Determining Compensation for Subsequent Use of Test Data Under FIFRA: A Value-Based or Cost-Based Standard?

INTRODUCTION

Disagreement plagues the pesticide industry over the issue of data compensation.[1] At the core of this debate is the following question: What standard, if any, does an arbitrator use in determining the compensation awarded the original submitter of test data when it is used by the EPA at the request of a subsequent applicant to support a "follow-on" pesticide registration under the mandatory data-licensing scheme in FIFRA.[2] The resolution of this question is of crucial importance to competing factions within the pesticide industry in the wake of the Supreme Court's recent decision in *Thomas v. Union Carbide Agricultural Products Co.*[3] In upholding the constitutionality of FIFRA's data-licensing scheme, the *Union Carbide* decision has opened the door for compensation claims to be submitted to arbitration under the statute. The debate arises from the fact that FIFRA does not provide the arbitrator with an explicit standard or formula to be used in determining the compensation to be awarded to an original data-submitter.[4] In response, two broad alternative theories for determining compensation have been advocated by representatives of competing factions within the pesticide industry.

Original data submitters — primarily composed of large chemical manufacturers with the resources to invent new pesticides and

1. The disagreement within the pesticide industry is reflected by the widely divergent views presented at a recent conference on data compensation held by the National Agricultural Chemical Association (NACA) in Washington, D.C. on September 11, 1985. For a brief summary of the meeting, see *NACA Data Compensation Session Hears Sharply Divergent Opinions*, Pesticide and Toxic Chemicals News, September 18, 1985, at 25-28.

2. Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) § 3(c)(1)(D), 7 U.S.C. § 136a(c)(1)(D) (1982), *as amended by* Federal Pesticide Act of 1978, Pub. L. No. 95-396, 92 Stat. 820 (1978).

3. _ U.S. _, 105 S. Ct. 3325 (1985).

4. FIFRA § 3(c)(1)(D)(ii), 7 U.S.C. § 136a(c)(1)(D)(ii) (1982) ("The terms and amount of compensation may be fixed by agreement between the original data submitter and the applicant, or, failing such agreement, binding arbitration under this subparagraph.").

develop the costly test data required to register them — argue that compensation should be based on the value of the test data to a "follow-on" registrant. The essence of a value-based standard is that compensation should include more than just a share of the testing costs; compensation should also take into account the economic benefits enjoyed by "follow-on" registrants when they enter the market without suffering the delay involved in developing test data and obtaining regulatory approval. In other words, value-based compensation includes the opportunity costs suffered by the original data submitter as a result of the regulatory delays involved in bringing a new pesticide to market.

In contrast, "follow-on" registrants — primarily composed of smaller competing manufacturers and formulators — argue that compensation should be based on an equitable sharing of the actual cost of producing the test data alone. Within this cost sharing framework, there is further debate as to whether equitable sharing should be calculated on a market share or a per capita basis. If calculated on a market share basis, then the costs of the test data would be divided between registrants based on a comparison of either their present market share or prospective market share. If calculated on a per capita basis, then the costs of the test data would be equally divided.

The stakes are high in this debate. In the central decision issued to date, *Stauffer Chemical Co. v. PPG Industries*, the original data-submitter (Stauffer) was awarded value-based compensation.[5] By relying on Stauffer's data, the follow-on registrant (PPG) entered the market five years earlier than it would have if it had been forced to independently generate the test data and obtain regulatory approval. The arbitrators measured the value of this early market entry to PPG as approximately fourteen million dollars, while PPG's per capita share of the actual cost of developing the data was only approximately one and one half million dollars.

Including the *Stauffer* decision, only two arbitrator's decisions have been issued under FIFRA's data-licensing scheme.[6] Both

5. Stauffer Chemical Co. v. PPG Industries, No. 16 199 077 82, Federal Mediation and Conciliation Service (June 28, 1983) (Birch et al., Arb.) [hereinafter cited as *Stauffer*]. For a detailed discussion of the *Stauffer* decision, see text at nn. 110-38, *infra*.

6. *Stauffer* and FMC Corp. v. Tricon International, No. 16 199 0033 84G, American Arbitration Association (Jan. 10, 1985) (Foy et al., Arb.) [hereinafter cited as *FMC*]. For a detailed discussion of the *FMC* decision, see *infra*, text accompanying notes 139-49.

decisions address the issue of a standard for determining compensation, but neither resolves it satisfactorily. More importantly, the arbitrators in the *Stauffer* decision ignored important elements of the legislative history of the data-licensing scheme in granting value-based compensation. Despite the absence of explicit statutory guidance, an arbitrator need not act independently when determining "compensation." In its *Union Carbide* decision, the Supreme Court is careful to point out that the legislative history of the amendments to FIFRA are "far from silent" on the issue of FIFRA's standard for compensation.[7]

This note will explore the turbulent history of the data-licensing scheme in FIFRA to determine whether it provides an arbitrator with guidance in choosing a standard for compensation. By way of background, Section I will focus on the details of the 1972 and 1978 amendments to FIFRA which created the mandatory license requirement, and two recent Supreme Court decisions establishing its constitutionality. Section II will analyze the legislative histories of both the 1972 and 1978 amendments with an eye to understanding what they reveal about the issue of FIFRA's standard for compensation. Section III will then analyze the two arbitrator's decisions that have been issued thus far in light of Congress' purposes related to compensation as revealed in FIFRA's legislative history.

The results of these analyses support the follow-on registrant's claims that compensation should be based on the actual costs of developing test data. Congress enacted the compensation provisions to facilitate market entry and encourage competition in the pesticide industry without discouraging innovation. A value-based standard that includes the opportunity costs avoided by follow-on registrants defeats the competitive purposes of the compensation provisions. The arbitrators in *Stauffer* failed to adequately consider the legislative histories of the amendments to FIFRA and were prejudiced by factors irrelevant to the issue before them; as a result, they erred in awarding value-based compensation. However, within a cost sharing framework, Congress was silent on the question of how to equitably divide testing costs and left this issue to the reasonable determination of the arbitrators and parties involved.

7. 105 S. Ct. at 3340 (citations omitted).

I. FIFRA'S MANDATORY DATA-LICENSING SCHEME AND DISCUSSION OF RECENT SUPREME COURT DECISIONS UPHOLDING ITS CONSTITUTIONALITY

A. *1972 Amendments: The Federal Environmental Pesticide Control Act of 1972*

FIFRA was first adopted in 1947; at that time it was primarily a licensing and labeling statute designed to protect pesticide users from misbranded and adulterated pesticides.[8] License applicants were required to submit test data and a pesticides's formula to the Secretary of Agriculture in support of the claims made on their labels.[9] Disclosure of "any information relative to formulas of products" was prohibited, but the 1947 FIFRA was silent with respect to the use of submitted data in support of subsequent applications and the disclosure of health and safety data.[10]

In 1972, the reach of FIFRA was expanded through the passage of the Federal Environmental Pesticide Control Act of 1972.[11] The amendments transformed FIFRA into a comprehensive regulatory statute. The 1972 amendments also introduced a mandatory data-licensing scheme to FIFRA for the first time.[12] The EPA was authorized to consider data submitted by one applicant for registration as support for another application, provided the subsequent ("follow-on") applicant offered "reasonable compensation" to the original data submitter.[13] The amount of compensation was to be negotiated between the parties; if negotiations failed, the EPA was to resolve the dispute by conducting

8. FIFRA, Pub. L. No. 80-104, Law of June 25, 1947, ch. 125, 61 Stat. 163 (1947). For a discussion of the early history of FIFRA, *See* F. GRAD, TREATISE ON ENVIRONMENTAL LAW, § 8.02 (1985).

9. FIFRA, Pub. L. No. 80-104, Law of June 25, 1947, ch. 125, §§ 4(a) and (b), 61 Stat. 167-68 (1947). *See also* Ruckelshaus v. Monsanto Co., _ U.S. _, 104 S. Ct. 2862, 2864 (1984) (hereinafter referred to as "*Monsanto*"). The Department of Agriculture's responsibilities under FIFRA were transferred to the newly created Environmental Protection Agency in 1970. *See* Reorganization Plan No. 3 of 1970, 35 Fed Reg. 15623 (1970).

10. FIFRA, Pub. L. No. 80-104, Law of June 25, 1947, ch. 125, § 3(c)(4), 61 Stat. 166-67 (1947). However, in *Monsanto*, the Supreme Court stated that prior to 1972 "there is some evidence that the practice of using data submitted by one company during consideration of the application of a subsequent applicant was widespread and well known". 104 S. Ct. at 2877 (Discussion of evidence in footnote omitted). The legislative history of the 1972 amendments to FIFRA support this conclusion. *See* S. REP. No. 838 (Pt. II), 92nd Cong., 2d Sess., *reprinted in* 1972 U.S. CODE CONG. & AD. NEWS 3993, 4040.

