Appeal No. 13-3514

IN THE UNITED STATES COURT OF APPEALS
FOR THE SIXTH CIRCUIT

In re: BAYER HEALTHCARE AND MERIAL LIMITED FLEA CONTROL PRODUCTS MARKETING AND SALES PRACTICES LITIGATION

KEVIN SIMMS, et al.

Plaintiffs-Appellants,

v.

BAYER HEALTHCARE, LLC, et al.

Defendants-Appellees.

On Appeal From The United States District Court
For The Northern District of Ohio, Eastern Division
Case No.: 1:12-MD-2319; MDL No. 2319

BRIEF OF APPELLEES MERIAL LIMITED, MERIAL LLC, MERIAL, INC., AND BAYER HEALTHCARE, LLC

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IN THE UNITED STATES COURT OF APPEALS
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CORPORATE DISCLOSURE STATEMENT OF APPELLEES
MERIAL LIMITED, MERIAL LLC AND MERIAL, INC.

Pursuant to Sixth Circuit Rule 26.1, defendants-appellees Merial, Inc., Merial LLC, and Merial Limited make the following disclosure:

1. Is said party a subsidiary or affiliate of a publicly owned corporation? If Yes, list below the identity of the parent corporation or affiliate and the relationship between it and the named party:

Merial Limited, Merial LLC, and Merial, Inc. are subsidiaries of Sanofi S.A., a publicly owned corporation.

2. Is there a publicly owned corporation, not a party to the appeal, that has a financial interest in the outcome?

No.

/s/ Gregory A. Castanias October 9, 2013

IN THE UNITED STATES COURT OF APPEALS
FOR THE SIXTH CIRCUIT

KEVIN SIMMS, et al.

Plaintiffs-Appellants,

v.

BAYER HEALTHCARE, LLC, et al.

Defendants-Appellees.

CORPORATE DISCLOSURE STATEMENT OF APPELLEE
BAYER HEALTHCARE, LLC

Pursuant to Sixth Circuit Rule 26.1, defendant-appellee Bayer HealthCare, LLC makes the following disclosure:

1. Is said party a subsidiary or affiliate of a publicly owned corporation? If Yes, list below the identity of the parent corporation or affiliate and the relationship between it and the named party:

Bayer HealthCare, LLC is wholly owned by Bayer Corporation, which is a wholly owned subsidiary of Bayer World Investments B.V., which is wholly owned by Bayer AG. Bayer AG is publicly traded in Germany, and its American Depository Shares are publicly traded in the United States.

2. Is there a publicly owned corporation, not a party to the appeal, that has a financial interest in the outcome?

No.

/s/ John K. Sherk October 9, 2013

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REQUEST FOR ORAL ARGUMENT

Appellees Merial Limited, Merial LLC, Merial, Inc., and Bayer HealthCare, LLC respectfully request oral argument. Oral argument will clarify the legal and factual issues presented and assist the Court in resolving this appeal.

PRELIMINARY STATEMENT

Plaintiffs' brief on appeal is an exercise in revisionist history. It tries to paint a picture of a district judge adopting unfair and extraordinary procedures to the prejudice of plaintiffs. But plaintiffs' brief omits a dispositive—and inescapable—detail: *plaintiffs agreed to, and even advocated for, the procedures about which they now complain.* Whether viewed as waiver, invited error, or estoppel, plaintiffs' actions bar them from advancing their appellate arguments, and compel affirmance of the district court's judgment.

Nowhere—nowhere at all—in their 58-page brief do plaintiffs so much as mention that they expressly "agree[d]" to the district court's framing of their lawsuit as "a one-issue case" and the court's procedure for resolving it. (R.16, 5/1/12 Transcript, 207.)[1] And it is not as though they lacked the chance. Indeed, plaintiffs quote extensively from the district court's statements at the initial case-

[1] Citations to the district court record are noted as "(R.[docket #], [title], [Page ID #].)." Because documents filed under seal in the district court do not have Page ID numbers, this brief cites the native page numbers of those documents.

management conference on May 1, 2012. Yet they conveniently omit their own counsel's statements, which undermine the foundation of their appeal:

> JUDGE POLSTER: . . . . **This is a one-issue case. Okay?** I mean, does this product disperse over the pet's body? If it does, there's no case. If it doesn't, we've got a false representation. That's it. I mean, and it's false for everyone, because that's the only reason you would get the product. If it only works on the pet's neck, who cares, it's worthless.
>
> **MR. CLIMACO [counsel for plaintiffs]: Your Honor, we agree. That's the basic simplicity of the case.**

(*Compare id.* (emphases added) *with* Brief Of Plaintiffs-Appellants ("Pls.' Br.") at 27 (quoting the district court but omitting Mr. Climaco's statement).)

> JUDGE POLSTER: If [Defendants have] a good study since January 1, 2010, I'll give you two weeks to produce it, and **then it will be up to the plaintiffs to demonstrate conclusively to me through experts what's wrong with your study, or else they're out. I'll dismiss the claim**, and they can go to the Court of Appeals, and then they're not going to succeed. Okay? That will be as a threshold matter.
>
> If not, then I'm suggesting you confer with the plaintiffs and come up with a neutral entity to do the test and the protocol for doing it that both sides will accept the results. Okay? So are both defendants agreeable on that? I'll give you two weeks, and if you have any study from January 1, 2010 on, **then it's up to the plaintiffs to show why your study was inadequate, incomplete, false, fraudulent, whatever they want to say, through some expert,** I'll give them a reasonable time to try and do that, and you don't have to do anything. If not, we'll pick a neutral site, entity, and a protocol.
>
> **So do plaintiffs agree with that?**

MR. CLIMACO: Yes, we do, Your Honor.

(*Compare* R.16, 5/1/12 Transcript, 223–24 *with* Pls.' Br. at 28 (quoting the district court but again omitting Mr. Climaco's statement).)

At the case-management conference, plaintiffs' counsel expressed *none* of the reservations regarding the district court's procedure that plaintiffs now present to this Court. Rather, in subsequent briefing, plaintiffs offered a full-throated defense of the procedure:

> [T]he [district court's May 2, 2012] Order gives Defendants an early opportunity to both challenge the legal sufficiency of Plaintiffs['] claims and to concretely present their defense and comports with the goal of achieving the orderly and expeditious disposition of cases. . . . If the resolution of a single issue can resolve the case without trial, the transferee court is empowered to address that issue "as a matter of justice and judicial efficiency."

(R.24, Pls.' Resp. & Opp., 728–29 (quoting *Kaiser Indus. Corp. v. Wheeling-Pittsburgh Steel Corp.*, 328 F. Supp. 365, 371 (D. Del. 1971).)

Plaintiffs' counsel also did not claim any need for discovery—indeed, he emphasized that he did not want to "open[] up full scale discovery" in this case. (R.16, 5/1/12 Transcript, 221.) Nor did plaintiffs' counsel mention *Daubert v. Merrell Dow Pharmaceuticals Inc.*, or any concern about expert evidence. And when the district court emphasized that its procedure would result in an "all or nothing" resolution of the case, plaintiffs' counsel did not object. Instead,

plaintiffs' counsel requested additional time to submit evidence, which the district court granted. (*Id.* at 229.)

For their part, defendants Merial Limited, Merial LLC, and Merial, Inc. (collectively, "Merial"), and Bayer Healthcare LLC ("Bayer") *did* object to the district court's procedure, because, *inter alia*, it shifted the burden of proving falsity away from plaintiffs, and instead required defendants to first come forward with factual support for the *truthfulness* of their representations. (*See, e.g.*, *id.* at 234; *see also* R.19, Defs.' Mot. for Reconsideration, 243.) The district court nonetheless held plaintiffs to their agreement—so when plaintiffs failed to carry their burden of showing that defendants' studies were unreliable, the district court granted summary judgment in defendants' favor. (*See* R.62, Order, 2199.)

Plaintiffs now seek on appeal to reinvent their case and to revive claims they voluntarily abandoned below. But they cannot escape their own express agreement to the procedure used in the district court. And even if plaintiffs could escape their waiver, they fail to show any abuse of discretion in the district court's partial denial of their sweeping discovery requests or any reversible error in its application of the summary-judgment standard. This Court should affirm.

STATEMENT OF THE ISSUES

1. Are plaintiffs' assertions of error barred by the doctrines of waiver, invited error, or estoppel, in view of their express—and repeated—agreement to

the district court's framing of the single issue presented and its adoption of a procedure for resolving that issue without discovery?

2. Did the district court properly exercise its discretion by partially denying plaintiffs' request for sweeping discovery that would have ranged far beyond the issue plaintiffs agreed was dispositive?

3. Did the district court properly grant summary judgment when the record demonstrated that plaintiffs could not prove a dispositive issue on which they had agreed they bore the burden of proof?

4. Did plaintiffs waive their *Daubert* argument by failing to raise it in the district court, and is that argument meritless in any event?

5. Did the district court properly decline to address claims that plaintiffs voluntarily abandoned?

STATEMENT OF THE CASE

Plaintiffs are the named plaintiffs in ten purported class actions filed in nine federal district courts between October 2011 and January 2012.[2] Eight of these

[2] *See* Compl., *Balloveras v. Bayer Healthcare LLC*, No. 1:11-cv-24416 (S.D. Fla.); Am. Compl., *Bloom v. Bayer Healthcare LLC*, No. 11-cv-7173 (S.D.N.Y.); Compl., *Boykin v. Merial Limited*, No. 12-00289 (N.D. Cal.); Am. Compl., *Carthen v. Bayer Healthcare LLC*, No. 1:11-cv-02172 (N.D. Ohio); Compl., *Christina v. Bayer Healthcare LLC*, No. 3:12-cv-00047 (M.D. La.); Am. Compl., *Farrell v. Bayer Healthcare LLC*, No. 1:11-cv-01820 (W.D. La.); Am. Compl., *Gregg v. Bayer Healthcare LLC*, No. 3:11-cv-06011 (D.N.J.); Am. Compl., *Resnick v. Bayer Healthcare LLC*, No. 1:11-cv-07210 (N.D. Ill.); Compl.,

actions named Merial and Bayer as defendants, and two actions, *Boykins* and *Simms*, named Merial only.

The gravamen of plaintiffs' actions was the allegation that Merial and Bayer made misrepresentations in the advertisements for products they manufacture and sell to treat dogs and cats for fleas, ticks, and other infestations. *See, e.g.*, *Balloveras* Compl. ¶¶ 1–5. In particular, plaintiffs alleged that Merial falsely advertised its Frontline®, Frontline® Plus, Frontline® Top Spot, and Certifect® products (collectively, "Merial Products"), and that Bayer falsely advertised its Advantage® and Advantix® product lines (collectively, "Bayer Products"). *See, e.g.*, *id.* Plaintiffs initially asserted a panoply of claims sounding in state false-advertising and consumer-protection statutes, express and implied warranty, unjust enrichment, and the Magnuson-Moss Warranty Act. *See id.* ¶¶ 116–30; *Bloom* Am. Compl. ¶¶ 127–74; *Boykin* Compl. ¶¶ 41–91. Plaintiffs sought certification of classes of similarly situated consumers. *See, e.g.*, *Balloveras* Compl. ¶¶ 94–115.

