

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

BEFORE THE ADMINISTRATOR

In the Matter of)
)
Microft Systems International) Docket No. FIFRA-93-H-03
Holdings, S.A. and)
Alfred Waldner Company,)
)
Respondents)

ORDER GRANTING MOTION TO SET
ASIDE DEFAULT ORDER

By an order, dated August 10, 1994, Respondent, Alfred Waldner Company (Waldner), successor in interest to Microft Systems International Holdings, S.A., was directed to furnish specified information on or before September 23, 1994. The order was issued after Hofer-Real, business agent for Waldner, filed a document entitled "Appeal For Temporary Stay Of Order On Default," from an Order on Default, issued on July 15, 1994. The ALJ determined that the "appeal" should be regarded as a motion to set aside the default order pursuant to Rule 22.17(d) of the Consolidated Rules of Practice (40 CFR Part 22). Information requested by the August 10 order was for the purpose of determining whether "good cause" within the meaning of Rule 22.17(d) existed for setting aside the default order.^{1/}

^{1/} Rule 22.17(d) provides that "(f)or good cause shown, the Regional Administrator or the Presiding Officer, as appropriate, may set aside a default order."

The origin of this proceeding is fully set forth in the Order on Default and in the August 10 order and will be repeated here only insofar as necessary to an understanding of the decision reached. Suffice it to say, that on May 5, 1989, Microft, through its agent in the United States, Todhunter, Mandava & Associates, submitted applications for the registration of two pesticides: Insecticide 2000 Concentrate and Insecticide 2000 Ready-To-Use. The applications were supported by studies on a product referred to as "Clean-Kill Insecticide Concentrate" and stated, inter alia, that the formulation for Insecticide 2000 Concentrate is identical to that of "Clean-Kill Insecticide Concentrate." "Clean-Kill Insecticide Concentrate" is marketed in the United States under the name "BEP Insecticide Concentrate" (EPA Reg. No. 64321-1). These applications were granted on October 29, 1990, Insecticide Concentrate 2000 being assigned EPA Reg. No. 62212-1 and Insecticide 2000 Ready To Use being assigned EPA Reg. No. 62212-2.

The initial complaint, filed on December 28, 1992, alleged, among other things, that BEP Insecticide Concentrate contains only Permethrin as an active ingredient, while the active ingredients in Insecticide 2000 Concentrate and its dilute form, Insecticide 2000 Ready-To-Use, are Permethrin and Bioresmethrin. Therefore, Respondent's assertion that the formulations of Insecticide 2000 Concentrate and Clean-Kill Insecticide Concentrate are identical was allegedly false and in violation of FIFRA § 12(a)(2)(q) (7 U.S.C. § 136j(a)(2)(Q)). For this alleged violation, it was

proposed to assess Microft a penalty of \$5,000, the maximum permitted for a single violation of FIFRA.

Alleging that it was the successor to Microft, Respondent Waldner filed an answer to the complaint through Science Regulatory Services International (SRSI) on January 19, 1993, denying the allegations in the complaint and asserting that the claims in the registration were truthful when made.^{2/} SRSI alleged circumstances, including tests on a sample obtained from Microft, supporting its assertion that it had every reason to believe that the statement concerning Clean-Kill Insecticide and Insecticide 2000 being identical was accurate.

By a letter, dated April 22, 1993, the ALJ directed the parties, absent a settlement of this matter, to exchange pre-hearing information. Among other things, Respondent was directed to furnish an affidavit from Dr. Waldner as to whether he or his company had a pesticide product containing only Permethrin as an active ingredient at the time of the registrations at issue. Complainant filed its pre-hearing exchange on the due date as extended, July 16, 1993, while Waldner did not respond in any manner to the ALJ's order or to Complainant's motion for default, filed on September 10, 1993. Waldner's failures in this respect were the bases for the order on default, dated July 15, 1994.

^{2/} Complainant's motion to amend the complaint so as to add Waldner as a party respondent was granted by an order issued contemporaneously with the order on default.

In its "appeal for temporary stay," Mr. Otmar Hofer, business agent for Waldner, alleged that SRSI had withdrawn as registration agent for Waldner. Additionally, the "appeal" asserted that Mr. Waldner had been substantially delayed in completing research underlying preparation of the requested affidavit, because much of the information was not in his possession or control, but was in the possession or control of parties "inimical" to the Alfred Waldner Company.

Otmar Hofer, on behalf of Waldner, replied to the ALJ's August 10 order, by a letter, dated September 23, 1994. In answer to question No. 1 as to the identity of the firm which employed Dr. Waldner at the time "Clean Kill Insecticide" was developed, the letter stated that Steuerer GesmbH had been producing Clean Kill Insecticide 2000 since 1984 and that Mr. Waldner was the general representative for Steuerer for the whole area, apparently referring to Austria. In 1985, Steuerer granted another person "exclusive rights" for the above country, which led to a termination of Waldner's relationship with Steuerer. Studies by RCC, a research and consulting firm, obtained from Steuerer were used to support the registrations obtained by Microft.

