IN THE

Supreme Court of the United States

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

Petitioners,

v.

SYNGENTA CROP PROTECTION, LLC,

Respondent.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

BRIEF IN OPPOSITION

RUSSELL E. LEVINE, P.C.

Counsel of Record

HARI SANTHANAM

KIRKLAND & ELLIS LLP

300 North LaSalle Street

Chicago, Illinois 60654

(312) 862-2000

rlevine@kirkland.com

June 25, 2020

Counsel for Respondent

QUESTIONS PRESENTED

- 1. Whether this Court should impose a new single-entity requirement for direct patent infringement under 35 U.S.C. § 271(g), contrary to its plain language and legislative history.
- 2. Whether this Court should hold that the Federal Insecticide, Fungicide and Rodenticide Act ("FIFRA") precludes any and all actions for copyright infringement with respect to generic pesticide labels, contrary to the plain language and legislative history of both statutory schemes and before the district court and the Federal Circuit have had an opportunity to develop a record and substantively address Syngenta's copyright claims in the first instance.

CORPORATE DISCLOSURE STATEMENT

Syngenta Crop Protection, LLC is a wholly owned U.S. subsidiary of Syngenta Seeds, LLC. Syngenta Seeds, LLC is a wholly owned U.S. subsidiary of Syngenta Corporation, which in turn is a wholly owned U.S. subsidiary of Syngenta Crop Protection AG. Syngenta Crop Protection AG is a wholly owned non-U.S. subsidiary of Syngenta AG. Syngenta AG is a wholly owned non-U.S. subsidiary of Syngenta Group Co., Ltd.

RELATED PROCEEDINGS

Syngenta Crop Protection, LLC v. Willowood, LLC et al., No. 1:15-CV-274 (M.D.N.C.) (summary judgment on patent issues entered on March 27, 2017; summary judgment on copyright issues entered on April 10, 2017; final judgment entered on November 20, 2017).

Syngenta Crop Protection, LLC v. Willowood, LLC et al., Nos. 2018-1614, 2018-2044 (Fed. Cir.) (judgment entered on December 18, 2019).

In re Willowood USA Holdings, LLC et al., No. 19-11079 (Bankr. D. Colo.). (pending bankruptcy proceeding initiated under Chapter 11 of the Bankruptcy Act by Petitioners WW-LLC, WW-USA, WW-Azoxy, and related Willowood entities; plan of reorganization approved on March 3, 2020).

iv

TABLE OF CONTENTS

	Page
Question	s Presentedi
	e Disclosure Statementii
Related 1	Proceedingsiii
Table of	Authoritiesvii
Introduc	tion1
Opinions	Below3
Jurisdict	ion3
Relevant	Statutory Provisions4
Stateme	nt of the Case5
A.	Syngenta's Claims Asserting Infringement of the '138 Patent6
В.	Syngenta's Claims Asserting Copyright Infringement9
Reasons	for Denying the Petition12
	s Court Should Deny Review of the ent Question
A.	The Federal Circuit's Application of 35 U.S.C. § 271(g) Does Not Present Any Conflicts or Issues of Significance Warranting this Court's Review
В.	The Federal Circuit Correctly Held that § 271(g) Does Not Impose a Single-Entity Requirement
	1. The Plain Language of § 271(g) Confirms that It Does Not Impose a Single-Entity Requirement15

TABLE OF CONTENTS-CONTINUED

		<u>Page</u>
	2.	Other Sections of Title 35 Further Confirm that § 271(g) Does Not Impose a Single-Entity Requirement
	3.	The Plain Language of § 271(g) Forecloses Reliance on the Legislative History, Which If Anything Confirms that § 271(g) Does Not Impose a Single-Entity Requirement
	4.	The Federal Circuit's Decision Does Not Impermissibly Extend Syngenta's Patent Monopoly23
		urt Should Deny Review of the t Question24
A.	Rem Add Inst	Federal Circuit's Decision, Which handed to the District Court to ress Various Issues in the First ance, Is Interlocutory in Nature Not Ripe for this Court's Review24
В.	that Cop	Federal Circuit Correctly Held FIFRA Does Not Preclude All yright Protection in Pesticide els
	1.	No Conflict Exists Between FIFRA and Copyright Law that Would Preclude All Copyright Protection in Pesticide Labels26

