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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

BEFORE THE ADMINISTRATOR

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In the Matter of American Cyanamid Company, Claimant v. Thompson-Hayward Chemical Company, Respondent	)	FIFRA COMP Docket No. 25

OPINION

This is a proceeding under Section 3(c)(1)(D) of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, 7 U.S.C. 136a (c)(1)(D) (Supp. V, 1975) ("FIFRA"), to determine the reasonable compensation to be paid to producer of test data by a registrant who has used the data in registering a pesticide. American Cyanamid Company (American Cyanamid), the claimant herein, is the producer of the data, and Thompson-Hayward Chemical Company (Thompson-Hayward), respondent herein, is the registrant who used the data. These proceedings have been instituted and the undersigned has been designated to preside pursuant to the authorization and direction of the Acting Administrator dated October 13, 1976 (41 FR 46020).

American Cyanamid has filed a motion to "dissolve" this proceeding asserting that certain jurisdictional prerequisites have not been met. In the alternative, American Cyanamid claims that the procedures established by order of January 7, 1977, are unfair and

unauthorized by Section 3(c)(1)(D), and that the proceedings should be stayed until these rules have been corrected. A response to this motion has been filed by Thompson-Hayward, and a reply by American Cyanamid. On consideration of the papers and of the file which has been received from the Director of the Agency's Registration Division, which constitutes the only record in this proceeding at this time, the motion to dissolve is denied. A stay of these proceedings is granted for the purpose of obtaining certain information from the EPA's Registration Division, as hereafter discussed more fully, and in all other respects the motion for a stay is also denied.

The Facts

The only papers before me at this time relating to the claim for compensation are those contained in the official file of the EPA's Registration Division, which were certified and forwarded in accordance with the published procedures established by the Acting Administrator. See 41 FR 46020. The papers were served upon the parties pursuant to Section 2 of the rules of procedure, which I have issued, and they have not been questioned or supplemented in the moving papers or in the response.

The file discloses that on December 5, 1974 Thompson-Hayward made an offer to pay reasonable compensation to the extent provided under Section 3(c)(1)(D) for use of test data produced by another

registrant and which may be used to support its registration application for DE-FEND-TOX. (EPA Reg. No. 148-RRGR) (Exhibit A to this opinion).[1/] Notice of Thompson-Hayward's registration application was then published in the Federal Register. 40 FR 1737 (1975). The active ingredients were listed as consisting of toxaphene 47.7%, dimethoate 8.0%, and xylene 23.5%. Id.[2/] Pursuant to that notice American Cyanamid filed a claim for compensation for certain identified test data which it had submitted in connection with the registration of CYGON 267.[3/] The applicable active ingredient was stated to be dimethoate (which as noted above was listed as an active ingredient of Thompson-Hayward's DE-FEND-TOX), and the data was described as showing the safety of CYGON 267 (Exhibit B to this opinion).

1/ The offer was submitted pursuant to the interim policy statement published by the EPA on November 14, 1973. 38 FR 31862. In accordance with the procedures set forth therein the offer to pay applied only to the use of data which had been first submitted on or after October 21, 1972. Id.

2/ The notice stated that Thompson-Hayward was proceeding under Section 2(c) of the Interim Policy Statement. Under this provision, registration was requested on the basis of use patterns, efficacy and safety previously established under FIFRA. See 38 FR 31863 (1973).

3/ The data was identified by reference to certain Pesticide Petitions. (Exhibit B infra.)

By letter dated March 25, 1975, a copy of American Cyanamid's letter was sent by the EPA to Thompson-Hayward who was also instructed to submit a revised application meeting the requirements of option 2(a) or 2(b) set forth in the Interim Policy Statement (Exhibit C to this opinion). The letter specifically stated that Thompson-Hayward, if it wishes the EPA to continue to process the registration application, must (Exhibit C):

> Acknowledge that your application relies upon the data identified in the American Cyanamid correspondence referred to above and request that the Agency consider such data in support of your application; or,
>
> Request our approval that processing of your application continue to proceed under option 2(c) of the Interim Policy Statement without reliance on the data identified in the American Cyanamid correspondence, but relying only on other relevant data which you must specify as supporting your application; EPA will not give such approval unless we believe that any rights that American Cyanamid may have under Section 3(c)(1)(D) will not be prejudiced by so doing.

American Cyanamid was also informed by letter dated March 25, 1975 that Thompson-Hayward had been notified of American Cyanamid's claim and its attention was again called to the procedures set out in the Interim Policy Statement (Exhibit D to this opinion).

On April 3, 1975 Thompson-Hayward replied to EPA's letter of March 25, 1975 as follows (Exhibit E to this opinion):

> We are replying to your letter of March 25, 1975 and in regard to our registration application for DE-FEND-TOX, EPA File Symbol 148-RRGR.

