UNITED STATES
ENVIRONMENTAL PROTECTION AGENCY

BEFORE THE ADMINISTRATOR

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2013 MAY 31 PM 4: 11

In re FIFRA Section 6(b) Notice of Intent to Cancel Registrations of, and Notice of Denial of Applications for, Certain Rodenticide Bait Products	)))))	FIFRA Docket No. 661

RECKITT BENCKISER'S REPLY BRIEF IN SUPPORT OF ITS MOTION FOR AN EXPEDITED DETERMINATION THAT EPA'S EXISTING STOCKS DECISION IS WITHIN THE SCOPE OF THE HEARING

EPA's Assistant Administrator for Chemical Safety and Pollution Prevention ("Respondent") issued a Notice of Intent to Cancel ("NOIC") under Section 6(b) of FIFRA to cancel the registrations of certain rodenticide products produced and marketed by Reckitt Benckiser LLC ("Reckitt" or "the Company"). As a means of putting greater pressure on Reckitt's customers and retailers, Respondent stated that the Agency would bar the sell-through of any Reckitt products remaining on the market post-cancellation, and, of particular significance to the issue at hand, Respondent chose to incorporate the sell-through bar in the NOIC itself.

At issue in Reckitt's pending motion is not the merits of the sell-through ban, but rather Respondent's extraordinary claim that Respondent and Respondent alone can decide whether the sell-through ban is subject to administrative review. Respondent's position has no support in the statutory text of FIFRA and is inconsistent with basic principles of administrative law. Thus Reckitt's motion must be granted, and the disposition of existing stocks addressed as part of the cancellation hearing before the ALJ.

I. Background

Reckitt filed a Motion for an Expedited Determination that EPA's Existing Stocks Decision is Within the Scope of the Hearing on April 12, 2013. Reckitt filed this Motion because of two positions Respondent incorporated into the NOIC: (1) if Reckitt's products are cancelled, anyone in possession of the cancelled products will not be allowed to "sell through" their existing stocks (the "sell-through ban"); and (2) Reckitt may not challenge the sell-through ban in a FIFRA Section 6(b) hearing (the "hearing exclusion") (collectively, the "existing stocks determinations"). 78 Fed. Reg. 8123, 8126-27 (Feb. 5, 2013). In Respondent's April 25, 2013 Response to Motion Regarding Whether Disposition of Existing Stocks of Cancelled Products Is Within the Scope of the Proceeding ("Respondent's Brief" or "Response"), Respondent made several new arguments not included in the NOIC. Reckitt filed a motion for leave to file a reply on April 30, 2013, and the motion was granted on May 22, 2013.[1]

Respondent contends that the sell-through ban should be excluded from the Section 6(b) hearing for the following reasons: (1) The declaration to this effect in the NOIC, as well as Respondent's interpretation of case law, are binding on the ALJ, who lacks authority to determine the scope of the Section 6(b) hearing over which she presides; (2) the disposition of existing stocks is irrelevant to the cancellation hearing requested in response to the NOIC containing the existing stocks determinations; and (3) FIFRA 6(b) does not specifically state that

[1] The Order granting Reckitt leave to file this reply brief notes that "Petitioner Reckitt has not claimed, much less shown, any unique need for an expedited ruling on its pending Motion." To clarify, by "expedited," Reckitt intended to convey that it is seeking a decision on its motion before the parties exchange the primary discovery required by 40 C.F.R. § 164.50(b). This decision will clarify the scope of the hearing early in the process, thereby streamlining the issues and improving procedural efficiency. In addition, several of EPA's new arguments have since been addressed to some degree by other parties' briefs in this matter. As a result, Reckitt will avoid unnecessary repetition in this reply, but to avoid the argument that the Company has waived its right to assert the arguments made by the other parties, Reckitt incorporates these arguments by reference.

the disposition of existing stocks may be considered in the hearing, so Respondent can exempt that determination from ALJ review.

Respondent is wrong on all counts. First, Respondent may not unilaterally determine the scope of the Section 6 hearing; only the ALJ has the authority to decide the scope of the hearing, and she is not bound to blindly follow Respondent's decree or interpretation of case law. Second, the issue of the disposition of existing stocks is inextricably linked with the merits of the Section 6(b) hearing. Third, the language of FIFRA Section 6 does not permit Respondent to exclude an existing stocks determination from the hearing where Respondent incorporated the determination in a Section 6(b) notice. Finally, Respondent's assertions on the merits of the sell-through ban—while not relevant to the issue in this motion regarding the scope of the hearing—are inadequately supported and therefore arbitrary.