On plaintiffs' motion, the Judicial Panel on Multidistrict Litigation ("JPML") consolidated these cases before Judge Daniel A. Polster in the Northern District of Ohio. (R.1, Transfer Order, 1–3.) With plaintiffs' express agreement, and over defendants' objection, the district court narrowed the consolidated cases to a single

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Richardson v. Bayer Healthcare LLC, No. 8:11-cv-01707 (C.D. Cal.); Compl., *Simms v. Merial Limited*, No. 2:11-cv-08548 (C.D. Cal.).

issue and devised a procedure for resolving that issue without discovery. (R.16, 5/1/12 CMC Transcript, 207–34.) When plaintiffs failed to carry the burden of proof that they had acknowledged they bore under procedures to which they had expressly agreed, the district court granted summary judgment to defendants. (*See* R.62, Order, 2199.) This appeal followed.

STATEMENT OF THE FACTS

Because plaintiffs' claim, at its core, is that Merial and Bayer falsely advertised the manner in which their products work when applied to animals, we begin with a description of the federal regulatory scheme for these products as well as the submissions required by the Environmental Protection Agency or the Food and Drug Administration to obtain permission to make and market them.

A. Federal Regulators Approved Merial's And Bayer's Products And Labels Based On Scientific Studies

Spot-on flea and tick treatment products that are applied topically to pets and do not function systemically through the pet's bloodstream—in other words, products that kill fleas and ticks on contact rather than through their ingestion of the pet's blood—are considered pesticides under the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"), and are subject to regulation by the EPA. *See* 7 U.S.C. §§ 136–136a; R.60, Defs.' Reply In Support Of Their Mot. For Summ. J., Ex. A; R.20-8, Davis Decl. ¶¶ 11–12, 348. Except in narrow circumstances not relevant here, FIFRA prohibits the manufacture, sale, or distribution within the

United States of any pesticide product unless the EPA has registered the particular product composition and label language. *See* 7 U.S.C. § 136a. An applicant seeking registration of a pesticide product or label bears the burden of establishing, to the EPA, that the registration requirements have been satisfied. *See, e.g.*, *id.*; *see also* R.20-8, Davis Decl. ¶¶ 23–24, 351.

To obtain registration, the applicant submits scientific studies or cites to data supporting registration; the studies must be conducted according to EPA guidelines and Good Laboratory Practice standards. (R.20-8, Davis Decl. ¶¶ 28–32, 351–52.) For registration of spot-on pet products, the EPA requires product chemistry studies, six acute toxicity studies, companion animal safety studies, and efficacy studies. (*Id.* ¶ 35, 352.) Moreover, FIFRA and the governing regulations prohibit any "false and misleading statements" on a product label, including any "false or misleading statement concerning the effectiveness of the product as a pesticide." 40 C.F.R. § 156.10(a)(5)(ii).

By contrast, pet products that work systemically—*i.e.*, have an effect on insects and pests because of the product's distribution through the pet's bloodstream—are regulated as animal drugs by the FDA. (R.60, Defs.' Reply In Support Of Their Mot. For Summ. J., Ex. A; R.20-8, Davis Decl. ¶¶ 11–12, 348.) The FDA has promulgated its own rules and requirements for registration of systemically acting animal drug products. (*See id.*)

All of the Merial Products at issue in this case are spot-on products regulated by the EPA because their active ingredient, fipronil, does not work systemically through distribution via the pet's bloodstream, but instead is administered topically, disperses across the pet's skin via a process called translocation, and collects in the pet's sebaceous glands. (R. 45-14, Clark Decl. ¶¶ 18–21, 5–6.) Merial thus sought registration from the EPA when it introduced the Merial Products to the market in the 1990s. (*See id.*) Merial disclosed to the EPA at that time that trace amounts of fipronil may *enter* the pet's bloodstream due to the pet's grooming and scratching—but the scientific studies and data Merial presented to the EPA established that fipronil *works* topically, not systemically through the bloodstream. (*See id.*; *see also* R.59-4, Memorandum, 5.) The EPA agreed and granted registration of the Merial Products and their labels. (*See* R. 45-14, Clark Decl. ¶ 18, 5.) The formula and composition of the Merial Products has not changed in any meaningful way since their EPA registration. (*See id.* ¶¶ 18–21, 5–6.)

All but one of the Bayer Products at issue in this case are also spot-on products regulated by the EPA. (R.20-8, Davis Decl. ¶ 10, 348.) The active ingredients in those products include imadacloprid, permethrin, and pyriproxyfen. (*Id.*) Even though insignificant amounts of those ingredients may enter the pet's bloodstream, the ingredients do not work systemically. (*Id.* ¶ 15, 349; R.40-1, Davis Supp. Decl. ¶ 15.) Instead, those ingredients spread topically across the

pet's hair and body through the lipid layer of the pet's skin and kill fleas and ticks on contact. (*Id.*) The EPA granted registration of those Bayer Products and their labels based on the studies and data Bayer submitted. (*See id.* ¶ 39, 353.) The formula and composition of the spot-on Bayer Products have not changed significantly since their EPA registration. (*See id.* ¶ 40.)[3]

B. Plaintiffs Filed Suit And Moved For An MDL Before Judge Polster

Plaintiffs filed separate lawsuits across the country alleging that statements made by Merial and Bayer regarding their EPA- and FDA-approved products were false. On November 4, 2011, plaintiffs moved the JPML to transfer "all Related cases for pretrial consolidation and coordination to the Honorable Daniel A. Polster . . . of the Northern District of Ohio." Br. in Support of Pls.' Mot. at 12, MDL No. 2319 (DE 1-1 Nov. 4, 2011). Plaintiffs described Judge Polster as "an experienced jurist who has handled complicated and complex class action matters in the past." *Id.* at 12–13. Plaintiffs noted that Judge Polster had presided over other class actions brought by plaintiffs' counsel, and praised him for "manag[ing] [those] cases with remarkable efficiency and alacrity." *Id.* at 13. Plaintiffs further

[3] Because one of the Bayer Products at issue in this suit, Advantage® Multi, contains an active ingredient, moxidectin, whose mode of action is systemic, it is regulated as an animal drug by the FDA. (R.20-8, Davis Decl. ¶ 12, 348.) The FDA granted registration of that product, and its formula and composition have not changed significantly since that registration. (*Id.* ¶ 40, 353.)

asserted that "Judge Polster has demonstrated remarkable skill and industry with respect to complex litigation generally and MultiDistrict [*sic*] Litigation specifically." *Id.* at 13–14.

The JPML granted plaintiffs' motion and transferred the first six cases to Judge Polster on February 8, 2012. (R.1, Order, 1–3.) It transferred three more cases to Judge Polster on February 22, 2012, and one more on February 24, 2012. (R.2, Order, 4–5; R.3, Order, 6–7.)

C. Plaintiffs Expressly Agreed To The District Court's Framing Of The Case And Its Procedure For Resolving It Without Discovery

The district court convened a case-management conference on May 1, 2012. There, plaintiffs expressly agreed to, and endorsed, the district court's framing of the case as a single-issue dispute:

> JUDGE POLSTER: . . . . **This is a one-issue case. Okay?** I mean, does this product disperse over the pet's body? If it does, there's no case. If it doesn't, we've got a false representation. That's it. I mean, and it's false for everyone, because that's the only reason you would get the product. If it only works on the pet's neck, who cares, it's worthless.
>
> **MR. CLIMACO: Your Honor, we agree. That's the basic simplicity of the case.**

(R.16, 5/1/12 Transcript, 207 (emphases added).)[4]

[4] *See also* R.16, 5/1/12 Transcript, 217–18 (JUDGE POLSTER: "I mean, boiled down, this case is very straightforward. The plaintiffs are alleging that the defendants' product does not autodisperse across the surface of the pet's body as the defendants claim."); *id.* at 219 (JUDGE POLSTER: "[I]t boils down to one

Plaintiffs also expressly agreed with the district court's procedure for resolving that issue:

> JUDGE POLSTER: If [Defendants have] a good study since January 1, 2010, I'll give you two weeks to produce it, and **then it will be up to the plaintiffs to demonstrate conclusively to me through experts what's wrong with your study, or else they're out. I'll dismiss the claim**, and they can go to the Court of Appeals, and then they're not going to succeed. Okay? That will be as a threshold matter.
>
> If not, then I'm suggesting you confer with the plaintiffs and come up with a neutral entity to do the test and the protocol for doing it that both sides will accept the results. Okay? So are both defendants agreeable on that? I'll give you two weeks, and if you have any study from January 1, 2010 on, **then it's up to the plaintiffs to show why your study was inadequate, incomplete, false, fraudulent, whatever they want to say, through some expert,** I'll give them a reasonable time to try and do that, and you don't have to do anything. If not, we'll pick a neutral site, entity, and a protocol.
>
> **So do plaintiffs agree with that?**
>
> **MR. CLIMACO: Yes, we do, Your Honor.**

(*Id.* at 223–24 (emphases added).)[5]

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basic contention, that they're claiming that you have misrepresented your product. And that is this self-dispersing mechanism, and that it covers the pet's body, entire body, with a single application. So that's what it boils down to."); *id.* at 227 (JUDGE POLSTER: "So the question simply is, does this product . . . translocate over the pet's body. If it does there is no case, if it doesn't you have a problem with what you're claiming, you have to stop claiming it.")

[5] *See also* R.16, 5/1/12 Transcript, 221 (JUDGE POLSTER: "If the defendants have done substantial tests, January 1, 2010 to the present, all right, in

Defendants objected to the district court's framing of the case and its proposed procedure. (*See, e.g.*, *id.* at 218–21, 234.) Bayer's counsel proposed an alternative procedure for briefing the scientific, regulatory, and other issues (*see id.* at 220–21), to which plaintiffs' counsel objected because it might open the door to discovery:

> MR. CLIMACO: Your Honor, it just seems to me that all we're doing [if Bayer's proposal is accepted] is *opening up full-scale discovery*.
>
> JUDGE POLSTER: Yeah. I don't quite understand.
>
> MR. CLIMACO: Neither do I. Let's do the test.

(*Id.* at 221 (emphasis added).)

Plaintiffs' counsel did not assert that plaintiffs needed discovery to satisfy their burden to demonstrate that defendants' studies were "inadequate, incomplete, false, [or] fraudulent." (*Id.* at 224.) Counsel likewise did not mention *Daubert* or

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the last two years, if they have tested their products and demonstrated this surface migration of the product over the pet's body, then simply produce those studies, and then it's up to the plaintiffs to demonstrate conclusively what's wrong with those studies, or else the case is gone. If the defendants haven't done it, then let's have it done."); *id.* at 222 (JUDGE POLSTER: "If you've got a substantial study since [January 1, 2010], then put that to the plaintiffs, and it's their burden to show what's wrong with it, or they're out."); *id.* at 225 (JUDGE POLSTER: "But again, if either Bayer or Merial has a thorough test from January 1, 2010 forward, I'm going to put the burden on the plaintiffs to show me what's wrong with your test."); *id.* at 228 (JUDGE POLSTER: "If you have got some substantial tests from January 1, 2010 forward that addresses this migration theory, then it will be up to the plaintiffs to show me, convince me what's wrong with those tests, or else they're out.").

any concern about expert procedures, even though the district court made clear that plaintiffs would be required to discharge their burden "through some expert." (*Id.*) And when the district court emphasized that its procedure would result in an "all or nothing" resolution of the case, plaintiffs' counsel did not object, but instead requested additional time to submit evidence, which the district court granted. (*Id.* at 229.)

