2018-1614, -2044

In The
United States Court of Appeals
For The Federal Circuit

SYNGENTA CROP PROTECTION, LLC,

***Plaintiff – Appellant*,**

v.

WILLOWOOD, LLC, WILLOWOOD USA, LLC, WILLOWOOD AZOXYSTROBIN, LLC, WILLOWOOD LIMITED,

Defendants – Cross-Appellants.

APPEALS FROM THE UNITED STATES DISTRICT COURT FOR THE MIDDLE DISTRICT OF NORTH CAROLINA IN NO. 1:15-cv-00274-CCE-JEP, JUDGE CATHERINE C. EAGLES.

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Rev. 10/17

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

Syngenta Crop Protection, LLC **v.** Willowood, LLC, et al.

Case No. 18-1614, -2044

CERTIFICATE OF INTEREST

Counsel for the:
☐ (petitioner) ☐ (appellant) ☐ (respondent) ■ (appellee) ☐ (amicus) ☐ (name of party)

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1. Full Name of Party Represented by me	2. Name of Real Party in interest (Please only include any real party in interest NOT identified in Question 3) represented by me is:	3. Parent corporations and publicly held companies that own 10% or more of stock in the party
Willowood, LLC	None	Willowood USA Holdings, Inc.
Willowood USA, LLC	None	Lariat Partners LP
Willowood Azoxystrobin, LLC	None	Dream Acquisition, LLC
Willowood Limited	None	

4. The names of all law firms and the partners or associates that appeared for the party or amicus now represented by me in the trial court or agency or are expected to appear in this court **(and who have not or will not enter an appearance in this case)** are:

None

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5. The title and number of any case known to counsel to be pending in this or any other court or agency that will directly affect or be directly affected by this court's decision in the pending appeal. *See* Fed. Cir. R. 47. 4(a)(5) and 47.5(b). (The parties should attach continuation pages as necessary).

None

6/8/2018
Date

/s/Steven E. Tiller
Signature of counsel

Please Note: All questions must be answered

Steven E. Tiller
Printed name of counsel

cc: Counsel of Record

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STATEMENT OF RELATED CASES

There is no other prior or currently pending civil action involving these same patents or copyrights at issue in this case. No other appeal from this same civil action was previously before this or any other appellate court. Counsel for the Appellees/Cross-Appellants know of no other U.S. court or agency proceeding that may directly affect, or be directly affected by, this Court's decision in this appeal.

INTRODUCTION

This brief is respectfully filed by Appellees/Cross-Appellants, Willowood LLC ("WW-LLC"), Willowood USA, LLC ("WW-USA"), and Willowood Limited ("WW-Ltd") (collectively, "Willowood" or "Appellees"). This appeal and cross-appeal arise from claims for patent and copyright infringement brought by the Appellant, Syngenta Crop Protection, LLC ("Syngenta"), in the United States District Court for the Middle District of North Carolina (Judge Catherine Eagles presiding) against Willowood with respect to a fungicide known as azoxystrobin that is applied to crops such as corn, wheat, and barley to prevent and treat certain fungal diseases. Syngenta contends that in importing and selling generic brands of azoxystrobin products in the United States, Willowood infringed four Syngenta patents, as well as the copyrights associated with Syngenta's labels for its azoxystrobin products. Two of the patents – US Patent Nos. 5,602,076 ("the '076 Patent") and 5,633,256 ("the '256 Patent") (collectively, the "Compound Patents") – include claims related to the azoxystrobin compound itself. The two additional patents at issue – US Patent Nos. 5,847,138 ("the '138 Patent") and 8,124,761 ("the '761 Patent") (collectively, the "Process Patents") – include claims for processes to manufacture azoxystrobin. The Compound Patents expired in February 2014 while the '138 Patent expired in December 2015. The '761 Patent remains in effect.

With respect to the Compound Patents, WW-USA imported a five kilogram sample of azoxystrobin into the United States for testing in 2013, approximately eight months prior to their expiration. Appx6720 at 111:25; Appx6721 at 112:3. Appellees did not, however, import any azoxystrobin into, or sell any product containing azoxystrobin in, the United States until after expiration of the Compound Patents. Appx6804 at 64:11-16. At trial, Willowood conceded that its importation of the five kg sample infringed the Compound Patents. The jury, however, rejected Syngenta's claim that it incurred $75.6 Million in damages, instead awarding Syngenta $75,600.

With respect to the '138 Patent, the district court held as a matter of law that Willowood could not be held liable under 35 U.S.C. § 271(g) absent a finding by the jury that the azoxystrobin imported by Willowood USA into the United States was made by a single entity or, if more than one entity was involved in its manufacture, that those entities were under the common control and direction of a single entity. Appx0014. The jury found that neither scenario occurred, and therefore, judgment was entered in favor of Willowood. Appx0001-0004. The district court's holding concerning application of the so-called "single entity" rule to 35 U.S.C. § 271(g) was correct and the jury's verdict was supported by more than sufficient evidence.

The jury further found that the '761 Patent was infringed, but again rejected Syngenta's claim for $75.6 million in damages, instead awarding Syngenta

$900,000. *Id*. The jury also found that WW-Ltd, a Hong Kong entity, did not import, sell, or offer to sell any azoxystrobin product in the United States, and therefore, the district court entered judgment in its favor. *Id*. This finding too was supported by sufficient evidence.

Finally, Syngenta also contended that Willowood infringed certain copyright interests it allegedly held in the labels that must accompany fungicide products through the stream of commerce. While Syngenta says that these labels "creatively tell Syngenta's story" to farmers about azoyxstrobin, the labels are in fact instruction manuals that convey factual information concerning the hazards, permitted uses, and instructions for how to use the chemical in the field. Indeed, much of the label contains language required or authored by the United States Environmental Protection Agency ("EPA").

The statute that regulates the marketing and sale of pesticide products in the United States (the Federal Insecticide, Fungicide and Rodenticide Act, or "FIFRA"),[1] however, expressly authorizes generic labels to contain language that is "identical or substantially similar" to that of previously approved labels, to facilitate generic competition and to ensure environmental protection and safety. Consequently, the district court properly held that Syngenta's copyright claim could not stand. Appx0033-0034.

[1] 7 U.S.C. §§ 136, *et seq*.

JURISDICTIONAL STATEMENT

The district court had jurisdiction over this action under 28 U.S.C. §§ 1331 and 1338(a), as an action for copyright infringement under 17 U.S.C. §§ 101 *et seq*. and patent infringement under 35 U.S.C. §§ 1 *et seq*. Appx270. This Court has jurisdiction of the appeal under 28 U.S.C. § 1295(a)(1). The appeal and cross-appeal arise from a final judgment issued by the district court on November 28, 2017, and its order denying Syngenta's motions for judgment on January 30, 2018. Appx0001-0004; Appx0089-0091. Syngenta timely filed its notice of appeal on February 5, 2018 and Willowood timely filed its notice of cross-appeal on February 19, 2018.

STATEMENT OF THE ISSUES

1. Whether the district court properly dismissed Syngenta's copyright claims since FIFRA expressly allows Willowood's pesticide labels to be "identical or substantially similar" to Syngenta's labels.

2. Whether the district court properly interpreted 35 U.S.C. § 271(g) to require that each step of the allegedly infringing process be practiced by a single entity, of, if multiple entities are involved, that they be directed or controlled by a single entity, in order for Willowood to be held liable.

3. Whether the district court properly entered judgment in favor of Willowood after the jury found that the azoxystrobin it imported into, and sold in, the United States was not made by a single entity nor did a single entity direct or control the multiple entities that carried out the patented steps.

4. Whether the district court properly entered judgement in favor of WW-Ltd., a Hong Kong entity, after the jury found that WW-Ltd did not import or sell any azoxystrobin into or in the United States.

5. Whether the district court erred in denying, in part, Willowood's motion to exclude Syngenta's damages expert as his opinion was based primarily on unreliable and inaccurate data.

STATEMENT OF THE CASE

With few exceptions, Willowood generally agrees with the accuracy of the facts as stated in Syngenta's Statement of the Case included in its brief. To the extent Willowood believes that Syngenta's inferences from the facts are inaccurate, or that additional facts are relevant, Willowood will address those matters in the course of its arguments below. Most particularly, Willowood disagrees with Syngenta's recitation of the role of WW-Ltd in connection with the accused sales and importation of azoxystrobin in the United States. Br. at 7-9. WW-Ltd also disputes Syngenta's assertion that WW-Ltd's only evidence admitted at trial that it did not import any azoxystrobin into the United States was the fact its shipments to WW-USA were "f.o.b. China." Br. at 11. Further, Syngenta's recitation of the evidence concerning the "single entity" rule with respect to the '138 Patent is incomplete. These facts and inferences will be addressed in detail below.

With respect to Willowood's cross-appeal, the following additional facts are pertinent. In the proceedings below, Syngenta originally intended to rely on the analysis of its damages expert, Dr. Benjamin Wilner, claiming that Syngenta incurred nearly $300 million in damages as a result of Willowood's alleged infringement. In his report, Dr. Wilner purported to show how Syngenta incurred over $75 million in damages from Willowood's alleged infringement of the Compound Patents, over $135 million in damages from Willowood's alleged infringement of the '138 Patent and copyrights, and over $270 million from Willowood's alleged infringement of the '761 Patent.[2] Appx4085-4156. Willowood moved to exclude the entirety of Dr. Wilner's opinions under *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), asserting, among other things, that his opinions were based on unreliable and inaccurate data. Appx3842-4078. The district court granted Willowood's motion as to Dr. Wilner's opinions regarding the '761 and '138 Patents, holding that "Dr. Wilner [had] not provided an adequate basis for use of his key benchmark…."[3] Appx9809-9810. The district court, however,

[2] With interest, these alleged damages totaled over $85 million, $150 million, and nearly $300 million, respectively.

[3] Syngenta's copyright claim was dismissed before Judge Eagles' *Daubert* ruling, so the district court did not specifically rule on the admissibility of Dr. Wilner's opinion as to that claim. Dr. Wilner's opinion as to damages associated with the copyright claim, however, was based on the exact same analysis he prepared regarding the '138 Patent. Appx4128-4129. Accordingly, Willowood assumes that this opinion would have been excluded for the same reasons that warranted exclusion of his opinion as to the '138 Patent.

further held that Dr. Wilner's opinions as to damages for infringement of the Compound Patents "[were] based on sufficient facts and data [and were] applied using a reasonable method in a justifiable manner." *Id*. The district court also allowed Dr. Wilner to testify that lost profits for infringement of the Process Patents were "at least as great as the [damages] for infringement of the [C]ompound [P]atents." *Id*. Willowood respectfully requests this Court to rule that Dr. Wilner's opinion admitted at trial should have been excluded under *Daubert*, and that Syngenta be excluded from offering any other expert testimony regarding its claimed damages.[4]

SUMMARY OF THE ARGUMENT

The district court correctly dismissed Syngenta's copyright claims as FIFRA permits applicants of generic pesticides (so-called "me-too applicants") to submit for EPA approval labels that are "identical or substantially similar" to those submitted and relied on by the original registrant. As approval of these labels is a prerequisite for the sale and use of these generic pesticides, any copyright claim is entirely precluded by FIFRA as a me-too applicant could not submit an identical, or even a substantially similar, label without copying that label.

[4] In the event that the Court grants Willowood's appeal of the district court's denial of its *Daubert* motion, Willowood does not request that this case be remanded solely for a new trial on damages. Rather, Willowood files this appeal merely in the event that the Court remands this case for a new trial for another, independent reason.

