IN THE CIRCUIT COURT OF THE THIRD JUDICIAL CIRCUIT
MADISON COUNTY, ILLINOIS

HOLIDAY SHORES SANITARY DISTRICT, Individually and on behalf of all others similarly situated,	)	
Plaintiff,	)	
v.	)	Case No. 2004-L-000710
SYNGENTA CROP PROTECTION, LLC, f/n/a SYNGENTA CROP PROTECTION, Inc., and GROWMARK, INC.,	)	
Defendants.	)	

DEFENDANT SYNGENTA CROP PROTECTION, LLC'S MEMORANDUM OF LAW IN RESPONSE TO PLAINTIFFS' BRIEF RE PRIVILEGE LOG ISSUES: FIFRA DATA COMPENSATION-RELATED MATERIALS

COMES NOW Syngenta Crop Protection, LLC ("Syngenta"), by and through its attorneys, and for its Memorandum of Law in Response to Plaintiffs' Brief re Privilege Log Issues states as follows with respect to the materials Syngenta has designated as Data Compensation Materials and sought clawback or withheld as privileged:

As discussed below, the Data Compensation Materials consist of materials prepared and exchanged in data compensation negotiations, settlements, and arbitrations under the Federal Insecticide, Rodenticide, and Fungicide Act, 7 U.S.C. § 136 et seq. ("FIFRA"), which are highly sensitive, trade secret information that is entitled to a high degree of confidentiality and protection under both FIFRA and general law and is protected by confidentiality agreements, protective orders, and settlement confidentiality. Data compensation proceedings themselves, except for limited materials, such as decisions that are made public in redacted form on a case-by-case basis, are likewise private and confidential. Moreover, most of these materials concern

only Syngenta's intellectual property rights under the unique and complex FIFRA data compensation provisions and are thus wholly irrelevant to Plaintiffs' claims.

As discussed below, the only Data Compensation Materials that are even potentially relevant to Plaintiffs' claims are the scientific study reports that Syngenta has submitted to EPA to support the registration of atrazine products under FIFRA. While Syngenta is willing to make available these study reports for Plaintiffs' review, consistent with FIFRA's protections and in order to protect Syngenta's data compensation rights and to prevent unauthorized use of the reports in foreign jurisdictions, the study reports must be reviewed under carefully controlled circumstances and the study reports themselves must not be publicly released or disclosed.

Accordingly, as set forth below, Syngenta seeks return of such materials inadvertently produced, firmly resists production of all Data Compensation Materials other than study reports, which would be made available under the terms set forth below, and properly declines to produce any such information other than any redacted decisions that have already been made public.

A. Background Regarding FIFRA Data Compensation Rights and Arbitrations.

FIFRA establishes a "mandatory data-licensing scheme" which allows persons seeking to obtain or expand pesticide registrations under FIFRA to unilaterally cite and rely on data submitted by others to EPA without permission of the original data submitter, in exchange for a binding offer to pay compensation to the data submitter. *See Ruckelshaus v. Monsanto*, 467 U.S. 986, 992, 994 (1984); FIFRA § 3(c)(1)(F)(iii), 7 U.S.C. § 136a(c)(1)(F)(iii). This scheme recognizes the data submitters' intellectual property rights in their data and the need to protect incentives for pesticide development and research. It does so by requiring persons who rely on others' data ("data citers") to obtain their own pesticide registrations to compensate the data submitter for the data citers' reliance on the data.