> We do hereby acknowledge that our application relies upon American Cyanamid data and we request the Environmental Protection Agency to consider such data in support of our application.

DE-FEND-TOX was subsequently registered on July 3, 1975. American Cyanamid was notified of the registration and advised also that Thompson-Hayward did acknowledge that their application did rely on American Cyanamid data and did request the EPA to consider such data in support of the application (Exhibit F to this opinion).

The file shows no further communication among the parties or between the parties and the EPA involving the use of American Cyanamid test data in the registration of DE-FEND-TOX or of any compensation to be paid for such use.

1. American Cyanamid's claim that EPA is without jurisdiction to determine reasonable compensation at this time.

American Cyanamid's jurisdictional argument is based on two contentions. First, it argues that there has not been an offer to pay reasonable compensation which complies with the statute. Second, it asserts that there has been no determination by the Administrator that the test data for which reasonable compensation is to be determined is not protected by Section 10(b) of FIFRA, 7 U.S.C. 136(h) (Supp. V, 1975).

With respect to the offer to pay compensation, the record clearly establishes that one was made by Thompson-Hayward. American Cyanamid's

position appears to be that the offer was deficient because it was not made directly to American Cyanamid and did not specifically delineate the data which Thompson-Hayward wished to have the Administrator consider. The statute requires, however, only that an offer to pay reasonable compensation be made. It is, of course, true that the words must be construed reasonably. The sufficiency of the offer here, however, should be judged in light of the circumstances under which it was made.[4/] The offer was made pursuant to the published procedures established by the EPA in its Interim Policy Statement, which required that all applications for registration submitted after November 14, 1973 contain an express offer to pay reasonable compensation as provided therein. The applicant was not required in the offer to identify the data relied on if it was proceeding under option 2(c) as was the case here.[5/] These procedures also provided that notice of the registration application be then published in the Federal Register so that producers may claim compensation for test data which

4/ The type of offer which American Cyanamid contends should be made may be desirable or even necessary in certain cases in order to enable a producer of test data to make a claim for compensation. See, e.g., Dow Chemical Co. v. Train, 9 BNA Env Rep. Cas. 1678 (E.D. Mich. 1976) This does not appear, however, to have been a problem in this case.

5/ 38 FR 31863. The offer was phased in general terms and would apply to any producer whose test data was involved. See Exhibit A infra. It also applied only to test data submitted to EPA in connection with an application for registration for the first time on or after Oct. 21, 1972 (the date of the enactment of the Federal Environmental Pesticide Control Act of 1972 (86 Stat. 973)). The file as presently constituted does not disclose whether the test data involved here was submitted prior or subsequent to October 21, 1972. While the propriety of the cut-off date may be an issue in the proceeding, I am, for the the purpose of this motion, assuming that the limitation does not affect the validity of the offer.

may be involved in the application.[6/] Given the published requirement that the registration application contain an express offer to pay, publication of the application was also notice to interested parties of the offer to pay for test data which may be relied on in that application. Again, in accordance with the interim policy procedures, American Cyanamid, in response to this notification, was able to submit a claim for compensation identifying the test data for which compensation was sought and the identification appears to have been sufficient to enable Thompson-Hayward to supplement its offer to pay by acknowledging that it did rely on the data, and to request the EPA to consider the data in support of Thompson-Hayward's registration application. Although done in stages, therefore, a fair construction of what ultimately developed in this case was an offer to pay reasonable compensation for the use of specific test data produced by American Cyanamid, which was sufficent to satisfy requirements of the statute.

American Cyanamid seems to suggest that Thompson-Hayward's offer was deficient because Thompson-Hayward thereafter did not make an active effort to negotiate directly with American Cyanamid over the amount and method of compensation. Brief in support of motion at 4. I find nothing in either the statute or the legislative history to support such a position. It would be meaningless to require the

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6/ 38 FR 31863.

parties to pursue negotiations where one of the parties, or perhaps both, are not really interested in negotiating, and a statute should not be construed to produce a foolish result. FTC v. Tuttle, 244 F.2d 605, 616 (2d Cir. 1957).

Where, for example, the applicant is not interested in negotiating, the producer is adequately protected by his right to have the reasonable compensation determined by the EPA, subject to review by the courts.[7/] The fact that neither party attempted to pursue negotiations after Thompson-Hayward acknowledged its reliance on American Cyanamid's test data seems to indicate that negotiations would have been unproductive. In any event, this appears to be Thompson-Hayward's view for it is in favor of going forward with these proceedings with certain qualifications.

