No. 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.

Appeal 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

APPELLANT SYNGENTA CROP PROTECTION, LLC'S CORRECTED RESPONSE AND REPLY BRIEF

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July 16, 2018	

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Abbreviation	Reference
Br.	Corrected Opening Brief of Appellant Syngenta Crop Protection, LLC
Opp.	Corrected Brief of Cross-Appellants
W-USA	Willowood USA, LLC
W-Ltd	Willowood Limited
W-LLC	Willowood, LLC
BIO Br.	Brief of Biotechnology Innovation Organization and CropLife International as *Amici Curiae*
NYIPLA Br.	Brief for *Amicus Curiae* New York Intellectual Property Law Association
NYIPLA	New York Intellectual Property Law Association
Generics Br.	Brief of *Amici Curiae* Aceto Agricultural Chemicals, Inc., *et al*.
Generics	Aceto Agricultural Chemicals, Inc., *et al.*
DOJ Br.	Brief for the United States as Amicus Curiae
EPA	U.S. Environmental Protection Agency
FIFRA	Federal Insecticide Fungicide and Rodenticide Act
Compound Patents	U.S. Patent Nos. 5,602,076 and 5,633,256
'138 Patent	U.S. Patent No. 5,847,138
'761 Patent	U.S. Patent No. 8,124,761
JMOL	Judgment as a Matter of Law

INTRODUCTION

Willowood asks this Court to affirm the decision below, which held that FIFRA precludes Syngenta's copyright claims, thereby creating an exception to copyright infringement for generic pesticide labels. To that end, Willowood, with amici Generics and the government, collectively devote over fifty-two pages to defending the district court's two-paragraph order. It is for Congress to create any such exceptions, and Congress has not done so.

Fundamentally, Willowood, Generics, and the government subscribe to the same legal errors that the district court made. They assert that FIFRA and copyright law are in conflict, or alternatively that FIFRA purportedly "authorizes" copying. In doing so, they misapprehend the nature of copyright protection and improperly equate "identically or substantially similar" pesticide labels with labels that are "copied." But as long as a generic manufacturer independently creates its label and does not copy (as Willowood did), there can be no copyright infringement, even if the resulting label is substantially similar. *Selle v. Gibb*, 741 F.2d 896, 901 (7th Cir. 1984). Moreover, reasoning that FIFRA's expedited review of generic products with "substantially similar or identical

compositions and labels" is an authorization to copy would eviscerate other forms of intellectual property embodied in the registered product.

Willowood, Generics, and the government also assume that pesticide labels consist entirely of "required elements" mandated by FIFRA or the EPA. But it is undisputed that substantial portions of pesticide labels simply are not required, or even suggested, by FIFRA or the EPA. Thus, in precluding any and all copyright protection in pesticide labels, the district court erred.

Notably, Willowood, Generics, and the government fail to identify any sound statutory basis or shred of legislative history to demonstrate that FIFRA precludes copyright protection in pesticide labels. At most, they complain it would be difficult to comply with both FIFRA and copyright law, and make unfounded predictions of dire consequences. If anything, these concerns are best addressed to Congress, not this Court. And in the words of the Supreme Court, "[p]erhaps the best indication that the sky will not fall [] is that it has not done so already." *Melendez-Diaz v. Mass.*, 557 U.S. 305, 325 (2009). It has been nearly fourteen years since the district court in *FMC* held that pesticide labels are entitled to copyright protection (contrary to the district court below). *FMC Corp. v.*

Control Sols., Inc., 369 F. Supp. 2d 539 (E.D. Pa. 2005). Yet Generics and the government have identified no evidence that the EPA has come to a grinding halt or that generic manufacturers have suffered anticompetitive effects under the status quo.

Next, in trying to defend the district court's order that the single-entity rule of 35 U.S.C. § 271(a) applies to § 271(g), Willowood disregards the plain language of § 271(g) and the cases that support interpreting § 271(g) according to that plain language. Instead, Willowood misconstrues the legislative history to argue that a single-entity rule is consistent with the alleged "purpose" of § 271(g). However, the legislative history of § 271(g) does not support Willowood's argument, and in any event, it cannot override the statute's plain language. Willowood's new argument concerning the "extraterritorial effect" of § 271(g) in the absence of a single-entity rule similarly lacks merit, and the premise for Willowood's argument was just recently rejected by the Supreme Court. Moreover, even if this Court were to apply a single-entity rule to § 271(g), the jury's verdict under that interpretation is not supported by substantial evidence, and Willowood fails to rebut Syngenta's arguments in this regard.

Nor did the jury have a legally sufficient evidentiary basis to find that W-Ltd did not infringe the Compound Patents. Regardless of whether W-Ltd sold 5 kg of azoxystrobin in the United States in 2013 (and the record confirms W-Ltd did), Willowood has not rebutted Syngenta's argument that W-Ltd's shipment of that azoxystrobin to the United States was an infringing "import" under the plain meaning of that word. Willowood also fails to rebut Syngenta's argument that the district court erroneously nullified the jury's verdict that all defendants, including W-Ltd, infringed Syngenta's '761 Patent.

Finally, this Court should dismiss Willowood's conditional cross-appeal, directed to damages opinions that Syngenta's expert may or may not offer on remand, because this this Court lacks jurisdiction over this procedurally improper cross-appeal. Willowood admits that it does not challenge the district court judgment or damages award. What Willowood seeks is essentially an advisory opinion on fact-intensive evidentiary issues that should be left to the district court to decide in the first instance on remand. Even if this Court were to entertain Willowood's cross-appeal, Willowood does not show that the district court abused its discretion.

REPLY IN SUPPORT OF SYNGENTA'S APPEAL

I. FIFRA Does Not Preclude Copyright Protection of Pesticide Labels.

Notwithstanding the sheer number of pages they devote to the copyright issue in this appeal, Willowood, Generics, and the government subscribe to the same fundamental legal errors that the district court made. Therefore, this Court should vacate the district court's ruling and remand for further proceedings with respect to Syngenta's copyright claims.

A. Willowood, Generics, and the Government Conflate "Identical or Substantially Similar" with "Copied."

As did the district court, Willowood, Generics, and the government misapprehend copyright law and improperly equate an identical or substantially similar label with one that is copied. *See, e.g.*, Opp. at 13, 15, 22; Generics Br. at 7-10; DOJ Br. at 2, 14-16, 20. It is well established, however, that copyright infringement requires copying, and "no matter how similar [] two works may be (***even to the point of identity***), if the defendant did not ***copy*** the accused work, there is no infringement." *Selle*, 741 F.2d at 901 (emphasis added). Thus, Willowood's insistence

that "FIFRA Plainly Authorizes Copying of Pesticide Labels" is wrong.[1] *See* Opp. at 13. At most, FIFRA provides for the expedited review of generic pesticides that are "identical or substantially similar in composition and labeling to a currently registered product." 7 U.S.C. § 136a(c)(3)(B)(i)(I). That is not the same thing as authorizing, much less requiring, copying.

Taken to its logical conclusion, Willowood's reasoning would lead to absurd results and essentially eviscerate any intellectual property that the original registrant holds in its product and label. Applying Willowood's reasoning, a generic manufacturer could argue that FIFRA authorizes it to disregard applicable trademark protection and copy the original registrant's trademark and trade name, and even use the same pictures as found on an original registrant's label, because that would ensure that the labels are identical. Yet, even Willowood found that reasoning to be improper and corrected references to "Syngenta" that

[1] Also contrary to well-established law is the government's contention that "substantial similarity is the test for copyright infringement." DOJ Br. at 21. Substantial similarity is only a proxy for demonstrating copying, which is what constitutes copyright infringement, and an inference of copying based on substantial similarity may be rebutted. *Keeler Brass Co. v. Cont'l Brass Co.*, 862 F.2d 1063, 1065 (4th Cir. 1988).

Willowood mistakenly included in early versions of its label that copied Syngenta's label. Opp. at 19; Br. at 19-20.

Similarly, under Willowood's reasoning, a generic manufacturer could argue that FIFRA authorizes it to infringe the original registrant's patents on the composition of the pesticide, because that would ensure the product is identical or substantially similar in composition to the registered product.[2] But surely, that too cannot be the case, as even Willowood does not challenge on appeal the judgment entered against it for infringement of Syngenta's Compound Patents. *See* Opp. at iii-v.

