UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

BEFORE THE ADMINISTRATOR

In the Matter of:	)	
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MICROBAN PRODUCTS COMPANY	)	**Docket No. FIFRA 98-H-01**
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DECISION UPON REMAND

This Decision Upon Remand concerns Section 12(a)(1)(B) of the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"), which makes it unlawful to distribute or sell a registered pesticide "if any claims made for it as a part of its distribution or sale substantially differ from any claims made for it as a part of the statement required in connection with its registration ... ." EPA's Complaint asserts that Respondent Microban committed 32 such violations based on 32 shipments of its Plastic Additive 'B' to Hasbro Products, Inc. ("Hasbro"). The Section in issue is part of Section 12(a)(1), which sets forth six categories of prohibited distributions or sales of which Section 12(a)(1)(B) is one. Thus, the section applicable in this proceeding provides:

> [I]t shall be unlawful for any person in any State to distribute or sell to any person –
> ...
> (B) any registered pesticide if any claims made for it as a part of its distribution or sale substantially differ from any claims made for it as a part of the statement required in connection with its registration under section 136a of this Title; ...

7 U.S.C.§ 136j(a)(1)(B).

I. The Board's Decision and Remand Order

The Environmental Appeals Board ("EAB" or "Board") described the central issue before it as " ...whether the Presiding Officer committed error in determining the number of violations of FIFRA Section 12(a)(1)(B)." The Board found that this Court erred in relying on the number of documents containing unapproved claims as the basis for determining the number of violations and that the focus should have been on the number of distributions and sales of the pesticide.[1]

[1]The Board stated that it has consistently found the number of violations of FIFRA Section 12(a)(1) to be based upon the number of proven distributions or sales and that other

It also held that sustaining a violation of Section 12(a)(1)(B) requires an explicit finding that an unapproved claim was made "as a part of" the alleged distributions or sales.[2]

Starting with the words employed in the statute, the Board posited that the first question to be answered is whether Congress' intent was clear from the language used in the particular provision. Citing its holding in *McLaughlin Gormley King Co.*, 6 E.A.D. 339 (EAB 1996), the Board stated "that 'the unit of violation' under FIFRA section 12(a)(1)(B) ... must be based on the number of proven distributions or sales... ." In this case that translates into "the number of proven distributions or sales of the registered pesticide by Microban to Hasbro." Looking to Section 12 (a)(1), it emphasized that "[a]ny potential violation of this section must involve the act of distributing or selling." One then examines, the Board stated, the Section's subparagraphs (i.e. paragraphs A through F) for a description, in greater detail, of the types of distributions or sales that are unlawful.

For Section 12(a)(1)(B), such distributions or sales are unlawful "if any claims made for it as a part of its distribution or sale substantially differ from any claims ... in connection with its registration." Thus, the Board informed that a single shipment of a pesticide would constitute one violation "*if the elements of paragraph (B) are satisfied*." (emphasis added). By that standard, multiple shipments would constitute multiple violations "if the elements of paragraph (B) are satisfied *with respect to each shipment*." (emphasis added).[3]

Accordingly, the Board rejected the Court's view that the gravamen of the offense for a Section (B) violation is the prevention of unapproved claims. Instead, where claims are made which substantially differ from those made as part of the registration and thus are unapproved, no violation can be established without being linked to a distribution or sale. For that reason, the Board emphasized that the focus must be on the number of sales or distributions of the pesticide. Thus, showing linkage between the sale or distribution is a critical factor in determining the number of violations: "If, on the other hand, multiple unapproved claims are linked to only one

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administrative law judges had used that basis as well. Further, it found no logical reason for applying a different measure for the unit of violation for a paragraph (B) violation than for the other paragraphs of 12(a)(1) (i.e. paragraphs (A) through (F)).

[2]To sustain a violation in this case, that requirement means there must be a finding that "the unapproved claims identified in the five documents were made 'as a part of' the alleged distributions or sales of Microban Plastic Additive 'B' to Hasbro."

