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UNITED STATES
ENVIRONMENTAL PROTECTION AGENCY

BEFORE THE ADMINISTRATOR

In the Matter of)	Docket Nos.:
)	
McLAUGHLIN GORMELY KING CO.)	FIFRA 94-H-10
)	
S. C. JOHNSON & SON INCORPORATED)	FIFRA 94-H-11
)	
TAKASAGO INTERNATIONAL CORPORATION U.S.A.)	FIFRA 94-H-12
)	
AGREVO ENVIRONMENTAL HEALTH)	FIFRA 94-H-13
)	
PRENTIS INCORPORATED)	FIFRA 94-H-14
)	
GOODDEED CHEMICAL CO. (USA) DIVISION OF ENDURA S.P.A.)	FIFRA 94-H-15
)	
Respondents.)	

ORDER ON MOTIONS

This matter is before me on Complainant's motion to amend the complaints and Respondents' motions to dismiss and for attorney fees under the Equal Access to Justice Act. All motions are denied for the reasons hereafter stated.

Background

The EPA, acting pursuant to the Federal Insecticide, Fungicide and Rodenticide Act ("FIFRA"), section 14(a)(1), 7 U.S.C. §136l(a)(1), issued the above six complaints alleging in each case that Respondent had violated FIFRA, section 12(a)(2)(Q), 7 U.S.C. §136j(a)(2)(Q), by falsely representing that a study on Piperonyl Butoxide of which Respondent was a sponsor was conducted in

compliance with the FIFRA Good Laboratory Practice ("GLP") standards, 40 C.F.R. Part 160. Each Respondent is a registrant of a technical grade of Piperonyl Butoxide and admits to being a member of the Piperonyl Butoxide Task Force II.¹

The charges arise out of a report (hereafter "Study") entitled "Absorption, Distribution, Metabolism and Excretion (ADME) Studies of Piperonyl Butoxide in the Rat", which was submitted to the EPA by the Task Force in support of the registration or amended registration of each Respondent's technical grade of Piperonyl Butoxide. The Study was done for the Task Force by the Biological Test Center, an independent testing facility. Attached to the Study was a compliance statement signed by the Chairman of the Task Force that all aspects of the study were conducted in accordance with the EPA's GLP standards.

The Complaint charged that the Study failed to comply with the GLP standards in four respects:

1. The testing facility failed to maintain all raw data, documentation, records, protocols, specimens and final reports

¹ McLaughlin Gormely King Co. (Docket No. FIFRA 94-H-10) is the registrant of "Technical Piperonyl Butoxide", EPA Reg. No. 1021-974; S. C. Johnson & Son, Inc. (Docket No. FIFRA 94-H-11) is the registrant of "Piperonyl Butoxide Technical For Manufacturing Purposes Only", EPA Reg. No. 4822-363; Takasago International Corp. USA (Docket No. FIFRA 94-H-12) is the registrant of "TPC Technical Piperonyl Butoxide", EPA Reg. No. 24061-1; Agrevo Environmental Health (Docket No. FIFRA 94-H-13) is the registrant of "Butacide Technical Piperonyl Butoxide", EPA REG. No. 4816-72; Prentis Inc. (Docket No. 94-H-14) is the registrant of "Prentox Piperonyl Butoxide Technical", EPA Reg. No. 655-113; and Gooddeed Chemical Co. (Docket. No. FIFRA 94-H-15) is the registrant of "Pieronyl Butoxide Technical Grade", EPA REG. No. 47932-1.

generated as a result of the study, contrary to the requirements of 40 C.F.R. §160.190(a).

2. The study did not include in the final report the signed and dated report of one of the investigators and failed to have the study director sign and date the final report, contrary to the requirements of 40 C.F.R § 160.185.

3. The quality assurance unit of the testing facility failed to include in its statement contained in the Study the dates that its findings were reported to management and the study director, contrary to the requirements of 40 CFR § 160.35(b)(7).

4. The compliance statement in the application with which the study was submitted did not describe in detail all the differences between the practices used in the portion of the study that was conducted at Rutgers University and the GLP standards, contrary to the requirements of 40 CFR §160.12(b).