TABLE OF CONTENTS-CONTINUED

	<u>P</u>	age
	2. Willowood's Policy Arguments Are Unfounded and Best Directed to Congress, Not This Court	29
	3. The Federal Circuit's Decision Addressing FIFRA Does Not Conflict with the Second Circuit's Decision in SmithKline Addressing a Facially Different Hatch-Waxman Provision	32
III.	The Pending Bankruptcy Proceedings Make This Case a Poor Vehicle	34
ſV	Conclusion	35

vii

TABLE OF AUTHORITIES

Page(s)
Cases
Akamai Techs., Inc., v. Limelight Networks, Inc., 797 F.3d 1020 (Fed. Cir. 2015) (en banc)
Azar v. Allina Health Servs., 139 S. Ct. 1804 (2019)
Bates v. Dow Agrosciences LLC, 544 U.S. 431 (2005)
Bilski v. Kappos, 561 U.S. 593 (2010)
BMC Resources, Inc. v. Paymentech, L.P., 498 F.3d 1373 (Fed. Cir. 2007)13, 17
Brulotte v. Thys Co., 379 U.S. 29 (1964)23, 24
Dean v. United States, 556 U.S. 568 (2009)16
Diamond v. Diehr, 450 U.S. 175 (1981)15
Ex parte Collett, 337 U.S. 55 (1949)20
FMC Corp. v. Control Sols., Inc., 369 F. Supp. 2d 539 (E.D. Pa. 2005)29, 32
Gemsco, Inc. v. Walling, 324 U.S. 244 (1945)
Keeler Brass Co. v. Cont'l Brass Co., 862 F.2d 1063 (4th Cir. 1988)28, 30
Kimble v. Marvel Entm't, 576 U.S. 446 (2015)23, 24

viii

TABLE OF AUTHORITIES—CONTINUED

	Page(s)
Lamar, Archer & Cofrin, LLP v. Appling, 138 S. Ct. 1752 (2018)	18
Limelight Networks, Inc. v. Akamai Techs., I 572 U.S. 915 (2014)	
Locomotive Firemen v. Bangor & Aroostook I 389 U.S. 327 (1967)	
Melendez-Diaz v. Mass., 557 U.S. 305 (2009)	29
Morton v. Mancari, 417 U.S. 535 (1974)	27
Mount Soledad Mem'l Ass'n v. Trunk, 567 U.S. 944 (2012)	24
Muniauction, Inc. v. Thomson Corp., 532 F.3d 1318 (Fed. Cir. 2008)	13, 14
Mycogen Plant Sci., Inv. v. Monsanto Co., 252 F.3d 1306 (Fed. Cir. 2001)	22
Patsy v. Bd. of Regents of State of Fla., 457 U.S. 496 (1982)	29
POM Wonderful LLC v. Coca-Cola Co., 573 U.S. 102 (2014)	28
Reg'l Rail Reorg. Act Cases, 419 U.S. 102 (1974)	27
Rodriguez v. United States, 480 U.S. 522 (1987)	18
Ruckelshaus v. Monsanto Co., 467 U.S. 986 (1984)	27

TABLE OF AUTHORITIES—CONTINUED

<u>Page(s)</u>
Selle v. Gibb, 741 F.2d 896 (7th Cir. 1984)28, 30
SmithKline Beecham Consumer Healthcare, LP. v. Watson Pharm., Inc.,
211 F.3d 21 (2d Cir. 2000)
Springfield v. Kibbe, 480 U.S. 257 (1987)
United States v. Oregon, 366 U.S. 643 (1961)20
Virginia Military Inst. v. United States, 508 U.S. 946 (1993)24
Wrotten v. New York, 560 U.S. 959 (2010)24, 26
Zenith Elecs. Corp. v. Exzec, Inc., 182 F.3d 1340 (Fed. Cir. 1999)27
Zoltek Corp. v. United States, 672 F.3d 1309 (Fed. Cir. 2012) (en banc)13, 14
Statutes
7 U.S.C. § 136a (2018)
7 U.S.C. § 136a(c)(3)(B)(i)(I) (2018)
11 U.S.C. § 362 (2018)
21 U.S.C. § 355(j)(2)(A)(v) (2018)
28 U.S.C. § 1254(1) (2018)
28 U.S.C. § 1498(a) (2018)13

