Data Citation, Compensation and Cost Sharing: Pitfalls and Traps for the Unwary

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FOREWORD: Pesticide data compensation and cost sharing disputes take on many different forms, each turning on distinct facts and issues. Because prior awards are not binding, arbitrators are not required to apply any preset body of principles or even consider prior awards when issuing a decision. Therefore, data compensation obligations cannot be predetermined with any certainty. Nonetheless, arbitrators commonly are guided by the principles applied by past arbitrators and do, in fact, regularly consult prior decisions. The outcomes in past awards, therefore, are instructive for both data owners and follow-on registrants who are involved in data cost negotiations or anticipating arbitration. The data owner or follow-on registrant who understands the relevant issues and principles is one step ahead in the highly regulated and fast-changing U.S. pesticide industry. We hope that this article will help to facilitate that process.

General Principles

Introduction

The cost to generate a full set of data required to register a pesticide with the United States Environmental Protection Agency (EPA) can range from several hundred thousand dollars (US) for non-food antimicrobial pesticides, to tens of millions of dollars for conventional agricultural pesticides.

Under U.S. law, registration applications must be fully supported by either submitting all required data, citing existing data previously submitted to EPA, or else formulating the product from already registered active ingredients purchased from another company (under the so-called "formulator's exemption").

To cite another company's data, the composition and proposed uses of the "follow-on" or "me-too" applicant's pesticide must be substantially similar to a previously registered product. In addition, the applicant must offer to compensate the data owner, in writing, for using the data. If the two companies are unable to reach a voluntary agreement on the amount of compensation owed, either may initiate binding arbitration to resolve the dispute.

Compensation or Cancellation

Fortunately for follow-on registrants, EPA does not require that they actually pay compensation before obtaining a registration. All that is necessary, from EPA's standpoint, is for a follow-on applicant to certify that it has made all required compensation offers.

Once a compensation offer is made, it is up to the parties to resolve any compensation dispute separately from EPA. EPA will not become involved in determining what, if any, compensation is due. Under U.S. law, any dispute must be resolved through negotiation or, if necessary, binding arbitration under the auspices of the American Arbitration Association (AAA).

If the parties are unable to negotiate a settlement, in most cases, it is the data owner that files for arbitration. Absent settlement, a full arbitration proceeding can last two or more years and consume hundreds of thousands of dollars in transaction costs.

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Because EPA is not involved in resolving data compensation disputes, the time required to negotiate or arbitrate a dispute will not delay the time required to obtain a me-too registration. This means that follow-on applicants typically can sell and earn profits on me-too products for several years before they actually pay any compensation. However, if a follow-on registrant fails to comply with a data compensation agreement or an arbitration award, the data owner may petition EPA to cancel the me-too registration.

Because the cost to arbitrate is high, it often is in the best interest of the parties to settle and avoid arbitration. Unfortunately, data owners sometimes decide it is better to fight a war of attrition by pushing the dispute into costly arbitration in the hope that the me-too applicant will withdraw its registration rather than arbitrate. Likewise, me-too applicants sometimes decide it is cheaper to arbitrate and delay paying full compensation, while trying to capture sufficient market share to ultimately pay a final award. In our experience, arbitrators are willing to adjust awards against a party that forced a dispute into arbitration by taking unreasonable settlement positions. It is therefore important that all attempts to settle on reasonable terms be fully documented, and that settlement offers be drafted with the expectation that an arbitrator ultimately may review them.

Mistakes Are Costly

Given the cost of arbitration and the cost of the underlying data, there is a lot at stake. The best strategy for companies on both sides of a dispute is to understand data citation and compensation principles, recognize evolving trends and develop realistic strategies and expectations.

Ill-informed or inexperienced data citation and compensation strategies can have significant adverse effects on a company. There are substantial risks for protracted and costly disputes, as well as paying or obtaining inappropriate compensation. Data owners understandably want to obtain maximum compensation when another company cites their data to register a competing product with EPA, while follow-on applicants want to minimize their data costs.

In our experience, most companies – both follow-on applicants and data owners – do not understand data compensation issues. As a result, companies on both sides of the issue often make unsound business decisions or become entangled in lengthy disputes driven by unrealistic expectations.

This article, by the law firm of Wright & Sielaty, P.C., arises from our extensive experience helping companies evaluate and resolve data citation and compensation obligations. Our goal is to help companies understand evolving principles, case law and tactics in order to formulate and implement successful data citation and compensation strategies.

This document is an overview, and is not intended to be an all-inclusive discussion on data compensation. We do hope, however, that it will be a useful guide for existing and future registrants in today's highly regulated and fast-changing pesticide industry.

Guiding Principles

Many of the issues raised by parties seeking to resolve data compensation disputes have been addressed and extensively analyzed in prior arbitration decisions. Those decisions, however, are not binding precedent for future arbitrators, nor do they dictate how other companies should resolve compensation disputes.

Prior arbitration decisions, at most, provide guidance on how some arbitrators have resolved specific data compensation and cost-sharing disputes, but should not be taken as any indication on how another dispute may be resolved. In our experience, arbitrators are swayed more by the unique facts in each case than by any general compensation or cost-sharing formula.

In fact, if prior decisions teach anything, it is that there are no set formulas. For example, past awards have ranged from a small fraction of the

data costs to many times the cost of the disputed data.

Our final introductory point is a word to the wise: Companies that take extreme positions in data compensation and cost sharing disputes often do poorly. Arbitrators view negatively those companies that take unreasonable negotiation positions and drive the dispute into arbitration. (Unlike litigation in federal courts, negotiation positions may be admissible as evidence in an arbitration hearing.)

We also have seen cases where companies that take extreme positions live to regret it. It is not uncommon for companies to end up on the other side of the fence, with original data submitters becoming me-too registrants and me-too registrants becoming original data submitters. Extreme positions taken on one side of an issue then end up being used against a company when it is on the other side of the issue.

About Us:

Wright & Sielaty, with our consulting firm ChemReg International, is the largest integrated legal, scientific and regulatory practice group in the U.S. primarily devoted to helping companies on issues regarding conventional pesticides, antimicrobial pesticides and bio-pesticides. Our clients include both follow-on registrants and data owners. In most cases, we are able to successfully negotiate favorable data compensation settlement agreements for our clients. Where negotiations have failed, our attorneys and consultants have been involved in many of the leading data compensation arbitrations of the last fifteen years.

Data Compensation by Me-Too Applicants

Under the Federal Insecticide, Fungicide and Rodenticide Act ("FIFRA"), no pesticide may be sold or distributed in the United States, or produced or imported for sale in the United States, unless it is first registered with EPA.[1] To obtain a registration an applicant is required, among other things, to submit or cite data in support of its application.

Specifically, FIFRA requires that an application contain "a full description of the tests made and results thereof ... or alternatively a citation to data that appears in the public literature or that previously had been submitted to [EPA]." FIFRA § 3(c)(1)(F).

An applicant may satisfy EPA's requirements by independently generating and submitting its own data, by citing data in the public literature, or by citing data that another registrant already has submitted to the Agency for an identical or substantially similar product. *Id.*

In most cases, me-too applicants opt to cite existing data rather than generate and submit their own data. Generally, it is cheaper to cite existing data. It also takes less time to obtain a registration using existing data already in EPA's files than it does to generate and wait for EPA to review new data.

