9-17-92

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

BEFORE THE ADMINISTRATOR

In the Matter of	)	
	)	
Dr. Robert Schattner, President, and Sporicidin International Inc., a/k/a Sporicidin Co.,	)	Docket No. FIFRA-92-H-02
	)	
Respondents	)	

ORDER GRANTING MOTION FOR DISCOVERY

The complaint in this matter under section 14 of the Federal Insecticide, Fungicide and Rodenticide Act, as amended (7 U.S.C. § 136l) seeks penalties totaling $430,000 based on separate sales or distribution of Respondents' product "Sporicidin Cold Sterilizing Solution," which was allegedly misbranded. The conclusion that the product was misbranded is apparently based on a test or tests conducted by the Food and Drug Administration, which indicated that the product was ineffective.

Respondents, hereinafter Sporicidin, answered, denying that "Sporicidin Cold Sterilizing Solution" (SCSS) was misbranded and denying allegations of sales or distribution referred to for lack of information sufficient to form a belief.

Under date of July 17, 1992, Sporicidin filed a request for the production of documents. The request was not designated as a motion and did not contain any allegations or recitals indicating that granting the request would comply with Rule 22.19(f), "Other discovery" (40 CFR Part 22).

Sporicidin asked that EPA be compelled to produce all documents relating to the testing or analysis, between September 1, 1990, and July 13, 1992, of any Sporicidin product by Juan Negron, an EPA Chemist, or by Kenneth Wang, Christine R. Landa, Dean F. Hill or any other employee or contractor who performed a chemical analysis of any Sporicidin product during that time period. Documents requested were to include, but not be limited to (a) all chain of custody sheets for each sample tested or analyzed; (b) all laboratory raw data worksheets; (c) all protocols indicating or specifying procedures to be used in the chemical analysis;[1/] (d) all laboratory notebooks used to record data on testing procedures or deviations; (e) a description of all other chemicals used in the analyses; (f) all laboratory equipment, instruments, reagent, and environmental controls reports; (g) all quality control and quality assurance documents, including any "QA Alert" forms; (h) all reports of inspections or certifications that any analytical equipment or instrument (including but not limited to a gas chromatograph) used in the testing or analysis was properly functioning and properly calibrated at the time of conducting each test or analysis; and (i) all documents regarding any confirmatory testing conducted after EPA personnel or contractors realized that the testing indicated that the product did not meet the chemical

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[1/] In its Reply To Complainant's "Objection To Respondents' Motion To Compel Production Of Documents," dated September 1, 1992, at 19, Sporicidin corrected the reference to "chemical analysis" in Item 4(e) of its request for production to "AOAC Sporicidal Testing." It appears that the reference was intended to be "Item 4(c)."

specifications claimed on the label and/or specified in EPA Registration No. 8383-5.

Sporicidin emphasized that its request was not limited to documents generated in testing of samples relied upon by the Agency in bringing the instant action.

Sporicidin also asked for the resumes and curriculum vitae of Juan Negron, of Kenneth Wang, of Christine R. Landa, of Dean F. Hill, of the person or persons who signed Block 13 ("Signature Of Lab Supervisor") on EPA's Exh Nos. 44 and 45, and of any other EPA employee or contractor who, between September 1, 1990, and July 13, 1992, (a) performed any test or analysis of any Sporicidin product; (b) was the immediate supervisor of the person who performed the test or analysis; or (c) reviewed, for the purpose of approving on behalf of the laboratory, results of the test analysis.

Additionally, Sporicidin asked for a copy of each record in EPA's possession describing the training and experience that the named individuals and of any other individuals who performed any test or analysis of any Sporicidin product between September 1, 1990, and July 13, 1992, have acquired to develop competence and skill in the performance of chemical or other analysis of glutaraldehyde-based and phenol-based disinfectants and sterilants.

Sporicidin also requested all documents as recited above concerning tests or analyses on any Sporicidin product by the Food and Drug Administration between September 1, 1990, and July 13, 1992, as well as appropriate documents showing the names, training

and experience, resumes and curriculum vitae of each person involved in the test.