The district court also correctly held that liability under 35 U.S.C. § 271(g) must be premised on a finding that a single entity performed each step of the patented process, or, if multiple entities practiced different steps, such entities were under the direction or control of a single entity. It is well settled that this requirement, often called the "single entity rule," applies to both direct and indirect infringement claims under §§ 271(a) & (b). If the single entity rule is not applied to § 271(g) claims, as Syngenta contends, process patent owners would have greater rights against foreign infringers than they do against domestic infringers. Such a result would be in clear contravention of the legislative intent of § 271(g) and the presumption against interpreting U.S. statutes to provide unintended extraterritorial effect.

The district court was further correct in denying Syngenta's JMOL motion asserting that sufficient evidence did not exist to support the jury's finding that the azoxystrobin imported into the United States by WW-USA was not manufactured by a single entity or under the direction or control of a single entity. Substantial evidence was admitted into evidence at trial to support the jury's finding in this regard. In particular, the jury heard evidence from the president of the company that manufactured the azoxystrobin at issue that such azoxystrobin was manufactured by multiple companies pursuant to arms-length arrangements in place for several years before Willowood began its importation and that each of these companies was incapable of performing the manufacturing steps performed by the other. Moreover,

evidence was admitted that neither Willowood, nor any other entity, controlled, directed, or even instructed the other entities on how to conduct their individual processes.

The district court was also correct in denying Syngenta's JMOL motion seeking to impose liability on WW-Ltd notwithstanding the jury's verdict to the contrary. Substantial evidence was admitted at trial on which a reasonable jury could rely to rule in favor of WW-Ltd. In particular, the jury heard evidence that WW-Ltd merely arranges for delivery of azoxystrobin to a port in China or Hong Kong and that WW-USA then arranges and pays for shipment to the United States, arranges for the product to clear US customs, formulates the azoxystrobin into final products, and then sell such products throughout the United States. This evidence, in combination with WW-Ltd's purchase order with WW-USA indicating that the sale of azoxystrobin is made "f.o.b. Hong Kong," provides ample support for the jury's verdict in favor of WW-Ltd.

Finally, Willowood respectfully requests that this Court overturn the district court's denial of certain aspects of its *Daubert* motion regarding Syngenta's damages expert, Dr. Wilner. As set forth in Willowood's motion to exclude the entirety of Dr. Wilner's report, Dr. Wilner's damages opinions were based almost exclusively on inaccurate and unreliable budgets prepared by Syngenta. Dr. Wilner

also made no effort to investigate the reliability of these prognostications. Accordingly, Dr. Wilner's opinions should have been excluded.

STANDARD OF REVIEW

Willowood does not dispute Syngenta's summary of the standard of review except as follows. Syngenta's appeal of the issues related to 35 U.S.C. § 271(g) and WW-Ltd's liability are based, in part, on assertions that the jury's factual findings were "not supported by substantial evidence." Br. at 49 and 62. On appeal from a motion for judgment as a matter of law (JMOL), a court must view all evidence in the light most favorable to the nonmovant and draw all reasonable inferences in the nonmovant's favor "without weighing the evidence or assessing the witness' credibility." *Dennis v. Columbia Colleton Med. Ctr., Inc*., 290 F.3d 639, 645 (4th Cir. 2002); *Biers v. Cline*, 2018 WL 798646, at *2 (4th Cir. Feb. 2018) ("A court may grant judgment as a matter of law only if, viewing the evidence in a light most favorable to the non-moving party and drawing every legitimate inference in that party's favor, the only conclusion a reasonable jury could have reached is one in favor of the moving party."). "The question is whether a reasonable jury, viewing the evidence in the light most favorable [to the nonmovant], could have properly reached the conclusion reached by the jury." *Benesh v. Amphenol Corp.*, 52 F.3d 499, 502 (4th Cir. 1995). Reversal is appropriate only if a reasonable jury could not find in favor of the nonmovant. "[I]f reasonable minds could differ, [the appellate

court] must affirm." *Dennis*, 290 F.3d at 645 (*citing Sales v. Grant*, 158 F.3d 768, 775 (4th Cir. 1998)). As shown below, the jury's findings on these issues were supported by significant evidence, and thus, the district court's rulings on these issues were correct.

ARGUMENT

I. The District Court Correctly Dismissed Syngenta's Copyright Claims Because They Are Precluded by FIFRA as a Matter of Law.

The district court correctly held that FIFRA precludes copyright protection for pesticide labels as against the labels of me-too registrants because "FIFRA contemplates that a 'me-too' applicant will copy from the original pesticide label…." Appx033-034. In so holding, the district court properly construed the plain language of 7 U.S.C. § 136a(c)(3)(B)(i)(I), rejected the contrary holding of *FMC Corp. v. Control Solutions, Inc.*, 369 F. Supp. 2d 539 (E.D. Pa. 2005), and drew support from *SmithKline Beecham Consumer Healthcare, LP v. Watson Pharm., Inc*., 211 F.3d 21 (2d Cir. 2009).

A. Background to FIFRA

FIFRA prohibits the sale and distribution of pesticides, including fungicides like azoxystrobin, not registered with EPA. 7 U.S.C. § 136a. To approve an application for registration, the EPA must find, among other things, that the pesticide's labeling complies with FIFRA and that, "when used in accordance with widespread and commonly recognized practices, [the pesticide] will not cause

unreasonable adverse effects on the environment." *Id*. at § 136a(c)(5). Thus, the EPA must review substantial scientific data and information included on the proposed labels for each pesticide product. 40 C.F.R. §§ 156 and 158. Each applicant must either submit its own scientific data or cite to relevant data previously submitted to the EPA, in which case it may have to pay compensation to the original data submitter for reliance on the data. *Id.* at § 152.50(f); *see also* 7 U.S.C. § 136a(c)(1)(F)(iii).

The applicant also must submit a proposed product label to the EPA for approval. 40 C.F.R. § 152.50(e). The approved label must accompany the pesticide container through the stream of commerce (*see* 7 U.S.C. § 136(p)), and is integral to registration. It is the primary means by which the EPA establishes and enforces the terms of registration and regulates the pesticide's use. While typically referred to as a "label," it is, in reality, an instruction manual delineating the lawful conditions for using, storing, and disposing of the pesticide product, thus ensuring it will not cause unreasonable adverse environmental impacts. *Id.* at § 136(q)(1)(F). It is a violation of FIFRA to use a registered pesticide in a manner inconsistent with the approved labeling. *Id.* at § 136j(a)(2)(G). FIFRA's substantive and labeling standards apply to both new pesticides and generic versions of previously registered pesticides (known as "me-too" registrations).

EPA regulations prescribe many specific statements that must be included on a label concerning the pesticide's hazards, and require other content such as an ingredient statement, precautionary remarks, and directions for use. *See* 40 C.F.R. § 156.10 (cross-referencing other provisions). For many aspects of the label, the EPA provides recommended language in various publications, both in its Label Review Manual and other publications. *See* Appx02974 n.2 and n.3; Appx03008-03116; Appx00770-00834. The directions for use must be "stated in terms which can be easily read and understood by the average person likely to use or…supervise" the pesticide's use. 40 C.F.R. § 156.10(i)(l)(i).

B. FIFRA Plainly Authorizes Copying of Pesticide Labels.

FIFRA's primary goals include encouragement of competition, reduction of barriers to entry for generic products, and streamlining of the EPA review process for me-too applications. *Thomas v. Union Carbide Agric. Prods. Co.*, 473 U.S. 568, 571 (1985); *Ruckelshaus v. Monsanto Co.*, 467 U.S. 986, 1015 (1984). Hence, FIFRA requires expeditious approval of generic products:

> The Administrator shall, as expeditiously as possible, review and act on any application…that…[1] would be ***identical or substantially similar*** in composition ***and labeling*** to a currently registered pesticide…or…[2] would differ in composition and labeling from such currently registered pesticide only in ways that would not significantly increase the risk of unreasonable adverse effect on the environment.

7 U.S.C. § 136a(c)(3)(B)(i)(I) (emphasis added).

The first clause of this provision explicitly permits a generic label to be "identical or substantially similar" to the original label. This provision was enacted in 1988, well after Congress' overhaul of the Copyright Act in 1976. Pub. L. No. 100-532 (Oct. 25, 1988). By specifically authorizing me-too applicants to submit identical labels in order to expedite generic registration, Congress could not also have intended to subject such labels to copyright infringement claims. Such a result would vitiate the language and pro-competitive purposes of § 136a(c)(3)(B)(i)(I). Therefore, contrary to Syngenta's contention (Br. at 31), FIFRA precludes copyright protection for pesticide labels.[5]

Syngenta argues that Congress effectively ratified a district court's contrary holding in *FMC Corp. v. Control Solutions, Inc.*, 369 F. Supp. 2d 539 (E.D. Pa. 2005) by not explicitly amending the statute to reverse *FMC*. Br. at 33-34. The Supreme Court, however, has repeatedly cautioned against exactly this reasoning, because it is "impossible to assert with any degree of assurance that congressional failure to act represents affirmative congressional approval of [a courts'] statutory interpretation." *Cent. Bank, N.A. v. First Interstate Bank, N.A.*, 511 U.S. 164, 186

[5] For the same reason, *Pom Wonderful LLC v. Coca-Cola Co*., 134 S. Ct. 2228 (2014), relied on by *amicus* New York Intellectual Property Law Association ("NYIPLA"), is inapplicable. Unlike here, the two statutes in *Pom Wonderful* had *complementary* purposes, and, unlike FIFRA, the statutory text did not suggest an intent to limit the other statute's applicability. *Id*. at 2236-39.

(1984) (*quoting Patterson v. McLean Credit Union*, 491 U.S. 164, 175, n. 1 (1989)). Even when Congress has specifically considered but failed to enact corrective legislation, such inaction "lacks persuasive significance because several equally tenable inferences may be drawn from such inaction, including the inference that the existing legislation already incorporated the offered change." *Pension Benefit Guaranty Corp. v. LTV Corp*., 496 U.S. 633, 650 (1990).

Kimble v. Marvel Entm't, LLC, 135 S. Ct. 2401 (2015), relied on by Syngenta, is inapposite. There, the Supreme Court refused to stray from bedrock principles of *stare decisis*, partly because Congress had not acted in more than fifty years to overturn that Court's prior decision. *Id*. at 2409-10. Principles of *stare decisis* are not at issue here. *Kimble* says nothing about whether Congress' inaction effectively ratifies a lone district court decision like *FMC*, and this Court would "walk on quicksand" to "try to find in the absence of corrective legislation a controlling legal principle." *Helvering v. Hallock*, 309 U.S. 106, 121 (1940).

Syngenta further asserts that "[w]here Congress sought to modify existing intellectual property law rights through FIFRA, it did so directly and explicitly[,]" citing 1978 amendments that added data compensation and exclusive use provisions to protect original registrants' property interests in scientific data they generate to support pesticide registrations. Br. at 32. But again, FIFRA's explicit authorization for me-too applicants to copy prior labels in order to facilitate competition provides

sufficient evidence of Congress' intent. *C.f., SmithKline*, at 28 (Hatch-Waxman amendments, which permit drug label copying, demonstrate Congress' intent to override Copyright Act).

Moreover, as Syngenta itself makes clear, those 1978 amendments did not modify property rights, but rather conformed FIFRA to longstanding state laws that grant proprietary rights in the data. *Id*. Congress saw fit to compensate original registrants for some of their scientific data that support a label – but not the language on the label.

In short, whether or not any portion of a label's language is otherwise copyrightable (a proposition which, as discussed below, Willowood disputes), the plain language of FIFRA precludes copyright protection as to Syngenta's labels. Application of copyright protection to any portion of those labels would entirely negate FIFRA's express grant of permission for generic labels to be identical to Syngenta's labels and subvert the purposes underlying that grant of permission.