I. The ALJ Has the Authority to Determine the Scope of the Section 6 Hearing and Is Not Bound to Follow Respondent's Declarations or Interpretations

As a threshold matter, the explicit statutory language of FIFRA addresses directly the issue in dispute in this motion. FIFRA Section 6(d) states clearly that the scope of a Section 6(b) hearing is established by the issues identified by Respondent in the NOIC and by the "issues raised by the objections filed by the applicant." *See* FIFRA § 6(d).[2] Despite this unambiguous statutory language, Respondent asserts the power to include an issue in the NOIC and then unilaterally exclude that issue from the Section 6 hearing, notwithstanding any objections by the parties. Respondent further asserts that the ALJ is bound to follow Respondent's interpretation of a prior case that is clearly distinguishable from the matter before this Tribunal. Contrary to

[2] This has also been EPA's longstanding position. *See* 37 Fed. Reg. 9476, 9477 (May 11, 1972) ("The issues to be considered in the hearing are defined by the order of cancellation or suspension or denial of registration and the objections thereto filed by the registrants or applicant.").

Respondent's assertions, however, the ALJ decides the scope of the hearing over which she presides, and the applicability of potentially relevant case law.

A. The ALJ Alone Has the Authority to Determine the Scope of the Hearing

Respondent proclaims that the ALJ is bound to follow Respondent's declaration in the NOIC that the sell-through ban is not within the scope of the Section 6 hearing:

> [T]he ALJ's role in determining the scope of the proceeding is fundamentally adjudicative: The ALJ is obliged to respect the texts she interprets and is prohibited from substituting her own judgment for that of the institutional authors. If it were the case that the NOIC were silent or ambiguous in regard to existing stocks of cancelled products, and could reasonably be interpreted as placing in question the disposition of existing stocks, then the ALJ would indeed have authority to issue an order that the disposition of existing stocks is within the scope of the proceeding. However, the NOIC in this proceeding is neither silent nor ambiguous, nor amenable to interpretations as putting the disposition of existing stocks at issue. Reckitt's motion unabashedly asks the ALJ to disregard the express, unmistakable intent of the Respondent as to a policy decision duly delegated to the Respondent, and instead adopt a different policy choice.

Respondent's Brief at 10-11. This sweeping assertion of virtually unchecked authority is fatally flawed, for several reasons.

First, FIFRA provides that all cancellation decisions are subject to administrative review. FIFRA § 6(b); 7 U.S.C. 136d(b). EPA's hearing rules clearly state that the ALJ has authority to "hear and decide questions of facts, law, or discretion" and "to take actions and decisions in conformity with the statute or in the interests of justice." *See* 40 C.F.R. § 22.4(c)(7); 40 C.F.R. § 164.40(d).[3] Respondent may not shield these decisions from administrative review or usurp the ALJ's authority to interpret the law. *In re Reduce Pre-Harvest Interval for EBDC*

[3] Reckitt recognizes that this proceeding is governed by the Rules of Practice in 40 C.F.R. Part 164, but the Consolidated Rules of Practice in 40 C.F.R. Part 22 are also pertinent in evaluating the general authority of the ALJ.

Fungicides on Potatoes, Docket No. EPA-HQ-OPP-2007-0181 (January 16, 2008 Order) at 9, *available at* http://www.epa.gov/oalj/orders/ebdc-scope-hg-011608.pdf (rejecting EPA's attempt to use an Amended Notice of Hearing to exclude issues from the hearing and noting that "[i]f an allegation is made that the Administrator's delegate abused his discretion in making a determination . . . , the ALJ has authority to rule on the allegation." (emphasis added)).[4]

Second, Respondent's assertion that EPA's positions are "entitled to a measure of deference," *see* Respondent's Brief at n.7, rings hollow. While courts generally grant some deference to Agency interpretations of law in areas where the relevant statute is silent and where Congress has granted agencies authority to address any statutory ambiguities, *see Chevron v. Natural Resources Defense Council,* 467 U.S. 837, 843-844 (1984), that doctrine is inapplicable here. As a threshold matter, the statute is not silent. As noted above, FIFRA 6(d) explicitly states that a Section 6(b) hearing shall address the issues raised by a party's objections.

Additionally, deference is generally intended for Agency decisions that have the force of law, such as rulemakings or adjudications, and does not apply to "interpretations contained in policy statements, agency manuals and enforcement guidelines." *See Christenson v. Harris County,* 529 U.S. 576, 587 (2000). While Agency decisions without the force of law may be entitled to some lesser deference depending on the formality and consistency of the position, *see U.S. v. Mead Corporation,* 533 U.S. 218, 228 (2001), Respondent's position here, contained in a legal brief contesting the subject matter jurisdiction of the ALJ, does not merit even this lesser

[4] Respondent asserts in its Brief that *EBDC* is inapt on this point because it involved a different part of the Subpart 164 regulations than those at issue here. *See* Respondent's Brief at 13-14. Respondent appears to have overlooked that the ALJ's conclusion in *EBDC* on this issue was rooted in the Administrative Procedure Act (APA), which governs adjudications under Subpart B of 40 C.F.R. pt 164 as well as Subpart D. Any differences between the Subpart B and Subpart D regulations do not lessen or excuse EPA's obligation to comply with the APA.

deference. *See Bowen v. Georgetown Univ. Hosp.*, 488 U.S. 204, 212 (1988) (agency deference may not be required where an interpretation was adopted for the purpose of litigation and is "wholly unsupported by regulations, rulings, or administrative practice"); *see also Nat'l Wildlife Fed'n v. Browner*, 127 F.3d 1126 (D.C. Cir. 1997) (deference to agency interpretation offered in the course of litigation appropriate only where it reflects the agency's "fair and considered judgment on [the] matter" (citations omitted)); *U.S. Steel Mining Co. LLP v. Director, OWCP*, 386 F.3d 977, 986 (11th Cir. 2004) ("deference is due when an agency has taken a constant and unchanging—and reasonable—position on the proper interpretation of its regulation").

