

# NOTES

## Compensating Manufacturers Submitting Health and Safety Data to Support Product Registrations After *Ruckelshaus v. Monsanto*

Congress regulates chemical products marketed in the United States to ensure that they are safe and effective for the people who use them and not harmful to the human and natural environments.<sup>1</sup> A major concern of Congress is to develop adequate information on product safety and effectiveness to enable government decision-makers to make appropriate regulatory decisions and to assist the public to make informed purchases.<sup>2</sup> Chemical substances are pervasive in the United States, and include such common products as drugs, cosmetics, insecticides, and food additives.<sup>3</sup> Since regulation of these products has been achieved through piecemeal regulatory actions aimed at particular industries, the regulations sometimes treat similar products inconsistently.

Congress has addressed the need for adequate information about various kinds of chemical products in three ways: by appropriating government money for research,<sup>4</sup> by requesting a particular federal agency to conduct the research,<sup>5</sup> and by requiring industry to develop adequate data by placing on it the burden of determining whether a product is safe and effective.<sup>6</sup> Shifting the burden to industry has economic and social advantages. With such a program, product manufacturers develop health and safety data on a product before placing the product on the market; manufacturers expedite

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1. *See, e.g.*, 7 U.S.C. § 136a (1982) (FIFRA); 15 U.S.C. § 2601(b)(1) (1982) (TSCA); 21 U.S.C. § 355(b) (1982) (new drugs); 21 U.S.C. § 360b (1982) (new animal drugs); 21 U.S.C. § 348 (1982) (food additives); 21 U.S.C. § 376 (1982) (color additives); 21 U.S.C. § 357 (1982) (antibiotics).

2. *See, e.g.*, 7 U.S.C. § 136a(c)(2)(A) (1982) (FIFRA); 15 U.S.C. § 2609 (1982) (TSCA). The recent disaster in Bhopal, India, reinforces society's need to have adequate information about the health effects of industrial chemicals. The chemical involved in the Bhopal accident, methyl isocyanate, was responsible for injuring or killing more than 200,000 people. Workers on duty at the time of the accident believed the chemical was harmful only as an eye irritant. *N.Y. Times*, Jan. 30, 1985, at 6, col. 2 (midwest edition).

3. *See infra* notes 90-172 and accompanying text.

4. *See, e.g.*, 7 U.S.C. § 136r (1982) (FIFRA); 15 U.S.C. § 2609(a) (1982) (TSCA); 15 U.S.C. § 2054(c) (1982) (Consumer Product Safety Act of 1972).

5. *See, e.g.*, 7 U.S.C. § 136r (1982); 15 U.S.C. § 2609(a) (1982); 15 U.S.C. § 2054(a)(2) (1982) (directing the Consumer Product Safety Commission to "conduct such continuing studies and investigations of deaths, injuries, diseases, other health impairments, and economic losses resulting from accidents involving consumer products").

6. *See, e.g.*, 7 U.S.C. § 136a (1982); 15 U.S.C. § 2601(b)(1) (1982).

the development of data in order to market the product as soon as possible; and manufacturers develop data only for those products with market potential. A company may not market a product until it submits adequate health and safety data for the product to the appropriate regulatory agency. Once submitted, the health and safety data can be made available to the public either through a specific disclosure provision in the statute or through the general disclosure provision of the Freedom of Information Act.<sup>7</sup> Problems are created, however, when companies in competition with the submitter obtain the data through a public disclosure provision or use the data to obtain permission from the regulatory agency to market the product themselves. Although manufacturing processes and product formulae can be protected when health and safety data are disclosed,<sup>8</sup> free riders may avoid the substantial costs of developing health and safety data as well as the risks inherent in marketing a new product.<sup>9</sup>

Regulations requiring companies to develop health and safety data before marketing a product attempt to prevent free-rider problems.<sup>10</sup> Contradictory

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7. 5 U.S.C. § 552(a)(1) (1982). Congress enacted the Freedom of Information Act ("FOIA") to make available to the public information held by the federal government. *Id.* The FOIA exempts certain things from disclosure, including "trade secrets and commercial or financial information obtained from a person and privileged or confidential." *Id.* § 552(b)(4). It has been noted, however, that "absent specific statutory language to the contrary, agency regulations generally have uncritically labeled health and safety data as proprietary and thus exempted such information from disclosure under the [FOIA]." McGarity & Shapiro, *The Trade Secret Status of Health and Safety Information*, 93 HARV. L. REV. 837, 838 (1980). In *Chrysler Corp. v. Brown*, 441 U.S. 281 (1979), the Supreme Court held that federal agencies have some power to release information within a FOIA exemption. The Court said, "in order for such regulations to have the 'force and effect of law,' it is necessary to establish a nexus between the regulations and some delegation of the requisite legislative authority by Congress." *Id.* at 304. Later in the opinion, the Court explained that "[t]his is not to say that any grant of legislative authority to a federal agency by Congress must be specific before regulations promulgated pursuant to it can be binding on courts in a manner akin to statutes. What is important is that the reviewing court reasonably be able to conclude that the grant of authority contemplates the regulations issued." *Id.* at 308.

8. *See, e.g.*, 7 U.S.C. § 136h(d)(1) (1982) (FIFRA); 15 U.S.C. § 2613(b) (1982) (TSCA); 21 U.S.C. § 71.15a(h)(2)(i) (1982) (food additives); 21 U.S.C. § 171.1(h)(2)(i) (1982) (color additives); 21 U.S.C. § 431.71(f)(1) (1982) (antibiotics); 21 U.S.C. § 601.51(f)(1) (1982) (biological products).

9. The average cost of health and safety data for a new drug has been estimated to be between \$2.7 and \$4.7 million. Clymer, *The Economics of Drug Innovation*, in *THE DEVELOPMENT AND CONTROL OF NEW DRUG PRODUCTS* 112 (1971), *quoted in* McGarity & Shapiro, *supra* note 7, at 849. For pesticides, the average cost of health and safety data has been estimated at between \$5 and \$7 million. S. REP. No. 334, 95th Cong., 1st Sess. 30 (1977), *cited in* McGarity & Shapiro, *supra* note 7, at 849. One author has said, "the barriers to entering the market are the large capital investment required for manufacturing facilities, the large cash reserves necessary either to purchase patent licenses or to sort through a large number of chemicals looking for a suitable pesticide, and the network of salesman to distribute the product. Regulatory requirements are also a barrier to entering the market, but if all the regulatory requirements disappeared, it would still be impossible for a small firm to get into the pesticide manufacturing business." Davies, *The Effect of Federal Regulation on Chemical Industry Innovation*, 46 LAW & CONTEMP. PROBS. 41, 46-47 (1983).

10. *See infra* note 91 and accompanying text.

policy goals within a single regulation have, however, often resulted in inadequate protection of the original data submitter. To bolster their position, original data submitters argued that the health and safety data they produced to support a product registration were "trade secrets" which, as property, should be paid for when "taken" by the government.<sup>11</sup> In a recent decision, *Ruckelshaus v. Monsanto*,<sup>12</sup> the United States Supreme Court agreed with this position, holding that just compensation is required under the taking clause of the fifth amendment when the government appropriates health and safety data after having explicitly assured the submitter at the time of submission that the data would not be used for any purpose other than those specifically mentioned in the regulation.<sup>13</sup> The *Monsanto* decision, however, leaves many questions unanswered, including what constitutes "just compensation" for use of data, and how the ruling may apply to other data-reporting regulations.

This Note begins by examining the *Monsanto* decision and the Supreme Court's approach to determining whether data disclosure and use constitute a "taking."<sup>14</sup> The Note then examines several statutory approaches to com-

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11. See *infra* note 54. The *Restatement* defines trade secrets as "any formula, pattern, device or compilation of information which is used in one's business, and which gives him an opportunity to obtain an advantage over competitors." RESTATEMENT OF TORTS § 757 comment b (1939). This definition, which would include health and safety data, is a change from the common law position. See *Public Citizen Health Research Group v. FDA*, 704 F.2d 1280, 1286 (D.C. Cir. 1983); McGarity & Shapiro, *supra* note 7 at 863; Connelly, *Secrets and Smokescreens: A Legal and Economic Analysis of Government Disclosures of Business Data*, 1981 Wis. L. REV. 207, 230. Some courts have restricted trade secret protection to the production process itself, including any "unpatented, secret, commercially valuable plan, appliance, formula, or process which is used for the making, preparing, compounding, treating, or processing of articles or materials which are trade commodities." U.S. *ex rel. Norwegian Nitrogen Prods. Co. v. United States Tariff Comm'n*, 6 F.2d 491, 495 (D.C. Cir. 1925). Even if not a trade secret, health and safety data has been protected as confidential commercial information under exemption four of the FOIA. 704 F.2d at 1290. See also *National Parks and Conservation Ass'n v. Morton*, 498 F.2d 765, 766 (D.C. Cir. 1974). See generally Annot., 21 A.L.R. FED. 224 (1974).

12. 104 S. Ct. 2862 (1984).

13. *Id.* at 2875. The decision explicitly overruled the dicta of Justice Holmes in *E.I. duPont de Nemours Powder Co. v. Masland*, 244 U.S. 100 (1917). Justice Holmes said in that case, "[t]he word 'property' as applied to trade-marks and trade secrets is an unanalyzed expression of certain secondary consequences of the primary fact that the law makes some rudimentary requirements of good faith. Whether the plaintiffs have any valuable secret or not the defendant knows the facts, whatever they are, through a special confidence he accepted. The property may be denied but the confidence cannot be." *Id.* at 102.