11. Federal Environmental Pesticide Control Act of 1972 (FEPCA), Pub. L. No. 92-516, 86 Stat. 973 (1972).

12. FEPCA, Pub. L. No. 92-516, § 3(c)(1)(D), 86 Stat. 973, 979-80 (1972).

13. *Id.*

administrative hearings.[14] Compensation decisions were subject to judicial review in a federal district court only at the instigation of the original data-submitter, and the reviewing court was precluded from reducing the amount of compensation awarded by the EPA.[15]

The 1972 data-licensing scheme was limited by the trade secret provisions in FEPCA.[16] Original data-submitters were allowed to designate any portions of their submitted material as "trade secrets or commercial or financial information."[17] The EPA was prohibited from publicly disclosing such information, and could not consider it in support of a subsequent (follow-on) application without the original submitters consent.[18] If the EPA disagreed with the designation of certain information as "trade secrets or commercial or financial information," the original submitter was authorized to institute a declaratory judgment action in federal district court.[19]

Effective operation of the 1972 mandatory data-licensing scheme was blocked by litigation. The initial failure to establish an effective date in the Act for mandatory licensing led to litigation over the possibility of the retroactive application of the compensation requirement to data already in the EPA's files.[20] In 1975, Congress resolved this problem by amending Section three to provide that data submitted in support of earlier applications are subject to the compensation provisions only if submitted after December 31, 1969.[21] However, judicial decisions which expanded the category of data protected as "trade secrets or commercial or financial information" continued to block the effective

14. *Id.*

15. *Id.*

16. FEPCA, Pub. L. No. 92-516, §§ 10(a)-10(c), 86 Stat. 973, 989 (1972).

17. *Id.* at § 10(a).

18. *Id.* at § 10(b).

19. *Id.* at § 10(c).

20. *See* Amchen v. GAF, 391 F. Supp. 124 (N.D. Ga. 1975). Such litigation was over data already in the EPA's files under registrations prior to the enactment of FEPCA (October 21, 1972), and prior to the effective date of its registration provisions. 38 Fed. Reg. 31862 (Nov. 19, 1973).

21. FIFRA § 3(c)(1)(D), 7 U.S.C. § 136a(c)(1)(D) (1982), as amended by the Federal Pesticide Act of 1975, Pub. L. No. 94-140, § 12, 89 Stat. 751, 755 (Nov. 25, 1975). Under the 1975 amendment, the obligation to pay for the use of such data applies only with respect to applications for registrations or registrations submitted on or after the enactment of FEPCA (October 21, 1972).

operation of mandatory licensing.[22] Little room was left for the application of the mandatory licensing scheme because such a large percentage of the submitted test data was protected under the rubric of trade secret.[23]

B. *1978 Amendments: The Federal Pesticide Act of 1978*

In response to these and other regulatory problems, FIFRA was amended again with the passage of the Federal Pesticide Act of 1978.[24] Both the mandatory licensing and trade secret provisions of the Act were changed substantially to their present form.[25] In their complexity, the current provisions reflect the difficult history of the mandatory licensing scheme. Since the 1978 amendments, FIFRA divides submitted test data into three categories based on their date of submission:

[1] Data submitted in support of an application for the original registration or new use of a pesticide which is registered after September 30, 1978, the effective date of the 1978 amendments, are protected from use by another applicant for ten years from the date of registration.[26] This is known as a ten year "exclusive use" period. The EPA may not consider such data in support of a later follow-on application for ten years without the permission of the person who originally submitted the data. After the expiration of the ten year exclusive use period, the person who submitted the original data is also entitled for the following five years to compensation for the use of this data in the manner discussed below.[27]

22. FEPCA, Pub. L. No. 92-516, §§ 10(a)-10(c), 86 Stat. 973, 989 (1972). The EPA argued for a narrow statutory definition of "trade secret or commercial or financial information" that did not encompass data related to the safety or efficacy of a pesticide product. However, the courts disagreed with EPA's interpretation and found that Congress had accepted the broad definition of "trade secret" set forth in section 757 of the Restatement of Torts. *See* Mobay Chemical Corp. v. Costle, 447 F. Supp. 811 (W.D.Mo. 1978); Chevron Chemical Co. v. Costle, 443 F. Supp. 1024 (N.D.Cal. 1978); Dow Chemical Co. v. Train, 423 F. Supp. 1359 (E.D. Mich. 1976).

23. The legislative history of the 1978 amendments to FIFRA indicates that these decisions effectively prevented the EPA from considering the data submitted by one applicant when reviewing a later application by another. *See* S. REP. No. 334, 95th Cong., 1st Sess. 7 (1977); H.R. REP. No. 663, 95th Cong., 2nd Sess. 18 (1977). *See also Monsanto*, 104 S. Ct. at 2865.

24. Federal Pesticide Act of 1978, Pub. L. No. 95-396, § 2(a), 92 Stat. 820 (1978).

25. FIFRA §§ 3(c)(1)(D), 10, 7 U.S.C. §§ 136a, 136h (1982).

26. *See* FIFRA § 3(c)(1)(D)(i), 7 U.S.C. § 136a(c)(1)(D)(i) (1982).

27. *See* FIFRA § 3(c)(1)(D)(ii), 7 U.S.C. § 136a(c)(1)(D)(ii) (1982).

[2] Data submitted after December 31, 1969, the date set by Congress in the 1975 amendments to provide for a starting point for compensation of earlier data, and before September 30, 1978, the effective date of the 1978 amendments, may be considered by the EPA in support of an application by any other person, but only if the new applicant has made an offer to "compensate" the person who submitted the original data.[28] This requirement only applies within a fifteen year period following the date of the original submission of the data.

[3] Data submitted in support of an application for registration prior to January 1, 1970, or data for which exclusive use or compensated use periods described above have expired, may be freely considered by the EPA in support of any other applications.[29]

In every case in which a follow-on applicant is required to pay compensation, he is required to send the original data-submitter an offer to pay for use of the data.[30] If at the end of ninety days after the date of delivery of the offer there is no agreement on the amount and terms of compensation, nor on a procedure for reaching such an agreement, then either party may initiate arbitration proceedings by requesting the Federal Mediation and Conciliation Service to appoint an arbitrator. The procedures and rules of the Service apply to the proceedings and to the selection of an arbitrator.[31]

The findings and determinations of the arbitrator are "final and conclusive, and no official or court of the United States shall have power or jurisdiction to review any such findings and determinations, except for fraud, misrepresentation, or other misconduct by one of the parties to the arbitration or the arbitrator. . . ."[32] Action on the registrant's application is not to be delayed during the fixing of compensation through arbitration. If the Administrator of the EPA determines that either the original data submit-

28. *Id.* Note that the "reasonable compensation" language of the 1972 data-licensing provisions was changed to "compensate."

29. *See* FIFRA § 3(c)(1)(D)(iii), 7 U.S.C. § 136a(c)(1)(D)(iii) (1982).

30. FIFRA § 3(c)(1)(D)(ii), 7 U.S.C. § 136a(c)(1)(D)(ii) (1982). Under current regulations, he may also file such an offer directly with the EPA to avoid the necessity of having to make an individual offer of compensation. 40 C.F.R. § 152.86 (1985).

31. *Id.* The Federal Mediation and Conciliation Service has published interim final regulations which establish that the roster of commercial arbitrators maintained by the American Arbitration Association (AAA) will be utilized, and the FIFRA arbitration rules of the AAA will be followed for the arbitration of pesticide compensation disputes. 45 Fed. Reg. 28105 (1980).

32. *Id.*

ter or applicant failed to participate in the negotiation or arbitration, or failed to comply with an agreement or arbitration decision, then he shall order the original submitter to forfeit his right to compensation or "deny the application or cancel the registration of the pesticide in support of which data were used without further hearing."[33] He must, however, furnish fifteen days notice of his intent to act by certified mail.