C. The EPA Has Consistently Interpreted and Implemented FIFRA to Permit the Copying of Labels.

An important factor influencing the court's decision in *FMC* was the EPA's failure to appear in support of the private defendant's position. *FMC*, 369 F. Supp. 2d at 570. But on many occasions since then – including in this case – the EPA has made plain that it disagrees with *FMC* and interprets FIFRA as precluding copyright

infringement. Less than three months after *FMC* was decided, in response to a trade association inquiry, the EPA summarized why *FMC* conflicts with FIFRA, noting: "It has been the practice of the Office of Pesticide Programs since…1978 to strongly encourage 'me-too' product labels to be identical or substantially similar to the labels of the products on which their registrations are based." Appx03547. Subsequently, in 2006 and 2009, when two other registrants asserted copyright infringement actions against me-too applicants concerning their pesticide labels, senior EPA officials submitted detailed declarations explaining why the agency's interpretation and implementation of FIFRA are in direct conflict with copyright infringement claims. Appx01164-01183.[6]

In this case, the EPA again weighed in with an extensive analysis supporting this same position. Appx2962-3548 and Appx 3825-3837. As the EPA put it: "the FIFRA 'me too' standard, which is intended to streamline review and registration of "me too" products, endorses label copying…." Appx02990. This interpretation of FIFRA by the EPA is entitled to deference. *Chevron U.S.A. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984).

Syngenta contends that the district court conflated FIFRA's substantial similarity standard with copyright law. According to Syngenta, whereas "substantial

[6] The declarations are publicly available on each of the district court's dockets. Those cases both settled before any rulings on the merits.

similarity" under copyright law is simply evidence of whether a work has been copied, under FIFRA "the question whether two labels are substantially similar … is a substantive one based on FIFRA's core requirement that a product not present a risk of 'unreasonable adverse effects on the environment." Br. at 40. Syngenta thus contends that "pesticide labels can be substantially similar under FIFRA even if they differ in their selection, arrangement, and presentation of information, such that they would not be substantially similar under copyright law." *Id*.

Syngenta's argument ignores the plain language of FIFRA, as well as important limitations of copyright law, as FIFRA § 136a(c)(3)(B)(i)(I) expressly permits a generic label to be *identical* – not just substantially similar – to previously approved labels. Moreover, nothing in this language limits this authorization to the information conveyed as opposed to the manner in which it is conveyed. To the contrary, this provision offers the generic applicant two alternative ways to satisfy FIFRA's substantive risk standard: (1) if the product composition and label are identical or substantially similar to the original product, this provides ready assurance that the substantive standard is met; or (2) if the label is not identical or substantially similar, the EPA must engage in a more extensive (and time-consuming) analysis to determine whether the differences would significantly increase environmental risks.

As the EPA stated, identical or substantially similar language "facilitates expedited review and approval of the generic…pesticide in accordance with the statutory scheme." Appx2988. To this end, the EPA noted, "variability in label language increases the chance of misuse due to user confusion and requires far greater EPA resources to determine whether such differences may 'significantly increase the risk of unreasonable adverse effects on the environment.'" Appx2979.

The facts of this case bear out the EPA's statements and demonstrate why, in practice, adopting Syngenta's position would lay waste to FIFRA's fundamental purposes. As Syngenta notes, after this case was initiated, Willowood revised its label language for its azoxystrobin products in an effort to avoid Syngenta's copyright claims, and EPA eventually approved the revised label language for those products. Br. at 37 n.8. In fact, however, this process was neither quick nor easy, as the EPA rejected many proposed revisions submitted by Willowood – including proposed changes in the formatting of information – to ensure compliance with FIFRA's substantive requirements. Appx2980-2981. But even then, Syngenta contended that the EPA-approved revised language continued to infringe its copyrights. Appx2794.

EPA has neither the resources nor the expertise to review me-too labels in relation to copyright law. Appx2984. Under Syngenta's approach, no generic could be confident that any label approved by EPA will be non-infringing unless and until

a copyright claim is adjudicated. Injecting such uncertainty into the registration process would eviscerate FIFRA's authorization to submit identical or substantially similar labels, and create a significant disincentive to generic competition.

In addition, Syngenta's assumption that copyright protection necessarily would apply to the selection and arrangement of identical or substantially similar scientific information contained on a pesticide label is incorrect. *See* Section I.D, *infra*. In this regard, *amicus* NYIPLA acknowledges that "protectable material [on a pesticide label] likely will be *de minimis*" because of "limiting doctrines in copyright law." But the NYIPLA (which has no demonstrated experience with FIFRA) then goes on to speculate that it is nonetheless "*possible* that an original label *might* contain some copyrightable material." Br. at 20-24 (emphasis added). NYPILA cites as an example photographs or illustrations of dead bugs that might appear on a pesticide label for decorative purposes. *Id*. at 22-24. Such speculation is irrelevant here, not only because Syngenta's labels do not contain any such photographs or illustrations, but because Syngenta (understandably) has not identified any specific portions of its label that it maintains are subject to copyright protection. Rather, Syngenta highlighted large swaths of its labels copied by Willowood, without delineating which portions it concedes are not subject

to copyright protection and those that are purportedly copyrightable. Appx0600-0681.[7]

D. Construing FIFRA to Preclude Copyright Protection for Syngenta's Labels Best Preserves the Purposes of Both Statutes.

Where two laws conflict, courts should attempt to adopt an interpretation that preserves the principal purposes of each. *Cathedral Candle Co. v. United States ITC*, 400 F.3d 1352 (Fed. Cir. 2005); *Zenith Elecs. Corp. v. Extec, Inc.*, 182 F.3d 1340 (Fed. Cir. 1999). In *SmithKline*, the Second Circuit applied this principle to hold that the Hatch-Waxman Amendments, which authorize copying of drug labels by generic producers in order to facilitate generic drug competition, precludes copyright infringement claims with respect to such labels. 211 F.3d at 28-29. The Court noted that this result did not undermine the purpose of the Copyright Act because the "profit sought by the creator of the pioneer drug label flows primarily

[7] Syngenta erroneously states that significant portions of its label contain "efficacy information" that EPA does not require. Br. at 25 n.6. In fact, EPA *does* review and compare all aspects of the label including efficacy-related language. Appx02998 and 03833-03834. Syngenta's argument again conflates label *language* with underlying *data*. The EPA has generally waived the requirement that applicants submit efficacy data for agency review. 40 C.F.R. § 158.400(e). EPA therefore does not typically assess the accuracy of efficacy information reflected on the label. However, efficacy data provides scientific support for (among other things) the directions for use that must appear on the label and that are extensively regulated. 7 U.S.C. § 136(q)(1)(F); 40 C.F.R. § 156.10(j). Contrary to Syngenta's assertion, the EPA does in fact review and compare all aspects of the label, including efficacy related language. Appx02998; Appx03833-03834. *Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 440 (2005), cited by Syngenta, likewise addresses the waiver concerning submission of efficacy data, not EPA review of label language.

from the administrative approval of the drug and the patent and exclusivity periods free from competition that follow;" not from the language of the label. *Id*. at 29.

The same is true here with respect to pesticides. Like the Food and Drug Act, FIFRA authorizes the copying of labels. Thus, as the EPA noted, a holding that FIFRA precludes copyright infringement claims "preserves the specific mandates of FIFRA for 'me too' labels without undermining the purposes of the Copyright Act." Appx02990-02991. This is especially the case because the limiting doctrines under copyright law (including those identified by *amicus* NYIPLA), discussed in more detail below, make it highly questionable that any portions of Syngenta's pesticide labels could be subject to copyright protection.

First, as noted above, much of the label language is either expressly mandated by EPA regulation or authored and recommended for use by the EPA. Second, precisely because copyright protection can extend only to the expression of an idea but not to the idea itself, manuals, product labels and instructional manuals are generally not entitled to copyright protection. *Sassafras Enter., Inc. v. Rosh Co., Inc.*, 889 F. Supp. 343 (N.D. Ill. 1995) (description of what a product does and how it is used is generally non-copyrightable); *CMM Cable Rep, Inc. v. Ocean Coast Props., Inc.*, 97 F.3d 1504, 1519 (1st Cir. 1996) ("forms of expression dictated solely by functional considerations" are not subject to copyright protection).

Third, there are a limited number of ways to express the ideas underlying the descriptive and functional text contained in Syngenta's labels. For example, there are simply a limited number of ways to say "begin applications prior to or in the early stages of disease development." Thus, the idea "merges" with the expression, rendering the expression non-copyrightable. *See, e.g., ATC Distribution v. What Ever It Takes Transmission Parts, Inc.*, 402 F.3d 700, 707-08 (6th Cir. 2005); *Nat'l Nonwovens, Inc. v. Consumer Products Enter, Inc.*, 397 F. Supp. 2d 245, 255 (where instructions for product's use were purely functional and there were a "limited number of verbal formulations" to convey the information, copyright protection did not apply).

At least 30 of the 53 pages of Syngenta's Azoxy 2.08SC label, which it contends are copyrightable, consist of a four-column table, an example of which is below, identifying the crops on which EPA has approved its use, the target diseases to be treated, the application rate (in lbs/acre), and remarks regarding application. Appx0424-0509.

Crop	Target Diseases	Use Rate fl oz product/A (lb ai/A)	Remarks
Artichoke, Globe	Ramularia leaf spot (*Ramularia cynarae*)	11.0-15.5 (0.18-0.25)	Begin applications prior to or in the early stages of disease development, and continue as needed throughout the season at a 2- to 3-week interval, up to and including the day of harvest. Do not apply at less than 7-day intervals. Applications may be made by ground, air or chemigation. For ground applications, apply in 50-200 gallons of water per acre to obtain coverage without excessive runoff. For aerial applications apply in a minimum of 5 gallons of water per acre. An adjuvant may be added at specified rates. Do not apply more than one application of Quadris or other Group 11 fungicides before alternation with a fungicide that is not in Group 11.

There are an extremely limited number of ways to express the information contained in these directions for use. In fact, when Willowood sought to revise its own labels by changing the table format for directions for use to a narrative format in order to avoid claims of copyright infringement, the EPA required Willowood to reinstate the information in table format. Appx3129-3200 (Azoxy 2.08 SC Label); Appx3201-3339 (AzoxProp Xtra label). By requiring the information to be conveyed in table format here, the EPA further restricted the number of ways to express this information.

While there are a limited number of ways to clearly express the label's information in a way that can be "easily read and understood" by the average user, there are often dozens, or even hundreds, of EPA-approved generic versions of a particular product. Appx2996. Where, as here, there are at most a limited number of ways to express information, such that copyrighting could exhaust all possibilities

of future use of a substance, copyright protection is not available. *Morrissey v. Proctor & Gamble Co*., 379 F.2d 675, 678 (1st Cir. 1967); *Yankee Candle Co. v. Bridgewater Candle Co.*, 259 F.3d 25, 36, n.6 (1st Cir. 2001) ("sharply limited" number of ways exist to depict fruits and flowers on labels indicating the scent of candles).

Even if there were hundreds of ways to convey the same scientific information, application of copyright laws to every product label would mean that numerous generic labels must convey the same basic information but avoid infringing not only the label of the original registrant, but also every previously approved generic label. This would serve no rational purpose. Rather, it would severely undermine FIFRA's goals by deterring generic entry and increasing the risk of confusion in the market (and hence the risk of environmental harm and personal injury) by requiring the same information to be conveyed to farmers in many different ways. Appx2979.

Syngenta's labels consists essentially of textual language reflecting or containing raw factual data concerning the use and application of azoxystrobin. For example, Syngenta's label includes the following:

USE INSTRUCTIONS

Application: Thorough coverage is necessary to provide good disease control. Make no more spray solution than is needed for application. Avoid spray overlap, as crop injury may occur.

Adjuvants: When an adjuvant is to be used with this product, the use of an adjuvant that meets the standards of the Chemical Producers and Distributors Association (CPDA) adjuvant certification is recommended.

