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BEFORE THE ENVIRONMENTAL APPEALS BOARD
U.S. ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C.

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ORDER SETTING ORAL ARGUMENT

IN THE MATTER OF: :
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: :
BAYER CROPSCIENCE LP, and : FIFRA Appeal No.
NICHINO AMERICA, INC. : 16-01
: :
Docket No. FIFRA-HQ-2016-0001:
_____:

Wednesday,
June 22, 2016

Administrative Courtroom
Room 1152
EPA East Building
1201 Constitution Avenue, NW
Washington, DC

The above-entitled matter came on for hearing, pursuant to notice, at 1:00 p.m.

BEFORE:

THE HONORABLE KATHIE A. STEIN
Environmental Appeals Judge

THE HONORABLE MARY KAY LYNCH
Environmental Appeals Judge

THE HONORABLE MARY BETH WARD
Environmental Appeals Judge

ORIGINAL

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ALSO PRESENT:

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1:00 p.m.

1
2
3 MS. DUNCAN: The Environmental Appeals
4 Board of the United States Environmental
5 Protection Agency is now in session for oral
6 argument in re: Bayer CropScience, LP, Nichino
7 America, Inc., docket number FIFRA-HQ-2016-0001,
8 FIFRA appeal number 1601. The Honorable Judges
9 Mary Beth Ward, Kathie Stein, Mary Kay Lynch
10 presiding. Please turn off all cell phones, and
11 no recording device allowed. Please be seated.

12 JUDGE STEIN: Good morning, everyone.
13 Thank you for coming today and appearing for this
14 oral argument which was obviously scheduled on
15 relatively short notice after the EPA filed its
16 brief, but we are aware of the importance of this
17 proceeding, and the importance of proceeding
18 relatively expeditiously, at the same time giving
19 due consideration to the importance and
20 complexity of the issues in this case.

21 Could we please have the parties state
22 their appearances and who is with them today

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1 starting with Bayer?

2 MS. SZMUSZKOVICZ: Good afternoon to
3 the entire board. My name is Kathy Szmuszkovicz
4 and I represent Bayer CropScience in this matter.
5 With me today in the courtroom is the division
6 counsel from Bayer, Kristina Kring, the vice
7 president of environmental safety for Bayer, Dr.
8 Peter Coody, the head of federal registrations
9 for Bayer, Charlotte Sanson, and the individual
10 responsible for flubendiamide registration, Nancy
11 Delaney.

12 From Nichino, we have the vice
13 president of regulatory, Dr. Lydia Cox right
14 behind me and her outside counsel, Mr. Ken
15 Morris. With me from Beveridge and Diamond are
16 my colleagues David Barker, Daniel Eisenberg, and
17 Robert Dewey.

18 JUDGE STEIN: Thank you, and would you
19 like to reserve five minutes for rebuttal?

20 MS. SZMUSZKOVICZ: We would, and if I
21 may also just introduce the assistant general
22 counsel here Kirstin Landis and her outside

1 counsel, Warren Lehrenbaum is here as well.

2 JUDGE STEIN: Okay, thank you all for
3 joining us today. EPA?

4 MS. GOERKE: Good afternoon, my name
5 is Ariadne Goerke, and with me are Bob Perlis
6 from EPA, and Scott Garrison from EPA.

7 JUDGE STEIN: Thank you. We will
8 proceed with Bayer first.

9 MS. SZMUSZKOVICZ: Thank you again,
10 Your Honors, and may it please the board, the
11 registrants appreciate your providing this
12 opportunity for the parties to appear before you
13 to address the questions that you may have as you
14 deliberate on the final EPA decision in this
15 matter.

16 We also especially appreciate the
17 statutory schedule places an unusual burden on
18 the EAB to make its final determination in a very
19 short period of weeks, and we thank you and those
20 who are working with you for your work to
21 complete this undertaking in a thoughtful way.

22 Today, the registrants wish first and

1 foremost to address your questions. To the
2 extent there's time, we do have remarks prepared
3 on several issues of first impression presented
4 by this case. And finally, as Judge Stein
5 invited, we would like to reserve five minutes
6 for rebuttal.

7 JUDGE STEIN: Well, let me begin then
8 with questions because we have several. Reading
9 through the briefs and the administrative law
10 judge's decision, it appears that the lawfulness
11 of the condition in question is at the heart of
12 this appeal.

13 Under 6(e)(2), the statute prescribes
14 the scope of this hearing. What authority does
15 the board have in light of that statute to
16 consider whether the condition is lawful or not?

17 MS. SZMUSZKOVICZ: We're pleased that
18 you see the heart of the issue as being whether
19 the registrants are entitled to a 6(b) hearing.
20 The statutory authority is clear that when EPA
21 has rendered a decision based on unreasonable
22 adverse effects on the environment, a section

1 6(b) hearing should ensue. That was made clear
2 in the Reckitt Benckiser case.

3 JUDGE STEIN: Right, no, I understand
4 your argument about 6(b), but directing your
5 attention specifically to 6(e) which provides
6 that the only matters for resolution at that
7 hearing shall be whether the registrant has
8 initiated and pursued appropriate action to
9 comply with a condition or conditions within the
10 time period provided, or whether the conditions
11 have been satisfied within the time period
12 provided, and whether the administrator's
13 determination with respect to the disposition of
14 existing stocks is consistent with that chapter.

15 MS. SZMUSZKOVICZ: Right.

16 JUDGE STEIN: As I understand it, this
17 proceeding has been brought under 6(e). I
18 understand you're challenging that, but under the
19 terms of 6(e), what authority does the board have
20 to even consider whether the condition is lawful?

21 MS. SZMUSZKOVICZ: Well, the -

22 JUDGE STEIN: I mean, it strikes me

1 that that is beyond the statute, so I'd like to
2 hear your response to that question.

3 MS. SZMUSZKOVICZ: Well, to begin
4 with, as we understand it, the board is looking
5 at this issue de novo. There has been no EPA
6 final decision as to the cancellation, as to the
7 decision on whether 6(e) or 6(b) is proper until
8 this tribunal makes that decision.

9 And we would say that EPA's bringing
10 of the matter to the ALJ under 6(e) was a
11 contrivance, that all of the conditions of
12 registration that were lawful had been met, that
13 the only so-called condition of registration that
14 EPA is alleging was not met, never was properly
15 put in place, and never was properly triggered,
16 and that really it is the job of the EAB to look
17 at the agency's behavior, decisions, actions,
18 whether it met its obligations under the statute
19 at this point fresh, and determine whether or not
20 this case is properly before you under 6(e).

21 JUDGE STEIN: Right, but there's
22 nothing in 6(e) that you could point me to that

1 would give us authority to look at the lawfulness
2 of the condition, is that correct?

3 MS. SZMUSZKOVICZ: Nothing within
4 6(e), but 6(e) is a contrivance in this
5 situation. One needs to really stand back as the
6 voice of the agency to say is it lawful for OPP
7 to insist on waivers of rights that are unlawful
8 in order to avoid its statutory obligations under
9 the statute?

10 And you would not be the first
11 tribunal to admonish OPP on this. Two recent
12 tribunals have done so, and it's a repeated
13 issue, very important to be addressed and
14 stopped.

15 JUDGE STEIN: Doesn't the registration
16 itself on its face speak to the question that
17 suspension would be under 6(e)?

18 MS. SZMUSZKOVICZ: It's interesting
19 that you use that terminology "suspension"
20 because throughout this proceeding -

21 JUDGE STEIN: I meant cancellation.
22 Let me correct myself.

1 MS. SZMUSZKOVICZ: And perhaps we'll
2 have an opportunity to talk about suspension
3 under 6(e) because it's very important that EPA
4 continues to say it needed the provision that
5 you're referring to, but it has the authority
6 under 6(c) to suspend a product whenever it
7 determines that there's a need to do so quickly.

8 JUDGE STEIN: Right, I was just
9 directing your attention to page two of the cover
10 letter on what is labeled "PBNX-07" -

11 MS. SZMUSZKOVICZ: Yes.

12 JUDGE STEIN: - which says, "Your
13 release for shipment of these products
14 constitutes acceptance of the conditions of
15 registration as outlined in the preliminary
16 acceptance letter for flubendiamide dated July
17 30, 2008. If these conditions are not complied
18 with, the registration will be subject to
19 cancellation in accordance with Section 6(e) of
20 FIFRA." Isn't that something that the company
21 has been aware of since the time that it - since
22 2008?

1 MS. SZMUSZKOVICZ: Yes, absolutely,
2 and all of the parties to this matter have
3 acknowledged that the acceptance letter that you
4 referred to was unconventional and unique. It
5 was the provision regarding voluntary
6 cancellation that the applicants found
7 objectionable. They tried to remove it from the
8 letter. EPA refused.

9 There was no choice other than to sign
10 the letter and accept these conditions, but the
11 registrants did so with the understanding that
12 there would be good faith scientific discussions
13 and exchange, which did not take place, and also
14 with a fervent commitment that if the science
15 dictated, the products would be cancelled, and
16 the science did not dictate that.

17 JUDGE LYNCH: Can I - the notice
18 itself includes the same language about
19 cancellation proceedings will be conducted under
20 6(e), correct?

21 MS. SZMUSZKOVICZ: It does.

22 JUDGE LYNCH: And then let me ask you,

1 if - I understand your arguments, but if a
2 cancellation proceeding was properly brought in a
3 case under 6(e), could the legality of the
4 conditions be challenged?

5 MS. SZMUSZKOVICZ: We do believe so
6 because the issue of whether a fundamental -
7 whether the condition itself is legal is a
8 necessary predicate to determining whether there
9 was any requirement to fulfill the condition.
10 All of the legal conditions were fulfilled, the
11 data requirements.

12 JUDGE LYNCH: I'm not talking about
13 your case. I'm just talking about -

14 MS. SZMUSZKOVICZ: In general?

15 JUDGE LYNCH: - in general. So you're
16 saying that in any 6(e) proceeding, if a party
17 wanted to challenge the legality of a condition,
18 they could do so, and -

19 MS. SZMUSZKOVICZ: I don't think this
20 tribunal needs to go that far and -

21 JUDGE LYNCH: Well, let me ask - so
22 can you answer the question?

1 MS. SZMUSZKOVICZ: Yeah, and I would
2 not say so. I would not say so. I would say
3 this case presents a unique set of facts, and the
4 tribunal need only reach a conclusion based on
5 the record here.

6 JUDGE LYNCH: In terms of the legality
7 of the condition in this case, is it your
8 position that the condition was illegal in 2008?

9 MS. SZMUSZKOVICZ: Yes, and I think
10 there was a recognition that it was very unusual
11 and the registrations would not be granted
12 without it, but the registrants went into the
13 proceeding anticipating, as they had experienced
14 in other matters, that there would be a good
15 faith discussion of the data and the conclusions,
16 which did not occur here.

17 JUDGE LYNCH: But you're saying it was
18 not unusual, but you're saying that it was
19 illegal in 2008?

20 MS. SZMUSZKOVICZ: Yes, because -

21 JUDGE LYNCH: In 2009?

22 MS. SZMUSZKOVICZ: And it was - yes,

1 it was a -

2 JUDGE LYNCH: And '10?

3 MS. SZMUSZKOVICZ: And '10 - a
4 contrivance to help EPA try to protect itself
5 from having to go through the process that it's
6 obligated to do and that courts have told it it
7 is obligated to do under section 6(b) when it
8 makes an unreasonable adverse effects
9 determination.