The framework for determining the scope of data relied on and resolving the amount of compensation owed for that reliance is set forth in a complex set of statutory and regulatory provisions. *See* FIFRA § 3(c)(1)(F) & (c)(2)(B), 7 U.S.C. § 136a(c)(1)(F) & (c)(2)(B); 40 C.F.R. 152 Subpart E. Among other things, these provisions establish: (1) a 10-year exclusive use period after the first registration of a product, which can be extended for certain reasons and during which data cannot be cited without authorization of the data submitter; (2) establish a 15-year compensability period from the date of submission for data that fall outside the exclusive use period; (3) allow data citers to choose between a broad "cite-all" or a targeted "selective" method of identifying the data on which they are relying; and (4) set forth standards and procedures for determining the scope of the data relied on and the amount of compensation owed. *Id.*

Applicants must submit offers to pay to all data submitters on whose data they are relying at the time of application for registration. FIFRA § 3(c)(1)(F)(iii). If the parties cannot reach agreement on the amount of compensation owed, pursuant to FIFRA, either party may initiate a binding arbitration process to resolve the data citer's compensation obligations. FIFRA § 3(c)(1)(F)(iii) & (c)(2)(B); *Cheminova A/S v. Griffin L.L.C.*, 182 F. Supp. 2d 68, 72-73 (D.D.C. 2002). The administration of data compensation arbitrations has been delegated to a private service provider, the American Arbitration Association, and FIFRA data compensation arbitrations proceed under the FIFRA Arbitration Rules, which are binding on the participants. *See* 29 C.F.R. § 1440.1 and Appendix; *Cheminova*, 182 F. Supp. 2d at 77.

Syngenta routinely receives offers to pay from pesticide applicants and registrants who wish to rely on data submitted by Syngenta to EPA in support of their own registrations. McFarland Aff. ¶ 8. Syngenta carefully protects its data compensation rights and vigorously

pursues the compensation it is owed under FIFRA from competitors who rely on Syngenta's data to support registrations for their own competing products. *Id.* ¶ 9. Syngenta typically enters into confidential negotiations with data citers in an effort to resolve their compensation obligations and, if necessary, pursues its compensation rights through confidential data compensation arbitrations. *Id.* ¶ 10.

B. Study Reports Must Not Be Produced Without Strict Limitations To Prevent Public Dissemination And Unauthorized Use.

In support of applications for new pesticide product registrations or to maintain or expand existing registrations, applicants submit detailed study reports to EPA that describe the study design, work conducted, and the data and results obtained for each study. FIFRA allows data citers to cite previously submitted studies in exchange for an offer to pay compensation, but data citers are not entitled to receive copies of the study reports and are not required to submit them with their applications. *See* FIFRA § 3(c)(1)(F)(iii); 40 C.F.R. 152.93 ("An applicant may demonstrate compliance for a data requirement by citing a valid study previously submitted to the Agency. The study is not to be submitted to the Agency with the application.").

In order to protect data submitters' proprietary interests in their studies and preserve their rights to data compensation, study reports submitted to EPA are not published by the submitters or EPA. If a study is published, it could be cited freely by subsequent applicants without compensation. *See* FIFRA § 3(c)(1)(F) (allowing pesticide applicants to freely cite studies "in the public literature"); 40 C.F.R. 152.94 ("An applicant may demonstrate compliance for a data requirement by citing, and submitting to the Agency, . . . [a] valid study from the public literature."). Moreover, copies of unpublished proprietary studies could be submitted and used by competitors to obtain regulatory approvals for pesticide products in jurisdictions outside the United States, without compensation to the data submitters for the use of their data.

FIFRA's disclosure provisions balance the public interest in the study reports submitted by registrants on which EPA bases its registrant decision and the need to restrict access to such studies to protect the data submitter's right to compensation, to avoid disclosure of confidential business information, and to prevent unauthorized use in other jurisdictions. FIFRA allows for public access to the study reports, but the review is carefully limited and controlled to ensure that the data submitters' data compensation rights are not extinguished and to ensure that competitors cannot gain access to proprietary studies developed and submitted by U.S. companies to support their competing products in other countries.

FIFRA § 10(d) provides that study reports submitted to EPA "shall be made available for disclosure to the public," except for information regarding manufacturing and quality control processes and information regarding the identity of or methods for testing, detecting, or measuring any inert ingredients added to the product, which can only be disclosed where necessary in certain circumstances. FIFRA § 10(d), 7 U.S.C. § 136h(d). However, the study reports are not publicly posted by EPA and access to copies of the study reports is strictly limited and tracked. EPA must ensure that it does not disclose study reports to "any employee or agent of any business or entity engaged in the production, sale, or distribution of pesticides in countries other than the United States or in addition to the United States or to any other person who intends to deliver such data to such foreign or multinational business or entity unless the applicant or registrant has consented to such disclosure." FIFRA § 10(g)(1).