[3]The Board emphasized that the *number* of unapproved claims made in association with each distribution or sale has no bearing in determining the number of Section 12(a)(1)(B) violations, as that is identified solely by the number of distributions or sales. Thus, whether one shipment with a dozen unapproved claims is involved or one shipment with only a single unapproved claim, in both instances there would be a single violation of Section 12(a)(1)(B).

distribution or sale, ...only a single violation of FIFRA section 12(a)(1)(B) would result." [4] The Board found its plain reading, requiring, for each count, a sale or distribution linking with each unapproved claim, was also consistent with the consumer protection goal of FIFRA of protecting purchasers from being induced into buying a pesticide based on unapproved claims that are potentially false or misleading.

With the standard announced, the Board proceeded to apply it to the present case. It noted that a Section 12(a)(1)(B) violation has five elements:

1. a person charged with the violation
2. the person must be located in a state
3. the person must have distributed or sold a registered pesticide to another.
4. there must be claims made for the registered pesticide *as a part of* its distribution or sale which substantially differ from any claims made for it as a part of the statement required in connection with its registration.

Finding that this the Court's decision failed to properly construe the fourth element, both as to liability and as to the number of violations, the Board stressed that the "as a part of" language went "virtually unnoticed" in the decision.[5] Thus, the Board again emphasized that a linking, or "nexus," must be established between the unapproved claims and the distribution or sale.[6] Accordingly, to determine if unapproved claims were made as a part of the distribution or sale of Microban's Additive "B" there must be an explicit finding that the unapproved claims identified

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[4]The Board stressed that the interpretation of a statute must not be guided by a single sentence or a part of a sentence but instead to the entire provision and to its object and policy. Thus, it noted that part of reading the "plain language" involves examining the purpose of the statute.

[5]While the Board determined that insufficient attention was paid to the sale or distribution aspect of a Section 12(a)(1)(B) determination, the Court did not ignore the requirement: "That is not to say that the sale or distribution element is irrelevant. There must be a showing, as there was here, that there was at least some sale or distribution of the pesticide as a necessary element of establishing a Subsection 12(a)(1)(B) offense." February 18, 1999 Order Determining Number of Violations. The Board went on to observe that, if possible, a court should give effect to every clause and every word of a statute. It noted that the Court's February 18, 1999 Order found that the five documents were not tied to the 32 sales or distributions but existed independently of them. It stated that such a finding would run contrary to the Section 12 (a)(1)(B) requirement that, to establish a violation, the claims in those documents must be made *as a part of* the distribution or sale.

[6]The Board noted that in *Sporicidin International, Inc*., such a "sufficiently close link" was found. It also observed, with approval, that *Sporicidin* held that the claims and the sales or distributions did not have to be contemporaneous. *In the Matter of*: *Sporicidin International, Respondent*. 3 E.A.D. 589, June 4, 1991, 1991 WL 155255 (E.P.A.).

in the five documents were made "as a part of" the distribution or sale to Hasbro.

The Board added: "[F]or purposes of remand only, ... some or all of the unapproved claims may have had some connection to the nascent, and ultimately, ongoing contractual relationship ... between Microban and Hasbro involving the distribution or sale of Microban Plastic Additive "B." " However, it left it to the Court to determine whether the claims were made as a part of the distribution or sale. This determination, it opined, "appear[ed] to be a mixed question of law and fact..." To resolve it, the EAB stated that it was necessary to closely examine "the nature of the contractual relationship as it evolved, and how the parties implemented it ..." To accomplish this, the Board suggested that the "each of the specific documents containing unapproved claims be examined in this respect." As applied to Microban's undated brochure, this would mean determining when the Brochure was provided to Hasbro, whether it was provided before the agreement was made with Hasbro, whether it was intended to induce the purchase of "Additive B," whether the brochure was provided to Hasbro at any time during the agreement, and whether the Brochure was physically included with shipments of "Additive B." The answers to these questions, the Board stated, "could elucidate whether the unapproved claims ... were made 'as a part of' the distributions or sales of Microban Additive "B" to Hasbro."