Relevant Time Periods

Although FIFRA encourages companies to cite, rather than generate duplicate data, there is a significant limitation. No data submitted to support the registration of a pesticide containing a new, never-before registered active ingredient may be cited for ten years after the date of that first registration.[2]

This limitation is known as the "exclusive use" period. Even so, a me-too applicant may still obtain a registration during the exclusive use period either by submitting its own data or by obtaining permission from the original registrant to use the existing data.

Although data within the ten-year exclusive use period require the permission of the data owner before they can be cited, no permission is

[1] There are exceptions to this general rule, but they are outside the scope of this article.

[2] Although there are ways to extend the ten-year exclusive use period, that issue is beyond the scope of this article.

required to cite data outside the exclusive use period. This issue is commonly misunderstood, and the simple fact is that there are no restrictions under FIFRA on the right to cite such data, other than making a compensation offer and insuring that they are pertinent to the me-too product.

There is one other time period that is important to understand. To be compensable, a study must have been submitted to EPA within fifteen years of being cited. In other words, a study may be cited and relied upon by another company, without any obligation to pay compensation, if it has been on file with EPA for more than fifteen years.

Cite-All verses Selective Cite Applications

Under EPA regulations, a me-too applicant uses one of three methods to cite another registrant's data: the (1) "cite-all" method, (2) "selective" method or (3) "selective cite-all" method.

Under the "cite-all" method, the follow-on applicant cites ***all*** data in EPA's files that are "pertinent" to the Agency's consideration of the requested registration.

Specifically, the applicant certifies that it is relying upon all non-exclusive data in EPA's files that are "pertinent" to the Agency's consideration of its application. To be pertinent, the data must be one of the types of data that EPA would require to be submitted to support the initial registration of the pesticide under the data requirements in effect on the date EPA approves the application. 40 C.F.R. §§ 152.80, 152.86(d)(2)(ii).

To use the cite-all method of support, the applicant must first show that the chemical composition of the me-too product is substantially similar to the data owner's product. Unfortunately, there are no established standards for determining if a me-too product is substantially similar to a previously registered product.

The exact composition of another company's product, other than the name and percentage of the active ingredient, is treated by EPA as confidential and will not be disclosed. Me-too applicants therefore should undertake on their own to understand as much as possible about the composition of the previously registered product, and be prepared to convince EPA that the characteristics of the two products are similar enough to justify reliance upon a common set of data.

The me-too applicant also must send a written compensation offer to all companies listed on EPA's Data Submitters' List ("DSL") for the same active ingredient. 40 C.F.R. § 152.86.

Under the "selective" method, the follow-on applicant identifies and lists in its application the specific data requirements that apply to its product and intended uses, and then lists the specific studies it is relying upon to satisfy each of those requirements. Only "valid" studies may be selectively cited.

To be valid, a study must "have been conducted in accordance with the Good Laboratory Practice standards of 40 CFR part 160 or generally accepted scientific methodology and that EPA has not determined to be invalid." 40 C.F.R. § 152.83(e). Under this method, the compensation offer is made only to the original data submitters for the actual studies cited by the follow-on applicant. 40 C.F.R. § 152.90.

A third, less-utilized method, is a cite-all option within the selective method – "selective cite-all." In our experience, this method often combines the best features of the commonly used cite-all and selective-cite methods, while avoiding the unique problems associated with each.

ChemReg International, the scientific and regulatory consulting firm associated with Wright & Sielaty, routinely evaluates for clients the cost and time required to obtain a registration under the cite-all, selective-cite, and selective cite-all methods. These evaluations provide companies with important information needed to make sound business decisions on the best way to register a product for sale in the U.S.

Under this method, the follow-on applicant lists in its application the specific data requirements that apply to its product, and cites all data in the Agency's file for only those requirements. The offer to pay is limited to any data owner listed on the DSL who submitted data pertinent to the requirements listed in the application. 40 C.F.R. § 152.95.

Petitions to Deny Pending Applications

Regardless of the method used, EPA requires follow-on applicants to furnish certain information in the offer to pay and to certify such information with the Agency. An applicant who fails to fully comply with EPA's regulations faces the risk of a challenge to its registration from the original data submitter, as well as EPA cancellation or denial of its application or registration. *See* 40 C.F.R. § 152.99.

As already noted, the follow-on applicant is not required to actually pay or reach agreement with the data owner on the appropriate amount of compensation before EPA will issue the follow-on registration. The Agency normally will render a final decision on the application as long as a compensation offer has been submitted to the data submitter, even if no compensation has been paid.

While a registration application is pending, EPA's regulations allow a data owner to file a petition asking EPA to deny the application. If the applicant relied upon the cite-all method, the primary grounds for such a petition is to claim that the me-too product is not substantially similar to the data owner's product. If the two products are not substantially similar, then the data generated for the original product arguably do not satisfy data requirements for the me-too product.

A data owner also can raise a substantial similarity argument if the applicant relied upon the selective-cite method. In addition, the data owner can argue that the studies selectively cited in the me-too application are not adequate, by themselves, to fully satisfy all relevant requirements. This latter argument, however, is not available to challenge a cite-all application, because all data on file with EPA are adequate to maintain the original data owner's registration, and therefore are considered adequate by EPA to register any substantially similar product with similar uses.

Some of the most significant decisions by EPA to cancel or deny registrations have arisen from cases handled by Wright & Sielaty attorneys who petitioned EPA on behalf of clients. For example, EPA recently issued a Notice of Intent to Suspend the registration of a DCI recipient that refused to offer to jointly develop or share in the cost of developing the required data, while also failing to submit its own data. Wright & Sielaty also routinely defends against petitions to cancel or deny registrations, and no petition asserted against any of its clients has ever succeeded.

Cost Sharing by Existing Registrants

After EPA issues a registration, a registrant may be required to submit additional data to support the continued registration of the pesticide. The obligation to generate additional data after a product initially is registered may arise as part of reregistration or under a separate "data call-in" ("DCI"). *See* FIFRA § 3(c)(2)(B).

To satisfy a DCI, each registrant may separately generate the required data. Alternatively, a DCI recipient may offer to any other DCI recipient, in writing, to jointly develop the data or share in the costs of developing the data ("cost-share"). *Id.* If a DCI recipient fails to offer to jointly develop or cost share (absent submission of its own data), or fails to abide by a joint development or cost sharing agreement, other recipients may petition EPA to suspend the recalcitrant company's underlying registrations.

If a registrant does not want to generate the data, either on its own or in conjunction with other registrants, its only options are to challenge the

validity of the DCI or else voluntarily cancel its registration.

Negotiation, Arbitration and Compensation

Typically, parties do not engage in substantive negotiations over data compensation until EPA issues the me-too registration. However, there is no barrier to earlier negotiations if the parties so desire.

If the follow-on registrant and data owner cannot reach agreement on the amount or terms of compensation, either party may initiate arbitration. Arbitration may be initiated within 90 days after the follow-on applicant makes an offer to pay or, in the case of a data call-in, 60 days after a party offers to share costs or jointly develop the data. FIFRA §§ 3(c)(1)(F)(iii) and 3(c)(2)(B)(iii). The arbitration then will be conducted by the American Arbitration Association pursuant to the FIFRA Arbitration Rules at 29 C.F.R. Part 1440.