Most important, the fundamental premise underlying the doctrine of judicial deference to agency decisions does not apply here. Deference under *Chevron* and its progeny presumes that an Agency is both acting at the direction of Congress and exercising authority in the area of its regulatory expertise. *See Chevron,* 467 U.S. at 865. In this instance, Respondent asserts that EPA is "entitled to a measure of deference owing to its institutional expertise regarding the regulation of pesticides pursuant to FIFRA." *See* Respondent's Brief at 10, n.7. But Respondent's purported expertise in pesticide regulation—of dubious relevance even to the merits of cancellation in a *de novo* ALJ review—has nothing to do with the purely legal question of whether Respondent may exempt from ALJ review one issue that Respondent chose to include in the Section 6(b) cancellation notice merely because Respondent wants to do so. This issue has no conceivable relationship to Respondent's technical or regulatory expertise, so none of the doctrines of judicial deference are applicable here.

B. The ALJ Is Not Bound to Follow Respondent's Interpretation of Case Law

Respondent relies heavily on *In re Cedar Chemical Co.*, 2 E.A.D. 584, nn.7,9, 1988 WL 525242 (June 9, 1988) (Decision of the Administrator) for the proposition that EPA is not

required to subject a ban on sell-through of existing stocks to a Section 6 hearing.[5] *See* Respondent's Brief at 2-5. As Reckitt explained in its Motion, Respondent's interpretation is flawed because *Cedar Chemical* involved a NOIC that *did not address* the issue of existing stocks. Indeed, the Administrator in *Cedar Chemical* observed that "In the present instance, the notice calling the hearing did not identify existing stocks as being among the issues for resolution at the hearing." *Cedar Chemical* at n.9. Remarkably, Respondent contends that this statement supports its position. *See* Respondent's Brief at 3-4. This contention is nonsensical. The only cancellation notice before the Administrator in *Cedar Chemical* was one that was silent on the issue of existing stocks. In this context, the excerpt above cannot support the conclusion Respondent seeks here—that Respondent can bar a hearing on an issue that is identified in a cancellation notice—for the simple reason that such a notice was not at issue in *Cedar Chemical*. In reality, the Administrator in *Cedar Chemical* directly refutes Respondent's contention, stating that "Obviously, if an issue is identified in the cancellation notice, it fits within the framework of the proceeding and may be litigated in a hearing." *Cedar Chemical* at n.9.

Respondent's Brief fails to address this fatal flaw in reasoning. Significantly, the case upholding the Administrator's determination in *Cedar Chemical* focuses on precisely the point that Respondent now fails to confront. *Northwest Food Processors* upheld the Administrator's decision by relying on the fact that the existing stocks decision was *not mentioned* in the NOIC. *Northwest Food Processors Ass'n v. Reilly*, 886 F.2d 1075, 1078 (9th Cir. 1989) (noting that

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[5] Respondent similarly invokes *In the Matter of Shell Oil Company*, et al., 1 E.A.D. 517, 523-524, 1979 WL 52074 (April 9, 1979) to support its argument. *See* Respondent's Brief at 6. But *Shell Oil* states only that the NOIC "serves much the same function as a complaint in any other administrative proceeding, and as such it 'set[s] a standard of relevance which shall govern the proceedings at the hearing.'" This statement in fact supports Reckitt's argument that a determination made in a NOIC is properly part of a cancellation hearing. It certainly does not authorize Respondent to exclude from a 6(b) hearing matters that are within the scope of a cancellation notice.

including existing stocks in a cancellation hearing where the NOIC was silent on existing stocks would be "very unfair" because "the notice of intent to cancel did not even hint that [Intervenor's] interests could be adversely affected by an existing stocks order resulting from the cancellation hearing.").

Rather than address this central flaw in Respondent's invocation of *Cedar Chemical,* Respondent instead argues that the case stands for the proposition that registrants are never entitled to a hearing on existing stocks: "FIFRA does not confer any hearing rights on opponents of an existing stocks determination. Hearing rights in a cancellation proceeding are conferred by FIFRA §§ 6(b) and (d), whereas existing stocks determinations are made under FIFRA § 6(a)(1) . . . ." Respondent's Brief at 3. Respondent's argument fails, however, because the sell-through ban in this case was announced in the *NOIC issued pursuant to Section 6(b).* Even assuming *arguendo* that *Cedar Chemical* stands for the proposition that an existing stocks order issued separately under Section 6(a)(1) does not give rise to the right to a hearing, that proposition is of no help to Respondent here, where Respondent has attempted to bar the sell-through of existing stocks in a putative determination included in the Section 6(b) notice. In other words, the NOIC here is a Section 6(b) notice that contains a provision related to existing stocks. It is not a Section 6(a)(1) order, nor has Respondent alleged that it is. Respondent chose to issue a 6(b) notice that included among its provisions a ban on the sell-through of existing stocks. Nothing in *Cedar Chemical*, or in any other authority cited by Respondent, supports the proposition that the public hearing provisions of Section 6(d) do not apply to some portions of a Section 6(b) notice merely because the Agency arguably could at some point implement those portions of the notice under separate statutory authority.

