BEFORE THE DIRECTOR OF THE
DEPARTMENT OF PESTICIDE REGULATION
STATE OF CALIFORNIA

In the Matter of the Registration of
Borathor Max PT, Reg. No. 81824-11-AA
Request for Determination and Cancellation

DIRECTOR'S DETERMINATION
Docket No. D-09-001

Nisus Corporation, Data Owner
100 Nisus Drive
Rockford, Tennessee 37853

Ensystex II, Registrant
2713 Breezewood Avenue
Fayetteville, North Carolina 28303

Statutory Framework

Food and Agricultural Code (FAC) section 12811.5 requires a pesticide registration applicant to offer to pay, and to pay, a share of the cost of data previously submitted by another registrant of a similar product in specified situations. The applicant must share in the cost of data already submitted to the Department to support the previous registration of a similar product when: (1) the data is required to support the registration of the applicant's product and the applicant does not submit its own data to obtain or support registration; (2) the applicant does not have written permission from the owner of data to rely upon the data to support the applicant's product registration; and (3) the applicant is not a party to an arbitration award, data compensation or data cost-sharing agreement in connection with the federal registration of the applicant's product that covers use of the data to support California registration. If the data was submitted to the Department of Pesticide Regulation (Department) before August 2005, there is no obligation under the statute to pay for data first submitted by the data owner to the U.S. Environmental Protection Agency (U.S. EPA) or the Department more than 15 years prior to the date of the applicant's California registration.[1]

The statute provides that the data owner may seek to enforce the cost-sharing obligation of the applicant by bringing an action in any California court of competent jurisdiction or by seeking a determination by the Director that the applicant did not satisfy its obligation and cancellation of the applicant's product. Subsections (d) through (g) of FAC section 12811.5 establishes the process, requirements, and limitations that govern a claim for cost-sharing and the administrative remedy for a failure to comply. The statute sets out a series of sequential steps that must be followed, and allows the diversion of the process to the Director only if there is a refusal by the applicant to proceed to the next step. The process begins with the applicant identifying the owner of the data that support its registration and making an offer to pay. If the

[1] Although not required to support the Director's determination in this case, in the interest of facilitating further negotiations between the parties, it is noted that the Director does not agree with the Nisus position that cost-sharing is required if the time period between the registration of the applicant's product and the submission of the data to *either* the Department or U.S. EPA is less than 15 years. The proper interpretation is that there is no requirement for data compensation as long as the time period between the applicant's registration and the submission of data is longer than 15 years to one or the other of the named agencies.

applicant cannot identify the owner of the data, the data owner must inform the applicant that it owns the data relied upon within 12 months of the registration of the applicant's product or the obligation is absolved. Negotiation over the amount of cost that must be shared can continue as long as the parties are willing, but at any time after 90 days either party may initiate a binding arbitration proceeding to resolve the issue. The Director only has authority to find that the applicant has failed to meet its obligation under the statute if it fails to make an irrevocable offer to pay, fails or refuses to participate in a proceeding to reach an agreement, or fails to comply with an order or to pay an award resulting from the proceeding. If the Director determines that an applicant did not meet these obligations under the statute, the director cancels the registration of the applicant. See FAC section 12811.5(f).

Factual and Procedural Background

On March 3, 2008, Ensystex II, Inc. (Ensystex) submitted an application to U.S. EPA to register Borathor Max PT (Borathor) and identified the studies supporting its application, specifically listing those studies that it owned, those studies that were too old to require the payment of compensation, and those that belonged to Nisus. Prior to submission of this application, Ensystex sent a letter dated February 20, 2008 making an offer to pay Nisus for citation to its data to support the federal registration of Borathor. In the federal application, Ensystex identified six studies and offered and agreed to pay compensation as required under the applicable federal law, the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). Subsequent to this application, the parties entered into negotiations over data compensation under the federal statutory scheme, apparently commencing with a letter from Nisus to Ensystex dated April 29, 2008, responding to the Ensystex offer to pay, in which Nisus indicated that it required that a non-disclosure agreement governing settlement discussions be entered into before the it would agree to provide and explain the method it used to arrive at a compensation amount.

The potential for compensation for use of the data to support a possible California registration was specifically raised in a Nisus letter to Ensystex on September 24, 2008. Ensystex's Borathor Max PT product was registered in California on December 8, 2008. Ensystex claims, and it was not disputed by Nisus, that after substantial negotiations, it sent Nisus counsel the final executed version of the nondisclosure agreement on October 14, 2009 that would allow the parties to proceed with substantive negotiations. The petition submitted to the Director by Nisus seeking cancellation of Borathor was dated December 11, 2009 and was sent simultaneously to Ensystex. There is no evidence in the record that Nisus initiated any communication with Ensystex to pursue substantive negotiations between October 2009 and the date of the December Nisus petition to the Director. Ensystex asserts that it did receive a separate letter from Nisus at the same time as the petition laying out its data compensation claim and inviting them to enter into substantive negotiations.[2] By a letter dated January 25, 2009, written in conjunction with its response to the Nisus petition, Ensystex made an offer to pay

[2] Neither party provided this correspondence due to terms of the non-disclosure agreement.

Nisus for one study, specifically referencing California's data-cost sharing provisions found in FAC section 12811.5, and requested that Nisus indicate the amount of compensation requested.

