasses the claimed species.”⁶⁴ When deciding whether the claimed chemical was an obvious result from the prior art reference, “[t]he courts gradually moved to a more holistic view of chemical compounds that considered chemical properties in addition to chemical structure.”⁶⁵ The Jones court, in particular, determined that a species falling within the prior art disclosed genus does not necessarily result in structural similarity and therefore, prima facie obviousness.⁶⁶ “Every case, particularly those raising the issue of obviousness under section 103, must necessarily be decided upon its own

⁵⁹ *Graham v. John Deere Co.*, 383 U.S. 1, 3 (1966).

⁶⁰ 35 U.S.C.S. § 103.

⁶¹ *Graham*, 383 U.S. at 17-18.

⁶² Marsillo, *supra* note 48, at 30.

⁶³ See *Merck & Co. Inc. v. Biocraft Laboratories, Inc.*, 874 F.2d 804 (Fed. Cir. 1989) (using generally applicable lists of compounds in a particular disclosed genus to render obvious any species that happens to fall in it as a method of analysis in the obviousness inquiry).

⁶⁴ Marsillo, *supra* note 48, at 31.

⁶⁵ *Id.* at 30; see *In re Baird*, 16 F.3d 380 (Fed. Cir. 1994); see also *In re Jones*, 958 F.2d 347 (Fed. Cir. 1992).

⁶⁶ *Jones*, 958 F.2d at 349-350.

facts.”⁶⁷ “The test of obviousness . . . is highly fact-specific by design.”⁶⁸ “The mere fact that a device or process utilizes a known scientific principle does not alone make that device or process obvious.”⁶⁹ One could extrapolate this concept to suggest that a chemical composition possessing the same properties would also, not alone, make the new use of an old chemical obvious. Even if this were true, it would be difficult to argue that an expert could not predict the result which suggests obviousness from routine experimentation.⁷⁰

Given the history of cases decided over the years, chemicals published years ago in the literature as fumigants are not patentable as alternatives to methyl bromide. This is because such chemicals would be considered anticipated from the prior art and therefore, not novel. Further, because some of the most promising alternative chemicals to methyl bromide tend to have similar structures and properties, their discovery as alternative fumigants through R&D would be considered obvious to a person having ordinary skill in the art. On the other hand, if one looks at the method-of-use patent granted to Sepracor, Inc. for the specific use of a previously patented Claritin metabolite in treating allergies,⁷¹ one may come to a different conclusion. It seems as though it would be obvious to one skilled in the art that a metabolite of the allergy drug Claritin would be useful in treating allergies. This is similar to requesting a method-of-use patent on a known fumigant for the specific use of treating various insects in place of nematodes as is described in the prior art.⁷² This patenting opportunity is quite tenuous as metabolite patents have a mixed record in the courts.⁷³ Legal experts agree, defending a metabolite patent requires the holder “to show that it took some serious work and brainpower to identify the . . . metabolite to make the case that it deserves a separate patent.”⁷⁴

⁶⁷ *Id.* at 350.

⁶⁸ *In re Brouwer*, 77 F.3d 422, 425 (Fed. Cir. 1996).

⁶⁹ *Uniroyal, Inc. v. Rudkin-Wiley Corp.*, 837 F.2d 1044, 1053 (Fed. Cir. 1988).

⁷⁰ *See id.*

⁷¹ *See Amy Barrett, New Teeth for Old Patents*, BUS. WK., Nov. 30, 1998, at 92, (discussing strategies used by pharmaceutical companies holding patents to block or delay generic competition).

⁷² *See Lehman, supra* note 16.

⁷³ Barrett, *supra* note 71; *see, e.g., Carey Krause, BMS Wins Round in Generics Battle Blocking Buspirone Market Entry; Bristol-Myers Squibb*, CHEM. MKT. REP., Mar. 26, 2001, at 16.

⁷⁴ Barrett, *supra* note 71.

