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Part II

THE LINURON DECISION: IMPACT ON PESTICIDE REGISTRANTS, IMPLICATIONS FOR DATA COMPENSATION DISPUTES UNDER FIFRA

[Editor's Note: On Dec. 22, 1988, a panel of arbitrators ordered two generic pesticide manufacturers to pay a potential total of $1.5 million to Du Pont Co. to compensate the firm for health and safety studies it conducted to support the registration of the pesticide linuron (12 CRR 1475).

The linuron case was only the second to be decided under the Federal Insecticide, Fungicide, and Rodenticide Act by a panel from the American Arbitration Association since the act was amended in 1978 to establish a system outside the Environmental Protection Agency to resolve data compensation disputes. Under the statute as it stood between 1972 and 1978, disputes were decided under the environmental agency's internal administrative law system.

On the following pages, attorneys for Du Pont and for one of the generic manufacturers involved in the case, Drexel Chemical Co., review the arbitration panel decision and its possible significance for resolution of other data compensation disputes.

GENERIC PESTICIDE PRODUCERS

by James P. Rathvon
C. Thomas Cates
Jeffrey F. Liss [1]

A generic chemical company seeking to compete in an established pesticide market faces several difficult challenges.

First, the company will have to develop or find a separate source of supply of the active ingredient of the pesticide, since the original producer/registrant of the pesticide almost certainly will not agree to sell to it. This may prove quite difficult and may require overseas arrangements that could pose some risk in terms of price and reliability of supply.

The new competitor also will have to break into sales territories currently dominated by the entrenched, original registrant—no mean feat, particularly for a smaller company without substantial marketing resources. And the generic company must hope that the pesticide market in which it has elected to compete will remain commercially viable long enough to realize a financial return—a somewhat risky proposition in the fast-moving agricultural chemical field, where new patented products often are introduced almost as soon as the old ones have come off patent.

In addition to these market risks, the generic producer also will face the prospect of paying substantial sums to the original registrant as "data compensation" under the Federal Insecticide, Fungicide, and Rodenticide Act Section 3(c)(1)(D), and might face additional data cost-sharing obligations under FIFRA Section 3(c)(2)(B).

In brief, FIFRA Section 3(c)(1)(D) permits a generic pesticide producer to rely on previously submitted health and environmental data regarding the pesticide in order to obtain its registration, provided that the subsequent or "follow-on" generic registrant offers to pay compensation to the original data submitter (that is, the original registrant) for reliance on that data.

Similarly, FIFRA Section 3(c)(2)(B) authorizes the Environmental Protection Agency to require registrants to submit additional data (to fill identified "data gaps"), through data "call-ins," under which the registrants may continue to sell their product if they agree to develop jointly or share in the cost of the additional data.

Often, the original registrant will perform call-in tests on its own, necessitating follow-on competitors to agree to share in the costs of the data. If the original data submitter and the follow-on registrant cannot agree on compensation for data under Section 3(c)(1)(D), or on how costs of call-in data should be divided under Section 3(c)(2)(B), their dispute must be resolved through binding arbitration. [2]

The U.S. Supreme Court in 1985 stated that Congress intended the "data-sharing" provisions of FIFRA "to streamline pesticide registration procedures, increase competition, and avoid unnecessary duplication of data-generation costs" (*Thomas v. Union Carbide Agricultural Products Co.*, 473 US 568, 571).

In fact, however, these provisions have tended to operate as a barrier to entry to pesticide markets for follow-on registrants, particularly after the issuance in 1983 of the FIFRA Section 3(c)(1)(D) data compensation arbitration decision in *Stauffer Chemical Co. v. PPG Industries Inc.*

[1] Rathvon is a senior associate and Liss is a partner in the law firm of Piper & Marbury in Washington, D.C. Cates is a partner in the law firm of Burch, Porter & Johnson in Memphis, Tenn. The authors were counsel for respondent Drexel Chemical Co. in the linuron arbitration.

[2] The American Arbitration Association has been delegated the authority to arbitrate all FIFRA data disputes. *See* 29 CFR Part 1440.

0148-7973/89/$0+.50

There, PPG, the "follow-on" registrant of the herbicide butylate, was ordered to pay the original registrant, Stauffer, both 50 percent of Stauffer's out-of-pocket data generation costs and additional "value" compensation, in the form of a five-year running royalty on PPG's butylate sales. The award was designed to reflect PPG's alleged "early entry" into the butylate market by virtue of relying on Stauffer's data to obtain its registration.

The award in *Stauffer v. PPG* produced an immediate and severe chilling effect on competition by generic companies in pesticide markets. Succinctly put, many generic companies concluded after *Stauffer v. PPG* that the uncertainties regarding the scope of their data compensation obligations—and in particular the potential for onerous royalties—were simply too great to warrant entry into the pesticide field.

Those companies that did obtain follow-on registrations after *Stauffer v. PPG* often found it difficult to negotiate reasonable data compensation agreements with original data submitters, who frequently insisted on both equal-share reimbursements of their data generation costs and substantial royalties as compensation.