The main hindrance to resolving data compensation disputes and avoiding arbitration is that FIFRA and its implementing regulations do not explicitly define "compensation" or "costs," or provide any formula for calculating how much compensation or cost sharing is owed. It therefore is up to the parties to argue over what is appropriate "compensation" or "cost sharing."

Although there is no standard formula for calculating compensation under FIFRA, past arbitration awards provide extensive guidance on a number of key issues. Those awards illustrate that arbitrators try to formulate awards that are consistent with FIFRA's intended goals and purposes.

Those goals include providing fair compensation, streamlining pesticide registration procedures, providing incentives to pesticide producers, simplifying EPA registration procedures, increasing competition and avoiding unnecessary duplication of data-generation costs. *See In re I. Pi. Ci. and Albaugh, Inc.*, AAA No. 16-171-00216-95, at 3 (Order Denying Motion to Dismiss, July 11, 1996); *Thomas v. Union Carbide*, 473 U.S. 568, 572 (1985).

Advantages and Disadvantages: The Cite-All Method

The follow-on registrant's compensation obligation is directly tied to the method of citation selected in its application, and there are advantages and disadvantages to each method.

An advantage of the cite-all method is that it provides for more rapid review and processing of the application by EPA, thereby allowing the follow-on applicant to enter the market earlier than if it were to independently generate the data or cite data under the selective method. Cite-all is also the least complicated method; the applicant does not need to determine the specific data requirements that apply to its product, or the specific studies that are needed to satisfy those requirements.

However, the arbitrator – absent agreement by the parties – is left to determine which data are "pertinent" (*i.e.*, relevant to EPA's consideration of the application) and therefore compensable. Other than the cost of the data, this often is the central issue in dispute.

Under the cite-all method, the follow-on applicant may have to pay for more than the minimum amount of data required. *See* 49 Fed.Reg. 30884, 30891 (August 1, 1984). For example, if there are two studies that satisfy the same data requirement, arbitrators typically require that compensation be paid for both studies.

Also, an applicant cannot use the cite-all method if there are exclusive use data and the owner denies authorization. Under this scenario, the follow-on applicant would have to cite non-exclusive data, if there are any, under the selective or selective cite-all methods.

Advantages and Disadvantages: The Selective Method

Under the selective method, the follow-on applicant can reduce its compensation obligation because it only pays for data that it selectively identifies and lists in its application. EPA's approval of the application and the designation of data eliminates any dispute during an arbitration over whether the data are adequate or required for registration, and therefore are compensable. *See Dow AgroSciences v. Gharda* (April 16, 2001) (citation of data under the selective citation method is an assertion made to EPA by an applicant that *prima facie* establishes the relevance and compensability of the selected studies). Data not cited, therefore, are not required or compensable as to that specific registration.

In a precedent-setting case recently decided by EPA, the data owner petitioned EPA to deny a pending application by a Wright & Sielaty client. The petition argued that the selective-cite application, which was limited to non-food uses, was required to also cite food use data. According to the petition, those additional studies were necessary for EPA to conduct a full risk assessment. Based on the arguments advanced by Wright & Sielaty, EPA denied the petition and ruled that a selective cite application must only list data directly relevant to the product's proposed uses.

Another advantage is that a follow-on applicant is not obligated to cite or pay for data that are duplicative of the data it has independently generated.

The selective method, however, is the most complicated method because the follow-on registrant – before submitting its application – must first determine which specific studies it will rely upon and whether those studies, by themselves, satisfy relevant requirements.

EPA also generally processes a selective-cite application less quickly than a cite-all application because the Agency has to first determine the sufficiency and acceptability of each study. For the follow-on applicant, this delay by the Agency could translate into a postponed entry into the marketplace and lost sales.

Advantages and Disadvantages: The Selective Cite-All Method

The selective cite-all method combines the simplicity of the cite-all approach with many of the cost advantages of the selective method. Unlike cite-all, where the applicant risks paying for ***all*** data in EPA's files that arguably are pertinent to the active ingredient, the selective cite-all approach allows the applicant to limit compensation to studies submitted for specifically-listed requirements that are relevant to its specific formulation and intended uses.

The selective cite-all method is also less complicated than the selective method. The applicant makes a general offer to pay for specific data requirements, without needing to identify the specific studies in EPA's files that are relevant to those requirements. It also is a relatively easy application for EPA to process, which avoids the lengthy delays commonly associated with a selective-cite application.

Arbitration Procedural Issues

General Arbitration Principles

As already mentioned, either party can initiate arbitration if the parties are unable to agree on the amount or terms of compensation.

In an arbitration proceeding, the data submitter (generally the "claimant") is the party that bears the burden of proof for much of the evidence. "This is reasonable. It is the Claimant who owns the data, possesses the supporting documentation

including the reams of correspondence with EPA." *Proem v. Grapetek Ltd.* (June 17, 1999). (In an arbitration, the follow-on registrant usually is the "respondent.")

The follow-on registrant and data submitter equally bear the costs of the arbitration proceeding, including the fees and expenses of the AAA and of the arbitrator, and the costs of the court reporter and any transcript of the proceeding. Each side is otherwise generally responsible for its own costs and fees, including witness and attorney fees.

The one award that required a party to pay the other party's attorney fees was overruled on that issue on appeal. *See Mevinphos Task Force v. Gowan* (Aug. 25, 1987); enforced except as to award of fees, *Gowan Co. v. Mevinphos Task Force*, Docket No. 87-6739 (C.D. Cal., Dec. 21, 1987).

Prior arbitration decisions generally have required the follow-on registrant to pay the award in one lump sum within or between 30 and 60 days of the decision. See *Microgen v. Lonza* (May 10, 2000) (payment within 30 days); *Abbott v. Agtrol* (July 15, 1991) (payment within 30 days); *Union Carbide v. Thompson-Hayward* (July 13, 1982) (payment within 30 days); *Phosphine Task Force v. Bernardo Chemicals* (March 5, 1998) (payment within 45 days); *DowElanco v. Albaugh* (June 1, 1998) (payment within 45 days); *Enviro-Chem v. Lilly Industries* (July 22, 1999) (payment within 60 days); *Avecia v. Mareva* (August 15, 2002) (payment within 60 days).

Requests by the follow-on registrant to pay the award over time generally have been denied. *See, e.g., Amvac v. Termilind* (Oct. 26, 1998).

Arbitrator Selection

Although the FIFRA Arbitration Rules generally provide for a single arbitrator, parties typically request a panel of three arbitrators to hear a case. The American Arbitration Association will then make an appointment from its roster of arbitrators.

Despite the prevailing practice of having three arbitrators oversee data compensation disputes, a party may insist on a single arbitrator.

A recent decision recognized the right of smaller, follow-on registrants to insist on a single arbitrator, despite the data owner's request for three arbitrators. *Aventis v. Burlington* (Jan. 4, 2002.) This will help minimize the significant transaction costs associated with data compensation arbitrations.

In a case handled by Wright & Sielaty, we represented the me-too registrant. AAA initially appointed three arbitrators over the objections of our client. On appeal, AAA was overruled. It is now established law that when the parties cannot agree on the number of arbitrators, a single arbitrator is required.