Efficacy: Under certain conditions conducive to extended infection periods, use another registered fungicide for additional applications if maximum amount of Willowood Azoxystrobin 2.08SC has been used. If resistant isolates to Group 11 fungicides are present, efficacy can be reduced for certain diseases. The higher rates in the rate range and/or shorter spray intervals may be required under certain conditions of heavy infection pressure, with highly susceptible varieties, or when environmental conditions are conducive to disease.

INTEGRATED PEST (DISEASE) MANAGEMENT

Willowood Azoxystrobin 2.08SC should be integrated into an overall disease and pest management strategy whenever the use of a fungicide is required. Cultural practices known to reduce disease development should be followed. This should include selection of varieties with disease tolerance, removal of plant debris in which inoculums overwinters, and proper timing and placement of irrigation. Consult your local agricultural authorities for additional IPM strategies established for your area. Willowood Azoxystrobin 2.08SC may be used in State Agricultural Extension advisory (disease forecasting) programs which recommend application timing based on environmental factors favorable for disease development.

Crop Tolerance: Plant tolerance has been found to be acceptable for all crops on the label, however, not all possible tank-mix combinations have been tested under all conditions. When possible, it is

Appx546. Such facts and basic information about a product are simply not copyrightable. *Feist Publ'ns, Inc. v. Rural Tel. Serv. Co., Inc.*, 499 U.S. 340, 344-45 (1991); 17 U.S.C. § 102(b). This is so even if, as Syngenta claims, it spent substantial time and money to conduct the science reflected on its labels make such information copyrightable. *Feist* at 349 (rejecting "sweat of the brow" doctrine"). In fact, as noted above, in enacting the 1978 FIFRA amendments, Congress specifically decided to protect the inventor's property interests in its scientific *data* (by requiring the generic to pay compensation for relying on the data), but not the written language on the label that reflects that data.

For all the foregoing reasons, applying FIFRA's plain meaning, which precludes copyright protection for pesticide labels, is consistent with the underlying purposes and doctrines of copyright law.

II. The District Court Properly Interpreted 35 U.S.C. § 271(g) as Requiring that a Single Entity Make the Product Resulting from the Patented Process.

The purpose of 35 U.S.C. § 271, the title of which is "Infringement of Patent," is to provide patent owners with a remedy against infringers. It is beyond question, however, that a process patent may not be infringed unless each element of a claim of that patent is practiced. That is, if a process patent requires a party to engage in multiple steps to infringe, practicing less than all of those required steps does not constitute infringement. *BMC Resources, Inc. v. Paymentech, L.P.*, 498 F.3d 1373, 1378-79 (Fed. Cir. 2007). It is also beyond question that importation of a non-infringing product made according to a non-infringing process does not give rise to liability under the Patent Act. Yet, Syngenta's interpretation of § 271(g) would impose liability for these very acts as Syngenta seeks to impose liability for the importation of products manufactured by multiple parties practicing less than all of the patented steps of a patent.

A. Failing to Apply the Single Entity Rule to § 271(g) Would Be Contrary to Its Legislative History and Would Impermissibly Expand the Extraterritorial Scope of § 271(g) Beyond Congress' Intent.

The principle that a process claim is infringed only if each step of the claimed process is practiced is founded on the proposition that direct infringement requires a single party to practice every step of a claimed method. *Id.* at 1380. For if a single party practices less than all the steps of the patented process, that party would simply be performing individual non-patented steps.

It has long been held, however, that a party cannot avoid liability for patent infringement simply by having a third party or parties carry out one or more of the claimed steps on its behalf. Accordingly, where the actions of multiple parties combine to perform every step of a claimed process, the claim is infringed if one party exercises "control or direction" over the entire process such that every step is attributable to a single entity. *Muniauction, Inc. v. Thomson Corp*., 532 F.3d 1318, 1329 (Fed. Cir. 2008). Consequently, in order to infringe on a multi-step process claim, a single party must perform each step, or a single party much control or direct the other parties involved in practicing the process. *Id*. at 1330. This proposition has become known as the "single entity" rule.

The single entity rule was affirmed, and expanded, by the Supreme Court in *Limelight Networks, Inc. v. Akamai Technologies, Inc.*, 134 S. Ct. 2111 (2014). There, the Court confirmed Federal Circuit precedent holding that liability for direct

infringement under 35 U.S.C. § 271(a) requires performance of all claimed steps of a process patent to be attributable to a single entity. *Id*. at 2117. The Court went on to hold that liability for inducement to infringe under § 271(b) must similarly be predicated on the actions of a single entity. *Id*. To hold otherwise, the Court found, would deprive § 271(b) of ascertainable standards and require courts to develop two parallel bodies of infringement law. *Id*.

Notwithstanding the Supreme Court's application of the single entity rule to allegations of both direct and indirect infringement under §§ 271(a) and (b), Syngenta argues that 35 U.S.C. § 271(g) does not require application of this well-established rule. As this Court is aware, however, § 271(g) is simply another form of direct infringement[8] enacted to close a loophole in the statutory scheme for the protection of process patent owners. *Ajinomoto Co. v. Archer-Daniels-Midland Co.*, 228 F.3d 1338, 1347 (Fed. Cir. 2000); *Eli Lilly & Co. v. Am. Cyanamid Co.*, 82 F.3d 1568, 1571-72 (Fed. Cir. 1996). In that regard, prior to enactment of § 271(g), the owner of a process patent had a remedy only if the unauthorized use of its patented

[8] *See, e.g., W.L. Gore & Associates, Inc. v. Medtronic, Inc*., 874 F. Supp. 2d 526, 542-43 (E.D. Va. 2102) *aff'd*, 530 F. App'x 939 (Fed. Cir. 2013) ("Gore has brought this action for infringement under both 35 U.S.C. §§ 271(a) and 271(g), the two U.S. statutes governing direct infringement."); *McRO, Inc. v. Namco Bandai Games Am., Inc.*, 23 F. Supp. 3d 1113, 1121 (C.D. Cal. 2013) ("While § 271(a) makes it an act of infringement, ...to make an article by a patented process, § 271(g) makes it an act of infringement to sell an article made by a patented process. Both involve direct, not indirect, liability.").

process occurred entirely within the United States. *See, e.g., NTP, Inc. v. Research in Motion*, 418 F.3d 1282, 1317-18 (Fed. Cir. 2005). That same patent owner had no remedy, however, if those same individuals practiced some or all of the patented process abroad to manufacture products later imported into the United States for sale or use. *Id.*

To close this loophole, § 271(g) was enacted to "grant patent owners the *same* protection against oversees infringers as they already enjoyed against domestic entities[]" under § 271(a). *Mycogen Plant Sci., Inc. v. Monsanto Co.*, 252 F.3d 1306, 1318 (Fed. Cir. 2001), *judgment vacated on other grounds*, 535 U.S. 1109 (2002) (emphasis added). The legislative history of § 271(g) confirms the *Mycogen* court's analysis:

> *…[T]he process patent bill [ultimately codified, in part, as 35 U.S.C. § 271(g)] was crafted to apply equally to the use or sale of a product made by a process patented in this country whether the product was (and the process used) in this country or a foreign country.* The bill is prompted by the use of patented processes in other countries followed by the importation of the resulting products into this country. *The use of the process in this country is already an act of infringement under existing patent law, and such an infringing party would be subject to the jurisdiction of the U.S. courts. Thus, the inclusion of a domestic process patent infringement in the scope of a bill to extend protection to the products is regarded by the Committee [on the Judiciary] as a formality…, with little or no practical consequences in patent enforcement….*
>
> *[35 U.S.C. § 217(g)] will prevent circumvention of a U.S. process patentee's rights through manufacture abroad and subsequent importation into the United States of products made by the patented process.*

S. Rep. 100-83 at 27-28, Process Patents Amendments Act of 1987 (June 23, 1987) (emphasis added). As the legislative history makes clear, although its focus is on the importation of products, the primary purpose of § 217(g) is to preserve the force of the patented processes that create those products. *Synaptic Pharm. Corp. v. MDS Panlabs, Inc.*, 265 F. Supp. 2d 452, 460 (D. N.J. 2002).

Nothing in the legislative history of § 271(g), however, suggests that Congress intended to provide patent owners with broader protections for the unauthorized use of their patented processes outside the United States than within the United States. *Deepsouth Packing Co. v. Laitram Corp*., 406 U.S. 518, 520 ("[W]e…insist on a clear congressional indication of intent to extend [patent protection] before we [can] recognize the monopoly claimed here. Such an indication is lacking.").[9] As Congress has not evidenced any intent to broaden the extraterritorial effect of the Patent Act, this Court should not expand the scope of § 271(g) to activities that are clearly not infringing under any other set of circumstances. But that is precisely what Syngenta's reading of the statute would do. Under § 271(a), if multiple parties combine to perform every step of a patented process but those actions are not attributable to a single entity, their actions would *not* give rise to infringement

[9] The Supreme Court in *Deepsouth* further said "[w]e…require a clear and certain signal from Congress before approving the position of a litigant who…argues that the beachhead of [patent protection] is wider, and the area of public use is narrower, than courts had previously thought." *Id.* at 531.

liability. Under Syngenta's interpretation of § 271(g), however, if those *same parties* engaged in those *same actions outside of the United States*, liability would be imposed if the resulting product was imported into the United States. This result would be in clear contravention of § 271(g)'s purpose to grant process patent holders the same (not broader) protections against oversees infringement of their patented processes as they already enjoy against domestic infringement,[10] and would violate the presumption against extraterritorial application of the patent laws. *Microsoft Corp. v. ATT*, 550 U.S. 437, 454 (2007) (US patent laws, like other US laws, are to be understood and interpreted against an interpretation of extraterritorial reach unless explicitly indicated).

In its attempt to avoid application of the single entity rule, Syngenta argues that § 271(g)'s use of the passive voice indicates that as long as the patented process is utilized in its entirety to produce a product imported into the United States, it does not matter who carries out that process. Syngenta relies on a series of cases

[10] *Amici* Biotechnology Innovation Organization ("Bio") and CropLife International ("CropLife") contend that Syngenta's construction of § 271(g) would not give patentees greater rights than those available under § 271(a), or impose any unfairness on potential infringers, because § 271(g) and related sections of the Patent Act provide certain limits on an infringer's liability not found in § 271(a). While it is true that § 271(g) and other sections of the Patent Act provide certain limits on an infringer's liability and the damages recoverable for such infringement not found elsewhere in the Act, those provisions do not change the fundamental fact that, under Syngenta's proposed construction of § 271(g), patent infringement liability may be imposed for actions engaged in outside of the United States that would not give rise to such liability if engaged in within the United States.

purportedly holding that a statute's use of the passive voice means that the occurrence of an event, not the actor or actors engaged in that event, is key to interpreting the statute. Specifically, Syngenta argues that § 271(g)'s use of the passive voice requires this Court to focus on whether something happened (here, whether a product was made by the process claimed by Syngenta's US patent), not on whether that activity was an infringing activity. Syngenta's reliance on these cases, however, is misplaced as in each case, the court's interpretation was predicated on, and consistent with, the legislative history of the statute at issue. As discussed above, that is not the case with respect to Syngenta's proposed interpretation of § 271(g).

For example, in *Dean v. United States*, 128 S. Ct. 1849 (2009), at issue was a statute that created enhanced sentencing for certain crimes committed with a gun. The Court held it proper to construe the statute so as not to require proof that the offender intended to discharge his weapon, because that result furthered the statute's purpose – to dissuade individuals engaged in violent or drug trafficking offenses from carrying a gun. *Id.* at 1855-56.

Similarly, in *Special Devices, Inc. v. OEA, Inc.*, 270 F.3d 1353 (Fed. Cir. 2001), this Court found that the purpose of the statute at issue (35 U.S.C. § 102(b)) was to encourage inventors to seek patent protection promptly. *Id.* at 1357, *citing Woodland Trust v. Flowertree Nursery, Inc.*, 148 F.3d 1368, 1370 (Fed. Cir. 1998).