14. This Note assumes that the benefits gained by public disclosure outweigh any inconvenience to individual companies. For an excellent discussion of the policies for and against disclosure, see McGarity & Shapiro, *supra* note 7, at 839-857. The problem was summarized as follows:

Disclosure may, for example, reduce the incentives for new product research and development by preventing companies from fully recouping the high cost of generating the required test data, and by making it easier for competitors to duplicate and license breakthroughs. Nondisclosure, on the other hand, may hamper scientific progress, deny consumers the opportunity to make fully informed product use decisions, increase the risks that agency decisions based on faulty data or analysis

pensation, including the exclusive-use period authorized by the Federal Insecticide, Fungicide, Rodenticide Act ("FIFRA") and the compensation schemes set up in FIFRA and the Toxic Substances Control Act of 1976 ("TSCA"). The Note concludes by proposing a cost-sharing program that allows an originator of data to receive compensation based on the number of subsequent manufacturers who wish to market the product. A cost-sharing program relieves the original data submitter of the burden of solely paying for health and safety data for competitive products, while remaining consistent with the philosophy that the cost of developing health and safety data should be a necessary cost of marketing a product.

## I. COMPENSATION UNDER THE TAKING CLAUSE

### A. *The Supreme Court's Decision in Ruckelshaus v. Monsanto*

One way to compensate a company for submitting health and safety data in order to obtain a registration to market a product is to identify the data as a trade secret or some other property interest. Under the taking clause of the fifth amendment, any taking of private property by the government for a public purpose requires "just compensation."<sup>15</sup> Trade secrets have not, however, always been considered property. State law first began protecting trade secrets to prevent discovery of manufacturing processes and formulae by "improper means," including breaches of confidence by former employees and others.<sup>16</sup> Although intended to maintain such standards of commercial ethics, trade secret protection also encouraged inventiveness.<sup>17</sup> State trade secret law, therefore, supplemented the protection provided by patent and copyright law.<sup>18</sup> As trade secret law developed, some states began to recognize

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will remain undiscovered, and encourage potentially hazardous duplicate human testing.

*Id.* at 838. See also REVIEW PANEL ON NEW DRUG REGULATION, U.S. DEP'T OF HEALTH, EDUCATION, AND WELFARE, INTERIM REPORT, AN EVALUATION OF FDA'S TRADE SECRET AND FREEDOM OF INFORMATION POLICIES (November 15, 1976) [hereinafter cited as REVIEW PANEL].

15. "No person shall be . . . deprived of . . . property, without due process of law; nor shall private property be taken for public use, without just compensation." U.S. CONST. amend. V. " 'Taking' is, of course, constitutional law's expression for any sort of publicly inflicted private injury for which the Constitution requires payment of compensation." Michelman, *Property, Utility and Fairness: Comments on the Ethical Foundations of 'Just Compensation' Law*, 80 HARV. L. REV. 1165, 1165 (1967).

16. See 4 RESTATEMENT OF TORTS § 757(a), (b) (1939).

17. If a company can keep a successful commercial product or process secret, it is able to keep the product or process from its competitors, and thereby reap monopolistic profits by being the sole company manufacturing the product or using the process.

18. The Supreme Court has held that state trade secret law is not preempted by federal patent law. *Kewanee Oil Co. v. Bicron Corp.*, 416 U.S. 470, 484 (1974). The Court did not fear that extending trade secret protection to clearly patentable innovations would undermine the disclosure policy of patent law, reasoning that trade secret law "provides for weaker protection in many respects from the patent law." *Id.* at 489-90.

that trade secrets deserved protection as property because of their similarity to other forms of intangible property.<sup>19</sup>

In *Ruckelshaus v. Monsanto*,<sup>20</sup> the Supreme Court decided for the first time that trade secrets could be considered property if state law made them so. Monsanto manufactured various chemical products subject to the registration requirements of FIFRA.<sup>21</sup> FIFRA requires companies seeking to market a product in the United States to submit adequate health and safety data on the product in order to obtain a registration for the product.<sup>22</sup> A company may not market a product in the United States unless it obtains a registration.<sup>23</sup> Subsequent applicants intending to market the same product may, however, rely on the first applicant's health and safety data in certain circumstances.<sup>24</sup> In addition, the health and safety data can be made available to interested parties through a data-disclosure provision in the statute.<sup>25</sup> Monsanto argued that disclosure of the data to the public and use of the data by subsequent applicants were unconstitutional under the taking clause,<sup>26</sup> and that the use of the data to support product registrations for subsequent applicants amounted to a taking for a private rather than a public purpose.<sup>27</sup>

The Supreme Court unanimously agreed that trade secrets, like certain other intangible property, are "deserving of the protection of the Taking Clause."<sup>28</sup> The Court went on to say that health and safety data are protected by the taking clause of the fifth amendment as long as state law recognizes the data as a trade secret.<sup>29</sup> The Court had more trouble deciding whether government use of health and safety data amounts to a taking. Three factors

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19. 1 MILGRIM, TRADE SECRETS § 1.01[2]. See also Note, *Constitutional Limitations on Government Disclosure of Private Trade Secret Information*, 56 IND. L.J. 347, 357 n.56 (1981).  
20. 104 S. Ct. 2862 (1984).

21. The district court found that Monsanto had spent in excess of \$23.6 million in developing the health, safety and environmental data necessary to obtain product registrations under FIFRA. 564 F. Supp. 552, 560 (E.D. Mo. 1983).

22. 7 U.S.C. § 136a(c)(2)(A) (Supp. 1985).

23. *Id.*

24. See *infra* notes 59-60 and accompanying text.

25. 7 U.S.C. § 136a(c)(1)(D)(ii) (Supp. 1985).

26. *Monsanto*, 104 S. Ct. at 2873.

27. *Id.* at 2879. The Court refused to rule that using submitted data for purposes of the data consideration provision of FIFRA amounted to use for a private rather than a public purpose. *Id.* at 2880. Although recognizing that the most direct beneficiaries of the data consideration provision were subsequent applicants, the Court believed that Congress had public purposes in mind when it passed the provision, finding "Congress believed that the provisions would eliminate costly duplication of research and streamline the registration process, making new end-use products available to consumers more quickly." *Id.* at 2879. This deference to congressional opinion as to what is in the public interest is consistent with recent decisions by the Court dealing with takings that have shown increasing liberality in determining what constitutes a public use. See, e.g., *Hawaii Hous. Auth. v. Midkiff*, 104 S. Ct. 2341 (1984); *Berman v. Parker*, 348 U.S. 26, 32 (1957) ("[w]hen the legislature has spoken, the public interest has been declared in terms well-nigh conclusive").

28. *Monsanto*, 104 S. Ct. at 2873.

29. *Id.* at 2874.

necessary to determine whether a taking has occurred were outlined in a previous case.<sup>30</sup> Those factors were “the character of the governmental action, its economic impact, and its interference with reasonable investment-backed expectations.”<sup>31</sup> The Court emphasized that its previous decisions had shown that no “set formula” exists by which to determine whether a governmental action amounted to a taking, and that such a determination was “essentially an ad hoc, factual’ inquiry.”<sup>32</sup> The Court, nevertheless, found the factor of “reasonable investment-backed expectations” to be dispositive of the taking question.<sup>33</sup>

FIFRA was first adopted in 1947<sup>34</sup> and has been amended several times during its history. The Court examined three time periods during the Act’s lifespan in order to determine whether Monsanto had a reasonable investment-backed expectation concerning its data during the three primary versions of FIFRA.<sup>35</sup>

FIFRA was intended to be a licensing and labelling statute when it was first enacted.<sup>36</sup> Although the Secretary of Agriculture could require an applicant to support the claims it made on a product label by submitting test data,<sup>37</sup> the statute was silent before 1972 as to the authority of the government to use or disclose the submitted data. The United States Department of Agriculture (“USDA”), however, instituted a policy of not disclosing data submitted in support of a product registration.<sup>38</sup> In addition, the district

30. The three factor test was originally set out in *Penn Central Transp. Co. v. New York City*, 438 U.S. 104, 124 (1978). *See also* *Kaiser Aetna Co. v. United States*, 444 U.S. 164, 175 (1979).

31. *Monsanto*, 104 S. Ct. at 2875 (quoting *PruneYard Shopping Center v. Robbins*, 447 U.S. 74, 83 (1980)).

32. *Monsanto*, 104 S. Ct. at 2874 (citations omitted).

33. *Id.* at 4891 (“[W]e find that the force of this factor is so overwhelming, at least with respect to certain of the data submitted by Monsanto to EPA, that it disposes of the taking question regarding that data.”).

34. Pub. L. No. 80-121, 61 Stat. 163 (1947).

35. The three periods were from 1947 to October 21, 1972, October 22, 1972 to September 30, 1978, and November 1, 1978 to the present. The Court did not consider the FIFRA amendments of 1975. Although not affecting the preexisting compensation system, the 1975 amendments did clarify that the compensation requirement applied only to data submitted after January 1, 1970, and to subsequent applications filed after October 21, 1972. Pub. L. No. 94-140, § 12, 89 Stat. 751, 755 (1975).

36. Pub. L. No. 80-121, §§ 3(a), 4(a), 61 Stat. 166-67 (1947).

37. *Id.* § 4(a), (b). In 1970, the Environmental Protection Agency (EPA) replaced the United States Department of Agriculture (USDA) as the agency in charge of administering pesticide registrations under FIFRA. No real change in administration philosophy occurred at that time. *See* Reorganization Plan No. 3 of 1970, 35 Fed. Reg. 15,623, 15,624 (1970).