Arbitration Awards Are Final and Enforceable

FIFRA arbitration awards are final and, absent fraud or misconduct, may not be appealed or reviewed in a court of law. Awards, however, are enforceable in court. *See Cheminova v. Griffin* (June 29, 2001) (in affirming final arbitration order, the court held, in part, that arbitration awards are "binding," "final and conclusive" and "judicially enforceable").

The *Cheminova* decision affirms the right of a data owner to obtain payment from a reluctant me-too registrant in two ways: First, by requesting that EPA cancel or deny the follow-on registrant's application/registration unless the award is paid; Second, by enforcing the arbitration award through a court order. These two remedies are not mutually exclusive, and the data owner can pursue both remedies simultaneously. It is not clear, however, whether EPA would cancel a registration after a data owner succeeded at collecting on an arbitration award via a court order.

The *Cheminova* decision is significant because it clarifies that a follow-on registrant may not simply walk away from an arbitration award that it

deems excessive. In addition to potentially losing its registration, the follow-on registrant is subject to judicial liens against its other assets and may be precluded from reentering the market unless and until the award is satisfied. As a result, companies must carefully consider the scope of a potential arbitration award before proceeding with a follow-on application.

Arbitration Proceedings: Typical Claims

As part of an arbitration proceeding, a data owner normally submits a claim seeking compensation for the data costs it incurred to obtain and maintain its pesticide registration.

No two data compensation claims are alike; each claim takes into account unique facts and circumstances. Nonetheless, a typical data compensation claim includes various components.

All claims include direct and indirect costs. Those costs are then adjusted to account for general overhead, inflation or interest. Added to adjusted costs are any enhancements, like a risk premium or the value of any early market entry. Once adjusted costs plus enhancements are computed, the claimant typically seeks to split the amount on a *per capita*, equal basis to arrive at the total claim sought in the arbitration.

Wright & Sielaty recently succeeded in winning the largest data compensation award ever issued in an arbitration involving an antimicrobial pesticide. The me-too registrant was ordered to pay over $2.2 million dollars in compensation for approximately $3.9 million in direct costs incurred by the data owner.

Although these are typical components of a claim, an arbitrator may not always consider all of them in a final award.

Direct and Indirect Costs

Direct costs may include protocol preparation and review, the development and conduct of a study, and data evaluation by research and development staff. Sometimes it also includes the cost of preliminary or range finding studies that may not have been submitted to EPA, but arguably were necessary to generate the final data.

Indirect costs are those costs related to the development of the data, like administrative and overhead expenses. It also may include the regulatory support costs of internal staff and outside consultants, and the cost to resolve questions and issues EPA may have raised regarding the data.

Adjustments and Discounts

The data submitter may also seek an adjustment to its costs, such as inflation or interest, to reflect current capital costs. The follow-on registrant, alternatively, may seek a discount if the follow-on registrant is not granted a physical copy of the data ("hard copy,") or is unable to use the data to satisfy regulatory requirements before state regulatory authorities and foreign countries.

The me-too registrant also may seek to have the claimed costs reduced on a pro-rated basis over the relevant fifteen-year compensability period for the data. Arbitrators, however, generally have not adopted this argument.

Add-Ons

On top of adjusted costs, the data submitter may argue for one or more cost add-ons. An add-on could include, for example, a premium to reflect the regulatory risk borne by the data submitter and avoided by the follow-on registrant in developing the data, the risk that EPA might deny or delay the registration or require more testing, or the risk that the data may be adverse.

Additionally, a cost add-on might include a premium for "early market entry" to reflect the added value to the follow-on registrant for using existing data and entering the market sooner than if it had chosen to generate new studies.

Another add-on might be an enhancement for "lost opportunities," based on the idea that if the capital the data submitter used for the studies had been available for other opportunities, the data

submitter could have made use of the capital more profitably.

As discussed below, arbitrators do not always accept these enhancements.

Allocating Costs Between the Parties

After computing any costs, adjustments, discounts or enhancements, the arbitrator must decide how to allocate the resulting amount between the parties. Data submitters generally argue in favor of an equal allocation of the adjusted costs on the theory that me-too registrants have equal rights to the data to support EPA registrations. Under this theory, me-too registrants should bear an equal, or *per capita*, share of the costs.

The follow-on applicant, whose market share is generally smaller than the data owner, often argues that costs should be divided based on the parties' relative market shares. Under this theory, compensation should be linked to the value of the data to each company, which depends on resulting sales.

Recent Trends in Arbitration Awards

Overview

Since the early 1980s, there have been roughly two dozen public pesticide data compensation awards, with almost half of these awards in just the past five years. Many more cases have remained confidential or were resolved short of a full arbitration hearing.

While prior arbitration awards are not binding on future arbitrators, our experience shows that arbitrators consult and are guided by the principles applied in past awards when issuing their own decisions.

Of more importance to most arbitrators, however, are the unique facts of each case and their perception of the parties. As a result, there are no clear compensation formulas and similar cases can result in seemingly contradictory rulings. Nonetheless, key trends in prior awards are instructive on how a future arbitrator may decide an issue.

The Fifteen-Year Compensability Period

A follow-on applicant is obligated to compensate the data submitter if the data are cited within 15 years of their original EPA submission date. After the expiration of the 15-year period, EPA may consider the data in support of the follow-on application without any obligation to pay.

FIFRA is silent on whether the 15-year compensation period is tied to the date an application is submitted to EPA, the date a compensation offer is sent, or the date a registration is issued by EPA.

Most prior awards have assumed that the data are cited on the date an application is approved. However, a recent data compensation award rejected this view, and, on the basis of arguments presented by Wright & Sielaty, held that the 15-year period runs backward from the date the follow-on application was filed with EPA.

The difference in dates is significant for both follow-on applicants and data submitters, because the application date may be several years earlier than the registration date. Using the earlier date, therefore, means that more data are compensable.

Acting in Bad Faith

Consistent with FIFRA's goal of reducing regulatory barriers and enhancing competition, data owners who invoke costly FIFRA arbitration proceedings to deter competitors should expect to have their compensation awards reduced or eliminated entirely. *Microgen v. Lonza* (June 9, 1997). Compensation might also be reduced where the data submitter has unrealistically inflated its claim. *Id.*

Actual Historic Costs Verses Estimated Costs

In determining direct costs, arbitrators normally will base an award on the data submitter's proven, actual historic costs. Those costs can be documented with evidence such as invoices from

outside contractors and contemporaneous study-by-study time records.

Arbitrators consistently rely on historic costs, when available, as the most reliable measure of the data submitter's compensable costs. Arbitrators generally reject arguments by follow-on registrants that actual, documented costs should be ignored in favor of what they might have paid to develop the data on their own. *See Cheminova v. Griffin.*

Estimates of what it hypothetically might have cost the follow-on registrant to produce the data are a less certain method of proof. Replacement cost estimates are generally used only when a data submitter is unable to prove its actual costs or lacks contemporaneous records. *See Dupont v. Griffin and Drexel* (Dec. 22, 1988); *DowElanco v. Albaugh.*

Lack of Reliable Records

Data owners who do not keep good records of their expenses for producing the data will bear the risk of receiving significantly less than the amounts claimed.