Before making study reports available for review, EPA is required to obtain an "affirmation from any person who intends to inspect data that such person does not seek access to the data for purposes of delivering it or offering it to sale . . . and will not purposefully deliver or negligently cause the data to be delivered to such business or entity or its agents or

employees." *Id.* False statements made in such affirmations are expressly subject to criminal prosecution as false statements under 18 U.S.C. § 1001. *Id.* at (g)(3). EPA must also maintain records of all persons to whom data are disclosed and their affiliation and provide that information to the data submitter. *Id.* at (g)(2).

For the same reasons, access to the study reports is tightly controlled and limited in the context of FIFRA data compensation arbitrations. Study reports are typically made available by the data submitter only for inspection as proof of the work conducted, costs incurred, and relevance to the data citer's application, and protective orders or confidentiality agreements strictly limit the access to the study reports to certain individuals. Paper or electronic copies of the studies are generally not provided unless presented at an evidentiary hearing, and if so provided, copies are strictly limited and controlled and must be returned or destroyed at the end of the arbitration. The atrazine study reports included in the Data Compensation Materials have been made available for review by Syngenta to opposing parties in data compensation arbitrations, but only under strict protective orders which limited access to narrowly defined individuals and did not permit the individual reviewing the materials to retain or disseminate copies. McFarland Aff. ¶12.

Unlike other Data Compensation Materials, the atrazine study reports contain scientific information that may be relevant to Plaintiffs' claims. Therefore, Syngenta is willing to allow carefully controlled and limited access to its atrazine studies, and stands ready to negotiate with Plaintiffs regarding an appropriate protective order regarding such review. Among other things, the study reports should be made available for review only by appropriate designated individuals, and Plaintiffs must be required not to release or allow the study reports to become generally available. To protect Syngenta's data compensation rights and to avoid substantial competitive

harm, it is critical that copies of the study reports do not become generally available and are not widely disseminated or posted on the Internet, for example. McFarland Aff. ¶13. For all of these reasons, Syngenta continues to demand that Plaintiffs immediately return the copies of the study reports that were inadvertently produced by Syngenta under Paragraph 13 of the *Holiday Shores* Protective Order. Syngenta will make the study reports available to Plaintiffs for inspection in a manner that strictly controls access to the study reports, prohibits their dissemination, and protects against their public disclosure at trial or otherwise.

C. There Are Strong Arguments Against The Disclosure Of Data Compensation Materials Other Than Study Reports.

Unlike the study reports, however, the rest of confidential Data Compensation Materials should not be produced or disclosed in any fashion. They are not only highly confidential, they concern compensation owed to Syngenta for others' reliance on Syngenta's data to obtain pesticide registrations under FIFRA, an issue which is utterly irrelevant to Plaintiffs' claims.

1. Data Compensation Materials Exchanged In The Course Of Compensation Negotiations Are Kept Strictly Confidential.

FIFRA contemplates that after the offer to pay is issued the parties will enter into negotiations to try to reach agreement on the amount of data compensation owed. FIFRA § 3(c)(1)(F)(iii), 7 U.S.C. 136a(c)(1)(F)(iii). To facilitate these discussions, and in the course of the arbitration proceedings that follow if necessary, the parties exchange information relevant to the compensability and costs of the studies relied on and the calculation and allocation of those costs to the data citer. These Data Compensation Materials consist of highly confidential, proprietary, and competitively sensitive information that are kept strictly confidential and whose public disclosure would cause significant competitive injury to either or both parties.