The Linuron Decision

In the linuron proceeding, the issue of the appropriate formula for establishing compensation under FIFRA was again joined in a battle royal.

Following *Stauffer v. PPG*, Du Pont claimed some $14 million in data compensation from two linuron generic manufacturers—Drexel Chemical Co. and Griffin Corp.—as follows:

- Lump sum payments of about $4 million from each company, representing each company's per capita share (25 percent)[3] of Du Pont's linuron test costs, alleged to total about $16 million; and
- Royalty payments representing one-half of each company's estimated linuron profits during the first five years of sales (or an additional $1 million from Drexel and $5 million from Griffin).

Respondents Drexel and Griffin, on the other hand, opposed Du Pont's request for royalties as not justified by the law or the facts of the case, challenged many of Du Pont's nearly 800 linuron tests as not eligible for compensation, and urged that compensation for Du Pont's truly compensable tests should be based strictly on each company's market share in linuron.[4]

The two respondents argued that use of market shares, as opposed to equal shares, as a basis for data compensation more properly reflected the proportional benefit each registrant received from the data supporting the registration of the pesticide. The respondents emphasized that the award of additional "value"-based royalties further would discourage market entry by follow-on registrants.

The parties, recognizing the precedential importance of the proceeding, litigated these and several other hotly contested issues concerning the FIFRA data compensation system vigorously and at great cost. The hearing itself spanned 16 days of testimony and argument, and involved nearly 30 lay and expert witnesses, a transcript of more than 10,000 pages, and 16 volumes of exhibits, plus several additional volumes of authorities.

The enormous transactional costs required to litigate the case became a concern to the arbitrators, who took the unusual step of attaching to the award a detailed history of the proceeding as Appendix A. The arbitrators explained that the appendix "fully exemplifies the present complexity and unsettled nature of pesticide data dispute arbitrations" and that "it is against this background and with the hope that the findings, determinations, and conclusions of this arbitration tribunal will materially assist in stabilizing and simplifying such proceedings, that this award is rendered." (Award at 5-6.)

Formula For Compensation

Declaring that "a proper formula for compensation is one which considers the realities of the market place, including the risks of entry into a given pesticide market" (Award at 23), the arbitrators essentially embraced Griffin and Drexel's market share approach to compensation, and thus rejected Du Pont's request for royalties.

The arbitrators' formula for compensation included several features that deserve mention. First, the panel distinguished between "compensation" under FIFRA Section 3(c)(1)(D) and "cost-sharing" under FIFRA Section 3(c)(2)(B), concluding that "compensation" under Section 3(c)(1)(D) is "broader based than the cost-sharing, data gap-specific provisions of Section 3(c)(2)(B)."

Thus, with respect to "old" (that is, previously submitted) data subject to Section 3(c)(1)(D), the arbitrators ruled that Drexel and Griffin each must pay a share of the costs of that data, based on each registrant's highest annual market share in the five-year period after receipt of its initial technical linuron registration, provided that each registrant pay at least a minimum of 10 percent of the costs. In contrast, with respect to "new," call-in data required under Section 3(c)(2)(B), the arbitrators ruled that each registrant must pay a share of those costs based on its highest annual market share in the five-year period following issuance of the call-in, but with no 10 percent minimum payment.

Second, the arbitrators imposed certain special conditions with respect to "hard copy" of Section 3(c)(2)(B) data. Du Pont argued that its refusal to provide hard copy of the call-in data to respondents should not be a factor in determining compensation. Drexel and Griffin had argued that the absence of hard copy should lead to a discount on compensation.

The arbitrators essentially agreed with respondents, ruling that if either Drexel or Griffin's market share were to approach its per capita share (25 percent), then that respondent would pay no more than 90 percent of its per capita share (22.5 percent) in the absence of hard copy. Moreover, just as Du Pont has the option not to provide hard copy, Drexel and Griffin have the option to decline it, thus triggering the discount.

Regardless of whether hard copy is provided, the arbitrators ordered that Du Pont, upon request by Drexel or Griffin, must submit call-in data to any state for state registration purposes.

Third, the panel, agreeing with Griffin and Drexel, concluded that the obligation to share in the cost of call-in data is triggered only when those data are accepted by EPA as satisfying applicable data requirements. Accordingly, the arbitrators ruled that "cost-sharing" of call-in studies not

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[3] Initially, Du Pont claimed compensation against three linuron registrants, Drexel, Griffin, and Aceto Chemical Co. Aceto subsequently settled with Du Pont, and was dropped from the case.

[4] At the hearing, respondents presented expert testimony supporting use of a "lifetime market share" approach, by which each registrant's share of the data costs would be based on its market share over the commercial lifetime of the pesticide.

0148-7973/89/$0+.50

yet submitted or accepted by EPA must await EPA acceptance. Thus, as each call-in study performed by Du Pont is accepted by EPA, Drexel and Griffin will be required to pay their applicable shares of the costs of the studies.