Arbitrators have not been inclined to accept at face value a summary statement of costs without backup documentation because of concerns that the costs are overstated or padded. *See Union Carbide v. Thompson-Hayward.*

Another service provided by Wright & Sielaty is to audit the files of data owners to insure that they are collecting and maintaining the type of evidence necessary for maximum compensation. In our experience, data compensation disputes are won or lost years before the data are cited, based upon the quality of the files and documentation maintained by the data owner.

For example, in *Abbott v. Agtrol*, the arbitrator reduced costs because the data submitter failed "to adopt the reasonable practice of keeping daily or weekly records of their time devoted to [the pesticide product]." This failure "introduced an unnecessary element of uncertainty and imprecision into its calculations."

In *Avecia v. Mareva*, a 25% discount was applied to the direct cost of those studies that were based on cost estimates, rather than contemporaneous business records. Those estimates included summaries prepared with litigation in mind, long after the costs had been incurred. They also were unaccompanied by contemporaneous cost records.

"FIFRA is not a new statute ...[t]o the extent that [data submitters] failed to develop or maintain adequate records, it does not seem inequitable to reduce cost estimates made well after the fact by as much as 25%." *Id. See also Enviro-Chem v. Lilly*; *DowElanco v. Albaugh*; and *Dupont v. Griffin.*

Data owners must maintain contemporaneous accounting records for indirect costs, as well. In *Avecia v. Mareva*, overhead and indirect costs were reduced to 20% from the data submitter's request of 36% because the data submitter:

> "...failed to maintain contemporary accounting records to support its claim for indirect costs. . . . While the Arbitrator understands that it is difficult to allocate indirect costs, particularly over a long period of time, it is clear that the burden of going forward with the basis for the allocation, particularly when it involves a substantial sum of money, as it does here, falls to the original data submitter."

Data owners should, therefore, put into place a system to maintain accurate records of direct and indirect data development costs, including, for example, daily or weekly time records (where costs are based on time devoted to a project), invoices and all contemporaneous cost records.

Even minimally credible contemporaneous documents may be considered adequate, as long as they are kept in the ordinary course of business.

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As held in *Avecia v. Mareva*: "This arbitrator is inclined to respect those data costs that are supported by minimally credible contemporaneous documents, whether submitted by independent laboratories or affiliated laboratories, so long as they appear, as they do in this case, to be documents prepared in the ordinary course of business."

EPA Data Classifications

Under EPA's regulations, a cite-all applicant cites all data in the Agency's files that are pertinent to EPA's consideration of the requested registration. Only those data pertinent to the application are compensable.

It has not been unusual for original data submitters to assert that all data having even remote relevance to the me-too pesticide are pertinent and therefore compensable. *See Proem v. Grapetek.* The follow-on applicant, on the other hand, often contends that pertinent data are limited to studies explicitly "required" or requested by EPA, that EPA has reviewed and that EPA has expressly classified as acceptable for satisfying specific registration requirements. *Id.*

The arbitrator in a recent decision adopted a novel approach by defining compensability based on EPA's classification of the data. *See Avecia v. Mareva.* In that case, data classified by EPA as "core," "acceptable," "core minimum," "favorably reviewed," and "guideline reference" were found to be pertinent, *i.e.*, relevant to EPA's consideration of the follow-on application and therefore 100% compensable. Data classified as "upgradeable," "no decision," "in review" and "decision deferred," but nonetheless designated as relevant to a particular EPA guideline, were found to be "pertinent" but only 80% compensable because they were not fully dispositive of the issue they addressed. Data classified as "not yet reviewed" and "extraneous," without any guideline designation, were held not pertinent and not compensable.

In other arbitrations, data classified by EPA as "rejected" or "unacceptable" have not been compensable. The cost of studies that partially satisfy EPA requirements often are discounted by arbitrators.

Based on these prior awards, data owners should diligently monitor and upgrade EPA's classification of their data or risk receiving only partial compensation. This especially is true for data classified by EPA as less than fully acceptable, or if EPA never reviewed or otherwise classified the data.

Inflation Adjustments

It is not uncommon for an arbitrator to include an inflation adjustment to compensate the data submitter for the capital costs of the required studies.

- In *Cheminova v. Griffin*, the award included interest from the date of the follow-on registrant's application to recognize the cost of capital expended by the data submitter in developing and producing the data.
- In *Proem v. Grapetek*, the arbitrator combined inflation and interest by applying an average prime interest rate, from the midpoint in time of the expenditures, as a proxy for inflation and real interest costs.
- In *Amvac v. Termilind*, the panel adjusted data invoice costs to reflect the fact that studies were conducted and paid for in the past, thereby allowing the data submitter to recover compensation for current capital costs.

A more recent decision even went so far as to award an interest factor of 11%, well-above the data submitter's requested 3%. *Avecia v. Mareva.*

This adjustment continues the trend of earlier data compensation cases which recognized that an interest component is needed "to prevent a windfall to those who had not committed such capital" and "to place [the claimant] in approximately the same position it would have been in if [the respondent] had paid its share ... when the expenses were actually incurred." *FMC v. Tricon* (Jan. 10, 1985). *See also American Cyanamid v. Aceto* (Feb. 28, 1989) and *Amvac v. Termilind.*

An inflation or interest adjustment, however, is not automatic. Arbitrators are not likely to recognize the effects of inflation without sufficient evidence. In *Enviro-Chem v. Lilly*, the arbitrator could not make a finding on pre-judgment interest where the data submitter did not present any evidence on interest rates or argue for pre-judgment interest. Data owners, while likely to receive an inflation-adjusted award, will only do so if supported by sufficient evidence.

Allocating Costs

Just as FIFRA does not explicitly define what data are compensable, the statute is similarly silent on how costs should be allocated among the parties – or in other words, how to slice up the pie. While data submitters generally argue in favor of an equal or *per capita* allocation of the data costs, follow-on registrants typically propose that costs be allocated based on the parties' relative market shares.

Prior decisions have not uniformly disposed of the issue, but the trend is toward apportioning costs equally among the registrants on a modified *per capita* basis, based on the number of registrants of technical products.

- In *Cheminova v. Griffin*, data development costs were divided equally between the two registrants with the follow-on registrant responsible for a 50% share.
- In *Microgen v. Lonza*, the parties were ordered to share costs on a *per capita* basis, with a hard copy discount.
- In *Proem v. Grapetek*, the follow-on registrant was required to pay 1/5th of the compensable costs because there where five entrants in the field.
- In *Enviro-Chem v. Lilly*, the award was based on a *per capita* allocation, with the follow-on registrant obligated to pay 1/3rd of the compensable costs.

These recent cases reaffirm the trend of earlier cases, which similarly awarded costs using a pure or modified *per capita* methodology. *See Abbott v. Agtrol; Stauffer v. PPG Industries*; and *Union Carbide v. Thompson-Hayward.*

In using a *per capita* approach, arbitrators have reasoned that allocating costs on an equal basis best effectuates the purposes of FIFRA and the realities of EPA registration, and ensures that each competitor bears an equal cost for an equal right to the data. *Id.*

Modified Per Capita Awards

While arbitrators in some cases use a straight *per capita* allocation formula, other arbitrators have adjusted the *per capita* allocation to account for other factors, or to reflect conditions in the marketplace.