Instead of interpreting FIFRA as completely precluding copyright protection in pesticide labels, the proper approach is to give force to both FIFRA and copyright laws, as expected under the rules of statutory construction. Contrary to Willowood's assertion, courts may not simply interpret two statutes to "preserve[] the principal purposes of each" (Opp. at 21), but must "regard each as effective," barring "a clearly expressed

[2] Using Willowood's reasoning, a generic manufacturer could even go so far as to argue that FIFRA authorizes it to infringe a patent on the method of manufacturing the pesticide product, because the method of manufacturing could affect the impurity profile of the product such that it was not "identical or substantially similar" to the composition of the registered product. *See* Appx6964 at 20:11-22:22; Appx7478-7480.

congressional intention to the contrary." *Ruckelshaus v. Monsanto Co.*, 467 U.S. 986, 1018 (1984) (quoting *Reg'l Rail Reorg. Act Cases*, 419 U.S. 102, 133-34 (1974)); *see also Morton v. Mancari*, 417 U.S. 535, 551 (1974) ("The courts are not at liberty to pick and choose among congressional enactments, and when two statutes are capable of co-existence, it is the duty of the courts, absent a clearly expressed congressional intention to the contrary, to regard each as effective."); *Zenith Elecs. Corp. v. Exzec, Inc.*, 182 F.3d 1340, 1347 (Fed. Cir. 1999) (explaining that the first principle in a case involving two statutes "is to give effect to each federal law. Each has equal standing, and equal claim for recognition.").

Here, FIFRA and copyright law are compatible—a generic manufacturer may submit an identical or substantially similar label to that of a registered pesticide, as contemplated by FIFRA, but may not simply copy the entirety of the registered pesticide's label, including both required and non-required elements of the label, as prohibited by copyright law. *See POM Wonderful LLC v. Coca-Cola Co.*, 134 S. Ct. 2228, 2240 (2014) ("[N]either the statutory structure nor the empirical evidence [] indicates that there will be any difficulty in fully enforcing each statute according to its terms."). Alternatively, a generic

manufacturer may obtain authorization from the original registrant so that it may lawfully copy the original registrant's label.

Willowood does not identify anything in FIFRA's statutory language or its legislative history that conveys any clear expression of congressional intent to preclude copyright protection. *See id.* at 2237 (reasoning that no "textual provision in either statute discloses a purpose to bar" claims under the other statute). Nor does Willowood identify any actual EPA policy that requires copying. Indeed, in describing the amendments that Willowood made to its label after Syngenta filed its complaint, the government never states that Willowood had to "copy" Syngenta's label to satisfy the EPA. DOJ Br. at 10. Instead, the government is careful to say only that the "EPA required several additional revisions to the labels to improve clarity and ensure satisfaction of FIFRA's standards." *Id.* Similarly, Willowood, when describing the same revision process, also does not state that it had to copy Syngenta's labels, just that the "process was neither quick nor easy." Opp. at 19; *see also* Generics Br. at 7-10 (arguing that it is more difficult to create a label independently than it is to copy one).

Whether independently creating a label takes more work than copying an existing label, however, does not justify overriding copyright protection in pesticide labels. And no one is trying to make review of pesticide labels more difficult for the EPA by asking it to review the labels of generic manufacturers "in relation to copyright law," as Willowood suggests. *See* Opp. at 19. The responsibility lies with generic manufacturers to create a label that satisfies the EPA's requirements and respects copyright laws. Moreover, even if a generic manufacturer's label were identical or substantially similar to the original registrant's label, it would not infringe the original registrant's copyright if it was independently created. *See Keeler*, 862 F.2d at 1065 (explaining that a defendant may rebut a presumption of copying "with evidence of independent creation").[3]

Because an identical or substantially similar label is not necessarily one that is copied, there is no basis for Willowood's speculation that

[3] Notably absent from both Willowood and the government's recitation of the facts is that Willowood admitted to copying Syngenta's labels. Br. at 19-20. Syngenta's copyright claims are based on the fact that Willowood ***copied*** Syngenta's labels, not simply that Willowood's labels were "substantially similar." DOJ Br. at 10; Appx285-286 (¶¶ 80, 85), Appx290 (¶ 112), Appx291 (¶ 122).

Congress intended FIFRA to preempt copyright protection in pesticide labels. *See* Opp. at 14. Generic manufacturers are given the benefit of an expedited review for EPA approval of an already-approved pesticide, without having to develop or test the product, in order to enter a market built by the original registrant. The alleged "pro-competitive" purpose of 7 U.S.C. § 136a(c)(3)(B)(i)(I) does not mean that generic manufacturers also can ignore copyright laws and free-ride off of the efforts of original registrants by copying the entirety of their labels.

B. Willowood, Generics, and the Government Assume that All Elements of a Pesticide Label are "Required Elements."

Syngenta does not dispute that certain portions of a pesticide label may be mandated or suggested by the EPA (e.g., certain precautionary statements and hazard language), and has made clear that its copyright claims are not directed to these "required elements." *See* Appx2805-2806. But Willowood, Generics, and the government improperly assume that the ***entirety*** of a pesticide label consists of such "required elements." Opp. at 22; DOJ Br. at 11-13, 15. In fact, Willowood goes so far as to say that applying copyright protection "to ***any portion*** of [Syngenta's] labels would entirely negate" the permission that FIFRA purportedly grants a

generic manufacturer to submit a label identical to that of a registered pesticide. Opp. at 16 (emphasis added). This ignores that many aspects of a pesticide label are not mandated or even suggested by the EPA.

For example, Syngenta attached to its complaint copies of Willowood azoxystrobin product labels, with the language Willowood copied from Syngenta's labels for corresponding products highlighted. Appx2794, Appx9704-9787. In support of its summary judgment motion, Willowood submitted a declaration by its regulatory consultant, Janelle Kay, in which she further annotated those labels, crossing out any highlighted language that purportedly was required, or suggested by the EPA. Appx773-774. A review of those annotated labels shows that significant portions of those labels include information that is neither mandated nor suggested by the EPA, and for which Syngenta is entitled to copyright protection.[4] Appx781-862.

[4] Syngenta understands the district court's reference to "the required elements of pesticide labels" to refer to the portions of a pesticide label where the EPA mandates the specific language that must be used. *See* Appx33-34. The EPA may require certain categories of information, but not specify the language that must be used for those categories. *See* Br. at 27-31.

For its part, the government is inconsistent as to which parts of a pesticide label it contends are supposedly required. The government acknowledges "FIFRA would not preclude any copyright claims based on" "elements of a label that FIFRA does not require." *See* DOJ Br. at 17 n.4. It also states that the composition and label of a generic pesticide must be the same only "in broad terms." *Id.* at 16. Elsewhere, however, the government does not make those qualifications. For example, despite conceding that only a portion of the label includes the "critical health and safety information" mandated by FIFRA, *id.* at 15, the government asserts in blanket fashion that "Congress wanted and expected [generic] applicants to copy the original EPA-approved labels," *id.*

Further, although Syngenta does not agree with the NYIPLA's assessment of the level of copyright protection that a pesticide label should be afforded,[5] the NYIPLA does identify various categories of information that are not required by FIFRA or the EPA, demonstrating that a pesticide label contains more than just "required elements."

[5] Among other things, the NYIPLA discusses various copyright doctrines that may or may not apply to the contents of a pesticide label, which the district court never addressed. NYIPLA Br. at 20-25. Such issues of copyrightability should be left to the district court to decide in the first instance.

NYIPLA Br. at 20-25. The most that the district court found was that FIFRA precludes copyright protection of the "required elements" of a pesticide label. Appx33. Thus, as the NYIPLA puts it: it was "error [for the district court] to say that a FIFRA-compliant label will be *per se* infringing (and further error to infer preclusion from that)." *Id.* at 22.

C. The Government Overstates the Impact of Finding FIFRA Compatible with Copyright Law.

Claiming the sky will fall, the government asserts that FIFRA's scheme "could not function" unless FIFRA precludes copyright protection in pesticide labels. DOJ Br. at 13; *see also id.* at 14 (asserting "scheme is unworkable"). But in 2005, a district court affirmatively held that FIFRA does not conflict with copyright law and does not require "verbatim or nearly wholesale copying of another registrant's label … to obtain expedited review by the EPA of a label." *FMC*, 369 F. Supp. 2d at 560. "Perhaps the best indication that the sky will not fall [] is that it has not done so already." *Melendez-Diaz*, 557 U.S. at 325. The government's arguments amount to unsubstantiated policy arguments, which are best directed to Congress, not the courts.

The government argues it "would be impracticable" to provide expedited review of pesticide labels if FIFRA does not preclude copyright

law. DOJ Br. at 12. But it does not identify any evidence that the EPA has been unable to provide that expedited review to generic manufacturers since *FMC* was decided nearly fourteen years ago, or even that the process for reviewing generic applications has slowed down since *FMC*. Willowood and Generics similarly do not identify any such evidence. To the contrary, Generics, by their own admission, have been operating under the understanding that courts will enforce both FIFRA and copyright law consistent with *FMC* since 2005, and they do not argue that it is impossible to comply with both laws or that the "scheme is unworkable," only that it is harder to comply with both laws.[6] Generics Br. at 7, 9. But the fact that it might be harder to comply with both laws does not justify precluding copyright protection in pesticide labels.