D. The District Court Implemented Its Procedure Over Defendants' Objections And With Plaintiffs' Encouragement

The district court entered an order formalizing its procedure on May 2, 2012. (R.17, Order, 237.) The district court distilled the "key issue" to be "whether [d]efendants' products truly perform as claimed, namely, whether the products, after applied as directed, migrate across the pet's body (a.k.a. translocate)." (*Id.* at 238.) The district court then identified the specific translocation statements at issue.

First, the district court noted Bayer's claim that:

> After topical application of the product, imidacloprid is rapidly distributed over the animal's skin within one day of application. It can be detected on the body surface throughout the 28-day treatment interval. Imidacloprid localizes in the lipid layer of the skin surface, which spreads not only over the surface of the skin but also onto the hair.

(*Id.* at 237–38.)

Second, the district court identified Merial's claim that:

> The products spread over the pet's body by a process called translocation. When applied, these products are gradually dispersed by the pet's natural oils, collecting in the oil glands in the skin. It is then 'wicked' onto the hair over the next 30 days. The translocation process can take up to 24 hours to complete.

(*Id.* at 238.)

The district court ordered defendants—by May 15, 2012, only 13 days after the order issued—to "forward to the Court and Plaintiffs' counsel any studies conducted after January 1, 2010, that substantiate Defendants' . . . assertions" regarding translocation. (*Id.*) The district court allowed plaintiffs until July 16, 2012 "to refute the[se] studies," stressing plaintiffs' burden to show that defendants' studies "are unreliable, inaccurate, or incomplete, *or these cases will be dismissed*." (*Id.* (emphasis added).)

Defendants moved the district court to reconsider its May 2, 2012 order, pointing out that the district court's procedure improperly shifted the burden of proof, arbitrarily designated the January 1, 2010 cut-off date for defendants' studies, infringed defendants' right to a jury trial, and otherwise prejudiced defendants. (R.19, Defs.' Mot. for Reconsideration, 243.) Plaintiffs did not object to the May 2, 2012 order, or its directive that plaintiffs' cases "will be dismissed" if they failed to carry their burden of proof. (R.17, Order, 238.) Rather, plaintiffs opposed defendants' motion for reconsideration and encouraged the district court

to adhere to its order, which plaintiffs maintained was authorized by Federal Rule of Civil Procedure 16 and within the transferee court's power:

> [T]he [May 2, 2012] Order gives Defendants an early opportunity to both challenge the legal sufficiency of Plaintiffs[']claims and to concretely present their defense and comports with the goal of achieving the orderly and expeditious disposition of cases. . . . If the resolution of a single issue can resolve the case without trial, the transferee court is empowered to address that issue "as a matter of justice and judicial efficiency."

(R.24, Pls.' Resp. & Opp., 728–29 (quoting *Kaiser Indus. Corp.*, 328 F. Supp. at 371).) Plaintiffs also asserted that "no argument can be made that [the] Court's Order deprived Defendants of their 7th Amendment right[s]." (*Id.* at 731.)

The district court denied defendants' motion and implemented its proposed procedure. (R.27, Order, 746.)

E. Defendants Submitted Studies Establishing Their Translocation Claims

Defendants complied with the order and submitted scientific studies establishing their translocation claims on May 15, 2012. (R.20, Bayer Submission, 259; R. 21, Merial Objections, 354.) Merial submitted two studies regarding the Merial Products: the 1997 Cochet Study that Merial submitted in support of its EPA registration application, and an August 2009 study conducted by scientists at the University of California-Riverside (the "Dyk Study") using "the same formulation of FRONTLINE Plus available to consumers today." (R.21, Merial

Objections, 355; *see also* R.21-1, Cochet Study, 358; R.21-2, Dyk Study, 364; R.21-3, Product Packaging, 709.) Both studies demonstrate that fipronil disperses across the pet's body and does not work systemically through the bloodstream. (R.21, Merial Objections, 355.)

Bayer submitted three published studies postdating, and four studies predating, January 1, 2010. (R.20, Bayer Submission, 259–66.) These studies established Bayer's translocation claims. (*See id.*) Bayer also submitted a declaration from Dr. Wendell Davis, a Manager of Clinical Development Projects in the Research and Development Department at Bayer Animal Health. (R.20-8, Davis Decl. 346.)

Following these submissions, the district court "modif[ied] [its May 2, 2012] order slightly" to permit it to consider the Dyk Study from the University of California-Riverside scientists published in August 2009. (R.22, Order, 714.) The district court reasoned that "the study is quite current," and "the author of the study used the same formulation of Merial's product, Frontline Plus, that is available to consumers today." (*Id.*)

The district court accepted defendants' submissions and concluded that "both Defendants have produced recent studies substantiating their claims." (*Id.*) It therefore reiterated that "Plaintiffs have two months . . . to produce scientific

evidence to refute the studies, *otherwise this case will be dismissed*." (*Id.* (emphasis added).)

F. Plaintiffs Failed To Carry Their Burden To Establish That Defendants' Studies Were Unreliable, Inaccurate, Or Incomplete

Plaintiffs responded to defendants' submissions by filing a motion for extension of time. (R.29, Pls.' Mot., 749.) Plaintiffs premised this motion in part on the contention that they needed additional time for "an independent expert to design and implement a study . . . to determine the validity of Defendants' translocation claims." (*Id.* at 749–50.)

The district court expressed its "displeas[ure] with the lateness of Plaintiffs' request" and observed that it "gave Plaintiffs 60 days to respond" to defendants' submissions, which was "actually longer than the 30 days Plaintiffs' counsel originally requested." (R.32, Order, 790.) The district court further observed that "Plaintiffs' motion suggests that they are not doing what they are supposed to." (*Id.*) That is, plaintiffs were conducting a study regarding the veracity of the translocation claims rather than "attack[ing] Defendants' studies by showing they are flawed or unreliable or inaccurate." (*Id.*) Nonetheless, the district court "begrudgingly" granted plaintiffs' requested extension. (*Id.* at 791.)

Plaintiffs filed their "critique" of defendants' studies on July 31, 2012. (R.35, Pls.' Critique.) Plaintiffs opened their critique by quoting the district court's framing of this case as a single-issue dispute and procedure for resolving it.

(*See id.* at 1–2.) But plaintiffs did not identify any expert or scientific evidence suggesting that defendants' studies were unreliable, inaccurate, or incomplete, despite the district court's direction that they do so. (*See id.* at 2–29; R.16, 5/1/12 Transcript, 224 (directing that plaintiffs must discharge their burden "through some expert"); R.22, Order, 714 (directing plaintiffs "to produce scientific evidence to refute [defendants'] studies, otherwise the case will be dismissed").) Instead, plaintiffs attempted to discredit defendants' studies through lawyer arguments (R.35, Pls.' Critique, 2–27)—and many of those arguments proved to be demonstrably false as a matter of fact and basic science (R.41, Merial's Resp., 3–4; R.40, Bayer's Resp., 5–11).

Plaintiffs also submitted "two separate studies to verify Defendants' translocation claims," even though that issue ventured beyond the district court's framing of the case as focused exclusively upon defendants' studies. (R.35, Pls.' Critique, 28.) The first study ("Gregg Study") was conducted by one of the plaintiffs and his school-aged son, and involved only Frontline Plus, one of the Merial Products. (*See id.* at 31–32.)[6] Plaintiffs contended that the Gregg Study "proved that Frontline Plus does not translocate over the body of the pet" because, 24 hours after application, Mr. Gregg did not detect fipronil "on the tested dog [at]

[6] As plaintiffs noted, the Gregg Study was Mr. Gregg's son's middle-school science project. (R.35, Pls.' Critique, 32 n.21.)

locations other than where initially applied." (*See id.*) But the Gregg Study and its methodology were flawed: Mr. Gregg is an interested plaintiff, is not a scientist, and has no education or training as a bioanalytical chemist. (R.41, Merial's Resp., 4.) Mr. Gregg's methods did not meet bioanalytical standards, and his results were not audited or subject to peer review and, by his own admission, were incomplete. (*See id.* at 4–5.) Moreover, Mr. Gregg used the wrong solvent to extract fipronil from the skin of the dog, did not properly identify and quantify what he extracted, and did not use proper controls. (*See id.* at 5–7.) Plaintiffs later admitted that Mr. Gregg lacks "the qualifications and expertise to be considered an expert" and therefore withdrew the Gregg Study for purposes of summary judgment. (R.59, Pls.' Opp. To Defs.' Mot. For Summ. J., 21 n.14.)

Plaintiffs' second study ("Experimur Study") was designed by Dr. Randy Jones, plaintiffs' putative expert, who drafted a companion report ("Jones Report"). (R.35, Pls.' Critique, 28–31.) Plaintiffs asserted that the Experimur Study and Jones Report demonstrated that "the active ingredients" in the Merial Products and the Bayer Products "do not translocate and are systemically absorbed." (*Id.*) The Experimur Study, however, was incomplete, had not been subject to peer review, relied on contaminated samples, and did not use a control group. (R.40, Bayer Resp., 11–19.) Moreover, the Experimur Study actually *proved* Merial's and Bayer's translocation claims because it detected the active ingredients at all

locations on the surface of the test animals' bodies. (*Id.* at 17–19; R.41, Merial's Resp., 7.) The Experimur Study also demonstrated that the active ingredients did not function systemically via the pets' bloodstream because it measured only minuscule levels of those ingredients in the bloodstream relative to the levels in the hair and skin samples. (R.40, Bayer Resp., 17–19; R.41, Merial's Resp., 7–13.)

The district court convened a telephone conference on August 13, 2013, two weeks after receiving plaintiffs' submission. The district court noted that it had reviewed the studies and concluded that defendants "had a good faith basis for making" their translocation claims. (R.45-2, 8/13/2013 Tr., 2.) The district court further noted that the small number of consumer complaints regarding the Merial Products and the Bayer Products suggested that few consumers could claim an injury in any event. (*See id.*) Accordingly, the district court encouraged the parties to resolve the case "efficient[ly]" by either negotiating a modification of defendants' product along with a modest fee for plaintiffs' attorneys, or submitting to a neutral study that would determine what representations defendants could make about their products. (*Id.* at 3.) The parties conferred but could not agree to either proposal.

Thereafter, on August 31, defendants filed their responses to plaintiffs' critique. Those responses documented the myriad flaws in the Gregg Study, the Experimur Study, and the Jones Report. (R.40, Bayer Resp.; R.41, Merial's Resp.)

In support of its response, Merial submitted a declaration from Dr. Jeffrey Clark, an independent consultant with over 30 years of experience in animal and human pharmaceutical product development. (R.41-1, Clark Decl.) Bayer submitted a supplemental declaration from Dr. Davis. (R.40-1, Davis Supp. Decl.)