TABLE OF AUTHORITIES—CONTINUED

<u>1</u>	Page(s)
35 U.S.C. § 271(a) (2018)	passim
35 U.S.C. § 271(f) (2018)	3, 18, 19
35 U.S.C. § 271(f)(1) (2018)	8, 18
35 U.S.C. § 271(g) (2018)	passim
35 U.S.C. § 287(b) (2018)	8, 19
35 U.S.C. § 287(b)(1)(A) (2018)	19
35 U.S.C. § 287(b)(1)(C) (2018)	8, 19
35 U.S.C. § 287(b)(3)(B)(iii) (2018)	8
35 U.S.C. § 287(b)(4)(A)(iii) (2018)	8
35 U.S.C. § 287(b)(5)(C)(i) (2018)	8
35 U.S.C. § 295 (2018)	8
Other References	
A. Krishnakumar, Passive-Voice References in Statutory Interpretation,	1.0
76 Brook. L. Rev. 941 (2011)	
H. Rep. No. 98-857 (1984)	
S. Rep. No. 100-83 (1987)	21

INTRODUCTION

This case centers on Syngenta's intellectual property relating to azoxystrobin, a breakthrough agricultural fungicide that Syngenta (through its predecessors) developed and that growers throughout the world use to protect a wide range of crops. In the proceedings below, Syngenta asserted (among other claims) that Willowood infringed Syngenta's U.S. Patent No. 5,847,138 ("the '138 patent") under 35 U.S.C. § 271(g) and further infringed Syngenta's copyrights in its product labels. A unanimous panel of the Federal Circuit correctly rejected Willowood's novel arguments that § 271(g) imposes a single-entity requirement and that the Federal Insecticide, Fungicide and Rodenticide Act ("FIFRA") precludes any and all copyright protection in pesticide labels. Willowood identifies no decision, either by this Court, the Federal Circuit, or any other court, that presents a legitimate conflict with the Federal Circuit's decision here or that otherwise raises any issues of significance warranting this Court's review.

With respect to both the patent and copyright questions presented in the Petition, Willowood asks this Court to ignore the unambiguous, plain language of the applicable statutory provisions and rewrite these provisions based on tenuous policy rationales that Willowood selectively gleans from the legislative history—all of which the Federal Circuit considered and soundly rejected. This Court has often cautioned against usurping Congress' role to rewrite clear statutory provisions, and it should decline to do so here. See, e.g., Azar v. Allina Health Servs., 139 S. Ct. 1804, 1815 (2019) (explaining "courts aren't free to rewrite clear statutes under the banner of our own policy concerns"); Gemsco, Inc. v. Walling, 324 U.S.

244, 260 (1945) ("The 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.").

Willowood's copyright question is especially this Court's review, given unsuited for interlocutory nature of the Federal Circuit's decision. See, e.g., Locomotive Firemen v. Bangor & Aroostook R. Co., 389 U.S. 327, 328 (1967) (per curiam) (denying certiorari because "the Court of Appeals [had] remanded the case" such that it was "not yet ripe for review by this Court"). Indeed, the Federal Circuit itself declined to reach the merits of Syngenta's copyright claims and remanded them to the district court so that it could develop a record and decide various underlying issues that it never reached. As the Federal Circuit recognized, the resolution of these underlying issues could obviate the need to address whether FIFRA precludes any aspect of Syngenta's copyright claims. Pet. App. 24a–25a. Thus, this Court should not exercise its certiorari jurisdiction to decide issues of preclusion in the first instance, particularly given that such a decision may be unnecessary depending on the outcome of the remand proceedings and given that any decision by this Court at this stage would be without the benefit of a full record.