For example, one arbitrator – although rejecting a market share approach altogether and finding a "presumption in favor of a *per capita* allocation" – declined to award a straight 50/50 equal share and allocated 1/3 of the costs to the follow-on registrant. This modified *per capita* allocation was based on the fact that the me-too registrant did not have the right to use the data before regulatory authorities other than EPA, or the right to receive cost reimbursement from subsequent follow-on registrants that might cite the data. *Avecia v. Mareva.*

Another panel focused on the follow-on registrant's opportunity to compete for sales in the marketplace. In *Amvac v. Termilind*, the panel adopted a modified *per capita* approach by awarding the data submitter compensation equal to either 42.5% or 47.5% of the cost of the compensable data, depending on whether the data was submitted before or after the registration was granted. This was justified based on the follow-on registrant's opportunity to compete in the marketplace and to recover data costs.

In *Amvac*, the panel concluded that the follow-on registrant likely could compete with the data submitter for sales of the product on a substantially even footing within a relatively short period of time, and would gain a market share equal to

that of the data submitter within two or three years.

A Market Share Approach is Uncommon

Panels that have applied a *per capita* methodology have concluded that a market share approach undermines the goals of FIFRA by forcing more successful companies to subsidize their less successful competitors (*Cheminova v. Griffin*); subsidize the entry into the market of new registrants (*Avecia v. Mareva*); or make data available on a risk free basis by linking compensation to the subsequent registrant's relative success in the marketplace (*Union Carbide v. Thompson*).

Arbitrators have also reasoned that there are practical difficulties with a market share approach. Future market shares inevitably depend on factors which are difficult, if not impossible, to predict. *See Cheminova v. Griffin* (panel declined to "speculate" as to the me-too registrant's future market share).

Only two older, published cases used market share as the basis for an award.

In *Ciba-Geigy v. Drexel*, the arbitrators concluded that there were reasons to believe that the me-too registrant was unlikely to compete effectively on an equal basis. The panel applied a market share methodology to a cost-share dispute based on the particular facts of the case. They held, however, that a market share approach may not always be the preferred solution and that slightly different facts could well require a different result. For example, a larger number of registrants, greater certainty as to the number of registrants, or greater or more frequent fluctuations in the market could well make equal sharing an appropriate methodology. "Indeed, we can visualize the possibility of a mixture of the two methodologies." *Id.*

In *DuPont v. Griffin* the arbitrators concluded that a *per capita* methodology had practical problems given the unique facts of that case. The panel offered only limited explanation in concluding that the follow-on registrant's share was 10% of the compensable data costs, plus an adjusted payment of the highest annual market share percentage achieved by the follow-on registrant over the next five years.

Other Factors Are Important

In some awards, the arbitrators did not use any set allocation formula and instead allocated costs based on other factors.

In *American Cyanamid v. Aceto*, the panel in a cost-sharing case recognized that both a *per capita* and a market share approach have merit. Nonetheless, they did not apply any one particular methodology and instead allocated 35% of the data costs to the subsequent registrant. Their rationale was that the me-too registration represented an equal license to sell product. However, the follow-on registrant was expected to have smaller sales profits over the period of the registration, and therefore lacked the ability to pay a large share of the data costs.

In *DowElanco v. Albaugh,* the panel rejected a *per capita* and a market share approach altogether. They looked at other evidence, such as proven data costs and capital risks, and decided that "a fair share" for the follow-on registrant was 15% of the compensable costs.

The *DowElanco* panel decided that a *per capita* approach involved too many open questions and uncertainties, such as determining how many companies are involved, what to do about multiple registrations, and what to do to adjust for future settlements, registrations or parties. A market share methodology, they reasoned, was too speculative to predict future sales and the profitability of the follow-on registrant. "The poorer player should not be rewarded with a lower entry fee nor should the successful applicant be forced to pay a higher cost simply because he is successful." *Id.*

Similarly, one panel declined to determine a specific cost allocation formula because of insufficient evidence. In *FMC v. Tricon* (Jan. 10, 1985), the arbitrators declined to say that *per capita* or market share allocations were never appropriate.

The panel reasoned that Congress intended for data development costs to be shared by the parties but declined to determine a specific cost allocation formula because of insufficient information.

As this line of decisions demonstrates, while there is a general presumption in favor of a *per capita* allocation, an arbitrator is just as likely to awards costs based on case-specific factors without regard to any set formula. Nonetheless, the recent trend toward allocating costs on a pure or modified *per capita* basis has significant ramifications for follow-on registrants.

Regardless of the follow-on registrant's current or future market share, the follow-on registrant in any data compensation proceeding should anticipate that compensable data costs may be awarded on a *per capita* basis, with a possible reduction in the award if there is not an equal right to the data outside of EPA or a right to any future compensation paid by subsequent registrants.

"Hard Copy" Discounts

A follow-on applicant does not need a physical or hard copy of the data to obtain a registration with EPA. Nonetheless, the applicant may need a hard copy or the permission of the data owner to obtain approvals from regulatory authorities in certain states, such as Arizona and California, and in foreign countries. Not surprisingly, therefore, a follow-on registrant frequently seeks an award that grants it a hard copy of the data, or alternatively, a discount to reflect the lack of hard copy rights and the follow-on registrant's inability to use the data outside of EPA.

In general, arbitrators have not required data owners to give follow-on registrants physical, hard copies of the data.

- In *Avecia v. Mareva*, the arbitrator refused to award hard copy rights after concluding: "It is unclear whether arbitrators in FIFRA proceedings have authority to require data generators to make available hard copies of their data to follow-on registrants or to condition their awards on such actions by data generators …."
- In *Cheminova v. Griffin*, the panel refused to consider the data submitter's offer to give the me-too registrant hard copies, reasoning that FIFRA authorizes arbitrators to determine data compensation but does not authorize arbitrators to award hard copies.

The follow-on registrant, however, is likely to receive a discount to reflect its inability to use the data outside of EPA. In three of the last four data compensation awards, the award has included a discount because the data owner did not voluntarily provide the follow-on registrant with hard copies of the data.

- In *Avecia v. Mareva*, the follow-on registrant's share of costs were reduced from a 50% *per capita* share to a 30% share based, in part, on the fact that the follow-on registrant could not use the data before state regulatory authorities, most notably California.
- In *Cheminova v. Griffin*, the arbitrators reduced the data submitter's total data compensation award by 5% to reflect the follow-on registrant's lack of hard copy rights.
- In *Microgen v. Lonza* (May 5, 2000), the arbitrators ordered a reduction in the data compensation award by 20% for some data, and 25% for other data, in the event that the original data submitter refused to provide hard copies. Hard copy discounts were awarded in earlier cases as well.
- In *DowElanco v. Albaugh* the arbitrators discounted the award by 5% to reflect the fact that the data could not be used in California, which constituted 10% of the relevant U.S. market.
- In *Abbott v. Agtrol*, the panel reduced the data compensation award where the original data submitter did not provide hard copies.
- In *Cheminova v. Griffin*, the award was discounted even though the parties submitted very little reliable evidence regarding the value of hard copies and the testimony was somewhat contradictory.

As these cases suggest, data owners who do not voluntarily grant hard copy rights to the follow-on registrant should anticipate receiving a discounted award. In our experience, most data owners are willing to risk a reduced award rather than give hard copies to a competitor for use in other jurisdictions.