7/ Neither party has cited any legislative history to support its contentions. The only information I have gleaned from the legislative history which seems to have a bearing on the question is the fact that H.R. 10729, the predecessor of the amending Federal Environmental Pesticide Control Act of 1972, 86 Stat. 973, as originally drafted would have required the consent of the producer of the data before the data could be used by a subsequent applicant for registration, and it was in this form that the Bill first passed the House. See H.R. Rep. No. 92-511, 92d Cong. 1st Sess. 20 (1971); 117 Cong. Rec. 40061 (1971). The provision was strongly opposed in the Senate, particulary by the Senate Commerce Committee, which favored unrestricted use of data. See Sen. Rep. No. 92-970, 92d Cong. 2d Sess. 12 (1972). A compromise in the form of the present mandatory licensing of test data was finally reached. See H.R. Rep. No. 92-1540, 92 Cong. 2d Sess. 31 (1972); 118 Cong. Rec. 33922 (1972); (remarks by Senator Miller). It seems clear that the mandatory licensing was to accomodate the interests of both the producer and the subsequent user of the data. A reasonable interpretation consequently is that the offer to pay was to serve the purpose of first giving the parties the opportunity to negotiate on the amount and terms of payment, if they so desired, but not to require either party to negotiate as a prerequisite to having the EPA determine the compensation.

To conclude, in considering American Cyanamid's jurisdictional argument, it is unnecessary for me to decide whether Thompson-Hayward's offer to pay, standing by itself, would have complied with Section 3(c)(1)(D). I need only determine whether the offer to pay, when it is considered under the circumstances in which it was made, and as it has been supplemented by correspondence between the EPA and the parties, complies with the statute, and I hold that it does.[8/]

American Cyanamid also asserts that in registering DE-FEND-TOX, the EPA made no determination that the data involved is not protected by Section 10(b) of FIFRA, 7 U.S.C. 136h(b) (Supp. V, 1975), i.e., that it does not contain trade secrets or privileged or confidential commercial or financial information. While this fact, if it were so, may be relevant to the question of whether the pesticide was properly registered, its relevancy to this proceeding to determine reasonable

8/ Thompson-Hayward in its statement filed pursuant to Section 2(c) of the rules of procedure issued herein asserts that to adequately present its position in this proceeding it will need more specific reference to data for which compensation is claimed than what is contained in American Cyanamid's claim for compensation, and that it will also need a statement from the EPA stating with specificity which of the data was actually used in determining Thompson-Hayward's registration. The latter contention is considered further below. My holding here with regard to American Cyanamid's jurisdictional argument is that the data was sufficiently identified in connection with the offer to pay to meet whatever requirements may be imposed by Section 3(c)(1)(D) in that respect. If further identification of the test data is necessary, this can be taken care of in the administrative proceeding, as hereinafter set forth.

compensation for use of data relied upon is not clear.[9/] In any event, the record now before me is barren of any factual support for American Cyanamid's claim that the EPA acted in direct contravention of Section 3(c)(1)(D) in registering the pesticide. To accept the claim under these circumstances would be contrary to the strong presumption to which administrative officials are entitled that they have performed their duties in accordance with law. Pacific States Box & Basket Co. v. White, 296 U.S. 176, 185-86 (1935); Kalvar Corp. v. United States, 543 F.2d 1298, 1301 (Ct. Cl. 1976).

The two cases relied on by American Cyanamid, Dow Chemical Co. v. Train, 9 BNA Env. Rep. Cas. 1678 (E.D. Mich. 1976), and Mobay Chemical Co. v. Train, 394 F.Supp. 1342 (W.D. Mo. 1975) are readily distinguishable. Both cases involve suits by producers of test data to enjoin the EPA from considering their tests in registering other pesticides. In both cases the district courts focused their attention almost entirely on how the producers could protect their right to compensation by means other than in an administrative proceeding to determine compensation.[10/]

9/ What consideration should be given in determining compensation to whether the data is protected by Section 10(b), and, if it is, how that affects the producer's right to compensation may be issues in this proceeding, but I do not have to reach them for the purpose of deciding this motion. It should be noted that in claiming compensation under Section 3(c)(1)(D), American Cyanamid did not single out any of the data as being excluded because it was protected by Section 10(b) (Exhibit B, infra.)

10/ Procedures for having compensation determined administratively were not established by the EPA until October 1976. See 41 FR 46020.

