LITIGATION

Compensating Pesticide Innovators Under FIFRA

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"Premarket regulation of new products sets the pesticide industry apart from most other innovative industries, where no government approval is required prior to market entry."

Twice in two years the Supreme Court has upheld section 3(c)(1)(D)(ii) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)—the provision in the federal pesticide law that permits one company to rely on another company's research data to obtain "me-too" pesticide registrations in return for payment of compensation.[1] FIFRA does not provide a formula or standard for compensation. Instead, the statute leaves the determination of compensation to the discretion of private arbitrators. Under the statute as amended in 1978, neither the Environmental Protection Agency (EPA) nor the courts play any role in determining compensation. The only judicial review afforded is in cases of "fraud, misrepresentation, or other misconduct."

The key issue confronting data submitters and me-too registrants, therefore, is how to measure compensation.

Compensation and Innovation

In most cases, the data submitter is also the pesticide innovator. New product innovation is an important form of competition in the pesticide industry. To engage in this type of competition, a pesticide innovator must assume enormous risks. Typically, the innovator pours tens of millions of dollars and years of effort into a research and development (R&D) program with the hope of eventually developing a few successful new products. The innovator's financial stake grows as R&D proceeds through synthesis and screening, biological and field testing, process engineering and formulations research, toxicology and other EPA-required testing, and scaleup and market planning. At any point, a project may have to be abandoned for any number of reasons. Overnight, the innovator's potential winner can become a big loser.

The pesticide innovator must not only assun the risks of R&D, but must also bear the su stantial costs involved in obtaining EPA registr tions before marketing a new pesticide. Pr market regulation of new products sets th pesticide industry apart from most other i novative industries, such as the electronics computer industries, where no governme approval is required prior to market entr

The most obvious costs of premarket regul tion are the pesticide innovator's out-of-pock expenses (both direct and indirect) for conduc ing EPA-required registration tests. In adc tion, the innovator bears other costs relate to obtaining registrations. It takes time—fo or five years or longer—to conduct EPA-require tests and to obtain EPA review and approv for a new active ingredient. Were it not f time delays resulting from premarket regul tion, the innovator could be selling its ne pesticide and earning profits sooner. Thu premarket regulatory delays result in lost prc its (and shortened patent lives). Moreover, prc its are lost not only when initial registratic is sought for a new active ingredient, but al when other EPA premarket actions are require —such as registering new formulations or ne uses. These lost profits are the "opportuni costs" of premarket regulation borne by inn vators in the pesticide industry.

The pesticide innovator's burden is quite di ferent from that of the pesticide imitator—th "me-too" registrant. By using the innovato data, the me-too registrant avoids the ve same risks and costs that the innovator ha to incur in bringing a product to marke Specifically, by imitating a well-establishe previously registered pesticide, the me-too regi

[1] *Ruckelshaus* v. *Monsanto Co.*, 467 U.S. ____, 104 S. C 2862 (1984), and *Thomas* v. *Union Carbide Agricultu Products Co.*, 473 U.S. ____, 105 S. Ct. 3325 (198

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trant avoids the risks of shepherding a product through the R&D process. Furthermore, by using the innovator's data, the me-too registrant avoids the expense and time of conducting EPA-required tests and awaiting EPA review and approval.

This disparity produces an economic distortion in the marketplace: both the innovator and the me-too registrant are selling exactly the same product, but the me-too registrant has used the innovator's data to avoid the substantial risks and costs that the innovator had to incur in introducing the product. If left uncorrected, this economic distortion could reduce the innovator's incentives for engaging in pesticide R&D. Most economists agree that incentives must be maintained if companies are to continue engaging in high-stakes R&D. This is especially true in the pesticide industry, where the risks of R&D are so high and the costs of premarket regulation are so great.

Compensation for use of the innovator's data can help correct this distortion by offsetting some of the risks and costs the innovator incurred—and the me-too registrant avoided—prior to marketing their products. Compensation can strike an economic balance between the innovator and the me-too registrant and thereby maintain incentives for R&D. This is not merely the economic function that compensation can serve—it is the *very purpose* that Congress intended compensation to serve.

At least two methods of calculating compensation are consistent with this economic function and legislative goal. One approach is based on the value received by the me-too registrant from use of the innovator's data. The other is based on the true costs incurred by the innovator in generating the data. Because these approaches actually represent two sides of the same coin, the landmark decision in the only arbitration completed to date under section 3(c)(1)(D)(ii) [*Stauffer Chemical Co.* v. *PPG Industries, Inc.*, AAA Docket No. 16-199-077-82 (June 29, 1983)] can be interpreted either way.