II. The Parties' Post-Remand Briefs

As EPA characterizes the purpose of the hearing on remand, it is "to further analyze the nexus between the unapproved claims and the 32 shipments." EPA Post-Rehearing Brief at 2. It contends that a clear and direct association between each sale or distribution is evidenced by the purchase order for each shipment. EPA points out that Respondent has admitted that every shipment, "received a purchase order from Hasbro." Further, sections of the License and Supply agreement specifically incorporate and reference the terms of that License and Supply agreement into every purchase order. Pointing to the language of Exhibit E of that agreement, EPA notes that specific claims about the effect of the pesticide are contained within it. *Id*. at 3. Thus, by virtue of the License and Supply agreement's incorporating the terms of the agreement into every purchase order, the particularized link between each shipment and the unapproved claims is demonstrated and consequently the "as a part of its distribution or sale" element of the violation is demonstrated. *Id*. at 4. Because each purchase order incorporated the terms of the License and Supply agreement, EPA contends that the License and Supply agreement is "clearly tied to every advertisement concerning Microban protection through [the incorporation] requirement." *Id*. at 5. EPA also asserts that the five documents with unapproved claims are linked to each of the 32 sales or distributions to Hasbro.

Respondent Microban contends that as EPA completely failed to provide any new evidence to show the required linkage or nexus between the sales and the unapproved claims, the case must be dismissed. Respondent's Post-Rehearing Brief at 1-2. It noted that the purpose of rehearing following the Remand Order was to allow EPA the opportunity to show a nexus between the unapproved claims and each of the 32 shipments of Respondent's product. However, all EPA did at the rehearing was to recall Dr. Brenda Mosley. This testimony, in Respondent's view, offered nothing new regarding any nexus between the claims and the shipments. *Id*. at 4. To the

contrary, Microban contends that Dr. Mosley's testimony offered support for Respondent's position, since she acknowledged that the License and Supply agreement between Microban and Hasbro was not considered in determining the number of violations.[7] Nor, Respondent points out, was the License and Supply agreement alleged to be a violation in the Second Amended Complaint. In addition, the fact that EPA chose to name 32 of the shipments for deterrence purposes, and not because of any link between the claims and the sales, shows that the shipments were selected arbitrarily. *Id*. at 5.

Beyond these points, Respondent asserts that, while it had no duty to present evidence refuting linkage where EPA has not satisfied its burden, the testimony of its witness, Barnwell Ramsey, demonstrates there was no linkage. Ramsey testified that none of the unapproved claims accompanied the 32 shipments and no additional claims were made to those who received them. Tr.53-74.

In its Reply, EPA contends that the Board did not require new evidence. Rather it directed that the remand inquiry determine whether the unapproved claims were a part of the sale or distribution, whether the License and Supply agreement also contained unapproved claims and, if applicable, the appropriate penalty. EPA Post-Rehearing Reply at 2. EPA also reasserts that linkage between the unapproved claims and the 32 shipments has been established through the License and Supply agreement. This is so, because the contract is a "requirements contract" under which each purchase is not a discreet contract, but rather involves the performance of the existing License and Supply agreement. Thus, EPA contends that the unapproved claims in that agreement are carried over with each of the 32 shipments. *Id*. at 3.

EPA also takes issue with Microban's characterization of the purpose of the remand. It contends that neither a rehearing nor further evidence was required by the remand. Rather, it asserts that the Remand required "an analysis of the linkage ... ." EPA presented such an analysis at the Rehearing by showing "the contemporary connection between the five documents found to have unapproved claims and the 32 shipments." *Id*. 3-4. EPA believes that it demonstrated the unapproved claims in the overarching License and Supply agreement were "directly tied" to each of the shipments. It established this by showing that Hasbro directed all shipments from Microban under the License and Supply agreement. *Id*.

EPA also disputes Microban's claim that the License and Supply agreement was not considered, nor alleged to be a violation in the Second Amended Complaint. It points to page 9 of the Second Amended Complaint, where reference is made to page 3 of Exhibit E to Microban's License and Supply Agreement and to paragraph 26 at the same page 9, where it refers to the Respondent's use of the term "germs" and its consistent definition of that term and "bacteria" to mean microorganisms infectious to man. These show that EPA clearly itemized

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[7]Dr. Mosley testified that she did not look at the terms of the License and Supply agreement. Consequently, she never considered it in her penalty calculation. Rather, she confirmed that she looked solely to the number of invoices to determine that there were 32 separate violations. Rehearing Tr. at 47-48.

each distribution to violative claims. *Id*. at 5-6.