The government also overstates the competitive effect on generic manufacturers if FIFRA is not found to preclude copyright protection in pesticide labels. *See* DOJ Br. at 1 ("The question in this case is whether a brand-name pesticide manufacturer can effectively prevent [generic]

[6] Generics also offer no support for their speculation that more copyright claims will be filed against generic manufacturers (compared to the "several" that have been filed and settled over the past decade) if the status quo is maintained, and they fail to acknowledge that if a label is not copied, it does not infringe a copyright. Generics Br. at 9-10.

competition by asserting copyright-infringement claims based on the label."). To be sure, the government does not identify any evidence that there has been an anti-competitive effect on generic manufacturers since *FMC* was decided, and it offers no support for the idea that generic manufacturers are being kept out of the relevant pesticide markets for "the nearly century-long term of the copyright." DOJ Br. at 19.

D. This Court Should Not Address Issues of Copyrightability in the First Instance.

As an alternative ground for upholding the district court's summary judgment ruling, Willowood argues that Syngenta's pesticide labels are not copyrightable for various reasons. Opp. at 22-27. The district court, however, never reached the question of what aspects of Syngenta's labels are copyrightable because of its erroneous holding that FIFRA precludes ***any*** copyright protection in pesticide labels. Appx33-34. Therefore, arguments as to copyrightability are "not ripe as grounds for this [C]ourt to sustain the district court's summary judgment order." *Semcon Tech, LLC v. Micron Tech., Inc.*, 660 Fed. App'x 908, 914-15 (Fed. Cir. 2016)

(declining to consider alternative grounds for upholding the district court's ruling that the district court's order did not address).[7]

In any event, the originality required for a work to be entitled to copyright protection is low—it "means only that the work was independently created by the author (as opposed to copied from other works), and that it possesses at least some minimal degree of creativity." *Feist Publ'ns, Inc. v. Rural Tel. Serv. Co.*, 499 U.S. 340, 345 (1991) (emphasis added). "Others may copy the underlying facts from the publication, but not the precise words used to present them." *Id.* at 348. As the court in *FMC* held, a pesticide label "is the proper subject of a copyright," and there is "no reason to afford any less copyright protection to the partially regulated instructions on a commercial product label than

[7] The government similarly argues that this case could be decided on the alternative ground that Willowood's labels are a "fair use" of Syngenta's copyrighted labels. DOJ Br. at 22-28. In addition to the fact that the district court did not make any findings on this issue in the first instance, neither Willowood nor Syngenta has raised the issue before this Court. As the government recognizes, "analyzing fair use 'is not to be simplified with bright-line rules, for the statute, like the doctrine it recognizes, calls for case-by-case analysis.'" DOJ Br. at 23 (quoting *Campbell v. Acuff-Rose Music, Inc.*, 510 U.S. 569, 577 (1994). Given the need for an analysis specific to the facts of this case, and the fact this Court does not have the benefit of the full record on this issue before it, it should decline the government's invitation to address fair use.

to the instructions on a non-regulated or regulated consumer product label." 369 F. Supp. 2d at 561.

Moreover, the "merger doctrine" that Willowood cites (Opp. at 23) applies only to situations "[w]hen there is essentially only one way to express an idea." *Soc'y of Holy Transfiguration Monastery, Inc. v. Gregory*, 689 F.3d 29, 53 (1st Cir. 2012); *see also Decker Inc. v. G & N Equip. Co.*, 438 F. Supp. 2d 734, 741-42 (E.D. Mich. 2006) (holding that merger doctrine did not preclude copyrightability of descriptions in product catalog); *FMC*, 369 F. Supp. 2d at 566-67 (same as to pesticide labels). Here, the fact that Willowood was able to revise its azoxystrobin labels in such a way as to satisfy the EPA demonstrates that there is more than one way to express the ideas found in Syngenta's azoxystrobin labels. Appx2793-2794.

In short, the copyrightability of Syngenta's product labels is a question best left for the district court to resolve in the first instance, with the benefit of a full record.

II. The "Single Entity" Rule Does Not Apply to 35 U.S.C. § 271(g).

In trying to defend the district court's order, Willowood ignores the plain language of § 271(g), misrepresents § 271(g)'s legislative history, and raises unfounded concerns about the "extraterritorial" effect of § 271(g) if the single-entity rule were not applied to it. Therefore, this Court should reverse the district court's entry of judgment in favor of Willowood regarding infringement of the '138 Patent.

A. Willowood Does Not Identify Any Support in the Statutory Language or Related Case Law that Supports Reading a Single-Entity Rule into § 271(g).

Willowood makes no attempt to identify support in the plain language of § 271(g) for a single-entity rule, and it does not identify any applicable case law support for its position. Rather, Willowood makes a failed attempt to distinguish Syngenta's cited authorities.

As Syngenta explained in its opening brief, the plain language of § 271(g) does not impose a single-entity rule, because it uses passive language to specify "a product made by a process patented in the United States." Br. at 42-46 (citing cases). This passive language does not place any limits on who made the product by a patented method—whether one entity or multiple entities. *See, e.g.*, *Dean v. United States*, 556 U.S. 568,

571-72 (2009) (explaining that passive language does not limit the number of actors); *Special Devices, Inc. v. OEA, Inc.*, 270 F.3d 1353, 1355 (Fed. Cir. 2001) (same); *Zoltek Corp. v. United States*, 672 F.3d 1309, 1327 (Fed. Cir. 2012) (en banc) (approving infringement theory under § 271(g) involving multiple entities carrying out claimed process); *Trs. of Columbia Univ. in City of N.Y. v. Roche Diagnostics GmbH*, 272 F. Supp. 2d 90, 108 (D. Mass 2002) (explaining that § 271(g) does not limit who makes the product).

Willowood acknowledges that § 271(g) uses passive voice, but dismisses the statutory language and the entire body of case law that addresses the proper interpretation of such language. According to Willowood, Syngenta's cited cases are inapplicable because the statutory interpretations adopted in those cases were consistent with the legislative history, whereas (in Willowood's view) Syngenta's interpretation of § 271(g) is not. Opp. at 32-34. Willowood's reasoning, however, falls short. As an initial matter, Syngenta's interpretation of § 271(g) ***is*** consistent with the legislative history of the statute, as discussed below.

More fundamentally, Willowood offers no basis to cast aside the unambiguous, plain language of § 271(g) in view of policy rationales that Willowood selectively gleans from the legislative history. As the Supreme Court has explained, "[t]he plain words and meaning of a statute cannot be overcome by a legislative history which, through strained processes of deduction from events of wholly ambiguous significance, may furnish dubious bases for inference in every direction." *See Gemsco, Inc. v. Walling*, 324 US 244, 260 (1945); *see also United States v. Oregon*, 366 U.S. 643, 648 (1961); *Ex parte Collett*, 337 U.S. 55 (1949). Indeed, the cases Syngenta cites do not hinge on interpretations of legislative history, but rather on the plain language of the statute at issue. *See, e.g., Dean*, 556 U.S. at 571-72 ("We start, as always, with the language of the statute.").

Willowood's analysis of *Roche* is similarly flawed. Opp. at 34-35. In *Roche*, the issue was not whether a single entity performed the patented process overseas, as Willowood appears to suggest—it was whether the product that Roche shipped to the United States was, in fact, manufactured using the patented process. 272 F. Supp. 2d at 100. The court explained that "it is irrelevant under Section 271(g) who

manufactured the goods as long as the goods were manufactured using a patented process." *Id.* at 108. Thus, the court found that the passive language of § 271(g) does not impose any limitations on who performs the patented process.

This Court went even further in its *en banc* decision in *Zoltek*, where it approved an infringement theory under 28 U.S.C. § 1498(a) that was based on actions that this Court found would amount to direct infringement under § 271(g), even though the two steps of the process patent at issue were performed by *different entities in different locations*. 672 F.3d at 1326-27. Willowood responds that *Zoltek* "did not provide any analysis of § 271(g)" and should not be considered because it would be inconsistent with the legislative purpose of § 271(g). Opp. at 35-37. To the contrary, this Court expressly addressed direct infringement under § 271(g) at length as a basis for liability under §1498(a). *Zoltek*, 672 F.3d at 1323. This Court further stated that its conclusion "is supported by precedent; ***the legislative histor[y] of … the enactment of section 271(g)***; and Congress's intent to create a comprehensive scheme meant to protect contractors, inventors, and the United States." *Id.* at 1326 (emphasis added).

The only new authority that Willowood cites is an unpublished ITC case that interprets 19 U.S.C. § 337(a)(1)(B)(ii), which Willowood seeks to analogize to § 271(g). Opp. at 37-38 (citing *In re Matter of Certain Rubber Antidegradants*, No. 337-TA-533, 2008 WL 1727623 (I.T.C. Apr. 2008)). As an initial matter, Willowood did not raise this argument before the district court; nor is it responsive to any new issue raised by the district court's order or Syngenta's brief. *See* Appx2551-2556; Appx14; Br. at 41-48. It is also disingenuous for Willowood to argue that the proper interpretation of § 271(g) ***can*** be gleaned from the ITC's interpretation of § 337(a)(1)(B)(ii), while simultaneously arguing that the proper interpretation of § 271(g) ***cannot*** be gleaned from this Court's interpretation of 28 U.S.C. § 1498(a) in its *en banc Zoltek* decision. Opp. 35-38.