This purpose was promoted, the Court found, by its rejection of a "supplier exception" to the on-sale bar as sought by the patent owner. *Id*. at 1355-56. *See also, Gladstone, Realtors v. Village of Bellwood*, 441 U.S. 91, 99 (1979) (finding petitioner's proposed construction to be inconsistent with the statute's terms and legislative history).

While the statutes at issue in each of these cases included passive language, each court's interpretation was premised on the legislative intent and history underlying each statute. In contrast, Syngenta's interpretation of § 271(g) is inconsistent with its intent and legislative history.

Syngenta's reliance on *Trustees of Columbia Univ. v. Roache Diagnostics GmbH*, 272 F. Supp. 2d 90 (D. Mass. 2002), is similarly misplaced. There, defendant contended that it could not be held liable under § 271(g) because a third-party, not it, had practiced the patented process. In rejecting this argument, the court held that under § 271(g), it did not matter that the defendant did not perform the patented process; defendant was liable because it imported products made by that patented process. *Id.* at 108. The court made clear, however, that under § 271(g), "direct infringement" was a necessary prerequisite to liability as to the importer of a product made abroad by a patented process:

> Under either theory [§§ 271(b) or 271(g)], Roache's [the importer's] liability depends on GI [the foreign manufacturer]. [Roache] is liable only if GI's underlying actions directly infringed the [Columbia] patents. Under § 271(b), if there is no direct infringement by GI,

> Roache cannot be liable for inducing infringement....Under § 271(g), Roache can only be held responsible if it imported a product made by a patented process into the United States....*If the product shipped by Roache into the United States was made by a process that did not directly infringe upon Columbia's patents, then Roache cannot have violated § 271(g)*.

Id. at 100 (emphasis added). As the patents were directly infringed by a single entity (GI), the court held Roache liable as the importer of the resulting product. *Id*. Thus, this decision actually supports Willowood's position here, not Syngenta's.

B. This Court's Holding in Zoltec Does Not Support Syngenta's Position.

Finally, Syngenta devotes considerable space to this Court's decision in *Zoltek Corp. v. United States*, 672 F.3d 1309 (Fed. Cir. 2012), to support its position. *Zoltek*, however, did not provide any analysis of § 271(g). Rather, it addressed the potential liability of the United States under 28 U.S.C. § 1498, which provides that whenever a patented product is used or manufactured by or for the United States without license, the patent owner's sole remedies shall be by action against the United States. *Zoltek*, 672 F.3d at 1326. The Court was careful to make clear that § 1498 operates entirely independently from the U.S. Patent Act: "although a § 1498 action may be similar to a Title 35 action, it is nonetheless only parallel and not identical." *Id*. at 1321. As § 1498 creates its own independent cause of action, the Court clarified that its opinion had no effect on its analysis of § 271:

> Accordingly, we hold that for the purposes of § 1498, the use or importation "within the United States [of] a product which is made by a process patented in the United States" constitutes use of the invention without lawful right because the products embodied the invention itself. *We add that nothing in this opinion shall be construed to affect our Title 35 jurisprudence.*

Id. at 1326 (emphasis added).

The *Zoltek* court went on to make clear that blind adherence to the literal language of a statute to determine its meaning can be a fool's undertaking. "The decisions are legion in which [courts] have refused to be bound by the letter [of a statute], when it frustrates [its] purpose…." *Id*. at 1323, *citing Cabell v. Markham*, 148 F.2d 737, 739 (2d Cir. 1945) (citing Justice Homes for the proposition that "it is not an adequate discharge of duty for courts to say: [w]e see what you are driving at, but you have not said it, and therefore we shall go on as before."). The *Zoltek* court then discussed the Supreme Court's approval of Judge Learned Hand's comments in *Cabell*:

> Of course it is true that the words used, even in their literal sense, are the primary, and ordinarily the most reliable, source of interpreting the meaning of any writing: be it a statute, contract, or anything else. But it is one of the surest indexes of a mature and developed jurisprudence not to make a fortress out of the dictionary, but to remember that statutes always have some purpose or object to accomplish, whose sympathetic and imaginative discovery is the surest guide to their meaning.

Id. at 1324, *citing Watt v. Alaska*, 451 U.S. 259, 266 (1981). As a result, and despite the use of inconsistent language by § 1498, the *Zoltek* Court focused on the

legislative purpose behind § 1498, holding that because that purpose was clear, a rigid adherence to the language of the statute would be improper. Even if use of the passive voice in § 271(g) might suggest that the single entity rule does not apply (a proposition with which Willowood does not agree), strict adherence to that language would inappropriately exalt form over substance by expanding the extraterritorial reach of § 271(g) beyond what Congress intended.

C. The International Trade Commission Rejected a Similar Argument to that Being Made by Syngenta Here When Interpreting 19 U.S.C. § 337(a)(1)(B)(ii).

The International Trade Commission ("ITC") rejected a position similar to Syngenta's position here, in interpreting 19 U.S.C. § 337(a)(1)(B)(ii). *In re Matter of Certain Rubber Antidegradants*, 2008 WL 1727623 (April 2008). That provision makes unlawful:

> (B) *The importation into the United States, the sale for importation, or the sale within the United after importation,…of articles* that - …
>
> (ii) *are made*, produced, processes, or mined under, or *by* means of, *a process covered by the claims of a valid and enforceable United States Patent.*

(emphasis added). The italicized language above is substantially similar to the passive language of § 271(g) on which Syngenta so heavily relies.

In *Rubber Antidegradants*, the petitioner contended that § 337(a)(1)(B)(ii) merely "requires that the accused imported article be made by means of a process

covered by the asserted claims regardless of whether two entities collectively practice the process." *Id*. at *19. The ITC rejected this position, holding that there was nothing in the statute or legislative history of § 337(a)(1)(B)(ii) to support it:

> Neither [Petitioner] nor the other parties have referred to any definitive holding by our appellate court as to whether all the steps of a claimed process must be performed by one person in order find a violation of section 337(a)(1)(B)(ii). Notwithstanding the various arguments made by [Petitioner], the relevant inquiry is one of statutory construction. In our view, [Petitioner] has failed to demonstrate that its position on statutory construction is correct…. [T]here is nothing in the statute or the legislative history raised by [Petitioner] that supports its contention.

Id.

Just as the ITC held that the legislative history of § 337(a)(1)(B)(ii) does not support liability under it without a finding of direct infringement, Syngenta's construction of § 271(g) is not supported by its legislative history. Willowood respectfully submits that the ITC's analysis is relevant and instructive, and this Court should reject Sygnenta's construction of § 271(g).

D. Imposition of the Single Entity Rule to § 271(g) Would Not Impose An Undue Evidentiary Burden on Patentees as Asserted by Amici Bio and CropLife.

In addition to many of Syngenta's arguments addressed above, *amici* Bio and CropLife contend that imposition of the single entity rule under § 271(g) would impose an undue evidentiary burden on patentees, and would somehow undermine the provision's purpose by eliminating certain protections. In this regard, *amici* primarily rely on *Nutrinova Nutrition Specialties and Food Ingredients GmbH v.*

Int'l Trade Comm'n, 224 F.3d 1356 (Fed. Cir. 2000), to argue that foreign manufacturers are sometimes less than forthright, and may even be obstructive, when responding to a patentee's efforts to discover the details of the manufacturing process and the identity of those engaged in that process overseas. While this may in fact be the case in some situations, *amici* fail to explain why the occasional recalcitrant manufacturer should override the stated purpose of § 271(g).

Moreover, *amici* fail to address why identifying the foreign manufacturers of a particular product is any more difficult than identifying the process by which a particular product is made. There is no dispute that § 271(g) requires the patentee to prove that a product is, in fact, made by its patented process. In most cases, discovery concerning the manufacturing process will thus be required. In the limited circumstances where multiple parties are practicing the patented process, there is no reason to believe that investigating the relationship of those multiple parties will impose any significantly different obligations on the patentee.

Further, to the extent a defendant in an infringement claim premised on § 271(g) is alleged to be the entity that exercises control or direction over the allegedly infringing process by arranging for the manufacture of the product by multiple entities, it will be subject to discovery as a party to the case. Accordingly, the patentee will very likely be able to investigate the issue of control and direction through normal discovery processes available to one party against another party.

Moreover, the concern raised by *amici* was specifically addressed by Congress when it passed a related statutory provision. Anticipating that it may occasionally be difficult to conduct discovery of foreign manufacturers to establish infringement, Congress enacted 35 U.S.C. § 295, which provides:

> In actions alleging infringement of a process patent based on the importation, sale, offer for sale, or use of a product which is made from a process patented in the United States, if the court finds –
>
> > (1) that a substantial likelihood exists that the product was made by the patented process, and
> >
> > (2) that the plaintiff has made a reasonable effort to determine the process actually used in the production of the product and was unable to so determine,
>
> the product shall be presumed to have been so made, and the burden of establishing that the product was not made by the process shall be on the party asserting that it was no so made.

As such, where a patentee is unable, after reasonable efforts, to determine how a product was made or who made that product, it can seek relief under § 295 and request a presumption that the product was made in an infringing manner, including by, or at the control of, a single entity.[11]

[11] Bio and CropLife also discuss at length the large investment that must sometimes be made to manufacture agricultural and pharmaceutical products. The apparent implication – that application of the single entity rule to § 271(g) would somehow dissuade companies from making those investments because of the likelihood of infringement – is unsupportable. In fact, the large expenditures necessary to manufacture any particular product greatly reduce the likelihood that a party, or multiple parties, will practice the patented process as those parties will be forced to make those same significant expenditures.

E. The Language of § 271(f) Does Not Support Amici's Position that § 271(g) Must Not Be Interpreted to Require a Single Entity to Practice the Patented Process.

Amici also cite to § 271(f), which provides that the supply of components made in the United States for assembly outside the country constitutes inducement of infringement if "such combination occurred within the United States," to argue that Congress knows how to explicitly invoke the concepts of infringement under § 271(a) when it intended to do so. This reasoning, however, is incorrect. As the Supreme Court held in *Limelight*, the inclusion of this precise language in § 271(f) ("…if such combination occurred within the United States…") actually illustrates that "when Congress wishes to impose liability for inducing activity that does not constitute direct infringement, it knows precisely how to do so." *Limelight*, 134 S. Ct. at 2118. The Court went on to hold that "courts should not create liability for inducement of non-infringing conduct where Congress has elected not to extend that concept." *Id*.[12]

The same can be said of *amici's* arguments here. *Amici*, along with Syngenta, seek to utilize § 271(g) to extend the scope of process patent protection outside the United States to include certain non-infringing conduct, *i.e.*, conduct of manufacturers not under the direction or control of a single party who practice less

[12] Reliance on § 271(f) to interpret § 271(g) is fundamentally questionable in the first place as § 271(f) is not applicable to method claims. *Cardiac Pacemakers, Inc. v. St. Judge Medical, Inc.*, 576 F.3d 1348 (Fed. Cir. 2009).

than all steps of a claimed process. Without Congress' clear and certain signal that § 271(g) was enacted to impose liability for this precise activity, this Court should not do so.

III. The Jury's Determination that Willowood Did Not Infringe the '138 Patent is Supported by Substantial Evidence.

As a fallback to its misguided interpretation of § 271(g), Syngenta argues that substantial evidence does not support the jury's finding that the azoxystrobin imported by Willowood was not made by a single entity or under the direction and control of a single entity such that Willowood did not infringe the '138 Patent. Br. at 50. Attempting to impose its subjective interpretation of the evidence, Syngenta contends that either "(i) TaiHe carried out both the etherification and condensation reactions [the two steps claimed by the '138 patent] used to manufacture Willowood's azoxystrobin technical, or (ii) Willowood directed or controlled the entities that carried out these reactions." *Id*. Syngenta, however, cites only to discrete examples of favorable evidence, while ignoring significant and glaring contradictory evidence.