Identifying The Compensable Data

In the proceeding before the arbitration panel, Du Pont took what may be characterized as a "kitchen sink" approach to data compensation, seeking reimbursement for virtually every test—dating back to the late 1950s—the company ever conducted on linuron.

The arbitrators, however, ruled that only about 10 percent of Du Pont's nearly 800 claimed linuron tests were eligible for compensation. Below, we explain how the arbitrators dealt with several contested categories of data.

Pre-1970 Tests

FIFRA Section 3(c)(1)(D) authorizes compensation only for studies submitted after Dec. 31, 1969. Du Pont sought compensation for numerous tests originally submitted to the federal government before 1970, arguing that they had been resubmitted to EPA after 1970 for bona fide registration purposes.

Drexel and Griffin opposed compensation for any tests originally submitted prior to 1970, regardless of resubmission. The arbitrators sided with respondents, concluding that "submission of data prior to Jan. 1, 1970, precludes compensability of those data by resubmission." (Award at 13.)

Efficacy Studies

Du Pont sought compensation for more than 500 efficacy studies. Drexel and Griffin argued that they should not be required to pay compensation for Du Pont's efficacy studies because EPA had waived the requirement to submit efficacy tests prior to the time Drexel and Griffin obtained their linuron registrations.

Du Pont, however, advanced three separate justifications for obtaining compensation for its efficacy studies. First, Du Pont pointed out that FIFRA requires accurate labeling of all pesticide products, that Drexel and Griffin's linuron product labels are substantially similar to Du Pont's, and that Du Pont's efficacy studies support the information, claims, and directions for use on those labels.

Second, Du Pont contended that EPA's regulations require that efficacy studies be performed by registrants, even if they need not be submitted. Third, Du Pont pointed out that it had submitted many of its efficacy studies to EPA in 1984 during the agency's special review of linuron and that those studies supported continued registration of the pesticide under EPA's benefit-risk analysis standard.

The arbitrators rejected all three arguments. The arbitration panel pointed out that Drexel and Griffin's "offer to pay" statements to Du Pont (which are prescribed by EPA regulation) committed the respondents only to pay for each item of data in EPA's files that "is one of the types of data that EPA would require to be submitted" if the application sought the initial registration for the pesticide.

Since the requirement to submit efficacy data had been waived by EPA before Drexel and Griffin sought their registrations, the arbitrators reasoned that such data were not "one of the types of data" for which respondents agreed to pay compensation. Thus, the arbitrators concluded that EPA's efficacy waiver "preclud[es] compensation for efficacy data." (Award at 17.)

Special Review Data, Product Chemistry Tests

As noted above, Du Pont submitted numerous efficacy tests, as well as several other studies, to EPA during the "special review" of linuron. Drexel and Griffin contended that such voluntary submissions were not eligible for compensation. The arbitrators agreed, ruling that only additional data specifically required by a data call-in under Section 3(c)(2)(B) were eligible for compensation.

The arbitrators also ruled that Du Pont's product chemistry tests were not eligible for compensation because the tests were specific to Du Pont's own products. Indeed, Drexel and Griffin had submitted their own product chemistry tests to support registration of their own linuron products.

Pre-Registration Standard Studies

In 1984, a year or so after Drexel and Griffin obtained their linuron registrations, EPA issued a registration standard for linuron, reflecting the agency's "thorough review of the scientific data base" for the pesticide.

The registration standard included a bibliography listing those linuron studies in EPA's files that were deemed to satisfy current FIFRA data requirements. Drexel and Griffin contended that only those studies that were included in the registration standard bibliography were eligible for compensation under Section 3(c)(1)(D). Du Pont, emphasizing that Drexel and Griffin had used the "cite-all" method of data reliance (40 CFR 152.86), contended that all of the tests in EPA's files at the time of Drexel and Griffin's applications should be eligible for compensation (Reference File 71:1008).

The arbitrators determined that many pre-registration standard tests were not eligible for compensation, including pre-1970 tests, efficacy tests, and product chemistry tests. However, the panel did award Du Pont compensation for several tests that were not included in the registration standard. The arbitrators explained that post-1970 data that were "sufficiently viable" (that is, rated at least "core supplemental" by EPA) and were of the "type" required for the follow-on registrant's registration, were eligible for compensation under Section 3(c)(1)(D).

It should be pointed out, however, that had Drexel and Griffin obtained their registrations after the issuance of the registration standard, the result here might have been different. In that event, Drexel and Griffin could have made use of EPA's "selective method" of data reliance (40 CFR 152.90), under which a registrant can obtain a registration by:

- Specifically citing only the data listed in the registration standard as meeting current requirements; and
- Agreeing to share in the cost of any additional data required to fill data gaps identified in that standard.

Invalid Studies, Public Literature Studies

Although the arbitrators granted Du Pont compensation for pre-registration standard data rated by EPA as only "core supplemental," the arbitrators excluded from compensation several Du Pont studies determined by EPA as invalid or as not providing any relevant information for registration purposes.