Moreover, the pending bankruptcy proceedings, which Willowood briefly mentions in a footnote, Pet. 2 n.1., make this case a poor vehicle. All but one of the Petitioners has filed for Chapter 11 bankruptcy in the U.S. Bankruptcy Court for the District of Colorado, Case No. 19-11079-KHT. And Willowood has maintained that at least the patent question raised in the Petition is not relevant or applicable to Willowood

Limited, the one Petitioner that has not filed for bankruptcy. Thus, depending on the outcome of the bankruptcy proceedings, the questions presented may become, in whole or in part, moot.

Finally, Syngenta notes that, in light of the bankruptcy filings, the district court proceedings are currently subject to an automatic stay of litigation under 11 U.S.C. § 362. Syngenta has moved the bankruptcy court to lift the stay, and the Willowood Debtors have opposed. At the same time, non-party Generic Crop Science, LLC, which has acquired substantially all of the Willowood Debtors' assets, is currently funding Willowood's counsel to prosecute this appeal. Willowood did not identify this buyer in its Petition, and it is unclear what interests this buyer has with respect to the issues raised in the Petition, why it is funding this appeal, or how its interests may change were this Court to grant review or as the bankruptcy proceedings progress.

For all these reasons, and those discussed more fully below, this Court should deny the petition for a writ of certiorari.

OPINIONS BELOW

The Federal Circuit's opinion is reported at 994 F.3d 1344 and reprinted at Pet. App. 1a–39a. The district court's decisions at issue are unreported and reprinted at Pet. App. 40a–41a and 42a–71a.

JURISDICTION

The Federal Circuit entered judgment on December 18, 2019. Pet. App. 1a. Willowood filed the petition for a writ of certiorari on March 17, 2020 and has invoked the jurisdiction of this Court under 28 U.S.C. § 1254(1).

RELEVANT STATUTORY PROVISIONS

Section 271(g) of the Patent Act provides, in relevant part:

(g) Whoever without authority imports into the United States or offers to sell, sells, or uses within the United States a product which is made by a process patented in the United States shall be liable as an infringer, if the importation, offer to sell, sale, or use of the product occurs during the term of such process patent.

35 U.S.C. § 271(g) (2018).

Section 136a of FIFRA provides, in relevant part:

- (B) Identical or substantially similar
 - (i) The Administrator shall, as expeditiously as possible, review and act on any application received by the Administrator that—
 - (I) proposes the initial or amended registration of an end-use pesticide that, if registered as proposed,
 - [1] would be identical or substantially similar in composition and labeling to a currently-registered pesticide identified in the application, or that
 - [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 effects on the environment.
- 7 U.S.C. § 136a(c)(3)(B)(i)(I) (2018) (emphasis added to separately denote clauses [1] and [2]).

STATEMENT OF THE CASE

Syngenta is an agribusiness that researches, develops, manufactures, and sells crop-protection products, including fungicides, herbicides, insecticides. At issue in this case is Syngenta's intellectual property in its products containing azoxystrobin, a fungicidal compound that Syngenta (through its predecessors) developed and that is used to control fungal growth in a variety of crops. industry parlance, the term "azoxystrobin technical" refers to a relatively pure form of azoxystrobin, which may be used as an active ingredient (i.e., a biologically active component) to formulate "end-use" products that growers ultimately use on crops. commercially introducing azoxystrobin in 1997, Syngenta has manufactured, marketed, and sold products under azoxystrobin several including QUADRIS® and QUILT XCEL®.

