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UNITED STATES
ENVIRONMENTAL PROTECTION AGENCY

BEFORE THE ADMINISTRATOR

IN THE MATTER OF	)	
	)	
EASTMAN CHEMICALS DIVISION, EASTMAN KODAK COMPANY,	)	Docket No. TSCA-88-H-07
	)	
	)	
Respondent	)	

ORDER

The U.S. Environmental Protection Agency (sometimes complainant or EPA) served a motion on May 15, 1989 (hereinafter all dates are for the year 1989) to strike four affirmative defenses raised by respondent. The latter submitted its opposition to the motion on June 15; complainant served its rebuttal brief on June 26; and respondent replied to this on July 5. Respondent supplemented its opposition with a submissions of August 9 and September 5. In the interest of completeness, in attempt to contribute to clarity, and for the benefit of those readers not familiar with the arguments of the parties, their positions are set out below.

First Affirmative Defense:

Respondent asserts that the polymers identified in the complaint were identical to polymers listed on the Toxic Substances Control Act (TSCA) Inventory and were thus not "new chemical substances" subject to the premanufacture notification (PMN) requirements of TSCA. Complainant urges, however, among others, that the purported fact that respondent's end result chemical products are identical to beginning and ending products which were already on the TSCA Inventory has no influence concerning the issue of respondent's liability for the alleged failure to register its products created by using different reactants and an unregistered manufacturing process. The motion relates that the chemical and physical identity of a chemical end product is only one of the three criteria used by the EPA to determine when a chemical is "new;" that EPA also requires that a manufacturer, here respondent, to report, as part of the PMN, the product name, structure and formula in terms of component monomers; that respondent is asking the Administrative Law Judge (ALJ) to ignore EPA reporting requirements as published in the Code of Federal Regulation (C.F.R.); accept respondent's alternative method of identifying polymers; and apply a different set of reporting criteria for the facts of this case. Complainant also maintains that respondent is asking this forum to go beyond

its expertise and jurisdiction, and that respondent failed to seek judicial review when the regulation was promulgated and it cannot now be challenged in an administrative proceeding seeking the assessment of a penalty. Complainant argues that respondent must comply with EPA's definition of "new" as given in TSCA and in the regulations. The regulations define a "new chemical substance" to mean any chemical substance which is not included in the inventory compiled and published under subsection 8(b) . . . ." 40 C.F.R. § 710.2(r). The regulations also provide that "[t]o report a polymer a person must list in the description of the polymer composition at least those monomers used at greater than two percent (by weight) in the manufacture of the polymer." 40 C.F.R. § 710.5(c)(1). Complainant's position is that even assuming respondent's polymers listed previously on the Inventory are identical in their final chemical structure, it is of no consequence since the polymers were manufactured using monomers which were present at greater than two percent by weight; that respondent was required to report the polymer and identify the monomers; that respondent is not relieved of its obligation to file a PMN for the polymers for the reason that the formulation differences between respondent's chemical and those in the Inventory require the filing of a PMN for respondent's chemical substances.

In its opposition, respondent's position is that the two polyester polymers at issue in the subject proceeding are identical in physical and chemical structure to polymers listed by respondent as the Inventory; that this is the case even though the polymers were produced using "slightly different manufacturing processes and slightly different starting materials;" and that regardless of the initial reactants the polymerization reaction is the same in each of the processes and results in the formation of the same end product.

Section 5(a) of TSCA, 15 U.S.C. § 2604(a), provides, in pertinent part, as follows:

> (a) In general. - . . . no person may -
>
> (A) manufacture a new chemical substance . . ., or
>
> (B) manufacture or process any chemical substance for use which the Administrator has determined . . ., is a significant new use, unless such person submits to the Administrator, at least 90 days before such manufacturing or processsing, a notice . . . of such person's intention to manufacture or process such substance . . . .

Section 3(2)(A) of TSCA, 15 U.S.C. § 2602(2)(A), provides: "Except as provided . . . the term "chemical substance" means any organic or inorganic substance of a particular molecular identity, including - . . . . ." Section 3(9), 15 U.S.C. § 2602, states the term "new chemical substance" means any chemical substance which is not included in the chemical substance list compiled and published under [Section 8(b)]." The latter Section directs the Administrator, in part, to compile, keep current and publish a list of each chemical substance which is manufactured or processed in the United States. Respondent challenges EPA's position that a polymer having the same chemical composition and molecular identity as a polymer listed previously on the Inventory is a new chemical substance if it is produced from different starting reactants; that there is nothing in the language of TSCA to support such an interpretation; and that complainant ignores TSCA reliance on molecular structure, and not production process as the basis for defining the term "chemical substance."