Failing to address these fundamental infirmities of reasoning, Respondent instead asserts that the ALJ somehow is bound to accept the Agency's construction of *Cedar Chemical* as binding precedent, despite the glaring factual and legal differences. Respondent's Brief at 5 (claiming that "the *Cedar Chemical* interpretation [by Respondent] of the role of existing stocks in cancellation proceedings is settled law for purposes of this proceeding.") As the sole authority for this proposition, Respondent quotes a 40-year-old law review article: "[O]nce the agency has ruled on a given matter, [moreover,] it is not open to reargument by the administrative law judge." *Id.* n.5, *quoting* Joseph Zwerdling, *Reflections on the Role of an Administrative Law Judge*, 25 Admin. L. Rev. 9, 12-13 (1973). Of course, a law review article, however interesting, is of no persuasive value—it is nothing more than the opinion of the author, which has not been tested in an adversary proceeding. More fundamentally, in this instance Respondent engaged in an exercise in selective quotation, and the article in fact supports Reckitt's argument on this motion. It is clear from the context of the article that the passage quoted by Respondent refers to a potential difference of opinion between the ALJ and the final Agency decision-maker on "a given matter," that is, where the ALJ and the final Agency decision-maker disagree on the same specific matter. *Id* at 13. A different passage from the article addresses situations like the one here, where "it cannot be said that there are clearly and admittedly controlling and binding precedents which are admittedly dispositive." *Id.* This situation "leaves wide area requiring the exercise of the administrative law judge's judgment and discretion." *Id.*

While Respondent is certainly entitled to assert a creative construction of *Cedar Chemical* before the ALJ, Respondent's position is not binding on this Tribunal. Rather, only this Tribunal has the authority to consider the case, assess the parties' dueling interpretations of it, and determine whether and how it might or might not apply to the case at hand. In fact,

Respondent appears to concur that this Tribunal has the authority to decide the issue of the validity of Respondent's sell-through ban. In a recent jurisdictional brief filed before the U.S. Court of Appeals for the 10th Circuit, the Agency stated that:

> The Agency's decisions regarding the cancellation of Petitioner's products, including the scope of the cancellation hearing itself, will not be final, and an administrative record of those decisions will not be created for purposes of judicial review under Section 16(b) of FIFRA, until the Administrative Law Judge issues an initial decision that becomes final pursuant to 40 C.F.R. § 164.90(b), or the Environmental Appeals Board issues a final decision, concluding the administrative hearing process.

Respondent's Memorandum Brief in Response to the Court's Order Regarding Jurisdiction, May 28, 2013 at 5 (emphasis added). (*See* Exhibit A). Thus, in another forum, EPA has acknowledged that it is the ALJ, and not Respondent, who is authorized under FIFRA to decide the scope of the cancellation hearing, including whether the hearing does or does not address existing stocks.

II. Existing Stocks Considerations and Determinations Are Relevant to the Section 6 Cancellation Hearing

In response to Reckitt's Motion, Respondent said that the issue of existing stocks is excluded from the hearing because:

> [T]he disposition of existing stocks is not relevant to the question of whether the d-CON products identified in the NOIC meet the criteria for registration under FIFRA, because the continued sale and distribution of these products after cancellation would continue to cause unreasonable adverse effects on health and the environment, and because Reckitt has been on notice since at least 2008—and arguably 1998—that these products do not meet the criteria for registration under FIFRA.

Respondent's Brief at 2.[6] First, like the assertion that Reckitt's products should be cancelled, Respondent's claim that the sell-through of existing stocks will cause continued unreasonable adverse effects on health and the environment is merely Respondent's opinion, which Reckitt will contest in the upcoming Section 6(b) hearing. Similarly, Respondent's statement that Reckitt has been on notice since 2008 or 1998 that its products "do not meet the criteria for registration" is just plain wrong. Reckitt has certainly been on notice of Respondent's *position* on the relative risks and benefits of Reckitt's products, just as Respondent has been on notice since 2008 that the Company disagreed with Respondent and sought a hearing to resolve this issue. This proceeding is *de novo*, and Respondent fails to grasp that, despite the vehemence with which Respondent asserts the Agency's position, it is for the ALJ and the Environmental Appeals Board, and not Respondent, to decide whether or not the Company's products pose an unreasonable risk to the environment.