G. The District Court Instructed Defendants To Move For Summary Judgment And Partially Denied Plaintiffs' Motion For Discovery

The district court convened a status conference on September 4, 2012, and told the parties that it had reviewed defendants' responses to plaintiffs' critique. (R.44, 9/4/12 Transcript, 1122.) The district court reminded the parties that it had "already ruled that" defendants' studies substantiate their translocation claims and, thus, that defendants "have a basis for making those claims." (*Id.* at 1124.) The district court also reiterated that it "gave [Plaintiffs] an opportunity to show . . . why [Defendants are not] permitted to rely on their own studies, and [Plaintiffs] didn't do that." (*Id.* at 1126.) Thus, under the procedure to which plaintiffs had agreed, the district court would have been within its discretion to dismiss the cases at that point. (*See* R.17, Order, 238.)

Instead, however, the district court afforded plaintiffs one last chance, stating that "maybe the simplest thing to do is . . . have the Defendants file a motion to dismiss, have the Plaintiffs respond, [to] give [Plaintiffs] a chance to convince me otherwise." (R.44, 9/4/12 Transcript, 1124.) After recognizing that the parties had submitted evidence, the district court noted that "[i]t's really a

summary judgment" and instructed defendants to file a joint motion for summary judgment. (*Id.* at 1126.)

Plaintiffs' counsel then inquired whether plaintiffs would "have the opportunity to do some limited discovery." (*Id.*) The district court reminded plaintiffs that they already had been given the opportunity to refute defendants' studies but had failed to do so. (*Id.*) Yet the district court left the door open to plaintiffs seeking discovery if they could "specifically" identify the requested discovery and their need for it. (*Id.* at 1127.)

Defendants filed a joint motion for summary judgment on October 3, 2012. (R.45, Defs.' Mot. For Summ. J.) Defendants' motion rested on the fact that plaintiffs had failed to discharge the burden that they had acknowledged they bore under the procedure they had expressly endorsed. (R.45-1, Defs.' Memo., 15–28.) Indeed, the district court already had concluded that defendants' studies supported their translocation claims and that plaintiffs had failed to establish that those studies were unreliable, inaccurate, or incomplete. (*See id.*)

Plaintiffs responded two weeks later by filing a motion for discovery under Federal Rule of Civil Procedure 56(d). (R.46, Pls.' Rule 56(d) Mot.) Plaintiffs sought leave to conduct expansive discovery in the form of 30 pages of interrogatories addressed to each defendant, a 25-page request for production addressed to Merial, a 23-page request for production addressed to Bayer,

depositions of corporate representatives of each defendant, and eight other depositions. (R.46-2, Exhibit Interrogatories; R.46-3, Exhibit Merial Request For Production; R.46-4, Exhibit Bayer Request For Production; R,46-5, Exhibit 30(b)(6) Notices; R.46-6, Exhibit Expert Deposition Notices; R.46-7, Exhibit Subpoenas.)

The topics on which plaintiffs sought discovery swept far beyond the single issue that plaintiffs had previously agreed was dispositive. For example, plaintiffs' proposed interrogatories related to the "ingredients" and their quantities in defendants' products, "customer complaints regarding the efficacy or inefficacy of Defendants' products," the legal framework for EPA registration of spot-on pet products, and statements by defendants that did not relate to translocation. (*See* R.46-2, Exhibit Interrogatories, 11–26.) To the extent plaintiffs' proposed interrogatories even addressed defendants' translocation claims, they sought "all documents" related to translocation, and not merely studies postdating the district court's cut-off date. (*See id.* at 9–11.)

Plaintiffs' proposed requests for production likewise sought "all documents" related to a host of topics, including the ingredients of defendants' products, the EPA registration of defendants' products, any "adverse effects of any of Defendants[']] Products on humans," and a 1998 study in German. (R.46-3, Exhibit Merial Request For Production, 12–22; R.46-4, Exhibit Bayer Request For

Production, 9–20.) Plaintiffs asked to depose a corporate representative of each defendant on such varied topics as "customer complaints," "[e]lectronically stored information," "[d]ocument retention and destruction policies," and "[c]orporate organizational structure." (R.46-5, Exhibit 30(b)(6) Notices, 6, 12.) And plaintiffs demanded the depositions of Dr. Clark, Dr. Davis, and the authors of the studies defendants submitted in compliance with the district court's order. (R.46-6, Exhibit Expert Deposition Notices; R.46-7, Exhibit Subpoenas.)

Defendants opposed plaintiffs' broad-ranging discovery requests on several grounds. (R.47, Defs.' Joint Opp.) Defendants pointed out that this discovery "was neither requested, nor part of, the procedure ordered by the Court and specifically agreed to by Plaintiffs." (*Id.* at 1, 4–6.) Moreover, plaintiffs' voluminous requested discovery had "virtually nothing to do with whether Plaintiffs established that Defendants' submissions were unreliable, inaccurate, and incomplete." (*Id.* at 7.) Instead, plaintiffs' discovery requests indicated "that their real goal" was to abandon their agreement to the district court's procedure and "start their case anew." (*Id.* at 8.)

The district court entered an order granting plaintiffs' motion in part and denying it in part. (R.49, Order, 1889.) The district court noted that "[i]n accordance with the protocol established by the Court" with plaintiffs' consent, defendants submitted "recent studies published in peer-reviewed journals that

substantiate their advertised claims." (*Id.*) "Thus, the only meaningful discovery would be evidence calling into question the validity of these studies." (*Id.*)

The district court therefore denied "most of Plaintiffs' discovery requests" but ordered defendants to produce "all consumer complaints received from January 1, 2009, to the present . . . about the products at issue in this case." (*Id.*) The district court reasoned that "[i]f it turns out Defendants received a large volume of consumer complaints relative to sales about the effectiveness of their products, that would call into question Defendants' reliance upon the studies as a basis for their advertised claims." (*Id.*)

H. The District Court Granted Summary Judgment To Defendants

After defendants produced the consumer complaints, plaintiffs filed an opposition to the motion for summary judgment (R.59, Pls.' Opp. To Defs.' Mot. For Summ. J.), to which defendants replied (R.60, Defs.' Reply In Support Of Their Mot. For Summ. J.). On leave of the district court, plaintiffs filed a surreply. (R.61, Pls.' Surreply Brief.)

The district court entered an order granting defendants summary judgment on March 19, 2013. (R.62, Order, 2199.) The district court recounted its framing of the case and procedure for resolving it, and noted its prior ruling "that Defendants have produced studies substantiating their representations about the dispersion of their products over the surface of pet's skin." (*Id.* at 2199–2200.)

Thus, according to the district court, "the only question . . . is whether there are so many consumer complaints challenging Defendants' representations about dispersion that they call into question the validity of Defendants' studies." (*Id.* at 2200.) The district court held, however, that the number of such consumer complaints was "insignificant." (*Id.* at 2201.)

The district court also dismissed as "a red herring" the fact that "some product has been found in the bloodstream of pets." (*Id.*) In the first place, that fact "is irrelevant to the question whether Defendants have reliable, accurate and complete scientific studies to back up their dispersion claims." (*Id.* at 2202.) Moreover, "Plaintiffs' evidence that small amounts of product may be in the blood does not prove that Defendants' dispersion claims are wrong." (*Id.*) And, finally, "the detection of small amounts of product in the blood is not material because Defendants' labeling and advertising does not make any claim regarding whether any amount of the product can get into the blood." (*Id.*)

The district court entered judgment the same day. (R.63, Judgment Entry, 2203.) Plaintiffs' notice of appeal followed. (R.64, Notice of Appeal, 2204.)

SUMMARY OF ARGUMENT

I. Plaintiffs' appellate claims of error are barred by the doctrines of waiver, invited error, and estoppel. Plaintiffs repeatedly and expressly agreed to the district court's framing of this case and procedure for resolving it without

discovery. Indeed, plaintiffs wholeheartedly endorsed the district court's approach right until summary judgment, when it became apparent that the court would hold them to their agreement and dismiss their claims for failure to satisfy the burden of proof that they previously had acknowledged they bore. Plaintiff cannot now seek the benefit of reversal of a procedure that they agreed to, encouraged, and endorsed.

II. The district court properly exercised its discretion when it partially denied plaintiffs' motion for discovery under Rule 56(d). Plaintiffs' expansive discovery was irrelevant to the single issue that plaintiffs agreed was dispositive: whether defendants' studies were unreliable, inaccurate, or incomplete. Plaintiffs, moreover, failed to support their discovery motion with a sufficient declaration of the material facts they hoped to discover. And in all events, the irrelevant discovery plaintiffs requested at the eleventh hour would not have changed the outcome in the district court.

III. The district court properly granted summary judgment to defendants because plaintiffs failed to establish the existence of any genuine issue on their burden to prove that defendants' studies were unreliable. Plaintiffs' purported evidence, including the Experimur Study and the Jones Report, could not create such an issue because that evidence *proved* defendants' translocation claims and was inadmissible in any event. And plaintiffs are simply incorrect that the progression of the case to summary judgment somehow relieved them of the

burden they eagerly embraced, because the summary-judgment procedure tests the sufficiency of a party's *evidence* without affecting the parties' *burdens*.

IV. Plaintiffs waived their *Daubert* challenge to defendants' studies and declarations because they failed to assert it in the district court, even as they wholeheartedly endorsed the district court's procedure requiring disclosure of those studies. In any event, plaintiffs' *Daubert* challenge is meritless.

V. The district court did not err in failing to address other issues and claims because plaintiffs abandoned all such issues and claims when they agreed to the district court's framing of the case and procedure for resolving it.

STANDARD OF REVIEW

"This Court will not decide issues or claims not litigated before the district court." *White v. Anchor Motor Freight, Inc.*, 899 F.2d 555, 559 (6th Cir. 1990).

"[This Court] typically review[s] a district court's case-management decision made pursuant to Rule 16 for abuse of discretion." *Miller v. Am. Heavy Lift Shipping*, 231 F.3d 242, 252 (6th Cir. 2000).

This Court reviews a district court's decision on a motion for discovery under Rule 56(d) for an "abuse of discretion." *United States v. Dairy Farmers of Am., Inc.*, 426 F.3d 850, 862 (6th Cir. 2005).

This Court "review[s] an order granting summary judgment de novo," *Kentucky Commercial Mobile Radio Serv. Emer. Telecomms. Bd. v. TracFone*

Wireless, Inc., 712 F.3d 905, 912 (6th Cir. 2013), and reviews a district court's evidentiary rulings, including its decision to admit or to exclude expert testimony, "for abuse of discretion," *Sigler v. Am. Honda Motor Co.*, 532 F.3d 469, 478 (6th Cir. 2008).

ARGUMENT

I. PLAINTIFFS' WHOLEHEARTED ENDORSEMENT OF THE DISTRICT COURT'S PROCEDURE CONSTITUTES WAIVER, INVITED ERROR, AND ESTOPPEL OF THEIR APPELLATE CLAIMS OF ERROR

"'[A]n attorney cannot agree in open court with a judge's proposed course of conduct and then charge the court with error in following that course.'" *United States v. Aparco-Centeno*, 280 F.3d 1084, 1088 (6th Cir. 2002) (quoting *United States v. Sloman*, 990 F.2d 176, 182 (6th Cir. 1990)). Several intersecting legal doctrines confirm this commonsense point.