10 JUDGE LYNCH: And are you - were you
11 barred from going to court or any - taking any
12 other action to challenge the legality then?

13 MS. SZMUSZKOVICZ: The question of
14 judicial efficiency and - is an important one
15 here because there should be -

16 JUDGE LYNCH: That wasn't my question,
17 but -

18 MS. SZMUSZKOVICZ: Yes, but there
19 should be, there should be - I think that the
20 registrants recognize that to go into court and
21 use the resources of the courts and EPA when in
22 the end, had there been a good faith discussion

1 and an actual meritorious decision based on
2 unreasonable adverse effects, it would have been
3 unnecessary, would be a poor use of everyone's
4 resources.

5 JUDGE LYNCH: But you could have gone
6 into court?

7 MS. SZMUSZKOVICZ: Well, I'm not
8 opining on whether a court would have viewed us
9 as reaching the jurisdictional bar to get into
10 court. We could have tried, but I'm not sure
11 that that would have succeeded.

12 JUDGE WARD: But counsel, you also had
13 the option of turning down the conditional
14 registration with these conditions which would
15 have prompted a 6(b) hearing at that time,
16 correct?

17 MS. SZMUSZKOVICZ: That's a false
18 option with all respect to everyone who has
19 suggested it because at the point of this
20 decision, we had before us a very remarkable
21 product after \$125 million of investment, and
22 demonstrated to EPA that it had a worker safety

1 profile that it was very safe, remarkably safe
2 across the board to humans, mammals, birds, fish.

3 The only issue is the issue of impacts
4 on benthic invertebrate aquatic organisms.
5 Ironically, today the agency at the very same
6 entrance that we came in, will be greeted by
7 members of the public who are saying that the
8 agency is not taking enough action to protect
9 beneficial insects.

10 This is an insecticide the EPA has
11 said is practically nontoxic to bees,
12 pollinators, and other beneficial insects. So to
13 suggest that there really was an option, either
14 from EPA's perspective or ours, of turning down
15 this product in the face of that remarkable
16 profile, is not practically - is not a practical
17 solution.

18 JUDGE WARD: It was a choice.

19 MS. SZMUSZKOVICZ: It wasn't a real
20 choice. It wasn't a real choice. There is no
21 registrant who has ever made that choice, and
22 there is not a registrant that would make that

1 choice.

2 JUDGE WARD: Is there anything in the
3 record demonstrating that you objected at that
4 time that the condition was illegal?

5 MS. SZMUSZKOVICZ: The discussions
6 that went back and forth were between non-
7 lawyers, and there were plenty of objections to
8 the provision. There was a length negotiation,
9 and the final agreement was predicated on the
10 fact that there would be a measured scientific
11 dialogue, which did not take place here.

12 JUDGE WARD: But you didn't object
13 that it was illegal at the time?

14 MS. SZMUSZKOVICZ: No, there was not
15 an - I'm not aware that there were lawyers
16 involved at the time.

17 JUDGE LYNCH: I mean, it was - you
18 mentioned the amount of money you spent. Is
19 there a dollar cut off?

20 MS. SZMUSZKOVICZ: No, that was just
21 to suggest that there had been a substantial
22 investment in a product that has a remarkable

1 safety profile, and it really would have been a
2 disservice to the public to deprive it of that
3 tool.

4 The other factor that's been lost in
5 the maelstrom is that this product is used for a
6 huge array of minor use crops, so minor crops
7 that can't often afford having the support of a
8 registration.

9 The federal agency that is tasked with
10 helping to facilitate these IR-4 has been very
11 involved in the expansion of the product, and in
12 fact, complained to EPA that they were completely
13 cut out of the discussions on cancellation,
14 existing stocks, and Judge Biro took no note of
15 that whatsoever.

16 It's remarkable to have a federal
17 agency commenting in this kind of setting. It's
18 remarkable to see the array of grower groups
19 across the country, the organization that
20 represents all retailers and distributors saying,
21 "Something is wrong here, and we're depending on
22 the EAB as the final word of EPA to correct what

1 has been done so far."

2 JUDGE STEIN: Before we turn to the -
3 you have raised a number of questions about the
4 good faith dialogue, and we'll get there in just
5 a moment.

6 MS. SZMUSZKOVICZ: Thank you.

7 JUDGE STEIN: But I wanted to go back
8 to the options. I mean, I think a couple of
9 options have been identified. You say these were
10 false choices, one of which was to attempt to
11 appeal to federal court, accept the registration
12 and attempt to appeal to federal court. The
13 other of which is to tell the EPA you wouldn't
14 accept the registration on those terms. Were
15 there any additional options available to you?

16 MS. SZMUSZKOVICZ: We don't think so.
17 It's been suggested that the parties could have
18 taken the registration and then - to amend it,
19 but that's exactly what happened in the
20 Woodstream case. The party made a timely request
21 for amendment. EPA did not act on it. Even
22 after the matter went into federal court, EPA

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1 failed to ever act on the amendment request, and
2 the reason was because it would have triggered
3 the 6(b) hearing. There's a pattern here.

4 JUDGE STEIN: Well, you can't assume
5 that that's how EPA would have treated this
6 request, can you? I mean, I assume that's just
7 speculation on your part?

8 MS. SZMUSZKOVICZ: Well, I don't think
9 there's any reason to - there's never been an
10 instance where EPA has acted on such an
11 amendment. And when you look at the pattern of
12 behavior by the Office of Pesticide Programs,
13 whether it's in Reckitt Benckiser, whether it's
14 in the sulfoxaflor case, whether it's in the
15 Woodstream case, every single action is to avoid
16 section 6(b) hearings.

17 Because EPA does not want us, despite
18 all of the rhetoric about transparency, it does
19 not want to subject its science to real peer
20 review, to interagency input, to input from the
21 growers and other stakeholders, and to go before
22 the scientific advisory panel, to go before the

1 National Academy of Sciences and defend their
2 science.

3 "Too risky," is what EPA said in a
4 letter recently that's part of the - that's one
5 of the documents in evidence, and too much
6 effort.

7 JUDGE STEIN: Okay, so as I understand
8 the sequence of events, what EPA proposed
9 initially was a firm date for the end of this
10 registration.

11 MS. SZMUSZKOVICZ: Right.

12 JUDGE STEIN: And my understanding,
13 and correct me if I'm wrong, is that the
14 documents in the record reflect that that was a
15 condition that your clients did not want to
16 accept, and therefore proposed an alternative.
17 Is that a correct or incorrect understanding of
18 the record?

19 MS. SZMUSZKOVICZ: They did not want
20 to accept it and they deleted it. EPA proposed
21 this alternative. Our -

22 JUDGE STEIN: In response to your

1 deletion of the firm date?

2 MS. SZMUSZKOVICZ: Deletion. And it's
3 interesting -

4 JUDGE STEIN: So another option would
5 have been to simply accept the firm date as EPA
6 proposed?

7 MS. SZMUSZKOVICZ: I suppose someone
8 could have accepted that. These companies
9 decided not to, and that's to a temporal issue
10 that's really, I think, critical also. EPA gave
11 a period of years in that first registration, and
12 then extended it, and extended it, and extended
13 it again.

14 And as of this summer, EPA proposed,
15 EPA proposed, and Judge Biro was inaccurate in
16 her statement on this, that the registrations be
17 extended another three years while the companies
18 responded to EPA's request for additional data
19 and analysis. The suggestion that EPA, "needed"
20 this immediate cancellation at the point that it
21 decided it wanted, it just doesn't hold up under
22 the facts here.

1 JUDGE STEIN: Doesn't the statute
2 specify conditions under which conditional
3 registrations can be granted? I mean, aren't
4 there - I mean, I'm assuming that EPA's not free
5 just to say, you know, to grant a conditional
6 registration for an unlimited period of time.

7 MS. SZMUSZKOVICZ: Well, the statute -
8 that's also an important point and it
9 distinguishes our case from some of the ways that
10 other registrants have argued it. We do think
11 that EPA has fairly broad discretion to impose
12 conditions beyond conditions requiring data,
13 which is explicitly mentioned in the statute.
14 But we think in this case, it went too far.

15 We're not asking you to draw what the
16 bright line is, but we do acknowledge that it
17 goes beyond asking for data, which is
18 specifically mentioned in the statute. It just
19 doesn't go to asking people to waive rights to
20 something they don't even know how it's going to
21 transpire in the future.

22 JUDGE LYNCH: Well, related to the

1 conditions and your view that you can challenge
2 the legality of the conditions, if you can
3 challenge the legality of the conditions, can a
4 third party challenge the legality?

5 MS. SZMUSZKOVICZ: That gets into a
6 really complicated jurisdictional question under
7 the statute. I think that a person could
8 petition EPA concerning an agency action, and
9 based on a decision, and if they have the - and
10 if the agency renders a decision on that that's a
11 final agency action, that could potentially be
12 appealed. I think there's a first amendment
13 right to raise issues. The statute itself is
14 quite limited in who can bring which type of
15 actions at what time.

16 JUDGE LYNCH: And if the condition or
17 a condition was determined to be illegal, what's
18 your view of what that means for the registration
19 for the conditional -

20 MS. SZMUSZKOVICZ: Really, and it's
21 such a good, another really good question. In
22 this case, it would mean you simply delete that

1 condition. The rest of the registration is
2 lawful. The rest of the conditions were
3 obviously met, and EPA had no need, because it
4 had the statutory authority, to suspend the
5 product if it needed to, to have this provision.

6 So this particular legal provision
7 could be excised without any effect on the
8 remainder of the registration. It's an unusual
9 situation because EPA was asking for something it
10 already had the legal authority to do under the
11 statute.

12 JUDGE LYNCH: So counsel, could I
13 follow up? Is it your position that EPA could or
14 could not include a time limitation in the
15 registration? Going back to the first, I guess,
16 first condition that EPA had proposed, would that
17 have been lawful?

18 MS. SZMUSZKOVICZ: It's not a question
19 before the board, but I believe that it would be
20 unlawful under FIFRA. And this is an area that
21 has never been tested, but to have an automatic
22 expiration date would mean depriving the

1 registrants of all of their 6(b) rights. So for
2 the same reasons that we're talking about here,
3 our position would be that an automatic
4 expiration is unlawful. That's not before you,
5 but as long as you've asked, that's our answer.

6 JUDGE LYNCH: But - sorry.

7 JUDGE WARD: I was going to say so you
8 had 6(b) rights. You still have 6(b) rights I
9 suppose arguably, right? You could have at that
10 time not accepted the conditional registration.
11 Then you would have had your opportunity for a
12 6(b) hearing, correct?

13 MS. SZMUSZKOVICZ: It would not have
14 been a 6(b) hearing. 6(b) hearings apply to
15 products that are on the market and being sold,
16 and where EPA has proposed to remove them. The
17 type of hearing that we would have had in that
18 situation, we would not have been on the market.
19 We would have received a denial which would be a
20 final agency action, and we'd be appealing the
21 denial, all the while the product could not be
22 sold.

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1 JUDGE WARD: Okay, but I think going
2 back to the time limitation point, reading the
3 statute regarding conditional registrations, it
4 talks about conditional registrations for a
5 period of time.

6 MS. SZMUSZKOVICZ: Right.

7 JUDGE WARD: And so reading that, at
8 least the plain language would suggest that
9 generally speaking, conditional registrations
10 would have or would be time limited, which is a
11 provision that you objected to in exchange for
12 something that would give you arguably greater
13 rights under this conditional registration, not
14 fewer rights.

