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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

BEFORE THE ADMINISTRATOR

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

ACCELERATED DECISION DISMISSING CLAIM FOR COMPENSATION

This is a proceeding under the amended Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA") Section 3(c)(1)(D), 7 U.S.C. 136a(c)(1)(D) (Supp V, 1975), to determine reasonable compensation to be paid by respondent Thompson-Hayward Chemical Company ("Thompson-Hayward") to claimant American Cyanamid Company ("Cyanamid") for test data submitted by Cyanamid in registering a pesticide and relied upon by Thompson-Hayward to register a similar product.

The claim for compensation arises out of the application of Thompson-Hayward to register the pesticide DE-FEND-TOX, which is comprised of the following active ingredients: Toxaphene 47.7%, Dimethoate 8.0%, and Xyene 23.5%. Pursuant to the procedures established by the interim policy statement issued by the EPA on November 14, 1973, 38 Fed. Reg. 31862, Cyanamid, by letter dated February 7, 1975, filed a claim for compensation with respect to

safety data submitted in the registration of the pesticide CYGON 267. Thompson-Hayward acknowledged that it relied upon the Cyanamid data in its registration application and the pesticide was registered on July 7, 1975.

This proceeding to determine reasonable compensation for claims under Section 3(c)(1)(D) of FIFRA has 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 Fed. Reg. 46020).

On March 10, 1977, I issued an order and opinion denying a motion by Cyanamid to dissolve or stay these proceedings, except to grant a stay until the Director of the EPA's Registration Division had, in accordance with my direction, furnished a statement identifying which of the test data for which Cyanamid claimed compensation in its letter of February 7, 1977, was considered by the EPA in registering Thompson-Hayward's product, DE-FEND-TOX. That statement was submitted by the Acting Director of the Registration Division on April 13, 1977, and the stay expired according to its terms.

Thompson-Hayward has now filed a motion for an accelerated decision asserting that the claim for compensation should be denied since the statement of the EPA's Registration Division discloses that none of the data for which compensation has been claimed was submitted on or after January 1, 1970. That motion has been opposed by Cyanamid. In addition, the parties, pursuant to my request, have

submitted their comments on the applicability of the decision of the Administrator in Dow Chemical Company v. Velsicol Chemical Corporation, FIFRA COMP. Docket Nos. 4 through 18 (filed May 25, 1977) to this case. In that decision it was held that when the claim for compensation was made with respect to data used in a registration issued prior to the enactment on November 28, 1975, of the amendments to FIFRA by Pub. L. No. 94-140, 89 Stat. 754, a producer of test data is only entitled to compensation for data submitted to the EPA in connection with an application for registration for the first time on or after October 21, 1972.

On consideration of the papers, I conclude that Cyanamid's claim for compensation must be dismissed on the grounds that none of the data was submitted to the EPA in connection with an application for registration for the first time on or after October 21, 1972.

In his statement of April 13, 1977, the Acting Director, Registration Division, states that according to the EPA's records the test data for which Cyanamid claimed compensation in its letter of February 7, 1975, was submitted by Cyanamid to the EPA in 1962 and 1967. Cyanamid does not question the truth of this statement in its opposition to the motion for an accelerated decision, but instead argues generally that the statement provides no basis for relief because Cyanamid is given no opportunity to cross-examine the Acting Director.

Cross-examination is not necessary, however, unless the facts are disputed. See Intercontinental Industries, Inc. v. American Stock Exchange, 452 F.2d 935, 942 (5th Cir. 1971), cert. denied, 406 U.S. 918 (1971). And, if there is a genuine issue of a material fact, it would not be proper to grant an accelerated decision. 40 C.F.R. 168.37(a). Here, Cyanamid could have demonstrated the existence of a genuine issue, if there is one, for the dates on which Cyanamid submitted the pertinent test data to the EPA are surely within Cyanamid's own knowledge, and are a matter on which Cyanamid is probably as well-informed, if not more so, than the EPA. It is concluded, therefore since there has been no showing by Cyanamid that the facts may be otherwise, that there is no real dispute about the dates on which Cyanamid's data was submitted, and no reason, therefore, for cross-examination of the Acting Director on the issue.