In answering the Respondent's claim that EPA chose the 32 shipments arbitrarily, EPA maintains that it presented "evidence to directly tie all 32 shipments ... to unapproved claims. That it decided not to pursue all 54 shipments does not reflect arbitrariness, but rather the Agency's discretion[8] in deciding which claims to pursue, a discretion that considers a number of prosecutorial factors. *Id*. at 7.

Last, EPA responds to Microban's claim it failed to show any linkage or nexus between the claims and the shipments. To do this, it reiterates that the License and Supply agreement, which was adhered to by Microban and Hasbro for each of the 32 shipments, provides the necessary linkage and nexus. That License and Supply agreement, it insists, is "the foundation of every shipment that ties the term 'germ' and specifically names disease causing organisms to the 32 shipments." *Id*.at 9. It is that agreement that sufficiently ties the other five documents to the 32 distributions. *Id*. Further, EPA maintains that Microban has ignored the brochures, faxes, phone calls, and newspaper quotes of Microban statements to Hasbro. These show that, contrary to Microban's claim, additional claims were made to those who received shipments. While Ramsey's testimony refers to the "freight forwarder" and those listed in the "ship to" box for the invoices, EPA asserts that "the purchaser of the product certainly received additional information." *Id*. EPA also contends that "[t]he recipient of the shipments would be included in Respondent's statements regarding health benefits that were quoted in the newspapers." Such newspaper statements amount to "additional claims" that are designed to reach customers and it asserts that "[t]he recipients of the distributions are likely to read such a story." *Id*.

In its Response to EPA's Post-Rehearing Brief, Microban reiterated its position that EPA had not provided any new evidence to demonstrate a linkage or nexus between the unapproved claims and each of the 32 shipments.[9] As a consequence it contends no prima facie case was established and the case should be dismissed. R's Post-Rehearing Response Brief at 1,7. Microban notes that the Board spoke to the possibility of a connection between the documents with unapproved claims and the contracts between Hasbro and Microban, but it observes that the Board did not reach the conclusion that the evidence established such a connection. For that reason it remanded the matter.

Microban also asserts that the Board's decision in *Sporicidin* stands for the proposition that, to establish a violation, the "nexus," or "sufficiently close link," between the claims and the sales

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[8]EPA cites to *Heckler, Secretary of HHS v. Chaney et al*, 470 U.S. 821 (March 20, 1985) regarding the Agency's enforcement discretion.

[9]Microban asserts that EPA has not acquiesced in the standard established by the Board to show a FIFRA Section 12(a)(1)(B) violation. It notes that EPA, while believing that the evidence meets the Board's standard and shows a sufficiently close link, also contended that the "as part of language" in that Section could be construed more broadly. R's Post-Rehearing Response Brief at 7.

or distribution of a pesticide, requires "more than a general connection between unapproved claims and a shipment ..." *Id*. at 3. EPA's mere assertion that the unapproved claims were a part of the overall contractual agreement and were incorporated by reference into orders, or found among Hasbro's documents, does not meet the Board's test.

Respondent further notes that, for the first time in the proceeding, EPA has argued that Appendix E of the Agreement between Microban and Hasbro was incorporated by reference into each of Hasbro's purchase orders.[10] Microban challenges that contention, arguing that EPA did not present evidence as to the parties' intentions regarding incorporation by reference. Instead, Microban asserts that Appendix E has no "relevant function" to the purchase orders and accordingly it should not be assumed that it was incorporated by reference into each purchase order. Offering its own interpretation of the Agreement, Respondent maintains that Section 9.5 incorporates by reference only those terms and conditions which are relevant to a purchase order.[11] Microban also points to its own evidence regarding Appendix E and the 32 shipments, noting that Barnwell Ramsey testified that the Appendix played no role vis-a-vis purchase orders or shipments. Ramsey stated that Appendix E did not accompany the shipments nor did any of the unapproved claims. On this basis Microban contends that as the claims did not accompany any shipment, nor are they specifically associated with one, and since the claims were not given to those who received the shipments, no violation has been shown. Further, Respondent asserts that EPA's own policy provides that multiple violations require that "the elements of proof for the violations [be] different."[12] FIFRA Enforcement Policy at 25.