IV. CRITICISM OF THE PATENT LAWS

“Some [commentators] see patents as essentially unfair”⁷⁵ and characterize a patent as a “Faustian bargain.”⁷⁶ Others say, “[a] patent gives the public something it did not have before — a new process, a machine, or a chemical composition. The ‘bargain’ is a fair one, because the public is rewarded with the new technology, and the inventor has the incentive to invent.”⁷⁷

“Since the 1980’s, bipartisan government policies have encouraged scientists and universities to patent their discoveries, attract venture capital and form companies to convert knowledge into products.”⁷⁸ The pharmaceutical industry started campaigning in the early 1980’s for a change in patent law that would extend patent protection for drugs and pesticides.⁷⁹ The industry argued that “the patent life of drugs is shortened by the time consumed by regulatory review.”⁸⁰ The Pharmaceutical Research and Manufacturers Association (PhRMA), previously known as Pharmaceutical Manufacturers Association, claims that “drugs approved in 1981 lost an average of ten and two tenths years of [their statutory] patent lives before their first sale.”⁸¹ The PhRMA also contends that the “lost patent life life [sic] reduces incentives to invest in drug research . . . [and] erodes the U.S. competitive position in an important high technology”⁸² These concerns were partially alleviated for the pharmaceutical industry when a patent term restoration act was passed in 1984.⁸³ This act “provides up to five additional years of patent protection . . . for new brand-name drugs to provide more incentive for pharmaceutical companies to in-

⁷⁵ Joseph N. Hosteny, *The Sky is Falling; Or, Over-Reaction to the Anecdote*, INTELL. PROP. TODAY, May 2000, at 8 (espousing the strengths and weakness of the current patent system).

⁷⁶ James Gleick, *Patently Absurd*, N.Y. TIMES, Mar. 12, 2000, § 6 (Magazine), at 44.

⁷⁷ Hosteny, *supra* note 75, at 8 (presenting an example of a client who invented new tools and methods for installing artificial knees which would not have been economical without patent protection).

⁷⁸ Tom Abate, *Scientists’ ‘Publish or Perish’ Credo Now ‘Patent and Profit’*, SAN FRANCISCO CHRONICLE, Aug. 13, 2001, at D1 (discussing new incentives that guide the advancement of scientific knowledge).

⁷⁹ Marjorie Sun, *The Push to Protect Patents on Drugs; The Drug Industry Nearly Won Last Year, But then the Political Winds Changed*, 222 AM. ASS’N FOR THE ADVANCEMENT OF SCI. 593, 593 (1983).

⁸⁰ *Id.*

⁸¹ *Id.*

⁸² *Id.*

⁸³ 35 U.S.C.S. §§ 155, 156 (2002).

vest in research and testing of new drugs and to alleviate in part the unintended effects of the FDA [Food and Drug Administration] approval process on the length of pharmaceutical patent terms.”⁸⁴

The pharmaceutical and agricultural chemical fields are both “highly patent-sensitive industries”⁸⁵ where a patent is the first step in obtaining venture capital to assist in the funding of R&D required for approval by the appropriate regulatory agency.⁸⁶ This is especially true for small to medium companies who cannot afford to absorb the risk of developing a chemical which may prove to be economically unprofitable.⁸⁷

Nobel Peace Prize winner, Norman Borlaug, realizes the value of bioscience research to enable the world’s farmers to double “gross food production by the year 2025 to feed the world’s burgeoning population.”⁸⁸ Borlaug is credited with saving more human lives than anyone else in history by “breeding the high-yield dwarf wheat that sparked the Green Revolution.”⁸⁹ Borlaug is quoted as saying, “Let’s not tie science’s hand through excessively restrictive regulations. The issue of intellectual property rights must be addressed.”⁹⁰ The same holds true for discovering chemical alternatives to methyl bromide, as bioscience research depends on pest-free environments for success.

An excellent example of the discouraging effect of Environmental Protection Agency (EPA) policy and regulation occurs in the area of

⁸⁴ George W. Neuner, *Extending Market Exclusivity for Original Patented Brand Name Drugs*, INTELL. PROP. TODAY, June, 1999, at 8.

⁸⁵ Daniel Makina, *Trips Agreement on Trial*, FIN. MAIL (SOUTH AFRICA), Mar. 16, 2001, at 17 (discussing the effects of the World Trade Organization agreement on trade-related aspects of intellectual property rights (Trips) on patent rights in South Africa).