The 1978 amendments also provide procedures for joint development and the sharing of costs related to "defensive data" — i.e. additional test data required by the EPA to maintain in effect an existing registration of a pesticide.[34] Upon notice from the EPA that additional test data is required, a registrant has ninety days to either furnish evidence to the EPA that appropriate steps are being taken to secure the additional data, or agree with one or more registrant's to either jointly develop or share in the cost of developing the additional data.[35] If the parties cannot agree on the details of a joint development or cost sharing arrangement within sixty days after notifying EPA of their intent to cooperate, then either registrant may initiate arbitration proceedings by requesting the Federal Mediation and Conciliation Service to appoint an arbitrator.[36] Again, the procedures and rules of the service apply to the proceedings and to the selection of an arbitrator; and the findings and determinations of the arbitrator are "final and conclusive" and not subject to judicial review except in the cases of fraud, misrepresentation or misconduct.[37]

The trade secret provisions of FIFRA were also amended by providing for the disclosure of all health, safety and environmental data, notwithstanding the prohibition against the disclosure of "trade secrets," provided that the use of such data is subject to the licensing scheme outlined above.[38] A strict prohibition remains on the disclosure of information that reveals "manufacturing or quality control processes" or certain details related to added inert ingredients unless the EPA Administrator determines

33. *Id.*
34. FIFRA § 3(c)(2)(B), 7 U.S.C. § 136a(c)(2)(B) (1982).
35. FIFRA § 3(c)(2)(B)(ii), 7 U.S.C. § 136a(c)(2)(B)(ii) (1982).
36. FIFRA § 3(c)(2)(B)(iii), 7 U.S.C. § 136a(c)(2)(B)(iii) (1982).
37. *Id.*
38. FIFRA § 10(d), 7 U.S.C. § 136h(d) (1982).

that "disclosure is necessary, to protect against an unreasonable risk of injury to health or the environment."[39]

C. *Judicial Action Since 1978: The Monsanto and Union Carbide Decisions*

Effective operation of the 1978 data-licensing scheme has also been blocked by litigation. The mandatory license was repeatedly challenged by original data-submitters as an unconstitutional "taking" of property without just compensation in violation of the Fifth Amendment, and the arbitration provisions were also challenged as an impermissible intrusion on the power of the judiciary in violation of article III.[40]

After many years of litigation, both of these issues were resolved by the Supreme Court in the course of two decisions, rendered, respectively, in 1984 and 1985. In June 1984, the Supreme Court held in *Ruckelshaus v. Monsanto Co.*[41] that the mandatory license does not result in an uncompensated taking in violation of the Fifth Amendment. In July, 1985, the Court held in *Thomas v. Union Carbide Agricultural Products Co.*[42] that the requirement for binding arbitraton does not violate the requirements of article III relating to proper judicial tribunals.

In resolving the Fifth Amendment issue, the Court in *Monsanto* held that with respect to data submitted prior to October 22, 1972 and after September 30, 1978, the mandatory license established by the 1978 amendments to FIFRA did not constitute a "taking" of property. However, the Court ruled that the operation of the data-licensing scheme "may effect a taking with respect to certain health, safety, and environmental data constituting trade secrets under state law and designated . . . as trade secrets

39. *Id.*

40. Mobay Chemical Corp. v. Costle, 517 F. Supp. 252, 254 (W.D.Pa. 1981), *aff'd sub nom.* Mobay Chemical Corp. v. Gorsuch, 682 F.2d 419 (3d Cir.), *cert. denied*, 459 U.S. 988 (1982) (no taking in violation of the fifth amendment); Chevron Chemical Co. v. Costle, 499 F. Supp. 732 (D.Del. 1980), *aff'd*, 641 F.2d 104 (3d Cir.), *cert. denied*, 452 U.S. 961 (1981) (no taking in violation of the fifth amendment); Union Carbide Agricultural Products Co. v. Ruckelshaus, 571 F. Supp. 117 (S.D.N.Y. 1983), *vacated and remanded*, 104 S. Ct. 3566, *aff'd on rehearing*, No. 76 Civ. 2913 (R) (S.D.N.Y. Sept. 4, 1984), *rev'd sub. nom.* Thomas v. Union Carbide Agricultural Products Co., _ U.S. _, 105 S. Ct. 3325 (1985) (district court held arbitration provisions unconstitutionally restricted access to judicial review in violation of Article III); Petrolite Corp. v. EPA, 519 F. Supp. 966 (D.D.C. 1981) (no taking in violation of the fifth amendment).

41. 104 S. Ct. 2862 (1984).

42. 105 S. Ct. 3325 (1985).

upon submission to the EPA between October 22, 1972 and September 30, 1978."[43] The Court further held that if such a taking occurs it is for a public purpose, and a Tucker Act remedy is available to original data submitters to provide just compensation for the use of their data.[44]

Challenges to the constitutionality of the arbitration scheme established by the 1978 amendments were held to be not ripe for review by the Court. Monsanto could not demonstrate actual injury because an arbitration had not yet taken place under the statute.[45] However, operation of the arbitration scheme was held to be a precondition to a claim for compensation under the Tucker Act.

One year later, the Court resolved the issues it had not reached in *Monsanto* relating to the arbitration provisions in *Thomas v. Union Carbide Agricultural Products Co.*[46] The challenge to the arbitration provisions on article III grounds was held to be ripe for review because, in contrast to *Monsanto*, actual arbitration had taken place to fix the amount of compensation an applicant should pay for the use of previously submitted data.[47] In addition, the EPA now had procedures in place through which applicants could meet the requirements of the mandatory license, and

43. 104 S. Ct. at 2882.

44. When the United States takes property for a public purpose, the injured party is able to seek just compensation under the Tucker Act, 28 U.S.C. § 1491 (1982).

45. 104 S. Ct. at 2882, citing Duke Power Co. v. Carolina Environmental Study Group, Inc., 438 U.S. 59 (1978); Regional Rail Reorganization Act Cases, 419 U.S. 102 (1974).

46. 105 S. Ct. 3325 (1985). Initially, a federal district court for the Southern District of New York held that the arbitration provisions were an unconstitutional assignment of judicial power in violation of article III. Union Carbide Agricultural Products Co. v. Ruckelshaus, 571 F. Supp. 117 (S.D.N.Y. 1983). The district court, rather than strike down the arbitration provisions alone, enjoined the entire FIFRA data use and compensation scheme. The Supreme Court vacated this judgment, and remanded it back to the lower court for reconsideration in light of the *Monsanto* decision. Ruckelshaus v. Union Carbide Agricultural Products Co., 104 S. Ct. 3566 (1984). On remand, the district court reinstated its prior judgment enjoining the operation of the data-licensing scheme as violative of article III. Union Carbide Agricultural Products Co. v. Ruckelshaus, No. 79 Civ. 2913 (RO) (S.D.N.Y. Sept. 4, 1984). In October 1984, the Supreme Court granted EPA's request for a stay of the injunction pending disposition of the appeal of the case. Ruckelshaus v. Union Carbide Agricultural Products Co., 105 S. Ct. 237 (1984).

47. 105 S. Ct. at 3333. One of the appellants, Stauffer Chemical Co., had engaged in an arbitration lasting months. For a discussion of the award granted by the arbitrators, see *infra*, text accompanying notes 110-38.

numerous registrations had been issued under those procedures.[48]

In upholding the constitutionality of the arbitration provisions, the Court held that FIFRA does not confer "private rights" which require adjudication or review by an article III court, but instead confers "public rights."[49] The Court rejected the argument that litigation between private parties necessarily involves private claims to be decided by article III courts, and held that the public nature of the remedies defines the claim as asserting essentially public rights.[50] The Court further emphasized that the arbitration provisions have their own system of internal sanctions and rely "only tangentially, if at all, on the judicial branch for enforcement."[51] The danger of encroachment on the article III powers is minimized in such a case. Although cases such as this involve the government's administration of its own programs, the presence of public rights does not depend on the federal government as a party to the action.[52]

The Court left open the question of whether a private party could initiate an action in court to enforce a FIFRA arbitration,

48. In August 1984, the EPA promulgated regulations that implemented the data-licensing scheme. 49 Fed. Reg. 30,884 (1984), *enacting* 40 C.F.R. Part 152 (1985).

Prior to August 1984, EPA's attempts to implement mandatory licensing were frustrated by court decisions. Following the enactment of the 1978 amendments, EPA issued an interim final rule known as their "cite-all" regulations. 44 Fed. Reg. 27,932 (1979). Regardless of whether an applicant had developed his own test data sufficient to meet EPA registration standards, the "cite-all" regulations required an applicant to rely on all information in EPA's files relevant to an evaluation of his product, and to compensate prior applicants accordingly. In June 1982, the Third Circuit declared the "cite-all" regulations invalid because the EPA had failed to follow proper notice and comment procedures required by the Administrative Procedure Act. *See* Mobay Chemical Corp. v. Gorsuch, 682 F.2d 419 (3d Cir. 1982).

In December 1982, EPA reproposed its 1979 "cite-all" regulations essentially unchanged, with a proper 60 day comment period. 47 Fed. Reg. 57,624 (1982). However, in January 1983, a district court for the District of Columbia invalidated the "cite-all" regulations because they were inconsistent with options given to applicants by FIFRA. National Agricultural Chemicals Association v. EPA, 554 F. Supp. 1209 (D.D.C. 1983). While EPA was formulating new rules in response to this decision, the lower court in *Monsanto* ruled that the mandatory data-licensing scheme in FIFRA was unconstitutional, and enjoined the EPA from implementing it in any way. Monsanto Co. v. Acting Administrator, EPA, 564 F. Supp. 552 (E.D.Mo. 1983). For a discussion of *Monsanto*, see *supra*, text accompanying notes 41-45.