Regardless, the ITC based its decision in *Rubber Antidegradants* on the fact that § 337(a)(1)(B)(ii) was specifically enacted to overrule this Court's predecessor's decision in *Amtorg*, a case that the ITC noted did not concern whether a single entity or multiple entities performed the claimed process. 2008 WL 1727623, at *19 (citing *In re Amtorg Trading Corp.*, 75 F.2d 826 (C.C.P.A. 1935)). Thus, the ITC reasoned "it is going

too far to say that Congress intended to address an issue [in § 337(a)(1)(B)(ii)] that was not present in [*Amtorg*]." *Id.* In contrast, Congress's intent in enacting § 271(g) was not to overrule a specific case, but to address more broadly concerns about a gap in the protection offered to process-patent owners.

In short, Willowood fails to overcome the plain language of § 271(g) and the prevailing case law addressing the proper interpretation of such case law.

B. The Legislative History of § 271(g) Does Not Support Imposing a Single-Entity Rule.

Willowood mischaracterizes the legislative history of § 271(g) to assert that the single-entity rule of § 271(a) should be read into § 271(g). *See* Opp. at 30-35. The legislative history as a whole, however, confirms that Congress did not intend to limit § 271(g) as Willowood suggests.

First, Willowood relies on an out-of-context portion of the legislative history that does not support importing a single-entity rule into § 271(g). Opp. at 30-31 (citing S. Rep. No. 100-83 at 27-28). Notably, this portion of the legislative history refers to the obligation of the United States under its trade treaties to apply § 271(g) uniformly, regardless of "whether the product was made (and the process used) in this country or

in a foreign country." S. Rep. No. 100-83 at 27. In this context, Congress contemplated that § 271(g), if applied uniformly to products manufactured both domestically and abroad, would have little practical impact in enforcing patents against domestic manufacturers.

The language Willowood cites does ***not*** suggest, however, that Congress intended § 271(g) to offer process-patent owners the same protection against overseas manufacturers as they ***already*** enjoyed against domestic manufacturers through other provisions of § 271, as Willowood argues. Opp. at 30. Indeed, the legislative history expressly states that the "purpose of [the] amendment" that resulted in § 271(g) was to "provide[] patent owners the ***new*** right to sue for damages" for the sale, offer for sale, use or importation "into the United States a product made by their patented process."[8] S. Rep. No. 100-83 at 13 (emphasis added).

Second, Congress found that the law, as it existed before § 271(g) was enacted, provided "inadequate protection" and expressed a clear

[8] Willowood's reliance on the alleged "stated purpose" of § 271(g) to respond to BIO/CropLife's argument regarding the discovery issues that would arise if the single-entity rule were applied to § 271(g) is misplaced because it misrepresents this "stated purpose." Opp. at 38-39.

intent that § 271(g) would expand the protections offered to owners of process patents directed to "method[s] of manufacture." S. Rep. No. 100-83 at 13-14. Congress was especially concerned that process patents were being circumvented by "the entry of the goods made elsewhere [outside of the U.S.]," which "clearly encroached[d] on the rights of the patent owner." *Id.* at 14.

Congress also noted that other industrialized nations had given "uniform, full protection" to both product and process patents, while the United States treated the two differently. S. Rep. No. 100-83 at 20. That is, before § 271(g) was enacted, product-patent owners had the right to exclude others from making, using, or selling their claimed invention, whereas process-patent owners only had the right to exclude others from using the claimed invention. *Id.* at 14. By enacting § 271(g), Congress sought to expand the rights of process-patent owners "to also cover the importation, use or sale in the United States of products resulting from the process." *Id.* at 14; *see also id.* at 22.

Third, the language Congress chose to use in § 271(g), as compared to § 271(f), is instructive. Infringement under § 271(f) is limited to situations where the components supplied from the United States are

going to be combined overseas "in a manner that would infringe the patent if such combination occurred within the United States." 35 U.S.C. § 271(f); *see also* BIO Br. at 10-11. If Congress similarly wished to limit infringement under § 271(g), it could have chosen to draft § 271(g) to refer to "a product which is made by a process that is patented in the United States *where that process is performed in a manner that would infringe the patent if performed in the United States*," akin to the language in § 271(f) (enacted four years before § 271(g)).

In fact, Congress has often borrowed limiting language from other statutory provisions when it intends to import similar limitations. *See Lamar, Archer & Cofrin, LLP v. Appling*, 138 S. Ct. 1752, 1761 (2018) (explaining that where Congress did not use language limiting the scope of a statute, the statute should not be interpreted as being so limited, especially where Congress used limiting language elsewhere in the code). Congress did not choose to do so with respect to § 271(g), however, and the "single-entity" rule of § 271(a) should not be read into § 271(g). *See Diamond v. Diehr*, 450 U.S. 175, 182 (1981) ("[W]e have more than once cautioned that courts should not read into the patent laws limitations

and conditions which the legislature has not expressed." (internal citations and quotation marks omitted)).

C. Section 271(g) Does Not Require a Single-Entity Rule to Prevent Extraterritorial Effect.

Willowood also raises a new argument that the single-entity rule should be applied to § 271(g) to prevent "broaden[ing] the extraterritorial effect of the Patent Act." Opp. at 31; *see also id.* at 41-42. Nothing about § 271(g), however, is directed to extraterritorial conduct.

To determine whether a patent statute has an extraterritorial effect, a court must identify the "focus" of the statute and "ask[] whether the conduct relevant to that focus occurred in United States territory." *WesternGeco LLC v. ION Geophysical Corp.*, 138 S. Ct. 2129, 2136 (2018). Applying this principle to § 271(f)(2), the Supreme Court recently found that "[t]he conduct that § 271(f)(2) regulates—*i.e.*, its focus—is the domestic act of 'suppl[ying] in or from the United States.'" *Id.* at 7 (citations omitted). Similarly, the "focus" of § 271(g) is the domestic act of "import[ing] ***into the United States*** or offer[ing] to sell, sell[ing], or us[ing] ***within the United States*** a product made by a process patented in the United States." 35 U.S.C. § 271(g) (emphasis added). Any "overseas events," such as the use of the patented process, are "merely

incidental to the infringement" and "do not have 'primacy' for purposes of the extraterritoriality analysis." *WesternGeco*, 138 S. Ct. at 2138 (citations omitted).[9]

Therefore, there is no basis for Willowood's contention that in the absence of a single-entity rule, § 271(g) would raise extraterritoriality concerns. *See* Opp. at 41.

III. The Jury's Verdict That Willowood Did Not Infringe the '138 Patent Is Not Supported by Substantial Evidence.

The district court also erred in denying Syngenta's motion for JMOL that Willowood infringed the '138 Patent. If the single-entity rule applies to § 271(g) (which it does not), no reasonable jury could have found that Tai He did not perform all the steps of the '138 Patent's process, or that Willowood did not control or direct the performance of those steps.

In trying to rebut the evidence presented at trial demonstrating that Tai He performs all the steps of the '138 Patent, Willowood misrepresents the testimony of Mr. Shen as "corroborat[ing]" the

[9] *WesternGeco* also makes clear that rules applying to § 271(a) should not automatically be applied to other subsections. 138 S. Ct. at 2134 (lost foreign sales damages are not recoverable under § 271(a), but are available under § 271(f)).

testimony of Mr. Wu. Opp. at 44. But the quoted testimony attributed to Mr. Shen does not appear anywhere in the record. Mr. Shen did testify that he was "able to observe the manufacture of azoxystrobin," but nowhere did he state that "Tai He was equipped only to perform the condensation step." *See id.*; Appx6993 at 137:5-14. Instead, what Willowood describes as a "corroboration" of Mr. Wu's testimony is a citation back to that same testimony by Mr. Wu. *See* Opp. at 44; Appx6980 at 84:14-17.