In the first place, the doctrine of waiver holds that a party that endorses a court's course of conduct intentionally relinquishes the right to object to it later. *See id.*; *see also United States v. Olano*, 507 U.S. 725, 732–33 (1993) (waiver is "the intentional relinquishment or abandonment of a known right").

"[A] branch of the doctrine of waiver" is "[t]he doctrine of invited error[,] a cardinal rule of appellate review." *Harvis v. Roadway Express, Inc.*, 923 F.2d 59, 60–61 (6th Cir. 1991). The invited-error rule "refers to the principle that a party may not complain on appeal of errors that he himself invited or provoked the court

or the opposite party to commit." *Id.* at 61. In other words, this rule prevents "a party from inducing an erroneous ruling and later seeking to profit from the legal consequences of having the ruling set aside." *Id.*; *see also United States v. Hanna*, 661 F.3d 271, 273 (6th Cir. 2011). This rule "is based on reliance interests similar to those that support the doctrines of equitable and promissory estoppel." *Harvis*, 923 F.3d at 61.

Similarly, "[j]udicial estoppel is an equitable doctrine that preserves the integrity of the courts by preventing a party from abusing the judicial process through cynical gamesmanship, achieving success on one position, then arguing the opposite to suit an exigency of the moment." *Teledyne Indus., Inc. v. Nat'l Labor Relations Bd.*, 911 F.2d 1214, 1217–18 (6th Cir. 1990). "'Where a party assumes a certain position in a legal proceeding, and succeeds in maintaining that position, he may not thereafter, simply because his interests have changed, assume a contrary position.'" *Lorillard Tobacco Co. v. Chester, Willcox & Saxbe, LLP*, 546 F.3d 752, 757 (6th Cir. 2008) (quoting *New Hampshire v. Maine*, 532 U.S. 742, 749 (2001)).

This Court's decision in *Harvis v. Roadway Express, Inc.*, is instructive. The plaintiff in that case pled a claim under 42 U.S.C. § 1981, and the district court allowed that claim to go to the jury. *See* 923 F.3d at 60. Citing an intervening decision of the U.S. Supreme Court, the plaintiff then argued on appeal that the

district court had erred in allowing his § 1981 claim to go to the jury and, thus, that the jury's rejection of that claim should not be given preclusive effect. *See id.* This Court rejected that argument on a straightforward application of the invited-error doctrine:

> Having induced the court to rely on a particular erroneous proposition of law or fact, a party in the normal case may not at a later stage of the case use the error to set aside the immediate consequences of the error. Plaintiff cannot complain that the District Court allowed a jury to consider his § 1981 claim [because] [h]e requested a jury trial and thus "invited" the error of a jury verdict in this case.

Id. at 61.

Applying *Harvis*, this Court has routinely prevented a party's challenge to an action by the district court that the party agreed to, encouraged, endorsed, or requested. *See, e.g.*, *Hanna*, 661 F.3d at 273 ("[T]he district court's decision below to sentence Hanna under § 2S1.1(a)(2) was directly in response to Hanna's urging that it take that very course. . . . [T]he doctrine of invited error therefore precludes reliance on this error as grounds for reversal."); *United States v. Certain Real Property 566 Hendrickson Blvd.*, 986 F.2d 990, 997 (6th Cir. 1993) ("Consequently, in light of claimant's affirmative act of seeking summary judgment and his failure to request a stay, we find claimant's contention, that the District Court should have stayed the federal forfeiture proceeding, to be meritless."); *see also R.H. Cochran & Assocs. v. Sheet Metal Workers Int'l Ass'n*

Union No. 33, 335 F. App'x 516, 521–22 (6th Cir. 2009) (invoking invited-error rule because "the Union suggests no reason why it should not be precluded from complaining about the district court's consideration of affidavits submitted by it").

Plaintiffs waived any right to "charge the [district] court with error," *Aparco-Centeno*, 280 F.3d at 1088, "invited" any such error, *Harvis*, 923 F.2d at 61, and are estopped from challenging the district court's framing of the case and procedure for resolving it, *Teledyne Indus.*, 911 F.2d at 1217–18. At the initial case-management conference, plaintiffs expressly "*agreed*" with the district court that the "basic simplicity" of their case was the "one[] issue" of whether defendants' products "disperse over the pet's body." (R.16, 5/1/12 Transcript, 207 (emphasis added).) Plaintiffs further "*agree[d]*" with the district court's procedure of giving defendants two weeks to produce studies, even as the district court emphasized that "then it will be up to the plaintiffs to demonstrate conclusively to me through experts what's wrong with your study, or else they're out. *I'll dismiss the claim.*" (*Id.* at 223–24 (emphases added).)

Plaintiffs' unconditional endorsement of the district court's procedure did not end there. Plaintiffs resisted Bayer's proposed alternative procedure because they did not want to "open[] up full-scale discovery." (*Id.* at 221.) Moreover, plaintiffs did not object when the district court formalized its procedure in a written order. (R.17, Order, 237.) To the contrary, when defendants objected to the order

and moved for reconsideration, plaintiffs offered a spirited defense of the procedure, which plaintiffs believed would "achiev[e] the orderly and expeditious disposition" of this case by "resol[ving] . . . a single issue." (R.24, Pls.' Resp. & Opp., 728–29.) In plaintiffs' view, "[t]he Court simply adhered to the dictates of F.R.C.P. 16 . . . while saving both sides considerable time, effort and money." (*Id.* at 727.) Plaintiffs even went so far as to refer to the district court's procedure as advancing "justice and judicial efficiency." (*Id.* at 729.)

Plaintiffs' subsequent critique of defendants' studies quoted the district court's order, reiterated their embrace of it, and contended that they were entitled to prevail under it. (R.35, Pls.' Critique, 1–2.) And even after defendants moved for summary judgment, plaintiffs did not quarrel with the district court's framing of the case, but instead sought discovery ostensibly to bolster their argument that "Defendants' Studies are unreliable, inaccurate, and incomplete." (R.46, Pls.' Rule 56(d) Mot., 2.) In fact, plaintiffs did not ask the district court to depart from the procedure that they had wholeheartedly endorsed until their reply brief in support of their Rule 56(d) motion, when it had become clear that the district court would hold them to the procedure and dismiss their claims. (R.48, Pls.' Reply, 1.)

Try as they might, Plaintiffs cannot now escape their waiver by suggesting that the district court's procedure—and their endorsement of it—somehow changed over the course of the proceedings. *See* Pls.' Br. at 15–18. In the first

place, plaintiffs' contention that the district court's May 16 order "modified" the procedure "by directing plaintiffs to refute defendants' studies with *scientific evidence*," Pls.' Br. at 15 (emphasis in original), misstates the record. During the initial case-management conference, plaintiffs *agreed* that they bore the burden to establish the unreliability of defendants' studies "through some expert." (R.16, 5/1/12 Transcript, 224.) Plaintiffs thus did *not* object in the district court to the May 16 order's characterization of the evidentiary component of their burden, much less demonstrate prejudice from the court's alleged verbal shift from requiring "expert" evidence to requiring "scientific" evidence.

Moreover, plaintiffs' suggestion that the district court "added a[] new element to the process" at the August 13, 2012 telephone conference when it characterized their case as "a false advertising case" and observed that defendants had a "good faith basis" for their translocation claims, Pls.' Br. at 17, again ignores the fact that plaintiffs *agreed* to this characterization. Plaintiffs themselves purported to plead false advertising claims in their complaints. *See, e.g.*, *Carthen* Am. Compl. ¶¶ 116(f), 128, 134. Plaintiffs further agreed at the initial case-management conference that the "basic simplicity of the case" is whether defendants' translocation claims were "false representation[s]" (R.16, 5/1/12 Transcript, 207)—in other words, whether defendants had a basis in reliable scientific studies for their translocation claims (*see id.* at 223–24). Plaintiffs thus

did not object to the district court's characterization of their claims at the August 13 telephone conference either immediately or in their motion for discovery. (R.46, Pls.' Rule 56(d) Mot., 2.) Rather, plaintiffs waited until they faced certain defeat before first taking issue with the district court's approach. (*See* R.48, Pls.' Reply, 1.)

In sum, having encouraged the district court to implement its procedure over defendants' objections, plaintiffs cannot now "seek[] to profit from the legal consequences of having the [procedure] set aside," *Harvis*, 923 F.2d at 61, or ensnare this Court or defendants in the "cynical gamesmanship" of "achieving success on one position, then arguing the opposite to suit an exigency of the moment." *Teledyne Indus.*, 911 F.2d at 1217–18. Plaintiffs may now regret the positions that they urged in support of what they hoped would be an expedient and favorable resolution of their claims. But there is no basis to allow plaintiffs to start their case anew, and their effort to shift positions now is fundamentally unfair to defendants. After all, under plaintiffs' view, they could have benefitted from any *victory* they received under the district court's procedure, but may not be burdened with any *defeat* under that procedure, even when they wholeheartedly endorsed it from the start. The doctrines of waiver, invited error, and estoppel foreclose this heads-I-win, tails-you-lose result. *See, e.g.*, *Aparco-Centeno*, 280 F.3d at 1088;

Harvis, 923 F.2d at 61; *Teledyne Indus.*, 911 F.2d at 1217–18. Plaintiffs have presented no ground for reversal.

II. THE DISTRICT COURT PROPERLY EXERCISED ITS DISCRETION IN DENYING PLAINTIFFS' MOTION FOR DISCOVERY ON IRRELEVANT MATTERS

A district court has broad discretion in ruling on a motion for discovery under Rule 56(d). *See Dairy Farmers*, 426 F.3d at 862. "A district court does not abuse its discretion in denying discovery when the discovery requested would be irrelevant to the underlying issue to be decided." *Id.*; *see also Green v. Nevers*, 196 F.3d 627, 632 (6th Cir. 1999). District courts, moreover, at all times retain authority to deny discovery that would be "overly broad" or "unduly burdensome." *Info-Hold, Inc. v. Sound Merch., Inc.*, 538 F.3d 448, 457 (6th Cir. 2008).

A party seeking discovery under Rule 56(d) must submit an "affidavit or declaration that, for specified reasons, it cannot present facts essential to justify its opposition." Fed. R. Civ. P. 56(d). The moving party also must demonstrate "its need for discovery, what material facts it hopes to uncover, and why it has not previously discovered the information." *Cacevic v. City of Hazel Park*, 226 F.3d 483, 488 (6th Cir. 2000).

Even where the moving party seeks relevant discovery on a proper declaration, this Court considers a number of factors in determining whether a district court abused its discretion in ruling on a Rule 56(d) motion, including: "(1)

when the [movants] learned of the issue that is the subject of the desired discovery; (2) whether the desired discovery would have changed the ruling below; (3) how long the discovery period had lasted; (4) whether the [movant] was dilatory in its discovery efforts; and (5) whether the [non-movant] was responsive to discovery requests." *CenTra, Inc. v. Estrin*, 538 F.3d 402, 419 (6th Cir. 2008).