49. 105 S. Ct. at 3335-37. In reaching this holding, the Court distinguished *Northern Pipeline Construction Co. v. Marathon Pipeline Co.* 458 U.S. 50 (1982).

50. 105 S. Ct. at 3338.

51. *Id.*

52. 105 S. Ct. at 3336.

although it indicated that other provisions of law raise that possibility. Finally, the court noted that the arbitration scheme does not completely preclude review of the arbitration proceeding— a provision is included for judicial review of cases involving fraud, misrepresentation, or misconduct.[53] As a result, the Court concluded that such review preserves the "appropriate exercise of the judicial function."[54]

In *Union Carbide*, the Court also left unresolved the issue of whether FIFRA's "standard for compensation is so vague as to be an unconstitutional delegation of legislative powers" in violation of article I.[55] In their briefs, appellees emphasised that the language of FIFRA does not provide guidance on what standard to use in determining "compensation", and further argued that nothing appears in "FIFRA or its legislative history to define this right or to establish a standard for its determination."[56] In support of their contention, appellees cited two district court opinions,[57] comments made by the Federal Mediation and Conciliation Service in the federal register,[58] and statements made by former EPA administrator Douglas M. Costle found in the legislative history of the 1978 amendments.[59]

However, the Court refused to rule on this question because it had not been adequately briefed or argued, and the issue was left open for determination on remand.[60] In dicta, the Court cautioned that "[a] term that appears vague on its face may derive

53. 105 S. Ct. at 3339. *See* FIFRA § 3(c)(1)(D)(iii), 7 U.S.C. § 136a(c)(1)(D)(iii) (1982).

54. 105 S. Ct. at 3339, quoting Crowell v. Benson, 285 U.S. 22, 54 (1932).

55. 105 S. Ct. at 3339 (citing A.L.A. Schecter Poultry Corp. v. United States, 295 U.S. 495 (1935)).

56. Brief for Appellees Union Carbide Agricultural Products Co. at 28-30, Thomas v. Union Carbide Agricultural Products Co., 105 S. Ct. 3325 (1985).

57. *Id.* (citing Sathon, Inc. v. American Arbitration Association, No. 84 C 6019, slip op. at 7 (N.D. Ill. Mar. 30, 1984), *appeal dismissed*, No. 84-1540 (7th Cir. July 3, 1984) ("there is nothing in the statute (or the regulations promulgated thereunder) relating to the standard to be applied in such proceedings"); Monsanto Co. v. Acting Administrator, EPA, 564 F. Supp. 552, 561, 567 (E.D. Mo. 1983), *vacated on other grounds*, Ruckelshaus v. Monsanto Co., 104 S. Ct. 2862 (1984) ("there are no discernible guidelines outlining the factors which constitute just compensation for use of [a submitter's] data")).

58. *Id.*, citing 45 Fed. Reg. 55,394 (1980) ("neither the House or Senate specified a formula or other guidance on the valuation of data for compensation purposes") and 45 Fed. Reg. 28,107 (1980) ("[t]he statutory scheme of FIFRA provides that the arbitrators will determine the standards on a case-by-case basis. . .").

59. *Id.*, citing H.R. REP. No. 663, 95th Cong., 1st Sess. 59 (1977) (testimony of Douglas M. Costle). *See* discussion of the context of Mr. Costle's remarks *infra*, text accompanying notes 90-92.

60. 105 S. Ct. at 3339-40.

much meaningful content from the purpose of the Act, its factual background, and the statutory context."[61] The Court further stated that "[a]lthough FIFRA's language does not impose an explicit standard, the legislative history of the 1972 and 1978 amendments is far from silent" on the question of FIFRA's standard for compensation.[62] Section two will analyze the legislative histories of both the 1972 and 1978 amendments to FIFRA in an attempt to discover what they say on this issue.

II. Legislative History of 1972 and 1978 Amendments to FIFRA

A. *Legislative History of the 1972 Amendments: The Federal Environmental Pesticide Control Act of 1972*

The mandatory data-licensing provisions of the 1972 amendments to FIFRA[63] emerged as a compromise between differing versions of the original bill (H.R. 10729) supported alternatively by the Senate Committee on Agriculture and Forestry and the Senate Committee on Commerce.[64] The Committee on Agriculture and Forestry supported a version of the bill that prohibited data submitted in support of an application for pesticide registra-

61. *Id.*, quoting American Power & Light Co. v. SEC, 329 U.S. 90, 104 (1946).

62. 105 S. Ct. at 3340, citing S. Conf. Rep. No. 1188, 95th Cong., 2nd Sess. 18 (1978); S. Rep. No. 334, 95th Cong., 1st Sess. 4,8,31 (1977); S. Rep. No. 838, 92nd Cong., 1st Sess. 69, 72-73 (1972); *Hearings on Extending and Amending FIFRA before the Subcommittee on Department Investigations, Oversight, and Research of the House Committee on Agriculture*, 95th Cong., 1st Sess. *passim* (1977).

63. FEPCA, Pub. L. No. 92-516, § 3(c)(1)(D), 86 Stat. 973 (1972). *See supra*, discussion of the 1972 amendment's mandatory data-licensing scheme at text accompanying notes 12-22.

64. On November 9, 1971, the House passed a clean bill, H.R. 10729. This bill was referred to the Senate Committee on Agriculture and Forestry on November 19, 1971. On December 16, 1971, the Chairman of the Senate Committee on Commerce wrote to the Chairman of the Committee on Agriculture and Forestry asking for rereferral of the final bill to the Committee on Commerce if and when the Committee on Agriculture and Forestry chose to report a pesticide bill. The Chairman of the Committee on Agriculture and Forestry agreed to rereferral to the Committee on Commerce. After extensive hearings, on June 7, 1972, the Committee on Agriculture and Forestry ordered that H.R. 10729, the Federal Environmental Pesticide Control Act of 1972, be both reported to the Senate and referred to the Committee on Commerce. The Committee on Commerce held hearings on June 15 and 19, 1972, and reported their version of the bill to the Senate on July 19, 1972. The Committee on Commerce recommended sixty-five amendments to the Committee on Agriculture and Forestry's version of the bill that were divided into fifteen groups, including the amendments to data-licensing. *See* S. Rep. No. 838 (Pt. II), 92nd Cong., 2nd Sess. (1972), *reprinted in* 1972 U.S. Code Cong. & Ad. News 3993, 4023-28 [hereinafter referred to as "1972 S. Rep. No. 838, *reprinted at* ___"].

tion from being considered by the EPA in support of subsequent applications without the consent of the original data-submitter.[65] This would have given original data submitters "exclusive use" of their data without restriction. The Committee on Commerce supported an amendment that would strike the exclusive use provision from the bill, and allow the EPA to freely consider such data in support of subsequent applications.[66] This would have given follow-on registrants "free use" of previously submitted data in support of their registrations.

The battle for an exclusive use provision was led by the National Agricultural Chemical Association (NACA) — a trade association primarily representing large chemical companies that develop and manufacture pesticides. The essence of NACA's argument was that "no one is going to invest substantial amounts in research to meet. . . requirements for data if competitive companies can thereafter use that data to register and sell in competition the same product."[67] Proponents of exclusive use consistently argued that its purpose was to give manufacturers "an incentive to undertake the research necessary to develop better and safer pesticides."[68] NACA also emphasized that exclusive use did not directly or *indirectly* extend patent protections to original data submitters because subsequent applicants always had the option to register and market a product based on their own test data.[69] While acknowledging that duplication of test data might result, NACA argued that such replication would be beneficial to

65. *See* 1972 S. REP. No. 838, *reprinted at* 4034-35.

66. *See* S. REP. No. 970, 92nd Cong., 2d Sess. (1972), *reprinted in* 1972 U.S. CODE CONG. & AD. NEWS 3993, 4096 [hereinafter referred to as "1972 S. REP. No. 970, *reprinted at* ___"). The legislative history suggests that "as a matter of practice but without statutory authority," the EPA considered submitted test data "to support the registration of the same or similar product by another registrant" prior to the 1972 amendments. *See* S. REP. No. 838, *reprinted at* 4040. This view was reiterated by the Supreme Court in *Monsanto*, 104 S. Ct. at 2877.

67. 1972 S. REP. No. 838, *reprinted at* 4035.

68. *Id.* at 4034.