Cyanamid also urges that the statement from the EPA's Registration Division is defective because it is limited only to data cited by Cyanamid in its letter of February 7, 1975, and does not identify all of the data relied upon in support of the registration. The only data used by Thompson-Hayward, however, which is relevant, is that which has been produced by Cyanamid. As to that data, the Acting Director has dealt with all data for which Cyanamid in its letter of February 7 claimed compensation at the time Thompson-Hayward registered its product. There is no indication in the letter itself that it was not intended to be complete as to the data listed, and

it is the only evidence in the record before me of data for which Cyanamid might be entitled to compensation. If Cyanamid is now contending that the record is incomplete, it has not sought to correct the deficiency either in its papers filed in opposition to the motion for an accelerated decision, or by filing a statement supplementing the record as it was required to do under Rule 2(c) of the Rules of Procedure issued herein. In the absence of any showing by Cyanamid to the contrary, it is concluded, therefore, that the statement of the EPA's Registration Division does not omit any Cyanamid data which ought to be considered in deciding this motion for an accelerated decision. Again, it should be noted that, for the reasons stated above, the only omission which might be significant would be of data that was submitted for the first time on or after October 21, 1972.

The question remains then whether given the facts that Thompson-Hayward's product was registered prior to the enactment of the amendment to FIFRA by Pub. L. 94-140, 89 Stat. 754, in November 28, 1975, and that all the data for which compensation is claimed was submitted prior to October 21, 1972, Cyanamid has established a valid claim for compensation under Section 3(c)(1)(D).

Section 3(c)(1)(D) was added by the Federal Environmental Pesticide Control Act of 1972, Pub. L. No. 92-516, 86 Stat. 973 ("FEPCA"), which was enacted on October 21, 1972. Originally, the statute was silent on when the data had to be submitted to be compensable. This was changed by the 1975 amendment which provided

that Section 3(c)(1)(D) was to apply only to data submitted on or after January 1, 1970. 7 U.S.C. Section 136a(c)(1)(D) (Supp V, 1975).

In the case of Dow Chemical Co. v. Velsicol Chemical Corp., FIFRA COMP. Docket Nos. 4 through 18 (May 25, 1977), the Administrator affirmed the ruling of Administrative Law Judge Levinson that a producer of test data is entitled to compensation only for data submitted on or after October 21, 1972. In that case the registration had been approved prior to November 28, 1975. Judge Levinson in his decision gave weight to the EPA's interpretation of Section 3(c)(1)(D) set out in its Interim Policy Statement of November 14, 1973. (38 Fed. Reg. 31862). No reasons have been shown by Cyanamid for reaching any different result in this case.

Even if I did not consider Dow Chemical Co. v. Velsicol Chemical Corp. controlling in this case, I would reach the same result. Not only for the reasons stated by Judge Levinson and affirmed by the Administrator but also for the reasons hereafter stated, I conclude that the administrative construction in the Interim Policy Statement of November 14, 1973, is a proper construction of the Act.

Section 3(c)(1)(D) prior to its amendment in 1975, as already noted, was silent on whether all data was to be compensable or only data submitted after the effective date of the Act. Consequently, it can hardly be said that Section 3(c)(1)(D) on its face compelled a reading that it applied to all data whenever submitted. Indeed the provision

could reasonably be read as applying only to test data submitted pursuant to the new registration requirements of FEPCA. Thus, recourse to the legislative purpose in enacting Section 3(c)(1)(D) is appropriate. See United States v. American Trucking Association, 310 U.S. 543(1940); Portland Cement Assn. v. Ruckelshaus, 486 F.2d 375, 379-80 (D.C. Cir 1973).

With respect to Congress' purpose in enacting Section 3(c)(1)(D), the Interim Policy Statement of November 14, 1973, states that the major purpose of Section 3(c)(1)(D) is to foster research and development of new pesticides by assuring a degree of protection for the investment made by the developer in procuring the test data to secure registration of the new pesticide, 38 Fed. Reg. at 31862. This seems to be in accord with the legislative history. The debate over Section 3(c)(1)(D) centered not on what data should be compensable but whether there should be any restriction whatever on the use of the data.[1/] In explaining why test data should not be free to all it was stated:

> The purpose of the provision...is to give manufacturers an incentive to undertake the research necessary to develop better and safer pesticides. The costs of testing a product to determine the pests for which it is effective, the commodities on which it can safely be used and the proper method of application can be very great. If the product is not patentable or if the patent protection has expired, there is nothing to prevent a competitor from registering a similar product. Under such circumstances the first applicant has no opportunity to recover his research costs and little incentive for undertaking that research. The provision proposed to be stricken by the Commerce Committee amendment is designed to provide the necessary incentive for the production of safer and better pesticides to protect health and the environment.

S. REP. No. 92-838 (Part II), 92d Cong. 2d Sess. 12 (1972).

1/ See S. REP. No. 92-970, 92d Cong. 2d Sess. 12-19 (1972); S. REP. No. 92-838 (Part II), 92d Cong. 2d Sess. 11-21 (1972).

Given such a purpose, the reasonable construction of the statute does appear to be that it was intended to cover only the production of new data, and not to make compensable the large volume of test data which had already been developed and submitted to the Agency under the risk that it would also be used to register the same or similar products of others.[2/] Such a construction is also in accord with the general rule that, "retroactivity, even where permissable, is not favored, except upon the clearest mandate." Claridge Apartments Co. v. Commissioner, 323 U.S. 141, 164 (1944).

