UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

BEFORE THE ADMINISTRATOR

In the Matter of Herbicides: Dinitro Technical and Ancrack Herbicide	)	FIFRA Docket No. 407

Decision on Motion for Reconsideration

Under date of September 19, 1979, Thompson-Hayward Chemical Company has moved for reconsideration of the decision, dated August 31, 1979, denying its motion to dismiss this Sec. 6(b)(2) proceeding insofar as Dinitro Technical is concerned. The basis for the motion is that none of the data which Dow alleges that Thompson-Hayward was required to but failed to submit with its application for the registration of Dinitro Technical (application received March 12, 1975; granted June 9, 1975) was required by the Interim Policy Statement (38 FR No. 222 at 31862-64, November 19, 1973) in effect at the time. Neither Dow nor counsel for Respondent has responded to the motion for reconsideration within the time specified by Sec. 164.111 of the Rules of Practice.

In its petition for the cancellation of Dinitro Technical, Dow has alleged that Thompson-Hayward was required to but failed to submit with its application for the registration of Dinitro Technical the following:

1. Materials identifying and delineating the data which it wished the Administrator to consider in support of its application.

2. Materials evidencing that it had made an offer to pay reasonable compensation to the owner or owners of data which the Administrator was to consider in support of the application, or evidencing the owner's or owners' permission.

3. Materials evidencing the owner's or owners' permission for the use of any data protected by Sec. 10(b) of the Act.

(Petition of The Dow Chemical Company For Cancellation, dated August 8, 1977).

Thompson-Hayward concedes that it did not submit the listed materials with its application, but contends that it submitted all materials required by EPA in 1975 and that if EPA made a mistake in establishing the requirements to support an application for registration, Dow may not rely on that mistake as a ground for canceling Thompson-Hayward's registration. The Interim Policy Statement provided (38 FR 31803) in pertinent part:

> All applications for registration, whether for new registrations, amendment of existing registrations or renewals, submitted to EPA on or after the date of this notice shall contain:
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> 1. An express, written offer to pay reasonable compensation to the extent provided under sec. 3(c)(1)(D) for use of any test data submitted to EPA in connection with an application for registration for the first time on or after October 21, 1972; and
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> 2. One of the following:
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> (a) All required supporting data;
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> (b) Specific references to all required data to be considered in support of the application; such references may be to data contained in or submitted in connection with other applications or other registrations, or in the open literature, but shall be to sources easily available to the Agency and shall be clearly identified; or
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> (c) A request that registration proceed on the basis of use patterns, efficacy and safety previously established under FIFRA. An applicant proceeding under this paragraph (c) may submit additional data to support the efficacy and safety of specified uses contained in his application; as to such data, the application will be treated as proceeding under paragraph (a).

Thompson-Hayward's application requested that the application be processed on the basis of previously established use patterns, efficacy,

and safety (2(c) of the Interim Policy Statement) and contained the general offer to pay statement required by the Interim Policy Statement quoted above. (See The Dow Chemical Company v. Thompson-Hayward Chemical Company, FIFRA Comp. Docket No. 49). Notice of Thompson-Hayward's application along with notices of other applications for registration was published (40 FR 15932, April 8, 1975).. Thompson-Hayward's application was accepted on June 9, 1975 (EPA Reg. No. 148-1213) and Dow's claim for compensation, dated June 2, 1975, was received by EPA's Registration Division on June 11, 1975. Accordingly, no opportunity appears to have been afforded for compliance with procedures contemplated by the Interim Policy Statement which provide that after receipt of a claim for compensation an applicant proceeding under 2(c) would be required to do one of the following: (a) submit a revised application meeting the requirements of 2(a) or 2(b); (b) acknowledge in writing that the application relies on data that the claimant has identified as data upon which it is asserting a claim for compensation; or (c) obtain EPA approval to continue to proceed under 2(c) without reliance on the data identified by the claimant but on other relevant data specified by the applicant in support of its application.