Moreover, contrary to Willowood's assertion, Mr. Shen did not testify that "Tai He did not have the appropriate permit from the Chinese government to perform the etherification step," or the ability to treat waste water and fumes from the etherification step. Opp. at 44. In the testimony Willowood cites, Mr. Shen refers to Willowood's (unsuccessful) attempt to find a way to manufacture azoxystrobin without using the etherification and condensation steps in a manner that infringed the '138 Patent. Appx6992 at 132:12-133:9. Mr. Shen explained the problems with changing how the azoxystrobin is manufactured in order to avoid infringing Syngenta's '138 Patent, not the problems with Tai He performing the etherification step. *Id.*

Willowood also misrepresents the timing of Mr. Shen's first visit to Tai He. According to Willowood, Mr. Shen verified that Tai He did not perform both the etherification and condensation steps before Willowood purchased azoxystrobin from Tai He. Opp. at 45. The record contradicts this assertion. Tai He and W-Ltd entered into a supply agreement on March 26, 2013, and Tai He provided W-Ltd with 5 kg of azoxystrobin shortly thereafter. Appx7412; Appx6720-6721 at 111:25-112:8. Tai He also provided Willowood with a document describing its manufacturing process in 2013, which is the document Willowood used to prepare its July 24, 2013, EPA Process submission stating Tai He performed both the etherification and condensation steps. Appx8482-8489, Appx7274-7275, Appx7295-7297, Appx7300-7302. But Mr. Shen testified that his first visit to Tai He took place in 2014. Appx6993 at 136:12-14.

Even to the extent that multiple entities performed the steps of the '138 Patent, they did so under Willowood's "control or direction," as Syngenta explained in its opening brief. Br. at 55-58. Willowood entirely ignores this Court's precedent that an entity controls or directs the acts of another when it "conditions participation in an activity or receipt of a benefit upon performance of a step or steps of a patented method and

establishes the manner or timing of that performance." *Akamai Techs., Inc. v. Limelight Networks*, 797 F.3d 1020, 1023 (Fed. Cir. 2015) (*en banc*). Here, as the record evidence demonstrates, Willowood conditioned Tai He's receipt of a benefit (Willowood's purchase of azoxystrobin) upon the performance of the steps of the '138 Patent, and established the manner of that performance (by Willowood instructing Tai He to divide the azoxystrobin manufacturing between entities). Br. at 55-58.

On the evidence presented, "a reasonable jury would not have a legally sufficient evidentiary basis to find" that Tai He did not perform both the etherification and condensation steps of the '138 Patent or that Willowood did not control or direct the performance of those steps. *See* FED. R. CIV. P. 50(a). The district court thus erred in denying Syngenta's motion for JMOL on this issue.

IV. The Jury's Verdict That W-Ltd Did Not Infringe the Compound Patents Lacks Substantial Evidence.[10]

The jury was tasked with deciding whether W-Ltd sold or offered for sale 5 kg of azoxystrobin in the United States in 2013, ***or*** whether W-Ltd imported that 5 kg of azoxystrobin into the United States. Appx230-232, Appx266. Willowood argues that "only WW-USA, not WW-Ltd, was equipped to sell, and did sell, azoxystrobin products in the United States." Opp. at 54. That argument fails for two reasons: (1) it fails to address W-Ltd's ***importation*** of 5 kg of azoxystrobin into the United States, and (2) it focuses on the sale of azoxystrobin products to third-party customers, rather than the sale of azoxystrobin technical (i.e., pure azoxystrobin) from W-Ltd to W-USA.

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[10] Since Syngenta filed its opening brief, W-USA and W-LLC paid the judgment for their infringement of the Compound Patents. *Syngenta Crop Protection, LLC v. Willowood, LLC et al.*, No. 1:15-cv-274, Dkt. No. 391 (M.D.N.C. June 20, 2018). The issue of W-Ltd's infringement of the Compound Patents, however, is not mooted by this payment. The district court found that W-Ltd was not liable for infringing the '761 Patent based upon the jury's finding that W-Ltd was not liable for infringing the Compound Patents. Appx91. While that finding was in error (see Section V *infra*), if W-Ltd is liable for infringing the Compound Patents, it also must be found to infringe the '761 Patent. *See* Appx6522-6523. Similarly, if this Court reverses the district court regarding infringement of the '138 Patent, W-Ltd must be found to infringe the '138 Patent for the same reasons it infringes the Compound Patents. *Id.*

First, to understand what it means to "import," the term must be given its ordinary meaning. *Taniguchi v. Kan Pacific Saipan, Ltd.*, 566 U.S. 560, 566 (2012) ("When a term goes undefined in a statute, we give the term its ordinary meaning."); 35 U.S.C. § 100 ("import" not defined in patent statutes). The ordinary meaning of "import" is "bringing an article into a country from the outside." *See Cunard S.S. Co. v. Mellon*, 262 U.S. 100, 122 (1923). In this regard, there can be no dispute that W-Ltd brought the azoxystrobin technical into the United States from outside the United States.

Indeed, Mr. Heinze, who served as W-USA's president and CEO, testified that "[t]he transportation [of the azoxystrobin] is all coordinated by the mainland China team, [W-Ltd]." Appx6795 at 25:3-16. W-Ltd ships the azoxystrobin technical "door to door," arranging for the shipment of azoxystrobin not only ***to*** an entry point in the United States, but also ***within*** the United States from that entry point to its ultimate destination. *Id.* It is W-Ltd who "makes the arrangements" with "a freight forwarding company" to deliver the azoxystrobin technical to its ultimate destination in the United States. Appx6795 at 25:17-24. And it is W-Ltd that pays that third-party freight forwarding company for

arranging the transportation of the azoxystrobin technical. Appx6795 at 27:3-14.

In trying to respond to this evidence presented at trial, Willowood cites to Mr. Heinze's testimony and asserts that W-USA is responsible for ensuring that the azoxystrobin technical is delivered to its ultimate destination. Opp. at 53. The cited testimony, however, does not support this argument. Rather, Mr. Heinze testified that "[t]he transportation is ***all*** coordinated" by W-Ltd for "door to door" shipment, and that W-Ltd uses a freight forwarding company with offices in Hong Kong, China, and the United States to help facilitate the transportation. Appx6795 at 25:3-24 (emphasis added).

Willowood also suggests that W-USA pays for the shipment of the azoxystrobin technical to the United States. Opp. at 53. At the time the azoxystrobin technical is brought into the United States, however, W-Ltd is the party who has paid for the shipment. Only later does W-USA reimburse W-Ltd for that expense. Appx6795 at 27:3-14. Therefore, W-Ltd is the entity that imported the azoxystrobin technical. *See Roche*, 272 F. Supp. 2d at 109 ("It is undisputed that Roche shipped the cells into the United States, and thus imported them under the statute.").

Second, Willowood's focus on whether W-Ltd sold azoxystrobin products (a.k.a., end-use products) to third-party customers in the United States misses the point. Opp. at 53-54. The question, as set forth in Syngenta's opening brief, is whether the sale of 5 kg of azoxystrobin technical in 2013 from W-Ltd to W-USA took place in the United States. Br. at 62. Willowood does not even attempt to address the controlling law that states a foreign company that sells and ships an infringing product to a customer in the United States has sold the product in the United States. *See N. Am. Philips Corp. v. Am. Vending Sales, Inc.*, 35 F.3d 1576, 1579 (Fed. Cir. 1994); *see also Snap-on Inc. v. Robert Bosch, LLC*, No. 09-cv-6914, 2011 WL 4901313, at *1-2 (N.D. Ill. Oct. 14, 2011). Nor does Willowood address the controlling law that states that a sale can take place in more than one location. *See Carnegie Mellon Univ. v. Marvell Tec. Grp., Ltd.*, 807 F.3d 1283, 1308 (Fed. Cir. 2015); *Transocean Offshore Deepwater Drilling, Inc. v. Maersk Contractors USA, Inc.*, 617 F.3d 1296, 1310-11 (Fed. Cir. 2010).

Instead, Willowood recycles its argument that the sale from W-Ltd to W-USA was made "f.o.b. Hong Kong" such that title to the azoxystrobin technical transferred from W-Ltd to W-USA in Hong Kong. Opp. at 52-

53. Yet, as this Court has explained, there is no "controlling significance" to the location of where title transferred from W-Ltd to W-USA, however. *Philips*, 35 F.3d at 1579-80. Because W-Ltd sold and shipped azoxystrobin technical to W-USA, that sale was made in the United States—even if it *also* was made in Hong Kong when title to the azoxystrobin was purportedly transferred.

Considering ***all*** the evidence, even viewed in the light most favorable to Willowood, "a reasonable jury would not have a legally sufficient evidentiary basis to find" that W-Ltd did not import 5 kg of azoxystrobin into the United States in 2013 ***and*** that W-Ltd did not sell 5 kg of azoxystrobin to W-USA in the United States. *See* FED. R. CIV. P. 50(a); *Dotson v. Pfizer, Inc.*, 558 F.3d 284, 292 (4th Cir. 2009). The district court, thus, erred in denying Syngenta's motion for JMOL on this issue.

V. The District Court Nullified the Jury's Verdict that W-Ltd Infringed the '761 Patent.

There is no dispute that Question 1 of the verdict form—set forth under the heading "The Compound Patents"—is the only instance in which the verdict form separately asked the jury to decide W-Ltd's liability (as distinct from the liability of the other Willowood entities).