Finally, the arbitrators indicated that studies that were publicly available were not eligible for compensation. It appears that at least one Du Pont study was excluded from compensation on this basis.

Costing The Compensable Data

For most of its tests, Du Pont did not present invoices establishing the actual costs incurred to conduct the study in question, but instead relied upon general estimates. Drexel and Griffin contested many of Du Pont's cost estimates and presented expert testimony as to how much various studies should cost.

The arbitrators awarded the costs Du Pont claimed only for the "small percentage of the tests supported by invoices." (Award at 31.)

Where no invoice or other reliable business cost record was presented, the arbitrators used respondents' estimates or some combination of the varying figures put forward. For all tests, the arbitrators capped reimbursement for "management overhead"—such as the additional costs associated with overseeing the study and submitting the results to EPA—at 15 percent of the actual test cost.

For "old" tests compensable under Section 3(c)(1)(D), the arbitrators applied a price inflator/deflator factor—tied to the cost of living—to arrive at costs in 1986 dollars (the year the arbitration proceeding was initiated). For new, Section 3(c)(2)(B) data, the arbitrators awarded simple interest of 10 percent per-year on each test, calculated from the date the test was submitted to EPA to 30 days after the date Drexel and Griffin receive an invoice for sharing the cost of the test.

The Bottom Line

Based on the determinations described above, the arbitrators awarded Du Pont the following sums:

▸ *Section 3(c)(1)(D)—Compensation for Reliance on "Old" Data.* The arbitrators determined that the cost of Du Pont's "old" data was $668,520. Accordingly, because Drexel's largest market share during the five years (1983-1987) after it obtained its linuron technical registration was only 2.83 percent, Drexel was ordered to pay the minimum 10 percent share of these costs—$68,852.

Griffin's largest market share during the five-year period (1983-1987) following receipt of its linuron technical registration was 18.29 percent. Accordingly, Griffin must pay $125,930 (18.29 percent of $668,520).

▸ *Section 3(c)(1)(B)—"Cost-sharing" of Du Pont's "New" Data.* The arbitrators determined that the cost of "new" data already *submitted* by Du Pont *and accepted* by EPA to be $2,018,854. Since these data were required by EPA's 1984 data call-in, Drexel and Griffin must pay their highest annual market share for the 1984-1988 period. Based on market data through 1987, Drexel must pay 2.83 percent or $57,134, and Griffin 18.29 percent or $369,248. These sums are subject to upward adjustment if Drexel or Griffin's market share in 1988 exceeds their previous highest market share.

Du Pont currently is conducting or has pending before EPA 28 other studies, 26 pursuant to the 1984 call-in and two required by a 1986 call-in. Drexel and Griffin must share in the cost of these studies if and when they are accepted by EPA. Based on current estimates of test costs and likely market shares, Drexel's future payments are unlikely to be as high as the combined amount of $125,986 now due. Griffin's future payments likely will be in the same approximate range or slightly higher than its current liability of $495,178.

In sum, Du Pont will receive immediate payments of $125,986 from Drexel and $495,178 from Griffin, or a total of $621,164, with total future payments of about the same size. Thus, Du Pont's total award is likely to amount to only about 10 percent of the $14 million it sought from Drexel and Griffin.

Precedential Importance Of The Decision

The linuron decision is clearly a major victory for the generic pesticide producers involved in the case. However, the importance of the decision extends far beyond this specific dispute.

Concerned that pesticide registrants not be forced again to incur the enormous transactional costs required to litigate the issues addressed in the proceeding, the arbitrators sought to establish broad, workable principles to be used to resolve future FIFRA data disputes among registrants.

The panel's intention that its rulings in the linuron case serve as precedent for future FIFRA data disputes could not have been made more clear. As pointed out earlier, the arbitrators stated in the award that they hoped that their "findings, determinations, and conclusions ... will materially assist in stabilizing and simplifying" FIFRA proceedings. Moreover, at the end of Appendix A to the award (setting forth the history of the proceeding), the arbitrators included a lengthy rationale for the pesticide industry to accept the rulings of the panel as precedent.

"It is the hope of the arbitrators that the detailed and yet broad consideration that the parties gave to the case in its presentation to us and the findings and conclusions which we have set forth in the award will be of some assistance to those (working in the pesticide industry) who are faced with determining a course of action or a conclusion in the future," the arbitrators wrote. "Through these efforts in future compensation cases arising under an application for a registration or under a call-in where the registrants are required to produce the data, or share in the cost of data, we sincerely hope that the *severe transaction costs* which this particular arbitration has required *will be avoided*. ...

"The parties here have all indicated that while they realize this case would be relatively expensive because of its timing in the development of the FIFRA registration system, nevertheless, it was hoped, certainly on behalf of the new entrants, that it might be a precedent which would permit other entrants to have a predictable idea of what costs would be involved for the use of the data and of the possible transaction costs for entering the field if agreement with the data base submitter could not be obtained and resort to the arbitration procedure was necessary.