Accompanying the motion for reconsideration is an affidavit, dated September 18, 1979, of Ms. Dusty Miller, Pesticide Registration Coordinator for Thompson-Hayward and the individual who signed and supervised the application for the registration of Dinitro Technical. The affidavit states that the application was submitted under the 2(c) method of the Interim Policy Statement, and the affiant's belief that under such method EPA did not require materials identifying the data to be relied upon and further, that there was no way such materials could have been identified

by an applicant because no indexes or lists of data in EPA files to which EPA would refer in considering a "2(c)" application were available to applicants.[1/] The affidavit states Ms. Miller's understanding that in 1975 EPA could not readily identify data in its files and cites the statement in the Interim Policy Statement to the effect that in the case of a product proceeding to registration under 2(c), it may be impossible to determine in the future what data were considered in support of the application. With respect to the alleged requirement for a direct offer to pay compensation to the owner, the affidavit states the belief that EPA did not in 1975 require such materials in support of a 2(c) application and further, that because there was no way for an applicant to identify the data, there was no way to identify the owner until a claim for compensation had been made. Moreover, there was no way for a 2(c) applicant to verify that data for which an owner claimed compensation was in EPA's files or would be relied upon by EPA in granting a registration. The affidavit points out that Thompson-Hayward submitted the offer to pay required by the Interim Policy Statement and that Dow was notified of that fact. Concerning materials evidencing the owner's consent for the use of Sec. 10(b) data, the affidavit merely states the

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1/ The Court in Mobay Chemical Corp. v. Costle, 447 F. Supp. 811 (D.C. Mo., 1978), ruled that the statute contemplated and required an offer of compensation by the subsequent applicant directly to the original submitter or owner of the data. While recognizing that the lack of a central index or filing system by which the identity of the original applicant could be determined created a "catch 22" to the statutory scheme, the Court, nevertheless, held that the difficulty of making such an offer could not obviate a requirement of the statute, 447 F. Supp. at 822, footnote 14.

belief that EPA did not require such materials in support of a 2(c) application for registration. The affidavit, being uncontroverted and consistent with Thompson-Hayward's application for registration and the Interim Policy Statement is accepted as accurate. Accordingly, it is found as a fact that Thompson-Hayward's application for registration complied with requirements of the Interim Policy Statement.

One of the reasons for denying the motion to dismiss was that the legitimate confusion surrounding the effective date of Sec. 3(c)(1)(D) alluded to by the courts (Mobay Chemical Corp. v. Costle, (Note 1, supra) and Amchem Products Inc. v. GAF Corp., 594 F. 2d 470 (5th Cir., 1979) was not applicable here because, if a regulation was required in order for Sec. 3(c)(1)(D) to be effective, the Interim Policy Statement constituted such a regulation, at least insofar as EPA's good faith in issuing registrations in accordance therewith was concerned. That analysis failed to recognize certain assumptions concerning the effective date of Sec. 3(c)(1)(D) underlying the Interim Policy Statement. For example, EPA took the position that 3(c)(1)(D) applied only to data submitted to the Agency on or after October 21, 1972, the date of enactment of the amendments to FIFRA effected by the Federal Environmental Pesticide Control Act of 1972.[2/] This position serves to explain in part the failure of the Interim Policy Statement to recognize the possibility that data in EPA files relied upon to support another application might

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2/ This position has been rejected by courts which have considered the question. Rohm and Haas Company v. Costle and Amchem Products, Inc. v Costle (Unreported), Civil Nos. 78-6 and 78-12 (U.S. D.C. E.D. Pa., March 30, 1979) and Amchem Products, Inc. v. GAF Corp., supra.

be entitled to confidential treatment under Sec. 10(b) and thus could not be so used without the consent of the original submitter or owner.[3/]