38. Under the pre-1972 regulatory scheme, manufacturing processes and formulae were explicitly protected. 7 U.S.C. § 135(b), (c) (1964) (superseded 1972). In addition, the USDA, the agency responsible for administering FIFRA from its birth in 1947 to 1970, had instituted a policy of not disclosing data submitted in support of a product registration. *See, e.g.*, 7 C.F.R. § 1.4(b)(15) (1962); 7 C.F.R. § 370.13(d) (1968).

court in *Monsanto* found that it was not the policy of the Department of Agriculture to use the data to support a subsequent applicant's registration of the same or a similar product.<sup>39</sup> The Supreme Court found nevertheless that the initial data submitters, prior to 1972, did not have a "reasonable expectation that the [USDA] or [EPA] would not use the data it had submitted when evaluating the application of another."<sup>40</sup> The Court reasoned that there had been no finding that the policies of the EPA or the USDA were "publicly known" or that Monsanto had ever been given an explicit guarantee that the data it submitted prior to 1972 would only be used to support its product registration.<sup>41</sup>

Equally unpersuasive to the Court was Monsanto's argument that the Federal Trade Secrets Act, passed in 1948, prevented the government from using or disclosing its health and safety data.<sup>42</sup> The Trade Secrets Act prohibits an employee of the federal government from disclosing, in any way not authorized, any trade secret information he happens to come across during the course of his official duties. Any federal employee disclosing or in any way profiting from a trade secret risks fine and imprisonment.<sup>43</sup> The Court did not believe, however, that the Act was a guarantee of confidentiality or sufficient to be an "express promise" that the data would not be used for purposes other than obtaining a product registration for the original submitter.<sup>44</sup>

Congress amended FIFRA substantially in 1972.<sup>45</sup> The 1972 amendments mandated that certain test data be produced and submitted to the EPA

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39. 564 F. Supp. at 564. The Supreme Court in *Monsanto* disagreed with the district court, saying that "[a]lthough the evidence against the District Court's finding seems overwhelming, we need not determine that the finding was clearly erroneous in order to find that a submitter had no reasonable expectation that the [USDA] or EPA would not use the data it had submitted when evaluating the application of another. The District Court did not find that the policy of the Department was publicly known at the time or that there was any explicit guarantee of exclusive use." 104 S. Ct. at 2877 n.14.

40. *Monsanto*, 104 S. Ct. at 2877 n.14.

41. *Id.* The Supreme Court did not go into detail to help illuminate when a policy of a government agency would be "publicly known," or whether a policy that is publicly known but not explicitly set out in a regulation or statute could ever be the basis of a "reasonable investment-backed expectation."

42. 18 U.S.C. § 1905 (1982) ("Whoever . . . publishes, divulges, discloses, or makes known in any manner or to any extent not authorized by law any information coming to him in the course of his employment or official duties . . . which information concerns or relates to the trade secrets, processes, operations, style of work, or apparatus, or to the identity, confidential statistical data, amount or source of any income, profits, losses, or expenditures of any person . . . shall be fined not more than \$1000 or imprisoned not more than one year, or both.").

43. *Id.*

44. *Monsanto*, 104 S. Ct. at 2876. Justice O'Connor, dissenting in part, disagreed with the Court's assessment of the Trade Secrets Act, saying "[i]t seems to me that the criminal sanctions in the Trade Secrets Act therefore created at least as strong an expectation of privacy before 1972 as the precatory language of § 10 created after 1972." *Id.* at 2884.

45. FIFRA was amended by the Federal Environmental Pesticide Control Act of 1972, Pub. L. No. 92-516, 86 Stat. 973 (1972) [hereinafter cited as 1972 Amendments].

before a product could be used, shipped or marketed in the United States.<sup>46</sup> The amendments also specifically addressed the question of use and disclosure of data obtained through the pesticide registration procedure.<sup>47</sup> Any health, safety or environmental data submitted on a product could be disclosed to the public.<sup>48</sup> The EPA could also use any of the submitted data in considering the application of a subsequent applicant, provided that the later applicant payed the original submitter "reasonable compensation."<sup>49</sup> Compensation was only required of subsequent applicants who wished to use the original applicant's data to support a registration within fifteen years of the original submission. If the two companies could not agree on an amount, the matter was submitted to the EPA for determination.<sup>50</sup> Under the 1972 amendments, however, the EPA was explicitly prohibited from using or disclosing any trade secrets of the original data submitter.<sup>51</sup> A data submitter could designate any portions of its data as a trade secret. Since the amendments did not define what the term "trade secret" was to encompass, submitting companies designated all health and safety data as trade secrets.<sup>52</sup> Between 1972 and 1978, the year FIFRA was again amended explicitly to exclude health and safety data from the trade secret exemption,<sup>53</sup> the question whether health and safety data could be trade secret material was litigated frequently.<sup>54</sup>

The *Monsanto* Court found that the trade secret exemption of the 1972 amendments provided Monsanto and similarly situated companies an "explicit governmental guarantee" sufficient to warrant a reasonable investment-backed expectation that data marked "trade secret" and submitted to support a product registration would not be used or disseminated without permission.<sup>55</sup> Data submitters during this period, however, may have had less assurance that their data would remain inviolate with the EPA than the

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46. The amendment specifically required manufacturers to show that a pesticide would not cause "unreasonable adverse effects on the environment." *Id.* § 3(c)(5)(C), (D).

47. *Id.* § 10(a)-(c).

48. *See id.* § 10.

49. *Id.* § 3(c)(1)(D).

50. *Id.* The Administrator's decision could be reviewed judicially upon the instigation of the original data submitter.

51. *Id.* § 10(a).

52. 7 U.S.C. § 136h(c) (1982) required the EPA to give a manufacturer 30-days notice before it released the manufacturer's health and safety data designated as trade secrets. The EPA did not determine whether the manufacturer's designation of data as a "trade secret" was valid until a request for the data was made. If the EPA proposed to disclose the data over the original submitter's objection, the original submitter was authorized to institute a declaratory judgment action in a federal district court. 1972 Amendments, *supra* note 45, § 10(c).

53. Pub. L. No. 95-396, 92 Stat. 819 (1978).

54. *See, e.g.,* *Mobay Chem. Co. v. Gorsuch*, 682 F.2d 419 (3d Cir.), *cert. denied*, 459 U.S. 988 (1982); *Chevron Chem. Co. v. Costle*, 641 F.2d 104 (3d Cir.), *cert. denied*, 452 U.S. 961 (1981); *Amchem Prods. Co. v. Costle*, 594 F.2d 470, *modified*, 602 F.2d 724 (5th Cir. 1979); *Petrolite Corp. v. EPA*, 519 F. Supp. 966 (D.D.C. 1981).

55. 104 S. Ct. at 2878. The Court relied on the definition of trade secrets that appears in the *Restatement of Torts*. *See supra* note 11.



Supreme Court believed. The 1972 amendments explicitly protected trade secrets, not health and safety data. The EPA believed that no test data were entitled to confidential treatment unless they revealed manufacturing processes or formulae.<sup>56</sup> The fact that the issue was litigated extensively with inconsistent outcomes in different courts belies the assertion that the data submitters during this period had any "reasonable" expectations at all.<sup>57</sup>

The 1978 amendments to FIFRA explicitly excluded health and safety data from the trade secret exemption.<sup>58</sup> Congress attempted to placate original data submitters by providing additional limitations on the use of data submitted to support product registrations. The amended Act provided that the EPA could not use the data to support a subsequent company's registration of a product without the permission of the original data submitter for a period of ten years from the date of submission.<sup>59</sup> The original data submitter was entitled to an offer of compensation from subsequent applicants that wished to use its data during the five-year period after the ten-year exclusive time.<sup>60</sup> Since the 1978 amendments made clear the EPA's authority to use and disclose the data, the *Monsanto* Court found that no data submitter could have had a reasonable investment-backed expectation concerning data submitted after 1978. The Court stated that "as long as Monsanto is aware of the conditions under which the data are submitted, and the conditions are rationally related to a legitimate government interest, a voluntary submission of data by an applicant in exchange for the economic advantages of a registration can hardly be called a taking."<sup>61</sup> In a footnote, the Court reasoned that Monsanto could always forego registering its products in the United States and instead sell only in foreign markets.<sup>62</sup>

The *Monsanto* case involved determining whether a regulation was in fact a compensable taking.<sup>63</sup> Justice Holmes anticipated some of the problems

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56. See, e.g., *Chevron Chem. Co. v. Costle*, 443 F. Supp. 1024, 1026 (N.D. Cal. 1978).

57. See *supra* note 54 and accompanying text.

58. See, e.g., 7 U.S.C. § 136a(c)(1)(D) (1982) (data use provision); 7 U.S.C. § 136h(b) (1982) (release to other federal agencies and at public hearings); 7 U.S.C. § 136h(d) (1982) (disclosure to the public); 7 U.S.C. § 136h(e) (1982) (disclosure to contractors).

59. 1972 Amendments, *supra* note 45, § 3(c)(1)(D)(i).

60. *Id.* § 3(c)(1)(D)(iii).

61. *Monsanto*, 104 S. Ct. at 2876 (borrowing reasoning from *Westinghouse Elec. Corp. v. Nuclear Regulatory Comm'n*, 555 F.2d 82 (3d Cir. 1977)). The Supreme Court explicitly rejected the argument that requiring a submitter of data to give up its property interest was an "unconstitutional condition on the right to a valuable government benefit." 104 S. Ct. at 2875.

62. *Monsanto*, 104 S. Ct. 2876 n.11.