The district court properly exercised its discretion in this case when it partially denied plaintiffs' motion to conduct sweeping discovery in the form of 30 pages of interrogatories addressed to each defendant, a 25-page request for production addressed to Merial, a 23-page request for production addressed to Bayer, depositions of corporate representatives of each defendant, and eight other depositions. Plaintiffs' broad-ranging requests veered into irrelevant matters far removed from the single issue that plaintiffs expressly and repeatedly agreed was dispositive, and plaintiffs failed to satisfy the requirements of Rule 56(d) in any event. The Court should affirm the judgment.

A. Plaintiffs' Proposed Discovery Was Irrelevant To The Single Issue They Agreed Was Dispositive

Plaintiffs' requested discovery was "irrelevant to the underlying issue to be decided" on summary judgment. *Dairy Farmers*, 426 F.3d at 862. The district court—with plaintiffs' agreement and encouragement, *see supra* Part I—narrowed this case to the single issue of whether plaintiffs could show, through expert evidence, that the studies defendants produced were "unreliable, inaccurate, or

incomplete." (R.17, Order, 238.) Yet nowhere in the 19 pages of their brief devoted to this issue, *see* Pls.' Br. at 24–43, do Plaintiffs explain why they needed *any* discovery in order to prove that issue "through some expert" (R.16, 5/1/12 Transcript, 224).

Nor could plaintiffs do so: The question whether the studies are unreliable, inaccurate, or incomplete turns on the *studies themselves*, not on any information in *defendants' possession*. Plaintiffs implicitly acknowledged as much through their repeated statements and conduct in the district court. Indeed, at the May 1 case-management conference, plaintiffs not only failed to request, but *affirmatively opposed*, "opening up full-scale discovery" in this case. (*Id.* at 221.) Plaintiffs, moreover, did not seek discovery when they filed their response to defendants' studies. (R.35, Pls.' Critique.) Rather, they attacked defendants' studies only through lawyer argument aimed at the methodology and conclusions of the studies themselves. (*See id.* at 2–27.) The fact that plaintiffs opted to rely exclusively on lawyer argument not only doomed their case under the burden that they had acknowledged they bore, but also belies their later claim that they needed discovery from defendants in order to refute the studies.

Even now, plaintiffs' description of their requested discovery demonstrates its irrelevance to the single issue that they agreed was dispositive. For example, plaintiffs contend that they should have been permitted discovery into the opinions

of Dr. Clark and Dr. Davis, whether defendants' translocation claims were "false, deceptive or misleading," the "dispersion of defendants' products on the hair or skin of animals by human touching or petting or the animal's own grooming," and the views of the authors of defendants' studies. Pls.' Br. at 36–38. Plaintiffs also sought discovery on such wide-ranging, disparate topics as:

- The "ingredients" and their quantities in defendants' products, the legal framework for the EPA registration of defendants' products, and statements by defendants that did not relate to translocation (*see* R.46-2, Exhibit Interrogatories, 11–26);

- Any "adverse effects of any of Defendants[']s Products on humans" and a 1998 study in German (*see* R.46-3, Exhibit Merial Request For Production; R.46-4, 12–22; R.46-4, Exhibit Bayer Request For Production, 9–20); and

- Defendants' "[e]lectronically stored information," "[d]ocument retention and destruction policies," and "[c]orporate organizational structure" (R.46-5, Exhibit 30(b)(6) Deposition Notices 6, 12).

Likewise, the declaration plaintiffs submitted from one of their attorneys, Margaret Metzinger, sought discovery regarding "marketing, . . . sales representations, electronically stored information, FDA regulatory issues and compliance, EPA regulatory issues and compliance, Defendants' respective corporate organizational structures and any communications or interaction with the NAD (National Advertising Division) of Better Business Bureau." (R.46-1, Metzinger Decl. at 3–4, ¶ 10.) It also sought "facts" regarding Dr. Davis's qualifications, the standard for determining whether levels of an active ingredient

in an animal's bloodstream were "significant," and the veracity of defendants' translocation claims. (*See id.* at 4–5, ¶¶ 11–15.) And it sought deposition testimony from Dr. Clark regarding studies that the district court *did not even consider* because they *predated* the court's cut-off date. (*See id.* at 5–6, ¶¶ 17–19.)

None of this requested discovery bore any relevance to whether defendants' studies were "unreliable, inaccurate, or incomplete." (R.17, Order, 238.) The district court's partial denial of plaintiffs' motion for discovery, therefore, was proper. *See Dairy Farmers*, 426 F.3d at 862.

B. Plaintiffs Failed To Satisfy The Requirements Of Rule 56(d)

Plaintiffs' discovery motion not only sought irrelevant material, but also failed under Rule 56(d). Indeed, each of the factors the Court has deemed relevant to its review of a denial of a Rule 56(d) motion dramatically underscores that the district court's exercise of discretion was proper.

First, plaintiffs "learned of the issue that is the subject of the desired discovery," *CenTra*, 538 F.3d at 420, no later than the district court's initial case-management conference, when the district court framed the case as a single-issue dispute with plaintiffs' unconditional endorsement (R.16, 5/1/12 Transcript, 207, 223–24). Plaintiffs, however, *opposed* "opening up full-scale discovery" at that time. (*Id.* at 221.) In fact, plaintiffs did not seek discovery until months later, only after it became apparent that the district court would hold plaintiffs to the

procedure that they had agreed to and dismiss their case for failing to discharge the burden that they had acknowledged they bore.

Second, "the desired discovery would" not "have changed the ruling below," *CenTra*, 538 F.3d at 420, because plaintiffs sought discovery only of irrelevant matters, *see supra* Part II.A.

Third, the period for plaintiffs to file their critique of defendants' studies was extensive, and the district court granted plaintiffs all of the time—and more—that they requested to complete the critique. *See CenTra*, 538 F.3d at 420; R.32, Order, 790 (noting that the district court "gave Plaintiffs 60 days to respond," which was "actually longer than the 30 days Plaintiffs' counsel originally requested").

Fourth, plaintiffs were "dilatory," delaying for months—until the district court's dismissal of their suit was imminent—before raising any request for discovery. *CenTra*, 538 F.3d at 420.

Fifth and finally, defendants were "responsive to discovery requests" and promptly produced the discovery that the district court ordered. *Id.*

For these reasons as well, there was no abuse of discretion in the district court's partial denial of plaintiffs' motion for discovery.

C. Plaintiffs Offer No Basis To Ignore The Deficiencies In Their Rule 56(d) Motion

Plaintiffs offer four arguments in an attempt to overcome the flaws in their motion for discovery, all of which fail. *First*, plaintiffs recount at length the

procedural history of the case and contend that the district court's "unconventional process" of placing this case on a "fast[] track," Pls.' Br. at 27, 43, violated the "general" rule that summary judgment should not be granted until there has been "adequate time" and opportunity for discovery, *id.* at 24; *see also id.* at 25–39. But plaintiffs ignore that this general—and undisputed—rule has no application here because, as plaintiffs conveniently omit, they *affirmatively agreed* to narrow this case to a single issue and to litigate it on a "fast track." *See supra* Part I. The cases plaintiffs invoke thus fail to support their position because *none* involved a party that had agreed to resolve a case without discovery, and several *upheld* summary judgment or denial of a motion for discovery.[7]

Plaintiffs' factual premise that the district court afforded them insufficient time and opportunity to conduct discovery, *see* Pls.' Br. at 25–27, is likewise fatally flawed. Even though plaintiffs initially *eschewed* "opening up full-scale discovery" (R.16, 5/1/12 Transcript, 221) and encouraged the district court to

[7] *See, e.g.*, *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986) (vacating reversal of summary judgment) (cited at Pls.' Br. at 24); *Elvis Presley Enters., Inc. v. Elvisly Yours, Inc.*, 936 F.2d 889, 893 (6th Cir. 1991) (upholding denial of motion for discovery) (cited at Pls.' Br. at 25); *Ball v. Union Carbide Corp.*, 385 F.3d 713, 720 (6th Cir. 2004) (upholding denial of motion for discovery) (cited at Pls.' Br. at 25); *White's Landing Fisheries, Inc. v. Buchholzer*, 29 F.3d 229, 231–32 (6th Cir. 1994) (reversing summary judgment entered prior to discovery where plaintiff had not agreed to forego discovery) (cited at Pls.' Br. at 25); *CenTra*, 538 F.3d at 418–20 (reversing denial of motion for discovery where plaintiff had not agreed to forego discovery) (cited at Pls.' Br. at 25–26); *Cacevic*, 226 F.3d at 488 (upholding denial of motion for discovery) (cited at Pls.' Br. at 26).

implement its procedure of reducing the case to "a single issue . . . as a matter of justice and judicial efficiency" (R.24, Pls.' Resp. & Opp., 728–29), the district court allowed plaintiffs to move for discovery and granted them as much time as they requested to file that motion. Thus, that the district court *denied* plaintiffs' motion for improper discovery does not mean that it deprived them of all *opportunity* to seek discovery, as plaintiffs charge. *See* Pls.' Br. at 26; *cf. also Alspaugh v. McConnell*, 643 F.3d 162, 167–68 (6th Cir. 2011) (distinguishing between failure to accord opportunity for discovery and denial of Rule 56(d) motion) (cited at Pls.' Br. at 26); *Vance v. United States*, 90 F.3d 1145, 1149 (6th Cir. 1996) (similar) (cited at Pls.' Br. at 26).

Second, plaintiffs continue to elide the question presented and suggest that their requested discovery was relevant to whether defendants' translocation claims were "false, misleading, and/or deceptive" and "the veracity" of those claims. Pls.' Br. at 41–42. But those issues were *not* before the district court at summary judgment because—with plaintiffs' agreement—the district court had reduced the case to whether defendants' studies were "unreliable, inaccurate, or incomplete." (R.17, Order, 238.)

Third, plaintiffs extend their exercise in revisionist history when they assert that although they "said relatively little about the need for discovery" at the initial case-management conference, their position was "clear" that "they should be

entitled to discovery." Pls.' Br. at 29. Yet the quotes plaintiffs provide suggest only that plaintiffs sought "testing" and "science" in the form of the studies that the district court ordered defendants to submit. *See id.* And plaintiffs make no attempt to square their purported request for discovery with their objection to "opening up full-scale discovery" (R.16, 5/1/12 Transcript, 221), or the fact that they did *not* seek discovery in support of their critique of defendants' studies and delayed requesting discovery until they were on the brink of defeat.

Finally, plaintiffs take aim at the consumer-complaint discovery the district court *granted* them, and argue that such discovery was "unlikely to be useful" because "plaintiffs could not use data regarding consumer attitudes about the effectiveness of defendants' products to refute defendants' dispersion claims." Pls.' Br. at 39–40. Plaintiffs, however, do not explain why they sought to discover consumer complaints in the first place, if that evidence was "unlikely to be useful" to them. *See id.* Moreover, plaintiffs fail to come to grips with the implications of their position: if they are correct that the consumer complaints were unhelpful, then the district court should have *denied* their request to discover them. *See, e.g.*, *Dairy Farmers*, 426 F.3d at 862. And, of course, the fact that the district court should have *denied* the consumer-complaint discovery has no bearing on whether it should have *granted* any of the other irrelevant discovery plaintiffs sought. To the

contrary, because plaintiffs failed to properly seek any relevant discovery, the district court's judgment should be affirmed.