69. *Id.* at 4037-41. Under both the 1972 and current version of FIFRA, normal seventeen year patent protections run concurrently with the compensated use or exclusive use protections provided by mandatory licensing. However in the pesticide industry, once a potential commercial pesticide candidate is discovered it usually takes between fourteen and twenty-two years to complete the development process. *Monsanto*, 104 S. Ct. at 2871. Because of the unusually long time that it takes to bring a pesticide product to market, patent law provides little protection for the pesticide developer.

the goal of establishing the safety of a pesticide and its effect on the environment.[70]

The Committee on Commerce was opposed to the exclusive use provisions for two main reasons. First, it emphasized that exclusive use would create "barriers to entry in the pesticide industry" far greater than those provided by patent law which would have an anticompetitive effect on the industry.[71] Second, the Committee on Commerce argued that by requiring manufacturers to invest resources in costly duplicate testing, the exclusive use provisions stifled the very incentive to invest in new research and development which it ostensibly was designed to encourage.[72] The Committee on Commerce was supported in its views on the anticompetitive effect of exclusive use by the Attorney General, who advised Congress that instead of furthering "the remedial purposes of the bill," the provision "serves rather to insulate the first applicant for registration from the competition of later applicants."[73] The EPA also stated that "the effect of this provision is to afford additional economic protection, foster monopoly, and it may tend to restrict pesticide business to large manufacturers."[74]

The data-licensing scheme in the 1972 amendments emerged as a compromise position between the exclusive use and free use poles of this debate. Congress demonstrated its desire to encourage market entry and competition in the pesticide industry by denying exclusive use protection to original data-submitters. In addition, by granting original data-submitters the right to "reasonable compensation," Congress recognised that allowing the free use of test data might dampen the incentive to undertake new research and development.

It is inconsistent with the market entry and competitive goals of this compromise to argue that reasonable compensation should be measured by the value of the test data to a follow-on registrant. If the opportunity costs that are avoided by follow-on reg-

70. *Id.* at 4041.

71. 1972 S. REP. No. 970, *reprinted at* 4096-4103.

72. *Id.* at 4096.

73. *Id.* at 4096-98 (April 28, 1972 letter from Acting Attorney General Richard G. Kliendienst). The Attorney General's views were shared by two law professors who were invited to comment on the exclusive use provision. *Id.* at 4098-4103 (Feb. 21, 1972 letter from John G. Stedman, Professor of Law at the University of Wisconsin, and Feb. 9, 1972 letter from John J. Flynn, Professor of Law at the University of Utah).

74. 1972 S. REP. No. 838, *reprinted at* 4043.

istrants are included when calculating reasonable compensation, then, effectively, the original data-submitter is granted the equivalent of exclusive use protection for the use of his data. Follow-on registrants would be required to pay compensation costs equivalent to the costs they would incur if they were prevented from relying on previously submitted data by an exclusive use provision and forced to develop the test data themselves. In rejecting NACA's exclusive use proposals, Congress intended to facilitate market entry for smaller chemical manufacturers and avoid duplicate testing; while a value-based standard might avoid duplicate testing to a degree, it would unquestionably defeat the competitive considerations that led to the creation of the mandatory data-licensing scheme. Therefore, Congress intended that reasonable compensation be based on an equitable sharing of the actual costs of developing test data.

This conclusion, drawn from an analysis of the general purposes of the data-licensing scheme in the 1972 amendments, is supported by specific language in the legislative history. The Committee on Agriculture and Forestry, in responding to the objection that an exclusive use provision would unduly extend patent protections, stated:

> If the product is not patentable or if the patent protection has expired, there is nothing to prevent a competitor from registering a similar product. Under such circumstances, the first applicant has no opportunity to *recover his research costs* and little incentive for undertaking that research.[75]

Further on, in response to objections that exclusive use would lead to duplicate testing, the Committee stated:

> The Committee on Agriculture and Forestry does not believe that there will be any great diversion of funds to duplicate testing. Rather this provision is likely to result in *equitable sharing of research costs*. There would be little reason for duplicate testing if a second registrant could share in the test data of the first by paying part of the cost.[76]

Finally, in a section entitled "Legislative intent with respect to section 3 (c)(1)(D)," Senate Report No. 838 states:

> Thus it was decided that fairness and equity require a sharing of the governmentally required *cost of producing the test data* used in support of an application other than the originator of such

75. *Id.* at 4034 (emphasis supplied).
76. *Id.* (emphasis supplied).

> data. If no agreement can be reached, the Administrator is vested with authority to determine the reasonable share of the *cost of the test data used*, including subsequent reallocations upon requests for use of such data by additional applicants.[77]

As the Court in *Union Carbide* suggests, the legislative history of the 1972 amendments is not silent on the issue of FIFRA's standard for compensation. It indicates that Congress intended "reasonable compensation" to be calculated as an equitable share of the actual cost of developing test data.[78] A value-based standard that includes the opportunity costs incurred by the original data-submitter would conflict with both Congress's general purpose in creating a mandatory data-licensing scheme in FIFRA, and specific language in the amendment's legislative history.

B. *Legislative History of the 1978 Amendments: The Federal Pesticide Act of 1978*

The legislative history of the 1978 amendments is more complex than that of the 1972 amendments; however, many of the same parties pitched battle over many of the same policy considerations and proposals debated in 1972. The current data-licensing scheme finally emerged as a compromise crafted in a Conference Committee convened to resolve differences between a House amendment and the final Senate bill.[79] Before examining this final compromise, it is important to look at the contours of the debate which led to this impasse between the two houses of Congress.

Mirroring its stance in 1972, NACA initially proposed that mandatory licensing be eliminated, and that original data-submit-

77. *Id.* at 4092 (emphasis supplied).

78. This conclusion is shared by EPA administrative law judge Harwood who ruled in the only two decisions rendered under the 1972 data-licensing scheme that Congress intended follow-on registrants to pay only a share of the actual cost of producing the test data. Judge Harwood rejected proposals that original data-submitters be awarded royalty-like compensation that would include the opportunity costs avoided by follow-on registrants. *See* Ciba-Geigy Corp. v. Farmland Industries, Inc., Nos. 33, 34 & 41 (Aug. 19, 1980), Final Order issued (April 30, 1981), affirmed by the Administrator (July 28, 1981); *See also* Union Carbide AgriculturaL Products Co. v. Thompson-Hayward Chemical Co., Dkt No. 27 (July 13, 1982).

79. *See* H. CONF. REP. No. 1560, 95th Cong., 2nd Sess. (1978), *reprinted in* 1978 U.S. CODE CONG. & AD. NEWS 2043; S. CONF. REP. No. 1188, 95th Cong., 2nd Sess. (1978); *See also* 124 CONG. REC. 29756 (1978) (statement of Sen. Leahy).

ters be granted twelve year exclusive use protection.[80] NACA again argued that "it is illogical to expect that a company will risk the investment in research and testing if the fruits of that research, if successful, are to be immediately available to competitors who have no obligations to support the failures."[81] In addition, NACA argued for eliminating mandatory licensing because the "determination of 'reasonable compensation' would be an administrative nightmare."[82]

At first, NACA's proposals for exclusive use protection were opposed by the Pesticide Formulator's Association (PFA)[83]— a trade association representing small-to-medium sized pesticide manufacturers and formulators. In essence, the PFA argued that the 1972 data-licensing scheme could work, provided that Congress removed the confusion over the definition of "trade secret" and established guidelines for determining "reasonable compensation." The PFA suggested guidelines that would establish a "cost basis" for compensation based on one and one-half (1 1/2) times the original cost or "reproduction costs," whichever was less.[84] Compensation would take place over five years and be apportioned according to a market share comparison.

In a last minute compromise, NACA and the PFA joined in support of a proposal to create a ten year exclusive use period for submitted test data. The PFA agreed to this compromise in part because it included a provision that allowed for the equitable sharing of the cost of developing "defensive data" — i.e. data demanded by the EPA to maintain ("defend") the registration of a previously registered pesticide.[85] NACA's willingness to equitably share the costs of developing defensive data was considered to be an important concession by the PFA because the research and development costs of the industry as a whole had significantly increased in prior years as a result of more stringent EPA regula-

80. *Extending and Amending FIFRA: Hearings Before the Subcommittee on Department Investigations, Oversight and Research of the House Committee on Agriculture*, 95th Cong., 1st Sess. 187, 198 (1977) [hereinafter cited as *1977 House Hearings*].

81. *Id.* at 199.

82. *Id.* at 198.

83. *Id.* at 231-47.

84. *Id.* at 236-37.