63. Through the commerce clause, the federal government regulates interstate commerce to promote health, safety and general public good. U.S. CONST. art. I, § 8. The power of eminent domain allows the government to appropriate private property for a public use upon payment of "just compensation." U.S. CONST. amend. V. Although traditionally "viewed as operating within separate ambits," regulations under the commerce clause sometimes affect property interests as much as direct takings under the taking clause. Gannon, *FIFRA and The Taking of Trade Secrets*, 8 B.C. ENVTL. L. REV. 593, 611 (1980). One author has noted that "[w]here

that occur when regulations approach takings in their effects in his famous majority opinion in *Pennsylvania Coal Co. v. Mahon*.<sup>64</sup> Justice Holmes explained there that the real problem in evaluating whether a taking of property has occurred is determining "upon whom the loss of the changes desired should fall."<sup>65</sup> This is the same analysis underlying tort law.<sup>66</sup> Applying a tort analysis to the FIFRA regulations to evaluate whether the same result would have been achieved had the Court not focused on the investment-backed expectations of Monsanto is therefore appropriate.<sup>67</sup>

Congress was serving the public interest in enacting the FIFRA data reporting requirement.<sup>68</sup> Monsanto and other data submitters benefit from the regulation as much as private citizens.<sup>69</sup> The Supreme Court had in fact, prior to *Monsanto*, upheld regulations that affected interests in data in ways similar to the FIFRA data reporting requirements. In fact, the Court quoted from one of these cases, *Corn Products Refining Co. v. Eddy*,<sup>70</sup> in its

regulation ends and 'taking' begins has been an important factor in a number of 'taking' cases." *Id.* at 610. See also *Nectow v. City of Cambridge*, 277 U.S. 183, 188 (1928), quoted in *Penn Central Transp. Co. v. New York City*, 438 U.S. 104, 125 (1978) ("[I]n instances in which a state tribunal reasonably concluded that the 'health, safety, morals or general welfare' would be promoted by prohibiting particular contemplated uses of land, this Court has upheld land use regulations that destroyed or adversely affected recognized real property interests."); Michelman, *supra* note 15, at 1192.

64. 260 U.S. 393 (1922).

65. *Id.* at 416. See also L. TRIBE, *AMERICAN CONSTITUTIONAL LAW* § 9-4, at 464 (1978) (presenting the problem as a "choice between (1) leaving the harm where the government action initially imposed it, and (2) taking steps to spread the harm more widely or at least differently.").

66. Sax, *Takings and the Police Power*, 74 *YALE L.J.* 36, 50 (1964).

67. The expectation of property owners may be the major concern of the current members of the Supreme Court. The Court has not, however, abandoned the other factors entirely. In *Williamson County Regional Planning Comm'n v. Hamilton Bank*, 105 S. Ct. 3108 (1985), the Court said, "this Court consistently has indicated that among the factors of particular significance in the inquiry are the economic impact of the challenged action and the extent to which it interferes with reasonable investment-backed expectations." *Id.* at 3119 (emphasis added).

Focusing solely on the expectations of property owners in other takings contexts leads to absurd results unintended by the Court's position in *Monsanto*. Such an emphasis may, for example, lead to the invalidation of some prospective zoning or historic designation ordinances simply because a landowner buys for one purpose but fails to build before a new ordinance is enacted that makes the intended use impermissible. By focusing on one "factor" over others in a particular takings dispute, the Court increases uncertainty and prevents predictability in the takings area generally.

68. "[I]t is not a tort for government to govern." *Dalehite v. United States*, 346 U.S. 15, 57 (1953) (Jackson, J., dissenting).

69. See, e.g., *Agins v. City of Tiburon*, 447 U.S. 255, 262 (1980) ("The zoning ordinances benefit the appellants as well as the public by serving the city's interest in assuring careful and orderly development of residential property with provision for open space."); *Penn Central*, 438 U.S. at 134-35 ("Unless we are to reject the judgement of the New York City Council that the preservation of landmarks benefits all New York citizens and all structures, both economically and by improving the quality of life in the city as a whole—which we are unwilling to do—we cannot conclude that the owners of the terminal have in no sense been benefited by the Landmarks Law.").

70. 249 U.S. 427 (1919).

discussion in *Monsanto* of FIFRA's post-1978 data reporting requirement.<sup>71</sup> *Corn Products* involved a Kansas law that required manufacturers to label the percentages of ingredients in syrup. The petitioner alleged that such information was held as a trade secret and that the regulation amounted "to a taking of its property without due process of law."<sup>72</sup> The Court held that "[t]he rights of a manufacturer to maintain secrecy as to his compounds and processes must be held subject to the right of the State, in the exercise of its police power and in promotion of fair dealing, to require that the nature of the product be fairly set forth."<sup>73</sup>

*Monsanto*, on the other hand, can be seen as creating the risk that prompted the regulation. A "creation of the harm" or "noxious use" test was first introduced by the Supreme Court in holding railroads responsible for the costs of building grade separations necessitated by the fear of accidents where trains intersected public highways.<sup>74</sup> The Court reasoned in those cases that "[h]aving brought about the problem, the railroads are in no position to complain because their share in the cost of alleviating it is not based solely on the special benefits accruing to them from the improvements."<sup>75</sup> Like the railroads, the chemical industry presents special risks to society even though it plays an essential role in the economy.

Although the Supreme Court in *Monsanto* required the government to pay just compensation under the taking clause for health and safety data used to support a subsequent registration between 1972 and 1978, the Court did not delineate what would constitute adequate compensation under the taking clause. The Court refused to find that any taking had occurred before arbitration under the statutory compensation scheme had taken place: "We cannot preclude the possibility that the arbitration award will be sufficient to provide *Monsanto* with just compensation."<sup>76</sup> This wait-and-see approach has several disadvantages. First, it delays the award of compensation until after the fifteen-year statutory period of mandatory compensation. For those

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71. 104 S. Ct. at 2876.

72. *Corn Products*, 249 U.S. at 431.

73. *Id.* at 431-32. See also *National Fertilizer Ass'n v. Bradley*, 301 U.S. 178 (1937) (reaffirming *Corn Products* in a case involving a South Carolina statute requiring labelling of fertilizer bags). These cases, while going beyond FIFRA in that they require manufacturing formulae to be disclosed, can be distinguished from FIFRA since they involved information that was already available to the manufacturer.

74. See, e.g., *Atchison, Topeka and Santa Fe Ry. v. Public Utils. Comm'n*, 346 U.S. 346 (1953); *Nashville, Chattanooga and St. Louis Ry. v. Walters*, 294 U.S. 405 (1935); see generally *Sax*, *supra* note 66, at 48-50.

75. *Atchison*, 346 U.S. at 353.

76. *Monsanto*, 104 S. Ct. at 2878-79 n.16. Implicit in the Court's analysis is the belief that destroying the exclusive use, rather than "taking" the data, is central to the question of compensation. The Court recognized that *Monsanto* may still use its data "as bases from which to develop new products or refine old products, as marketing and advertising tools, or as information necessary to obtain registration in foreign countries." *Id.* at 2878. See also *Note*, *supra* note 19, at 368; *Gannon*, *supra* note 63, at 605.

companies that submitted data in 1978—the last year of the “explicit governmental guarantee” of confidentiality for trade secrets—it could be as late as 1993 before they can seek compensation. Second, since it is nowhere made explicit what constitutes “just compensation” for the “taking” of health and safety data, additional litigation will be required after the statutory compensation mechanism has run its course to determine what compensation is appropriate to satisfy the taking clause. By enacting the compensation scheme, Congress intended to reduce the amount of work for the courts, not to create additional burdens for them.<sup>77</sup> Finally, relying on the statutory arbitration method for determining the appropriate level of compensation focuses on the value of the health and safety data rather than the “secrecy” that is lost. What has been “taken” by a regulation allowing an agency to use data submitted to support one product registration to support the applications of subsequent companies is the exclusivity of the data, rather than the data itself.<sup>78</sup>

### B. Compensation for “Takings” of Trade Secrets

The *Monsanto* Court distinguished between the right given in the statute to obtain compensation from a subsequent applicant who relies on the original data to register a product, and the right under the Constitution to “just compensation.” The Court explained that “[e]xhaustion of the statutory remedy is necessary to determine the extent of the taking that has occurred. To the extent that the operation of the statute provides compensation, no taking has occurred and the original submitter of data has no claim against the Government.”<sup>79</sup> The question of what, in addition to the statutory compensation, may be necessary to compensate the original submitter of data to satisfy the taking clause was not addressed by the Court.<sup>80</sup>

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77. See *supra* text accompanying note 7.

78. See *supra* note 63 and accompanying text. If no subsequent applicant requests to use the data to support a product registration, the original submitter receives no compensation. The data may still have been revealed through the public disclosure provision. The Supreme Court's standard, therefore, is anomalous because the use to which the property is put is the key to determining whether compensation is required, rather than whether a “taking” has occurred in the first instance.

In *Penn Central Transp. Co. v. New York City*, 438 U.S. 104, 136 (1978), the Court legitimized a New York City landmark law that prevented the owners of the Grand Central Terminal from adding additional stories above the terminal or changing the terminal's facade. Although the present use of the terminal brought the owners a “reasonable return,” they could not use the property exclusively. While the exclusivity of trade secrets has greater historical foundation, no theoretical difference exists between the exclusive use of trade secrets and the exclusive use of land, as long as some use of the secret remains after the taking.

79. *Monsanto*, 104 S. Ct. at 2881 n.21.

80. *But cf.* *Monsanto Co. v. EPA*, 552 F. Supp. 552, 568 (1981).