Second, the availability of sell-through of existing stocks is relevant to—and an important part of—the risk-benefit analysis in the Section 6 hearing. The ability to continue buying and using the product during a post-cancellation sell-through period is directly relevant to the unreasonable risk standard. First, the risks of immediately prohibiting the sale and use of a product upon cancellation inform the risks of cancelling the products in the first place. Second, the risk-benefit calculus for cancellation might change depending on whether there is a reasonable regime for transitioning to alternative products (if any). The need to allow continuing use of a product for an upcoming spawning season, infestation occurrence, or other events, and

[6] While the merits of whether sell through of existing stocks is justified for any cancelled products is not relevant to Reckitt's motion regarding the scope of the hearing, the Company addresses these issues here for the purpose of responding to Respondent's arguments. As noted in footnote 1, above, Reckitt seeks to have the scope of the hearing resolved so that the parties can understand and prepare for the scope of this hearing and, at the appropriate time, present arguments and evidence on the issue of existing stocks.

the corresponding effects on public health that could result from the immediate prohibition on the distribution or continued use of a public health pesticide following cancellation, could materially affect the benefits analysis that is a statutory prerequisite to cancellation. These concerns are particularly relevant where the transition to a new product requires providing training for applicators and users of alternative products, especially in the case of pesticides used to combat pests of significance to public health.[7] The cancellation risk-benefit analysis that FIFRA requires is therefore bound to whether EPA may provide relief for users via sell-through as they transition to new products, train poison control centers about new active ingredients, and educate doctors and veterinarians about the hazards of new products. In seeking to remove the sell-through prohibition from the scope of a Section 6(b) hearing, Respondent effectively deprives the registrant and other adversely affected parties of an important opportunity to contribute information relevant to the risk-benefit analysis.

Finally, Respondent compares the Agency's existing stocks determinations for Reckitt's products to the one the Agency made for toxaphene. Respondent's Brief at 22, n.15. Respondent says that, unlike toxaphene, where the use of existing stocks would be the best means of disposing of them, "[Respondent] has concluded that the d-CON products at issue in this proceeding would pose greater risk to health and the environment if they were used than if they are disposed of as waste." *Id.* Respondent provides no evidence or basis for how this conclusion was reached. As a result, rather than supporting Respondent's case, the toxaphene decision emphasizes that Respondent has failed to conduct any meaningful review of the existing

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[7] FIFRA Section 2(bb) provides that "[t]he Administrator shall consider the risks and benefits of public health pesticides separate from the risks and benefits of other pesticides. In weighing any regulatory action concerning a public health pesticide under this Act, the Administrator shall weigh any risks of the pesticide against the health risks such as the diseases transmitted by the vector to be controlled by the pesticide."

stocks issues in this case, and certainly has failed to describe a decision-making process or rationale—if any—in either the NOIC or in the Response.

III. The Language of FIFRA Section 6 Does Not Permit Respondent to Exclude The Existing Stocks Determination from the Hearing

In the Response, Respondent contends that "[t]he structure of section 6 compels a conclusion that the section 6(a) authority over existing stocks is — like the subjects of sections 6(c), 6(e), 6(f) and 6(g) — wholly irrelevant to, and outside the scope of, a hearing under sections 6(b) and 6(d)." Respondent's Brief at 8. However, as noted above, FIFRA is clear that the scope of a Section 6 hearing is established by the issues identified by EPA in its NOIC and by the registrant in its Statement of Objections.[8] 7 U.S.C. § 136d(d). Respondent announced the sell-through ban in a NOIC issued under Section 6(b). That determination therefore was subject to objections raised by the registrant or other adversely affected parties. *See* 40 C.F.R. § 164.22. Reckitt and three other parties filed hearing requests that specifically include objections to Respondent's existing stocks determinations. As a result, pursuant to FIFRA Section 6(d), those determinations are within the scope of the Section 6(b) hearing.

The language of FIFRA Section 6 supports this interpretation. Sections 3(c)(2)(B) and 6(e) explicitly reference existing stocks in the context of delineating the scope of the abbreviated hearings contemplated for actions taken under those two provisions. In contrast, Section 6(b) does not limit the scope of the cancellation hearing; the hearing is bounded only by the guidance in Section 6(d) that the contents of the NOIC and the objections filed in response establish the

[8] Respondent spends several pages rebutting an argument Reckitt does not make: that a statement of objections can expand the scope of a hearing beyond the issues contained in a notice. *See* Respondent's Brief at 6-11. But Reckitt nowhere makes such an assertion. Rather, Respondent brought the issue of existing stocks into this proceeding by issuing a determination on existing stocks in a 6(b) cancellation notice. The authorities Respondent relies on all support the well-established conclusion that the issues in a NOIC are subject to a 6(b) hearing. Reckitt agrees.

scope of the hearing. The limitations on scope contained in sections 3(c)(2)(B) and 6(e) show that Congress knew how to limit the scope of hearings where it felt that was appropriate; conversely, Congress chose not to limit the cancellation hearing under 6(b).[9]

FIFRA's legislative history confirms that hearings initiated under Section 6(b) are intended to address the full range of issues permitted in Section 6(d). The legislative history makes clear that the only reason Section 6(e) mentions existing stocks is because hearings under that provision are meant to be abbreviated versions of a Section 6(d) hearing. *See* Statement of Douglas M. Costle, EPA Administrator, H.R. Rep. 95-663 at 61 (April 27, 1977) (stating a Section 6(e) hearing "should be confined to whether or not the conditions were met and how existing stocks should be handled [because] Public resources should not be devoted to long, drawn-out cancellation procedures for these types of registrations."). Hearings initiated under Section 6(b), in contrast, are intended to be *un*abbreviated and provide a complete review of EPA's actions, including its recommendations with respect to the disposition of existing stocks where such determination is in the Section 6(b) NOIC.