85. *Id.* at 514-23. *See also Extension of the Federal Insecticide, Fungicide, and Rodenticide Act: Hearings Before the Subcommittee on Agricultural Research and General Legislation of the Senate Committee on Agriculture, Nutrition and Forestry*, 95th Cong., 1st Sess. 3-6, 69-73 (1977) [hereinafter cited as *1977 Senate Hearings*].

tions pertaining to previously registered pesticides. The compromise proposed that disputes over the sharing of defensive data costs be submitted to binding arbitration outside of the EPA.[86]

The EPA supported a proposal that would keep the 1972 data-licensing scheme intact, but exclude health and safety data from protection as "trade secrets." Both the EPA and the Department of Justice opposed the industry compromise for the same market entry and anti-monopoly considerations which led them to fight "exclusive use" in 1972.[87] The EPA emphasized that:

> Exclusive use and data compensation are alternative means of protecting the economic interests of the developer of registration data but each has a different impact on competition within the industry and ease of entry into the market. . . .[e]xclusive use of data will reduce competition and the right to entry in the market as contrasted by the Administration's bill [that provides for data compensation].[88]

In a series of letters to Congress, the Department of Justice agreed with this conclusion.[89]

Both the EPA and the Department of Justice commented on FIFRA's standard for compensation during these early hearings. EPA Administrator Costle testified that his agency "lacked expertise" in this area and was "uncomfortable in the role of judge as to the economic value of the data in question." Consequently, he urged Congress to "make more explicit what factors it feels are pertinent in determining reasonable compensation."[90] Taken out of context, this testimony has been relied on in support of the contention that Congress failed to provide arbitrators with a standard for determining compensation under the 1978 amendments to FIFRA.[91] This argument conveniently ignores the fact that Mr. Costle made his comments before Congress had begun serious

86. *See 1977 House Hearings* at 518-19, 522-23; *1977 Senate Hearings* at 72-73.

87. *See 1977 Senate Hearings* at 148-50, 271-74. *See also Economic Impacts of Proposed Amendments to FIFRA*, EPA Ofc. of Pesticide Programs (June 20, 1977), *reprinted in* S. REP. No. 334, 95th Cong., 1st Sess. 58-68 (1977).

88. *1977 Senate Hearings* at 148-49.

89. S. REP. No. 334, 95th Cong., 1st Sess., 89-103 (1977) (June 8, 1977 letter from Asst. Attorney General Patricia M. Wald opposing initial NACA proposals, and June 15, 1977 letter from Asst. Attorney General Wald opposing the "industry compromise.").

90. H. REP. No. 663, 95th Cong., 1st Sess. 59 (1977), *reprinted in* 1978 U.S. CODE CONG. & AD. NEWS 1998, 2032. [hereinafter cited as 1977 H. REP. No. 663].

91. Brief for Appellees Union Carbide Agricultural Products Co. at 28-29, Thomas v. Union Carbide Agricultural Products Co., 105 S. Ct. 3325 (1985).

consideration of the 1978 amendments, and refers only to EPA's limited experience under the 1972 data licensing scheme. However, his testimony does help explain why Congress later chose to delegate the responsibility of determining compensation to an arbitrator with experience in the pesticide industry, rather than the EPA.[92]

More importantly, Assistant Attorney General Patricia M. Wald, in a letter to Congress on behalf of the Department of Justice, emphasized the connection between the standard used in determining compensation and the competitive purposes of the Act's mandatory data-licensing scheme. She warned that:

> [t]he compensation provisions could be used to effect anti-competitive ends in dealing with both competing manufacturers of technical pesticides and formulators of end-use products from the technical materials. There are inherent problems in determining what constitutes 'reasonable' compensation for data. Thus, the provision could provide a tool for extending patent monopoly by pricing data out of reach of small competing manufacturers and for exercising control of the end-use and/or end-users after initial sale of the patented material. We consider both types of action inconsistent with competitive policy.[93]

Her comments highlight the danger involved in adopting a standard for compensation that exceeds an equitable sharing of the actual cost of developing test data. The application of a value-based standard that includes the opportunity costs avoided by follow-on registrants when they gain immediate market entry runs the risk of pricing small manufacturers out of competition.

Following the recommendation of its subcommittee, the Senate Committee on Agriculture adopted a bill (S. 1678) that did not fully accept either the industry compromise or the EPA's proposals, but clearly favored the Administration's position.[94] The Committee eliminated the "trade secret" protection accorded health and safety data under the 1972 amendments by giving "trade secrets" a narrower definition, and rejected industry's arguments for "exclusive use" protection.[95] However, original data submitters were given the right to compensation for seven

92. 1977 H. REP. No. 663, *reprinted at* 2016.

93. S. REP. No. 334, 95th Cong., 1st Sess. 91 (1977) (June 8, 1977 letter from Asst. Attorney General Patricia M. Wald).

94. *Id.* at 7-8, 17-19. *See also* 123 CONG. REC. 25706-710 (1977).

95. *Id.* at 8.

years.[96] If the parties could not agree on compensation, then they were to submit to arbitration under procedures almost identical to those provided by present law. [97] With respect to "defensive data," joint development or cost sharing arrangements were permitted and an arbitration provision was included to resolve any disputes.[98] On the question of a standard for compensation, the Committee simply stated that "[t]he subcommittee agreed that the amount and terms of reasonable compensation would be determined by the parties involved— the original submitter of data and the later applicant who wishes to rely on it. . . ."[99] In keeping with the market entry and competitive purposes of mandatory licensing, the Bill's floor manager, Senator Leahy, stated that the compensation "mechanism protects the data developer's right to recover his *data generation costs* while guaranteeing small companies entry to the market and protecting them against an unfair competitive situation."[100]

The House passed a bill (H.R. 8681) that was closer to the industry compromise than the Administration's proposals.[101] In a crucial markup session of the Subcommittee on Department Investigations, Oversight, and Research, a proposal to provide for a ten year period of compensated use was rejected in favor of industry's ten year "exclusive use" proposals by a roll call vote of 6 to 5.[102] However, concessions on the trade secrets issue led to a compromise proposal that provided for five years of "exclusive use" protection to be followed by five years of compensation for the use of data by follow-on registrants.[103] "Defensive data" was accorded the same protections as original data.[104] If the parties could not agree on compensation, then they were to submit to arbitration under procedures similar to present law.[105] There were minor differences between the House and Senate bill's language with respect to the procedures to be used in the case of arbitration.

96. *Id.*
97. *Id.* at 8, 17-18.
98. *Id.* at 8, 18-19.
99. *Id.* at 8.
100. 123 CONG. REC. 25706 (emphasis supplied).
101. 1977 H. REP. NO. 663, *reprinted at* 1996-98.
102. *Id. reprinted at* 2013-16.
103. *Id. reprinted at* 2015.
104. *Id.*
105. *Id. reprinted at* 2016.

The final version of the 1978 amendment's data-licensing scheme emerged as a compromise drafted by the Conference Committee formed to resolve the differences between the House and Senate. The Conference Committee granted ten year "exclusive use" protection to data submitted after the enactment of the 1978 amendments.[106] In introducing the compromise, Senator Leahy, a member of the Conference Committee, emphasised that:

> [b]y limiting exclusive use to data pertaining to pesticides ingredients not previously registered, and only for a 10 year period, the conferees have largely confined exclusive use coverage to chemicals that are patentable and for a term generally shorter than the patent life enjoyed by pesticides. The anticompetitive aspects of exclusive use have therefore been essentially neutralized.[107]

The Conference Committee granted 15 years of compensation for the use of data submitted between the enactment of the 1972 and 1978 amendments, and the use of "defensive data."[108] Since patent protections had already expired on most of the data submitted between 1972 and 1978, exclusive use protection would have had a chilling effect on market entry and competition, and effectively extended patent protections afforded to original data submitters. The extension of exclusive use protection to the submitters of defensive data would also have resulted in wasteful duplication and discouraged joint development ventures. In addition, providing defensive data with exclusive use protection would have taken away the concession won by the PFA in return for their support of NACA's exclusive use proposals.

Therefore, the Conference Committee enacted a data-licensing scheme that would encourage innovation and competition, discourage duplication, and assist the small pesticide manufacturer and formulator. In the words of Senator Leahy:

> The Conference substitute on the data issue is an appropriate compromise between the need to encourage innovation and the need to provide an equitable and less expensive process for producing pesticide safety data. I believe it recognises the needs of both large and small firms.[109]

106. FIFRA § 3(c)(1)(D)(i), 7 U.S.C. § 136a(c)(1)(D)(i) (1982). *See* text accompanying note 26, *supra*.

107. 124 CONG. REC. 29756 (1978).

108. FIFRA § 3(c)(1)(D)(ii), 7 U.S.C. § 136a(c)(1)(D)(ii) (1982) and FIFRA § 3(c)(2)(B), 7 U.S.C. § 136a(c)(2)(B) (1982). *See supra.* text accompanying notes 28, 35-37.

109. *Id.*

Ten years of exclusive use protection is accorded to data submitted after the enactment of the 1978 amendments in order to encourage future research and development. As a balance to the exclusive use protections won by industry for newly submitted data, the compensation provisions were enacted to facilitate market entry and encourage competition.