Respondent also is of a mind that the purposes of TSCA would not be served by adopting the interpretation of complainant. Citing portions of the legislative history, respondent urges that Congress enacted the PMN requirements to ensure the prevention of harm to the health and the environment by permitting careful premarket scrutiny of chemical substances before they are first manufactured and released into the marketplace. Respondent contends that the statutory goals are attained by requiring the submission of a PMN for substances different in molecular identify from those chemicals listed on the Inventory; that nothing further is gained by an interpretation of TSCA which requires the submission of PMN for polymers which are identical in chemical and physical composition and structure to polymers listed on the Inventory, but are manufactured using slightly different starting materials; that EPA had an opportunity to weigh any dangers at the time the polymers were listed previously on the Inventory; and that it is a wasteful practice to have the additional review procedure advocated by complainant.

In its rebuttal brief complainant observes that respondent admits that the chemical subtances were produced using slightly different manufacturing processes and slightly different starting materials. Complainant opines that such a statement is an admission by respondent that the polymers it produced were new chemical substances; and there is nothing more complainant must prove to establish its prima facie case. Complainant iterates that the end-product is not the sole criteria for determinig when a chemical is a new chemical substance for reporting purposes; that even if respondent were to prove that its chemical substance, in the end-product form, is identical to other end-product chemicals on the Inventory, the use of different processes and different reactants makes them "new chemical substances" by definition for Inventory reporting purposes. Complainant contends further that respondent does not present a question of law worthy of a full hearing; the time to comment on a regulation has long since expired; that the issue is not new since it was proposed in the public comments (Comment Number 80) to the inventory and rejected. 42 Fed. Reg. 64589 (December 23, 1977). The Comment was that "[a]ny chemical substance

known as a polymer should be excluded from the inventory, provided that each constituent monomer and precursor chemical is reported." The Response was that "The Administrator does not agree with the proposal to exclude reporting of all polymers . . . ."

Respondent notes, however, that EPA has failed to refer to any language in TSCA, the regulation pertaining to the PMN, or those concerning Inventory Reporting which defines a new chemical substance as the basis of the starting reactants from which the substance is produced, and ignores the statutory language of "molecular identity" in the definition "chemical substance." Respondent also observes that Fed. R. Civ. P. 12(f) has a 20-day time frame for filing a motion to strike after service of a pleading and that following the suspension of settlement negotiations in this case complainant did not file its motion until 61 days thereafter. Thus, respondent contends the motion is untimely. Answering complainant's contention that it is well past the time to comment on the Inventory Reporting Regulations, respondent asserts that "nowhere do the regulations articulate the 'definition' of a new chemical substance that EPA now urges." Respondent's position is that because it had no notice of EPA's current interpretation of the

regulations it had no reason to comment, and upon which nothing to comment. That aside, respondent maintains that the principal question involved in the proceeding concerns whether or not it has complied with the appropriate section of TSCA and the regulations, and that such questions are appropriate to raise as a defense in an administrative enforcement proceeding.

As a final thought, respondent maintains that Section 8 of TSCA, 15 U.S.C. § 2607(a), does not give EPA substantive rulemaking authority with regard to the PMN requirements of Section 5 of TSCA, 15 U.S.C. § 2604, since Section 8 concerns itself with Inventory Reporting and does not address the filing of PMNs. It is urged further that under Section 8(a)(2)(A) the Administrator is required to maintain records and reporting concerning "[t]he common or trade name, the chemical identity, and the molecular structure of each chemical substance or mixture for which such a report is required." Respondent argues stoutly that this does not in any way support EPA's contention that separate reporting is required for chemicals which are identical merely because they are produced from different starting materials.