Absent from Syngenta's discussion is the testimony and documentary evidence from which the jury objectively could have concluded – and, in fact, did conclude-that (a) Tai He did not perform all steps of the claimed method; namely, both the etherification and condensation steps, and (b) Tai He (who conducted the condensation step) and Guosheng (who conducted the etherification step) did not

work at the direction, or under the control, of Willowood or any other entity. Accordingly, Syngenta's appeal on this issue should be denied.

A. The Record Establishes That Tai He Performed Only the Condensation Step, and not the Etherification Step, of the Azoxystrobin Manufacturing Process.

As the district court correctly held, for Syngenta to prove infringement of the '138 patent, "all steps of [the] claimed method [must be] performed by, or attributable to, a single entity." Appx14 (*quoting Akamai*, 797 F.3d at 1022). That is, Syngenta must shoulder the burden of proving that Tai He conducted both the etherification and condensation steps of the claimed manufacturing process.

Most notably absent from Syngenta's recitation of the facts is the testimony of Mr. Wu Xiaolong, Tai He's President, which alone is sufficient evidence upon which the jury could have based its verdict. Mr. Wu, one of only two eyewitnesses to testify at trial to the purportedly infringing manufacturing process, repeatedly testified that Tai He performs only the condensation step and purchases the intermediate compound resulting from the etherification step from a separate entity - Lianyungang Guosheng Chemical Co., Ltd. ("Guosheng") - in an arms-length transaction. Appx6978 at 76:10-24; Appx6979 at 79:12-17; Appx6980 at 84:5-13. Importantly, Mr. Wu testified that nobody other than Tai He performed the condensation step (Appx6979 at 80:15-20), and inversely, that Guosheng never performed the condensation step. Appx6979 at 79:22-25.

Mr. Wu further testified that Tai He began production of azoxystrobin in 2011 (two years before it began any relationship with Willowood) for approximately thirty customers (Appx6976 at 69:15-70:1) and that the equipment at the Tai He facility was capable of performing *only* "the last step...condensation." Appx6980 at 83:14-84:4; *id*. at 84:14-17. This was confirmed by Brian Heinze, WW-USA's President, who testified that "Mr. Wu, who owns the factory, reconfirmed that he only carries out the condensation step, [and] that he buys an intermediate up through the etherification step from another company, Guosheng." Appx6797-6798 at 36:16-37-6.

This testimony was also corroborated by the only other eyewitness to the manufacturing process to testify at trial, WW-Ltd's General Manager, Mr. Shen Shoajun ("Mr. Shen" or "SSJ"). Mr. Shen, a chemist by training (Appx6986 at 109:1-2), personally inspected Tai He's facility *before* Willowood purchased any azoxystrobin from it. In this regard, Mr. Shen testified that he "was able to observe the production on the production line to confirm that Tai He was equipped only to perform the condensation step." Appx6993 at 137:5-14; *see also* Appx6980 at 84:14-17. Moreover, Mr. Shen testified that Tai He did not have the appropriate permit from the Chinese government to perform the etherification step, nor did Tai He have the "capability for the treatment of waste water and waste fumes…" resulting from the etherification step. Appx6992 at 132:23-133:9.

Further demonstrating Tai He's lack of involvement with the etherification step is Willowood's trial exhibit 17 (the "Process Description"), prepared by Tai He and sent to Willowood to memorialize the complete manufacturing process of the azoxystrobin it sold to Willowood. Appx8232-8241. Therein, Tai He makes clear that the etherification step is performed by Guosheng, while the condensation step is performed by Tai He. Appx8235.

Importantly, and contrary to Syngenta's selective recitation of the record, the Process Description was used by Mr. Shen to verify the division of labor for the manufacturing process.[13] Mr. Shen testified that *before* Willowood purchased azoxystrobin from Tai He, he visited Tai He and all the other facilities involved in the manufacturing process, including Guosheng, and confirmed that each plant was conducting the steps as described in the Process Description. Appx6993 at 136:12-137:14; Appx6991 at 130:3-22; Appx6992 at 134:6-16. With specific reference to Tai He's involvement, Mr. Shen testified as follows:

[13] Syngenta places considerable emphasis on Mr. Shen's email references to the original application that Willowood filed with the EPA, which mistakenly indicates that Tai He performs both the etherification and condensation steps. Br. at 52-53. Mr. Shen testified, however, that when he referenced the EPA application in those emails, he was referring to the Process Description, which he believed had been filed with the EPA. Appx6991 at 130:3-22; Appx6992 at 134:6-16. Indeed, when presented with the EPA application at trial, Mr. Shen testified that he had never seen that document until that day. Appx6990 at 124:23-125:3.

> Q: How did you confirm that the azoxystrobin Willowood Limited was going to purchase from Tai He was made consistent with the [Process Description] during your audit visit?
>
> A: I brought [the Process Description with me]…to [Tai He]. I was with the production manager on the production line, and I observed them pouring the materials -- the raw materials into the reactor. That include[d] the raw material intermediates. And I also observed the equipment; everything conformed to what's described in the [Process Description] document.

Appx6993 at 135:21-136:7. Testimony also revealed that Mr. Shen did not just visit Tai He and the other facilities involved in the manufacturing process one time; he visited them no less than three times - each time confirming that Tai He only performed the condensation step, and not the etherification step. Appx6994 at 140:4-22; Appx6994 at 141:18-142:1. Mr. Heinze also testified that he received pictures taken by Mr. Shen during one of these visits, which confirmed that each of the factories was carrying out the various steps of the production of intermediates in accordance with the Process Description. Appx6798 at 40:18-23.

In short, two eye-witnesses - Messrs. Wu and Shen - confirmed that Tai He performed only the condensation step while Guosheng performed the etherification step. Their testimony was corroborated by documentary evidence, the Process Description, which also clearly delineates the independent roles of Tai He and Guosheng. Accordingly, and regardless of any potentially contradictory evidence cited by Syngenta, the jury had substantial evidence upon which to base its verdict.

B. No Single Entity Controlled or Directed the Independent Operations of Guosheng and Tai He.

Citing again to only a snapshot of the record, Syngenta suggests that Willowood directed or controlled Tai He and Guosheng in the production of azoxystrobin. In this regard, courts are to consider "general principles of vicarious liability" in determining whether "all steps of a claimed method are performed by or attributable to a single entity." *Akamai*, 797 F.3d at 1022; *see also Travel Sentry, Inc. v. Tropp*, 497 F. App'x 958, 965 (Fed. Cir. 2012) ("a party is liable for direct infringement only if that party exercises 'control or direction' over the performance of each step of the claim, including those that the party does not itself perform."). This Court in *Akamai* held that an entity will be responsible for others' performance of method steps where "that entity directs or controls [those] others' performance." *Akamai*, 797 F.3d at 1022. However, acts such as "mere guidance or instruction in how to conduct some of the steps of the [process] patent" do not rise to the level of "direction or control." *Glob. Patent Holdings, LLC v. Panthers BRHC LLC*, 586 F. Supp. 2d 1331, 1335 (S.D. Fla. 2008), *aff'd*, 318 F. App'x 908 (Fed. Cir. 2009).

Substantial evidence offered at trial and ignored by Syngenta contradicts any notion that Willowood directed or controlled the operations of Guosheng or that it directed Tai He and Guosheng to separate the etherification and condensation processes. Mr. Shen (Appx7673 at 72:4-7), Mr. Heinze (Appx6757-6758; Appx6798 at 40:2-6), Mr. Wu (Appx6984 at 102:8-18), and Willowood Ltd.'s

president, Vijay Mundhra (Appx7684 at 105:14-20), all rejected the notion that Willowood directed or controlled Tai He or Guosheng's operations. Notably, the record contains the following exchange:

> Q. Mr. Shen, did you ever instruct Mr. Wu, or anyone at Tai He, how to manufacture azoxystrobin?
>
> A. No.
>
> Q. Why not?
>
> A. Because Tai He then [already had] customers. They [had] been in production for azoxystrobin for many years. Their technology [was] a mature one. They had their supplier for the intermediates and there were not -- would not be possible for them to make any changes.
>
> * * *
>
> Q. Do you believe that Mr. Heinze, Mr. King, Mr. Middione,[14] or Mr. Mundhra ever instructed Tai He on how to conduct the manufacturing of azoxystrobin that it sells to Willowood Limited?
>
> A. No.
>
> Q. How do you know that?
>
> A. Because [Messrs. Heinze, King, Middione, and Mundhra] don't speak Chinese, and people from Tai He, including Mr. Wu, they cannot speak English. So most -- all the things [were communicated] by me between both sides.

[14] Messrs. King and Middione were co-owners of Willowood USA along with Messrs. Heinze and Mundhra.

Appx6992 at 131:17-24. With these examples alone, the jury had more than sufficient evidence to support its verdict and, therefore, the district court's denial of Syngenta's motion for judgment as a matter of law was proper. But there is more.

As noted above, Mr. Wu testified that Tai He had been manufacturing azoxystrobin since 2011 - several years before connecting with Willowood - and was selling to approximately thirty customers. Appx6976 at 69:15-70:1. Both Messrs. Wu and Shen confirmed that Tai He's facilities were equipped to perform only the condensation step, and that those facilities could not perform the etherification step. Appx6980 at 83:14-84:4; *id*. at 84:14-17; Appx6993 at 137:5-14; Appx6980 at 84:14-17; Appx6992 at 132:23-133:9. This demonstrates that even before Tai He contemplated selling azoxystrobin to Willowood, Tai He had a process in place by which it purchased the etherification intermediate from Guosheng - and did so at its own discretion, with no direction or control from Willowood.

Finally, with respect to Tai He' relationship with Guosheng, Mr. Wu testified that Tai He did not exclusively purchase its etherification intermediate from Guosheng (Appx6978 at 78:17-25), that neither Tai He, nor its affiliates, instruct Guosheng how to make the etherification intermediate (Appx6980 at 86:12-24), and that Mr. Wu does not personally own any interest in Guosheng, sit on its board, or act as an officer of the company (Appx6980-6981 at 86:25-57:17). Thus, any

argument that Guosheng was an alter ego or otherwise related to Tai He could not withstand the evidence.

Syngenta's argument on this issue attempts to supplant the jury's conclusions and inferences with its own subjective view of the record, when in fact the jury had abundant evidence supporting its verdict. Accordingly, the district court properly denied Syngenta's motion JMOL as to the '138 Patent.

IV. The District Court Correctly Entered Judgment as a Matter of Law in Favor of WW-Ltd on All Claims.

WW-Ltd is a Chinese entity based in Hong Kong. Appx6708 at 99:11-12. As relevant here, it purchases technical grade azoxystrobin from a separate Chinese company, Tai He, which it then sells to WW-USA pursuant to an arms-length contract under which WW-Ltd submits invoices to WW-USA for the cost of the product plus a commission equal to 2.5 % of the sales price. Appx6713 at 104:3-8; Appx6794 at 21:6-22:17.

Contrary to Syngenta's contention, substantial evidence was admitted at trial to rebut Syngenta's contention that WW-Ltd is an "affiliate" of WW-USA. WW-Ltd. is owned entirely by Mr. Vijay Muhndra. Appx6708 at 99:8-10. On the other hand, during the relevant time Mr. Mundhra was but one of four co-owners and managers of WW-USA. Appx6792 at 15:16-16:4. Neither Mr. Heinze, WW-USA's co-founder and president, nor any of the other co-owners and managers of WW-USA, have had any ownership or management interest in WW-Ltd. *Id*.

Syngenta's selective review of the trial record ignores the considerable evidence that supports the jury's finding that WW-Ltd's sale of azoxystrobin to WW-USA did not take place in the United States, and that WW-Ltd did not import azoxystrobin into the United States. The district court therefore properly denied Syngenta's motion JMOL as to WW-Ltd's liability.