Access to the Data For Use Before Other Regulatory Authorities

In some cases, the issue has not focused on hard copy rights, but on whether the owner should be required to submit the data on behalf of the follow-on registrant to other regulatory authorities in the U.S., such as California.

While some arbitrators have granted this right, other arbitrators have declined. In *Enviro-Chem v. Lilly*, the arbitrator concluded that FIFRA's data compensation provisions apply only to the use of data before EPA and not other regulatory jurisdictions. *See also DuPont v. Griffin.*

In *American Cyanamid v. Aceto*, however, the cost-sharing award required the data owner to give the follow-on registrant the right to rely on the data to support, obtain and maintain state, local and federal approvals. As reasoned by the arbitrators, federal registration would be of reduced value if one of the parties could not rely on the data to obtain all state and local clearances needed for sales throughout the U.S.

Prior awards, however, have not required the data owner to grant access to the data for use in foreign countries.

In *Avecia v. Mareva*, the arbitrator ruled that "FIFRA … is an American statute designed … to satisfy EPA's requirements. FIFRA Arbitrators cannot begin to consider word-wide uses of the data, or requirements for purposes other than EPA registrations, without holding endless proceedings; and it is not clear how much jurisdiction we have to do so. Nothing in FIFRA seems to authorize Arbitrators to compel access to original data submitter's data for use outside the United States."

In *DowElanco v. Albaugh*, the panel found no basis for a discount for the inability to use the data in foreign countries.

To summarize, while the data owner sometimes is required to make its data available (short of providing hard copies) to the follow-on registrant to obtain regulatory clearance from U.S. states and municipalities, it probably will not have to make its data available for use outside of the U.S.

Future Compensation by Third Parties

Prior awards have sometimes required the data submitter to equally share with the follow-on registrant any future compensation payments received from third parties. This ensures not only that the original data submitter does not recover the same costs twice, but also that the follow-on registrant does not pay more than its share.

- In *Cheminova v. Griffin*, the data owner was required to equally share with the follow-on registrant any future data compensation payments it received from third parties.
- In *Microgen v. Lonza*, the follow-on registrant was granted the right to share equally in any data compensation paid by other registrants following the award. *Accord, Enviro-Chem v. Lilly* and *Amvac v. Termilind.*
- In *Avecia v. Mareva,* however, the award was discounted because the follow-on registrant did not have a right to any offsetting future compensation from other companies that might cite the same data.

A data owner, therefore, should be prepared to grant offset rights to the follow-on registrant or risk a reduced award.

Data Cost Enhancements

The trend in FIFRA arbitration awards has been to grant a risk premium or other enhancement on top of the direct and indirect costs. These cost add-ons typically take the form of a "risk premium," value for "early market entry," or "lost opportunity" costs.

The risk premiums awarded in prior cases typically have ranged from 5% to 25% of total compensable costs, with as much as 60% being awarded in one case.

- In *Proem v. Grapetek*, a "nominal" 5% risk premium was awarded where some risk was obviously involved, even though the original registrant did not offer any proof of risk.
- In *Avecia v. Mareva*, a "modest" 10% risk premium was awarded, rather than the 50% requested by the data submitter, where the arbitrator held there was insufficient information to measure the benefits of any risk avoidance.
- In *Cheminova v. Griffin*, a 10% risk premium was awarded, even though the chemical had a long history in the U.S. and was considered to be relatively safe. Even so, the arbitrators ruled that there was still no guarantee that EPA would accept the original registrant's studies or not demand additional data.
- In *Amvac v. Termilind*, a 25% risk premium was awarded because no one knew at the outset how much it would cost to satisfy EPA's requirements, whether those costs could be recouped from future sales, or whether the studies might reveal environmental or other problems that might cause EPA to restrict or prohibit the sale of the product.
- In *DowElanco v. Albaugh*, a 25% risk premium was awarded where the follow-on registrant bore none of the data submitter's risks, including the risk that the studies would not work or would be rejected by EPA, and that there might be administrative delays.
- In *Microgen v. Lonza*, a 60% risk premium was awarded where the data submitter was in relatively unchartered waters as far as EPA was concerned, it took six years for EPA to approve the data submitter's registration, and the data had more value after the tests were completed and accepted by EPA.

In these awards, a risk premium or other enhancement was considered consistent with FIFRA's goal of encouraging competition by preventing the follow-on registrant from taking advantage of the initial registrant's efforts without bearing the costs and risk of doing so. See *Microgen v. Lonza* (June 9, 1997).

Moreover, arbitrators have ruled that a risk premium ensures that follow-on registrants do not force initial registrants to accept less compensation simply to avoid the delay and costs inherent in FIFRA arbitration proceedings. A risk premium also acts to penalize the follow-on registrant who unreasonably delays settlement of data compensation disputes. *Id.*

The largest risk premium ever awarded in a data compensation case, on a percentage basis, resulted from arguments developed and briefed by a Wright & Sielaty attorney.

Risk Premiums Not Automatic

Although risk premiums and other enhancement are becoming relatively common, they are not automatic. Some arbitrators have refused to award compensation for any value that is not directly related to the costs of producing the data.

For example, one of the arbitrators in *Abbott v. Agtrol* concluded in a minority opinion that FIFRA does not authorize compensation for "elements other than the cost of producing the test data."

In *I.Pi.Ci. v. Albaugh* (July 15, 1991), a "reasonable and rational relationship" between the costs of generating the data and the compensation sought was required.

Other arbitrators have denied a risk premium or other enhancement because the evidence was insufficient or the calculations too speculative.

- In *Abbott v. Agtrol*, the majority opinion, while concluding that FIFRA does not preclude a risk premium or other enhancement, found that the data submitter "failed to sustain its burden of proof" on its early market entry value claim.

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- In *Enviro-Chem v. Lilly*, the data submitter failed to present any evidence that it would have been able to redirect its research and development efforts into other activities that would have proven fruitful in the highly speculative and uncertain world of pesticide development registration. The arbitrator ruled that although an original registrant faces risks that a me-too applicant avoids, it gets a head start in the market, allowing it to develop good customer relations and brand loyalty. This can be a significant advantage that in many circumstances fully compensates the original data submitter for the risk it undertook.
- In *Amvac v. Termilind*, the panel rejected the data submitter's claim for an early market entry premium because calculating any early market entry value was too speculative.

Arbitrators generally reject claims for lost opportunity costs. However, a data owner has a good chance to receive some type of enhancement to the award for risk or early market value, but only when supported by adequate evidence. Like most issues in data compensation, such add-ons are not automatic or guaranteed.

Task Force Agreements Not Uniformly Applied

In some awards, arbitrators have been guided by risk premiums used in DCI data generation task force agreements. Those premiums typically total 25% to 50% of the compensable costs. *See Amvac v. Termilind* (panel looked to other evidence in the record on the issue of risk – namely, task force agreements. Those agreements generally provide a "risk premium" payment of at least 25% … and that is the risk premium to which Claimant is entitled.")

The arbitrators in the two most recent data compensation cases, however, awarded a risk premium payment of only 10% -- significantly less than that used in task force agreements. *See Avecia v. Mareva* and *Cheminova v. Griffin*. In both cases, the arbitrators concluded that the rationale supporting a task force premium is distinct from any rationale supporting a data compensation premium.