Second Affirmative Defense:

In this defense respondent asserts that the regulations implementing requirements are merely interpretive and non-binding; it restates the argument that in any event none of the applicable regulations requires the filing of a PMN when a polymer identical in composition to a polymer listed in the TSCA Inventory is manufactured using a different monomer and that monomer is itself listed in the Inventory. Complainant states this is a flat-out misstatement of the law; that such a defense has been reviewed by ALJs and Article III Federal Judges in other circumstances; and an agency's interpretation of its own regulation must be given deference and will be sustained if not clearly erroneous or inconsistent with the regulations. Complainant urges that its interpretation of the regulation is based upon its need for information about the component monomers which create the polymers in order to make assessments of the respective benefits and harm of a chemical before allowing its production and is not erroneous or inconsistent with the regulation. [citations omitted] Complainant stresses that it is entirely possible, based upon a PMN, EPA may determine that a new manufacturing process presents a

greater risk to the environment than another; and that to allow the regulated community to decide on a piecemeal basis what information [EPA] needs is to frustrate the Congressional scheme devised under TSCA. It is pressed further that the second affirmative defense presents "pure legal issues and conclusion of law" and is suited for resolution by a motion to strike. (motion at 18). Complainant notes that to permit respondent's defense would mean that the ALJ would be required to accept respondent's thesis that chemical and physical identity are the only characteristics of polymers and monomers which trigger the reporting regulation and then find that EPA did not promulgate regulations which restated respondent's thesis. In complainant's view, respondent has misstated the regulation; that it engaged in an erroneous conclusions of law; that the defense cannot be sustained by argument; and that it is patently frivolous and should be struck.

The long and short of respondent's opposition is that the defense raises important and serious issues of law that are not susceptible to a motion to strike. The core of respondent's contention is that its conduct was consistent with EPA regulations; that to the extent the regulations may support a

contrary interpretation they are not binding, not substantive and do not reflect a correct interpretation of TSCA. Turning to the regulations, respondent observes that 40 C.F.R. § 720.40(b) requires the submission of a notice at least 90 calendar days before manufacture of a new chemical; that the regulations define a "new chemical substance" as "any chemical substance which is not included as the Inventory." 40 C.F.R. § 720.3(v); that a "chemical substance," is defined to include "any organic or inorganic substance of a particular molecular identity, ..." 40 C.F.R. § 720.3(e); and that the regulations cease to "further clarify" when a substance is deemed to be included in the TSCA Inventory. (Opposition at 15-16). Respondent notes that complainant stresses that manufacturers were required to report polymers for the initial TSCA Inventory by listing the starting monomers used at greater than two percent (by weight) in the manufacture of the polymers, 40 C.F.R. § 710.5(c), and that complainant argues that this regulation requires a PMN whenever a change is made in the monomers from which a listed polymer is produced. Respondent observes, however, that complainant has failed to cite any

expressed statement in the Inventory Reporting Regulations which supports such an interpretation; that it does not follow from the reporting requirements that any later change in respondent's activities resulted in a "new chemical substance" for which a PMN is required; and because EPA's interpretation of its own legislation is open to "serious question" it should not be in the context of a motion to strike. Further, respondent states that Section 5 of TSCA, 15 U.S.C. § 2604, does not grant specifically substantive rulemaking authority to EPA; that any rules promulgated thereunder are not "legislative" or "substantive" rules having the force of law, but merely interpretative rules setting forth EPA's view of TSCA; and that complainant's view of the PMN regulation is contrary to the plain language of TSCA which defines a chemical substance in terms of its molecular identity. (Opposition, at 18-20). Respondent concedes that an agency's consistent and longstanding interpretation is generally given deference by the courts. Respondent maintains, however, that complainant's interpretation is not longstanding. Rather, it is contrived argument to support its litigation strategy and should be challenged. Respondent states that

it will offer evidence, through the testimony of Dr. Donald Kreh, that EPA viewed the chemical composition of the final polymer, and not the identity of the starting monomers, to be the clinching consideration in determining when a PMN was required; that EPA itself recognized that polymers should be treated "less stringently than other chemicals since they are an inert, non-toxic category of substances;" that EPA's present interpretation of its regulations hinges upon the circumstances of the case that is in issue; and that the ALJ should defer any decision concerning EPA's interpretation of its regulation until the conclusion of the evidentiary hearing.