III. Discussion

As discussed above, the Board determined that the Initial Decision failed to properly evaluate

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[10]Throughout the post-remand phase, Microban has continued to argue a point that has been settled: the claims in the documents cited in the Complaint substantially differed from those allowed under the registration. However, in this particular instance, Microban's contention is distinct because it is addressing whether the claims in Appendix E were unapproved. As before, it maintains that the terms 'germs' and 'bacteria' are interchangeable and consequently the use of the former could not be unapproved. Because the claims within Appendix E were not among the unapproved claims charged in the Complaint, this issue is moot. *See infra* "Determination Regarding License and Supply Agreement, part III. B.

[11]Although this decision's determination regarding the License and Supply Agreement makes this argument moot, the Court notes that the Agreement's terms do not support Microban's reading that under the Agreement's Article 9.5, only parts of it are incorporated by reference.

[12]Respondent's interpretation of the Enforcement Policy is incomplete because the policy also provides that "A violation is independent if it results from an act ... which is not the result of any other charge for which a civil penalty is to be assessed *or* if the elements of proof are different." FIFRA Enforcement Policy at 25 (emphasis added).

the fourth element of a Section 12(a)(1)(B) violation. That element requires showing that claims made for a registered pesticide as a part of its distribution or sale substantially differ from those claims made as a part of the statement required in connection with its registration. Focusing on the "as part of" language, the EAB determined that the Court erred both in its liability determination and in the number of violations. The Remand emphasized that an unapproved claim must be made "as a part of" a distribution or sale.

To determine whether violations had been established, the Board directed that each of the documents with unapproved claims be examined to determine whether they were made "as a part of" a distribution or sale. Applying this approach to Microban's undated brochure, the Board stated it could be important to determine:

1. when the brochure was provided to Hasbro,
2. whether this was at a time before the agreement between Hasbro and Microban was made,
3. whether its purpose was to induce the purchase of the product,
4. whether the brochure was ever provided to Hasbro at any time during the License and Supply agreement, and
5. whether the brochure ever physically accompanied the shipments of the product.

Accordingly, the Board directed that the remand determine whether any unapproved claims were made as a part of the 32 shipments and whether the Agreement contains unapproved claims as alleged in the Second Amended Complaint and if so whether such claims were made as a part of the distribution or sale of Microban's Plastic Additive "B."

Per the Board's instruction, the Court first will proceed to address these questions for each of the unapproved claims.

A. The Court's Determinations Upon Remand

1. The Microban Undated Brochure

EPA noted that Exhibit C-35 (Joint Exhibit 51) is an undated Microban brochure, which it obtained in May 1997 but otherwise offered no information regarding the brochure's date Tr. 27. Respondent's Mr. Ramsey testified that the Microban Marketing Brochure was printed in June 1996. Tr. 73. The License and Supply Agreement was entered into on April 12, 1996. Thus the brochure came after the Agreement. By touting its benefits, a purpose of the brochure was to induce the purchase of the product. The brochure is not mentioned in the Complaint. Hasbro received the brochure, but the record does not reveal when or how this occurred. The brochure never physically accompanied the product. EPA asserts that the brochure is linked by "[t]he presence of [the] brochure with Hasbro and with Respondent." EPA Post-Rehearing Brief at 7.

2. The May 31, 1995 Microban "Presentation to Hasbro, Inc."

Obviously as this presentation occurred on May 31, 1995, it was before the License and Supply was entered into. A purpose of the presentation, by its nature, was to induce the purchase of the product. As the presentation preceded it, it was not provided to Hasbro during the License and Supply agreement. It never physically accompanied the shipments. EPA contends that the Presentation was a vehicle for Microban to induce Hasbro to assent to the License and Supply agreeement. EPA Post-Rehearing Brief at 6. However, there is no evidence in the record to support this contention.

3. Microban's "Public Relations Questions Regarding Microban."

This document was provided to Hasbro by Microban on January 13, 1997. Thus it was made at a time after the License and Supply agreement was entered into. This "question and answer" paper was prepared for a training session. A purpose of such a document, by its nature, is to induce the purchase of the product. Eleven of the invoice shipments were created after the date of this paper. Consequently, this also means that 21 were created before the date of this document. The document never physically accompanied the shipments of the product. EPA asserts that the linkage is that the document "serves as marketing assistance" and "has no other function than to support sales or distributions of Microban Additive 'B'." EPA Post-Rehearing Brief at 8.