The costs incurred by the data submitter and assigned to each study in the claim are proprietary information that is not publicly disclosed. McFarland Aff. ¶ 15. The documentation provided in support of these study costs typically involves private contracts and prices for work performed by external laboratories as well as highly sensitive information regarding the costs of internal research efforts, such as detailed hourly cost figures and other accounting information and the wages and benefits of employees who conducted the work. *Id.* ¶ 16. Moreover, because data citers typically argue that compensation should be adjusted to reflect the parties' current or projected data submitters' past profits, data compensation materials sometimes include competitive information such as past and projected sales revenues, profits, business plans, product roll-out plans, and the like from one or both parties. *Id.* ¶ 17. In addition, in order to determine how many parties to count as sharers in the allocation of data costs, the nature of private business agreements and arrangements between suppliers, distributors, and other partnering companies sometimes is disclosed. *Id.* ¶18. All of this information is highly sensitive, competitive business information that, if made public, could be used by competitors of both the data citer and the data owner for their own competitive advantage.

The need to protect this type of confidential business information and shield it from disclosure is well-recognized under FIFRA and the general law. For example, FIFRA's disclosure provisions provide that EPA "shall not make public information which . . . contains or relates to trade secrets or commercial financial information obtained from a person" except in very limited circumstances. FIFRA § 10(b); 7 U.S.C. § 136h(b). Federal officers and employees who knowingly and willfully disclose confidential business information protected under FIFRA § 10(b) are subject to prosecution and substantial penalties, including imprisonment. The Freedom of Information Act likewise exempts from disclosure "trade secrets and commercial or

financial information" that are "obtained from a person and privileged or confidential." 5 U.S.C. § 552 (b)(4).

Consistent with the highly sensitive and confidential nature of the information involved, Syngenta and other companies execute confidentiality agreements before exchanging confidential data compensation information. McFarland Aff. ¶ 19. These agreements prohibit the use of such information for any other purpose than the determining the scope of the data citer's compensation obligations, prohibit disclosure to third parties, limit the individuals (within each party or serving as experts to the parties) to whom the information may be disclosed, and require the return of confidential materials at the request of the party providing the information. *Id.* ¶20. Such confidentiality agreements were entered into and continue to protect the Data Compensation Materials that Syngenta disclosed and received in negotiating atrazine data compensation issues. *Id.* ¶ 21.

Data Compensation Materials concern the data submitters' intellectual property rights in their proprietary data and the compensation owed by data citers for their reliance on such data. Other than the study reports, they have no relevance whatsoever to the merits of Plaintiffs' claims. Requiring Syngenta to produce irrelevant Data Compensation Materials concerning atrazine would needlessly jeopardize substantial confidentiality interests and could result in substantial competitive business injuries to Syngenta and third parties. In addition, the production of any materials that were provided to Syngenta by other parties would violate the terms of applicable confidentiality agreements forbidding use of the information for other purposes and disclosure to third parties.

2. Settlement Discussions and Agreements Regarding Data Compensation Are Likewise Strictly Confidential.

Most data compensation disputes are resolved through a private settlement agreement reached by the data submitter and the data citer. McFarland Aff. ¶ 22. It is axiomatic that settlement discussions and the terms of settlement agreements should remain confidential and are inadmissible as a matter of public policy, in order to encourage the negotiated resolution of disputes by eliminating concerns that a settlement compromise or other settlement information might be disclosed and used against a party. *See, e.g.,* Fed. R. Evid. 408 advisory committee's note; R.Evid. 408. Data compensation settlement discussions, correspondence, and agreements are kept strictly confidential to ensure that parties are free to negotiate and reach settlements resolving data compensation disputes without fear that statements made, information disclosed, or agreements reached will be disclosed and used against them in subsequent data compensation proceedings or for other purposes. McFarland Aff. ¶23. Requiring Syngenta to disclose materials related to confidential settlement discussions and confidential agreements would be counter to the strong public policy in favor of settlement confidentiality and would violate express confidentiality provisions in confidentiality agreements governing settlement discussions and the settlement agreements themselves.