In its rebuttal brief, complainant meets respondent's argument that regulations promulgated under Section 5 are interpretive and not binding if contrary to the language of TSCA. Complainant notes that respondent failed to mention Section 8 of TSCA, 15 U.S.C. § 2607, which addresses Reporting and Retention of Information, and directs the Administrator to promulgate rules. Referring specifically to Section 8(a)(2)(A).

complainant stresses that Congress has placed the responsibility on EPA to regulate the release of new chemical substances, that it has not abdicated this charge to regulated community; and that respondent has purely and simply violated the Section 5 reporting regulations by failing to file a PMN.

In its response, respondent argues that this Section 8 does not give EPA substantive rulemaking authority with respect to PMN requirements of Section 5 of TSCA since Section 8 governs Inventory Reporting requirements and it does not address the filing of PMNs. Further, Section 8(a)(2)(A) does not support EPA's contention that separate reporting is required for chemicals which are identical in each of the respects mentioned in the statutory language because they are produced from different starting materials.

Third Affirmative Defense:

In this defense respondent maintains that "[e]ven if the polymers identified in EPA's complaint were subject to PMN requirements, the EPA regulations did not provide clear and adequate notice to [respondent] of the interpretation of TSCA on which EPA now relies. [Respondent] should not be subject to penalties for conduct which it reasonably believed was in accordance with TSCA and EPA's implementing regulations." In

its motion to strike complainant contends that this defense does not go to liabilty, but is concerned with mitigation of the penalty, and that such a defense should only be permitted during that portion of the hearing concerning the appropriate amount of civil penalty to be assessed. Respondent argues that the defense should not be struck in that it raises "significant issues of law and fact concerning the constitutional adequacy of the notice that ECD received of the interpretation of TSCA on which EPA now relies;" and that if a violation of a regulation can result in penalties, then the regulation "must be so framed as to provide a constitutionally adequate warning to those whose activities are governed." (Opposition at 24-25, citation omitted). Respondent returns to its theme that EPA's Inventory and PMN Regulations are silent concerning whether a PMN is required when an Inventory-listed polymer is produced using different starting materials, but its chemical identity is not changed; that EPA itself had reached the conclusion that PMNs were not needed for the polymers at issue in this proceeding; and that this defense has substantial factual and legal questions concerning the constitutional adequacy of the notice provided by EPA. Complainant in its rebuttal brief states that the constitutional sufficiency of notice through publication has been decided by the Supreme Court (citation omitted) and there is no need for the ALJ to revisit the issue.

Fourth Affirmative Defense:

In its last defense respondent states: "In any case the fine proposed by EPA is unreasonable and unwarranted under the criteria established in Section 16 of TSCA because (1) [respondent] at all times acted in good faith and without culpability, (2) [respondent] took all steps expected and required by EPA to mitigate the alleged violation, (3) [respondent] exhibited a cooperative and positive attitude, and (4) the alleged violation had no adverse impact on protection of health or environment because the affected polymers were identical in composition to polymers listed on the TSCA Inventory." Complainant's motion to strike this defense is similar to that put forward concerning the third affirmative defense, namely, that it is irrelevant to the liability aspects of the case, and may only be asserted properly concerning the assessment of a penalty. Respondent in its opposition, among others, notes the interrelationship of the liability and penalty issues and it would conserve time and resources to hear the evidence pertaining to both issues at the hearing.

Discussion

It is a firmly etched principle in the law that motions to strike affirmative defenses are to be approached with considerable circumspection; such pleadings are not favored. In this regard, see In the Matter of 3M Company (Minnesota Mining and Manufacturing), Docket No. TSCA-88-H-06, August 7, 1989, at 5-7. The undersigned ALJ adopts and incorporates by reference the thoughts expressed, and the authority cited, in that order. See also, the order of the undersigned ALJ In the Matter of Waterville Industries, Inc., Docket No. RCRA-I-87-1086, June 23, 1986, at 2-3. For complainant to prevail, the ALJ must be satisfied that there are no questions of fact, and that any questions of law are clear and not in dispute. An illustration of this would be the question concerning whether or not a statute of limitations is applicable to a proceeding. This is to be distinquished from a question concerning whether or not a statute of limitations has been tolled, where issues of fact may abound, together with disputes concerning law. The legal issue is as clear as consomme at the outset, in those situations concerning whether or not the statute of limitations is applicable, and clarity is not improved by an evidentiary hearing. In the Matter of 3M Company (Minnesota Mining and Manufacturing), supra, at 11-46; See also the undersigned ALJ's order In the Matter of Tremco, Inc., Incon Division, Docket No. TSCA-88-14-05, April 7, 1989, at 2-12.