"Hopefully, the parties to this arbitration who have contributed so much to the development of this award and the industry in general will feel that they have contributed to the development of the law of FIFRA. If precedents have thus been established, perhaps future arbitration panels would be willing to make appropriate preliminary rulings and thereby restrict the areas of testimony so that these future arbitrations could be accomplished in a relatively short period of time and the parties would not have the transaction costs as a deterrent from entering the pesticide field. Even more importantly, this might *help negotiators of compensation and of sharing in the cost of developing call-in data to reach solutions of their issues without resort to litigation.*" (Appendix A at 38-40, emphasis added.)

The challenge ahead for the pesticide industry is to have the wisdom to accept the linuron decision as precedent for resolving data disputes. Generic pesticide producers clearly should press for adherence to the principles enunciated in the decision in negotiations with other registrants.

0148-7973/89/$0+.50

Original registrants, in turn, should recognize the fairness of compensation based on a sharing of the costs of their truly compensable tests (that is, excluding pre-1970, efficacy, or other non-compensable tests), without additional royalties. This will enable the industry as a whole to move forward on the many issues and problems on which generic and original producers have common ground.

If the principles set forth in the linuron decision do become accepted by the pesticide industry, the decision will surely emerge as a major landmark in FIFRA jurisprudence. And with that acceptance, the barriers to entry into pesticide markets will be lowered and the fair and vigorous competition that Congress intended when it passed the data sharing provisions of FIFRA may at last become a reality.

THE ORIGINAL REGISTRANT

by John D. Conner Jr.
Lawrence S. Ebner
Stanley W. Landfair
Charles A. O'Connor III
Kenneth W. Weinstein [1]

On Dec. 22, 1988, a panel of three arbitrators awarded E.I. du Pont de Nemours and Co. approximately $1.5 million in compensation from Griffin Corp. and Drexel Chemical Co. under FIFRA Section 3(c)(1)(D) and Section 3(c)(2)(B) for their use of Du Pont's linuron data. The decision culminated a lengthy proceeding during which Griffin and Drexel tried to reduce compensation to a token payment that would discourage data submitters from pursuing further claims. Their efforts failed.

Griffin advocated an approach that would have required the company to pay between $0 and $100,000 for all of the data required to register, maintain in effect, and reregister its linuron products. Instead, Griffin must pay at least $1.1 million under the award.

Drexel—which the arbitrators found has a much smaller market share than Griffin—wanted to pay approximately $27,000. Instead, Drexel will be required to pay at least $215,000 under the award. Additional compensation from both parties will depend on their future sales.

The arbitrators' 40-page decision represents a complex compromise on numerous points of contention between the parties.

The panel's specific findings and determinations were partially favorable and partially unfavorable to both sides. The decision as a whole, however, reaffirms the principle established in the *Stauffer-PPG* case that compensation to data submitters should be substantial.

The *Du Pont* decision underscores the importance of the facts of each particular case to the ultimate compensation award. Because arbitrations are not judicial proceedings, each arbitration panel is free to interpret and apply FIFRA differently and as it sees fit to achieve an equitable result based on the specific facts of each case.

Decision Is Not A Binding Precedent

The *Du Pont* decision is not a binding "precedent" for future proceedings. Rather it reflects a fact-driven approach that future arbitrators may accept or reject.

In future cases, arbitrators may strike a different balanc between the competing goals of encouraging innovation an avoiding duplicate testing. They may decide that the regula tory burdens borne by the innovator, and the benefits be stowed on the imitator, require a different approach t compensation than the *Du Pont* arbitrators used.

The FIFRA compensation system not only permits, bu requires that compensation be flexibly tailored to suit th individual needs of each situation.

It is clear from the linuron award that the FIFRA arbitra tion system, which the me-too industry has lobbied fervently to abolish through legislation, is uniquely suited to produc case-by-case decisions based on the facts of each case. Th *Du Pont* decision is a reaffirmation that the FIFRA arbitra tion system works.

Du Pont Registered Product In 1961

Du Pont first registered linuron in 1961, having obtaine patent rights in the product under license from anothe company. Du Pont submitted all of the data to register th technical product and its various end-use products. Du Pon also submitted all of the data to maintain the registration in effect, including data to defend the product (successfully in an EPA special review and to comply with data call-in issued by EPA in 1984 and 1986 as part of the linuro reregistration process.

Griffin (in 1979) and Drexel (in 1982) cited Du Pont' existing data to obtain me-too technical and end-use linuro registrations. Griffin and Drexel later submitted offers t share in the cost of the new linuron data being develope solely by Du Pont to comply with 1984 and 1986 data call-in for reregistration.

Although they held linuron registrations throughout thi period, Griffin and Drexel did not begin marketing thei products until 1984 and 1986, respectively. Nevertheless without Du Pont's data, Griffin and Drexel would have n linuron registrations.