15 MS. SZMUSZKOVICZ: Well, those two
16 types of provisions are viewed as very different,
17 and EPA's sole witness at the ALJ hearing, Ms.
18 Susan Lewis, who is the head of the registration
19 division currently, said that those types of
20 provisions are very distinct and viewed that way,
21 and the reason is because there's nothing
22 automatic about cancellation.

1 There are - and the statute as a whole
2 needs to be read together. Section 6(b) provides
3 a very detailed process, which is backed up by
4 regulations, of what needs to happen before a
5 product is cancelled for failing to meet the
6 unreasonable adverse effects standard on the
7 environment.

8 The conditional registration issue,
9 and this is a point that EPA made in the Reckitt
10 Benckiser briefs, it's taking a different
11 position here, is that under 6(e), it's really a
12 question about the conditions and time, the
13 timing to those, the general of data, which is
14 the most common condition that you have. But an
15 automatic expiration would involve writing 6(b)
16 out of the statute, and that would be illegal.

17 JUDGE STEIN: Let me turn to a
18 slightly different area right now, and I'm going
19 to add more time because we have a lot more
20 questions, so.

21 MS. SZMUSZKOVICZ: Okay, thank you.

22 JUDGE STEIN: I see you have just a

1 minute left, but when the buzzer rings, if we can
2 add 15 more minutes to the clock after the clock
3 runs out. And the good faith question that you
4 would like to get to, and which we will get to,
5 the ALJ ruled against petitioners on that point
6 claiming that you had waived that objection by
7 failing to object in the initial objections that
8 you filed. Can you point me to where in your
9 objections you think you sufficiently preserved
10 that issue?

11 MS. SZMUSZKOVICZ: And we outlined
12 this in our briefs if you'll just give a moment
13 to find it, if you'll give me a moment to find
14 it. And in general, I would say that there has
15 been replete throughout the discussions the
16 objections in all of the briefs that we've filed
17 our position that we did not have the good faith
18 discussions that were envisioned back in 2008 and
19 that we normally -

20 JUDGE STEIN: Well, I've looked at
21 those objections pretty carefully, and under the
22 objection addressing compliance with conditions,

1 what I see in the request for hearing at 49,
2 paragraph 165 is, "Throughout 2015, scientists
3 from the registrants and EPA engaged in
4 discussions about the benefits and risks of
5 flubendiamide." So where in that would I find
6 Bayer's and Nichino's objection on good faith
7 grounds.

8 MS. SZMUSZKOVICZ: Good faith? Well,
9 the whole discussion about what occurred in
10 December and January - so starting with a meeting
11 in December, on December 15, in which the
12 assistant administrator led the meeting and the
13 highest officials of both companies were there,
14 the registrants were informed that that was the
15 final meeting. Never was it discussed or
16 explained that there was a change to the way that
17 EPA was doing its science and -

18 JUDGE STEIN: Right, well, I
19 understand factually you described and talked
20 about the meetings, but where did Bayer and
21 Nichino raise a legal objection to the good faith
22 dialogue? I don't see that, and if you could

1 point me to where you raised a legal objection to
2 that, that would be most helpful to the board.
3 And if you want to provide it in your rebuttal,
4 that would be fine.

5 MS. SZMUSZKOVICZ: We will do so.
6 It's remarkable, and there's an awful lot of
7 records available to you, but you do have a good
8 record available to you to make that finding.
9 Perhaps the most persuasive thing to me was
10 having Dr. Coody explain to me the ramifications
11 of appendix three, page 50, of a document that is
12 one of our exhibits, Exhibit 31, where buried in
13 one table in an addendum to a risk assessment is
14 the only place that you find that EPA relied on a
15 single endpoint, and that it wasn't the endpoint
16 about sediments that concerned it, it was the
17 endpoint about water.

18 Nowhere in EPA's decision document,
19 nowhere in the notice of intent to cancel,
20 nowhere in any document that we were provided in
21 advance of the demand for a cancellation, and to
22 me, that explains with a punctuation point

1 factually that there was not good faith. Did we
2 make a -

3 JUDGE STEIN: Am I right though that
4 the original endpoint that was agreed upon or
5 that was originally used was 0.028?

6 MS. SZMUSZKOVICZ: And EPA said that
7 is not the appropriate endpoint because it was in
8 water, pore water, rather than sediment, and
9 these are sediment dwelling aquatic
10 invertebrates.

11 So the registrants generated the data
12 to have the endpoint that EPA said was
13 appropriate, and EPA was relying on that from the
14 point that that endpoint became available up
15 through the summer. Then the assistant
16 administrator -

17 JUDGE STEIN: Can you give me an
18 indication where in the record EPA said it wasn't
19 the appropriate endpoint?

20 MS. SZMUSZKOVICZ: Yes, yes, yes. Let
21 me see if we have that in our science. And maybe
22 we should do that in the rebuttal too so as to

1 keep you -

2 JUDGE STEIN: That would be fine.

3 MS. SZMUSZKOVICZ: - to give you the
4 citations. We'll give you all of the citations
5 in the rebuttal.

6 JUDGE WARD: And Counsel, just picking
7 up that thread of the facts here, there was a
8 meeting December 15 with the registrants and EPA.
9 There was an email - there was a communication on
10 December 16 at which, at least reading it on its
11 face, it appears as if at that point, the
12 registrants understood that EPA had reverted to
13 the original lower toxicity endpoint.

14 There is further, at least reading the
15 record that we have before us, there appears
16 there was some information provided to the
17 registrants, and then a further meeting in
18 January, an all day meeting. And I think we read
19 the record as suggesting that there was a
20 discussion of the endpoint at that meeting. Is
21 that a fair reading of the record, and if not,
22 why not?

1 MS. SZMUSZKOVICZ: And there's a
2 number of people in the room who were at that
3 meeting. I personally was there, and I'm going
4 to speak from personal, my personal knowledge of
5 it.

6 JUDGE WARD: I think we need to stick
7 with what's in the record.

8 MS. SZMUSZKOVICZ: Okay, well, what's
9 in the record, EPA discussed a suite of toxicity
10 endpoints. At that meeting, what EPA presented
11 was that it would be looking at a suite of
12 endpoints. When you read Exhibit 31, PBNX
13 Exhibit 31, you see a table of a suite of
14 endpoints.

15 But not until you go to appendix
16 three, page 50, do you see one table on a page
17 with lots of tables that shows that the sole
18 endpoint that was being relied upon was the water
19 endpoint as opposed to the sediment endpoint, and
20 we'll tie that together with the EPA's statement
21 about why when they had the water endpoint, that
22 was not sufficient for the inquiry that it wished

1 to undertake that sediment, they wanted something
2 specific to sediment which is where these
3 invertebrates dwell.

4 JUDGE WARD: But there was some
5 dialogue -

6 MS. SZMUSZKOVICZ: There wasn't really
7 a dialogue.

8 JUDGE WARD: - at the meeting?

9 MS. SZMUSZKOVICZ: There was a
10 presentation by the EPA scientists about
11 apologizing for the unfortunate way in which the
12 discussions had arisen, and saying that they were
13 looking - assuring the registrants they were
14 looking at a suite of endpoints.

15 And then on the same day the
16 registration cancellation was demanded, buried in
17 a document that had been written the day before
18 and provided to the registrants, signed the day
19 before and provided to the registrants on January
20 29, back in appendix three, page 50, one table,
21 you find the answer to how EPA actually did the
22 calculation.

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1 That's not a transparent good faith.
2 You've got people coming in from across the
3 country, even as far away as Japan for Nichino's
4 parent company, to discuss the science, and
5 never, never was it explained that that one
6 endpoint would drive, let alone that the human
7 health aspects would not be taken into account,
8 the effects on non-target organisms, any of these
9 other factors that really need to be done under a
10 risk benefit balancing under FIFRA.

11 What the assistant administrator told
12 everybody in the room on December 15 is that he
13 would not have registered this product, and he
14 thought he could cancel it based on persistence
15 alone based on this one issue which was never
16 fully - EPA's scientific position was never fully
17 explained.

18 That's inconsistent with FIFRA, but
19 his entire staff heard it, and sure enough, the
20 next day, they apparently gave him the basis to
21 reach that conclusion.

22 JUDGE STEIN: Don't the decision

1 documents say that EPA looked at both endpoints
2 in their final decision?

3 MS. SZMUSZKOVICZ: And that's
4 precisely the point. It didn't. When you look
5 at the calculation that drives the decision, it
6 was based on one endpoint. I mean -

7 JUDGE STEIN: And is this argument
8 that you're laying out to us now, is this an
9 argument you made to the administrative law
10 judge?

11 MS. SZMUSZKOVICZ: The administrative
12 law judge, although she obviously reached a
13 conclusion about the risks and benefits, she did
14 not allow us to get into a real discussion of the
15 scientific merits.

16 JUDGE STEIN: But I'm asking about
17 when you got the documents on January 29, was
18 there anything that precluded you from writing
19 back to EPA about that?

20 MS. SZMUSZKOVICZ: Well, we did
21 respond to the request for cancellation. I must
22 say on that day, it was not possible to digest

1 everything new that we had been given. I can
2 assure you that the registrants spent most of the
3 holidays trying to figure out what was going on
4 and digesting what had been said in the meetings
5 in December, and that everybody immediately gave
6 high attention to reviewing EPA's documents.

7 But this is not something that was
8 readily available, and really, it appears that
9 EPA intended to obfuscate it. Why not explain
10 right in the decision document? Why not explain
11 in the risk assessment document? Why not explain
12 somewhere that this is the selection and why?

13 And the reason is the EPA cannot
14 justify in the face of its prior statements using
15 an endpoint that is on water when what the
16 concern is is sediment, and they specifically
17 said that's a higher tier study that should have
18 been done and that we would rely on, so the
19 registrants did it.

20 JUDGE STEIN: Okay, so one thing that
21 would be helpful for rebuttal is for me to
22 understand the exact sequence, because as I've

1 read those decision documents, I see a reference
2 to two endpoints, not one.

3 MS. SZMUSZKOVICZ: Okay.

4 JUDGE STEIN: What's the dialogue in
5 Bayer's view?

6 MS. SZMUSZKOVICZ: In Bayer's view, a
7 measured scientific dialogue would be a chance to
8 explore the data which was done, and then what
9 conclusions should be drawn based on the data.
10 And because EPA never shared its conclusion
11 relying on one sole endpoint, there never was an
12 opportunity to have that discussion. You can't
13 have a discussion about something you don't know
14 exists.

15 JUDGE LYNCH: And when you say
16 conclusion, conclusions about the data, or the
17 ultimate conclusion or determination? What are
18 you specifically referring?

19 MS. SZMUSZKOVICZ: Yeah, so they do -
20 they are different, but they do go hand in hand
21 in our program and interactions between the
22 agency and the scientists because there generally

1 is a common understanding of how the information,
2 once the conclusions are reached, how those
3 conclusions may affect the terms and conditions
4 of registration.

5 So they are very closely, very closely
6 intertwined, but the conclusion itself was not
7 something that was revealed to the registrants
8 until a chance to really parse through the
9 documents that were made available on January 29.

10 JUDGE LYNCH: And just so I'm clear,
11 just articulate what's the conclusion?

12 MS. SZMUSZKOVICZ: So there are a
13 couple of different elements to it, but the
14 element on the toxicity endpoint, if you were to
15 use the correct toxicity endpoint, you would have
16 an unmistakable conclusion that none of the water
17 monitoring ever hit that endpoint. That was
18 actually also true for the lower endpoint.