On March 27, 2015, Syngenta brought suit against Willowood, LLC ("WW-LLC"), Willowood USA, LLC ("WW-USA"), and Willowood Limited ("WW-China") (collectively, "Willowood") asserting patent and copyright infringement.¹ Pet. App. 5a–6a. As part of their generic pesticide business, these Willowood entities closely cooperate to obtain, import, formulate, and sell generic azoxystrobin products in the United States. *Id.* at 5a–6a, 51a. Willowood's supply chain

¹ Syngenta also sued Willowood Azoxystrobin, LLC ("WW-Azoxy"), which is named as a Petitioner and also is a debtor in the pending bankruptcy proceedings. Based on the testimony of Willowood's corporate designee in the district court proceedings, Syngenta understands that WW-Azoxy includes only one employee, has no day-to-day operations, and does not participate in Willowood's azoxystrobin business. Thus, Syngenta did not appeal the district court's rulings concerning this entity.

begins with WW-China, a company that contracts for the manufacture and purchase of azoxystrobin technical from its Chinese supplier, Yangcheng TaiHe Chemicals Corp. *Id.* at 6a, 8a, 51a. WW-China sells this azoxystrobin technical to WW-USA, its Oregonbased affiliate. *Id.* In turn, WW-USA and its wholly owned subsidiary, WW-LLC, contract with third parties to formulate the azoxystrobin technical into end-use products, which they market and sell to customers in the United States. *Id.* In some instances, they also directly sell azoxystrobin technical to customers in the United States for formulation into private-label products.

In its complaint against Willowood, Syngenta asserted (among other things) infringement of its '138 Patent and infringement of its copyrights in its product labels for QUADRIS® and QUILT XCEL®. *Id.* These claims and the proceedings related to these claims, which are the subject of Willowood's Petition, are discussed further below.

A. Syngenta's Claims Asserting Infringement of the '138 Patent

The '138 patent is directed to a two-step process that is suitable for making azoxystrobin on a commercial scale, which involves an etherification step followed by a condensation step. Pet. App. 51a. There is no dispute that Willowood's azoxystrobin technical is made using the patented process of the '138 patent. *Id.* at 8a, 51a. Indeed, Willowood had sought out several manufacturers in China in an attempt to find one that could manufacture azoxystrobin using a different process, but ultimately was unsuccessful and concluded: "It seems all the manufacturers in [C]hina for this product are using

the same process for the Etherification/Condensation [and that] these step[s] ha[ve] to be used in sequence and [are] very difficult to avoid." Corrected Non-Confidential Joint App. at Appx7482, Syngenta Crop Protection, LLC v. Willowood, LLC, 994 F.3d 1344 (Fed. Cir. 2019) (Nos. 2018-1614, -0244).

At the district court, Syngenta moved for summary judgment that Willowood infringed the '138 patent under 35 U.S.C. § 271(g) by importing into the United States and using, offering to sell, and selling in the United States azoxystrobin products made by the patented process. Pet. App. 51a-53a. Although the district court recognized that Willowood's azoxystrobin was made by the patented process, id. at 51a, it adopted Willowood's proposed interpretation of § 271(g) as imposing a single-entity requirement, whereby all of the steps of the claimed process must be performed by, or be attributable to, a single entity, id. at 52a-53a. The district court did not provide any explanation or analysis of how it reached this interpretation, and in fact noted that this issue had not been addressed previously by the Federal Circuit or other district courts.² Id. at 52a. Applying the single-entity requirement, the district court denied summary judgment, finding that there were genuine issues of material fact as to whether a single entity performed both steps of the claimed process. Id. at

² Willowood incorrectly states that the district court relied on this Court's opinion in *Limelight Networks*, *Inc. v. Akamai Techs.*, *Inc.*, 572 U.S. 915 (2014). Pet. 4. The district court did cite the Federal Circuit's decision on remand from this Court in *Limelight*, but only to explain what the single-entity requirement is, not to explain why that requirement applies to § 271(g). Pet. App. 52a (citing *Akamai Techs.*, *Inc.*, v. *Limelight Networks*, *Inc.*, 797 F.3d 1020, 1022 (Fed. Cir. 2015) (en banc)).

53a. At trial, the jury returned a verdict in Willowood's favor with respect to the '138 patent, finding that Syngenta did not prove that both steps of the claimed process were performed by or attributable to a single entity, and the district court subsequently entered judgment in Willowood's favor with respect to the '138 patent. *Id.* at 15a.