4. Microban's suggested label language for a Hasbro product.

This suggested label language was provided to Hasbro on October 28, 1996 via facsimile. Some of the invoices preceded this facsimile while others followed it. The document was provided after the License and Supply agreement became effective. A purpose of the suggested label language, by its nature, was to induce the purchase of the product. The suggested label never physically accompanied any of the shipments of the product. EPA contends that there is linkage by virtue of the fact that the facsimile followed the license and supply agreement and "correlates to the dates of the shipments alleged in the Complaint." EPA Post-Rehearing Brief. at 8.

5. Microban's "Facts about Microban" document.

This document has a copyright date of 1996. The record does not reveal when a document bearing the title "Facts about Microban" was provided to Hasbro or whether Hasbro receive the version entered into evidence as Exhibit C-43. The document is not mentioned in the Second Amended Complaint. Consequently, no finding can be made regarding the time of this document in comparison to the License and Supply agreement. A purpose of the document, by its nature, was to induce the purchase of the product. The document never physically accompanied the shipments of the product. EPA contends that the link with the sales is the existence of the document in the same year as many of the shipments. EPA Post-Rehearing Brief at 7.

B. Determination Regarding the License and Supply Agreement

As noted, Microban has objected to EPA's late argument that Appendix E to the License and Supply Agreement between Microban and Hasbro was incorporated by reference into each of Hasbro's purchase orders. It notes that EPA did not present evidence as to the parties' intentions regarding incorporation by reference. Further, it asserts that Appendix E has no "relevant function" to the purchase orders and accordingly it should not be assumed that it was incorporated by reference into each purchase order.

The Court notes that the Complaint makes only limited reference to the License and Supply agreement. Paragraph 26 includes the following :

> ... "In addition, on page three of Exhibit E to Respondent's "License and Supply Agreement with Hasbro, effective April 12, 1996, Respondent states that:
>
> > Generally, the "antibacterial" designation is used when product claims are targeted toward the control of bacteria only (e.g., staph., strep., e.coli., Salmonella, etc.). The "antimicrobial" designation is used when product claims for a broader range of organisms are anticipated (e.g., not only bacteria but also molds, fungi and yeasts).[13]
>
> This statement, in addition to defining bacteria in terms of microorganisms infectious to man, conveys to Hasbro the message that product claims target toward staph., strep, e. coli., and Salmonella are appropriate.

Complaint at pages 9 - 10. Count I realleges and incorporates paragraph 26. However, Paragraph 28 limits the claims that "substantially differ" from those claims made in connection with Microban's registration to those claims cited in "paragraphs 23, 24, and 25." Those paragraphs (i.e. 23, 24, & 25) only refer to Microban's January 13, 1997 "Public Relations Questions Regarding Microban," the May 31, 1995 "Presentation to Hasbro, Inc.," and the October 28, 1996 suggested label language Respondent provided to Hasbro. Thus, the Second Amended Complaint actually limits the claims of substantial differing claims to those three documents and accordingly it does not include the License and Supply Agreement as a basis for its Section 12(a)(1)(B) claim.

In deciding that there were 32 violations, EPA made that determination based solely on the number of invoices. EPA did not look at the terms of the License and Supply agreement in deciding there were 32 violations, nor did it consider it in the calculation of the penalty. Tr. 47.

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[13]The quoted language was originally designated as "CBI DELETED." At the request of the Court to review this CBI claim, Microban's Counsel waived its CBI claim as to this language. Facsimile from Microban Counsel, September 12, 2002.

Q: So for purposes of determining that there were 32 separate violations, you looked ***solely*** to the invoice system?

A: Yes, I did

Remand Testimony of Dr. Mosley at Tr. 47 - 48. (emphasis added).

Barnwell Ramsey, vice-president of operations for Microban, also testified at the Hearing upon Remand. Ramsey referred to the License and Supply agreement, testifying, without contradiction, that only normal shipping documents accompanied the 32 shipments and that none of the claims that are the subject of this action (i.e. the marketing literature or claims about the additive) accompanied any of the shipments. Tr. 66. Ramsey testified that the Microban Marketing Brochure was printed in June 1996. Tr. 73.