19 There had never been any detections in
20 any of the multi-million dollars worth of
21 groundwater monitoring data that exceeded that
22 endpoint. But EPA then took that endpoint and

1 inserted it into a model to predict certain
2 conclusions about the future, and those are the
3 conclusions.

4 JUDGE LYNCH: And the other term I
5 wanted clarification on is you referred to a new
6 conclusion in the January memo.

7 MS. SZMUSZKOVICZ: Yes.

8 JUDGE LYNCH: Which - what are you
9 referring to there?

10 MS. SZMUSZKOVICZ: Which would be that
11 using that old endpoint that had been superceded
12 by better data and putting it into a model would
13 predict that there would be an unreasonable
14 adverse effect on the environment, so it was
15 using that endpoint in conjunction with another
16 analysis.

17 JUDGE LYNCH: I wanted to go back for
18 a minute to the question about the challenge to
19 the legality of the condition. In your appeal
20 brief, you summarily dismiss the application of
21 Laches, but I'm not clear as to why. Why do you
22 think Laches, the Laches Doctrine can't be

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1 applied?

2 MS. SZMUSZKOVICZ: It does go back to
3 the discussion we were having earlier about the
4 fear dealing, the understanding of what would
5 take place in the wake of the submission of data,
6 and the registrants couldn't have agreed to
7 something that they never could have predicted
8 would happen.

9 They agreed that they would request
10 cancellation if there was a scientific
11 determination of unreasonable adverse effects on
12 the environment after the measured dialogue on
13 the data and the conclusions, but they never
14 could have imagined that there would be so much
15 effort put into - and millions of dollars put
16 into generating the data that EPA requested in
17 these meetings, and never be told what the actual
18 final analysis was and have a discussion about
19 it.

20 JUDGE WARD: Could I follow up on
21 that? So if here, if in fact you have the
22 opportunity to challenge whether there was or

1 wasn't a dialogue such that the condition was
2 triggered, then you've got the benefit of your
3 bargain. I mean, there's - there will be a - you
4 know, you had a hearing below. There will be a
5 decision by the board. You've had an opportunity
6 to take that issue on in this proceeding.

7 If that's true, then really I think
8 your point about the Laches is we didn't
9 challenge it because we assumed we would have the
10 measured dialogue, and if that didn't happen, we
11 would have a chance to contest it. We are having
12 that opportunity.

13 You want to go further and actually
14 challenge the legality of the condition itself,
15 not the condition - not whether or not there was
16 a measured dialogue, but whether they could have
17 included that kind of a condition at all, and I
18 think that's the question that we're wondering
19 why isn't that question barred by Laches?

20 JUDGE STEIN: You may go ahead and
21 answer.

22 MS. SZMUSZKOVICZ: And I think they

1 are tied together in that the - it's hard to have
2 envisioned how this would play out, and it is
3 hard to explain what is so very wrong about it
4 without an independent tribunal looking at the
5 actual attributes of the compound and seeing what
6 a work around this illegal provision was.

7 It's - without going back and having
8 that 6(b) hearing, EPA will be emboldened to
9 continue to issue press releases saying terrible
10 things about products and never subjected its
11 science to review, and it will use its power and
12 authority over the applicants who have no power
13 in that negotiating position, to insist upon
14 conditions that are seeking to eliminate
15 procedures that are - the registrants are
16 entitled to by statute.

17 JUDGE STEIN: Thank you very much.
18 You'll have a chance to respond during rebuttal.
19 And when we set the time for EPA, can we add 15
20 minutes to their time, please? So I'm going to
21 start with the same question that I asked counsel
22 for Bayer and Nichino.

1 Since she didn't get to make an
2 opening statement, neither will you. You can get
3 - you can weave it back in. But how is it that
4 the board has the authority to look at the
5 lawfulness of the condition in this proceeding?

6 MS. GOERKE: We would submit that what
7 the board has to look at was what was in our
8 notice of intent and what the ALJ has maintained
9 was appropriate under 6(e) which was were the
10 conditions of this registration met, and does our
11 determination for existing stocks comply with the
12 statute?

13 We would not maintain that whether the
14 condition was lawful was ever properly before the
15 ALJ or the board, that to challenge the - as we
16 have maintained in our brief, to challenge the
17 actual condition, they had that opportunity
18 multiple avenues which they clearly indicate they
19 do not consider a choice, but it is a statutorily
20 available option that they choose not to pursue.

21 So the fact that the finding - oh, go
22 ahead, Your Honor. I was just going to -

1 JUDGE STEIN: Well, so you would
2 submit that the ALJ went beyond the statutory
3 authority in determining whether the condition
4 was lawful or not?

5 MS. GOERKE: Well, I think she was
6 absolutely required to do so by the motion
7 because that was - you know, to say it was lawful
8 or not in terms of that that was exactly what
9 they were saying should be excluded. I am
10 maintaining that that was fully resolved at that
11 time, but it was a lawful condition.

12 JUDGE STEIN: I think I'm now
13 confused.

14 MS. GOERKE: Okay.

15 JUDGE STEIN: I think what the board
16 is struggling with is do we even have the
17 authority to look at the question in 2016 of
18 whether or not the condition was lawful? That's
19 a separate question from whether the condition
20 was complied with.

21 MS. GOERKE: Okay.

22 JUDGE STEIN: The ALJ in her ruling

1 appears to have ruled that the condition was
2 lawful. I'm asking whether that went beyond the
3 authority that she had in this proceeding.

4 MS. GOERKE: Oh, I'm sorry, then I
5 misspoke. I was thrown by not giving my prepared
6 remarks. I apologize, sorry. No, clearly when
7 we made that - when she made that determination
8 about the lawfulness of the condition, she looked
9 at the emails that went back and forth between
10 the registrant, and the registrant's regulatory
11 counsel, and EPA counsel in terms of an
12 understanding of the condition that was made at
13 the time in 2008 when it was accepted.

14 And it was clearly an integral - that
15 condition, the lawfulness of it, was an integral
16 part, the testimony indicated, for the EPA to
17 make the necessary finding that there would be no
18 unreasonable adverse effects. So that condition
19 itself she determined was not unlawful. Is that
20 not answering your question?

21 JUDGE WARD: So I think the challenge
22 here is that there is - the question is framed a

1 number of different ways. It's first framed by
2 the registrants as, you know, is this properly a
3 6(e) hearing? It really needs to be 6(b), and
4 then I think somewhat alternatively, although you
5 could say it's the other side of the same coin,
6 the condition itself is unlawful.

7 And I think what the board is
8 grappling with is do we even need to address is
9 this properly - well, do we need to address the
10 validity of the condition in determining first,
11 is it properly a 6(e) hearing?

12 And if we determine it's properly a
13 6(e) hearing because it's based on the agency's
14 assertion that they're seeking to cancel this
15 conditional registration under 6(e) because a
16 condition has not been complied with, if it's in
17 that box, then the next step is what are the
18 contours? What are the limits of that 6(e)
19 hearing? And in that 6(e) hearing, can you
20 challenge the validity of the condition itself?

21 MS. GOERKE: In the hearing?

22 JUDGE WARD: In the hearing, and if

1 this is properly a 6(e) hearing.

2 MS. GOERKE: If it's properly a 6(e)
3 hearing, I would still get back to that no,
4 challenging the lawfulness is not proper in a
5 6(e) hearing, so.

6 JUDGE WARD: But do we have to address
7 the lawfulness of the condition in determining
8 whether it's properly a 6(e) or a 6(b) hearing?

9 MS. GOERKE: No, I would say you do
10 not under the statute, no.

11 JUDGE STEIN: Thank you.

12 MS. GOERKE: Okay.

13 JUDGE WARD: So I wanted to follow up
14 on another issue and that concerns the scope of
15 what a voluntary cancellation proceeding would
16 have looked like under 6(f).

17 MS. GOERKE: Okay.

18 JUDGE WARD: If I understand the
19 conditional registration, that was the path that
20 the registrants arguably negotiated for, that if
21 EPA made a particular finding, they had a week to
22 request voluntary cancellation under 6(f).

1 MS. GOERKE: Yes.

2 JUDGE WARD: And in a 6(f) process,
3 how would that have played out, and maybe more
4 specifically, what opportunity would the
5 registrants have had to challenge the merits of
6 your unreasonable adverse effects determination?

7 MS. GOERKE: Not - they wouldn't have
8 had an opportunity through a voluntary
9 cancellation. When a registrant submits a
10 voluntary cancellation pursuant to 6(f), they -
11 this happens occasionally, and the registrants
12 here have done that previously for another
13 product, they submit their request for
14 voluntarily cancellation.

15 The agency publishes that in the
16 Federal Register. The agency can take comment
17 for either 30 to 180 days depending on whether
18 that's waived, and the agency ostensibly could
19 take comments on that. I mean, that's the
20 process allowed under 6(f).

21 JUDGE WARD: And could the registrants
22 have commented, and in those comments challenge

1 your determination as the basis for basically
2 having initiated that voluntary cancellation
3 process?

4 MS. GOERKE: I am not sure. I do not
5 know if they could have within that process. I
6 would think not, but I'm not familiar with that
7 actually. I just know as a process how that
8 works with 6(f) when they would -

9 JUDGE STEIN: What would have
10 precluded them from commenting?

11 MS. GOERKE: I don't think anything
12 would have precluded them from commenting in that
13 process. It clearly would have given them, you
14 know, additional opportunities to raise certain
15 things. But I mean, back to, if I could get back
16 to that particular condition when that was
17 negotiated as - you know, has been upheld
18 previously, the strict cancellation, you know,
19 provision where there is a draw dead for clarity.

20 I think initially this was viewed,
21 even though we're here at this time discussing
22 this eight years after the registration was

1 issued, you know, going back in terms of what the
2 intent was, what we were able to garner from
3 certain exhibits, we have the respondent exhibits
4 that go through the emails.

5 I think the view was, you know, we
6 initially wanted the cancellation date. The
7 registrants didn't prefer the cancellation date.
8 Then the view was we would prefer to have the
9 agency's, you know, the dialogue, which this is
10 also in the record, would prefer to have that
11 voluntary cancellation package like an agreement
12 that this will go away if later we find
13 unreasonable adverse effects as we did here, that
14 that would have already been in the agency's
15 hands.

16 I, you know, present to you that this
17 is how the negotiations back and forth between
18 EPA and the program typically occurs, various
19 measures, various conditions, these negotiations,
20 and that did occur in this circumstance in 2008.
21 And the circumstance now is that they wish they
22 wouldn't have taken that provision, yet it was

1 there, and it was an integral part for the agency
2 to make their unreasonable adverse effects
3 finding in 2008 in order to grant this
4 registration.

5 JUDGE WARD: But I want to go back to
6 the 6(f) proceeding because in the briefs you
7 filed before the ALJ, I think you described it as
8 a process that would allow for both an
9 opportunity for public comment, and an additional
10 opportunity to influence EPA's decision making.

11 And I'm trying to understand what that
12 opportunity to influence EPA's decision making,
13 what was that? In your view, what does that
14 entail? Does it include the registrants? Does
15 it include members of the public who may want
16 this pest - these pesticides to be on the market?

17 MS. GOERKE: I think it's open. It
18 could be growers. It could be distributors. It
19 could be, you know, environmental groups that
20 have concerns about the product. It is open.
21 That process is available for comment. How
22 indeed that, you know, how that process evolves,

1 you know, I just know that they could have
2 commented.