EPA's Objection

Under date of July 29, 1992, Complainant filed an "Objection To Respondent's Motion To Compel Production Of Documents," contending that Sporicidin had failed to satisfy its burden of persuasion under Rule 22.19(f) that additional discovery was appropriate. In an accompanying memorandum (Argument) in support of its objection, Complainant alleges that Sporicidin's request is over broad, vague and untimely, that granting the request will cause unreasonable delay to the proceedings, that Sporicidin hasn't shown that the evidence requested is relevant or material to its defense, that the motion does not rest on grounds for discovery recognized in the Consolidated Rules of Practice, that the request for resumes and curriculum vitae is premature and that Sporicidin hasn't shown that the documents requested are not otherwise obtainable.

Respondents' Reply

In a reply, filed September 1, 1992, Sporicidin explains that in a nutshell, the requested documents are: (1) the complete laboratory data that support the alleged test results upon which EPA relies in its CAC, and (2) documents presenting the qualifications of the personnel who generated that data" (Id. at 2).

Sporicidin points out that the Agency's principal evidence in this case will, of necessity, be the actual laboratory data supporting the FDA Minnesota laboratory's performance of the AOAC Sporicidal Test on samples of the SCSS, which are alleged to be misbranded. Sporicidin says that it has submitted substantial documentation concerning the numerous inherent uncontrollable variables that result in the lack of reliability, consistency and reproducibility that clearly characterize the AOAC Sporicidal Test. As examples, Sporicidin cites a 1990 GAO report which raises similar concerns and criticisms of the AOAC Sporicidal Test and other AOAC tests (C's Exh 62) and a bench opinion, Metrex Research Corporation v. United States of America and William K. Reilly, Civil No. 92-B-922 (D.C. CO 1992), wherein the Agency was unsuccessful in persuading the court the AOAC Sporicidal Test was reliable, at least as performed by the FDA Minnesota laboratory, which is the same laboratory whose tests are involved in the instant case. Moreover, Sporicidin notes that in the Federal Register of December 6, 1990, the Agency requested proposals to improve the reliability, consistency and reproducibility of the AOAC Sporicidal Test, or to develop a new test (R's Exh Y).

Sporicidin asserts that clearly, the complete laboratory data, and the qualifications of the personnel who generated the data are material and relevant to its defense (Reply at 3).

Turning to Complainant's specific objections, Sporicidin points out that the documents are in the sole possession of the Government and that it is within the Agency's power, not

Sporicidin's, to expedite production of the requested documents. Concerning the Complainant's apparent position that the documents should be requested under the Freedom of Information Act, Sporicidin asserts that the Agency has responded only partially to its FOIA request, dated January 10, 1992. For example, Sporicidin says that EPA has not provided the protocols for the testing in the EPA and FDA labs, has not provided a complete copy of the raw lab data and equipment preparation data sheets pertaining to the testing of SCSS by EPA and FDA or information as to the qualifications of the EPA and FDA lab personnel who generated the data.[2/]

As to Complainant's objection that Sporicidin hasn't shown that the required documents have significant probative value, Sporicidin responds that in order to demonstrate that the AOAC Sporicidal Test has been properly conducted, the testing must be documented as required by EPA's Good Laboratory Practices (GLP), 40 CFR § 160.12. Sporicidin says that it cannot prepare a full defense against mere conclusory numbers or statements in a summary of alleged test results and that test result summaries supplied by the Agency raise serious scientific questions and are suspect on

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[2/] Reply at 5, 6. Sporicidin points out that an FOIA request for resumes, curriculum vitae and training records of personnel involved would likely be denied as exempt from disclosure (Id. at 4). That this position has substantial merit is indicated by Hawaiian Independent Refinery, Inc., Docket No. RCRA-09-91-007 (Order Denying In Part And Granting In Part Motion For Discovery, July 14, 1992), wherein merely furnishing the address of a former EPA employee was objected to on Privacy Act grounds. The order directing that the address be furnished to Respondent has been certified for interlocutory appeal to the EAB.