Du Pont sought a multimillion dollar award, consistin primarily of a proposed royalty on the me-too registrant first five years of sales.

Drexel and Griffin filed a number of prehearing motions which prolonged the proceedings by more than a year. Whe the hearing finally began, Griffin and Drexel argued tha they should be required to pay no compensation at all anc alternatively, offered to pay a combined total of onl $127,315.20—a tiny share of the cost of the data.

After reviewing the record for nearly five months, th arbitrators concluded that both sides' positions were "i extremis."

The panel thus issued a compromise award intended t achieve a balance between the parties' interests, based o the particular facts of the case and Du Pont's right t meaningful compensation in return for Griffin's and Drex el's right to rely on Du Pont's data.

The award encompasses two FIFRA provisions: Sectio 3(c)(1)(D), which allows one company to use another com pany's data in return for payment of compensation; an Section 3(c)(2)(B), which allows one company to share in th cost of data being developed by another company to compl with a data call-in or for reregistration. [2]

[1] The authors are partners in the firm of McKenna, Conner & Cuneo.

[2] Section 3(c)(2)(B) also authorizes joint data developmen arrangements among registrants, but as the arbitrator determined, no such arrangement was involved in this case (Award, p. 18.)

0148-7973/89/$0+.50

Under Section 3(c)(1)(D)—compensation for the use of "old" data— Griffin must pay $125,930, based on the costs of the older compensable studies ($688,520) and the highest U.S. linuron market share Griffin achieved (18.29 percent) during the five-year period following receipt of its me-too linuron technical registration.

Drexel must pay $69,852, based on the costs of the older compensable studies ($688,520) and a minimum 10 percent share, which the arbitrators determined that a me-too registrant should be required to pay even if its market share is smaller than 10 percent. Drexel's was only 2.83 percent.

Under Section 3(c)(2)(B), cost-sharing payments for the use of Du Pont's "new" data,[1] Griffin must pay a minimum of $369,248, based on the cost of such new data ($2,018,854) and Griffin's 18.29 percent market share. If Griffin's 1988 market share is higher, the higher percentage will be used instead.

Drexel must pay a minimum of $57,134, based on the cost of such new data ($2,018,854) and Drexel's 2.83 percent market share. If Drexel's 1988 market share is higher, the higher percentage will be used instead.

For new data not yet submitted by Du Pont or awaiting EPA acceptance, as each new study is accepted by EPA to fulfill a reregistration requirement, Griffin and Drexel will be required to pay their highest linuron market share during the five-year period following the applicable data call-in times the cost of the study, plus 10 percent interest from the date of submission of the study. Based on the arbitrators' determinations, this should result in a minimum payment from Griffin of $646,228 and a minimum payment from Drexel of $89,504 (plus interest).[4]

Panel Provided Little Explanation

As with most arbitration awards, there is a dearth of explanation in the *Du Pont* award from the panel regarding its specific findings and determinations, and very little discussion of the specific facts and reasons that led to many of the panel's conclusions. For example, the panel declined to explain how it determined the parties' market shares, how it determined the costs of the studies, or how it concluded that certain studies were "in [the] public literature." (Award at 32.)

Similarly, the panel did not explain why it believed no compensation was due for studies "voluntarily" submitted during the linuron special review, or for the studies supporting the Du Pont labels which Griffin and Drexel copied. Nor did the panel explain why it elected to allocate costs on a market-share basis.

Further, the award is notable for many determinations made implicitly—for example, the panel's refusal to rule (as Griffin and Drexel requested) that royalties are an improper or inappropriate form of compensation under Section 3(c)(1)(D). In most areas of dispute, the award does not even address the parties' arguments.

Thus, many underlying facts and the panel's rejection of certain positions advocated by the parties are not apparent from the face of the award. This is consistent with arbitration practice, as authorities on the arbitral process and the FIFRA arbitration rules make clear.

In part for this reason, the Federal Mediation and Conciliation Service, charged under FIFRA with responsibility for administering FIFRA arbitrations, declined to attempt to write a substantive standard for compensation into the rules.

FMCS indicated that arbitrators would determine standards on a "case-by-case basis" (Reference File 71:0581).

It is for similar reasons, as FIFRA makes clear, that the arbitrators' findings and determinations are not subject to judicial review.

The arbitrators' general conclusions regarding compensation under Section 3(c)(1)(D) are consistent with the *Stauffer-PPG* case.

Griffin and Drexel insisted that Section 3(c)(1)(D) requires "cost sharing." But the arbitrators found that "there is no explicit compensation standard set forth" in Section 3(c)(1)(D) and that "compensation under Section 3(c)(1)(D) is broader based than the cost-sharing, data gap-specific provisions of Section 3(c)(2)(B)." (Award, pp. 14, 17.)[5]

The panel found that Congress intended FIFRA data compensation to streamline registration of me-too products, eliminate expensive and wasteful duplicative testing, foster competition within the industry, and encourage innovation. (Award p. 12.)