In a typical takings case involving real property, the measure of damages is the market value of the property appropriated by the government.<sup>81</sup> For the most part, the market value approach satisfies the policy of paying the owner "the full and perfect equivalent in money of the property taken."<sup>82</sup> In some cases, however, the Supreme Court has recognized that compensation as determined by the market value gives an inappropriate measure of the actual value.<sup>83</sup> The actual value of a trade secret, for instance, cannot be determined by looking to a market value since its value is not determined in the market.<sup>84</sup> As the Court said in *Monsanto*, "[t]he economic value of that property right lies in the competitive advantage over others that Monsanto enjoys by virtue of its exclusive access to the data, and disclosure or use by others of the data would destroy that competitive edge."<sup>85</sup>

A situation analogous to the taking of trade secrets exists when the government takes the fee simple interest in a private roadway, forcing the owner or an exclusive easement holder to share the road with the public. The Ninth Circuit Court of Appeals has determined in several cases that a market value approach is inappropriate in this situation, since the party subject to the taking can still use the roadway.<sup>86</sup> That court has awarded damages based on the theory that the exclusive use of the roadway was itself a property right which had been taken. In each case, however, the value of the exclusive use was left as a matter of proof to be determined by the trial court.<sup>87</sup>

The Supreme Court has found in another taking context that "[i]t is not fair that the government be required to pay the enhanced price which its demand alone has created."<sup>88</sup> The extent, therefore, that the value of the exclusive use of data is enhanced because of the requirement that data be submitted to support a product registration should probably be discounted when determining the appropriate level of compensation to satisfy the taking clause. In some cases, the registration requirement may provide the only real value to using the data "exclusively." However, since other manufacturers, rather than the government, compensate for the "taking" of the data in this context, the Court's prior concern over passing the cost of enhanced

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81. See *United States v. General Motors Corp.*, 323 U.S. 373, 379 (1945); see generally Annot., 11 A.L.R.4TH 12 (1982); Annot., 19 L. Ed. 2d 1361 (1968).

82. *United States v. Miller*, 317 U.S. 369, 373 (1943).

83. *General Motors*, 323 U.S. at 379.

84. See generally Johnson, *Remedies in Trade Secret Litigation*, 72 Nw. U.L. Rev. 1004 (1978).

85. 104 S. Ct. at 2878. Even so, the data remains valuable to the original submitter after it is submitted. See *supra* note 76.

86. See *United States v. 10.0 Acres of Land*, 533 F.2d 1092 (9th Cir. 1976); *United States v. 201.19 Acres of Land*, 478 F.2d 1042 (9th Cir. 1973).

87. See cases cited *supra* note 86.

88. *United States v. Cors*, 337 U.S. 325, 333 (1949).

value due to the regulation to the government may be unwarranted in this context.<sup>89</sup>

## II. THE EXISTING STATUTORY COMPENSATION SCHEMES

In addition to the constitutional "taking" rationale for compensating submitters of data to support product regulations, various policy reasons exist for compensating data submitters. Congress has addressed the need to compensate data submitters in several federal regulations requiring submission of data to obtain a registration for a product.<sup>90</sup> Since competing policy considerations exist for mitigating the effects of a regulation on a particular industry, no regulation concerning data submission and compensation has presented a concise, predictable approach to compensation. While legislative histories speak of the equitable goals of sharing costs and preventing "free rider" problems, for example, the statutory schemes often affect the regulated industry, either consciously or accidentally, by promoting innovation incentives or competition.<sup>91</sup> This section examines the three existing statutory approaches to compensation—exclusive use, mandatory compensation, and no compensation—and discusses how each manages the competing policy interests.

### A. *Exclusive Use Under FIFRA*

FIFRA is the only current statutory program requiring the submission of data to obtain a product registration that provides data submitters with the protection of an exclusive use period.<sup>92</sup> The Federal Environmental Pesticide Control Act of 1972 amended FIFRA by requiring the EPA to determine that a product for which a registration is sought will not cause "unreasonable adverse effects on the environment."<sup>93</sup> Under the amendments, a manufacturer seeking to register a product may satisfy the data reporting requirements by submitting either "a full description of the tests made and the results thereof upon which the claims are based, or alternately a citation to data that appear in the public literature or that previously had been submitted."<sup>94</sup> Although health and safety data may be disclosed to the public upon request, a competing manufacturer may not rely on data already in the possession

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89. See *infra* notes 118-20 and accompanying text.

90. 7 U.S.C. § 136a(c) (1982) (FIFRA); 15 U.S.C. § 2603(c) (1982) (TSCA). In discussing the rationale of Congress in devising a data use scheme, the *Monsanto* Court recognized the validity of using data on hand to support a subsequent registration "upon payment of compensation" to the original submitter. 104 S. Ct. at 2879.

91. See *infra* text accompanying notes 135-58.

92. 7 U.S.C. § 136a(c)(1)(D)(i) (1982).

93. See 1972 Amendments, *supra* note 45.

94. 7 U.S.C. § 136a(c)(1)(D) (1982).

of the EPA to support an application to register a product identical to one previously registered unless the subsequent manufacturer obtains the permission of the first manufacturer. If permission is denied, the subsequent applicant must either wait the exclusive use period of ten years from the date of the original application or develop adequate health and safety data on its own.<sup>95</sup>

The exclusive use period effectively protects the original data submitter from competition since the original submitter has little economic incentive to give its permission to a subsequent applicant if the product is profitable.<sup>96</sup> The original manufacturer will take advantage of this monopoly situation either "by refusing to sell its data or by exacting a cost of entry which would approximate the value of a monopoly."<sup>97</sup> This exclusive use protection is in addition to any protection from competition the original manufacturer may receive from patenting the product or the manufacturing process.<sup>98</sup> It also goes beyond the protection of formula and process trade secrets which is retained in the data reporting statutes.<sup>99</sup> Since the additional protection given by an exclusive use provision goes only to the manufacturer who developed the data first, it is necessary to ask whether such first development, in the words of Thomas Jefferson, is one of "the things which are worth to the public the embarrassment of an exclusive patent."<sup>100</sup>

The monopoly protection which results from the exclusive use period is likely to cost society more than is necessary to further the policy of maintaining incentives to innovation. An exclusive use period not only protects preexisting incentives to innovation, it creates an additional incentive. During the monopoly period, the original data submitter will maximize profits in the way of all monopolists: by restricting output and charging a higher price than could be maintained under competition.<sup>101</sup> As an author discussing the possibility of extending the exclusive use period to drug marketing has said, "[i]t is unlikely that such a price would reflect either the innovation's value to society, its cost to the firm, or the desirability or necessity of erecting sufficient protection to induce private investment."<sup>102</sup> The exclusive use pe-

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95. *Id.* § 136a(c)(1)(D)(i).

96. *But see* 49 Fed. Reg. 30888 (1984).

97. REVIEW PANEL, *supra* note 14, at 58.

98. *See supra* text accompanying note 18.

99. *See supra* text accompanying note 8.

100. *Quoted in* *Graham v. John Deere Co.*, 383 U.S. 1, 10-11 (1966). As the first Secretary of State, Thomas Jefferson was also the first administrator of the United States Patent Office.

101. *See generally* E. MANSFIELD, *MICROECONOMICS* 277-310 (1970); R. POSNER, *ECONOMIC ANALYSIS OF LAW* 41 (1976). The extent of monopolistic profits would, of course, depend on the number and quality of substitutes in the market. A monopoly would result only when there are no or few products available to compete with the monopolistic product.

102. REVIEW PANEL, *supra* note 14, at 58.

riod may, therefore, affect the pesticide market to an extent unexpected by Congress.<sup>103</sup>

In addition to being anticompetitive and causing monopoly profits, an exclusive use scheme results in duplicative testing of products by those companies unwilling to wait until the end of the protective period to market a product. Several problems exist with duplicative testing. First, duplicative testing increases the risk of exposure to products which, although approved for marketing, may be potentially dangerous under test conditions. This is an even greater problem when the test rule requires reporting the results of human exposures.<sup>104</sup> Second, it is economically inefficient to require the same tests for identical products.<sup>105</sup> This aspect of the exclusive use period is actually a disincentive to innovation since duplication of tests diverts limited research funds from being spent on development of new products to the inefficient duplication of tests that have already been completed.<sup>106</sup> Although duplicative testing does serve as a check on preexisting data,<sup>107</sup> it is not clear that such a check is necessary for all products upon which tests have been completed.<sup>108</sup> A more efficient system for gathering additional information on a product would be to authorize the regulatory agency to require additional data on a chemical or pesticide when it finds that the existing data are insufficient. Such authority exists currently under both FIFRA and TSCA.<sup>109</sup>

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103. During congressional debate, the proposed exclusive use period was opposed by Acting Attorney General Kleindeist. See S. REP. No. 92-970, 92d Cong., 2d Sess. (1972), reprinted in 1972 U.S. CODE CONG. & AD. NEWS 3993, 4097 ("Duplication of such tests is a waste to the economy and a needless and undesirable burden on any subsequent applicant."); S. REP. No. 92-970, 92d Cong., 2d Sess. (1972), reprinted in 1972 U.S. CODE CONG. & AD. NEWS 3993, 4043 ("The effect of this provision is to afford additional economic protection, foster monopoly, and it may tend to restrict pesticide business to large manufacturers. In addition, it would increase not only federal administrative costs, but those of the manufacturers as well, aside from unnecessarily increasing the application time."); S. REP. No. 92-970, 92d Cong., 2d Sess. (1972), reprinted in 1972 U.S. CODE CONG. & AD. NEWS 3993, 4096 ("As patent protection is granted to a substantial number of pesticides, this provision of the Bill imposes requirements on subsequent producers beyond the licensing fees that a patent holder may require."). The exclusive use provision was retained in the 1978 amendments as a result of a compromise. See Safir & Reagan, *Data Use and Compensation Under FIFRA*, 14 ENVTL. L. REP. (ENVTL. L. INST.) 10055, 10058 (1984).