Since the courts were not presented with the question of whether an administrative proceeding to determine compensation should be stayed, their language as to what an applicant who seeks to use another's tests must do by way of making an offer to pay to and negotiating with a producer as a prerequisite to the Agency's consideration of the data is inapplicable to this case or dictum so far as this case is concerned. The conclusions of the court in both Dow and Mobay that the EPA procedures (which at that time made no provision for administrative determinations of compensation) did not comply with Section 3(c)(1)(D) appear to have been based on the premise that the procedures did not adequately protect a producer's right to compensation. See Dow, supra, 9 BNA Env. Rep. Cas. at 1682-83, 1684; Mobay, supra, 394 F.Supp. at 1348-49, 1350. Whatever may have been the validity of that premise in the circumstances of those cases, it cannot be said to apply here as a ground for enjoining this proceeding. The very purpose of this proceeding is to determine the reasonable compensation which must be paid to the producer for use of the test data, and since the parties are being accorded a full adjudicatory hearing, American Cyanamid's rights to reasonable compensation will not be prejudiced. If there is error in the administrative determination, judicial review is expressly provided for by statute. Moreover, as noted above, the record does not disclose any facts showing that American Cyanamid's rights to compensation have been prejudiced by the procedures followed here. Finally, insofar as the language in

Dow and Mobay on which American Cyanamid relies (Brief in support of motion at 2-4) suggests that some greater obligation to make an offer to pay and to negotiate than was done here should be imposed on Thompson-Hayward as a prerequisite to this proceeding, such a holding does not seem to be justified either by the statute or the legislative history. Supra at 7-8.

2. The claim that the rules of practice issued herein are contrary to American Cyanamid's rights under Section 3(c)(1)(D).

American Cyanamid's objection to the rules of practice issued herein is directed to the requirement in Rule 2 that it submit a statement regarding its claim for compensation at this time. American Cyanamid asserts that it is unfair and unauthorized by Section 3(c)(1)(D) to require such a statement from American Cyanamid until Thompson-Hayward or the Administrator has informed American Cyanamid of the data considered in support of Thompson-Hayward's registration. Accordingly, it moves that the proceeding should be stayed until this has been done. Thompson-Hayward, in its response, agrees that there has not been a sufficient delineation of the data, but urges that EPA and not itself should be the one to make a more specific identification and it requests that the proceeding be stayed until the EPA has done so.

Both parties apparently have ignored the correspondence in the file in their arguments. A fair reading of this correspondence indicates that Thompson-Hayward relied upon and was requesting the EPA to consider all the test data cited by American Cyanamid in its claim for compensation. Exhibits B-F infra. If this is the case, I do not see why further identification of the data is necessary in order for the parties to determine whether the file as now constituted is complete and adequately states their respective positions, and for American Cyanamid to specify the amount of compensation claimed and the method of payment requested, and the other details requested in Rule 2 with respect to the use of the tests by others and the compensation received from such use.

If Thompson-Hayward's position is that American Cyanamid is not entitled to compensation for all the test data identified in its letter of February 7, 1975 (Exhibit B, infra), I agree that the burden should not be on American Cyanamid to show which data was actually "relied upon" by the applicant and "considered by the EPA in support" of the application so as to be compensable under Section 3(c)(1)(D). Concerning the obligations of Thompson-Hayward vis-a-vis the EPA in identifying the data, a few preliminary observations seem appropriate.

First, I do not think the purpose of Section 3(c)(1)(D) was to relieve the registrant of the burden of assembling the necessary data

to support its application, but only to prevent unnecessary duplicative testing.[11/] Consequently if Thompson-Hayward did not want to have all the data for which compensation was claimed considered by the EPA, it would appear that some reasonable effort should have been made by Thompson-Hayward to select the data to be considered. What effort, if any, was made by Thompson-Hayward in this regard is not disclosed by the record as presently constituted.

Second, if Thompson-Hayward's position is that it assumed that the EPA would undertake the burden of selecting specific data for consideration out of the mass of data for which compensation was claimed, I find nothing in either the interim policy statement or the file as it now stands to justify such an assumption.[12/] Accordingly, it would seem that Thompson-Hayward at least had the obligation at the time of registration to clarify its position as to what it conceived the EPA should do with respect to identifying specific data so that the EPA could have acted accordingly in determining whether the application was in proper form.

11/ See the explanation of the compromise substitute for the text of H.R. 10729, offered by the Senate Committee on Agriculture and Forestry, 118 Cong. Rec. 32258 (1972).

12/ Of course the EPA would undoubtedly review the data referred to to determine its sufficiency for the purposes for which it was offered, but it does not necessarily follow that the EPA would then pick and choose among the data if more data was referred to then may be required (perhaps because of differences in concentration or uses).

Nevertheless, the EPA should know whether it considered all the data or something less than all the data in registering the Thompson-Hayward product. Because it may serve to simplify the issues in this proceeding and possibly expedite them, I am, accordingly, pursuant to my authority under Section 2(g) of the rules, directing the Director of Registration to file a statement identifying which data cited in American Cyanamid's letter of December 7, 1975, was considered by the EPA in registering DE-FEND-TOX (EPA Reg. No. 148-1131). That statement is to be submitted by April 14, 1977, unless the time is extended as provided in the rules, and all further proceedings in this matter will be stayed until it is received.

Gerald Harwood

Gerald Harwood
Administrative Law Judge

March 10, 1977