Syngenta appealed the district court's judgment to the Federal Circuit. After conducting a careful and thorough analysis of the plain language of § 271(g), the broader context of the statutory scheme as a whole, and the legislative history, the Federal Circuit held that § 271(g) does not impose a single-entity requirement. Pet. App. 26a, 34a. Beginning with the plain language of § 271(g), the Federal Circuit explained that the "[statutory] language makes clear that the acts that give rise to liability under § 271(g) are the importation, offer for sale, sale, or use within this country of a product that was made by a process patented in the United States," and that "[n]othing in this statutory language suggests that liability arises from practicing the patented process." Id. at 26a–27a (emphasis in original).

The Federal Circuit next contrasted the language of § 271(g) with that of § 271(a) to explain why the single-entity requirement of § 271(a) did not apply to § 271(g). Pet. App. 27a (citing 35 U.S.C. § 271(a)). The Federal Circuit also examined the language of other provisions of Title 35, including §§ 271(f), 287(b), and 295, and concluded that the language of these provisions reinforced the conclusion that § 271(g) does not impose a single-entity requirement. *Id.* at 29a–32a, 34a (citing 35 U.S.C. §§ 271(f)(1), 287(b)(1)(C), 287(b)(3)(B)(iii); 287(b)(4)(A)(iii); 287(b)(5)(C)(i), 295)). Further, the Federal Circuit examined the

legislative history, including the portions on which Willowood relied, and concluded that the legislative history, as a whole, did not support applying a single-entity requirement to § 271(g). *Id.* at 32a–34a. Thus, the Federal Circuit, in a unanimous decision, reversed the district court's judgment with respect to the '138 patent. *Id.* at 35a.

B. Syngenta's Claims Asserting Copyright Infringement

Syngenta (through its predecessors) registered its azoxystrobin technical and end-use azoxystrobin products with the Environmental Protection Agency ("EPA") in 1997, along with the corresponding product labels. Since that initial registration, the EPA has approved numerous amendments to Syngenta's product labels to accommodate, among other things, further uses and applications of azoxystrobin.

Syngenta spent nearly eighteen years, and conducted over 9,000 plant trials, in developing its current QUADRIS® and QUILT XCEL® labels. These labels are approximately fifty-four and twenty-nine pages, respectively, and comprise narrative text and charts setting forth detailed directions for safe and effective use, storage, and disposal; application rate information; precautions; first-aid instructions; and environmental, physical, and chemical hazard information. Pet. App. 5a. Syngenta has registered these labels with the U.S. Copyright Office. *Id*.

In seeking approval for its generic azoxystrobin products, Azoxy 2SC and AzoxyProp Xtra, Willowood submitted proposed product labels with its applications to the EPA. It is undisputed that Willowood copied verbatim the language in these labels from Syngenta's QUADRIS® and QUILT

XCEL® labels. Corrected Non-Confidential Joint App. at Appx9042–43, Syngenta Crop Protection, LLC v. Willowood, LLC, 994 F.3d 1344 (Fed. Cir. 2019) (Nos. 2018-1614, -0244). Indeed, in the initial labels Willowood submitted to the EPA, Willowood made only a few changes to the label language that mainly involved substituting Willowood's company and product names for those of Syngenta. Notably, in its initial Azoxy 2SC label, Willowood mistakenly failed to replace all references to "Syngenta" "Willowood," which it later had to correct. Id. at Appx547 (stating on Willowood's initial Azoxy 2SC label that "Syngenta encourages responsible resistance management " (emphasis added)). Ultimately, the EPA approved Willowood's product registrations and the corresponding labels.