III. THE DISTRICT COURT PROPERLY APPLIED THE SUMMARY-JUDGMENT STANDARD TO THE DISPOSITIVE ISSUE ON WHICH PLAINTIFFS ACKNOWLEDGED THEY BORE THE BURDEN OF PROOF

Summary judgment is appropriate "against a party who fails to make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party . . . bear[s] the burden of proof." *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986); *see also Martinez v. Cracker Barrel Old Country Store, Inc.*, 703 F.3d 911, 914 (6th Cir. 2013). "In such a situation, there can be no genuine issue as to any material fact" warranting trial, "since a complete failure of proof concerning an essential element of the nonmoving party's case necessarily renders all other facts immaterial." *Celotex*, 477 U.S. at 322–23.

Once the moving party has demonstrated the absence of a genuine issue of material fact, the burden shifts to the nonmoving party, who "must set forth specific facts showing that there is a genuine issue for trial." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 250 (1986); *see also Peterson v. Johnson*, 714 F.3d 905, 910 (6th Cir. 2013). "The mere existence of a scintilla of evidence in support of the [non-moving party's] position will be insufficient" to discharge this burden; "there must be evidence on which the jury could reasonably find for" the non-moving party. *Anderson*, 477 U.S. at 252; *see also Matsushita Elec. Indus. Co. v.*

Zenith Radio Corp., 475 U.S. 574, 586 (1986) (a non-moving party cannot defeat summary judgment by "simply show[ing] that there is some metaphysical doubt as to the material facts"). Thus, "[t]he pivotal question" on summary judgment "is whether the party bearing the burden of proof has presented a jury question as to each element of its case." *Hartsel v. Keys*, 87 F.3d 795, 799 (6th Cir. 1996); *see also Martinez*, 703 F.3d at 914 ("The ultimate question is whether the evidence presents a sufficient factual disagreement to require submission of a particular legal claim to the jury or whether the evidence on the claim is so one-sided that the defendant should prevail as a matter of law.").

The district court properly granted summary judgment to defendants because plaintiffs failed to adduce admissible expert or scientific evidence on the issue that they agreed would resolve their claims. The Court should affirm the judgment.

A. Plaintiffs Failed To Present Admissible Expert Or Scientific Evidence That Defendants' Studies Were Unreliable

With plaintiffs' enthusiastic encouragement, the district court narrowed the question presented to whether plaintiffs could prove, through "some expert" (R.16, 5/1/12 Transcript, 224) or "scientific evidence" (R.22, Order, 714), that defendants' studies were "unreliable, inaccurate, or incomplete" (R.17, Order, 238). Yet plaintiffs identified *no* admissible evidence to sustain their burden either in the district court or in their brief to this Court. Rather, in their critique of defendants' studies and at summary judgment, plaintiffs resorted to lawyer argument to attack

the methodology and results of defendants' studies (R.35, Pls.' Critique, 2–27)—arguments that not only were unsupported by expert or scientific evidence but also proved false as a matter of fact and science (R.41, Merial's Resp., 3–4; R.40, Bayer's Resp., 5–11).

Plaintiffs now assert that the Experimur Study and the Jones Report "demonstrat[ed] flaws in defendants' studies," and complain that the district court gave that "evidence" insufficient weight. Pls.' Br. at 48–51. This contention is doubly flawed. In the first place, the Experimur Study and the Jones Report *confirmed* defendants' translocation claims because the Experimur Study detected the active ingredients in defendants' products at all locations on the surface of the test animals' bodies within 24 hours. (R.40, Bayer's Resp., 17–19; R. 41, Merial's Resp., 7.)

Plaintiffs thus are left with straining to manufacture a dispute as to whether defendants' products "enter the animal's bloodstream," Pls.' Br. at 49; *see also id.* at 51—but as the district court correctly concluded, this is "a red herring" (R.62, Order, 2201). Indeed, there is *no* dispute that trace amounts of the active ingredients in defendants' products may enter a pet's bloodstream, as was *disclosed* to federal regulators during product registration. (R.45-14, Clark Decl. ¶¶ 18–2, 5–6.) The Experimur Study and the Jones Report likewise measured

minuscule levels of those ingredients in the test animals' bloodstreams. (R.40, Bayer's Resp., 17–19; R. 41, Merial's Resp., 7–13.)

But the fact that defendants' products may *enter* the pet's bloodstream "is irrelevant to the question whether" defendants' studies demonstrating that their products *work* through translocation are "reliable, accurate, and complete." (R.62, Order, 2202.) Indeed, plaintiffs—either through the Experimur Study and Jones Report or otherwise—never refuted the commonsense notion that the pet's skin acts as a barrier to topically-applied products entering the bloodstream. (R.40, Bayer's Resp., 17–19; R. 41, Merial's Resp., 7–13.) Moreover, "[p]laintiffs' evidence that small amounts of the product may be in the blood" does not "prove that Defendants' dispersion claims are wrong" and is immaterial because "Defendants' labeling and advertising does not make any claim regarding whether any amount of the product can get into the blood." (R.62, Order, 2202.)

In all events, even if the Experimur Study and Jones Report had suggested the existence of a genuine issue of material fact, summary judgment still would have been warranted in defendants' favor because that "expert evidence" was inadmissible. *See, e.g.*, *Sigler*, 532 F.3d at 481–90 (declining to consider evidence inadmissible under *Daubert* in reviewing summary judgment ruling); *Brown v. Raymond Corp.*, 432 F.3d 640, 647–50 (6th Cir. 2005) (similar); *Bailey v. Floyd Cnty. Bd. of Educ.*, 106 F.3d 135, 145 (6th Cir. 1997) (to defeat summary judgment,

the evidence proffered by the non-moving party "need not be in admissible *form*, but its *content* must be admissible" (emphases in original)). The Experimur Study and Jones Report are not "the product of reliable principles and methods," Fed. R. Evid. 702, because they were prepared for litigation, have not been subjected to peer review, relied on contaminated samples, and did not use a control group, *see, e.g.*, Fed. R. Evid. 702, advisory committee notes, 2000 amendments (identifying "whether the technique or theory has been subject to peer review and publication" and "the existence and maintenance of standards and controls" as relevant factors); *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 593–94 (1993); *Daubert v. Merrell Dow Pharms., Inc.*, 43 F.3d 1311, 1317 (9th Cir. 1995) (considering whether expert conducted research independently or for the purpose "of litigation"); *see also* R.40, Bayer Resp., 11–19.[8]

Thus, far from "violat[ing] the cardinal rule against weighing the non-movant's evidence against that of the movants," Pls.' Br. at 50, the district court properly concluded that inadmissible evidence that purported to create a dispute on immaterial issues could not discharge plaintiffs' burden at summary judgment. *See, e.g.*, *Sigler*, 532 F.3d at 481–90; *Brown*, 432 F.3d at 647–50. Plaintiffs' failure to

[8] Consistent with their withdrawal of the Gregg Study at summary judgment due to Mr. Gregg's acknowledged lack of "the qualifications and expertise to be considered an expert" (R.59, Pls.' Opp. To Defs.' Mot. For Summ. J., 21 n.14), Plaintiffs do not rely on the Gregg Study on appeal, *see* Pls.' Br. at 43–54.

adduce admissible evidence regarding an issue on which they agreed they bore the burden of proof required summary judgment against them. *See Celotex*, 477 U.S. at 322; (R.62, Order, 2199–2202).

B. The Progression Of The Case To Summary Judgment Did Not Change Plaintiffs' Burden Of Proof

Plaintiffs advance three arguments in an attempt to undo the district court's summary judgment based on their failure to carry the burden they had expressly acknowledged, but none is persuasive.

First, plaintiffs misstate the question presented on summary judgment as "the veracity of defendants' advertising and marketing claims" or whether defendants' translocation claims are "false, misleading, and/or deceptive." Pls.' Br. at 44, 48. Plaintiffs thus once again ignore that they *agreed* that the dispositive issue was whether defendants' *studies* (which supported those advertising claims) were "unreliable, inaccurate, or incomplete" (R.17, Order, 238), and that their case would be dismissed if they failed to carry that burden (R.16, 5/1/12 Transcript, 207, 223–24).

Second, plaintiffs overplay this sleight of hand by arguing that the summary-judgment *procedure* somehow changed the *substantive* burden they agreed to assume. *See* Pls.' Br. at 45–47. In particular, plaintiffs argue that the progression of the case to summary judgment triggered some undefined concept of "conventional litigation" and relieved them of their obligation to prove the

unreliability of defendants' studies. *See id.* at 45. Yet Rule 56 and the summary-judgment procedure, as a matter of "convention" and law, have *no* effect on the parties' substantive burdens, but instead merely provide a procedure for assessing whether the nonmoving party can produce sufficient evidence to sustain its burden. *See, e.g.*, *Celotex*, 477 U.S. at 322; *McDonnell Douglas v. Green*, 411 U.S. 792 (1973). In fact, Rule 56 may "not abridge, enlarge, or modify any substantive right," 28 U.S.C. § 2072—so the progression of the case to summary judgment could not undermine, much less undo, plaintiffs' express agreement to the district court's framing of the case and procedure for resolving it, *see supra* Part I.

For this reason, the district court not only was not obliged to, but could not, consider plaintiffs' challenges to other "claim[s] defendants made concerning their products' properties." Pls.' Br. at 46. By their agreement, plaintiffs constructively amended their complaint to limit their case to the sole claim identified by the district court, and defendants were entitled to rely on those representations by plaintiffs as notice of the narrowed scope of their case. *See, e.g.*, *Static Control Components, Inc. v. Lexmark Int'l, Inc.*, 697 F.3d 387, 398–99 (6th Cir. 2012) (recognizing that a plaintiff's post-filing actions may constructively amend a complaint); *see also* 6A Wright & Miller Fed. Prac. & Proc. § 1493 (2010 ed.) (similar). Thus, the district court was free to encourage the parties to resolve the case, as it did at the August 13, 2012 conference, *see* Pls.' Br. at 47, but it could

not resurrect abandoned claims, nor could it enter a judgment on them in plaintiffs' favor merely because the case had progressed to the summary-judgment stage in the form encouraged—and agreed to—by plaintiffs, or because plaintiffs faced defeat under the burden they had embraced, *see id.*; *see also* 28 U.S.C. § 2072.

Plaintiffs' current theory that Rule 56 revived claims they previously had abandoned is also belied by the position plaintiffs asserted in their Rule 56(d) motion. There, plaintiffs argued that they needed discovery to "bolster their claims . . . that Defendants' Studies are unreliable, inaccurate, and incomplete," not to establish any of the claims that they previously had abandoned by their actions. (R.46, Pls.' Rule 56(d) Mot., 2.) Thus, contrary to plaintiffs' position on appeal that the summary-judgment process relieved them of their waiver or constructive amendment, and resurrected claims that they had abandoned, plaintiffs clearly understood at the time of summary judgment that the single relevant issue continued to be whether plaintiffs could prove that defendants' studies were unreliable. (*See id.*)

Finally, plaintiffs challenge the district court's use of the consumer-complaint evidence, complaining that the district court "exalt[ed] the *number* of consumer complaints over all other means," "fixat[ed] on the number of consumer complaints," and treated "the number of past consumer complaints as *the determinative factor*" at summary judgment. Pls.' Br. at 52–53 (emphases in

original). Plaintiffs grossly mischaracterize the record: in accordance with plaintiffs' agreement at the outset of the case, the district court treated plaintiffs' failure to refute defendants' studies as the determinative fact at summary judgment. (R.62, Order, 2199–2202.)