IV. Respondent's Sell-Through Prohibition Is Arbitrary and Capricious

Even assuming arguendo that Respondent could lawfully exclude the determination concerning existing stocks in the NOIC from those matters that may be considered in this proceeding, the existing stocks determinations set forth in the NOIC are without a proper

[9] Moreover, in 1972, when FIFRA was amended to create the current framework for cancellation hearings, Congress rejected an amendment that would have conferred more authority on EPA to limit and control the course of the hearing. *See* 118 Cong. Rec. 32248-32263 (1972) (containing language of bill as debated by Senate, excluding the proposed amendment). The rejected language read in relevant part: "All public hearings authorized by this subsection shall consist of the oral and written presentation of data or arguments in accordance with such conditions or limitations as the Administrator may make applicable thereto." H.R. 10729, 92nd Cong., at 96 (as reported by S. Comm. on Commerce, July 19, 1972). The fact that Congress considered, and rejected, language giving EPA greater control over the hearing is indicative of Congressional intent not to limit the scope of a Section 6(b) hearing.

substantive foundation and therefore is arbitrary and capricious. FIFRA requires that EPA undertake a risk-benefit analysis when it considers cancelling a product registration. *See* FIFRA § 6(b) and FIFRA § 2(bb). Similarly, according to its own policy, EPA must also conduct a risk-benefit analysis when considering whether to ban the sale of existing stocks of a canceled product. *See* 56 Fed. Reg. 29364 (June 26, 1991). Respondent has utterly failed to conduct the required analysis regarding the sell-through ban.

The extremely brief discussion of the sell-through ban in the NOIC shows that the Agency limited its risk-benefit analysis to whether the subject products meet the cancellation standard and did not conduct such an analysis for the sell-through ban. However, EPA's policy states that "[a] risk/benefit analysis for existing stocks purposes is somewhat different from the analysis that is performed by the Agency in determining whether or not to cancel a registration," because there are several additional criteria to consider. 56 Fed. Reg. 29364 (June 26, 1991) ("Policy").[10] The list of additional considerations in the Policy includes the risks resulting from the use of existing stocks, the quantity of existing stocks remaining at each level of the market, the amount of money users and others have already spent on existing stocks, and the risks and costs of disposal. *Id.*

Even though EPA has waged a campaign against Reckitt's products for years, the Agency has never requested the information necessary to consider the criteria in the Policy for a sell-through risk-benefit analysis. Further, several considerations that the Policy requires are based

[10] EPA's Amended Existing Stocks Policy states that EPA will generally allow a 30-day comment period for existing stocks determinations. *See* 61 Fed. Reg. 16632 (April 16, 1996). Since Respondent has already stated its intent to bar the sell through of existing stocks for Reckitt's products, and has even justified disparate treatment of Reckitt's products compared to those of settling registrants, it is clear that Respondent's position is in fact a *fait accompli*, and that any public comment period Respondent may provide will be of no real consequence, since the decision has already been made. This further demonstrates why ALJ review of Respondent's determination is necessary.

on information that is not available until and unless a registered product is cancelled (*e.g.*, the quantity of existing stocks in the market and money spent on existing stocks at the time of cancellation). The brevity and prematurity of the sell-through ban shows that it is based on insufficient evidence and is contrary to the Agency's own Policy.

In addition to failing to undertake the analysis required, Respondent based this existing stocks decision on the notion that registrants who voluntarily brought "safer" products to the market should not be competitively disadvantaged by registrants who declined to "improve" their product. 78 Fed. Reg. at 8126-27. But a registrants' competitive position is not part of the risk/benefit inquiry that governs an existing stocks decision. *See* 56 Fed. Reg. 29364. The fact that Respondent considered issues related to supposed competitive advantage suggests that Respondent has sought to unjustly punish Reckitt (and any retailer that continues to stock and sell the Subject Products) for exercising its statutory right to a cancellation hearing.

In the Response to Reckitt's Motion, Respondent expands slightly on the cursory discussion of the sell-through ban Respondent provided in the NOIC and makes several new arguments for the decision on existing stocks.[11] Respondent argues that the NOIC simply adheres to the "default" position suggested by the statutory definition of a canceled product. *See* Respondent's Brief at 17. Respondent also claims that Reckitt's products "will present significantly greater comparative risks than those presented by rodenticide products cancelled before the commencement of this proceeding." *Id.* at 20. Neither of these positions has merit.