their face. For example, Sporicidin says that a chain of custody sheet (EPA Exh 11) apparently pertaining to samples tested at the FDA Minnesota lab contains no test result information, no contemporaneous lab notes concerning the testing protocol or lab procedures or original observations of data. The same observations are made with respect to chain of custody sheets (EPA Exhs 42 and 43) pertaining to samples tested at the EPA Beltsville laboratory. Moreover, it is alleged that these exhibits have been altered significantly and that there is no laboratory data in the Agency's pre-hearing exchange or in any other material previously supplied by the Agency to support the analysis results alleged in Exhibits 44 and 45. The same is assertedly true as to chemical analysis results from EPA's NEIC lab alleged in Exhibit 27 (Reply at 7, 8).

Sporicidin says that the only actual contemporaneous evidence that EPA may have provided regarding testing done at the FDA lab is 17 pages of documents comprising Exhibit 30. Some of these pages are allegedly summaries or rewritten transcriptions rather than "raw" or contemporaneous laboratory notes. As an example of an incredible test result, Sporicidin points to a hydrochloric acid (HCL) resistance test result (part of EPA Exh 30) which purports to show that one set of spores was alive after 2 minutes' exposure to HCL, dead at 10 minutes' exposure, and alive at 20 minutes' exposure. Numerous other problems are also allegedly evident in the test results and partial laboratory data supplied to date.

Sporicidin maintains that documents provided by EPA (Exhs 11, 27, 28, 29, 42, 43, 44, 45, 46 and 47) do not include any evidence

which establishes the reliability of the chemical analysis or AOAC Sporicidal Test results (Reply at 9). It points out that some of the documents, e.g., Exhs 44 and 45, are hearsay, signed by someone who was not a witness to the events and that, while others, e.g., EPA Exh 27, may include the initials of an individual who actually witnessed the events recorded, there is no contemporaneous lab data provided and no way to "probe" the "evidence" and to cross-examine the individual responsible for producing the recorded information. The same observations are assertedly applicable to EPA Exhibits 46 and 47.

Sporicidin states that it does not request documents previously supplied by EPA, e.g., a document, captioned "Sporicidal Test Equipment, Media & Reagents," for each of FDA Samples 91-382-587 and 91-382-588, reported in EPA Exhs 46 and 47. It does, however, maintain its request for production of copies of laboratory notebook data and for equipment preparation data sheets for the equipment, media and reagents referenced on the mentioned documents. Additionally, Sporicidin maintains its requests for the protocols for chemical analysis testing performed at EPA's Beltsville and NEIC labs and for the protocol for the AOAC Sporicidal testing performed at the FDA Minnesota lab (Id. at 10).

Supporting its request for Items 4(f) and 4(g) of its July 17 Request For Product, Sporicidin says that these are quality-control and quality-assurance documents required by GLP and are relevant to determining: (1) whether the lab followed the protocol (which has not been provided); and (2) the reliability of the lab data (Reply

at 10). These items assertedly include individual equipment, media, etc., preparation data sheets for EPA Exhibits 28, 29, 30, 46 and 47. In sum, Sporicidin says that EPA has not provided complete laboratory data and points out that, if the mentioned exhibits are supported by GLP lab data, FDA lab documents exist regarding the preparation of all test equipment nutrients, etc. These documents allegedly will indicate whether the preparations were subject to Quality Assurance reviews.

Sporicidin affirms its request for contemporaneous lab notes and data from NEIC and EPA's Beltsville lab concerning any tests of SCSS between September 1, 1990, and July 13, 1992. Additionally, Complainant is asked to confirm that NEIC and the Beltsville lab used the same protocol for chemical analysis of SCSS. Complainant has indicated a willingness to ask NEIC for the protocols used in these tests and it may be assumed that, if the protocols are different, a copy of each is being requested.