3 JUDGE WARD: Would you have had to
4 respond to those comments on the merits?

5 MS. GOERKE: If -

6 JUDGE WARD: If they challenged your
7 unreasonable adverse effects determination in a
8 6(f) proceeding through their comments.

9 MS. GOERKE: I think we would say that
10 the unreasonable - on unreasonable adverse
11 effects, they could challenge it, but the actual
12 proceeding would need to be pursued under 6(b)
13 for unreasonable adverse effects, not the 6(f)
14 proceeding.

15 JUDGE WARD: So you wouldn't have to
16 respond to their comments on the merits?

17 MS. GOERKE: We could respond, but I
18 don't know if they'd have a right of action if we
19 didn't respond in a way that's, you know, they
20 felt satisfied about that.

21 JUDGE WARD: And so where I think that
22 leaves the agency is that there's no opportunity

1 for the company at this point in time to
2 challenge your 2016 determination of unreasonable
3 adverse effects, the one that you made that
4 triggered this -

5 MS. GOERKE: But that was the choice
6 they made when they accepted the condition.
7 That's the bind that we're in at this moment.
8 That was the choice they accepted when they took
9 the conditional registration with those explicit
10 conditions in it, that they were not going to get
11 to challenge the unreasonable adverse effects if
12 the next provision of that condition is they will
13 accept it.

14 That is how the agency was able to go
15 forward and issue the initial conditional
16 registration. So for it to be now that
17 challenging the unreasonable adverse effects
18 determination, this was not initiated via a 6(b)
19 process. These were the conditions that the
20 agency and the program relied upon in order to
21 issue this.

22 I think if you turn your attention to

1 the exhibits that go through the many
2 uncertainties and the risks that the agency
3 envisioned for this product to accumulate in the
4 environment, that condition was essential.

5 And so to say could they have raised
6 the unreasonable adverse effects within 6(f) and
7 what would we have done, I would speculate that,
8 as part of the conditions of their registration,
9 was not something that we would have envisioned
10 that they could have challenged. It is not
11 written into the registration.

12 It is clearly that they will accept
13 that once we have had a discussion about all of
14 the data, which we have submitted. We have had a
15 discussion about all of the data which also
16 brings me to the issue that was raised about what
17 was in their notice of intent and what was in
18 their objections they initially filed. What you
19 were seeing -

20 JUDGE STEIN: Before we leave this
21 topic and go to that however, I want to be sure
22 that I understand what the opportunities were

1 back in 2008 for the company to challenge what
2 the agency was proposing, and whether these were
3 real opportunities or not as counsel for Bayer
4 has argued.

5 So if I understand it - I'm not sure
6 I understand what the agency really is saying on
7 6(f) at this point, but I'd like to go to the
8 question of both a denial and a federal court
9 challenge and have the agency explain exactly
10 what they think were the company's options.

11 MS. GOERKE: Okay, the registrants had
12 a number of options available to them in 2008 and
13 thereafter. Among them, they could have proposed
14 alternative mitigation measures for the
15 cancellation on applications, or application
16 rates, geographical areas of use.

17 They could have declined the
18 registration and pursued a denial hearing. They
19 could have submitted a subsequent application to
20 acquire registrations without the cancellation
21 condition, and if denied, pursued a hearing on
22 whether they were entitled to registrations

1 without that condition.

2 Instead, they accepted the
3 cancellation condition in this registration and
4 pursued no other recourse. It is entirely a
5 result of their own choices that registrants find
6 themselves in the position where the only
7 proceeding available to them now is under section
8 6(e), but that does not make this section 6(e)
9 proceeding any less appropriate.

10 JUDGE STEIN: But how real were the
11 options that you laid out, so, like taking them
12 one by one? You're prepared to grant a
13 conditional registration. There is a condition
14 in there the company doesn't like.

15 (Simultaneous speaking)

16 JUDGE STEIN: They're saying they
17 don't like it now. Does the record reflect
18 whether there's even been a circumstance where a
19 company has voluntarily taken a denial in those
20 circumstances rather than taking a condition they
21 don't want?

22 MS. GOERKE: To my knowledge, they

1 haven't, but my understanding is that that is a
2 testament to the success of the program, and that
3 the registrants and the program work to ensure
4 that measures can be developed so that EPA can
5 make the finding, either in an unconditional
6 registration or in a conditional registration for
7 a limited period of time, that there are no
8 unreasonable adverse effects on the environment.

9 JUDGE STEIN: So if the company
10 accepted the conditional registration, could they
11 have filed in federal court seeking to excise the
12 - what was referred to in the correspondence as
13 the fast death -

14 MS. GOERKE: The cancellation
15 provision?

16 JUDGE STEIN: The cancellation.

17 MS. GOERKE: Yes.

18 JUDGE STEIN: Could they have done
19 that, and if so, how would the agency have viewed
20 that?

21 MS. GOERKE: So I just want to make
22 sure I understand. Is this when it's an

1 application or we have granted a registration -

2 JUDGE STEIN: You have granted a
3 conditional registration with this condition in
4 it. Could the companies have gone to court to
5 challenge the lawfulness of the condition at that
6 time?

7 MS. GOERKE: I don't know why they
8 couldn't have challenged that.

9 JUDGE WARD: Could I follow-up on the
10 one option of accepting a denial of the
11 registration? Then what would their options have
12 been if they had decided they didn't want to
13 accept the condition?

14 MS. GOERKE: If they did not want to
15 accept the condition and --

16 JUDGE WARD: And then?

17 MS. GOERKE: And then they would not
18 have received a registration.

19 JUDGE WARD: They would have denied
20 the registration. And then what steps could they
21 have pursued?

22 MS. GOERKE: They would pursue a

1 statutorial if they wanted the denial hearing, or
2 they could have, as we indicated, they could have
3 accepted the registration as it exists now and
4 submitted a new application with that condition
5 removed from it and have the Agency go through
6 the process to issue that registration similar to
7 a denial so they could have had their product on
8 the market.

9 JUDGE WARD: But if they had not
10 accepted the condition, they could have pursued a
11 denial hearing?

12 MS. GOERKE: If they didn't accept
13 this condition?

14 JUDGE WARD: Correct.

15 MS. GOERKE: They wouldn't have -- if
16 they didn't accept the condition and the terms
17 were clear in the actual preliminary acceptance
18 letter that became a part of this registration,
19 if they didn't accept any of these terms and
20 conditions, their registration was considered
21 null and void. There is no registration if they
22 didn't want to --

1 JUDGE WARD: It would have been
2 denied.

3 MS. GOERKE: Yes.

4 JUDGE WARD: You had said they could
5 have a denial hearing.

6 MS. GOERKE: Yes.

7 JUDGE WARD: Under what provision of
8 the statute?

9 MS. GOERKE: For the denial hearing?
10 Give me one moment. Sorry. It is --

11 JUDGE WARD: And the reason I'm asking
12 is I'm not quite clear on how the statutory
13 framework works here based on today's argument
14 because I think counsel for the registrants had
15 said if they hadn't accepted the condition, the
16 conditional registration, they wouldn't have had
17 an opportunity for a 6(b) hearing. They would
18 have, I presume, had to go to federal court. And
19 what I'm hearing, I'm hearing you say maybe
20 something different.

21 MS. GOERKE: It's 3(c)(6) is that
22 provision for the actual denial hearing in FIFRA.

1 JUDGE WARD: Okay.

2 MS. GOERKE: Okay.

3 JUDGE WARD: That's helpful. Thank
4 you.

5 MS. GOERKE: Okay.

6 JUDGE STEIN: So directing your
7 attention to another question, the statute in
8 6(d) refers, I believe, to substantial evidence
9 in talking about the hearing. Is this
10 preponderance of the evidence? Is there a
11 difference between substantial evidence on the
12 record and preponderance of the evidence?

13 MS. GOERKE: In 6(c)?

14 JUDGE STEIN: It's in 6(d).

15 MS. GOERKE: In 6(d), the hearing for
16 6(d).

17 JUDGE STEIN: 6(d) states that a
18 decision after a hearing shall be based on
19 "substantial evidence of record." I'm interested
20 in understanding what the Agency thinks that
21 means, and does it mean preponderance of the
22 evidence or something different?

1 MS. GOERKE: I would submit that it
2 means preponderance, substantial evidence.

3 JUDGE STEIN: Are you saying they're
4 the same? Okay. Thank you. Could we have an
5 answer that the court reporter can hear?

6 MS. GOERKE: Oh, I'm sorry. I'm
7 sorry. No, I don't, I don't know the -- I don't
8 --

9 JUDGE STEIN: You don't know the
10 difference?

11 MS. GOERKE: I don't know the
12 difference.

13 JUDGE STEIN: Okay, thank you.

14 JUDGE WARD: Could you turn, to
15 address the dialogue question, the Agency's view
16 as to what dialogue occurred and --

17 MS. GOERKE: Yes.

18 JUDGE WARD: -- how your view as to
19 how that satisfied the condition of the
20 registration?

21 MS. GOERKE: Right. As to the
22 argument that that wasn't triggered because it

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1 was a sufficient scientific dialogue; is that
2 correct? That is your question? We have
3 addressed this thoroughly in our brief, and we do
4 believe that this issue about substantial
5 dialogue was not appropriately before the ALJ.

6 What was laid out in the objections by
7 the registrants was issues about whether this was
8 appropriately a 6(b) versus a 6(e) hearing. If
9 it was appropriately laid out, the Agency would
10 have placed in additional information, which we
11 did not because it was not specifically raised
12 that this was a condition precedent. But the
13 information that meetings were held from the time
14 and the record indicates from December 2014 when
15 certain scientific studies that were required
16 pursuant to the registration were submitted, that
17 those studies, there were many discussions
18 throughout 2015 on the water monitoring report
19 with the Agency. So there were discussions.

20 When they're talking about dialogue,
21 as I'm understanding it, they're talking about
22 the concerns about the endpoint that was raised,

1 and we would submit that the discussions on the
2 science throughout did occur with not only the
3 scientists but the regulatory personnel. And,
4 again, because this was not specifically raised
5 until the actual hearing, we did not put forward
6 information in the record that showed the extent
7 of what information was shared when registrants'
8 council mentioned before the holidays they became
9 very well aware of this new information before
10 the January 29th decision memo. So we would say
11 that there was measured dialogue.

12 JUDGE WARD: But their argument is
13 that the meeting in January, which I presume is
14 after they received or learned that EPA had
15 reverted to the lower endpoint and whatever
16 material that was shared in advance of that
17 meeting, that it wasn't really a dialogue, that
18 EPA just came in and told them of their decision.

19 MS. GOERKE: Well, we listened to
20 their perspective on how they disagree with the
21 science conclusions. And back to the actual
22 conditions of this registration, it did not

1 require scientific consensus, it did not require
2 that they assent and agree to our science, and we
3 believe that there was enough discussion so that,
4 one, they understood where the Agency was coming
5 from. There were those concerns about how we
6 interpreted the various studies that were
7 submitted throughout the end of 2014 and all the
8 data up through then.

9 So we would submit that there was
10 dialogue, and it wasn't required to be dialogue
11 where they agree. This is a, this really comes
12 down to a scientific disagreement, that that is
13 not the heart of what the Agency's authority to
14 issue a Notice of Intent to Cancel because the
15 conditions of registration here were clearly not
16 met. And that is why the Agency took this action
17 that they did. We have not had opportunities
18 previously to do so because registrants
19 typically, you know, we can work through the
20 differences. Here that did not occur.