A. The District Court's Denial of Summary Judgment against WW-Ltd as to the Compound Patents Is Not Reviewable by This Court.

While Syngenta asserts that the issue before the district court was "purely a legal issue" predicated on undisputed facts (Br. at 60), the district court actually decided that there were several relevant issues of fact, in addition to the fact that WW-Ltd's sales of azoxystrobin to WW-USA were "f.o.b. Hong Kong," that should be decided by the jury. Appx0009. Moreover, although Syngenta now claims that the facts "did not change between summary judgment and trial" (Br. at 61), it argued to the district court that the facts became "vastly different" after Mr. Heinze's testimony, in a way that provided additional support for Syngenta's position. Appx06961 at 7:13-15. As discussed below, the jury plainly found that Mr. Heinze's testimony buttressed WW-Ltd's position, not Syngenta's.

Because the jury ultimately decided this issue on the merits based on the evidence presented at trial, the lower court's denial of summary judgment against WW-Ltd is not reviewable by this Court. *Ortiz v. Jordan*, 562 U.S. 180, 183-4 (2011); *Function Media, L.L.C. v. Google, Inc.*, 708 F.3d 1310, 1322 (Fed. Cir.

2013); *Glaros v. H.H. Robertson Co.*, 797 F.2d 1564, 1573 (Fed. Cir. 1986). Rather, this Court is limited to reviewing whether the lower court's denial of Syngenta's motion JMOL was proper in light of the evidence presented at trial. As discussed below, it was.

B. The District Court Properly Denied Syngenta's Motion JMOL as to WW-Ltd's Infringement of the Compound and Process Patents.

The shipments of azoxystrobin from WW-Ltd to WW-USA were made "f.o.b. Hong Kong," meaning that title to the goods passed to WW-USA in Hong Kong. Appx6794 at 23:12-18. This is a relevant fact in determining where the sale took place. *SEB S.A. v. Montgomery Ward & Co.*, 594 F.3d 1360, 1375 (Fed. Cir. 2010), *aff'd sub nom*. *Global Tech Appliances, Inc. v. SEB S.A.*, 563 U.S. 754 (2011). *See also Litecubes, LLC v. N. Light Prods*., 523 F.3d 1363, 1370 (Fed. Cir. 2008) (*quoting MEMC Elec. Materials, Inc. v. Mitsubishi Materials Silicon Corp.*, 420 F.3d 1369, 1377 (Fed. Cir. 2009) (sale f.o.b. outside the forum does not "necessarily" preclude a sale from occurring in the forum). In addition to the location where title to the goods at issue is transferred, factors such as "the place of performance" of the contract may be critical. *Transocean Offshore Deepwater Drilling, Inc. v. Maersk Contrs. USA, Inc*., 617 F.3d 1296, 1310 (Fed. Cir. 2010) (citing *Litecubes*, at 1371). The jury plainly found Mr. Heinze to be credible with respect to the following facts, which are sufficient to support its verdict as to WW-Ltd.

After purchasing azoxystrobin technical from TaiHe, WW-Ltd arranges for delivery of the product to WW-USA at a port in China –Shanghai or sometimes Hong Kong. Appx6794 at 24:11-16. WW-USA not only takes title to the product there, but it pays for an independent shipper to take possession of the product at the Chinese port for shipment to the United States. Appx6794 at 24:18–27:14; Appx6988 at 117:11-15. In addition, all decisions concerning how the product is to be shipped and to where it would be shipped in the United States were made by WW-USA. Appx6794 at 24:18-22; Appx6988 at 117:11-15. Upon the product's arrival at the chosen U.S. port, WW-USA, not WW-Ltd, was responsible for shepherding the product through customs and ensuring delivery to its ultimate destination (either for final product formulation or testing) in the United States. Appx6795 at 27:3-24.

Further, WW-USA, not WW-Ltd, made the arrangements to obtain the requisite registrations from the EPA. Appx6796 at 27:15-20; Appx6987 at 113:25-114:23. Mr. Heinze also testified that WW-USA, not WW-Ltd, markets and sells azoxystrobin products in the United States. Appx6715 at 106:15-16.

Syngenta relies heavily on a contract between WW-Ltd and Tai He, which indicates that WW-Ltd intended to apply for the necessary EPA approvals and was "desirous" of selling azoxystrobin in the United States. Br. at 62. Notwithstanding Syngenta's position and the contract's language, the jury was clearly entitled to credit Mr. Heinze's testimony that, in fact, WW-USA took care of the necessary

EPA registrations and only WW-USA, not WW-Ltd, was equipped to sell, and did sell, azoxystrobin products in the United States.

Taking all the evidence into account, drawing all reasonable inferences in the light most favorable to WW-Ltd, and without weighing the evidence or the witnesses' credibility, a reasonable jury could find as the jury found here – that WW-Ltd neither sold nor imported azoxystrobin technical in the United States. Accordingly, the district court properly denied Syngenta's motion JMOL.

C. The District Court Did Not Nullify the Jury's Verdict Concerning the '761 Patent.

In a last-ditch effort to overturn the district court's denial of its JMOL motion, Syngenta asserts that the court's ruling nullified the jury's purported verdict that all defendants infringed the '761 Patent. Br. at 68. Syngenta focuses on the fact that the question on the jury verdict form regarding whether WW-Ltd imported or sold azoxystrobin technical in the United States was placed under the heading "Compound Patents," and that this same question was not expressly repeated under the separate heading for "[t]he '761 Patent," which asked whether "the Defendants" infringed the '761 Patent. Appx0267-0268. Because the term "Defendants" was not specifically defined in that question, Syngenta concludes that the jury necessarily found that all Defendants, including WW-Ltd, infringed the '761 Patent.

Syngenta's hyper-parsing of the jury verdict form exalts form over substance and effectively ignores how the trial was conducted, what evidence the jury heard,

and what it actually found based on the evidence. Perhaps most important, Syngenta's argument implausibly assumes that in denying Syngenta's JMOL motion, the district court failed to understand its own instructions to the jury.

When Syngenta filed its motion for summary judgment, it argued that WW-Ltd should be found to have infringed both the Compound and Process Patents. Appx1617-1619; Appx1627-1633. The district court denied that motion, thus sending the issue of WW-Ltd's infringement of all patents to the jury. Appx0005. At trial, the jury heard evidence not only about WW-Ltd's provision of the 5 kg sample of azoxystrobin technical in 2013 (which is the sole basis for alleged infringement of the Compound Patents), it also heard evidence relating to WW-Ltd's subsequent sale of azoxystrobin technical in 2014 and beyond, after expiration of the Compound Patents and while the '761 Patent remained in effect. Indeed, as part of this appeal, Syngenta asserts that the evidence shows that WW-Ltd continued to sell azoxystrobin to WW-USA after expiration of the Compound Patents. Br. at 64.

The first question on the verdict form for the jury's consideration was whether Syngenta proved that "WW-Ltd imported…or otherwise sold or offered to sell azoxystrobin technical into the United States." Appx0266. This question was not limited to any specific time frame and, as noted, the evidence presented to the jury was likewise not time-limited. There is, therefore, no reason to assume that the jury's answer of "No" to that question was limited to Willowood's 2013 actions.

Consequently, the jury's verdict in responses to Questions 7 and 8 – that "the Defendants" did not carry their burden of proof as to non-infringement of the '761 Patent and that they owe Syngenta damages in the amount of $900,000 on account of that infringement – referred only to the U.S. defendants, not WW-Ltd. In denying Syngenta's motion JMOL, this is plainly how the district court construed its own instructions and the verdict form that it submitted to the jury. There is no basis for this Court to overturn that ruling.

V. The District Court Improperly Denied Willowood's Motions to Exclude the Testimony of Syngenta's Damages Expert.

It is well settled that the admissibility of expert testimony is a preliminary question of law for the trial court. *Daubert v. Merrell Dow Pharmaceuticals, Inc*., 509 U.S. 579 (1993). The proponent bears the burden of demonstrating its admissibility. *Bourjaily v. U.S.*, 483 U.S. 171, 175-76 (1987). In *Daubert*, the Supreme Court explained that the trial judge must perform a "gatekeeping" function to ensure that expert testimony "rests on a reliable foundation and is relevant to the task at hand." *Daubert*, 509 U.S. at 597. "When an expert opinion is based on data, methodology, or studies that are simply inadequate to support the conclusions reached, *Daubert* and Rule 702 mandate the exclusion of that unreliable opinion testimony." *Amorgianos v. National Railroad Passenger Corp.*, 303 F.3d 256, 266 (2d Cir. 2002). Thus, "any step that renders the analysis unreliable…renders the expert's testimony inadmissible." *Id.* at 267.

During the proceedings below, Willowood moved to exclude the opinions of Syngenta's damages expert, Dr. Ben Wilner, as unreliable. Appx3838-4078; Appx4461-4484. The court granted this motion in part, excluding Dr. Wilner's testimony as to approximately $210 Million of Syngenta's alleged $297 Million in damages purportedly incurred as a result Willowood's infringement of the Method Patents and copyrights on the grounds that he did not provide an adequate basis for his use of a key benchmark on which his entire opinion was premised. Appx09809-09810. The court, however, denied Willowood's motion as to Dr. Wilner's opinion regarding damages arising from Willowood's alleged infringement of the Compound Patents and further permitted Dr. Wilner to testify that Syngenta's damages arising from the alleged infringement of those patents were "at least as great as the [damages] for infringement of the Compound Patents." *Id.*[15] At trial, Willowood renewed its motion regarding Dr. Wilner's opinions, which were denied. Appx6961at 13:23-6963 at 16:9; Appx7045 at 94:10-11; Appx7072 at 9:10-16. As shown below, Dr. Wilner's opinions regarding Syngenta's damages allegedly incurred as a result of Willowood's infringement of the Compound Patents were based on unreliable data, and thus, his opinions should have been excluded.

[15] The jury ultimately rejected Dr. Wilner's opinions, instead adopting the testimony of Willowood's damages expert, John Jarosz, who opined that Syngenta's damages resulting from Willowood's infringement of the '761 Patent (the only other patent which the jury found had been infringed) was $900,000. Appx0266-0267.

A. Dr. Wilner's Opinions Were Based on Unreliable Data.

Dr. Wilner primarily relied on Syngenta's annual budgets for the sale of azoxystrobin products as a benchmark to calculate Syngenta's alleged damages related to the Compound Patents. Appx4113-4120; Appx6920 at 52:4-6922 at 59:9. Dr. Wilner calculated Syngenta's annual budget shortfalls for all azoxystrobin products in 2014 through 2017,[16] and then, with little justification, adjusted those shortfalls by the percentage which Syngenta failed to meet its budgets for those same years for mesotrione, an entirely different product applied to crops to combat weeds, whereas azoxystrobin combats certain fungal disease. *Id*. Using this method, Dr. Wilner calculated that Syngenta suffered damages totaling $85.6 Million (including interest). Appx3899-3904. Dr. Wilner's reliance on these budgets, however, was clearly insufficient under *Daubert*.

1. Syngenta Budgets are Inaccurate, and Thus, Unreliable.

Syngenta's budgets are wildly inaccurate. Appx6830 at 166:4-6832 at 175:21. Appx8941-8942. For example, Syngenta's 2009 azoxystrobin budget (five years before Willowood entered the market) overestimated both gross sales and profits by

[16] Syngenta asserted that Willowood's infringement of the Compound Patents caused it damages beginning in 2014 through 2017.