Appx266. There is also no dispute that the only instance in which the jury instructions separately instructed the jury about W-Ltd's liability was under the heading "The Compound Patents." Appx229-230. Nor is there any dispute that Syngenta expressly objected to Willowood's proposed jury instruction that would have instructed the jury to separately consider W-Ltd's liability as to each of the asserted patents. Appx6162-6163. Nonetheless, the district court erroneously concluded that the parties "implicitly agreed" to decide W-Ltd's liability for infringement of the '761 Patent based on the answer to Question 1 regarding the Compound Patents.

As an initial matter, Willowood fails to address Syngenta's argument and its supporting case law that Willowood has waived any specific noninfringement argument as to W-Ltd. It was incumbent on Willowood to incorporate any such defense into the jury instructions and verdict form, and to object to the extent that they contained something to the contrary. As reflected by the verdict form, jury instructions, and other record evidence, Willowood failed to do so, and thus waived any specific defense as to W-Ltd's infringement of Syngenta's '138 and '761 Patents. *See Mitsubishi Elec. Corp. v. Ampex Corp.*, 190 F.3d 1300, 1304

(Fed. Cir. 1999) (holding that objections to verdict form were waived due to failure to object; collecting cases); *Trandes Corp. v. Guy F. Atkinson Co.*, 996 F.2d 655, 666, n.12 (4th Cir. 1993) (holding that objections to jury instructions and verdict form were waived due to failure to object).

Furthermore, in attempting to defend the district court's decision, Willowood suggests that because the district court denied Syngenta's motion for summary judgment of infringement by W-Ltd of both the Compound Patents and the '138 and '761 Patents, it is proper to assume that any questions on the verdict form regarding W-Ltd necessarily applied to the Compound Patents *and* the '138 and '761 Patents. Opp. at 55. The record below belies this assumption. The district court, not the jury, decided Syngenta's summary judgment motion. Thus, the manner in which arguments were presented on summary judgment has no bearing on how the jury was instructed, and subsequently decided, W-Ltd's liability, or how the parties intended for the jury to decide W-Ltd's liability.

To the extent that the manner in which arguments were raised on summary judgment is even relevant, Syngenta argued that it was entitled to summary judgment that (1) "W-Limited, W-USA, and W-LLC

infringed" the Compound Patents (Appx1617), (2) "Willowood infringed the '138 Patent" (Appx1619) and (3) "Willowood infringes the '761 Patent" (Appx1627). Thus, from the time Syngenta filed its opening summary judgment brief, liability for infringement of the Compound Patents was determined separately for each individual Willowood entity, but liability for infringement of the '138 and '761 Patents was determined for the Willowood defendants collectively—as the district court's summary judgment order confirms. Appx31 (specifically identifying W-Ltd only in the context of the Compound Patents).

Willowood next states that there is "no reason to assume" that the verdict question about W-Ltd's liability was limited to its 2013 actions regarding infringement of the Compound Patents. Opp. at 55. This is not an assumption, however. The jury instructions were organized by the questions the jury would be answering on the verdict form. *Compare* Appx225-265 *with* Appx266-267. Under Question 1, regarding whether Syngenta proved that W-Ltd "imported … or otherwise sold or offered for sale azoxystrobin technical in the United States," the jury instructions expressly stated that "***we are talking here about the 5kg of azoxystrobin technical that came into the United States in 2013***."

Appx230 (emphasis added); *see also* Appx7143 (transcript of instructions as read to the jury). Thus, contrary to Willowood's assertion, the jury instructions expressly limited Question 1 on the verdict form to W-Ltd's 2013 actions.

Willowood further contends that the jury's answer to Question 7 on the verdict form, asking whether Defendants proved they did not infringe the '761 Patent, "referred only to the ***U.S.*** defendants." Opp. at 56 (emphasis added). But Willowood does not identify anything in the record to support this contention. *See id.* Nothing in the jury instructions suggests that the use of "Defendants" and "Willowood" in Question 7 of the verdict form is so limited. Appx249-250. In fact, Willowood's contention is contradicted by the district court's statement with respect to the verdict form that the Willowood defendants were treated "all together for all purposes except this infringement of the compound patent question." Appx7066.

Finally, Willowood argues that Question 1 of the verdict form, regarding W-Ltd's liability, applied to all patents because "this is plainly how the district court construed its own instructions and the verdict form that it submitted to the jury." Opp. at 56. That is an improper

extrapolation from the single sentence on this issue in the district court's JMOL order. *See* Appx91. The district court's order did not offer any explanation of how it was interpreting the jury instructions or verdict form, but rather concluded that "the parties implicitly agreed" about how liability for W-Ltd's infringement of the '138 and '761 Patents was to be determined. Appx91.

Ultimately, Willowood offers only speculation, not evidence, in its attempt to defend the district court's order denying Syngenta's JMOL motion regarding W-Ltd's infringement of the '761 Patent. The record shows the district court erred in concluding that "the parties implicitly agreed to resolve" W-Ltd's liability for the '761 Patent based on Question 1 of the verdict form. Appx91.

RESPONSE TO WILLOWOOD'S CROSS-APPEAL

STATEMENT OF THE ISSUES

1. Whether Willowood's cross-appeal should be dismissed because this Court does not have jurisdiction over a conditional appeal that, if granted, would merely provide an advisory opinion and fail to enlarge the rights of Willowood or lessen the rights of Syngenta.

2. Whether the district court properly denied Willowood's motion to exclude Syngenta's damages expert from testifying to his opinions based on benchmarks that the district court found to be sufficiently reliable and grounded in the facts of the case.

STATEMENT OF THE CASE

Willowood omits a number of key facts relevant to its contingent cross-appeal. Willowood sought and obtained EPA approval for its end-use azoxystrobin products under the "Formulator's Exemption" (Appx277-278), which provides an expedited registration process for formulators who purchase active ingredients from already-registered sources. 7 U.S.C. § 136a(c)(2)(D). In registering its azoxystrobin, Willowood falsely represented to the EPA that it qualified as a formulator because it was purportedly sourcing the azoxystrobin technical from Syngenta, when in truth Willowood never even sought to source it from

Syngenta.[11] *Compare* Appx9886-9893 (identifying Syngenta as its source to EPA), *with* Appx9928, Appx9953 (admitting in ¶¶ 46-50, in response to Syngenta's complaint (Appx279,) that Syngenta was not its source). Based on Willowood's false statements, the EPA approved Willowood's Azoxy 2SC and AzoxyProp Xtra product registrations on January 6, 2014, and June 11, 2014, respectively. Appx10186-10189. Without the Formulator's Exemption, Willowood would not have been able to obtain EPA approval and sell its azoxystrobin products as early as it did, effectively speeding up its time to market. Appx4265-4271, Appx 4213-4215.

To utilize the Formulator's Exemption, Willowood first needed to develop the formulations for its end-use products and have samples of those products prepared and tested so that it could show the EPA that its products were substantially similar to Syngenta's. Willowood did so by infringing Syngenta's Compound Patents before they expired in February 2014. In addition to importing five kilograms of azoxystrobin

[11] On February 4, 2014, Syngenta filed a petition to cancel Willowood's registration of Azoxy 2SC. Syngenta explained in its petition that Willowood obtained its registration through improper use of the Formulator's Exemption and false representations made to the EPA. Appx10272-10282. That petition is still pending before the EPA.

technical into the United States in 2013, Willowood further infringed by commissioning third-party Adjuvants Unlimited to develop formulations for its azoxystrobin products and by commissioning third-party Analytical & Regulatory Chemistry to analyze the resulting formulations in support of Willowood's EPA applications. Appx8-10. These infringing activities enabled Willowood to submit early azoxystrobin registrations to the EPA in August 2013 and January 2014, before Syngenta's Compound Patents expired. Willowood thereby obtained EPA approval for Azoxy 2SC in January 2014 and AzoxyProp Xtra in June 2014 (Appx10186-10189), much earlier than if it had not infringed Syngenta's patents and submitted its registration without a Formulator's Exemption.

Even with this regulatory head start, Willowood had to race to get its products on the market to make sales in 2014 and 2015. Willowood used a toll manufacturer (Agraform) who formulated Willowood's end-use products and had specific tolling deadlines that Willowood needed to meet in order to have its products formulated and available for sale by particular timeframes. Appx10075-10078. Willowood struggled to ship azoxystrobin to Agraform in time to meet several tolling deadlines in

2014 in order to be in a position to sell its products in late 2014 and early 2015. Appx10078-10082, Appx10086-10088, Appx10144, Appx10149-10150, Appx10160. Delays by even a few months would have substantially impacted Willowood's ability to sell in 2014-2015. *See* Appx10078-10082, Appx10086-10088, Appx10144, Appx10149-10150, Appx10160.

Had Willowood waited until after Syngenta's Compound Patents expired to (1) import its azoxystrobin, (2) develop its end-use products, and/or (3) conduct testing to support its EPA registrations, Willowood likely would not have made any azoxystrobin sales in 2014 or the first quarter of 2015, causing Willowood to miss most or all of the 2015 growing season. Appx4094, Appx6930. Thus, by infringing Syngenta's Compound Patents, Willowood gained at least a one-year head start in selling azoxystrobin products. Appx4119, Appx6930.