⁸⁶ Joy LePree, *Biotech Funds Slowed by Patent Office Logjam; Biotechnology; Drugs & Fine Chemicals*, CHEM. MARKETING REP., June 27, 1994, at 5; see also Gordon Graff, John M. Winton, Herbert C. Short, Shota Ushio, David Hunter & Reginald Rhein, *Biotechnology Growing Greener at Last; The Problems: Patents and Regulations*, CHEM. WK., Sept. 30, 1987, at 22 (discussing patent and regulatory hurdles for biotechnology products).

⁸⁷ Interview with Greg Burger, *supra* note 23; E-mail Interview with Rodrigo Rodriguez-Kabana, Distinguished Professor, Auburn University (Aug. 3, 2000) (on file with the San Joaquin Agricultural Law Review).

⁸⁸ Anne Cook, *Borlaug: Will Farmers be Permitted to Use Biotechnology?*, KNIGHT RIDDER/TRIB. NEWS SERVICE, at <http://www.biotech-info.net/borlaug-farmers.html> (June 14, 2001) (relating details of Norman Borlaug’s remarks at Tuskegee University in relation to the recently established Norman Borlaug/DuPont scholarship program at Tuskegee to support undergraduate and graduate students studying biosciences).

⁸⁹ Ronald Bailey, *Billions Served*, REASON, April, 2000, at 31.

⁹⁰ Cook, *supra* note 88.

gene-spliced plant and food research.⁹¹ “EPA and other government agencies in the U.S. and elsewhere hold gene-sliced foods to a far higher standard than other similar foods, even requiring the hugely expensive testing as pesticides of gene-spliced crop and garden plants . . . that have been genetically improved for enhanced pest or disease resistance.”⁹² “EPA’s policy is so potentially damaging and outside scientific norms that it has galvanized the scientific community, which has repeatedly and unequivocally condemned federal agencies’ policies.”⁹³ “[R]egulatory agencies have regulated foods from gene-sliced plants in a discriminatory and unnecessarily burdensome way. What we need is government policies that make scientific and common sense, and that do not punish innovation.”⁹⁴

In purely economic terms, the fact that “the law does not distinguish between inventions that require extensive research and inventions that amount to a momentary flash of insight,” the system is rendered “inequitable and perhaps even dangerous.”⁹⁵ Strangely enough, once patent protection is secured, it may be in jeopardy under threat from the U.S. Administration under the guise of the war on bioterrorism.⁹⁶ John R. Thomas comments that “the courts have been virtually silent on the philosophical underpinnings of the value placed on an invention as an improvement over prior technology.”⁹⁷

⁹¹ See Miller, *supra* note 26.

⁹² Miller, *supra* note 26 at 120.

⁹³ *Id.*

⁹⁴ *Id.*

⁹⁵ Gleick, *supra* note 76.

⁹⁶ See James Surowiecki, *No Profit, No Cure*, THE NEW YORKER, Nov. 5, 2001, at 46 (relating the fact that Tommy Thompson, Secretary of Health and Human Services, “negotiated” a half price deal with Bayer Corporation by threatening to break Bayer’s patent on the anthrax drug, Cipro); see also William Thomas, *The Cipro Looters*, NAVIGATOR, Dec. 2001, at 7 (describing the government’s action against Bayer Corp. concerning Cipro as a looter).

⁹⁷ John R. Thomas, *The Question Concerning Patent Law and Pioneer Inventions*, 10 BERKELEY TECH. L. J. 35, 40 (1995), available at http://www.law.berkeley.edu:80/journals/btlj/articles/10_1/Thomas/html/text.html.

V. STRATEGIES FOR PROVIDING INCENTIVES FOR THE DISCOVERY OF CHEMICAL ALTERNATIVES TO METHYL BROMIDE

A multitude of programs have been initiated for the purpose of discovering and incorporating alternatives to chemical pest control.⁹⁸ An EPA scientist working with the Pest Management Alliance Demonstration project stresses that “the alternatives have to be economically viable.”⁹⁹

There is a compelling argument for an economic nonobviousness standard, in addition to technical nonobviousness, to provide an incentive to the biotechnology industry where inventions are expensive and risky.¹⁰⁰ The same holds true for chemical and biological researchers searching for chemical alternatives to methyl bromide. Under an economic standard, public domain fumigants previously used for other purposes, which are likely to provide a non-ozone depleting replacement for methyl bromide, become patentable because they are not obvious from an economic standpoint. The protection of a patent would provide the incentive for researchers to take the risk of making the previously prohibitive investment required to successfully complete the extensive regulatory hurdles required for registration of new chemical pesticides.