21 JUDGE STEIN: How do you respond to
22 their argument that it wasn't until the January

1 29th decision memorandum and a footnote in an
2 attachment that the company understood what toxic
3 endpoint the Agency was relying on?

4 MS. GOERKE: And I think that goes
5 back to the question I was just responding to,
6 that if it was clearly laid out in their
7 objections, we would have put forward the
8 information that was given to them in December,
9 which comports with they did not first learn of
10 that in January buried in that document. But we
11 did not do so because that was not explicitly
12 laid out in their objections.

13 JUDGE STEIN: Okay. So assuming,
14 let's assume hypothetically that the Board is not
15 persuaded by the waiver argument, since you seem
16 to be hanging your hat here on the fact that the
17 objection was waived. If the Board decides to
18 reach the merits of the argument, can you give me
19 your best response to the company's argument?

20 MS. GOERKE: About the chronic --

21 JUDGE STEIN: The toxic endpoint that
22 they claim they didn't know about until January

1 29th.

2 MS. GOERKE: My response to that
3 argument was the change in the scientific
4 endpoint or our determination on whether there
5 were unreasonable adverse effects was not a
6 proper issue for the hearing because we pursued
7 action under FIFRA Section 6(e).

8 JUDGE STEIN: No, I'm talking about --
9 are you saying that the good faith dialogue is
10 not a proper issue for this hearing?

11 MS. GOERKE: No, that was not at issue
12 in the hearing whether there was good faith
13 scientific dialogue. That was not one of the
14 issues that were raised in the --

15 JUDGE STEIN: But I'm asking you --

16 MS. GOERKE: Okay.

17 JUDGE STEIN: -- if the Board does not
18 agree that that issue was waived, then what's
19 your answer? The Agency doesn't have one?

20 MS. GOERKE: Well, no, I guess that
21 the answer would be we would have to, if required
22 to do so, supplement the record and have

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1 testimony, whether that would be the appropriate
2 to submit that information for the record.

3 JUDGE STEIN: But the Agency didn't
4 move to re-open the record; is that correct?

5 MS. GOERKE: No, we didn't because we
6 supported the determination that was made by the
7 ALJ, that that was not properly, measured
8 scientific dialogue is a term of art that was put
9 forward by the registrants. That was not a term
10 and condition of their registration.

11 JUDGE WARD: But the registration
12 doesn't require dialogue.

13 MS. GOERKE: It said that we would
14 discuss, there would be discussion about the
15 science. I can point you to that. That is
16 Respondent Exhibit -- let's get right to what is
17 actually in the condition.

18 JUDGE WARD: What I'm reading is the
19 condition at 6(b) or the paragraph 6(b) which
20 states that the EPA scientists and their
21 scientists shall engage in dialogue about the
22 data and the Agency's conclusions.

1 MS. GOERKE: Yes. And we did have
2 dialogue about the data that was submitted by the
3 registrants and the conclusions that the Agency
4 came to regarding that data. So the chronic
5 toxicity endpoint that seems to be the issue that
6 the registrants are making before you, I mean,
7 the Agency generally relies on the most sensitive
8 endpoint. But the fact of having discussions
9 about the data, we did have discussions about the
10 data that were submitted by the registrants. The
11 registrants don't agree with our conclusions.

12 JUDGE WARD: In your view, does the
13 phrase "conclusions" include the choice which
14 endpoint to choose?

15 MS. GOERKE: Absolutely not. No, that
16 is not --

17 JUDGE WARD: And so you didn't need to
18 have a dialogue about that choice or conclusion?

19 MS. GOERKE: About the endpoint.

20 JUDGE WARD: That's your position?

21 MS. GOERKE: That that was not
22 required pursuant to the conditions, the terms

1 and conditions here, yes, that is correct.

2 JUDGE STEIN: So what does it mean to
3 have a dialogue about the data? What does that
4 encompass?

5 MS. GOERKE: That would encompass the
6 staff that did the assessments on the data, the
7 scientific staff to discuss the results of how we
8 came to our conclusions on such scientific data
9 with the registrants, which I submit did occur
10 here, back to this was a disagreement about the
11 science. So whether --

12 JUDGE STEIN: Would it not include a
13 discussion about the endpoints?

14 MS. GOERKE: It could include a
15 discussion about the endpoints if that did arise,
16 but, at the end of the day, if the registrants
17 disagree with the endpoint discussion, it was
18 still incumbent on the Agency to be able to make
19 their no unreasonable --

20 JUDGE STEIN: I understand the
21 difference between the two. I'm really just
22 trying to focus on what was within the scope of

1 this question of dialogue about the data, and I
2 thought you had said that the toxic endpoint was
3 not within the scope of that discussion. I don't
4 think the court reporter can interpret what
5 you're saying.

6 MS. GOERKE: I mean, if that has come
7 up in a meeting before, then they could have
8 discussed the endpoint. I'm saying it is not
9 required pursuant to the conditions of the
10 registration. That, to me, does not include the
11 view of what is in the data that was generated by
12 the registrants. The endpoint is how the Agency
13 can get to make their actual scientific findings
14 on whether there is unreasonable risk.

15 JUDGE WARD: If we didn't agree with
16 you on that point, what does the record show in
17 terms of the dialogue about the endpoint? The
18 conclusion or the choice that EPA ultimately
19 made?

20 MS. GOERKE: I don't think there is a
21 record that gets into the thoroughness of the
22 discussion on the endpoints because that was not

1 what we presented evidence on because that was
2 not in the objections.

3 JUDGE WARD: Okay. Could I follow-up
4 on a question about the existing stocks, which we
5 didn't have a chance to ask the registrants about
6 but --

7 MS. GOERKE: Sure.

8 JUDGE WARD: -- I'm sure we'll have an
9 opportunity on rebuttal. But I think you had, in
10 your brief to the Board, you are acknowledging
11 that your inclusion of the retailers isn't
12 covered by the express terms of the policy as it
13 relates to a condition, a conditional
14 registration being canceled because a specific
15 condition hasn't been satisfied. How is
16 including them then nevertheless consistent with
17 the statute?

18 MS. GOERKE: Excuse me. How including
19 them --

20 JUDGE WARD: Retailers, as opposed --

21 MS. GOERKE: Oh, because, typically,
22 the Agency makes, it has to be clear on whether

1 it covered distributors and others who have
2 product in their possession. Since they may not
3 sell an unregistered pesticide, we have to
4 specifically address what can happen in that
5 circumstance when it is in the possession of
6 retailers. So once a cancellation becomes
7 effective, what happens to that product? That is
8 why we addressed it.

9 JUDGE WARD: Well, I guess I'm asking
10 you why is your decision to preclude the use of
11 the existing stocks when they handed the
12 retailers that decision consistent with the
13 statute?

14 MS. GOERKE: I think the decision that
15 was made, you know, as we've indicated, the
16 reasoning was not just that the registrants
17 shouldn't benefit, but the registrants would
18 continue to benefit by virtue of the trade that
19 was allowed to continue since it was in the hand
20 in the distributors. So it was to be
21 all-inclusive, so it was going to get back to the
22 fact that the registrant did not comply with the

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1 terms and the conditions, and the program made
2 that determination not specifically to target
3 distributors but because the registrants would
4 still be benefitting from the distributors, you
5 know, selling the product and making the profit
6 for the registrants.

7 JUDGE WARD: Okay.

8 JUDGE STEIN: Bayer argues that there
9 were new conclusions in the January 29th, 2016
10 memo. Does the Agency agree with that, and, if
11 so, why and, if not, why not?

12 MS. GOERKE: New conclusions on --

13 JUDGE STEIN: In the January 29th,
14 2016 memo. That's the way I understand their
15 argument.

16 MS. GOERKE: There may have been
17 further and refined information from the time we
18 met with them in early January, but my
19 understanding is that the information that
20 ultimately became part of that decision was
21 shared with the registrants before the holidays,
22 mid to late December, in 2015. So there was not

1 complete new information. That was a surprise to
2 the registrants, but, once again, we did not have
3 that information before the ALJ because that was
4 not properly raised in their --

5 JUDGE STEIN: So what happened after
6 the January 6th meeting? Didn't Bayer submit
7 information?

8 MS. GOERKE: Bayer submitted
9 additional studies that the Agency quickly turned
10 around and reviewed to see if additional
11 mitigation would potentially allow certain label
12 uses for this product to continue.

13 JUDGE STEIN: What does it mean for a
14 registration to be time limited, and what is the
15 difference between a time-limited registration
16 and a conditional registration with a fixed
17 expiration date?

18 MS. GOERKE: Well, I don't think
19 there's much of a distinction. Time limited, in
20 this circumstance, was made more difficult, to
21 some extent, because of the voluntary
22 cancellation provision. It initially was for a

1 five-year period. And time limited could be
2 however the Agency and the registrant determined
3 what is the time necessary to have additional
4 studies be developed, if it's two years, three
5 years.

6 So the five-year period that was
7 established when this registration was issued was
8 subject to additional time frames that required
9 the Agency to take certain action at a time after
10 the five years. So I would speculate or submit
11 to you that there is not much of a difference
12 between a time limited and -- well, the
13 expiration date, at the time the expiration date
14 just sort of expires. The time limited, they
15 continue to submit, and they did, and we approved
16 extensions of those dates to allow for further
17 studies to be submitted. And, again, I would
18 submit the further discussion regarding the
19 results of those studies.

20 JUDGE WARD: I want to go back to the
21 question of the retailers or the distributors.
22 Is there anything in the record showing that EPA

1 looked at whether the retailers were, that
2 somehow the registrants were profiting or would
3 profit, I guess, following the Notice of
4 Cancellation from continuing to be allowed to
5 sell to the retailers? And once they buy them,
6 then they resell them? I mean, I'm just trying
7 to figure out what did EPA look at and what time
8 frame was EPA considering in including retailers
9 within the prohibition on the use of existing
10 stocks?

11 MS. GOERKE: At the time the
12 determination was made, within the same month as
13 EPA received registrants, that they refused to
14 comply with the conditions, EPA made the
15 determination and published the Notice of Intent
16 to Cancel that included distributors because we
17 were really taking a very strong position that
18 failure to comply with conditions would not allow
19 the Agency to continue to issue registrations
20 with such terms and conditions that would be able
21 to make the reasonable adverse effects findings.
22 So that distributors were just part of our

1 rationale because, just based on the
2 understanding that they would continue to profit,
3 our provision was that they could return product
4 back to the registrant so speculating that they
5 would be able to make profits on that.

6 JUDGE WARD: Is that in the record in
7 terms of an explicit finding by the Agency?

8 MS. GOERKE: No. The Agency's finding
9 exclusively under the note existing stocks was
10 based on the fact that it was a policy choice,
11 basically, that we were just going to go forward
12 under FIFRA, that it is not consistent with FIFRA
13 to allow registrants to benefit financially from
14 not complying with the terms and conditions of
15 their registration by declining to submit the
16 voluntary cancellation.

17 JUDGE WARD: So I guess I can
18 understand how that might apply to what the
19 registrants would sell following the issuance of
20 the Notice of Cancellation, but what about the
21 product in the hands, to the extent there is any,
22 product in the hands of the retailers so it was

1 purchased prior to the issuance of the Notice of
2 Cancellation?