In answer to question No. 2 as to the identity of the parties and the circumstances leading to information required for preparation of the affidavit requested of Dr. Waldner being in the possession and control of parties "inimical" to Alfred Waldner Company, the letter identified a Dr. Berger, senior, living in Vienna, who was formerly chief chemist and producer of Clean Kill

Insecticide 2000 for Steuerer for the period in question. Dr. Berger assertedly confirmed that he and his company had worked with two active Pyrethroids, but was reportedly unwilling to write out an affidavit, because he would never have anything [more] to do with Mr. Steuerer as he was so disappointed with him.

Attached to the Hofer letter were two pages of what was referred to as an "Opinion on Insecticide 2000" from the Higher Federal School and Pest- [Test] Institute for Chemical Industry, Vienna, dated May 6, 1984. This document reflects receipt of a sample of "Insecticide 2000" from "Steurer [Steuerer] Ges.m.b.H (Steurer [Steuerer] Ltd.)" and contains an "opinion on Insecticide 2000." The "opinion portion" of the document is illegible, but apparently relates to the effectiveness of the product in killing insects rather than its active ingredients. A similar document in German on the letterhead of the Austrian Foodstuffs Research Institute, Vienna, apparently reflects receipt of a sample of "Insecticide 2000" on October 12, 1994. These receipts or acknowledgements were apparently included with the Hofer letter as possible sources of samples of Insecticide 2000 which could be tested by EPA for their active ingredients.^{3/}

Also attached to the Hofer letter was an affidavit by Alfred Waldner, dated September 19, 1994. Mr. Waldner states that Hubert Steuerer under the business [name] of "Steurer Ltd. (sic)

^{3/} Assuming that samples of "Insecticide 2000" are still maintained at the test institutions, Waldner has not explained why he has not instigated the testing.

and Jesmond Ltd" manufactured "Insecticide 2000" and that this product contained Permethrin and Bioresmethrin or Bioallethrin at the time of the [May 6, 1984] expert opinion from the "High Federal School and Test Institute for Chemical Industry."^{6/} Mr. Waldner further states that this product was sold internationally for many years [under the names] "Insecticide 2000," "Clean Kill-Insecticide 2000," "Clean Kill," and "Bio-son."

Hofer's submission includes a statement, dated September 20, 1994, by Professor Fritz Schreiner, who describes himself as a scientist and an expert in pest control. Professor Schreiner states that Insecticide 2000 contains two active ingredients, Permethrin and Bioresmethrin, and that when this product was developed in 1984, the objective was to create a product effective against a wide range of household and public health pests which was less toxic than a normal Pyrethroid product. He further states that the product (Insecticide 2000) which contains the active ingredients Permethrin 0.175% and Bioresmethrin 0.075% is less toxic than a product which contains only Permethrin 0.25%. According to Professor Schreiner, a toxicological study which would compare Insecticide 2000 with this other product would show the

^{6/} The statement by Mr. Hubert Steuerer, Director of Jesmond Limited, dated February 3, 1993 (C's Pre-hearing Exch., Exh 6), states, inter alia, that the formula of the "Bio-Kill/Clean-Kill" batch (Jesmond Bio-Kill batch No. 0318503) supplied to RCC in 1986 in order to perform a.m. toxicity studies fully complies with the formula, data and documents in the application to EPA for the registration of BEP Insecticide. Mr. Steuerer denies that Jesmond's "Bio-Kill/Clean-Kill" insecticide has ever contained Resmethrin.

great toxic difference. On the supposition that the existing studies are based only on the one ingredient Permethrin, he asserts that a study with two ingredients would show "better figures and datas." He concludes by stating that the chemical datas which underly the studies and registrations are definitely correct.^{5/} Although his statement is not altogether clear, Professor Schreiner appears to be saying that the 1984 "Opinion" on Insecticide 2000 by the Higher Federal School and Test Institute For The Chemical Industry is more consistent with the product containing both Permethrin and Bioresmethrin as active ingredients than with the product containing only Permethrin.

As to question 3, which asked for test data supporting the assertion that Insecticide 2000 Concentrate contains both Permethrin and Bioresmethrin and an explanation for the circumstances under which the sample was drawn, Hofer asserted that the answer to this question was included in the answer to question No. 2. The sample EPA received from Microft was assertedly from a Microft production lot obtained at the time the applications for registration were submitted. Waldner's explanation for not replying to the order for a pre-hearing exchange or to the motion for default was that the possibilities for clarifying his position didn't "show up earlier."