First, these assertions do not satisfy the risk-benefit analysis required by EPA's own policy, nor do they render that analysis unnecessary. Second, the notion that such a "default"

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[11] As noted on pp. 4-5 above, the arguments EPA raises for the first time in its Response brief should not be accorded deference. *See, e.g.*, *U.S. Steel Mining Co. LLP v. Director, OWCP*, 386 F.3d 977, 986 (11th Cir. 2004) (courts "do not afford deference to ad hoc positions of agencies adopted in reaction to the exigencies of litigation").

position exists is undermined by the fact that the risk-benefit calculation for existing stocks contains different considerations from those involved in the cancellation process. Moreover, Respondent provides no reasoning for the determination that EPA's so-called "default position" is appropriate *in this case*, especially considering that Section 6(a)(1) provides discretion to deviate from such a default and that EPA often does so, as Respondent has here with respect to the other registrants subject to the NOIC. *See, e.g.*, 78 Fed. Reg. 11881, 11883 (Feb. 20, 2013); 78 Fed. Reg. 15949, 15950 (Mar. 13, 2013). Additionally, Respondent also does not address the obvious inconsistency in the approach towards the sell-through of Reckitt's products and the sell-through of the products of the parties who opted to voluntarily cancel their products. Retailers of Liphatech's products will have unlimited time to sell-through those products, *see* 78 Fed. Reg. 11881, 11883 (Feb. 20, 2013), which means that these products—which Respondent contends pose a risk equal to Reckitt's products—could remain in consumer distribution long after the cancellation hearing has ended. Respondent offers no meaningful defense to this obvious disparate treatment of Reckitt's products.

CONCLUSION

For the foregoing reasons, Reckitt respectfully requests a determination that Respondent's purported existing stocks sell-through prohibition in the NOIC is within the scope of the hearing to which Reckitt is entitled under FIFRA.

Dated: May 31, 2013

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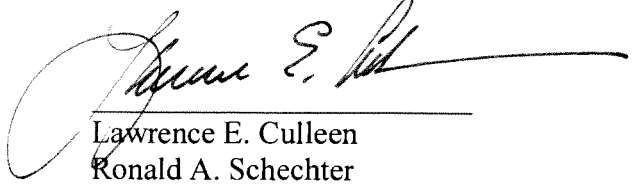

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EXHIBIT A

UNITED STATES COURT OF APPEALS
FOR THE TENTH CIRCUIT

RECKITT BENCKISER LLC, Petitioner, v. UNITED STATES ENVIRONMENTAL PROTECTION AGENCY, Respondent.	)	No. 13-9543

RESPONDENT'S MEMORANDUM BRIEF IN RESPONSE TO THE COURT'S ORDER REGARDING JURISDICTION

On April 13, 2013, Reckitt Benckiser LLC ("Petitioner") filed a petition for review ("Petition") of "a determination" made by the United States Environmental Protection Agency ("EPA") in a "Notice of Intent to Cancel Registrations of, and Notice of Denial of Applications for, Certain Rodenticide Bait Products entered on February 4, 2013" ("Notice"). *See* Docket # 10062245. On April 15, 2013, this Court issued an order suspending briefing on the merits, advising the parties that the Court is considering summary dismissal for lack of appellate jurisdiction, and requiring that the parties submit memorandum briefs on the following jurisdictional issue:

> Whether a final agency action which is subject to judicial review has been issued?

Order, Docket # 10062467.

Petitioner responded on May 6, 2013, stating that it does not believe the Court has jurisdiction, but "filed its petition for review . . . because the case law associated with judicial review under FIFRA may be viewed as unclear." Petitioner's Memorandum Brief in Response to the Court's Order of April 15, 2013 at 3, Docket # 10069160. The Court's jurisdiction over this matter is not unclear; there has been no final "order issued by the Administrator" after a "public hearing," both of which are prerequisites to judicial review by this Court under Section 16(b) of the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"), 7 U.S.C. § 136n(b).

Specifically, FIFRA Section 16(b), 7 U.S.C. § 136n(b), limits the jurisdiction of the courts of appeals to "case[s] of actual controversy as to the validity of any order issued by the Administrator following a public hearing . . . ." Orders reviewable under Section 16(b) must be final. *See Beyond Pesticides v. Whitman*, 360 F. Supp. 2d 69, 71 (D.D.C. 2004); *see also* FIFRA Section 6(h), 7 U.S.C. § 136d(h) ("*Final* orders of the Administrator under this section shall be subject to judicial review pursuant to section 136n of this title.") (emphasis added). "Public hearing" is not defined in FIFRA, but has been held to mean an administrative process sufficient to create a record for judicial review. *See United*

Farm Workers of Am. v. EPA, 592 F.3d 1080, 1083 (9th Cir. 2010); *Humane Soc'y of the United States v. EPA*, 790 F.2d 106, 110-12 (D.C. Cir. 1986); *Envtl. Def. Fund v. Costle*, 631 F.2d 922, 926-31 (D.C. Cir. 1980).