In addition, the *Du Pont* arbitration panel expressly recognized the "value-received" approach to compensation embodied in the *Stauffer-PPG* case. Rather than precluding any particular form of compensation under Section 3(c)(1)(D), the panel determined that "a cost related approach can be utilized for compensation if it is also coupled with a value to follow-on registrants for the ability to enter a pesticide market at a substantially reduced cost and, under optimum circumstances, with little or no regulatory delay." (Award, pp. 22-23.)

The arbitrators did not award Du Pont the separate royalty on sales that the company requested. Presumably, this was because there was a substantial delay between the time Griffin and Drexel obtained their registrations and the time they began marketing their products. Thus, the arbitrators apparently believed that the facts of this case did not compel a conclusion that Griffin and Drexel realized an early-entry benefit as a result of their me-too registrations.

In contrast, in the *Stauffer-PPG* case, the me-too registrant began selling the product as soon as it obtained its me-too registration.

In addition, Griffin's early entry/royalty period had expired, and Drexel's had mostly expired, by the time the award was rendered.

Nevertheless, the panel did conclude that a "proper formula" for compensation should consider the "realities of the market place" and should preclude "speculation as to business and market futures." (Award, p. 23.)

Based on the foregoing, we believe the panel implicitly suggested that a royalty may be appropriate where the facts of the case so warrant (for example, in *Stauffer-PPG* where the me-too registrant was just entering the market).

Further, the panel rejected implicitly many contentions raised by Griffin and Drexel to reduce the award, including, for example, arguments that market shares should be determined based on sales apportioned over the supposed "lifetime" of the product, and that the award should be reduced

[1] As noted, these payments are for Griffin's and Drexel's use of Du Pont's new data. No joint ownership of the data is involved, as would be the case in a joint data development task force or similar arrangement.

[4] The arbitrators concluded that neither Griffin nor Drexel should be required to pay more than 22.5 percent of the cost of the new data unless Du Pont agrees to provide them with "hard" copies of the data, upon request. (Award, pp. 29-30.)

[5] The *Stauffer-PPG* case did not involve Section 3(c)(2)(B) cost reimbursement.

0148-7973/89/$0+.50

by tax factors related to Du Pont's research and development activities.

In identifying the Du Pont studies for which Griffin and Drexel must pay compensation under Section 3(c)(1)(D), the panel allowed certain disputed categories and excluded others, based on specific evidence presented. (The panel did not explain how it resolved disputes regarding any particular studies.) For example, the panel determined that data submitted in support of a pesticide registration are compensable even if they do not fully satisfy specific data requirements, as long as they are scientifically relevant to the agency's determination to register the product.

The arbitrators ruled that "core supplemental" data submitted by Du Pont are compensable even if they "do not . . . coincide exactly with those requirements existing at the time a given [me-too] registration is granted." (Award, p. 16.)

The panel indicated that "there is no requirement in an EPA offer-to-pay statement under 40 CFR 152.86(d) that compensation under FIFRA Section 3(c)(1)(D) be applied only to data totally satisfying a specific requirement." (Award, p. 16.).

The arbitrators also stated that "after the date that a registration or reregistration standard has been issued by the EPA those data of the type required are set forth in that standard and may be compensable under Section 3(c)(1)(D) by subsequent applicants." (Award, pp. 16–17.)

The panel also found that Griffin's and Drexel's "cite-all" offers to pay compensation encompassed all of the data relied upon under the cite-all method, notwithstanding the fact that some of the offers were made under the now defunct "mandatory cite-all policy."[6]

Thus, mandatory cite-all did not abridge Du Pont's right to obtain compensation or diminish the body of data subject to compensation. (Award, pp. 4–5, 14.) The *Du Pont* panel, however, did not require Griffin or Drexel to pay compensation for their use of Du Pont's pre-1970 data, efficacy data, or data which Du Pont submitted for EPA's use in a linuron special review and which the arbitrators found did not fill a designated data gap.

Compensation Exclusions Of Certain Data Telling

The exclusions of certain data from compensation in the *Du Pont* case underscore the authority of each arbitration panel to make findings (including statutory interpretations) that differ from those of arbitration panels in other cases. For example, the *Stauffer-PPG* panel (which included one of the same arbitrators who sat on the *Du Pont* panel) allowed compensation for pre-1970 data which had been resubmitted by Stauffer after 1970 to support a registration action, and allowed compensation (in the form of a royalty) for Stauffer's efficacy data which had been "waived" subsequent to their submission.

Both decisions are equally available as "guidance" to future arbitrators, although neither decision stands as a binding precedent.

The *Du Pont* hearing concluded before the 1988 FIFRA amendments were enacted. The 1988 amendments contain numerous provisions that may affect future data compensation cases.

For example, the amendments reaffirm the value of previously submitted (that is, existing) data by requiring explicitly that applicants for reregistration certify that they have complied with Section 3(c)(1)(D) compensation requirements for the use of such data for reregistration (Reference File 91:0221).