104. See, e.g., 21 U.S.C. § 355(j)(1) (1982).

105. See R. POSNER, *supra* note 101, at 10 ("The terms 'value' and 'efficiency' are technical terms. 'Efficiency' means exploiting economic resources in such a way that 'value'—human satisfaction as measured by aggregate consumer willingness to pay for goods and services—is maximized.").

106. See S. REP. No. 92-970, 92d Cong., 2d Sess. (1972), reprinted in 1972 U.S. CODE CONG. & AD. NEWS 3993, 4096.

107. Safir & Reagan, *supra* note 103, at 10057.

108. If manufacturers knew the tests would be replicated, perhaps they would be less cautious in preparing the original data.

109. 7 U.S.C. § 136a(c)(2)(B) (1982) (FIFRA); 15 U.S.C. § 2603(a) (1982) (TSCA).



A fundamental theoretical difficulty exists, apart from the foregoing policy reasons, in awarding an exclusive use to a manufacturer simply because it develops the data to obtain a registration first. The Constitution gives Congress the 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."<sup>110</sup> Congress has statutorily limited patent protection to inventions that are new,<sup>111</sup> useful<sup>112</sup> and unobvious.<sup>113</sup> Similarly, copyright protection, although less demanding than patent protection, is limited to "original works of authorship fixed in any tangible medium of expression."<sup>114</sup> A copyright protects an author's expression but not his ideas or discoveries.<sup>115</sup> Facts and historical events are not protectible since "the discoverer merely finds and records. He may not claim that the facts are 'original' with him."<sup>116</sup> The main purpose of both patent and copyright law is to get information and ideas to the public; the exclusive use they provide is simply the means to effectuate that purpose.

An exclusive use period for data is not awarded because the data are new, useful, unobvious or original, but because the company submitting the data to support a product registration developed the data before its competitors. In fact, the data must be uniformly derived to satisfy the testing requirements of the registration statute.<sup>117</sup> If the product for which data is produced is new, useful and unobvious, then the originator of the product may obtain a patent in order to prevent others from making, using or selling that product

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110. U.S. CONST. art. 1, § 8, cl. 8.

111. 35 U.S.C. § 101 (1982).

112. *Id.* § 102.

113. *Id.* § 103 ("A patent may not be obtained [if] 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.").

114. 17 U.S.C. § 102(a) (1982). *See also* *Bleistein v. Donaldson Lithographing Co.*, 188 U.S. 239, 250 (1902) ("There is a very broad distinction between what is implied in the word 'author,' found in the Constitution, and the word 'inventor'. The latter carries an implication which excludes the results of only ordinary skill, while nothing of this is necessarily involved in the former.").

115. Shipley & Hay, *Protecting Research: Copyright, Common Law Alternatives and Federal Preemption*, 63 N.C.L. REV. 125, 125 (1984).

116. J.M. NIMMER, *NIMMER ON COPYRIGHT* § 2.03[E] (1985). A 1950 case in the Seventh Circuit protected an author's collection of facts by upholding an action for copyright infringement. In *Toksvig v. Bruce Publishing Co.*, 181 F.2d 664, 669 (7th Cir. 1950), the Seventh Circuit said, "[t]he question is not whether Hubbard could have obtained the same information by going to the same sources, but rather did she go to the same sources and do her own independent research?" *Toksvig* has been relied on to support the principle that facts are protectible under copyright law. *See, e.g.*, *Holdredge v. Knight Publishing Corp.*, 214 F. Supp. 921 (S.D. Cal. 1963). Most courts, however, have rejected *Toksvig*. *See, e.g.*, *Harper and Row Publishers, Inc. v. Nation Enterprises*, 723 F.2d 195 (2d Cir. 1983), *rev'd on other grounds*, 53 U.S.L.W. 4562 (1985); *Miller v. Universal City Studios, Inc.*, 650 F.2d 1365 (5th Cir. 1981); *Hoehling v. Universal City Studios, Inc.*, 618 F.2d 972 (2d Cir. 1980); *Rosemont Enter., Inc. v. Random House, Inc.*, 366 F.2d 303 (2d Cir. 1966), *cert. denied*, 385 U.S. 1009 (1967).

117. *See, e.g.*, 92 Stat. 842 (1978).

for seventeen years. To give exclusive use protection to data submitters or other persons who are neither authors nor inventors, however, may be beyond Congress's power under the patent clause of the Constitution.

Some critics view the exclusive use period as the only compensation scheme capable of adequately compensating the original data submitter for its lost profits.<sup>118</sup> This view, however, assumes the propriety of awarding monopoly profits to the first manufacturer to obtain a registration for a product. It fails to consider that the only reason the original data submitter gains monopoly profits in the first place is because the data reporting regulation created the competitive advantage for first submitters. Subsequent applicants have no additional advantage in the market than they did before the reporting requirement. To market the product, the subsequent applicant must still develop the product formulae and manufacturing processes that make production feasible or, if the originator has obtained a patent on either the manufacturing processes or formulae, must wait the period of the patent before marketing the product.<sup>119</sup> While the advantage of an exclusive use may rise to the status of an entitlement, the denial of which requires certain due process protection,<sup>120</sup> it is not an advantage that is necessary to replace a monopoly right that has been taken away.

Another argument is that an exclusive use period is necessary to protect innovation because the patent system inadequately protects the innovation incentives of chemical substance manufacturers.<sup>121</sup> There are two problems with the patent system which are unique to chemical and drug manufacturers. The first problem is that the time it takes to conduct health and safety testing cuts into the effective protection provided by a patent. The second problem, independent of the reporting requirement, is that some valuable chemical innovations are unpatentable because they fail to meet the statutory requirements of being new, novel and unobvious.

A manufacturer will usually obtain a patent on a product before it begins developing health and safety data to register the product.<sup>122</sup> If the manufacturer is able to obtain a patent, it will be able to exclude others from making, using, or selling the patented product for a guaranteed period of seventeen years.<sup>123</sup> If the product or the process of manufacturing the product fails to meet the requirements of patentability, any information which is revealed to the patent office during the patent process remains secret.<sup>124</sup> After

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118. McGarity & Shapiro, *supra* note 7, at 880 n.238.

119. *See supra* text accompanying note 8. The originator also receives the substantial economic benefit of being the first manufacturer in the market. *See* McGarity & Shapiro, *supra* note 7, at 852.

120. Safir & Reagan, *supra* note 103, at 10061.

121. *See, e.g.,* McGarity & Shapiro, *supra* note 7, at 850-51.

122. *See* Gannon, *supra* note 63, at 594 n.7.

123. 35 U.S.C. § 271(a) (1982).

124. *Id.* § 122.

a manufacturer obtains a patent, it must still obtain a registration in order to market the product in the United States. The manufacturer must develop and submit the required data, and wait until the data is processed by the appropriate regulatory agency.<sup>125</sup> Experts estimate that the effective period of patent protection is twelve years for pesticides<sup>126</sup> and ten years for drugs.<sup>127</sup>

Little information exists, however, to determine the extent of the impact of a shorter period of effective patent protection on the incentives to innovate in the industry. The term of patent protection is determined primarily by historical precedent rather than by scientific or economic calculation of the best period to encourage innovation.<sup>128</sup> Nothing is theoretically wrong, therefore, with extending the period of patent protection for those products subject to a regulation which delays their release in the market.<sup>129</sup> This would be the solution to the innovation problem most rationally related to existing innovation incentives. Before such a change is made, however, more information on the effect of the regulations on innovation is necessary.

Incentives to innovation are also lessened because obtaining patent protection for a chemical or drug is more difficult than for other products. In order to be patentable, an invention must satisfy the statutory requirements of novelty, utility and unobviousness.<sup>130</sup> It is the unobviousness requirement which presents special problems for chemical products.

Section 103 of the patent statute requires that a chemical compound be unobvious "as a whole" over the prior art.<sup>131</sup> Often, however, a new chemical will be similar in structure to other chemicals already known to the public. Since one of the policies of the patent law is to prevent products previously known to the public from being taken from the public domain by the granting of a patent, these chemicals are not patentable. This "structural obviousness" often precludes an inventor from obtaining a patent on a chemical compound no matter how useful it is to society.<sup>132</sup> Several courts have surmounted this difficulty with the idea of "relative significance."<sup>133</sup> Unlike other approaches to the unobviousness issue, "relative significance" focuses on the social and commercial uses of the chemical compound. If the uses of the new compound are more significant than what would have been expected from reference to structurally similar chemicals, then the compound is patentable. The theory

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125. See Davies, *supra* note 9, at 52.

126. Gannon, *supra* note 63, at 594 n.7.

127. See REVIEW PANEL, *supra* note 13, at 31 n.100.

128. See R. CHOATE & W. FRANCIS, PATENT LAW 82-83 (1983).

129. At present, a different statutory length applies to design patents—14 years—than to other patents—17 years. 35 U.S.C. § 173 (1982).

130. See *supra* text accompanying notes 95-97.

131. 35 U.S.C. § 103 (1982).

132. See Blodgett, *Relative Significance—A Concept in Chemical Structural Obviousness Cases*, 63 J. PAT. OFF. SOC'Y 69, 70 (1981); Marquis, *An Economic Analysis of the Patentability of Chemical Compounds*, 63 J. PAT. OFF. SOC'Y 3, 4 (1981).