In that proceeding, a panel of three arbitrators considered extensive testimony and evidence relating to the innovator's costs and the value received by the me-too registrant from using the innovator's data to obtain me-too registrations for a competing product. The result was a compensation award representing half the testing costs avoided by the me-too registrant (approximately $1.5 million), and a 10-year running royalty based on 50 percent of the me-too registrant's expected profits from the first five years of sales. (Despite the binding nature of FIFRA arbitration awards and the statute's express preclusion of judicial review, the me-too registrant immediately "appealed" the arbitrators' decision to federal district court on the theory that the arbitrators engaged in "misconduct" by failing to apply the "proper" compensation standard and awarding too much. The case is still pending.)

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Value Approach

The starting point for the value approach to calculating compensation is the fact that the me-too registrant usually receives a substantial economic benefit by using the innovator's data to avoid the costs of generating its own data.

First, by using the innovator's data, the me-too registrant avoids the considerable out-of-pocket expenses of conducting its own tests to satisfy EPA's preregistration data requirements. EPA-required tests, which include toxicology, environmental fate, residue chemistry, product chemistry, fish and wildlife, and field performance, can cost millions of dollars. By saving this substantial expense, the me-too registrant can increase its profits dollar-for-dollar.

Second, the me-too registrant also avoids the time it would take to generate a registration data package and obtain EPA review and approval. By using the innovator's data, the me-too registrant can obtain a registration, enter the market, and begin earning profits four to five years earlier than if it had taken the time to conduct its own testing. The profits on sales that the me-too registrant earns during this "early entry period" are profits that could not have been earned at all had the me-too registrant spent those years conducting tests rather than selling the pesticide.

In addition, at the end of the early entry period, the me-too registrant is four to five years further up the marketing curve than it would have been were it just entering the market after completing its own testing program. Thus, the me-too registrant not only earns "early entry profits" during those first years of sales, but earns extra profits in subsequent years as a result of the added market

"Value compensation... is sensitive to the pesticide's future market potential...."

momentum from the four to five-year head start.

In short, there are three types of profits that the me-too registrant can earn by using the innovator's data that could not have been earned had the me-too registrant conducted its own preregistration testing: (1) profits from avoiding the cost of preregistration research; (2) early entry profits; and (3) extra profits from added market momentum. These profits represent the value received by the me-too registrant from use of the innovator's data. Basing compensation on a share of these profits—that is, returning to the innovator a share of the value received by the me-too registrant from use of the innovator's data—corrects the economic distortion created by FIFRA's use of data provision, and strikes a balance between the data submitter and the me-too registrant. From an economic viewpoint, returning to the innovator a share of the value of its data helps offset the opportunity costs of generating the data that the innovator otherwise would have had to bear alone, notwithstanding the use of its data by a competitor.

From the perspective of the me-too registrant, payment of value-based compensation represents an investment with an attractive rate of return. In calculating compensation based on value, the me-too registrant's future profits must be discounted to present value, recognizing that a dollar in hand today is worth more than a dollar in hand tomorrow.

As long as the me-too registrant meets or exceeds the profit projections on which its value-based compensation payment is based, the me-too registrant comes out ahead. The higher the discount rate used in calculating compensation, the higher the me-too registrant's return on investment in using the innovator's data. No matter how substantial the value-based compensation may be, it cannot legitimately be regarded as a "market entry barrier" if the me-too registrant is going to come out ahead by paying the compensation and earning more than would have been earned had the me-too registrant incurred the time and expense of generating its own data.

Cost-Sharing Approach

Another approach to calculating compensation is based on the historical costs incurred by the innovator in generating the data, rather than on the value received by the me-too registrant from using the data. This is commonly called "cost-sharing."

In many situations, basing compensation on a share of the innovator's historical costs can provide a viable alternative to the value approach—as long as *all* the innovator's true costs are taken into account and shared. The most obvious category of costs that should be shared are the innovator's out-of-pocket expenses for conducting tests and generating the data relied on by the me-too registrant. Compensation should encompass the costs of all relevant studies. Innovators should be wary of artifices to "screen out" compensable studies or otherwise narrow the spectrum of compensable costs that should be taken into account in formulating a compensation award. As discussed, the innovator's costs also can include lost profits from regulatory delays in obtaining EPA approvals. These lost profits are as much a cost of generating the data as the cost of paying for the tests.

For products where the innovator's costs were high and future market potential remains bright, basing compensation on the innovator's true historical costs can approximate compensation based on the value received by the me-too registrant. Historical cost-sharing, however, may not be equitable in other circumstances. For example, consider an older product with a limited or declining market potential. If the innovator's costs were high, sharing historical costs could produce higher compensation than basing compensation on value. In other words, the me-too registrant may have to pay more than what use of the data is worth. Value compensation, on the other hand, is sensitive to the pesticide's future market potential because it is based on the actual value of using the data. Under the value approach, the me-too registrant's compensation payment is limited to a share of what the registrant reasonably can expect to earn from use of the data.

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Undoubtedly, there are other possible approaches to calculating compensation. As more data compensation disputes are arbitrated and decided, additional guidance will become available to data submitters and me-too registrants on how much compensation they can expect to receive or expect to pay.