The Notice at issue in this case was issued under FIFRA Sections 3(c)(6) and 6(b), which require such a notice to be issued in order to provide registrants and other interested parties notice of EPA's intentions to deny or cancel the registrations of certain products and the opportunity to request an administrative hearing under FIFRA Section 6(b). *See* 78 Fed. Reg. 8123 (Feb. 5, 2013); *see also* 7 U.S.C. §§ 136a(c)(6), 136d(b). In the Notice, EPA announced its "*intent* to cancel the registration" of certain of Petitioner's products, explained "how the Agency *intends* to treat existing stocks *when and if products are cancelled*," and articulated the Agency's position that the disposition of existing stocks would not be within the scope of any cancellation hearing requested pursuant to the Notice. *See* 78 Fed. Reg. 8123, 8126-27 (emphasis added). The Notice further stated that

> [i]n the event a hearing is held concerning a particular product, the cancellation or denial of the registration for that product will not become effective except pursuant to a final order issued by the Environmental Appeals Board . . . . or an initial decision by a presiding Administrative Law Judge that becomes a final order . . . .

Id. at 8126. Thus, on its face, the Notice is merely a preliminary document that envisions a final order issued after additional administrative process.

Indeed, FIFRA explicitly states that "proposed action" described in notices issued under Sections 6(b) and 3(c)(6) "shall become final and effective at the end of 30 days from receipt by the registrant, or publication, . . . whichever occurs later, unless . . . . either (i) the registrant makes the necessary corrections . . . or (ii) a request for a hearing is made . . . ." 7 U.S.C. § 136d. If a hearing is requested, an Administrative Law Judge receives "evidence relevant and material to the issues" and the Administrator issues an order "based . . . on substantial evidence of record of such hearing . . . ." *Id.* § 136d(d); *see also id.* § 136a(c)(6) (explaining that the applicant has the same remedies under Section 3 as under Section 6); 40 C.F.R. §§ 164.2 (defining FIFRA's "Hearing Examiner" as an "Administrative Law Judge"), 164.90-164.103 (describing initial decisions by Administrative Law Judges and appeals to the Environmental Appeals Board).

Petitioner has requested an administrative hearing under FIFRA Section 6(b) pursuant to the Notice, and preliminary steps have been taken in that proceeding, including the filing of briefs regarding the scope of the hearing. However, the assigned Administrative Law Judge has not yet decided whether the treatment of existing stocks is within the scope of the hearing, has not received any evidence regarding cancellation of Petitioner's products, and certainly has not issued an initial decision that can be appealed to the Environmental Appeals Board. And of course, there has been no final order issued by the Environmental Appeals Board.

The Agency's decisions regarding the cancellation of Petitioner's products, including the scope of the cancellation hearing itself, will not be final, and an administrative record of those decisions will not be created for purposes of judicial review under Section 16(b) of FIFRA, until the Administrative Law Judge issues an initial decision that becomes final pursuant to 40 C.F.R. § 164.90(b), or the Environmental Appeals Board issues a final decision, concluding the administrative hearing process.

Moreover, because the administrative hearing process has not been completed and therefore Petitioner's products have not yet been cancelled, the Agency has not issued a final order regarding how any existing stocks *of a cancelled product* will be treated. *See* 7 U.S.C. § 136d(a)(1). EPA's statement in the Notice regarding disposition of existing stocks in the event a final cancelation order is issued is merely a statement of the Agency's current intentions, consistent with EPA's 1991 policy statement on existing stocks. *See* Existing Stocks of Pesticide Products; Statement of Policy, 56 Fed. Reg. 29,362, at 29,365 (June 26, 1991). In the absence of a cancelled pesticide, there can be no final agency action with respect to existing stocks of a cancelled product reviewable under FIFRA Section 16(b).

Thus, EPA has not issued a final order following a public hearing that would be reviewable under FIFRA Section 16(b). Accordingly, no issues arising from the

Notice, including the existing stocks issues that Petitioner identifies, constitute final agency action ripe for review under FIFRA Section 16(b). The petition should be dismissed.

DATED: May 28, 2013

Respectfully submitted,

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Certification for ECF Pleading

Pursuant to CM/ECF User Manual Section II(I), I hereby certify that all required privacy redactions have been made, that any hard copies submitted to the clerk's office are exact copies of the ECF submission, and that the ECF submission was scanned for viruses with Microsoft's Forefront Client Security, Version 1.5.1993.0, which is updated daily, and, according to the program, is free of viruses.

Dated: May 28, 2013

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Certificate of Service

I hereby certify that I electronically filed the foregoing RESPONDENT'S MEMORANDUM BRIEF IN RESPONSE TO THE COURT'S ORDER REGARDING JURISDICTION with the clerk of the court for the United States Court of Appeals for the Tenth Circuit using the electronic case filing system of the court. The electronic case filing system sent a "Notice of Electronic Filing" to the following attorneys of record:

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In the Matter of Reckitt Benckiser LLC, et al., FIFRA Docket No. 661

CERTIFICATE OF SERVICE

I certify that the foregoing Reply Brief In Support Of Its Motion For An Expedited Determination That EPA's Existing Stocks Decision Is Within The Scope Of The Hearing, dated May 31, 2013, was served at the addresses listed below in the manner indicated.

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Dated: **May 31, 2013**

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