ENVIRONMENTAL APPEALS BOARD UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C.

In re:)	
)	
Bayer CropScience LP, and)	FIFRA Appeal No. 16-(01)
Nichino America, Inc.)	
)	
Docket No. FIFRA-HQ-2016-0001)	

MOTION TO REOPEN HEARING BY BAYER CROPSCIENCE LP AND NICHINO AMERICA, INC.

Pursuant to 40 C.F.R. § 164.110(b) and the June 9, 2016 Order of the Environmental Appeals Board ("EAB"), Bayer CropScience LP and Nichino America, Inc. (collectively, "Appellants" or "Registrants") hereby request that the EAB reopen the hearing to take evidence excluded by the Administrative Law Judge's ("ALJ") May 3, 2016 Order on Respondent's Motion to Limit Scope of Testimony ("MTL Order") (ALJ Dkt. #27) and the ALJ's May 10, 2016 ruling at the evidentiary hearing finding certain of Registrants' exhibits irrelevant and inadmissible for use in cross-examination of Susan Lewis. Counsel for Appellants conferred with counsel for Appellee United States Environmental Protection Agency ("EPA" or "the Agency"), who indicated that Appellee objects to this Motion.

I. PROCEDURAL HISTORY

The May 3, 2016 Order excluded Registrants' expert testimony and exhibits in their entirety and portions of Registrants' fact witness testimony related to the risks and benefits of flubendiamide, and found certain of Registrants' exhibits and other portions of Registrants' fact witness testimony admissible only on issues other than the substantive risks and benefits of flubendiamide. MTL Order at 10. The excluded evidence relates to the manner in which the risks and benefits of flubendiamide factored or did not factor into EPA's unreasonable adverse effects determination and proposed existing stocks determination.

This evidence is relevant to demonstrate that: (1) EPA sought cancellation through the unlawful "voluntary" cancellation provisions to shield its unsound determinations from substantive review; (2) EPA did not engage in the measured scientific dialogue mandated by the conditions of flubendiamide's registration; (3) EPA's risk-based cancellation of flubendiamide was based upon flawed modeling and ignored real-world monitoring data; (4) flubendiamide's benefits to agriculture and the environment far outweigh any alleged risk; and (5) prohibiting the sale or distribution of existing stocks of flubendiamide would be highly disruptive and harmful to agriculture. It is also relevant to correct EPA's mischaracterizations of flubendiamide's environmental profile, lest they color the ALJ's decisions on the lawfulness of EPA's cancellation and existing stocks determinations. The MTL Order provided that Registrants could "make a written offer of proof with regard to such evidence so that it may be included into the record for the purposes of appeal [to the EAB]." *Id.* at 10.

During the hearing on May 10, 2016, the ALJ ruled that certain documents relating to the Reckitt Benckiser pesticide cancellation hearing that Registrants sought to introduce into evidence for use in cross-examining EPA's witness were irrelevant and inadmissible. Corrected Hearing Tr. ("Tr.") (ALJ Dkt. #32) 64:12-13. The excluded evidence relates to pesticide registrations held by Reckitt Benckiser that were the subject of a FIFRA § 6(b) cancellation process initiated by EPA. These documents (PBNX 124-125) confirm that six of the twelve Reckitt Benckiser registrations EPA sought to cancel under FIFRA § 6(b) were conditional registrations issued under FIFRA § 3(c)(7), 7 U.S.C. § 136a(c)(7).

This evidence is relevant to demonstrate that conditional registrations may be cancelled pursuant to FIFRA § 6(b), that EPA previously sought cancellation of conditional registrations in a § 6(b) process, and that the ALJ erred in finding in the Order on Registrants' Motion for

Accelerated Decision ("MAD Order") (ALJ Dkt. #24) that conditional registrations may only be cancelled under FIFRA § 6(e). Registrants made an oral Offer of Proof regarding this evidence and its relevance to resolution of the hearing. *Id.* 64:17-65:21.

On May 19, 2016, Registrants submitted a written Offer of Proof (ALJ Dkt. #34) for the evidence excluded by the ALJ's May 3, 2016 Order and the May 10, 2016 ruling at the hearing.

II. ARGUMENT

A. The Evidence Was Improperly Excluded as Irrelevant.

The arguments establishing the relevance of both categories of excluded evidence are described in Registrants' Appeal Brief and are not repeated in full here.