133. See generally Blodgett, *supra* note 132.

of "relative significance" reflects the policy that "[t]he inventor of the universal cancer cure should not be denied effective patent protection because his compound is structurally similar to a compound known to be useful only as ballast for ships."<sup>134</sup> To the extent that health and safety regulations affect the incentives to innovation in the industry, it may be incumbent on Congress to amend the patent statute to account for the special circumstances in the industry.

### *B. The Just Compensation Schemes of FIFRA and TSCA*

Providing an additional incentive to innovation through the statutory compensation mechanisms may not be as appropriate a goal as protecting against registration requirements which create disincentives for companies to develop new and innovative products. To prevent these disincentives, the cost of developing sufficient health and safety data must not act as a sanction which is imposed only on the first manufacturer to register a product. Both FIFRA and TSCA provide for the payment of "just compensation" by subsequent manufacturers to the original submitter and any prior manufacturers that have paid compensation.<sup>135</sup> In their present form, however, both compensation schemes leave the question of what exactly is to be considered for compensation purposes to an arbitrator or the courts. The guidance which Congress and the EPA have given these adjudicatory bodies is inconsistent since it simultaneously promotes the policies of providing new innovation incentives, maintaining existing innovation incentives, forcing cost sharing, and encouraging competition. Providing for a just compensation mechanism does not end the inquiry as to what policies such a program should promote.

#### 1. Compensation Under FIFRA

After the exclusive use period under FIFRA, a manufacturer is protected through fifteen years after the original date of data submission by the requirement that any subsequent applicant must "offer to compensate" the original data submitter.<sup>136</sup> The terms and amount of the compensation are to be determined by agreement of the parties, or, if an agreement cannot be reached, by binding arbitration.<sup>137</sup> The 1978 amendment provides that "[t]he findings and determination of the arbitrator shall be final and conclusive, and no official or court of the United States shall have power or jurisdiction to review any such findings and determination, except for fraud,

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134. *Id.* at 74.

135. 7 U.S.C. § 136a(c)(1)(D)(ii) (1982) (FIFRA); 15 U.S.C. § 2603(c)(4)(A) (1982) (TSCA).

136. 7 U.S.C. § 136a(c)(1)(D)(ii) (1982).

137. *Id.*

misrepresentation, or other misconduct by one of the parties."<sup>138</sup> The amendment provides no basis by which the arbitrator may determine the appropriate amount of compensation, and the EPA has made clear its intention not to provide guidelines for determining the appropriate amount of compensation.<sup>139</sup> Instead, the EPA has left the determination of appropriateness to the Federal Mediation and Conciliation Service ("FMCS"), which has authority to manage arbitration pursuant to the Act.<sup>140</sup> Although the FMCS has provided for the arbitration procedures,<sup>141</sup> it has not provided guidelines respecting how compensation is to be determined.

The EPA did issue a proposed amendment to Title 21 of the Code of Federal Regulations in 1977 concerning the approach to compensation that the administrator would use under the 1972 compensation system.<sup>142</sup> A final rule was never issued, presumably because the EPA believed it was unnecessary after the 1978 amendment to FIFRA. Section 162.9(h) of the proposed amendment provided that the Administrator or an administrative law judge could determine a reasonable amount of compensation provided that certain procedural steps had been met. Section 162.9(i) would have given the Administrator or the administrative law judge the freedom to base their decision on what they found "reasonable under the circumstances, equitable to the parties and permitted by the law."<sup>143</sup> It also provided that they "might consider any factors relevant to this determination."<sup>144</sup> Realizing that the section provided little guidance for determining a dollar amount for any particular compensation award, the EPA specifically requested suggestions for a "precise formula" for determining compensation and for "comment regarding the factors appropriate to this determination."<sup>145</sup>

No reference exists in the public record as to the scope of the comments received. The broad range of opinion as to the purpose of a compensation scheme can, however, be seen in some of the "factors" which had previously been suggested and therefore set out in the proposed rule. While the "actual

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138. *Id.* The constitutionality under article III of this limited review was upheld recently in *Thomas v. Union Carbide Agricultural Prods. Co.*, 105 S. Ct. 3325 (1985). Between 1972 and 1978, the amount of compensation awarded was to be determined by the EPA Administrator and was subject to judicial review.

139. 44 Fed. Reg. 27,945 (1979) (to be codified at 40 C.F.R. § 162).

140. *Id.* at 27,949.

141. See 45 Fed. Reg. 55,394 (enacting procedure for appointing arbitrator, 29 C.F.R. § 1440.1(28) (1980)). The rule also established that "[t]he claimant shall have the burden of going forward to establish his entitlement to an amount of compensation [by a] preponderance of the evidence." 45 Fed. Reg. 55,394. See also 44 Fed. Reg. 43,292, 43,293 (1979) (to be codified at 29 C.F.R. pt. 1440) (proposed July 24, 1979). ("Congress has demonstrated its belief that the costs of generating information to evaluate pesticide risk be equally apportioned . . .").

142. EPA, 42 Fed. Reg. 31,284, 31,286 (1977) (to be codified at 40 C.F.R. pts. 162 & 173) (proposed June 20, 1977).

143. *Id.* at 31,285.

144. *Id.*

145. *Id.* at 31,286.

cost" of developing the data was the first factor mentioned, the comments on the proposed rule listed ten other factors, including 1) the "current cost of duplicating the data"; 2) "the estimated effect of the amount and method of compensation on research and development of pesticides"; 3) "the foreseeable nature, extent and profitability from marketing"; 4) "the ability of the applicant to pay compensation"; and, 5) "the extent to which the claimant has recovered, and/or may recover, his investment in the data by sale of the pesticide."<sup>146</sup> While the first and second of these factors promote the policies of preserving or creating innovation incentives, the third and fourth factors clearly would increase the amount of competition in the industry. Since conflicting policies are promoted by each of these factors, the effect that the data reporting requirement of FIFRA would have had on the pesticide industry is unclear.<sup>147</sup>

## 2. Compensation Under TSCA

The TSCA requires producers of chemicals to obtain a registration with the EPA to market each chemical in the United States.<sup>148</sup> In order to obtain a registration, a manufacturer must show that the chemical does not "present an unreasonable risk of injury to health or the environment."<sup>149</sup> Like FIFRA, however, TSCA allows the EPA Administrator to grant an applicant an exemption from the testing requirements if the chemical substance for which registration is sought is identical to a previously registered substance and submission of additional data would be duplicative of other data previously submitted.<sup>150</sup> The original submitter may demand payment of a "fair and equitable" reimbursement from any subsequent manufacturer that relies on its data to obtain a product registration.<sup>151</sup>

The regulations implementing the reimbursement scheme under TSCA assume that parties will arrange either to share the initial burden of developing health and safety data, or to share the costs once they are incurred. If the parties cannot agree, then either party may request that the Administrator of the EPA issue a reimbursement order.<sup>152</sup> The EPA has instituted a system, similar to commercial arbitration, of using hearing officers to adjudicate disputes. The Administrator reviews the arbitration and issues a

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146. *Id.*

147. In a recent statement, the EPA said, "Congress did not intend, however, that a scheme for compensation should function to exclude new products and producers from the marketplace." 49 Fed. Reg. 30,889 (1984).

148. 15 U.S.C. § 2601(b)(1) (1982). Under TSCA, data on health and safety are required for new and old chemicals. TSCA explicitly does not apply to pesticides. *Id.* § 2602(2)(B)(ii).

149. *Id.* § 2603(a).

150. *Id.* § 2603(c).

151. *Id.* § 2603(c)(4)(A).

152. 48 Fed. Reg. 31,787 (1983).

reimbursement order, basing his decision "on the record of the hearing, upon the petitions for review, and on written briefs and oral arguments if they are necessary."<sup>153</sup> The statute provides that any order by the Administrator may be reviewed by a federal court.<sup>154</sup>

Unlike FIFRA, TSCA provides some guidelines as to what elements should be considered when determining the amount of a "fair and equitable" reimbursement. The Act directs the EPA to "consider all relevant factors, including the effect on the competitive position of the person required to provide reimbursement in relation to the person to be reimbursed and the share of the market for such substance or mixture of the person required to provide reimbursement in relation to the share of the market of the persons to be reimbursed."<sup>155</sup> Although this scheme provides some indication to congressional intent, both competitive position and market share are difficult to ascertain.

The EPA has said that neither it nor any commenter was able to reduce "competitive position . . . to a quantitative measure."<sup>156</sup> The language of the statute is unclear regarding whether the "effect" which is to be corrected by considering competitive position is an unwarranted competitive advantage or an impediment to competition. The EPA believes the provision was intended to protect small businesses.<sup>157</sup> Why specific reference to small businesses was not provided in the legislation is unclear. If one of the goals of the reimbursement program was to protect small business, then businesses under a certain size could have been exempted from paying compensation altogether.

Market share is an even less helpful guideline for determining compensation. For the thousands of chemicals already on the market at the time TSCA was enacted, market share appears to be an equitable way to determine the amount any particular company should pay for testing.<sup>158</sup> A manufacturer seeking to register a new product has, however, no market at the time of applying for a registration to market a product. Market share would therefore be inappropriate in most situations.

Since the determination of what is an appropriate compensation under both FIFRA and TSCA depends on the view of the arbitrator or the Administrator, the likelihood either compensation program can consistently promote either an incentive-producing or competition-promoting policy is

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153. *Id.*

154. 15 U.S.C. § 2603(c)(3)(A) (1982).

155. *Id.*

156. 48 Fed. Reg. 31,788 (1983).