Here there are contested questions of law, and also probably some facts, which at times appear to overwhelm the stoutest mind. The key to the conundrum would appear to be whether or not the forum would be more enlightened following the reception and evaluation of the evidence pertaining to the defenses. The questions posed in the first and second affirmative defenses are difficult and complex; they are fraught with many legal and perhaps some factual questions. One is led ineluctably to conclude that the issues can best be resolved after being leached out in the sunshine of an evidentiary hearing. It would be premature to grant the motion at this stage in the proceeding; it could do a severe injustice to respondent by foreclosing a possibly valid defense. The ALJ does not share complainant's dyspeptic views concerning the results flowing from the failure to grant the motion or complainant's assertions that respondent is engaged in some form of sophism. At the conclusion of the receipt of evidence, the complainant's position may very well be vindicated, but as best one can decipher the pleadings that exist here and now, valid questions are raised by the first two defenses. They should not be precluded.

The ALJ concurs in complainant's thoughts that the third and fourth affirmative defenses address essentially the penalty and not the liability issue in this proceeding. Must an affirmative defense be confined solely to issues involving liability? Many defenses arise in this context, and for this reason, in a technical sense, the answer to the aforementioned question may appear to be in the affirmative. However, administrative agencies are not bound by the standards of the Fed. R. Civ. P. Traditionally, administrative agencies possess wide latitude in fashioning their own rules of procedure. 1/

The Toxic Substances Control Act (TSCA), 15 U.S.C. §2615(a)(2)(B), mentions certain factors to be considered in determining the amount of civil penalty, including the seemingly unlimited "such other matters as justice may require," Common garden intelligence dictates that defenses relating to the penalty question should not, solely for this reason, be amenable to a

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1/ See, In the Matter of Katzson Brothers, Inc., FIFRA Appeal No. 85-2 (Final Decision November 13, 1985); Oak Tree Farm Diary, Inc. v. Block, 544 F. Supp. 1351, 1356 n. 3 (E.D. N.Y. 1982); and Silverman v. Commodities Futures Trading Commission, 549 F.2d 28,33 (7th Cir. 1977).

motion to strike. The Consolidated Rules of Practice, 40 C.F.R. §22.24, lend support to this. In pertinent part, they provide that complainant, in addition to that of establishing liability, has the burden of going forward and proving that the proposed civil penalty is appropriate. Complainant has cited no persuasive legal authority which would preclude the asserting of affirmative defenses concerning the penalty questions under TSCA. A respondent is entitled to its full, not a half, day in court concerning either liability or penalty, or where, as sometimes occurs, the evidence will involve both questions. To limit defenses solely to the issue of liability as complainant advocates would tend to bifurcate the hearing. It would be less costly and contribute to judicial economy to try all the issues in one proceeding. In the Matter of Shetland Properties, Docket No. TSCA-I-87-1082, Order Denying Complainant's Motion to Strike Affirmative Defense, September 30, 1987.

The ALJ is not persuaded by respondent's argument concerning the untimeliness of the motion. The forum may consider an untimely motion and grant them if doing so seems proper. 2/ However, even when the motion to strike is technically appropriate and well-founded (which is not the situation here), they are often not granted in the absence of a showing of prejudice by the moving party.3/ Complainant here has not demonstrated that it would be prejudiced by failure to grant its motion.

IT IS ORDERED that complainant's motion to strike respondent's four affirmative defenses be DENIED.

Frank W. Vanderheyden
Administrative Law Judge

Dated: September 14, 1989

2/Wright & Miller, Federal Practice & Procedure: Civil § 1380, at 784-785.

3/Id. § 1381, at 800-801.

CERTIFICATE OF SERVICE

I hereby certify that a true copy of an "Order" dated and filed September 14, 1989 by Administrative Law Judge Frank W. Vanderheyden in the matter of Eastman Chemicals Division, Eastman Kodak Company, Docket No. TSCA-88-H-07 was mailed to the following:

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Maria A. Whiting
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Dated: September 14, 1989

AMENDED CERTIFICATE OF SERVICE

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Dated: September 15, 1989