Dr. Benjamin Wilner is an expert in economics, and was tendered as an expert at trial without objection by Willowood. Appx6917. Dr. Wilner's damages analysis used benchmarks to quantify the damages resulting from Willowood's head start in the market, resulting from its infringement of Syngenta's patents and copyrights. Appx4085-4156. On

April 10, 2017, Willowood filed a *Daubert* motion seeking to exclude Dr. Wilner's damages opinions in their entirety. Appx3838-3841. On July 20, 2017, the district court issued a *Daubert* Order that thoroughly analyzed Dr. Wilner's opinions, denying Willowood's motion in part. Appx50-62. The district court allowed Dr. Wilner to testify to his damages opinions based on certain benchmarks, and precluded him from rendering opinions based on other benchmarks.[12] Appx37-62. At the time of its *Daubert* Order, the district court had already dismissed Syngenta's copyright claims as precluded by FIFRA. Appx33-34 (dismissing copyright claims on April 10, 2017). Thus, the district court's *Daubert* Order did not address Dr. Wilner's damages opinions relating to Syngenta's copyright claims.

After a seven-day trial, the jury awarded damages to Syngenta for Willowood's infringement of Syngenta's Compound Patents and '761 Patent. Appx1-4. On November 20, 2017, the district court entered final judgment. Appx1-4. Willowood does not challenge the final judgment or the damages awarded. Opp. at 7 n.4.

[12] These other opinions and benchmarks are not at issue in Willowood's cross-appeal.

SUMMARY OF THE ARGUMENT

This Court should not exclude Syngenta's damages expert from offering opinions on damages on remand. As an initial matter, Willowood's contingent cross-appeal is improper and should be dismissed. Cross-appeals are only appropriate if a party seeks to reverse or modify the entered judgment. Willowood's cross-appeal does not challenge the district court's entered judgment and instead only asks this Court to render an advisory opinion in the event this case is remanded to the district court. This would merely result in affirmance of the entered judgment rather than its reversal or modification, and would usurp the district court's discretion on evidentiary issues.

Even if this Court were to set aside the jurisdictional issues raised by Willowood's cross-appeal, Willowood has not come close to showing that the district court abused its discretion in denying, in part, Willowood's motion to exclude Syngenta's damages expert's opinions. The district court issued a 26-page order thoroughly analyzing each of Dr. Wilner's damages opinions and allowed Dr. Wilner to testify to his opinions on certain benchmarks that the district court found to be sufficiently reliable. After performing a fact-intensive analysis of each of

Dr. Wilner's opinions, the district court found his opinions on these benchmarking analyses to be tied to the facts of the case and based on sufficient facts and reliable principles. Willowood further offers no basis to suggest that the district court abused its discretion in allowing Dr. Wilner to testify to these opinions.

ARGUMENT

I. This Court Should Dismiss Willowood's Procedurally Improper Conditional Cross-Appeal for Lack of Jurisdiction.

Disregarding bedrock jurisdictional principles, Willowood's conditional cross-appeal asks this Court to weigh in on the admissibility of opinions that Dr. Wilner may offer, on remand, with respect to the damages stemming from Willowood's infringement of Syngenta's copyrights and '138 Patent. This Court, however, lacks jurisdiction to engage in such hypothetical exercises and should allow the district court to decide evidentiary issues in the first instance. Therefore, pursuant to Federal Circuit Rule 27(f), Syngenta moves to dismiss Willowood's conditional cross-appeal for lack of jurisdiction.

Fundamentally, even if this Court were to decide Willowood's cross-appeal, it would not alter in any way the district court's judgment, which Willowood does not challenge on appeal. "A cross-appeal is only

necessary and appropriate … when a party seeks to enlarge its own rights under the judgment or to lessen the rights of its adversary under the judgment." *Bailey v. Dart Container Corp.*, 292 F.3d 1360, 1362 (Fed. Cir. 2002). In fact, this Court's "precedent [has] consistently warn[ed] against the improper use of a cross-appeal to reach issues that do not otherwise expand the scope of the judgment." *Aventis Pharma S.A. v. Hospira, Inc.*, 637 F.3d 1341, 1343 (Fed. Cir. 2011). Thus, a cross-appeal is improper when, even if successful, the cross-appeal would merely result in the affirmance of the judgment entered, rather than its reversal or modification. *See Bailey*, 292 F.3d at 1362.

Yet, that is precisely what Willowood seeks. Willowood admits that it is conditionally appealing the district court's *Daubert* Order "merely in the event that the Court remands this case for a new trial" on one of the issues Syngenta is appealing. Opp. at 7 n.4. Notably, Willowood is ***not*** appealing the judgment that the district court has already entered with respect to Willowood's infringement of Syngenta's Compound Patents and '761 Patent. *Id.* Thus, even if this Court were to accept the arguments Willowood raises, it would not result in the reversal or

modification of the district court's judgment. For that reason alone, this Court lacks jurisdiction to decide Willowood's cross-appeal.

Moreover, as discussed below, the "[a]dmission of expert testimony is within the discretion of the trial court." *Sundance, Inc. v. DeMonte Fabricating Ltd.*, 550 F.3d 1356, 1360 (Fed. Cir. 2008). What Willowood essentially seeks is an impermissible advisory opinion from this Court that would usurp the district court's discretion on evidentiary issues. *See Resonate Inc. v. Alteon Websystems, Inc.*, 338 F.3d 1360, 1368 (Fed. Cir. 2003) (dismissing cross-appeal filed "[i]n the event [the Federal Circuit] concludes that further proceedings are required in the district court" as an improper request for an advisory opinion). For example, as Willowood acknowledges, the district court dismissed Syngenta's copyright claims before it issued its *Daubert* Order and never addressed the admissibility of expert opinions concerning Syngenta's copyright damages. Opp. at 6 n.3. On remand, Willowood will have an opportunity to raise such evidentiary issues, and the district court is best suited to address these issues in the first instance.

Therefore, this Court should dismiss Willowood's procedurally improper conditional cross-appeal for lack of jurisdiction.

II. The District Court Did Not Abuse Its Discretion in Denying Willowood's Motion to Exclude Dr. Wilner's Testimony.

Even if this Court were to set aside the jurisdictional problems underlying Willowood's cross-appeal, Willowood has not come close to showing that the district court abused its discretion. Perhaps recognizing that it faces a tall order, Willowood dodges the applicable standard of review for its cross appeal and does not even mention it in its brief. *See* Opp. at 10-11, 56-66. It is well established, however, that evidentiary rulings on the admissibility of expert testimony are committed to the sound discretion of the district court. *Sundance*, 550 F.3d at 1360. This Court, in turn, reviews such evidentiary rulings only for abuse of discretion. *Id.*; *Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 138-39 (1999).

Under Federal Rule of Evidence 702, district courts serve as gatekeepers tasked with determining whether an expert is qualified and whether the expert's opinions are reliable. *Kumho*, 526 U.S. at 141-42; *Daubert v. Merrill Dow Pharms., Inc.*, 509 U.S. 579, 589-90 (1993). In carrying out this "flexible" inquiry, district courts are given "broad latitude." *Kumho*, 526 U.S. at 150. A district court does not abuse its discretion by admitting "relevant scientific evidence in the same manner

as other expert testimony and allow its weight to be attacked by cross-examination and refutation." *United States v. Baller*, 519 F.2d 463, 466 (4th Cir. 1975); *see also Daubert*, 509 U.S. at 596.

A. The District Court Correctly Determined that Dr. Wilner Applied a Reliable Benchmark Analysis.

The district court conducted a thorough, fact-intensive analysis of Dr. Wilner's damages opinions, as set forth in its 26-page opinion and order. Appx37-62. And the district court exercised its discretion to allow Dr. Wilner to testify to his damages opinions that applied certain benchmarks that the district court found to be sufficiently reliable. Appx37-50.

Specifically, Dr. Wilner applied a benchmarking analysis to determine Syngenta's lost profits resulting from the early market entry that Willowood obtained by infringing Syngenta's Compound Patents, '138 Patent, and '761 Patent. As part of this analysis, Dr. Wilner examined what he termed as Syngenta's "AZ Products-at-Issue," which include Syngenta's crop-protection fungicides that contain azoxystrobin as an active ingredient and are applied to planted crops. Appx4088-4089. Dr. Wilner then applied a benchmarking analysis in which he used Syngenta's actual and budgeted gross profits for the AZ Products-at-

Issue (in the aggregate) to determine how much of its budgeted gross profits Syngenta was able to achieve in the face of Willowood's early market entry and generic price pressure from Willowood ("intra-AZ benchmark"). Appx4116.