* * * * *

A value-based standard for determining compensation that includes the opportunity costs avoided by follow-on registrants defeats the competitive purposes of the compensation provisions in the 1978 amendment's data-licensing scheme. The Department of Justice's prescient concerns over the potential anticompetitive effects of the compensation provisions will become a reality if arbitrators choose to adopt a value-based standard. The legislative histories of both the 1972 and 1978 amendments to FIFRA indicate that Congress intended "compensation" to be calculated as an equitable share of the actual cost of developing test data.

Within this cost sharing framework, the question remains as to what constitutes an equitable sharing of the cost of developing test data. Should testing costs be divided on a market share basis, per capita basis, or some other method?

Arguably, the competitive goals of the compensation provisions favor the choice of a market share division of costs over a per capita division. However, this reasoning ignores the fact that these goals are substantially realized through the benefits which follow-on registrants receive from avoiding the opportunity costs suffered by the original data submitters. Once small manufacturers and formulators are given genuine access to the market, the division of the costs of test data on a per capita basis rather than a market share basis would have a minimal impact on the competitive structure of the pesticide industry.

In conclusion, the legislative histories of both the 1972 and 1978 amendments to FIFRA indicate that Congress intended that compensation be based on an equitable sharing of the costs of developing test data rather than on the value of the data to a follow-on registrant. However, the legislative histories are silent on the issue of how to equitably divide testing costs.

III. ARBITRATION DECISIONS UNDER THE 1978 AMENDMENTS: THE *STAUFFER* AND *FMC* DECISIONS

At present, only two arbitrator's decisions have been issued under the mandatory data-licensing scheme enacted by the 1978 amendments to FIFRA: *Stauffer Chemical Co. v. PPG Industries, Inc.*[110] and *FMC Corp. v. Tricon International.*[111] While both cases address the issue of a standard for determining compensation, each is concerned with a different aspect of this question because they were brought under different provisions of FIFRA.

This section will analyze the *Stauffer* decision and demonstrate that its choice of a value-based standard for determining compensation is inconsistent with the intent of Congress as revealed in the legislative histories of the amendments to FIFRA. In addition, it will briefly discuss the *FMC* decision and outline some of the useful suggestions it makes with respect to the equitable division of the costs of test data.

A. *The* Stauffer *Decision*

The *Stauffer* decision was rendered in an arbitration brought under section 3(c)(1)(D)(ii) of FIFRA and relates to compensation for the use of submitted test data by a follow-on registrant.[112] The underlying issue in *Stauffer* is whether compensation should include the value of the test data to the follow-on registrant or be

110. Stauffer Chemical Co. v. PPG Industries, Inc., No. 16 199 077 82, Fed. Mediation and Conciliation Service (June 28, 1983) (Birch et al., Arb.) [hereinafter cited as *Stauffer*].

Shortly after the arbitrator's decision was issued, PPG filed an action against both Stauffer and the EPA in federal district court for the District of Columbia to set aside the award. PPG Industries, Inc. v. Stauffer Chemical Co., No. 83-1941 (D.D.C. filed July 7, 1983). In its complaint, PPG challenged the FIFRA data-licensing scheme as an unconstitutional violation of article III, and in the alternative, argued that the arbitrator's were guilty of "misconduct" under the statute (7 U.S.C. § 136a(c)(1)(D)(ii)) because their grant of value-based compensation was *ultra vires*, i.e. outside the scope of their authority as vested by Congress. Stauffer cross-claimed against the EPA also seeking to have the data-licensing scheme invalidated as violative of article III, and counterclaimed against PPG seeking damages in the amount of the award should the statute be struck down, or, enforcement of the award. Both parties article III challenges were resolved by the Supreme Court in its *Union Carbide* decision. *See supra* note 40. However, PPG's claim that the arbitrator's decision constituted "misconduct" is still being litigated before the federal district court for the District of Columbia. The specific issues raised by that claim are outside the scope of this note.

111. FMC Corp. v. Tricon International, No. 16 199 0033 84G, American Arbitration Association (Jan. 10, 1985) (Foy et al., Arb.) [hereinafter cited as *FMC*].

112. FIFRA § 3(c)(1)(D)(ii), 7 U.S.C. § 136a(c)(1)(D)(ii) (1982). *See supra* text accompanying note 28.

based on the actual cost of developing the test data. An analysis of the *Stauffer* decision is particularly important because, contrary to the intent of Congress, the arbitrators used a value-based standard in awarding compensation.

The *Stauffer* decision, issued on June 28, 1983, was the first to be issued in an arbitration brought under the data-licensing scheme enacted by the 1978 amendments. In part, the existence of the decision eliminated barriers to standing in *Union Carbide*, and enabled the Supreme Court to uphold the constitutionality of FIFRA's arbitration provisions.[113]

The Stauffer Chemical Co. ("Stauffer") is the originator of a corn herbicide known generically as "butylate."[114] Stauffer obtained a basic United States patent for butylate in 1959; consequently, its patent protection expired in 1976.[115] Stauffer first registered butylate with the U.S. Department of Agriculture in 1968,[116] and has maintained sales of the product since that time. Following the enactment of the 1978 amendments, PPG Industries, Inc. ("PPG") applied to the EPA for the registration of butylate of its own manufacture, and relied on test data originally submitted by Stauffer after December 31, 1969 in support of its registration.[117] In compliance with FIFRA, PPG made an offer to compensate Stauffer for the use of the data; when the parties could not agree on an amount of compensation, Stauffer initiated an arbitration under the Act.[118]

After months of testimony consuming 2700 pages of transcript, an arbitration tribunal appointed by the Federal Mediation and Conciliation Service issued an unanimous decision. The arbitrators granted Stauffer a compensation award reflecting "a fair share of both the cost of testing required by current regulations and of the 'opportunity costs' that PPG avoided not only by avoiding the normal regulatory delay but also by its comprehensive copying of Stauffer's approved labels."[119]

In calculating the award to Stauffer, the arbitrators first determined that $2,930,000 (in 1983 dollars) was the actual cost Stauf-

113. Thomas v. Union Carbide Agricultural Products Co., 105 S. Ct. at 3333.
114. *Stauffer*, *supra* note 105, at par. 11.
115. *Id.* at par. 11, n.6.
116. *Id.* at par. 11.
117. *Id.* at par. 12.
118. *Id.* at par. 13.
119. *Id.* at par. 18.

fer incurred in developing the test data which PPG used in support of its own registration.[120] This figure excludes the cost of data submitted by Stauffer before 1970, as well as data from numerous tests "found to be substantially duplicative of other submitted data and therefore not required in support of PPG's registration."[121] However, the figure does include the cost of pre-1970 data resubmitted after 1969 that were not substantially duplicative of other data submitted. Using $2,930,000 as the basis, the arbitrators awarded Stauffer one half of these costs—$1,465,000 — to represent a "fair share" of the testing costs.[122] This per capita division of testing costs was made without discussing alternative methods of division.

In addition, the arbitrators granted Stauffer compensation based on the value of the data to PPG. They held that:

> PPG has . . . obtained an important economic benefit in being able to start marketing its butylate some five years earlier than it could have without reliance on Stauffer's data. By contrast, Stauffer incurred a corrresponding opportunity cost or loss of profits when it had to delay its marketing of butylate . . . For this cost avoidance or benefit of early market entry PPG likewise owes Stauffer compensation.[123]

However, because of the speculative nature of this value-based compensation, the arbitrators determined that it "can best and most reasonably be expressed as a fraction of the sales actually made and to be made by PPG over the next several years."[124]

As a result, by extrapolating from assumptions concerning PPG's prospective market share and profits related to sales of butylate, the arbitrators established a formula for determining running compensation to be paid to Stauffer for a period of ten years based on PPG's actual future sales. This formula is described in the decision as follows:

> Running Compensation (R) for every pound of butylate manufactured or otherwise acquired by PPG in the United States in the ten calendar years from 1983 through 1992, both inclusive, and not discarded but sold or otherwise transferred by PPG for use by third parties, which R shall be computed according to the formula

120. *Id.* at par. 20.
121. *Id.*
122. *Id.* at par. 21.
123. *Id.* at par. 14.
124. *Id.*

$$R = \$0.15/\text{lb.} \times Y/I$$

> Wherein Y is the Producer Price Index for Finished Goods published by the U.S. Bureau of Labor Statistics for the month of November preceding the year in which the respective sale or other transfer is made, and wherein I is such Producer Price Index published for November 1982, *with the proviso*, however, that the total number of pounds of butylate on which this compensation R is due in any year after 1987 shall in no event exceed the highest total number of pounds of butylate on which such compensation was due in any of the calendar years 1983 through 1987, both inclusive.[125]

Based on the arbitrator's calculation that PPG's butylate sales in the first five years should total approximately 47,250,000 pounds,[126] and assuming steady growth in sales for the following five years, PPG can expect to pay Stauffer approximately 14 million dollars plus inflation costs over ten years in addition to the lump sum of $1,465,000 discussed earlier.