Finding a 50% risk premium "excessive," the panel in *Cheminova* concluded:

> While the task force agreements are entitled to some weight, we conclude that there are also significant differences between the situations addressed in those agreements and the instant context. Task force agreements are written before costs have been incurred, by parties who have already agreed to share in those costs. Those parties have a strong incentive to set a steep penalty for late entrants, to encourage as many parties as possible to join the agreement early on. By contrast, the risk factor in the data compensation context is simply a means of compensating the original registrant after the fact for risks it has already borne, and is not a penalty for the follow-on registrant.
>
> Furthermore, [the data submitter] has already received significant compensation for the risks that it undertook in defending the … registration, by virtue of its exclusive access to the U.S. … market for nearly a decade. Under these circumstances … a 10% premium … is sufficient to compensate [the data submitter] for the business risks that it undertook.

The arbitrator in *Avecia* similarly concluded that "it was unclear if a risk premium of 50% in task force agreements is an inducement to sign on at the outset and, unlike in the instant context, the task force members receive equal rights to use the developed data."

Wright & Sielaty routinely works with clients that are involved in existing task forces, and assists companies in the formation of task forces to generate data required by an EPA data call-in. We also help manage task forces and, through ChemReg International, provide scientific support.

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Emerging Issues

Data compensation disputes need to be handled creatively. Unfortunately, many law firms and registrants are trapped by the same old arguments, such as *per capita* verses market share or risk premiums verses no premiums, without going further. We even have seen some attorneys routinely submit the same legal briefs, with the names of the parties simply changed, in case after case – even though the arguments have been routinely rejected.

In our experience, other emerging issues often are overlooked that can have much more impact on the outcome of a data compensation dispute. Time and again we see lawyers fighting costly philosophical battles over *per capita* verses market share, or risk premium verses no risk premium, and completely ignore other, more important factors because they fail to look at each case with fresh eyes.

Pending cases, some of which are being handled by Wright & Sielaty, have the potential to provide clarification on these emerging issues.

Who Paid for the Data?

One issue that commonly is overlooked is whether the data submitter actually paid for the underlying costs of the data. Not yet fully resolved in any prior arbitration award is whether, and to what degree, a data submitter is entitled to compensation for costs incurred by an affiliate, rather than itself.

Under FIFRA, the data submitter is the only party entitled to compensation. Within multinational companies, the U.S. affiliate typically is the data submitter. However, the U.S. affiliate often does not expressly pay for the data, but rather is given the data by its parent or some other related company.

The parent company, because it is not the data submitter (as that term is used in FIFRA), likely has no legal right to compensation.

If the cost of the data to the actual data submitter is zero, then arguably the data submitter is not entitled to any compensation. In such a case, what does it matter whether costs should be allocation on a market share or *per capita* basis? Likewise, if the risks associated with the data were borne by the parent company, rather than the affiliated data submitter, the traditional debates over risk premiums are less irrelevant.

Me-too applicants that ignore this issue do so at great risk. We have seen instances where me-too applicants agree to pay compensation without asking whether the data submitter actually paid for the studies. Instead, the me-too applicant simply assumes that all study costs were borne by the data submitter, and then overpays for the data.

Data owners who are given apparently free access to studies by parent companies also should take this issue into consideration. A mechanism should be adopted to quantify that they somehow paid for the data, possibly as a royalty or fixed component of the price paid for the technical grade active ingredient purchased from the parent company.

Such a solution, however, has risks. The argument that the data were paid for as part of the purchase price for the technical grade active ingredient could come back to haunt the original data submitter. If a me-too applicant also purchased product from the data submitter or its parent company (which is not uncommon), then the me-too applicant likewise can argue that it also paid for the data as part of the price it too paid for the product.

One case handled by a Wright & Sielaty attorney turned on this very point, and the client's data compensation obligations were offset by a portion of the price previously paid for products under the so-called "formulator's exemption."

What Is The U.S. Portion of the Data Costs?

Another issue often overlooked is whether the data submitter, or its affiliates, used the studies to satisfy regulatory requirements in other parts of

the world. If so, then the only costs that arguably should be compensable are the U.S. portion of the overall data costs.

In our experience, the *per capita* verses market share debate shrinks to insignificance if the focus can be shifted to how quantifying and apportioning the U.S. cost or value of the data as a subset of the worldwide cost of the data. Registrants should not simply assume that the full costs of the data are the same as the U.S. cost of the data.

One way to determine the U.S. portion of the total costs is to calculate the percentage of U.S. sales supported by the data as against the total worldwide sales supported by the data. In one of our cases where the issue was raised, however, the arbitrator was reluctant to force the parties to disclose actual sales data, and other methods were used to do the relevant calculations.

Each data compensation and cost-sharing dispute must be approached creatively and with fresh eyes. Although Wright & Sielaty represents both data owners and me-too registrants, our approach turns on the unique facts of each case. In addition, we avoid taking extreme positions that, in our experience, often cost clients more money in the long run by thwarting negotiations and resulting in adverse arbitration awards.

Often, Wright & Sielaty is able to force disputes to settle once these factors are raised. Nonetheless, this issue has not been squarely addressed in any published data compensation award.

Pre-Award Bonds

One other unresolved issue is whether a me-too applicant can be required to post a bond to cover any future data compensation award.

There have been two attempts by original data submitters to require the me-too applicant to post pre-award bonds. In both cases, arbitrators rejected those demands in ways that nonetheless left the issue open for consideration in other cases.

The FIFRA Arbitration Rules provide for posting a bond, but are unclear if pre-award bonds (as opposed to post-award bonds) are allowed:

> The decision shall contain a determination as to the compensation, if any respondent must pay to claimant, *or other remedy as appropriate*, the method of payment, *and may fix such other terms and conditions as may be reasonable under the circumstances, including the furnishing of a bond or other guarantee of payment by the respondent to the claimant.* (Emphasis added).

The rationale for pre-award bonds is that original data submitters should not be forced to pursue costly arbitration if the me-too registrant lacks the resources to pay any final award.

In the first case to consider this issue, the original data submitter unsuccessfully sought a bond to cover the full amount of its claim.

The second case was *Avecia v. Mareva*, with Wright & Sielaty representing Avecia. The proposed bond was to cover Avecia's transaction costs to pursue arbitration, to be applied against any final award. Avecia asked for a bond because of concern that Mareva lacked the resources to pay any final award. Avecia argued that Mareva unjustifiably forced Avecia to bear the cost of pursuing an arbitration award when it refused to settle the case.

In that arbitration proceeding, Avecia did not seek a bond until it was able to better estimate Mareva's financial wherewithal at the close of discovery. The arbitrator did not reject the principle of a pre-award bond, but was concerned that the request for the bond came late in the proceeding. As a result, he denied the request on procedural, rather than substantive, grounds.

Whether arbitrators in other cases will be more inclined to require pre-award bonds remains to be seen. Nonetheless, parties to data compensation arbitrations should expect that original data submitters routinely will be seeking such protection.

Conclusion

Pesticide data compensation and cost sharing issues are complex and must be carefully analyzed on the basis of FIFRA and the regulations, as well as past arbitration awards. Parties that understand these issues stand a better chance of achieving satisfactory data compensation and costing sharing outcomes – whether by negotiation or by arbitration.

For more information, or to discuss your specific data citation, compensation or cost sharing issues, please contact Cressy Stafford or Jim Wright at:

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