Each alleged noncompliance with the GLP standards was claimed to be a violation of FIFRA, section 12(a)(2)(Q), 7 U.S.C. §136j(a)(2)(Q), which makes it unlawful for any person to falsify all or any part of any information relating to the testing of any pesticide submitted to the EPA, and for each a separate penalty was requested.²

Respondents filed a motion to dismiss the complaint. One of the grounds for the motion was that the alleged failures of the study constituted a single violation of submitting a study that was

² \$5,000 was requested for Count I, and \$4,000 was requested for each of the other three counts.

falsely represented as complying with the GLP standards, and not four separate violations as alleged in the complaints. On April 19, 1995, I issued an order in which I ruled for Respondents on this issue. This order was affirmed by the Environmental Appeals Board ("EAB"), FIFRA Appeal Nos. 95-2 through 95-7, Order on Interlocutory Review (March 12, 1996).

The EPA, having lost the battle on their original claim that each alleged noncompliance with GLP standards constituted a separate violation of FIFRA, section 12(a)(2)(Q), now moves to amend the complaint. In the amended complaints, the EPA would charge the first three alleged deficiencies in GLP standards as a refusal to maintain or submit records in violation of FIFRA, section 12(a)(2)(B)(i). The submission of the compliance statement alleged to be false because of the deficiencies asserted in the first three counts and the asserted failure of the compliance statement to contain certain information as alleged in Count IV of the original complaint, is now alleged as a violation of FIFRA, section 12(a)(2)(Q). The penalty for the four counts would be increased from \$17,000 to \$20,000.³

Respondents oppose the motions to amend and move to dismiss the actions.

Statutes Involved

7 U.S.C §136j(a)(2)(B)(i) (FIFRA, section 12(a)(2)(B)(i)), makes it unlawful for a person:

³ The penalties for Counts II, III and IV have been increased from \$4,000 per count to \$5,000.

to refuse to--

(i) prepare, maintain, or submit any records required by or under section 136c [§5], 136e [§7], 136f [§8], 136i [§11], or 136q [§19] of this title;

7 U.S.C. §136j(a)(2)(Q) (FIFRA section 12(a)(2)(Q)), makes it unlawful for a person:

to falsify all or part of any information relating to the testing of any pesticide. . ., including the nature of any protocol, procedure, substance organism, or equipment used, observation made, or conclusion or opinion formed, submitted to the Administrator, or that the person knows will be furnished to the Administrator or will become part of any records required to be maintained by this subchapter;

Discussion

Under the rules of practice, amendments to the complaint after an answer has been filed are at the discretion of the administrative law judge.⁴ The Federal Rules of Civil Procedure are a useful guide in determining the standard to follow. The rule is that leave to amend shall be freely given when justice so requires. If the underlying facts or circumstances relied upon may be a proper subject of relief, complainant ought to be afforded an opportunity to test its claims on the merits, unless it results in undue delay, or dilatory motive on the part of the movant, or undue prejudice to the opposing party.⁵

The factual issues -- whether the acts constituted violations of the GLP standards, and Respondents strongly dispute that they did, -- are not affected by the amendments. Those issues remain the same, but three of the alleged violations of the GLP standards are

⁴ 40 C.F.R. §22.14(d).

⁵ Foman v. Davis, 371 U.S. 178 (1962).

now asserted to be a refusal to maintain records and submit data in violation of section 12(a)(2)(B)(i), rather than the submittal of false data to the EPA in violation of section 12(a)(2)(Q).⁶

The issue that is affected is the size of the penalty. The decision of the EAB leaves the maximum penalty at \$5,000, a result which Complainant is clearly unhappy with.⁷ With its new theory, Complainant hopes to sustain its right to a much larger penalty than \$5000 for these alleged GLP standard violations. In fact, it now seeks a \$20,000 penalty in lieu of the \$17,000 originally sought because as violations of section 12(a)(2)(B)(i), the alleged GLP violations are apparently considered to be graver than if they just constituted the false submission of data to the EPA.⁸