3 MS. GOERKE: You mean the actual
4 cancellation of our Notice of Intent --

5 JUDGE WARD: Of your Notice of Intent
6 to Cancel.

7 MS. GOERKE: Nothing. Everyone can --
8 the Notice of Intent to Cancel is what we intend
9 to do. Nothing becomes effective with
10 distributors or anyone until the actual
11 cancellation is effectuated. Once -- is that
12 what you're --

13 JUDGE WARD: No, I understand that.
14 So let's assume sometime in July or August the
15 cancellation goes into effect, so does the, I
16 guess, ban on existing use by the product in the
17 hands of the retailers, correct?

18 MS. GOERKE: Yes.

19 JUDGE WARD: Okay. But it doesn't,
20 that applies both to the product in their hands
21 as of the date of the cancellation, as well as
22 anything that they bought before you issued the

1 Notice of Intent to Cancel, correct? For the
2 retailers.

3 MS. GOERKE: No, not before the Notice
4 of Intent to Cancel. It's the cancellation date.

5 JUDGE WARD: Okay. So it's what --

6 MS. GOERKE: Yes, as of the
7 cancellation date, all of that goes, I mean --
8 yes.

9 JUDGE WARD: If I'm a distributor and
10 I bought product in December of 2015, and I
11 haven't yet sold it, just hypothetically
12 speaking, and then the cancellation becomes
13 effective in 2016, I can't then sell the product
14 I bought in 2015; is that correct? If it's still
15 in my hands.

16 MS. GOERKE: That is correct, yes.

17 JUDGE STEIN: I have a couple of
18 additional questions. Are there any limits on
19 the Agency's discretion to put conditions into a
20 registration, a conditional registration or a
21 registration? I'm not asking you what those
22 limits might be. I'm asking you whether there

1 are limits to EPA's discretion.

2 MS. GOERKE: Yes, there would be
3 limits. It has to be worked through an agreement
4 with the registrant, depending on the actual
5 product at hand. There would be --

6 JUDGE STEIN: I'm not asking about an
7 agreement. I'm asking whether, under the statute
8 and under EPA's authority, there are any
9 limitations to the kind of conditions or any
10 limitations that would somehow restrict EPA from
11 putting into a registration something that is
12 unlawful or beyond the scope, or is that --

13 MS. GOERKE: Well, the statute simply
14 says other conditions as the administrator may
15 prescribe. I would envision that those
16 conditions would have to be germane to the actual
17 product. It couldn't be something completely --
18 I guess I'm not understanding. Of course, it
19 couldn't be unlimited. It would have to be
20 something that is based on what the administrator
21 would deem would be something necessary for this
22 particular product and mitigation measure. So I

1 wouldn't say it's completely unlimited, but it's
2 certainly is not exclusively limited.

3 JUDGE STEIN: There's a lot of cases
4 that speaks to whether or not a private party can
5 assert Laches against the government. Is there
6 anything that restricts the government from
7 asserting a claim of Laches against a private
8 party?

9 MS. GOERKE: Not that I'm aware of,
10 no.

11 JUDGE WARD: Could you walk through
12 your Laches argument? I think you addressed it
13 in a footnote in your brief to the Board, but I'd
14 like to have you speak to what you think is the
15 strongest case for Laches, as well as do you have
16 any other case support then -- I hope I'm reading
17 this right -- a 1919 Supreme Court case?

18 MS. GOERKE: Yes.

19 JUDGE WARD: Going to Judge Stein's
20 question about the ability of the government to
21 assert Laches against a private party.

22 MS. GOERKE: I'm sorry. Beyond this

1 particular case, there is nothing that we -- do
2 you want me to walk you through the argument? Is
3 that what you --

4 JUDGE WARD: I just wanted you to
5 briefly walk me through your best facts for
6 Laches here.

7 MS. GOERKE: Okay. As we indicated
8 right here, since registrants did not initiate,
9 as we have maintained, a timely challenge to the
10 condition, this registration was issued in 2008,
11 it is not clear from the statute of limitations
12 that there is a challenge allowed to the legality
13 of any part of the registrations six years after
14 the actual registration was issued. Their lack
15 of timeliness raises the issue of that EPA did
16 not make a finding to issue this conditional
17 registration without this condition. The
18 condition at issue here, the voluntary
19 cancellation condition, was an essential part of
20 making the unreasonable adverse effects finding
21 because the Agency wanted to ensure that they
22 could have this product removed from the

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1 marketplace quickly if, indeed, we later
2 determined after the time limit and conditional
3 registration ended that the product did cause
4 unreasonable adverse effects.

5 And EPA, also we maintain that the
6 remedy, if the EPA were to find that this
7 condition was illegal, would be to invalidate the
8 registrations as null and void since this
9 condition was an integral part of issuing the
10 registration back to, we wanted to ensure that
11 this product could be removed if we later
12 determined it no longer met the standard of no
13 reasonable adverse effects on the environment.

14 And, of course, as we indicate here,
15 the factual issues of what was the thinking at
16 the time this was issued are difficult to discern
17 because the individuals who made the
18 determination are no longer at the Agency, senior
19 management and some of the senior personnel, I
20 understand, at Bayer.

21 So what we had to rely upon in terms
22 of the understanding that the registrants

1 knowingly, willingly participated in this
2 condition was that they have waived their ability
3 almost eight years later to say that this
4 condition was unlawful since the Agency maintains
5 that this condition was essential to issuing the
6 registration to begin with.

7 JUDGE WARD: And are you aware of any
8 more recent case law that addresses the question
9 of the government asserting Laches against a
10 private party?

11 MS. GOERKE: I am not.

12 JUDGE WARD: Okay.

13 JUDGE STEIN: I don't think the Board
14 has further questions. If you, you know, want to
15 use your three minutes remaining time, you may,
16 or it's up to you.

17 MS. GOERKE: Yes, I think I would
18 prefer to use my remaining time to go back to
19 some of the things that I was hoping to
20 specifically address. Just a second.

21 I would like to address the cases that
22 were referenced by counsel, Reckitt Benkiser and

1 Woodstream. With regards to Reckitt Benkiser,
2 those decisions did not involve any failure to
3 comply with conditions of registration and did
4 not address Section 6(e) proceedings, and the
5 registrants here are trying to stretch the
6 Reckitt court beyond their context.

7 Some of the Reckitt registrations were
8 Section 3(c)(7) conditional registrations, but
9 there was no indication that the registrant
10 failed to comply with any condition. The Reckitt
11 registration certainly did not include any
12 cancellation conditions, unlike Woodstream where
13 two district court judges each held that EPA has
14 the authority to impose a wide range of
15 conditions, especially including conditions that
16 canceled those conditional registrations without
17 any further process. The conditions at issue in
18 the instant case provided registrants with much
19 more process than the automatic cancellations in
20 Woodstream.

21 In summation, the ALJ correctly
22 decided in her corrected initial decision that

1 the voluntary cancellation provision was a lawful
2 condition of the registrations and registrants
3 did not initiate and pursue appropriate action to
4 comply with that condition, making these
5 registrations properly subject to cancellation
6 under Section 6(e). The ALJ also correctly
7 decided that EPA's determination with respect to
8 the disposition of existing stocks was consistent
9 with FIFRA.

10 EPA respectfully requests that the
11 Board uphold the orders issued in the Motion for
12 Accelerated Decision, Motion to Limit the Scope
13 of Testimony, and the ALJ's corrected initial
14 decision, and order the cancellation of
15 registrants' flubendiamide products, subject to
16 the existing stocks provision in the Notice of
17 Intent to Cancel. Thank you.

18 JUDGE STEIN: Thank you very much. I
19 appreciate your views, and now we'll turn it back
20 to counsel for petitioner for five minutes of
21 rebuttal. And I think, since we have one of the

22 --

1 JUDGE WARD: Counsel for Amici.

2 JUDGE STEIN: If counsel for Amici
3 would like to say a few words after the rebuttal,
4 I think we will provide that opportunity. But
5 having given you five minutes, I'm going to start
6 with a question. And my question relates to
7 substantial evidence. What does it mean that
8 Section 6(d) states that the decision after
9 hearing should be based on substantial evidence
10 of record? Does that mean preponderance of the
11 evidence, or does Bayer claim it means something
12 different?

13 MS. SZMUSZKOVICZ: Our understanding
14 of the standards is that they are a little bit
15 different and that substantial evidence is more
16 akin to looking at an arbitrary and capricious
17 standard than the preponderance of the evidence.
18 It's a fine line that we've often struggled to
19 parse in the case law, but that's our
20 understanding.

21 JUDGE STEIN: Has the Supreme Court
22 spoken to this question at all?

1 MS. SZMUSZKOVICZ: In the context of
2 any type of administrative proceeding?

3 JUDGE STEIN: Yes.

4 MS. SZMUSZKOVICZ: That's a good
5 question. I know there is court of appeals case
6 law, quite a bit, including in our area. And we
7 can get those citations to you.

8 JUDGE STEIN: Okay.

9 MS. SZMUSZKOVICZ: I don't recall a
10 Supreme Court case on the issue, but there may be
11 one also.

12 JUDGE STEIN: Okay. And I note that
13 Bayer has not briefed the burden of proof
14 question. Do you disagree that Bayer and Nichino
15 bear the burden of proof in this proceeding?

16 MS. SZMUSZKOVICZ: We do not. We
17 agree.

18 JUDGE STEIN: You agree. Thank you.

19 JUDGE WARD: I'd like to follow-up, if
20 I could, just to ask you to address the existing
21 stocks question and the question of the retailers
22 and the distributors.

1 MS. SZMUSZKOVICZ: Yes. So our
2 understanding is of the Notice of Intent to
3 Cancel is that, if it becomes a final notice of
4 the Agency by ruling of this Board, that, as of
5 that date, no further sale or distribution may be
6 made by registrants, distributors, or retailers.
7 And distribution includes, in our understanding
8 of the statute and the regulations, any movement
9 of the product, which is why our understanding is
10 that EPA took pains in the notice to say that
11 such material could be distributed for disposal
12 or export but couldn't otherwise be distributed.

13 So if a retailer had material that
14 had, our understanding is if a retailer had
15 material that had been purchased prior to the
16 effective date of the Notice of Cancellation,
17 that it could only distribute it back to the
18 registrant for disposal or for export, but it
19 couldn't further distribute it to someone, a
20 third party. And that's our understanding.

21 JUDGE WARD: I want to follow-up, as
22 well, how I am reading or how I read your brief

1 on the existing stocks question and the statutory
2 determination, which is I'm reading 6(e)(1), it
3 requires the administrator to make a finding both
4 that the sale or use is not inconsistent with the
5 purposes of the act and will not have
6 unreasonable adverse effects on the environment.
7 But I was reading your brief to suggest that, in
8 making that determination or when the Agency
9 makes that determination, it has to make both
10 findings. So here, even though it found the
11 first prong wasn't satisfied, it nevertheless
12 needed to proceed to prong two, which I'm not
13 sure how you can -- to me, you can't allow the
14 continued use unless you make both findings, you
15 make both findings. And having failed or having
16 found that the continued use wouldn't be
17 consistent with the statute, why would you need
18 to make the second, reach the second prong of the
19 test?

20 MS. SZMUSZKOVICZ: You would need --
21 this is the moment at which in a 6(e) hearing it
22 becomes such, it punctuates why we are in the

1 wrong place at the wrong time because EPA made an
2 unreasonable adverse effects on the environment
3 finding. It is trying to preclude anyone from
4 reviewing that. In their own policy on existing
5 stocks, the Agency has said when it makes a
6 finding based on unreasonable adverse effects on
7 the environment, it will look case by case at the
8 facts to determine what would be proper during
9 that period, final period of use or sale of the
10 product.