39%.[17] Appx8941-8942. Syngenta's 2010 budget was even farther off target as it overestimated gross sales by 39% and profits by 50%. *Id*. Syngenta's budgeting process remained highly inaccurate in 2011 when it underestimated gross sales and profits by 39%. *Id*. While Syngenta's 2012 budgets were relatively accurate, its budgets in 2013 (overestimates of gross sales and profit by 13% and 17%, respectively) and 2014 (overestimates of gross sales and profit by 24% and 26%, respectively) were, again, wildly inaccurate. *Id*.[18]

While Dr. Wilner did not rely the budgets of each individual product containing azoxystrobin offered for sale by Syngenta (he rather relied on only on budgets related to the sale of all azoxystrobin products combined), the budgets for each different azosystrobin-containing product sold by Syngenta are even less reliable, thus offering further proof that Syngenta's budgeting process is substandard, to say the least. In this regard, Syngenta's 2012 budgets for Syngenta's

[17] A table identifying Syngenta's azoxystrobin budgets versus actual sales for the years 2009 through 2016 was admitted into evidence at trial as DX 252. Appx8941-8942. Despite Syngenta's introduction of azoxystrobin to the market in 1997, Syngenta did not produce any financial information (budgets or sales data) prior to 2009. Thus, Willowood was unable to test Syngenta's budgeting acumen prior to that year.

[18] Willowood's damages expert, Mr. Jarosz, analyzed the impact of the budgets' unreliability and inaccuracy on the overall damages figure using Dr. Wilner's methodology. Appx7028 at 26:10-7029 at 28:16. He noted that if Syngenta's 2014 budget (which overestimated Syngenta's revenue by 24%) had been 20% lower, Syngenta's damages would have been zero using Dr. Wilner's methodology. *Id*.

eight azoxystrobin products ranged from overestimates of 42% to underestimates of 72%.[19] Appx09805-09806. Similarly, in 2013, Syngenta's budgets for its ten azoxystrobin products ranged from underestimates of 47% to overestimates of 28%. *Id*. Syngenta's budgets for the azoxystrobin products sold in 2014 and 2015 were no more accurate as they ranged from overestimates of 220% to underestimates of 165%. *Id*. Syngenta's non-azoxystrobin products budgets fare no better. For example, Syngenta's mesotrione budget projections for 2012 through 2015 range from overestimates of 100% to underestimates of over 5,000%.[20] Appx09807-09808.

Federal Rule of Evidence 702 makes clear that experts may offer opinions only if they are based on sufficient facts or data and are products of reliable principles and methods. Expert opinion based on inaccurate data is not sufficiently reliable to justify admission. For example, in *Sunlight Saunas, Inc. v. Sundance*

[19] A table identifying Syngenta's budgets versus actual sales of each azoxystrobin-containing product for the years 2012 through 2015 were attached to Willowood's Motion to Exclude Plaintiff's Damages Expert, Benjamin Wilner, as Exhibit C. Appx09805-09806. Syngenta did not produce budgets or other financial information for these products prior to 2012.

[20] A table identifying Syngenta's budgets versus actual sales of each mesotrione-containing product for the years 2012 through 2015 were attached to Willowood's Motion to Exclude Plaintiff's Damages Expert, Benjamin Wilner, as Exhibit D. Appx09807-09808. Syngenta did not produce budgets or other financial information for these products prior to 2012 despite sales of mesotrione products beginning in 2004.

Sauna, Inc., 427 F. Supp. 2d 1022 (D. Kan. 2006), defendants argued that the expert's methodology was flawed because "despite the historical inaccuracy of plaintiff's sales projections, [the expert] based his conclusions on the assumption that plaintiff...accurately projected its sales...." *Id*. at 1030. The court, after admonishing the expert for failing to independently analyze his client's projections, held that the expert's projections were

> more sleight of hand than consistent with generally accepted economic methodology. No reasonable jury would accept them as valid predictors of actual sales and [the expert's] opinions, which assume that the projections are [accurate], would not assist the trier fact.

Id. The court in *Celebrity Cruises Inc. v. Essef Corp.*, 434 F. Supp. 2d 169 (S.D.N.Y. 2006), came to a similar conclusion when it excluded two of the plaintiff's damages experts who based their opinions on the projected profits formulated by the plaintiff's management team. The court noted that the experts' lost profits analyses were flawed as the plaintiff's projections were inaccurate, and thus, unreliable. *Id*. at 184. "The [party's prognostications] are not enough" to justify admission of expert testimony based on those prognostications, the court held. *Id*. (*quoting Schonfeld v. Hilliard*, 218 F.3d 164, 173 (2d Cir. 2000)). *See also, Silicon Knights, Inc. v. Epic Games, Inc.*, 2011 WL 67448518, at *11 (E.D.N.C. Dec. 22, 2011) (holding that an expert's "projections…were based on unreliable and speculative forecasts," and therefore, his "claims for lost profits…were too speculative" to be admitted.).

Syngenta's budgets are the essential foundation for every opinion offered by Dr. Wilner. Indeed, Dr. Wilner conceded at trial that the accuracy of the budgets is critical to his damages model. Appx6935 at 109:12-23 ("If the bases of my model have inaccuracies, yes, my model would be inaccurate."). Yet, Dr. Wilner relied on historically inaccurate budgets. Accordingly, his opinions relying on those budgets were too unreliable to be admitted.

2. Dr. Wilner Failed to Verify Syngenta's Budgets.

Dr. Wilner's reliance on Syngenta's budgets is further flawed because he failed to test or verify the data on which they rely or the methodology by which they were prepared. Appx4113-4120. To understand the process by which Syngenta prepares its budgets, Dr. Wilner claims to have spoken to several Syngenta employees who told him that Syngenta engages in an 18-month process to determine the budget for any particular year, and that multiple people are involved in, and review, each budget. Appx6921 at 54:7-18. That is the extent to which he examined this allegedly "exacting" process.

However, while acknowledging that each product faces different market conditions "as exclusivity could change, new Syngenta products could be introduced, [competition and crop economics could change], [weather patterns could differ], *etc*." (Appx4113), Dr. Wilner failed to identify - in fact he did not even attempt to determine - what information was gathered by Syngenta in each year or

how that information was analyzed to derive an annual budget for each product. *Id*. As neither Dr. Wilner nor any other Syngenta witness offered any explanation for what factors were analyzed by Syngenta in preparing each budget or how those factors were taken into account when preparing each budget, Willowood was left to guess how Syngenta takes any information into account in preparing its budgets with no ability to validate or critique Syngenta's assumptions. Syngenta's budgeting process remained essentially a black box, and Dr. Wilner made no effort to open that box.

There is also no evidence that Dr. Wilner tested or validated Syngenta's assumptions in any way. Appx6936 at 114:10-23; Appx6937 at 117:12-118:10, 119:10-14. "When an expert relies on information given to [him] by a party or counsel, [he] must independently verify that information before utilizing it in his calculations." *King-Indiana Forge, Inc. v. Millennium Forge, Inc.*, 209 WL 3187685, at *2 (S.D. Ind. Sept. 29, 2009); *State Farm Fire & Cas. Co. v. Electrolux Home Prod., Inc.*, 980 F. Supp. 2d 1031, 1048 (N.D. Ind. 2013). An expert's reliance upon data supplied by counsel, without independent verification by the expert, is generally unreliable. *See, e.g., Munoz v. Orr*, 200 F.3d 291 (5th Cir. 2000).

In *Victory Records, Inc. v. Virgin Records America, Inc.*, 2011 WL 382743 (N.D. Ill. Feb. 3, 2011), plaintiff's expert relied on a benchmark to form the basis of his damages opinion. In excluding the expert's opinion, the court noted that an

expert's assumptions and projections must rest on "adequate bases," cannot be the product of mere speculation, and that if the principle assumptions underlying the expert's opinions lack the reliability expected by experts in the field, the opinion must be excluded. *Id*. at *1 (relying on *Park v. El Paso Bd. of Realtors*, 764 F.2d 1053, 1067 (5th Cir. 1985)). The court went on to hold that the expert's opinions, which were based primarily on the plaintiff's internal budgets, lacked the reliability demanded by Rule 702. *Id*. at *2. *See also, Zenith Elecs. Corp. v. WH-TV Broad. Corp.*, 795 F.3d 416, 420 (7th Cir. 2005) (a party's "internal projections...rest on its say so rather than a statistical analysis," and "represent hopes rather than the results of scientific analysis," and thus, opinions relying on them are generally inadmissible); *SF Meritor LLC v. Eaton Corp*., 646 F. Supp. 2d 663, 667 (D. Del. 2009) (excluding testimony of expert who "did not apply his own assumptions, based upon his expertise, to any financial data in order to project the party's future performance" but who instead "relied on" the party's own internal financial budgets "without knowing...the validity of the underlying data and assumptions upon which the [budgets] were based.").

The Court in *Victory Records* found the expert's opinions particularly concerning as he offered no basis for his conclusion that the plaintiff's internal projections provided an acceptable foundation for his opinion. *Victory Records*, at *2. *See also, Illinois Tool Works, Inc. v. MOC Prod. Co.*, 2012 WL 3561984, at *7

(S.D. Cal. Aug. 17, 2012) (despite expert's testimony that he based his reliance on "discussions" with plaintiff's employee that created the projections, the court refused to accept that "bear reliance on a 'rough estimate' given by [plaintiff's] own director of technology is the type of reliable method based on sufficient facts that *Daubert* envisions."); *Ask Chemicals, LP v. Computer Packages, Inc.*, 59 F. App'x 506, 510 (6th Cir. 2014) (holding that expert's "wholesale adoption of plaintiff's estimates, without revealing or…evaluating the bases for these estimates, goes beyond relying on facts or data and instead cloaks unexamined assumptions in the authority of expert analysis."); *Auto Indus. Supplier Stock Ownership Plan v. Ford Motors Co.*, 435 F. App'x 430, 454 (6th Cir. 2011) ("because [the expert] had no familiarity with the underlying source documents, he was not qualified to testify as an expert under Rule 702, because his expert opinion was not based on 'sufficient facts and data.'"). Similarly, where an expert's proffered opinion merely parrots information provided to him or her by a party, that opinion is generally excluded. *See, e.g. King-Indiana Forge, Inc., supra.; Ask Chemicals, LP*, *supra.*

While Dr. Wilner claimed to have learned of Syngenta's budget process through discussions with Syngenta employees, he offered no explanation or analysis of that process. More importantly, Dr. Wilner did not test or validate the accuracy of the budgets on which he relied. Instead, he simply adopted those budgets without review or analysis, thereby simply parroting Syngenta's beliefs about its future sales.

Thus, if any aspect of this case is remanded for a new trial or additional proceedings, Dr. Wilner's damages opinions should be excluded and Syngenta should be prohibited from offering any further expert evidence regarding its alleged damages.

CONCLUSION

For all the foregoing reasons, the Court should affirm the district court's grant of summary judgment in favor of Willowood on the copyright claims, affirm the district court's interpretation of 35 U.S.C. § 271(g) as requiring imposition of the single entity rule, affirm the district court's denial of Syngenta's motion JMOL with respect to non-infringement of the '138 Patent, and affirm the district court's denial of Syngenta's motion JMOL with respect to the liability of WW-Ltd (and, if appropriate, its denial of Syngenta's motion for summary judgment on that issue). Moreover, in the event this Court reverses and remands either (or both) the issue of copyright infringement or infringement of the '138 Patent, then the Court should also reverse the district court's partial denial of Willowood's *Daubert* motion, with instructions that on remand, Syngenta shall be precluded from submitting new or revised expert reports on damages.

Dated: June 8, 2018

Respectfully Submitted,

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CERTIFICATE OF FILING AND SERVICE

I hereby certify that on this 8th day of June, 2018, I caused this Corrected Brief of Cross-Appellants to be filed electronically with the Clerk of the Court using the CM/ECF System, which will send notice of such filing to all registered CM/ECF users.

Upon acceptance by the Clerk of the Court of the electronically filed document, the required number of copies of the Corrected Brief of Cross-Appellants will be hand filed at the Office of the Clerk, United States Court of Appeals for the Federal Circuit in accordance with the Federal Circuit Rules.

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CERTIFICATE OF COMPLIANCE

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Dated: June 8, 2018

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