To account for market factors that might have influenced Syngenta's budgets, Dr. Wilner also examined Syngenta's actual and budgeted gross profits on its mesotrione products, which share a number of market and product-lifecycle similarities with azoxystrobin, but notably did not face generic competition from Willowood.[13] As with the AZ Products-at-Issue, Dr. Wilner compared the actual and budgeted gross profits for Syngenta's mesotrione products to determine the extent to which Syngenta was able to achieve its budgeted mesotrione gross profits ("intra-meso benchmark"). Appx4116. Dr. Wilner then applied the intra-meso benchmark to adjust the lost profits he calculated using

[13] Mesotrione is an herbicide that is approved for the same major crops as azoxystrobin, including corn and soybeans. Appx4114, Appx6819. Moreover, until 2014, generic companies faced significant barriers to entry as to both mesotrione (Syngenta lost EPA data exclusivity over mesotrione in June 2014) and azoxystrobin (Syngenta's patents covering the azoxystrobin compound expired in February 2014). Appx4114-4115. Before Syngenta lost EPA data exclusivity over mesotrione in June 2014, generic companies were barred from relying on Syngenta's data to apply for EPA registrations for mesotrione. 7 U.S.C. § 136a(c)(1)(F).

the "intra-AZ benchmark." That is, Dr. Wilner assumed Syngenta would have achieved its budgeted amount of gross profits for the AZ Products-at-Issue to the same extent that Syngenta achieved its budgeted amount of gross profits for its mesotrione products. Appx4116. Dr. Wilner also conducted a number of supplemental analyses to confirm and corroborate his benchmarking analysis. Appx4116-4119.

After carefully examining Dr. Wilner's benchmarking analysis, the district court found it to be "tied [] to the facts of this case" and based on "sufficient facts" and "reliable principles." Appx48. And the district court concluded that Dr. Wilner's "benchmark methodology provides a reasonably reliable method of calculating gross profits in a hypothetical, non-infringing world." Appx48. Willowood does not, and cannot, offer any basis to suggest that such benchmarking analyses are inherently improper. In fact, this Court has recognized the use of benchmarks as a valid method of calculating lost profits in patent cases. *See Ericsson, Inc. v. Harris Corp.*, 352 F.3d 1369, 1379-79 (Fed. Cir. 2003); *Minn. Mining & Mfg. Co. v. Johnson & Johnson, Inc.*, 976 F.2d 1559, 1578-79 (Fed. Cir. 1992); *see also SynQor, Inc. Artedyn Techs., Inc.*, No. 2:07-cv-497, 2011 WL 3624998, *5 (E.D. Tex. Aug. 17, 2011).

B. Willowood Mischaracterizes Dr. Wilner's Benchmarking Analysis as Based on Inaccurate Budgets.

Willowood's principal complaint is that Dr. Wilner's benchmarking analysis utilized Syngenta's budgets, which Willowood contends are inaccurate. Opp. at 58-62. But to paint a bleak picture of Syngenta's budgets, Willowood mischaracterizes Dr. Wilner's analysis and points to straw-man budgets that Dr. Wilner never utilized. For example, Willowood asserts that Syngenta's azoxystrobin budgets from 2009-2011 were inaccurate. Opp. at 58-59. But Dr. Wilner did ***not*** rely on Syngenta's 2009-2011 azoxystrobin budgets in any of his calculations.[14] Similarly, Willowood points to variations in the budgets for individual azoxystrobin and mesotrione products. Opp. at 59-60. But, again, Dr. Wilner did ***not*** use the budget for any *individual* azoxystrobin or

[14] Nor is it surprising that Syngenta (or any company) would have had inaccuracies in its budgets from 2009-2011, during the height of an economic recession and a period of widely recognized market volatility that began to stabilize by 2012. Christina Romer, the Chair of the Counsel of Economic Advisors to the Obama Administration, has explained that "the aftermath of financial crises is highly variable." Appx10221. That is underscored, for example, by the volatility index that the USDA's Risk Management Agency used to determine crop insurance premiums, which shows that volatility in crop prices were historically high in 2010 and 2011 but stabilized by 2012, particularly for corn and soybean (the major crops for azoxystrobin). Appx10265-10267.

mesotrione product as a benchmark. Appx4115-4116. Rather, Dr. Wilner considered the budgets of *all* of Syngenta's AZ Products-at Issue and mesotrione products in the *aggregate*. Appx4115-4116.

Willowood itself admits that Syngenta's 2012 azoxystrobin budgets, on which Dr. Wilner did rely, were "relatively accurate." Opp. at 59. And to the extent Willowood identifies variations in the actual and budgeted gross profits in 2013 and 2014, these variations are fully explained by the record and accounted for in Dr. Wilner's benchmarking analysis, which he designed to capture the effect Willowood had on Syngenta's profits. Notably, by 2013, Willowood began targeting Syngenta's products, specifically announcing to customers that it would be releasing equivalents of Syngenta's branded products, and filed the first of its EPA applications. Appx10049-10057. It was not until 2014 that Syngenta recognized the effect Willowood was having on the market, and Syngenta responded by significantly lowering its azoxystrobin prices. Appx4098-4099, Appx4231, Appx4236.

Moreover, contrary to Willowood's suggestion, Dr. Wilner did not simply adopt Syngenta's budgets without testing and verifying them.[15] Among other things, Dr. Wilner reviewed and analyzed Syngenta's actual and budgeted sales and profits and additionally reviewed Syngenta business presentations and correspondence that provided further context for these budgets. Appx6918. To understand Syngenta's budgets and budgeting process, Dr. Wilner also spoke with several Syngenta employees with first-hand knowledge and experience with the sales, marketing, and finances relating to Syngenta's azoxystrobin, mesotrione, and other products. Appx6918. Indeed, at trial, Syngenta presented over two days of testimony by Syngenta employees who explained the rigorous, multi-year process by which Syngenta prepares its budgets. Appx6817-6823, Appx6876-6880. These employees also testified about the numerous market and product-lifecycle similarities that make

[15] The cases that Willowood cites in this regard are inapposite and involve egregious examples of experts who simply adopted sales projections without analysis. *See Sunlight Saunas, Inc. v. Sundance Sauna, Inc.*, 427 F. Supp. 2d 1022, 1030 (D. Kan. 2006); *Celebrity Cruises, Inc. v. Essef Corp.*, 434 F. Supp. 2nd 169 (S.D.N.Y. 2006); *Victory Records, Inc. v. Virgin Records America, Inc.*, 2011 WL 382743, at *1 (N.D. Ill. Feb. 3, 2011).

mesotrione an appropriate comparison for azoxystrobin (Appx6821, Appx6900-6902), and the direct impact that Willowood had on Syngenta in the market place (Appx6823, Appx6827-6830, Appx6864-6876). All of this informed Dr. Wilner's analysis.

Further, as the district court found, Dr. Wilner "accounted for imperfections in Syngenta's azoxystrobin budgets by adjusting them based on how well Syngenta budgeted gross profits for mesotrione" and "verified his analysis, considering other possible benchmarks and comparing his calculation of hypothetical gross profits with Syngenta's actual experience." Appx49. For example, Dr. Wilner examined other benchmarks such as market indices to confirm that his damages calculations were reasonable and conservative. Appx4116-4117. Dr. Wilner's calculations also show that Willowood received an approximately one-year head start in selling azoxystrobin by infringing the Compound Patents, which provides a real-life metric that independently corroborates his benchmarking analysis. Appx4119.

Ultimately, to the extent Willowood complains of inaccuracies in Syngenta's budgets, it was well within the district court's broad discretion to admit Dr. Wilner's benchmarking analysis and allow

Willowood to address any concerns on cross-examination. *See Daubert*, 509 U.S. at 596 ("Vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence."). In fact, at trial, Willowood devoted significant time to cross-examining Syngenta's witnesses on this issue and successfully convinced the jury to award significantly less in damages than Syngenta sought, underscoring that the issues Willowood raises go to weight of the evidence, rather than its admissibility. Appx1-4.

In short, as the district court found, Dr. Wilner's benchmarking analysis is sufficiently reliable and grounded in the facts of the case. For its part, Willowood offers no basis to suggest that the district court abused its discretion in denying, in part, Willowood's motion to exclude and permitting Dr. Wilner to testify to damages opinions that apply this benchmarking analysis.

CONCLUSION

With respect to Syngenta's appeal, this Court should (1) vacate the district court's grant of summary judgment on Syngenta's copyright claims and remand for further proceedings; (2) reverse the district court's

entry of judgment in favor of Willowood regarding infringement of the '138 Patent, enter judgment that W-Ltd, W-USA, and W-LLC infringed the '138 Patent, and remand for determination of willfulness and the damages attributable to this infringement; and (3) reverse the district court's entry of judgment in favor of W-Ltd regarding infringement of the Compound Patents and the '761 Patent and enter judgment that W-Ltd infringed these patents.

This Court should further deny Willowood's cross-appeal as procedurally improper and without merit.

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Respectfully submitted,

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