By a letter to the Department dated January 29, 2009, Ensystex responded to the Nisus petition to the Department seeking a determination and cancellation of its product and Nisus submitted an additional argument in support of its petition in a letter of the same date. Ensystex submitted a letter in reply to the January 29, 2009 submission of Nisus dated February 4, 2009, and Nisus replied by a letter dated February 8, 2009. The latter two letters were beyond the date set by the Director for the submission of argument or evidence. Although not required to consider the late submissions, they have been read and have been made part of the record in this proceeding.

Analysis

The provisions of FAC section 12811.5 (d) through (g), plus implementing regulations, reflect the underlying intent to encourage the parties to take all reasonable steps to resolve their data cost-sharing disputes between themselves before turning to the Director for a determination. This process begins with the mutual recognition by the parties involved that there is a valid data compensation claim. In this instance, Ensystex acknowledged that fact and agreed to pay Nisus whatever was required under federal law for use of its data in connection with the federal registration of its Borathor product. The issue of payment for the use of data for use in California was raised early on. Negotiations between the parties began by focusing on a non-disclosure agreement needed as a prerequisite to any substantive negotiations. These negotiations continued even as California registration for Borathor was sought and obtained. No evidence was submitted to show that Ensystex refused to participate in substantive negotiations on either the federal data compensation or the California cost-sharing obligation. In fact, it appears that the non-disclosure agreement was finally signed by Ensystex only two months before Nisus submitted this petition. No evidence has been presented showing that Nisus attempted to follow-up with Ensystex after it signed the non-disclosure agreement to pursue negotiations until after it filed this petition. Despite assertions by Nisus that Ensystex had not engaged in meaningful negotiation and that negotiations had "lengthened beyond the normal course and made no real progress," any delay of "meaningful negotiations" was a consequence of the need to reach the preliminary non-disclosure agreement. Apparently no substantive negotiations were possible on any data issues until that agreement was obtained.

Nisus seems to concede that Ensystex has not refused to engage in negotiations and has not provided any evidence to the contrary.[3] If dissatisfied with the progress of negotiations, Nisus could have initiated the binding arbitration specifically provided as an option under federal law. See Federal Insecticide, Fungicide Act (FIFRA), 7 U.S.C. Sec. 136a(c)(1)(F)(iii). If binding arbitration had been initiated resulting in an agreement or award it may well have

[3] Nisus states in its February 8, 2010 letter to the Director that "a failure to engage in meaningful negotiations does not signify that Ensystex has failed to engage in any negotiations at all."

resolved the need to enforce the data-cost sharing provisions in California because the issue would become moot. See FAC section 128ll.5(a)(2).[4]

Apparently, instead of either pursuing informal negotiations or initiating binding arbitration to resolve its data compensation and cost-sharing claims against Ensystex, Nisus preferred to cut the process short by seeking cancellation of the Ensystex product registration in California.[5] In so doing, Nisus petitioned the Director to cancel the Borathor registration without giving the prior detailed notice to the Ensytex of its claim for cost-sharing. This notice is required by section 6312(d) of title 3, California Code of Regulations to allow, in the words of the regulation, "the applicant the opportunity of at least ten days to promptly make an offer to pay." Instead, Nisus provided Ensystex with its petition at the same time it was provided to the Director. The Nisus petition provided to Ensystex listed the studies for which it claimed data cost-sharing for the first time. Not provided with the 10-day opportunity to make an offer to pay, Ensystex responded to the Nisus petition by providing Nisus with a specific offer to share in the cost of data under the provisions of FAC section 12811.5.

Conclusion

The Nisus request for determination and cancellation is premature. At this time there is no basis upon which to cancel the Ensytex's registration of Borathor. Ensystex made an offer to pay for Nisus data required to support the federal registration of Borathor; negotiations were initiated and use of the data for California registration was placed in issue; during that negotiation process, Nisus filed this petition without the warning required by regulation to provide the applicant the opportunity to make an offer to pay specifically for use in California that would avoid the need for the Department's involvement. The filing by Nisus of this petition in lieu of the required notice resulted in the response the notice was meant to elicit: Ensystex's specific offer to pay in connection with the California registration. At this point, Nisus can initiate binding arbitration under the provisions of both the federal and state law if it believes negotiations are not fruitful. Under FAC section 12811.5(f), unless Ensystex refuses to negotiate, or participate in an arbitration process initiated by Nisus, or refuses to comply with an order or award resulting from those proceedings, the Director has no basis upon which to cancel the registration of Borathor.

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[4] Given that federal registration is a precondition to California registration, it can be assumed that the intent and logical consequence of the FAC section 12811.5(a)(2) exemption for data that is the subject of an arbitration following federal registration was that the compensation for use in both arenas would be resolved at the same time.

[5] Nisus asserts that it was necessary to file this request to preserve its claim for compensation under FAC section 12811.5(d). This is a misreading of that provision. The 12-month limitation applies to the situation where the data owner fails to notify the applicant of its claim within 12 months of the applicant's registration. If this occurs, the applicant is absolved of it obligation to pay. That is not the situation here, and Nisus continues to have the ability to seek cancellation in any of the situations set forth in FAC section 12811.5(f).

Judicial Review

Under FAC section 12811.5(h), Nisus can seek court review of the Director's determination within 30 days of the date of the decision pursuant to section 1094.5 of the Code of Civil Procedure.

Dated: 18 March 2010

Mary-Ann Warmerdam, Director
Department of Pesticide Regulation