The excluded risk-benefit evidence is relevant to Registrants' challenge to: (1) the lawfulness of the voluntary cancellation provisions in their flubendiamide registrations; (2) EPA's claim that Registrants failed to comply with a condition of registration; and (3) the lawfulness of EPA's proposed existing stocks determination. *See* Appeal Brief Section III, pp. 24-30. The excluded evidence refutes EPA's risk-benefit analysis and conclusions that the ALJ cited and relied on throughout the Initial Decision. *Id.* at 25-26, 28-30. If admitted, the excluded evidence would show that the Agency's unreasonable adverse effects determination that triggered cancellation is premised upon flawed science, that EPA sought to fit the science to its desired cancellation outcome rather than engaging in a measured scientific dialogue with Registrants as required, that flubendiamide's benefits to agriculture and the environment outweigh any alleged risks, and that prohibiting any further sale or distribution of existing stocks of flubendiamide would be highly disruptive to growers.

The excluded exhibits and cross-examination relating to the Reckitt Benckiser proceeding are relevant to Registrants' challenge to the lawfulness of the voluntary cancellation provision and EPA's determination to cancel flubendiamide under FIFRA § 6(e). *See id.* at Section I(D),

pp. 11-12. Admission of these documents is necessary to correct the ALJ's erroneous findings that "conditional registrations are not entitled to the same lengthy procedures for cancellation under Section 6(b)," that "[c]ancellations of conditioned registrations fall under Section 6(e)," that "the plain language of the statute entitles Petitioners to a cancellation proceeding only under FIFRA Section 6(e)," and that the cases cited by Registrants in support of their position that cancellation should properly proceed under § 6(b) (including *Reckitt Benckiser*) "are all clearly distinguishable from the facts of this case because they involve general registrations, not conditional registrations." MAD Order at 22, 23, 24 & n.21. The exhibits show instead that EPA has previously pursued *risk-based* cancellation of conditional registrations under § 6(b) (in a hearing overseen by the same ALJ), and that the ALJ was mistaken in concluding that EPA may only cancel conditional registrations under § 6(e). The exhibits support Registrants' position that when EPA initiates a risk-based cancellation, it must do so under § 6(b).

B. The Evidence Should Be Admitted for Consideration by the EAB and to Ensure a Complete Record in the Event of a Judicial Appeal.

Once the EAB issues a Final Decision, either Registrants or EPA may exercise their right to appeal aspects of that decision in federal court. Because it is plainly relevant to the issues the parties raised in this proceeding, and to protect Registrants' rights and avoid a one-sided record on appeal, the excluded written testimony and exhibits should be admitted. Registrants will be prejudiced if the evidence cannot be considered by the EAB as it determines the Final Decision or by the appellate court in the event of an appeal by either party. In the interests of fairness and efficiency, Registrants therefore respectfully request that the EAB reopen the hearing and order all previously excluded evidence admitted into the record.

¹ Admitting these exhibits now cannot completely undo the prejudice to Registrants from being denied an opportunity to cross-examine EPA's witness on this subject, but it will at least ensure that errors of fact and law on which the ALJ's decisions were premised may be corrected in the Final Decision.

C. The Hearing May Be Reopened to Admit This Evidence Without Delaying a Final Decision.

Registrants seek to reopen the hearing for the limited purpose of admitting the evidence excluded by the ALJ's rulings into the record. The excluded evidence consists of exhibits and verified written statements that have each already been signed and declared true under penalty of perjury; Registrants do not seek to introduce any further live testimony. EPA cannot now reasonably seek to introduce its own additional testimony or cross-examine Registrants' witnesses if the hearing is reopened, given the Agency's prior representations to the ALJ. Specifically, in its Motion to Limit Scope of Testimony ("MTL") (ALJ Dkt. #18), EPA represented that regardless of the outcome of its motion, the Agency would "not be contesting in this proceeding any factual issues with respect to whether flubendiamide causes unreasonable adverse effects on the environment," would "not make any further arguments with respect to the sale and distribution of existing stocks," and would "neither raise nor contest in this proceeding scientific or economic issues related to whether flubendiamide causes unreasonable adverse effects on the environment." See MTL at 3-4, 6; Appeal Brief at 25 n.17. The ALJ granted EPA's motion based in part on those representations,² and the EAB must be able to rely on EPA's commitments as well.

Given these circumstances, the EAB may order Registrants' evidence admitted into evidence without the need for an additional live hearing and therefore without any delay in the resolution of this proceeding.

² MTL Order at 5 (quoting EPA's representation that it "will not present any factual testimony on risk-benefit issues . . . to support its position.").

Dated: June 13, 2016

Respectfully Submitted,

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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on this 13th day of June, 2016, a true and correct copy of the foregoing Motion to Reopen Hearing by Bayer CropScience LP and Nichino America, Inc. was filed electronically using the EPA EAB eFiling System; and served in the following manner to the below addressees:

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