^{5/} The September 23 letter, states that Professor Schreiner was in his (Mr. Hofer's) office on September 20, 1994, and looked over the registration matter, which presumably included the mentioned Test Institute opinion.

On September 30, 1994, Complainant filed a response to the Hofer letter, dated September 23, 1994, submitted on behalf of Waldner, contending that the motion to set aside the order on default should be denied. Complainant asserts that Waldner has failed to satisfy either prong of the "good cause" standard set forth in the August 10 order, i.e., a showing of a "good faith" defense to the allegations in the complaint and a justification for failing to comply with the pre-hearing exchange order or to respond to the motion for default.

Complainant points out that Waldner has not provided any test data or documentary evidence to support his assertion that Insecticide 2000 contained the same active ingredients as Clean-Kill Insecticide. According to Complainant, the September 23 letter, referring to unspecified "know-how" and studies received by Waldner from Steuerer, merely confirms that Steuerer, as head of the company manufacturing Clean-Kill Insecticide and as sponsor of the RCC studies, is in the best position to know the composition of his product. Complainant emphasizes that the hearsay statement attributed to Dr. Berger, former chief chemist for Steuerer, to the effect that his company worked with "two active Pyrethroids" does not rebut Complainant's prima facie case. Moreover, according to Complainant, a careful review of the record reveals no meritorious defense to the allegations of the complaint and that Waldner appears no more likely to prevail on the merits than he did when the Order on Default was issued.

Complainant also contends that Waldner has failed to justify its failure to comply with the order for a pre-hearing exchange or to respond to the motion for default. Referring to the statement in the letter, dated September 23, 1994, that the "solutions and possibilities in clarifying [Waldner's] position didn't show up earlier," Complainant says that it is difficult to read this statement as other than an admission that Waldner has no credible basis for his position and has spent the past year trying to find some solution. Complainant emphasizes that Waldner's affidavit does not state that he manufactured "Insecticide 2000," a product containing Permethrin and Bioresmethrin, but only that Steuerer Ltd. and Jesmond Ltd. did so. Given what is characterized as a lack of substance to the affidavit, Complainant maintains that it is incredible that the affidavit could not have been supplied previously. Moreover, Complainant points out that Waldner has not been responsive to the directive that the affidavit state whether he or his company had a product containing only Permethrin at the time of the registrations in question.

D I S C U S S I O N

It is established that "Clean-Kill Insecticide," which is marketed in the United States under the name "BEP Insecticide Concentrate" (EPA Reg. No. 64321-1), contains only Permethrin as an active ingredient. It is also established that Insecticide 2000 Concentrate contains both Permethrin and Bioresmethrin as active ingredients. Therefore, the submission of studies on the pesticide

identified as "Clean-Kill Insecticide" to support the registration of Insecticide 2000 Concentrate was erroneous and the assertion that the formulation of Insecticide 2000 Concentrate was identical to that of the mentioned Clean-Kill Insecticide was inaccurate. Inasmuch as FIFRA is a strict liability statute, these facts might be regarded as dispositive of the motion to set aside the default order.

It should be noted, however, that evidence proffered by Waldner relates to events dating from 1984, while the Steuerer affidavit refers to a "Bio-Kill/Clean-Kill" batch submitted to RCC for testing in 1986. The 1984 Test Institute "Opinion" was on a product submitted for testing by Steuerer identified as "Insecticide 2000." Mr. Waldner's affidavit states that Insecticide 2000 contained Permethrin and Bioresmethrin or Bioallethrin at the time. In this respect, he is supported by Professor Schreiner's opinion that the Test Institute "Opinion" results are more consistent with the product containing both Permethrin and Bioresmethrin than with a product containing only Permethrin. In any event, Professor Schreiner flatly states that "Insecticide 2000" contains both Permethrin and Bioresmethrin and there appears to be no dispute but that the product for which the registrations at issue here were granted contains both of the mentioned active ingredients.

Waldner's affidavit further states that "Insecticide 2000" was sold internationally for many years [under the names] "Insecticide 2000," "Clean Kill" and "Bio-Son." If established, these

assertions would support the contention in Waldner's answer that it had every reason to believe that the statement that the formulations of "Clean-Kill Insecticide" and "Insecticide 2000" were identical was accurate at the time it was made. Although Jesmond has denied that "Clean-Kill" insecticide ever contained Resmethrin, there is evidence of ill-will by Jesmond against Microft and Waldner which may affect the credibility of the Jesmond affidavit.^{6/}

FIFRA being a strict liability statute, Waldner's good faith belief that the representation that the formulations of "Insecticide 2000" and "Clean-Kill" insecticide were identical was accurate when made is not, strictly speaking, a defense to the violation of FIFRA § 12(a)(2)(g) alleged in the complaint. "Good faith," however, is a factor to be considered in determining the gravity of the violation and thus of the magnitude of the penalty, if any.^{7/} The "good cause" standard for setting aside a default order under Rule 22.17(d) has been held to require a showing of a strong probability of an outcome different from that reached by the default order, if a hearing were held. See, In The Matter of

^{6/} In a letter to Complainant's counsel, dated July 2, 1993, signed by Hubert Steuerer, Jesmond accused Microft of fraudulently misusing Jesmond's RCC-studies and other documents and expressed the hope that Microft would be criminally prosecuted (C's Pre-hearing Exch., Exh 13).