⁶ The original complaint in Counts I and III referred only to violations of the GLP standards under 40 C.F.R. Part 160. The amended complaint would make the failure of the testing facility to maintain all raw data, etc. alleged in Count I, and the failure of the testing facility to include in the final report the statement required by the quality assurance unit alleged in Count III, as also violations of Respondents' obligation to maintain records imposed under 40 C.F.R. §169.2(k). These changes are made apparently to shore up Complainant's position that the deviations from the GLP standards are also independent violations of section 12(a)(2)(B)(i). It is to be noted that compliance by the testing laboratory with GLP standards is not mandated. Order on Interlocutory Review, FIFRA Appeal Nos. 95-2 through 95-7 (March 12, 1996), at 3.

⁷ The penalty, of course, is in addition to the other sanctions available to the EPA for non-compliance with GLP standards, such as the EPA's refusal to consider the data reliable for the purposes for which it was submitted; or as the basis for canceling, suspending or modifying the marketing permit. 40 C.F.R. §160.17.

⁸ In computing the proposed penalty in the original complaint, three of the alleged GLP standard violations, Counts II, III and IV, were assessed as Level 3 violations, the classification applicable to MIDDLE LEVEL GLP violations, subject to a penalty of \$4,000 each. FIFRA Enforcement Response Policy, dated July 2, 1990, p. 19 and App. A-7. Now as refusals to maintain or submit records,

This is not a situation where a party will be nonsuited because of a technicality in pleading, if the amendment is not allowed. The EPA knows how to plead the refusal to maintain and submit data when it believes the facts warrant it. The facts are no different now than when the original complaint was issued. Complainant, however, was obviously wedded to its theory that the alleged GLP standard violations were each a violation of the prohibition against the submission of false data, regardless of what it may have thought about such acts being also illegal under some other FIFRA provision. Having lost on the theory on which it hoped to litigate the case, it now attempts to preserve its right to a penalty larger than \$5,000, on some other theory. This strongly resembles a strategy of piecemeal litigation which should not be favored because of its tendency to protract the proceedings, impose unnecessary expenses on the parties and waste judicial efforts. Respondents are also faced with the consequence that their successful efforts in striking down the EPA's original theory of liability has resulted only in subjecting themselves to a larger penalty. Such gamesmanship should not be condoned.

I find that allowing the amendment will be prejudicial to Respondents because of the threat of delaying the proceedings that

Counts II and III are assessed as Level 2 violations subject to a \$5,000 penalty. Count IV has also been raised from a Level 3 violation to a Level 2 violation, presumably on the basis that it is now based on all the deviations from GLP standards. FIFRA Enforcement Response Policy, App. A-3.

it entails. Respondents strongly dispute the claims that they violated the GLP standards and they are entitled to a reasonably prompt decision on the merits. I also find that allowing the amendments is unfair because it has exposed Respondents to the risk of a larger penalty not because of any change in the facts but only because of their successful efforts in striking down the original theory of liability.

Complainant's motion to amend the complaints, accordingly, is denied. This is without prejudice to Complainant's right to amend the complaints in accordance with the decision of the EAB, namely to plead one violation of section 12(a)(2)(Q). For purposes of this proceeding, the issue of the size of the maximum penalty should be considered as settled and the matter should now proceed to a hearing on the merits.⁹

Respondents have also moved to dismiss the complaints insofar as they allege a violation of section 12(a)(2)(Q). The record shows the following with respect to the alleged violations:

As to Count I, Respondents have asserted in their answers, and this has not been questioned by Complainant, that the data not kept

⁹ Since the same facts are involved, it does appear to be Complainant's position that any act constituting noncompliance with the GLP standards with respect to maintaining or submitting records is a separate violation of section 12(a)(2)(B)(i) by the applicant, notwithstanding that it cannot be considered a separate violation of section 12(a)(2)(Q). The theory appears to be a novel one since no precedent has been cited. Denial of the amendments does not prejudice Complainant's right to take such a position in some other case, if it believes the facts warrant it. On the other hand, allowing the amendments so that Complainant can salvage its right to a larger penalty by testing the validity of its theory in this case would be prejudicial to Respondents for the reasons stated.