This construction of Section 3(c)(1)(D) is also consistent with the legislative history relating to the amendments in 1975. The question of whether Section 3(c)(1)(D) was intended to apply to data submitted prior to October 21, 1972, was specifically considered.[3/] The Senate proposed to settle the question by an amendment making only data submitted on or after October 21, 1972, subject to compensation. In support of this amendment it was stated:

2/ The practice of the Agency to register "me too" products on the basis of test data already in its files, seems to have been well known in the industry. See Federal Environmental Pesticides Control Act: Hearings on H.R. 10729 Before the Subcomm on Agricultural Research and General Legislation of the Senate Committee on Agriculture and Forestry, 92d Cong. 2d Sess 245 (1972), and Federal Environmental Pesticides Control Act of 1971: Hearings on H.R. 10729 Before the Subcomm of the Environment of the Senate Comm on Commerce, 92d Cong. 2d Sess 140 (1972), for statement of representatives of the National Agricultural Chemicals Association on the practice.

3/ See H. R. REP. No. 94-497, 84th Cong. 1st Sess. 25, 61-67 (1975); S. REP. No. 94-452, 94th Cong. 1st Sess. 10 (1975): H.R. REP. No. 94-668, 94th Cong. 1st Sess. 5 (1975).

> In view of its [Section 3(c)(1)(D)] purpose, it would seem sound not to require cost sharing with respect to "old data". To make the provision applicable to "old data" could create a windfall for producers of this data since such data was prepared without any reasonable expectation that the law would require sharing of the costs of production.

See S. REP. No. 94-452, 94th Cong. 1st Sess. 10 (1975).

The actual amendment passed was a compromise which fixed the cut-off date as January 1, 1970. See H.R. REP. No. 94-668, 94th Cong. 1st Sess. 5 (1975). The date seems to be entirely a legislative determination. It is, nevertheless, indicative of Congress' unwillingness to require compensation for all data whenever produced, and to this extent confirms the construction of the 1972 Act, as applying only to data submitted after October 21, 1972, in the absence of some express provision that the statute should also cover an earlier date.

Cyanamid cites a stipulation by the Administrator in Mobay v. Train, Nos. 75CV238-W-4 and 76CV351-W-4 (W.D. Mo.) in which he apparently construed the 1975 FIFRA amendments as casting doubt upon the position in the Interim Policy Statement with respect to the October 21, 1972 cut-off date. Whatever may have been the Administrator's view of the law when he made the stipulation, his present view as revealed in Dow is that the position in the Interim Policy Statement is a correct construction of Section 3(c)(1)(D), and that is what I must be guided by. Nor is it necessary to reconcile the Administrator's decision in Dow with his earlier stipulation in Mobay. Even assuming there has been a change in the Agency's position,

the Administrator having taken a legal position in one matter is not locked into it for all purposes thereafter. See City of Chicago v. FPC, 385 F.2d 629, 637-38 (D.C. Cir. 1967).[4/]

Finally, Cyanamid argues that Thompson-Hayward waived its right to insist upon statutory compliance by admitting in its letter of April 3, 1975, that it relied on all the data submitted by Cyanamid and failing to object to the fact that some of the data had been submitted prior to October 21, 1972. It was not necessary, however, that Thompson-Hayward make such an objection in its April 3rd letter. It had already submitted an offer to pay compensation which was limited to data submitted to the EPA for the first time on or after October 21, 1972. This was in accordance with the procedures established in the Interim Policy Statement, 38 Fed. Reg. 31863, pursuant to which Cyanamid filed its claim. Accordingly, I do not find that Cyanamid has been misled so as to provide a basis for estoppel, or that there has been a failure to act by Thompson-Hayward which would amount to a waiver of its rights.

Accordingly, for the reasons stated claimant has failed to state a claim upon which relief can be granted. Pursuant to Section 13 of the Rules of Procedure issued herein, an accelerated decision dismissing these proceedings is granted.

4/ It is to be noted that in the EPA's proposed rules for claims determinations under Sec. 3(c)(1)(D), the Agency also takes the position that data submitted prior to October 21, 1972, is not eligible for compensation. 42 Fed. Reg. 31285 (June 20, 1977).

ORDER

These proceedings to determine compensation to be awarded to claimant for the use by respondent in registering the pesticide DE-FEND-TOX of test data produced by claimant is hereby dismissed on the ground that none of claimant's data relied on by respondent is compensable under Section 3(c)(1)(D).

Gerald Harwood
Gerald Harwood
Administrative Law Judge

July 26, 1977