3. Data Compensation Arbitrations Are Private, Confidential Proceedings.

As noted above, if the parties are unable to reach an agreement on compensation, the dispute will proceed to an arbitration proceeding administered by the American Arbitration Association (as delegated by the Federal Mediation and Conciliation Service) and conducted under the FIFRA Arbitration Rules. FIFRA § 3(c)(1)(F)(iii) & (c)(2)(B); 7 U.S.C. § 136a(c)(1)(F)(iii) & (c)(2)(B); 29 C.F.R. § 1440.1 and App.

Unlike court or administrative proceedings, arbitrations are inherently private. *See, e.g., Hutchings v. United States Indus., Inc.*, 428 F.2d 303, 312 (5th Cir. 1970) ("The arbitration process is a private one."); Robert M. Rodman, *Commercial Arbitration* § 1.2, at 4 (West's Handbook Series 1984) (same); Martin Domke, *Domke on Commercial Arbitration* § 5:4 (Gabriel Wilner, ed., rev. ed. 2003) ("All significant aspects of an arbitration proceeding must be treated by the arbitrator as confidential unless this requirement is waived by both parties or disclosure is required or permitted by law.").[1] Congress, by providing that FIFRA data compensation disputes be resolved through arbitration, indicated its intent that FIFRA proceedings be private and confidential, consistent with other types of arbitration. *See, e.g., Cheminova A/S v. Griffin L.L.C.*, 182 F. Supp. 2d 68, 74 (D.D.C. 2002) ("This Court must assume that, absent a plain indication to the contrary, Congress intended the FIFRA arbitration scheme to fit within existing arbitration law.") The confidentiality of these proceedings promotes the efficient resolution of data compensation disputes by assuring the parties that materials exchanged and statements made in an arbitration will not be used against them for other purposes or in subsequent data compensation disputes or arbitrations.

The confidentiality of FIFRA arbitration proceedings is reflected in the FIFRA Arbitration Rules and the protective orders that are issued pursuant to those rules. The Rules require arbitrators to "make such orders as required to protect the secrecy of confidential information or documents" and to "impose a sanction against any party who violates such orders." FIFRA Arbitration Rules, 29 C.F.R. § 1440 Appendix, Rule 20. Protective orders entered in FIFRA arbitrations routinely protect filings, discovery requests and disclosures,

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[1] *See also* 2004 Code of Ethics for Arbitrators in Commercial Disputes, Canon VI.B (Mar. 1, 2004) (providing that all arbitrators "should keep confidential all matters relating to the arbitration proceedings and decision").

motions, and hearing testimony as confidential information that may not be disclosed outside the arbitration or used for other purposes, with additional protections for materials designated as "highly confidential" or "restricted." Such protective orders were entered into and continue to protect the confidentiality of the atrazine data compensation arbitrations Syngenta has been involved in.

Unlike a court or administrative proceeding, data compensation arbitrations are not open proceedings and only persons who have a "direct interest in the hearing" may attend FIFRA arbitration hearings. *Id.*, Rule 18. Hearing testimony, including written testimony submitted in advance of a hearing, is confidential and not made public outside or disclosed outside of the arbitration proceeding. Many data compensation decisions and awards remain private and confidential, while others are publicly disclosed in a redacted form that protects the confidential information of the parties. Even where data compensation awards are made public, the underlying arbitration materials, documents, and testimony are not.

The data compensation arbitrations Syngenta has entered into with respect to atrazine were and remain confidential proceedings, and are governed by protective orders that ensure their confidentiality. McFarland Aff. ¶ 24. The materials that have been made public from these proceedings are redacted, public versions of the arbitrators' awards, which are irrelevant to Plaintiffs' claims but which Syngenta is nonetheless willing to produce. *Id.* ¶ 25.;

Requiring Syngenta to disclose confidential and protected arbitration documents, filings, or testimony would make public FIFRA arbitration proceedings that Congress determined should be private, would violate the terms of protective orders that are binding on Syngenta, and would thwart the vital confidentiality interests and expectations of Syngenta and other arbitration participants. Syngenta will therefore not disclose Data Compensation Materials related to

FIFRA arbitration proceedings, other than the redacted versions of any arbitration awards involving atrazine that have already been made public under the specific protective order covering each arbitration

4. The Protective Order Entered in the *Holiday Shores* Action Does Not Compel Or Justify Production Of Data Compensation Materials.