The district court permitted discovery of, and considered, consumer complaints because it believed that such complaints were the only evidence *in defendants' possession* that might undermine the reliability of their studies. (*See id.* at 2200–01 ("[I]f the 'facts on the ground' were that a significant percentage of customers reported that their pets had bites on their bodies in places other than where Defendants' products were applied, Defendants would no longer be reasonable in relying upon the studies validating their claims of topical dispersion.").) And even if the district court erred in relying on the consumer complaints, that error would not cure plaintiffs' failure to adduce admissible evidence to sustain their burden of proof and, thus, would not support reversal of the judgment. *See, e.g.*, *Celotex*, 477 U.S. at 322.

* * * *

In the end, the district court's inversion of the burdens of proof and production, which required defendants to first produce the studies supporting their marketing representations about their products and thus *advantaged* plaintiffs by assuming that they had stated a *prima facie* case of falsity, achieved the court's

intended efficiencies of process. Requiring defendants to come forward with the studies that justified their representations focused plaintiffs' proofs on the nub of their claims—were those representations supported? When plaintiffs failed to produce admissible evidence relevant to that question, the district court properly entered summary judgment in defendants' favor.

IV. PLAINTIFFS WAIVED ANY *DAUBERT* CHALLENGE TO DEFENDANTS' EVIDENCE, AND SUCH A CHALLENGE WOULD BE MERITLESS

"Generally, an argument not raised before the district court is waived on appeal[.]" *City of Columbus, Ohio v. Hotels.com, L.P.*, 693 F.3d 642, 652 (6th Cir. 2012) (internal quotation marks omitted); *see also United States v. Sandridge*, 385 F.3d 1032, 1035 (6th Cir. 2004) ("Issues adverted to in a perfunctory manner, unaccompanied by some effort at developed argumentation, are deemed waived."); *White*, 899 F.2d at 559.

For the first time on appeal, plaintiffs interpose a *Daubert* challenge to the studies and declarations that defendants submitted in response to the district court's May 2, 2012 order. *See* Pls.' Br. 54–56. However, even as they wholeheartedly endorsed the district court's procedure calling for such submissions, plaintiffs never suggested to the district court that *Daubert* governed those submissions, never moved to exclude them under *Daubert*, and never asked the district court to hold a *Daubert* hearing. In fact, plaintiffs' only mention of *Daubert* in the district

court came in their opposition to defendants' motion for summary judgment, when they argued that their *own* submission satisfied *Daubert*. (R.59, Pls.' Opp., 22–29.) Plaintiffs thus waived any *Daubert* challenge to defendants' studies and declarations. *See, e.g.*, *Hotels.com*, 693 F.3d at 652.

In any event, plaintiffs' newly minted *Daubert* challenge is meritless. The issue as framed by the district court—with plaintiffs' agreement—was whether defendants' studies reliably supported their translocation claims, *not* whether those studies were admissible in court to prove some ultimate fact. (*See* R.16, 5/1/12 Transcript, 223–24; R.17, Order, 238.) Thus, there was no basis to apply *Daubert* to defendants' studies, as plaintiffs implicitly acknowledged when they failed to invoke *Daubert* in the district court. *See, e.g.*, *Daubert*, 509 U.S. at 582 (addressing "the standard for admitting expert scientific testimony in a federal trial"); *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 152 (1999) (similar) (cited at Pls.' Br. at 55); *Gen. Elec. Co. v. Joiner*, 522 U.S. 136 (1997) (similar) (cited at Pls.' Br. at 55).

V. THE DISTRICT COURT WAS UNDER NO OBLIGATION TO ADDRESS CLAIMS THAT PLAINTIFFS HAD VOLUNTARILY ABANDONED

Finally, in a last-ditch effort to save their case, plaintiffs argue that the district court erred in failing to address issues and claims beyond the single issue that plaintiffs expressly agreed would be dispositive. *See* Pls.' Br. at 17–18, 56–58.

Of course, the district court had no basis—much less obligation—to address issues and claims that plaintiffs voluntarily abandoned in favor of embracing the single-issue approach to the case. *See supra* Part I; *Aparco-Centeno*, 280 F.3d at 1088; *Harvis*, 923 F.2d at 60–61; *Teledyne Indus.*, 911 F.2d at 1217–18. And the district court's passing mention of any abandoned issues and claims at the August 13 conference, *see* Pls.' Br. at 17–18, did not revive them, as plaintiffs acknowledged by continuing thereafter to treat the case as a single-issue dispute regarding whether "Defendants' Studies are unreliable, inaccurate, and incomplete." (R.46, Pls.' Rule 56(d) Mot., 2.) Again, by their actions in the district court, plaintiffs constructively amended their complaint and put defendants on notice that they were limiting their case to the claim identified by Judge Polster as the "one-issue case." For plaintiffs to try now to resurrect any other claim runs them headlong into the doctrines of invited error, waiver, and estoppel that control the correct outcome of this appeal.

CONCLUSION

This Court should affirm the judgment of the district court.

Dated: October 9, 2013

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE WITH RULE 32(a)

CERTIFICATE OF COMPLIANCE WITH TYPE-VOLUME LIMITATION, TYPEFACE REQUIREMENTS, AND TYPE STYLE REQUIREMENTS

1. This brief complies with type-volume limitation of Fed. R. App. P. 32(a)(7)(B) because this brief contains 13,576 words, excluding the parts of the brief exempted by Fed. R. App. P. 32(a)(7)(B)(iii).

2. This brief complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type style requirements of Fed. R. App. P. 32(a)(6) because this brief has been prepared in a proportionally spaced typeface using Microsoft Office Word 2007 in Font Size 14 Times New Roman.

DATED: October 9, 2013

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CERTIFICATE OF SERVICE

I hereby certify that on October 9, 2013, I electronically filed the foregoing under seal with the Clerk of Court using the CM/ECF system. I also caused the foregoing to be served upon the following counsel of record via email and UPS:

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APPELLEES' DESIGNATION OF RELEVANT DISTRICT COURT DOCUMENTS

Appellees Merial Limited, Merial LLC, Merial, Inc., and Bayer HealthCare, LLC, pursuant to 6th Cir. R. 28(c) and 30(b), hereby designate the following filings in the district court's electronic record:

Record Entry	**Description**	**Page ID#**
16	May 1, 2012 Transcript Of Proceedings	176–236
17	May 2, 2012 Order	237–239
19	Defendants' Motion For Reconsideration And For Extension Of Time	243–258
20	Defendant Bayer HealthCare LLC's Submission Pursuant To May 1, 2012 Case Management Conference	259–269
20-1 to 20-8	Exhibits A-H To Defendant Bayer HealthCare LLC's Submission Pursuant To May 1, 2012 Case Management Conference	270–353
21	Objections And Responses of Defendants Merial Limited, Merial LLC, And Merial, Inc.	354–357
21-1 to 21-3	Exhibits A-C To Objections And Responses of Defendants Merial Limited, Merial LLC, And Merial, Inc.	358–713
22	May 16, 2012 Order	714
24	Plaintiffs' Response And Opposition To Defendants' Motion For Reconsideration And Extension Of Time	718–736
27	June 8, 2012 Order	746
29	Plaintiffs' Motion For Extension Of Time	749–753
32	Order	790–91
35	Plaintiffs' Critique And Refutation Of Defendants' Study Submissions And Plaintiffs' Submission Of Their Translocation Studies	Filed under seal
35-1 to 35-7	Exhibits 1-7 to Plaintiffs' Critique And Refutation Of Defendants' Study Submissions And Plaintiffs' Submission Of Their Translocation Studies	Filed under seal

Record Entry	Description	Page ID#
40	Defendant Bayer HealthCare LLC's Response To Plaintiffs' Critique And Refutation Of Defendants' Study Submissions And Plaintiffs' Submission Of Their Translocation Studies	Filed under seal
40-1 to 40-8	Exhibits A-H to Defendant Bayer HealthCare LLC's Response To Plaintiffs' Critique And Refutation Of Defendants' Study Submissions And Plaintiffs' Submission Of Their Translocation Studies	Filed under seal
41	Merial's Response To Plaintiffs' Critique And Refutation Of Defendants' Study Submissions And Plaintiffs' Submission Of Their Translocation Studies	Filed under seal
43	September 14, 2012 Order	1119
44	September 4, 2012 Transcript Of Proceedings	1120–1131
45	Defendants' Memorandum In Support Of Their Motion For Summary Judgment	Filed under seal
45-2	August 13, 2012 Transcript Of Telephone Conference	Field under seal
45-4	Supplemental Declaration of Wendell L. Davis, D.V.M., Ex. D To Defendants' Motion For Summary Judgment	Filed under seal
45-14	Declaration Of Jeffrey N. Clerk, DVM, Ph.D., Ex. M To Defendants' Motion For Summary Judgment	Filed under seal
46	Plaintiffs' Fed. R. Civ. P. 56(d) Motion For Discovery And Memorandum In Support	Filed under seal
46-1	Declaration Of Margaret Metzinger, Ex. 1 To Motion For Discovery	Filed under seal
46-2	Plaintiffs' First Set Of Interrogatories To Defendants Bayer HealthCare, LLC And Merial Limited, Ex. 2 To Motion For Discovery	Filed under seal
46-3	Plaintiffs' First Request For Production Of Documents Propounded To Defendant Merial Limited, Ex. 3 To Motion For Discovery	Filed under seal
46-4	Plaintiffs' First Request For Production Of Documents Propounded To Defendant Bayer HealthCare, LLC, Ex. 4 To Motion For Discovery	Filed under seal
46-5	Notices Of Rule 30(b)(6) Depositions, Ex. 5 To Motion For Discovery	Filed under seal

Record Entry	Description	Page ID#
46-6	Notices Of Expert Depositions, Ex. 6 To Motion For Discovery	Filed under seal
46-7	Subpoenas To Testify At Depositions, Ex. 7 to Motion For Discovery	Filed under seal
47	Defendants' Joint Opposition To Plaintiffs' Fed. R. Civ. P. 56(d) Motion For Discovery	Filed under seal
48	Plaintiffs' Reply In Support Of Fed. R. Civ. P. 56(d) Motion For Discovery	Filed under seal
49	November 7, 2012 Order	1888–1889
55	January 7, 2013 Stipulated Protective Order	1927-1939
59	Plaintiffs' Opposition To Defendants' Motion For Summary Judgment	Filed under seal
59-1	August 12, 2012 Updated Jones Report, Ex. 1 To Plaintiffs' Opposition To Defendants' Motion For Summary Judgment	Filed under seal
59-3	October 22, 2012 Experimur Final Report, Ex. 3 To Plaintiffs' Opposition To Defendants' Motion For Summary Judgment	Filed under seal
59-4	Memorandum	Filed under seal
60	Defendants' Reply In Support Of Their Motion For Summary Judgment	Filed under seal
62	Memorandum Of Opinion And Order	2199–2202
63	Judgment Entry	2203
64	Notice Of Appeal	2204