Inexplicably, the arbitrators granted Stauffer this windfall without even mentioning the legislative histories of the amendments to FIFRA, and after a cursory and incomplete discussion of the purpose of the compensation provisions.[127] In their decision, the arbitrators suggest that apart from a desire to encourage the development of new pesticides, the purpose of data-licensing is the "avoidance of wasteful use of scientific manpower in duplicative testing and governmental review thereof."[128] Further on, they tacitly acknowledge the competitive purposes of data-licensing by claiming that the prevention of the manpower waste inherent in duplicative testing "directly encourages competition and lower pesticide costs to the public. . . ."[129]

While one purpose of data-licensing is to avoid duplicative testing, the Act, as well as its legislative history, does not indicate that it is only concerned with the waste of manpower; to the contrary, the presence of the joint development and cost sharing elements of the defensive data provisions demonstrates Congress' desire to avoid the economic waste inherent in duplicative testing as well.[130] In addition, one reason Congress rejected exclusive use

125. *Id.* at "Compensation Award," par. B.
126. *Id.* at par. 22.
127. *Id.* at pars. 4 & 7.
128. *Id.* at par. 4.
129. *Id.* at par. 7.
130. FIFRA § 3(c)(2)(B), 7 U.S.C. § 136a(c)(2)(B) (1982).

protection in favor of compensation in 1972 was their concern that the economic costs of duplicate testing would stifle the ability of smaller companies to invest in the new research that the data-licensing scheme was designed to encourage.[131]

More importantly, the arbitrator's claim that competition and lower pesticide costs results solely from preventing the waste of manpower inherent in duplicative testing is without substance. A look at the legislative histories of the amendments reveals that Congress recognized that the key to compensation and lower costs was the removal of barriers to entry into the pesticide market.[132] As a result, in 1978 they rejected exclusive use protection for data submitted between 1970 and 1978 in favor of the compensation provisions in an attempt to facilitate market entry for follow-on registrants.[133] If these registrants are now required to pay a value-based compensation that reflects the opportunity costs which they avoid as a result of immediate registration, then the barriers to market entry have been rebuilt. Under such circumstances, the availability of scientific manpower is of little consequence.

Why did the arbitrators grant Stauffer a windfall? They may have been unduly prejudiced by two factors specific to this case. First, PPG is one of the largest chemical companies in the U.S.;[134] they are not representative of the small manufacturer or formulator whose competitive position Congress sought to enhance by creating the compensation provisions. However, the size of a specific follow-on registrant should be irrelevant to an award of compensation. An administrative nightmare would result if arbitrators are asked to link the amount of compensation awarded to the specific competitive position of a follow-on registrant.

Second, when PPG registered butylate they not only relied on Stauffer's submitted test data but also copied Stauffer's approved labels.[135] The arbitrators acknowledge that Stauffer failed to copyright their labels and, consequently, they were "in the public domain for anyone to copy."[136] However, the arbitrators cite

131. 1972 S. REP. No. 970, *supra* n. 66 *reprinted at* 4096.

132. *See supra* text accompanying notes 93-109.

133. *See supra* text accompanying notes 106-09.

134. In 1985, PPG Industries was ranked by Fortune Magazine as the 89th largest U.S. industrial corporation with sales of approximately 4.2 billion dollars. Vol. 111, No. 9 Fortune 268 (April 29, 1985).

135. Stauffer, *supra* note 105, at pars. 15-16.

136. *Id.* at par. 15.

what they term as PPG's "slavish" copying as support for their decision to award Stauffer value-based compensation.[137] Even if the arbitrators believe that PPG's decision to copy Stauffer's unprotected labels was unethical, it was avowedly legal and not a basis for awarding any amount of compensation.

The arbitrator's decision to grant Stauffer compensation based on the value of the data to PPG is contrary to the competitive goals of the data-licensing scheme. As section II demonstrates,[138] the intent of Congress to facilitate market entry and encourage competition will be defeated if follow-on registrants are required to pay compensation that approximates the costs they would incur if they developed the test data themselves.

B. *The* FMC *Decision*

In contrast to *Stauffer*, the *FMC* decision was rendered in an arbitration brought under section 3(C)(2)(B) of FIFRA and is concerned with allocating the costs of developing defensive data between two companies holding registrations of the same pesticide.[139] The issue of whether a value-based standard or cost-based standard should be used in relation to defensive data is moot because this provision is explicitly concerned with "shar[ing] in the cost of developing such data."[140] As a result, the underlying issue in *FMC* is whether a market share basis, per capita basis, or some other method should be used in allocating the costs of developing the data. While the *FMC* decision does not resolve this issue, it does suggest some useful guidelines to be used in dividing the costs of test data.

The *FMC* decision is limited in scope. It is an initial decision requested by the parties to resolve the specific issue of allocating the costs of developing additional data in support of their registrations of "ethion."[141] FMC argued that the costs should be divided "equally or per capita."[142] Tricon argued that the costs should be allocated "on the basis of market share."[143] In their decision, the arbitrators did not choose one method of allocating

137. *Id.* at pars. 15-16.

138. *See supra* text accompanying notes 63-109.

139. FIFRA § 3(c)(2)(B), 7 U.S.C. § 136a(c)(2)(D) (1982). *See supra* text accompanying notes 34-37.

140. FIFRA § 3(c)(2)(B), 7 U.S.C. § 136a(c)(2)(D) (1982).

141. *FMC*, *supra* note 111, at 1-2.

142. *Id.* at 1.

143. *Id.*

costs over another; instead they suggested certain guidelines concerning the equitable division of the costs of test data. Following the issuance of the initial decision, the parties reached a settlement.

The arbtrators began with two basic principles concerning cost sharing. First, they emphasized that the statute itself does not require any specific method of allocating costs.[144] Second, they pointed to the legislative history of both the defensive data provisions and section 3(c)(1)(D) in holding that Congress intended that the costs be shared in some way.[145] From this foundation, they made the following findings.

First, both interest costs and inflation should be included in determining data development costs.[146] Second, if market share is chosen as a factor in determining cost allocation, then it should be based on a party's prospective market share "over a period of time that is at least as great as the period of time over which the costs to be allocated will be amortized under prevailing industry standards."[147] A company's past market share might be deceptive because companies are capable of transfering their registrations. Third, if a market share allocation is adopted, the arbitrators determined that consideration should be given to the volume of a company's sales both in the U.S. and overseas in countries where a U.S. registration is sufficient to meet their regulatory requirements.[148]

The *FMC* decision refuses to make a choice between a per capita and market share division of the costs of test data. To the contrary, the arbitrators conclude by stating:

> The per capita and market shares formulae strike us as only the initial negotiating positions of two parties who are seeking an agreement on sharing any type of cost. We don't think either formulae is likely to be the formula finally agreed on by two willing parties having very different shares of the market. Moreover, we are not satisfied that per capita and market share are the only bases for sharing costs and would like to explore other factors that might be considered by two willing parties who were seeking an agreement on cost sharing.[149]

144. *Id.* at 4.
145. *Id.* at 4-6.
146. *Id.* at 2, 6.
147. *Id.*
148. *Id.* at 2, 7.
149. *Id.* at 9-10.

The ambiguity of the *FMC* initial decision is reflective of the legislative histories of the amendments. Section II pointed out that within a cost sharing framework, the legislative histories are silent on the issue of how to equitably divide testing costs.[150] Both Congress and the *FMC* decision correctly recognize that this issue is best left to the reasonable determination of the parties involved.

Conclusion

In the current debate, the follow-on registrants are correct in asserting that compensation should be based on an equitable sharing of the actual costs of developing test data. Congress enacted the compensation provisions in an attempt to encourage competition without discouraging innovation in the pesticide industry. Value-based compensation rebuilds the barriers to market entry and competition which Congress tried to tear down when it chose compensation over exclusive use protection for data submitted between 1970 and 1978. In *Stauffer*, the arbitrators failed to adequately consider the purposes of the compensation provisions and were prejudiced by factors irrelevant to the issue before them; consequently, they erred in awarding value-based compensation. The arbitrators in *FMC* correctly recognized that within a cost sharing framework, the task of equitably dividing testing costs is left to the discretion of the arbitrators and parties involved, while also suggesting some useful guidelines for dividing testing costs. Most importantly, arbitrators should heed the Supreme Court's warning that Congress was "far from silent"[151] on the question of a standard for compensation. In response they should award cost-based compensation consistent with the purposes of FIFRA's data-licensing scheme.

Geoffrey H. Coll

150. *See supra* text accompanying notes 112-13.

151. Thomas v. Union Carbide Agricultural Products Co., 105 S. Ct. at 3340.