Sporicidin also reaffirms its request for complete lab data on all samples of SCSS which were tested at the FDA lab between the period September 1, 1990, and July 13, 1992. It is argued that these documents are relevant and material to Sporicidin's defense, even if they do not directly relate to particular test samples upon which Complainant has chosen to rely. Sporicidin alleges it needs the documents to determine, among other things:

> "(1) whether EPA/or FDA have run test after test after test on SCSS over the course of their Cooperative Agreement; and
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> (2) whether EPA is prosecuting the Stop Sale Order and the CAC based on selected test

> failures that are not representative of the totality of the testing that may actually have been performed.

[It is alleged] that the information that EPA has provided shows clearly that some samples have been tested more than once (See, for example, EPA Exhibit 26, item 20.)

Sporicidin [says it] wishes to discover:

(1) whether the particular samples of SCSS that EPA relies on in the CAC were tested more times than indicated on the documents that EPA has provided to Sporicidin; and

(2) whether other samples of SCSS were tested and had no failures, which would establish either:

(a) that the AOAC Sporicidal Test as performed at the FDA lab is inconsistent; or

(b) that there may have been off-specification batches due to an off-spec ingredient obtained from a supplier or a mis-formulation by one or both of Sporicidin's contract manufacturers.

[It is contended] that either of those scenarios would provide Sporicidin with information that is material and relevant to its defense, e.g., to the question of the reliability of the evidence produced by the FDA lab using the AOAC Sporicidal Test, and to the question of mitigation of any penalty for any violation, and also would provide evidence that EPA's other current enforcement action, the total Stop Sale Order against SCSS (i.e., instead of a Stop Sale Order against only certain batches), was overbroad and overkill." (Id at 13, 14).

Asserting that the experience, training, competence and qualifications of the technicians actually performing the tests are crucial to determining whether the results are scientifically valid, Sporicidin reiterates its request for the resumes,

curriculum vitae and documents showing experience and training of EPA and FDA personnel involved in the chemical analysis and sporicidal testing of its product (Reply at 15, 16). Additionally, Sporicidin requests EPA to confirm that the term "high-performance liquid chromatography" appearing on EPA Exhibit 27 is not the correct term for the procedure which may have been used in the analysis (Id. at 18).

D I S C U S S I O N

Sporicidin has made a compelling case for the requested discovery and there is not much to be said for Complainant's objections.[3/]

Under Rule 22.19(f), the ALJ can order "other discovery" upon findings that such discovery will not in any way unreasonably delay the proceeding, that the information is not otherwise obtainable and that the information has significant probative value. There is no difficulty in making the required findings here.

As pointed out in Safety-Kleen Corporation, Docket Nos. RCRA-1090-11-20-3008(a) and 11-11-3008(a) (Order on Discovery, December 6, 1991), cited by Complainant, Rule 22.19(f) doesn't prohibit delay attributable to discovery, but only that which is

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[3/] Complainant's objection that the request was "overbroad" appeared to have some initial validity, because the request was phrased in terms of "any Sporicidin product." Sporicidin's reply, however, makes it clear that the request is limited to tests or analyses of SCSS.

unreasonable (emphasis added).[4] A hearing date not having been set, it is clearly erroneous to characterize this proceeding as "very late in the trial schedule" (Argument at 3). Moreover, as Sporicidin points out the documents are in the sole possession of the Government and Sporicidin has no control over the length of time required for their production. The complaint, that Sporicidin isn't certain that some of the requested documents exist, disappears once it is shown that documents in this respect relate to whether the tests were conducted in accordance with GLP. If so, documents to support that fact exist.[5] In short, if Complainant is truly interested in an early resolution of this matter, it will make every effort to supply the documents sought by Sporicidin or inform Sporicidin and the ALJ that the documents do not exist. In view of the foregoing, I have no hesitation in finding that unreasonable delay within the meaning of Rule 22.19(f) will not result from the discovery sought by Sporicidin.

The next required finding is that the information sought is not otherwise obtainable. The requested documents are in the sole possession of the Government and, according to Sporicidin, a January 1992 FOIA request has only been partially answered.