The August 31, 2009 Protective Order in this action provides for confidential treatment of "Trade Secret" information, including "information, documents, or materials not in the public domain that are so proprietary or competitively sensitive that their public disclosure is very likely to cause competitive injury." August 31, 2009 Protective Order ¶ 3. As discussed above, all of the Data Compensation Materials meet this standard and, if produced, would be subject to the terms of the protective order. However, the existence of the Protective Order does not eliminate Syngenta's confidentiality concerns or compel production of Data Compensation Materials.

First, where confidential or trade secret information is requested, the burden is on the requesting party to show that the information is "sufficiently relevant and necessary to his case to outweigh the harm disclosure would cause to the person from whom he is seeking information." *Int'l Truck & Engine Corp. v. Caterpillar, Inc.*, 351 Ill. App. 3d 576, 581 (Ill. App. Ct. 2d Dist. 2004), citing *Greater Rockford Energy & Technology Corp. v. Shell Oil Co.*, 138 F.R.D. 530 (C.D. Ill. 1991). Second, courts have consistently recognized that protective orders are not a cure-all and that "[t]here is a constant danger inherent in disclosure of confidential information pursuant to a protective order." *Litton Indus., Inc. v. C&O Ry. Co.*, 129 F.R.D. 528, 531 (E.D. Wis. 1990). Thus, the party requesting disclosure "must make a strong showing of need." *Id.* Third, the protective orders are insufficient to protect the Data Compensation Materials since, among other things, they allow disclosure to any deponents in preparation for deposition and do not govern the use of Confidential Information at trial. *See* August 31, 2009 *Holiday Shores*

Protective Order at ¶¶ 6, 18. Finally, Plaintiffs have even failed to honor Defendant's clawback requests pursuant to the Protective Order so they should not be able to assert it as an offensive weapon under the circumstance present here.

As discussed above, the Data Compensation Materials consist of highly confidential, non-public information that, except for the scientific study reports, relate solely to Syngenta's intellectual property rights in data it has developed and submitted and the compensation owed by others who cite that data pursuant to FIFRA's complex data citation and compensation provisions. Any Syngenta information contained in the materials that is arguably relevant to Plaintiffs' claims should be requested directly from Syngenta rather than indirectly through the disclosure of these highly confidential and almost wholly irrelevant Data Compensation Materials. The Data Compensation Materials are therefore neither relevant nor necessary to Plaintiffs' claims and case. Moreover, the harm that would be caused by disclosure of Data Compensation Materials is significant, including disclosure of highly sensitive competitive information such as confidential sales, profits, and business plans, the elimination of valuable rights to data compensation, the exposure of private settlement discussions and negotiations, the violation of confidentiality agreements and protective orders, and the reversal of Congress's intent to maintain FIFRA data compensation arbitrations as private proceedings.

Based on the foregoing reasons and authorities, Syngenta Crop Protection, LLC respectfully requests that this Court: (a) sustain Syngenta's assertions of FIFRA protection, privilege, confidentiality and privacy with respect to any of its Data Compensation Materials, other than the study reports, on the basis that these are all highly confidential materials and Plaintiffs cannot meet their burden of showing that their relevance and Plaintiffs' need for them outweighs the substantial harm their disclosure could cause; and (b) provide a schedule pursuant

to which Syngenta and Plaintiffs are to confer and present a proposed Protective Order to govern the review of the atrazine study reports; and grant such other and further relief the Court deems just and proper.

DATE: June 20th, 2011

Respectfully submitted,
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CERTIFICATE OF SERVICE

The undersigned hereby certifies that on the 20th day of June, 2011, I caused to be served the attached via **hand delivery**, upon the following counsel:

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