It is also recognized that a probable major, albeit unstated, premise underlying the Interim Policy Statement was the assumption that until regulations were issued implementing the registration requirements of Sec. 3 of FIFRA of 1972, the Administrator possessed the authority pursuant to Sec. 4(b) to continue issuing registrations under FIFRA of 1947 without regard to the data compensation and confidentiality requirements of Secs. 3(c)(1)(D) and 10(b). The two year deadline for the issuance of regulations for the registration and classification of pesticides established by Sec. 4(c)(1) of FIFRA of 1972 was not met, such regulations being issued on July 3, 1975, effective August 4, 1975 (40 FR 28242 et seq.; 40 CFR Part 162). In a statement, Registration of a Pesticide Product, Consideration of Data by the Administrator in Support of An Application (41 FR 3339, January 22, 1976), EPA spelled out the position that the cited regulations for the registration of pesticides issued on July 3, 1975, eliminated paragraph 2(c) of the Interim Policy Statement as an acceptable method of support. Although this statement was issued after the enactment of the Insecticide, Fungicide and Rodenticide Act (Public Law 94-140,

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3/ EPA adopted the position that only the confidential formulae of a pesticide, manufacturing and quality control information and information in an application which had not yet been granted were entitled to protection from disclosure under Sec. 10(b) (General Counsel Memorandum, March 5, 1976). It may be, however, that the Registration Division was operating in accordance with the views expressed in that memorandum prior to its issuance. See 40 FR 22000 and 40 FR 28815 (May 20 and July 9, 1975, respectively), cited and quoted in Mobay Chemical Corp. v Costle, note 1, supra. This restricted view of data entitled to trade secret status has not been accepted by the courts. Mobay, supra, and cases cited.

November 28, 1975), which amended FIFRA including Sec. 3(c)(1)(D) in certain respects, the arguments made in the statement concerning the necessity for purposes of Secs. 3(c)(1)(D) and 10(b) of specifically identifying data relied upon to support each application seem to be equally applicable to registrations applied for and granted after October 21, 1972 and prior to November 28, 1975. It is, of course, true that the 1975 amendments to FIFRA were intended to eliminate doubt as to the effective date of 3(c)(1)(D) and seemingly eliminated data submitted to the Agency prior to January 1, 1970 as being the basis of a claim for compensation.[4/]

The foregoing discussion supports the conclusion that the Interim Policy Statement rested on erroneous assumptions and interpretations concerning the effect and application of FIFRA of 1972, in particular the relationship of Sec. 3(c)(1)(D) to Sec. 4. Moreover, Thompson-Hayward's registration having been issued in reliance upon such erroneous interpretation and prior to the 1975 amendments, the desire of Congress as expressed in the legislative history of the 1975 amendments that registrations issued on the basis of such interpretations not be invalidated and the unfairness and inequity perceived by the courts as reasons for refusing to invalidate such registrations would seem to support, if not require, the conclusion that cancellation under the circumstances prevailing herein is not an appropriate remedy. However, a troublesome aspect of such a conclusion is that relegating owners of data entitled to confidential treatment in accordance with Sec. 10(b) (as is Dow in the instant case) to compensation under Sec. 3(c)(1)(D) appears to be rewriting

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4/ See, however, Mobay Chemical Corp. v. Costle, ____ U.S. ____, 99 S. Ct. 644, 59 L. Ed. 2d _____ (1979) (FIFRA as amended does not address conditions under which pre-1970 data may be used in considering another application and thus petitioner's attack was on Agency practice and not on the statute; three-judge court held improperly convened).

the statute. As indicated in the decision on the motion to dismiss, Amchem Products, Inc. v. GAF Corp., supra, is slender authority for such a result because there the data was not shown to be trade secret and in Mobay Chemical Corp. v. Costle, the matter of Sec. 10(b) status of the data was remanded for determination by the Administrator in the first instance.

Although counsel for Respondent (Assistant Administrator) supported the motion to dismiss, it was pointed out in the original decision on the motion that the Respondent had broad authority to conduct a hearing under Sec. 6(b)(2) and that the rules of practice (40 CFR 164.91) authorizing accelerated decisions only in favor of Respondent did not appear to permit an administrative law judge to grant a motion to dismiss at the instance of a party other than Respondent at this stage of the proceeding, even if determined to be meritorious.[5/]

Conclusion

Upon reconsideration, the decision denying the motion to dismiss is affirmed.

Dated this 25th day of October 1979.

Spencer T. Nissen
Administrative Law Judge

5/ It would seem appropriate for the Respondent to withdraw the Notice of Intent to Hold a Hearing, if he considered that the Notice was improperly issued.