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[4] Complainant understandably doesn't emphasize the result in Safety-Kleen, supra, which was that Respondent was directed to, inter alia, produce requested documents or the references by which the documents were previously supplied to the Agency.

[5] It would seem that Complainant, as part of its prima facie case, would find it expedient to demonstrate that test results were based on GLP.

Although intending to rely on FDA tests to support the determination SCSS was misbranded, Complainant declines to produce requested documents or even to attempt their production on the ground the information is in the possession of another agency (Argument at 3). Moreover, Complainant says that Sporicidin has received all documents upon which Complainant intends to rely.[6/] This stance enables the Agency to pick and choose tests to be relied upon and whether other such tests were conducted and the results thereof are among the data Sporicidin seeks to discover. This data is in the possession of the Government and is not otherwise obtainable.[7/]

The final finding required for "other discovery" is that the information have significant probative value. "Probative value" denotes the tendency of a piece of information to prove a fact that is of consequence in the case. Chautaugua Hardware Corporation, EPCRA Appeal No. 91-1, Order On Interlocutory Review (June 24, 1991). As Sporicidin has made clear, the reliability, reproducibility and scientific validity of the AOAC Sporicidal Activity Test upon which the finding of misbranding was based is at issue in these proceedings. It should go without saying that

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6/ Complainant might ponder how he intends to obtain admission of test reports, which are essentially summaries or secondary information, into evidence without making the data from which the reports were compiled available to Sporicidin.

7/ Complainant's apparent position that information is otherwise obtainable, if it is obtainable under the FOIA, encourages circumvention of the Part 22 discovery rule and is rejected as bad law and bad policy.

whether other tests on SCSS were conducted and the results thereof are probative on the reliability of the tests and that the training and experience of personnel conducting the tests and whether the tests were conducted in accordance with GLP are also probative on that issue.

The required findings for other discovery in accordance with Rule 22.19(f) having been made, Complainant will be ordered to comply with Sporicidin's request for the production of documents.[8/]

O R D E R

Complainant is directed to comply with Sporicidin's request for the production of documents on or before October 23, 1992. Complainant is also directed to inform Sporicidin whether NEIC and the Beltsville lab used the same test protocols and, if the answer is negative, to supply a copy of each protocol. Additionally,

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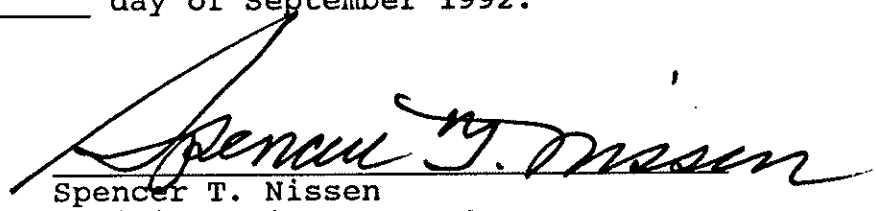
8/ Sporicidin's Second Request For The Production Of Documents, dated July 27, 1992, which asks for all delegations of authority from the Administrator to make final decisions under FIFRA, is, absent indications to the contrary from Sporicidin, considered to have been satisfied by documents supplied with Complainant's Objection To Respondent's Motion To Compel, dated August 7, 1992.

Complainant is directed to answer the question posed in Part II, para. F of Sporicidin's Reply To Complainant's Objection.[9/]

Dated this 17th day of September 1992.



Spencer T. Nissen
Administrative Law Judge

9/ After the discovery contemplated by this Order is completed, I intend to schedule a pre-hearing conference to discuss, inter alia, setting a date for hearing.

CERTIFICATE OF SERVICE

I do hereby certify that the forgoing Order Granting Motion For Discovery was filed in re Dr. Robert Schattner and Sporicidin International, Inc.; Docket No. FIFRA-92-H-02 and copies of the same were mailed to the parties indicated below:

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Dated: Sept. 18, 1992