Thus, EPA looked solely to the number of invoices to determine that there were 32 separate violations. Dr. Mosley admitted that she never looked at the terms of the License and Supply Agreement. As the Complaint and EPA testimony reflect, the License and Supply agreement was not considered in the Agency's determination of the number of violations. Accordingly, the Court determines that the License and Supply Agreement may not be considered a basis for establishing the alleged violations.

Further, even if hypothetically considered, Appendix E of the Agreement, while incorporated by reference into each of the 32 invoices,[14] has no connection with the unapproved claims named in Paragraphs 23, 24, and 25 of the Second Amended Complaint. Thus, the alleged unapproved claim (albeit not a claim asserted in the Complaint, nor at either the original hearing or the hearing upon remand) is not linked to the invoices. The focus of Appendix E concerns guidelines for the use of the Microban trademark and its logo. It is not, by any stretch, a vehicle for transmitting unapproved claims as part of a distribution or sale.[15] Accordingly, no

[14]The incorporation by reference of Appendix E technically occurred by the terms of the License and Supply Agreement, but it is worth noting that nowhere on any of the 32 invoices is there a reference to any of the five documents with unapproved claims, nor is there any reference to the License and Supply Agreement or to appendix E of that Agreement anywhere on the invoices.

[15]The Court also rejects EPA's claim that the brochures, faxes, phone calls, and newspaper quotes of Microban statements to Hasbro show that additional claims were made to those who received shipments. EPA's assertions that "the purchaser of the product certainly received additional information" and that "[t]he recipient of the shipments would be included in Respondent's statements regarding health benefits that were quoted in the newspapers" are rejected because they are no more than speculation. So too, its belief that such newspaper statements amount to "additional claims" that are designed to reach customers, together with the assertion that "[t]he recipients of the distributions are likely to read such a story" is not a supportable finding of fact in this record.

particularized link between the License and Supply agreement and the purchase orders has been established.

C. EPA's evidence upon remand.

EPA's sole witness on remand was Dr. Brenda Mosley.[16] Her testimony began with Exhibit C-33, (Joint Exhibit 51), the May 31, 1995 Presentation to Hasbro Inc. This document was prepared before the License and Supply agreement and before the sales and distributions alleged in the Complaint. Tr.20-21. In her view, the document was intended to persuade Hasbro how purchasing Microban's additive would benefit Hasbro. *Id.* Next, she discussed Exhibit C- 37, (Joint Exhibit 51), a facsimile from Microban to Hasbro, dated October 28, 1996. She noted that some invoices cited in the Complaint preceded this facsimile while others followed it. The facsimile refers to suggested changes in product labels. Turning next to Exhibit C-34 (Joint Exhibit 51), is another facsimile, with a January 13, 1997 date. It involved a public relations questions and answers form, which was prepared for a training session. Dr. Mosley observed that eleven of the shipments cited in the Complaint were dated after this facsimile. She noted that the facsimile includes the assertion that "Microban antimicrobial protection is being introduced into consumer products to address the growing public concern over the prevalence of germs and bacteria, such as E. coli, Salmonella, Staph and Strep." Tr. 25-26. EPA Exhibit C-35 (Joint Exhibit 51) is an undated Microban brochure, which EPA obtained in May 1997. Tr. 27.

The next document referred to by the witness was a document entitled "Facts about Microban," with a copyright date of 1996. EPA Exhibit C-43, (Joint Exhibit 51) (Respondent's Ex. 102). The witness read from a portion of the exhibit that "Microban protection is being introduced into consumer products to address growing public concern over the prevalence of germs and bacteria, such as E. coli, Salmonella, Staph., and Strep." Referring again to CBI document, Exhibit E, the License and Supply Agreement between Microban and Hasbro, with an effective date of April 12, 1996,[17] Dr. Mosley noted the section titled "Microban Claims and Guidelines for Trademark Use" and to the claims and guidelines in the License agreement that are permissible for one to use when referring to Microban's product. Tr. 35. Within the same guidelines section is a reference to a description of the designation "antibacterial" which notes that the term is used when product claims deal with control of bacteria such as strep and E. coli. Tr. 38.

Dr. Mosley conceded that none of the documents physically accompanied the shipments and

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[16]Dr. Mosley, an EPA Case Development Officer, also testified at the original hearing.