were radioactive scintillation caps on which the weights were first recorded. Respondents explained that shortly after the weights were so recorded, a technician of the testing facility transferred these data from the scintillation caps to scintillation printouts. The transferring technician authenticated the data transferred and the radioactive scintillation containers and caps were discarded as radioactive wastes.¹⁰

As to Count II, the study report submitted to the EPA contained a compliance statement signed and dated by the study director, but the study report itself was not signed and dated by the study director although he was identified in the study as the study director.¹¹

As to Count III, the study report listed the dates the Quality Assurance Unit of the testing facility inspected the study and the phases inspected, but the dates the findings were reported to management and the study director were not included.¹²

As to Count IV, the mass spectral analysis reported in the addendum to the report was done by Rutgers University and not the testing facility. The addendum to the Report contained a signed statement by the quality assurance officer of the Rutgers laboratory that the mass spectral analysis was carried out under GLP protocol by Rutgers University. The Addendum also contained an

¹⁰ Answers of Respondents to Count I.

¹¹ Respondents' Attachment 1, pp. 3, 5.

¹² Respondents' Attachments 6 and 7.

outline of the GLP program followed.¹³ The compliance statement submitted with the report referred only to the work done at the testing facility.¹⁴

Respondents argue that the deviations from the the GLP standards were trivial and were either unintentional or based upon a justifiable misunderstanding of what was required by the GLP standards. Such trivial deviations do not make a compliance statement false within the meaning of section 12(a)(2)(Q).

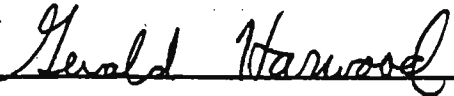
Contrary to what Respondents' argue, I do not read the order of the EAB as deciding whether Respondents' actions made their compliance statements false within the meaning of section 12(a)(2)(Q). The EAB did not reach that question and neither do I. Complainant's response to the motion was made while the issue of whether the complaints could be amended was unresolved. There is merit, therefore, to Complainant's claim, though unsupported by any factual showing, that the record should not be considered complete as to what are the undisputed material facts with respect to whether the compliance statement submitted by Respondents is false within the meaning of section 12(a)(2)(Q).

Respondents' motion to dismiss is denied. This is without prejudice to Respondents' right to renew the motion with such additional briefing as Respondents' deem appropriate in light of

¹³ Attachment 1, Addendum to report, pp. 64 - 66.

¹⁴ Attachments 6 and 7.

this order. Respondents' request for fees under the Equal Access to Justice Act is also denied. It is premature and not properly supported.¹⁵



Gerald Harwood
Senior Administrative Law Judge

Dated: July 2, 1996

¹⁵ See 40 C.F.R. Part 17. Although the requirements stated therein appear to have not been brought up to date, they appear to be reasonable and should be followed unless shown to be inapplicable in some respect.

In the Matter of McLAUGHLIN GORMELY KING CO., S.C. JOHNSON & SON, INC., TAKASAGO INTERNATIONAL CORP. U.S.A., AGREVO ENVIRONMENTAL HEALTH, PRENTISS, INC., AND GOODDEED CHEMICAL CO. (USA) DIVISION OF ENDURA S.P.A., Respondents
Docket Nos. FIFRA 94-H-10. 94-H-11, 94-H-12, 94-H-13, 94-H-14, 94-H-15

Corrected Certificate of Service

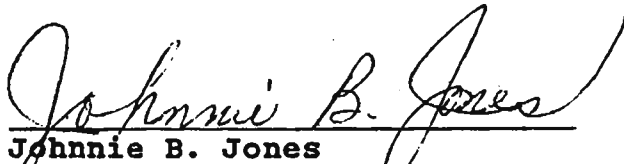
I certify that the foregoing Order On Motions, dated July 2, 1996 was filed and sent this day in the following manner to the addresses listed below:

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Dated: July 2, 1996