A novel interpretation of the utility requirement of Section 101 of the Patent Act, called the “prospective utility doctrine,” will allow an inventor to receive a patent, if it could be demonstrated that “one of ordinary skill in the art would reasonably believe that her invention has a significant chance of being matched with a significant use in the foreseeable future.”¹⁰¹ This doctrine more closely supports the Constitutional purpose of promoting the progress of the useful arts by taking into account the magnitude of the potential use of the invention, and at the same time securing protection at an early stage of their invention’s development, allowing for the raising of “the large sums of money necessary to develop inventions into [commercial] products.”¹⁰² This

⁹⁸ See Dennis Pollock, *Nature’s Pesticide*, THE FRESNO BEE, Aug. 18, 2001, at C1; see also Robert Rodriguez, *Growers Seek Safer Substitute*, THE FRESNO BEE, Jan. 28, 2001, at C1 (describing research on methyl bromide alternatives for use in drip irrigation systems, which is currently being conducted at the USDA, ARS in Parlier, CA).

⁹⁹ Pollock, *supra* note 98, at C5.

¹⁰⁰ Karen I. Boyd, *Nonobviousness and the Biotechnology Industry: A Proposal for a Doctrine of Economic Nonobviousness*, 12 BERKELEY TECH. L. J. 311, 343 (1997).

¹⁰¹ Nathan Machin, *Prospective Utility: A New Interpretation of the Utility Requirement of Section 101 of the Patent Act*, 87 CAL. L. REV. 421, 455 (1999).

¹⁰² *Id.* at 456.

doctrine would certainly be advantageous for the inventor seeking to patent a chemical alternative to methyl bromide by researching potentially useful public domain chemicals with similar properties, but which requires extensive monetary support to develop. In addition, these chemicals could arguably be shown to be novel as well under the current standards because they are not in public use as replacements for methyl bromide and would require extensive research to make that determination.

Another plan for providing an incentive for enhancing R&D on alternatives to methyl bromide involves the "rights of exploitation" legislation suggested by Rodrigo Rodriguez-Kabana.¹⁰³ This strategy could provide the necessary incentive to encourage a plethora of creative research so critical to the discovery of economically effective alternatives to methyl bromide.

VI. CONCLUSION

The current patent laws indirectly discourage the discovery of methyl bromide alternatives, however, the more direct deterrent for this research stems from the overwhelming R&D costs necessary to satisfy regulatory agency requirements. Private companies involved in R&D attempt to recover some of that cost by securing a patent on their discoveries, but if the acquisition of a patent is not feasible, R&D efforts are minimized.

The patent law as it stands today has proved to uphold its original purpose of providing a short-term monopoly on a new discovery in exchange for revealing the discovery to the public. The necessity for unencumbered cutting edge research in the pharmaceutical, chemical, and biotechnology fields as well as heightened environmental concerns in recent history combine to affirm the need for novel ways to maintain the forward progress of our liberty conscious society.

The most promising approach to overcoming the discouraging effects of costly regulations and subsequent difficulty in securing a patent on potential chemical alternatives to methyl bromide would be the enactment of "rights of exploitation"¹⁰⁴ legislation. This approach merits credence because it originates with those who are most interested in achieving the goal of discovering chemical alternatives to methyl bromide. This legislation would "promote the Progress of Sci-

¹⁰³ Interview with Rodrigo Rodriguez-Kabana, *supra* note 19.

¹⁰⁴ *Id.*

ence”¹⁰⁵ by allowing for the exploitation of unpatentable public domain chemicals, which would assist in unraveling one of societies most critical agricultural dilemmas. These rules could be tailored for all industries affected by extensive regulatory requirements, which would provide R&D incentives for new uses of public domain products or processes. The enactment of this type of legislation could potentially result in the research necessary to provide viable economic chemical solutions to the imminent proscription of one of agricultures most effective tools for the maximization of food and fiber.

GINA T. MILLER

¹⁰⁵ U.S. CONST. art. I., § 8, cl. 8.