157. *Id.* See also H.R. REP. NO. 94-1341, 94th Cong., 2d Sess. 21 (1976).

158. The EPA has decided to measure market share in terms of "production volume." 48 Fed. Reg. 31,788 (1983). The major difficulty of using production volume for cost apportionment purposes is that that information may itself be considered valuable commercial information by the companies.

minimal. This situation is not simply the result of the EPA's failure to promulgate a precise formula. For Congress, having given the EPA little guidance, conflicting guidance, or no guidance at all, to expect the EPA to develop a specific program to mitigate the impact of a regulatory program on an industry is to expect too much. A more rational approach to compensation would be for the EPA to develop a cost-sharing scheme for the present so that the cost of developing data will not fall only on the company that first seeks to market a product. Congress can develop incentives to promote innovation or competition as may prove necessary after evidence accumulates about the effect of the regulatory scheme on the affected industry. Although industry may be reluctant to release information regarding the impact of a regulation, the industry should have the burden of proving the necessity of an innovation-inducing or competition-promoting scheme since the information is in their hands.

### C. Data Reporting Regulations Which Provide No Compensation

The Food and Drug Administration ("FDA") administers several programs requiring data to be submitted to support a product registration. For new drug,<sup>159</sup> new animal drug,<sup>160</sup> and medical device<sup>161</sup> registrations, health and safety data are explicitly protected. In place of disclosure, the agency makes available summaries of the data. For food additives,<sup>162</sup> color additives,<sup>163</sup> biological products,<sup>164</sup> and antibiotics,<sup>165</sup> no scheme exists to protect health and safety data submitted to support a product registration. For food and color additives, data may be released to the public once a regulation is proposed.<sup>166</sup> For antibiotics and biological products, data may be released as soon as the registration of the product is approved.<sup>167</sup> Each product registration program, however, exempts from disclosure "manufacturing methods or processes, including quality control processes."<sup>168</sup> Each program also anticipates that data disclosure may be particularly harmful to some data submitters and therefore provides that disclosure is permissible "unless extraordinary circumstances are shown."<sup>169</sup>

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159. 21 U.S.C. § 355(b)(1)-(4) (1982); *see* 21 U.S.C. § 321(p) (1982) (definition).

160. 21 U.S.C. § 360b(a)(1) (1982).

161. 21 U.S.C. § 360j(h)(1)-(3) (1982).

162. 21 U.S.C. § 348 (1982); *see* 21 U.S.C. § 321(s) (1982) (definition).

163. 21 U.S.C. § 376 (1982); *see* 21 U.S.C. § 321(t)(1) (1982) (definition).

164. 42 U.S.C. § 262(a) (1982).

165. 21 U.S.C. § 357; *see* 21 U.S.C. § 357(a) (1982) (definition).

166. 21 C.F.R. § 71.1(c) (1985) (color additives); 21 C.F.R. § 171.1(h) (1985) (food additives).

167. 21 C.F.R. § 431.71(e), (f) (1985) (antibiotics); 21 C.F.R. § 601.51(e) (1985) (biological products).

168. *See supra* text accompanying note 15.

169. 21 C.F.R. § 71.15(a) (1985) (color additives); 21 C.F.R. § 171.1 (h)(1) (1985) (food additives); 21 C.F.R. § 431.71(e) (1985) (antibiotics); 21 C.F.R. § 601.51(e)(1) (1985) (biological products).



Although these statutory schemes provide no compensation to submitters of data, they have never been challenged in court. This may be because health and safety data in these areas have traditionally been disclosed through publication anyway. As the FDA has noted, "the safety, functionality, and effectiveness data contained in food and color additive petitions and antibiotic drug forms have no trade secret value and, since they are often published in scientific journals or given to customers or scientists or disclosed to the public in other ways, are not customarily regarded as privileged."<sup>170</sup>

Thinking of health and safety data as being in the public domain is consistent with the American system of open scientific debate.<sup>171</sup> Research builds upon previous research, leading eventually to a comprehensive understanding of a subject area. Although there may be economic and political reasons why health and safety data are disclosed in some circumstances and not others, there is no difference that can be linked to the nature of the data.<sup>172</sup>

The open disclosure regulations place an unfair burden on the first manufacturer that wishes to market a product. The government can constitutionally use and disclose the data without compensation after *Monsanto* since it has given submitters no basis on which to form a reasonable investment-backed expectation. Like the FIFRA and TSCA scheme, however, a program to distribute the costs of developing health and safety data among product registrants is fair since some costs would probably have been passed to all registrants in the form of a fee had the government developed the information itself. The following section suggests a program that has as its foundation the policy that costs should be shared equally by all manufacturers of a product.

### III. AN APPROACH TO COST SHARING

A cost-sharing scheme is the compensation approach that is most consistent with general notions of fairness.<sup>173</sup> Disclosing data to the general public can be justified as promoting the health and safety of the public. The cost of health and safety data should be viewed as an inevitable cost of doing business in a society which is concerned about the health and safety of its

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170. 39 Fed. Reg. 44,602, 44,632 (1974).

171. "The cause of knowledge is best served when history is the common property of all, and each generation remains free to draw upon the discoveries and insights of the past." *Hoehling v. Universal City Studios, Inc.*, 618 F.2d 972, 974 (2d Cir.), cert. denied, 449 U.S. 841 (1980).

172. The distinction is *not*, as the FDA has said, simply that new drug, new animal drug, and medical device notices "result in private licenses rather than in public regulations." 39 Fed. Reg. 44,633 (1974). Whether the word "license" is used makes no difference for the effect of the regulation. See also Safir & Reagan, *supra* note 103, at 10062.

173. See Michelman, *supra* note 15, at 1171.

citizens.<sup>174</sup> The EPA's use of data to register a product which will compete with a product already on the market is not as easy to justify. Allowing the subsequent applicant to receive a benefit by not having to pay for data simply because data have already been developed by a competitor is unfair for several reasons. First, the subsequent submitter has done nothing to deserve the benefit. The subsequent applicant, in fact, may be less deserving of any benefit than the original applicant, since the subsequent applicant probably has knowledge from the market history about the commercial potential of the product. The subsequent applicant can, therefore, avoid risks more easily than the original submitter.<sup>175</sup> The second inequity in the data use provision is that the first applicant has "paid" by doing the required testing while any subsequent applicant has not. Even if the original applicant had no expectation of receiving compensation when it first developed its data to support an application so that compensation in no way serves as an incentive to innovation, it is unfair for the subsequent applicant to be enriched at the expense of the former.

A workable cost-sharing system is possible only if the word "share" is used in its normal sense: equal benefit, equal cost. By requiring a second applicant to pay exactly half the costs of developing health and safety data on a product, the originator will be reimbursed and the subsequent applicant will be required to share costs. If a third applicant wished to rely on the data, that applicant would have to pay each of the prior applicants one-sixth of the total cost.<sup>176</sup> While an arbitrary date may still be set after which no payment of compensation would be required, at some point the cost of initiating proceedings to obtain compensation will likely be greater than the benefit gained by compensation. At that point, no prior applicant would pursue an action for compensation, and the data would truly be in the public domain.

This approach to compensation has a number of advantages over any scheme that relies on market share or that mixes economic incentives with cost-sharing. First, the amount of compensation could be ascertainable at the time any subsequent application is made. If the cost of developing the data is submitted along with the data, and some guidance as to the reasonable cost of the test requested is provided, the subsequent applicant would be on notice as to the approximate cost of obtaining a registration for a product. Second, it is a mechanism for determining compensation which is totally

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174. See *supra* text accompanying note 2.

175. To the extent that the cost of producing health and safety data makes taking the risk of marketing a product a less viable option, companies may be less willing to market new products.

176. The formula for determining the amount that a subsequent applicant must pay each former applicant is  $1/n(n-1)$ , where "n" equals the number of companies marketing the product, including the present applicant.

free of implicit assumptions about the proper policy to correctly affect the economic structure of the regulated industry. Paying half of what it costs to develop data may be too much for smaller manufacturers, but it is at most half as much as they would have had to pay if they had been required to develop the data themselves. The costs of lengthy arbitration are also eliminated. Third, it is a scheme that compensates the original data submitter for any royalty it might have received from marketing the data. In this sense, it most closely resembles the compensation that the original submitter would have obtained in a non-monopoly situation. Finally, a proportional cost-sharing program would be relatively easy to administer. Little difficulty would exist in determining the market share of a product for any particular manufacturer. The mathematical calculations involved would be elementary. While there may be questions as to the validity of items included in the cost calculations, they would be questions which are familiar to arbitrators and judges.<sup>177</sup> The appropriate regulatory agency could provide guidance on how to determine such issues as the appropriate amount of fixed costs to be included and the extent to which it is appropriate to compensate for data which goes beyond the requirements of the particular regulation.

#### IV. CONCLUSION

The federal government should continue to regulate industry as long as the health and safety of the public is threatened. For chemicals and other potentially dangerous products, adequate data on the health and safety of the product are necessary for customers to make truly informed decisions and for the public to know whether the social benefits of the product outweigh any potential risks. Health and safety data, as important to society as other information about the product, should be developed before the product is marketed. While the government may place the burden of developing such information on the industry marketing the product, it would be unfair if the burden is not shared equally by all manufacturers producing the product. Programs designed to compensate for the market effect of regulations should be sufficiently detailed so that the program remains true to the policies intended by the legislature.

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177. See, e.g., 48 Fed. Reg. 31,787, 31,789 (1983) (EPA regulation providing that under TSCA, "a portion of fixed costs, including rent, equipment, and salaries, should be eligible for reimbursement.").