[17]At the hearing the Court expressed some concerns about the process in which a document becomes eligible as CBI. (The Court Reporter, misunderstanding what was being said, mistakenly refers to these documents as "C *V* I")Tr. 31-32. EPA stated that Microban requested certain documents be considered CBI but Respondent's Counsel explained that redactions from the License and Supply Agreement were done by Hasbro. Tr. 33. .

that none of the documents were provided to Hasbro contractors. There was no evidence that any of the documents ever went to the people who received the shipments. Tr. 41.

D. Liability has not been established.

On this record, the Court determines that no violation has been established because a particularized link has not been established between the unapproved claims cited in paragraphs 23, 24, and 25 of the Second Amended Complaint and any of the 32 invoices.

Following Dr. Mosley's testimony, the Court noted that the remand testimony added no new information and that it was unlikely that the Board would have needed to remand the case if it had sufficient information before it to resolve the case. Tr. 39. It was also observed that nothing was presented in that testimony which particularly tied the statements to the 32 shipments. Under the Board's decision, in the Court's view:

> ... it seems ... that [EPA] would deal with shipment No. 1 and then show what connection there is, how these particular statements were connected to shipment No. 1. This is what the Board was talking about .

Tr. 40.

Thus, EPA never addressed each shipment and produced information individually connecting any of the unapproved statements to each invoice.[18]

The Court determines that the Board must have found the record incomplete or it would have resolved these questions without the need for a remand. For the same reason, the linking required by the Board, must mean more than simply showing the existence of a sale and/or a distribution together with an unapproved claim. If nothing more than that were required, the Board would not have required the particularized inquiry.[19] To conclude that all that is necessary to establish a violation is the presence of an unapproved claim and a sale or distribution would make the particularized inquiry a sham, if, at the end of the analysis, the merest showing would always be sufficient to show a nexus. If the latter were the test as applied it would be difficult to imagine a situation where an unapproved claim would not be a part of a sale or distribution.

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[18] Further, the Court is not the prosecutor. Its responsibility is limited to affording EPA with the opportunity to present its evidence, consistent with the Remand Order's directions.

[19] In effect, under such a construction, the "as part of" language would go "virtually unnoticed" because all one would need to show would be the fact of a sale or distribution. The Board clearly determined that this would not be sufficient, as it described the Court's reference to the presence of "at least some sale or distribution" as reducing that requirement to being "virtually unnoticed."

The reality is that EPA, having learned that Microban was making claims which were inconsistent with its registration, simply determined that the mere presence of 32 invoices for the Additive equated with 32 separate violations. The Board has explained that the inquiry is more involved than that. Because EPA has failed to show the requisite linkage, none of the 32 claimed violations of Section 12(a)(1)(B) has been established.[20]

E. Conclusion

For the reasons set forth above, Respondent is found not liable for any of the 32 violations alleged in the single Count of the Second Amended Complaint.

SO ORDERED.

William B. Moran
United States Administrative Law Judge

Dated: September 13, 2002
Washington, D.C.

[20]This case is distinguishable from that presented *In the Matter of*: *Sporicidin International, Respondent*. 3 E.A.D. 589, June 4, 1991, 1991 WL 155255 (E.P.A.). In that case the Respondent disseminated reports from a research company at a hospital where the product was being used. The reports made conclusions about the effectiveness of Respondent's pesticide product. Such acts did not occur in this instance. Barnwell Ramsey testified, without contradiction, that none of the unapproved claims accompanied the 32 invoice shipments and no other claims were made to those who received them. Tr.53-74.

In the Matter of Microban Products Company, Respondent
Docket No. FIFRA 98-H-01

CERTIFICATE OF SERVICE

I certify that a true copy of **Initial Decision Upon Remand**, dated September 13, 2002, was sent this day in the following manner to the addressees listed below:

Copy By Inter Office Mail to:

Attorney for Complainant: Mark Garvey, Esquire
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Copy By Regular Mail to:

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Original & Copy by Interoffice Mail to: Bessie L. Hammiel
Hearing Clerk
U.S. EPA
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Mail Code 1900C
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Nelida Torres
Legal Staff Assistant

Dated: September 14, 2002