^{7/} FIFRA § 14(a)(4) authorizes the issuance of a warning in lieu of a penalty when it is determined that the violation occurred despite the exercise of due care or did not cause significant harm to health or the environment.

Midwest Bank & Trust Company, et al., RCRA (3008) Appeal No. 90-4 (CJO, October 23, 1991). In this regard, one of the bases stated in the default order for upholding the maximum permissible penalty demanded in the complaint, i.e., that the potential for harm in using studies on a pesticide containing only Permethrin as an active ingredient to support the registration of a pesticide containing both Permethrin and Bioresmethrin as active ingredients was obvious, is contradicted by Professor Schreiner's assertion that a pesticide containing specified levels of both the mentioned active ingredients is less toxic than a pesticide containing only Permethrin as an active ingredient. It is concluded that Waldner has shown a strong probability of an outcome different from that reached by the default order as to the amount of any penalty, if not necessarily as to the violation, if a hearing were to be held.^{B/}

It is true, as Complainant alleges, that Waldner has not been responsive to the pre-hearing directive that he furnish an affidavit as to whether his company had or produced a product

^{B/} This standard is considered to be indistinguishable from the "good faith" defense standard used in the August 10 order. It should be noted that, while the existence of a "meritorious defense" has been held to be a requirement for setting aside an entry of default under FRCP Rule 55(c), which like Rule 22.17(d) applicable here requires a showing of "good cause," "good cause" does not require a showing of the likelihood of success on the merits. See Berthelsen v. Kane, 907 F.2d 617 (6th Cir. 1990).

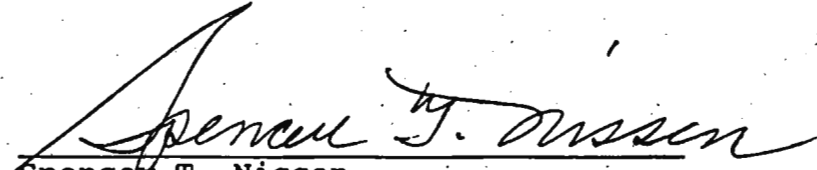
containing only Permethrin as an active ingredient at the time of the registrations at issue. Waldner was directed to furnish an affidavit as to a Permethrin only product, because he had made an issue of this question in his answer. This issue is, however of marginal relevance in view of the controlling issues as to whether "Insecticide 2000," as developed by Steuerer, contained Permethrin and Bioresmethrin as active ingredients and whether, as Waldner alleges, "Insecticide 2000" was marketed as "Clean-Kill" insecticide. Waldner's affidavit is directly responsive to these issues.

It is also true that Waldner has not satisfactorily explained his failure to furnish the affidavit at an earlier time, his failure to request an extension of time because of difficulties in obtaining information and his failure to respond in any manner to the motion for default. "Good cause" for failing to respond, however, is not an element of the "good cause" showing required for setting aside a default order. Midwest Bank & Trust Company, supra. Waldner has complied with the requisite standard, i.e., a showing of a strong probability of a different result as to at least the amount of the penalty if a hearing were held, and his motion to set aside the default order will be granted.

ORDER

The motion to set aside the order on default is granted.^{2/} Absent a settlement of this matter, the parties will on or before January 13, 1995, submit a schedule for suggested further proceedings.

Dated this 13th day of December 1994.


Spencer T. Nissen
Administrative Law Judge

^{2/} Setting aside the default order does not reinstate Waldner's registrations which have been canceled (59 Fed. Reg. 49395, September 28, 1994).

CERTIFICATE OF SERVICE

I do hereby certify that the foregoing Order Granting Motion to Set Aside Default Order was filed in re Microft Systems International; Docket No. FIFRA-93-H-03 and copies of the same were mailed to the following:

(Interoffice)

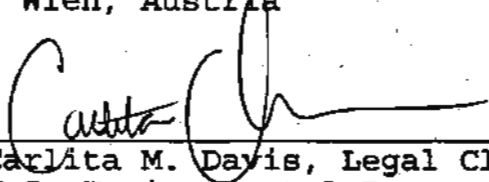
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