11 So it's a good example of how all the
12 issues are being completed in this proceeding.
13 It's why we thought that the registrant should be
14 allowed, at a minimum, to present risk and
15 benefit information because, during that period,
16 EPA has to demonstrate that during that period of
17 the sale of existing stocks there would be
18 unreasonable adverse effects on the environment,
19 not the broader question of over the whole life
20 of the use of the product would there be
21 unreasonable effects but during that short
22 period. And EPA didn't examine any of that and

1 said that it just refused to do that, that this
2 was a punitive action and they were not going to
3 evaluate what the real impact of using the stocks
4 would be.

5 EPA didn't take into account, and this
6 came out at the hearing, that Nichino's product
7 is unique to the United States. It's going to be
8 disposed of in the environment. Could that
9 possibly withstand scrutiny? It's an example,
10 let alone the impact on those people who are
11 expecting to be able to use the product should
12 have been taken into account.

13 JUDGE WARD: So I think I understand
14 your broader set of arguments and your arguments
15 about the policy and how to interpret the policy.
16 I'm focused, though, specifically on the
17 statutory language, which states EPA can allow
18 the continued use or sale if it makes findings
19 both, it has to find both A and B. If it can't
20 find A, why does it even need to reach B, as a
21 matter of statutory construction? I think that's
22 my question.

1 MS. SZMUSZKOVICZ: Because the concept
2 of risks and benefits and unreasonable adverse
3 effects is in virtually every decision that the
4 Agency makes. It's not a one-time thing. This
5 is a program that looks at every aspect of how a
6 product is made, distributed, sold, and used.
7 And it's completely consistent with the statute
8 that EPA would look at the question of, okay,
9 even if a condition wasn't met, is this period of
10 time, whatever the provision is that EPA has
11 allowed, and often it's years of time, to allow
12 existing stocks to clear the channel of trade
13 going to exceed the unreasonable adverse effects
14 standard? They are two really distinct, two
15 really distinct things.

16 JUDGE WARD: I understood your
17 argument. Thank you.

18 MS. SZMUSZKOVICZ: Yes, thank you.
19 Your Honor, in the interest of efficiency, I had
20 a couple of rebuttal points, but you had asked
21 for some specific citations. We want to be sure
22 to provide those, so should we go ahead and do

1 that first and get that --

2 JUDGE STEIN: I will be providing an
3 opportunity for that afterwards, so you don't
4 need to give me the citations right here.

5 MS. SZMUSZKOVICZ: All right, thank
6 you. We appreciate that opportunity. We have
7 just a few points in rebuttal, with your
8 indulgence. EPA expressed to the Court during
9 oral argument that it viewed the voluntary
10 cancellation provisions of the letter as
11 essential. That was the word that was used. And
12 this is a particularly poignant point for the EAB
13 that we hope you will emphasize. Throughout our
14 briefing, we have pointed out that EPA has the
15 authority under statute under Section 6(c) to
16 immediately suspend the use of a product, and
17 there are specific standards for doing so. It
18 had the ability to do so if it felt at any point
19 that it was required. Instead, it gave a
20 five-year period to generate data. It extended
21 that period time and time again based on review
22 of data that had been submitted.

1 Whatever you think of EPA's new
2 position about the need to immediately remove
3 this product from the marketplace based on its
4 past behavior, one thing is sure: it had the
5 authority to do it, and this provision was not
6 essential.

7 On the Laches point, there are a few
8 perspectives that we wanted to share from the
9 registrants' perspective. The registrants, in
10 thinking about this, would have had no practical
11 reason to go to court to challenge a condition
12 that they had no reason to believe would be
13 exercised to implement an unscientific and
14 unsound cancellation determination. If the
15 registrants had taken the registration with the
16 condition and immediately sued in court, EPA
17 would have said no final Agency action, we've
18 asked you to submit the data, we said we're going
19 to review it, we'll make a decision at the end of
20 that process.

21 JUDGE STEIN: Let me make sure I
22 understand what you're saying. Upon receipt of a

1 conditional registration, why isn't that
2 registration final Agency action to issue a
3 conditional registration?

4 MS. SZMUSZKOVICZ: So in other words,
5 on the legality of that point, the condition,
6 there was no reason to believe that EPA was going
7 to implement it in an illegal, unlawful way.

8 JUDGE STEIN: Right. But when a
9 company takes a permit, you can appeal certain
10 conditions of the permit. We get appeals all the
11 time from people who like most of the provisions
12 of their permit but not others. We hear those.
13 The terms of the permit get settled, and that
14 can't be re-looked at in the context of an
15 individual permit enforcement proceeding.

16 So I understand that a conditional
17 registration is a little different or a
18 registration is a little different. But I'm
19 trying to understand why it is that FIFRA is so
20 different that you can essentially take the
21 benefits of a conditional registration for all
22 these years and then come in later and say, oh,

1 by the way, I really didn't like that after all.

2 And so from a point of view of
3 certainty and finality, it at least occurs to us
4 it's a bit unusual for someone to say they can
5 reopen something years after the fact. And so I
6 guess I don't understand why the conditional
7 registration wasn't a final Agency action that
8 you could have challenged, unless I've
9 misunderstood your point.

10 MS. SZMUSZKOVICZ: And I think we're
11 thinking about it from the standpoint of the
12 practicalities also of going to court. The
13 companies and the companies and the Agency had
14 just concluded these negotiations. To turn
15 around and file a lawsuit against the Agency over
16 something that you didn't have any reason to
17 believe would end up being an issue doesn't seem
18 like the type of either successful type of
19 endeavor. It's certainly not something anybody
20 has ever tried before, and it does seem like it
21 would be an unnecessary imposition on the courts
22 over an issue that may never, never come to bear.

1 All the aspects of it seem to us that it would
2 not have been an appropriate thing to do.

3 And the other suggestions about
4 options, sure, file a new application. The fees
5 for a new application at the time were \$500,000.
6 Today, it's \$675,000. And to suggest that you
7 would ask EPA to amend something right away after
8 you've agreed, and, again, this is the agency
9 that is regulating our everyday life on all of
10 our products, I don't think it's realistic to
11 suggest that anyone would do that.

12 The whole discussion about what's a
13 dialogue in discussion I think can be pierced
14 very easily because you can't have a discussion
15 about something that you don't know is an issue.
16 We did not know, and counsel for EPA admitted
17 there's nothing in the record to suggest
18 otherwise, that EPA was going to rely on a sole
19 endpoint, and that endpoint was not the sediment
20 endpoint, which is on the issue of concern, but
21 the water endpoint. And as the questions from
22 the panel have indicated, it's even difficult,

1 knowing that that's the issue, to figure that out
2 in the record.

3 There is a difference between time
4 limited and expiration dates. And that's why
5 there was a negotiation over that. An expiration
6 date is considered something automatic. There
7 has never been a lawsuit over whether that's
8 legal, and a question was asked earlier about
9 that. We submit that it would not be legal if
10 EPA attempted to enforce an automatic expiration
11 precisely because of the provisions of Section
12 6(b).

13 I'll quickly close. This case is
14 another example of the Office of Pesticide
15 Programs seeking to evade its statutory
16 obligations under FIFRA Section 6(b). Even EPA
17 has termed this provision that we have been
18 discussing unconventional.

19 It's also a case in which the Office
20 is seeking to elevate a political objective over
21 science. The circumstances are so stark that the
22 registrants have found it necessary to undertake

1 the unusual step of requesting review. Neither
2 registrant has ever undertaken anything like this
3 before. And as you know, it's the very first
4 Section 6(e) proceeding. It's extraordinary, and
5 it's especially so considering that this involves
6 challenging the very agency that holds so much
7 power over the registrants' livelihood. This
8 point was driven home by the Office of General
9 Counsel's pointed questioning of the president of
10 one of the registrants during the hearing.

11 We thank you for your work already,
12 your attention today, and your good questions,
13 the work that we understand lies ahead. This is
14 a matter that calls out for the Environmental
15 Appeals Board to take a fresh look at the law and
16 the facts, and we thank you for doing so.

17 JUDGE STEIN: Thank you, counsel. I
18 think I want to proceed as follows: I would like
19 to give Amici a brief opportunity if she wanted
20 to make any further statement. It's not
21 essential. So if you would like to, you may.
22 And if not, then I will talk about next steps.

1 Absolutely.

2 MR. LEHRENBAUM: Thank you, your
3 Honor. I am Warren Lehrenbaum --

4 JUDGE STEIN: I'm sorry. I can't hear
5 you.

6 MR. LEHRENBAUM: I'm sorry. I am
7 Warren Lehrenbaum, an attorney at Crowell &
8 Moring representing Amici CropLife America, and I
9 appreciate the opportunity to speak to you just
10 briefly to reiterate, I think, the main point of
11 the brief that we offered below, which was that
12 we believe that it's clear from both the statute
13 and the legislative history that Section 6(b) is
14 the appropriate section upon which EPA can
15 proceed if it determines that a product needs to
16 be, a registration needs to be canceled because
17 of unreasonable adverse effects and that it was
18 unlawful to try to essentially bypass that
19 statutory mechanism by including this particular
20 condition of registration in the registration at
21 issue here and, in effect, by including that
22 condition of registration and acting in a manner

1 that we feel was unlawful, that that unlawful
2 provision could not be rendered lawful by virtue
3 of the registrants' acceptance of that condition.
4 The condition is unlawful as it is, regardless of
5 whether the registrant accepted it or not.

6 JUDGE STEIN: Okay.

7 MR. LEHRENBAUM: Thank you.

8 JUDGE STEIN: Thank you very much. If
9 I can have a minute to concur with my panel
10 members. Thank you very much for indulging us.
11 I think we would like to proceed as follows: This
12 is a very important case and it is a very
13 complicated case, and we also know the priority
14 everyone attaches to a prompt decision. The
15 Board would like to have post-argument briefs
16 from the parties, and we envision issuing an
17 order by no later than Friday of this week. And
18 in that order, we will set some parameters for
19 the length of the briefs.

20 We may identify particular issues that
21 we would like the parties to brief. I'm not
22 guaranteeing that, but I think we'll take a look

1 at and review what's happened here today and see
2 if we have any outstanding questions.

3 We would like those briefs submitted
4 by July 1st at noon. We'll give you a week for
5 those briefs. And we will, at that point we will
6 consider the record to be complete and closed and
7 we will proceed to try to make an expeditious
8 decision.

9 The Board envisions issuing a decision
10 by the end of July. We recognize that you might
11 prefer a prompter decision than that, but, at
12 this point, in light of the extensive briefing
13 and the request for oral argument and the issues
14 that we have discussed today, we would envision
15 taking the briefs on July 1st and proceeding to
16 render our final decision. It may be before the
17 end of July, but we envision it would be no later
18 than the end of July. If anyone has any concerns
19 about that, they can point that out in their
20 briefs. But this is a very expedited proceeding
21 and, at the same time, we want to be able to do
22 justice to the issues that have been presented to

1 us on all sides.

2 I also would like to thank the many
3 visitors who have come a long way to be able to
4 participate in this argument, and we appreciate
5 everyone's efforts to meet these expedited
6 deadlines. And we will continue to do our part,
7 as well.

8 Thank you very much. The argument is
9 now adjourned.

10 MS. DUNCAN: All rise.

11 (Whereupon, the above-referred to
12 matter went off the record at 2:54 p.m.)
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Before: US EPA/EAB

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