In addition, the new "fast-track" me-too registration procedure increases the value of data (including product performance data generated to support label claims) by encouraging (without requiring) me-too applicants to submit applications for products whose composition and proposed labeling are identical or substantially similar to the data of the submitter (Reference File 91:0214).

Future arbitration panels will have to consider these provisions of the amended law (among others) in deciding how to award compensation under the facts of other disputes.

Du Pont Sought Cost Sharing For New Data

Du Pont is generating its own new data to comply with two Section 3(c)(2)(B) linuron data call-ins. Although Du Pont's attempts to enter into a "cost sharing" agreement with Griffin and Drexel regarding such new data were unsuccessful, as the arbitrators agreed, Du Pont nevertheless requested arbitration alternatively under Section 3(c)(1)(D) and Section 3(c)(2)(B).[7]

The panel determined that the parties had made a "sufficient agreement" under Section 3(c)(2)(B) to subject their dispute to arbitration, because they had actively engaged in negotiations. (Award p. 17.)[8]

As a result, the arbitrators interpreted their mandate regarding Du Pont's new data as defining "the principal terms of agreement for a [Section 3(c)(2)(B)] data development cost sharing agreement among the parties." (Award, p. 25). This enabled Du Pont to recover a share of its costs of generating the new data from Griffin and Drexel now, pursuant to Section 3(c)(2)(B)(ii), rather than waiting several years for Griffin and Drexel to submit formal applications for reregistration and relying on Du Pont's data pursuant to Section 3(c)(1)(D). (See FIFRA Section 3(c)(2)(B)(v).)

In addition to the Section 3(c)(2)(B) cost allocation described above, the arbitrators imposed certain other terms on the Section 3(c)(2)(B) cost-sharing arrangement. These include requirements that Du Pont maintain actual cost records for the new data it is generating; respond to written inquiries from Griffin or Drexel regarding the status of pending studies; notify EPA following receipt of payment from Griffin or Drexel for a particular study regarding the percentages paid by Griffin and Drexel and that the test is a "joint submission"; and, upon request by Griffin or Drexel, submit any or all of the Section 3(c)(2)(B) data to any state for state registration purposes.

Arbitrators Exceeded Their Mandate

In our opinion, some of the panel's requirements exceed the arbitrators' mandate under Section 3(c)(2)(B). For example, FIFRA Section 3(c)(2)(B) draws a clear distinction between "joint data development arrangements" (which typically involve co-ownership of data) and, as here, mere

[6] The "cite-all" method allows applicants to cite (and offer to pay for) all relevant data in EPA's files that were available for data licensing.

[7] The arbitrators noted that Section 3(c)(2)(B) does not require registrants to jointly develop data. (Award, pp 19–20, n. 5.)

[8] The arbitrators also opined that registrants subject to a Section 3(c)(2)(B) data call-in are required to make "active and good faith efforts" to negotiate agreements to share in the costs of producing required data (or to jointly develop the data).

agreements "to share in the cost of producing the data." Thus Section 3(c)(2)(B)(ii) explicitly provides that me-too registrants that merely share in the cost of producing data have the right only "to examine and rely upon such data in support of maintenance of such [EPA] registration."

The statute does not provide such registrants the right to "hard" copies of the data, or the right to rely on the data for any purpose other than EPA registration.

For these reasons, we believe it is clear that the award does not confer in Griffin and Drexel any rights of joint ownership in Du Pont's data. Nor do we believe that the panel intended to grant any rights beyond those explicitly enumerated in the award.

This question, however, and such questions as the authority of the panel to require Du Pont to submit data for state registrations, appear academic in this case. Should the same questions arise in another arbitration, we believe that the arbitration panel will recognize, with adequate consideration, that it lacks authority to create rights in data not created by FIFRA itself.

Conclusion

The *Du Pont* award follows the *Stauffer-PPG* decision as only the second award under Section 3(c)(1)(D), and is the first award under Section 3(c)(2)(B) in the 10 years since the arbitration system was established. Most compensation matters have not resulted in arbitration, and a number of disputes have been settled prior to hearings after arbitration proceedings were initiated.

The awards in the *Stauffer-PPG* and *Du Pont* cases cannot be compared because the facts in each dispute were so markedly different. Furthermore, the generic industry's ongoing efforts to transform the decision in this particular dispute into a "formula" or "precedent" for future arbitrations undermine the very purpose of arbitration, which is to ensure that each dispute is decided on its own unique facts.

The conclusions we draw from the two decisions are these: First, compensation should be substantial, and should reflect the value of the data to the me-too registrants based on the realities of the marketplace. Second, the FIFRA arbitration system is working, and is providing data submitters and me-too registrants a forum to resolve compensation disputes based on the facts of each case.

Copies of the arbitration panel's decision in the linuron case can be obtained for a charge from BNA PLUS at (800) 452-7773 nationwide or (202) 452-4323 in Washington, D.C.

0148-7973/89/$0+.50