At the district court, Willowood moved for summary judgment on Syngenta's copyright claims, arguing that Syngenta's labels are not entitled to protection under various copyright principles, or alternatively that Willowood's copying was permitted by FIFRA or the fair-use doctrine. The day before the scheduled hearing on the parties' summary judgment motions, the United States filed a Statement of Interest with respect to Syngenta's copyright claims. The district court then set a briefing schedule whereby the parties responded to the Statement of Interest. Ultimately, in a two-page order, the district court granted Willowood's motion for summary judgment, holding that FIFRA "precludes" "copyright protection for the required elements of pesticide labels." Pet. App. 40a-41a. The district court, however, did not identify which portions or elements of Syngenta's labels it believed to be "required," and instead dismissed Syngenta's copyright claims in their entirety. *Id*. As a result, the district court did not reach the merits of the various underlying copyright issues presented on summary judgment. *Id*.

Syngenta appealed the district court's dismissal of the copyright claims to the Federal Circuit. As with its analysis of the patent issues, the Federal Circuit carefully and thoroughly analyzed the statutory language and concluded that "[b]ecause FIFRA does not, on its face, require a me-too registrant to copy the label of a registered product, the statute only conflicts with the Copyright Act to the extent that some particular element of Syngenta's label is both protected under existing copyright doctrines and necessary for the expedited approval of Willowood's generic pesticide product." Pet. App. 19a. Federal Circuit further explained that determination [would require it] to review the merits of Syngenta's copyright claims, which the district court did not reach." Id. Thus, the Federal Circuit, unanimous on this issue as well, vacated the district court's grant of summary judgment with respect to Syngenta's copyright claims and remanded so that the district court could develop a record and address the merits in the first instance. Id. at 19a, 24a–25a.

REASONS FOR DENYING THE PETITION

- I. THIS COURT SHOULD DENY REVIEW OF THE PATENT QUESTION.
 - A. The Federal Circuit's Application of 35 U.S.C. § 271(g) Does Not Present Any Conflicts or Issues of Significance Warranting this Court's Review.

Although Willowood attempts to cast the Federal Circuit's decision as "turn[ing] patent law on its head," Pet. 10, the reality is far from it. It is well established that direct infringement of a patented method may occur under either § 271(a) or § 271(g). Pet. 14; Pet. App. 28a–29a. In this case, Syngenta asserted that Willowood directly infringed the '138 patent under § 271(g) by importing, using, offering to sell, and selling products made by the patented process. Indeed, it is undisputed that Willowood's azoxystrobin is made using the process claimed in the '138 patent.' Pet. App. 35a, 51a–52a.

Faced with these circumstances, Willowood raised a novel defense—that it did not infringe because it had arranged for the patented method to be carried out in China by multiple entities—a defense that, as discussed further below, both ignores and flouts the plain language of the statute. In addressing this defense, more than three decades after § 271(g) was enacted, the Federal Circuit characterized it as "an issue of first impression" and soundly rejected it, holding that § 271(g) does not impose a single-entity

³ As noted, Willowood, in fact, sought out to no avail various manufacturers in China to see if they could manufacture azoxystrobin using a different process.

requirement. Pet. App. 26a. Willowood does not identify any decision by this Court or the Federal Circuit that presents a conflict with the Federal Circuit's interpretation of § 271(g) in this case or that otherwise suggests that this case raises issues of significance warranting this Court's review.

Although the Federal Circuit has previously interpreted § 271(a), a separate and distinct provision for direct infringement, as imposing a single-entity requirement, the Federal Circuit has never applied this requirement to § 271(g), for good reason in light of its plain language. As articulated by the Federal Circuit, the single-entity requirement of § 271(a) limits direct-infringement liability circumstances "where all steps of a claimed method are performed by or attributable to a single entity." Pet. App. 27a (citing BMC Resources, Inc. v. Paymentech, L.P., 498 F.3d 1373, 1378-79 (Fed. Cir. 2007)); Muniauction, Inc. v. Thomson Corp., 532 F.3d 1318, 1329-30 (Fed. Cir. 2008). Willowood does not identify any decision by the Federal Circuit that has applied this single-entity requirement, or suggested that it applies, to § 271(g). If anything, in an earlier case addressing government liability under 28 U.S.C. § 1498(a), the Federal Circuit, sitting en banc, suggested that the patentee could pursue a theory of infringement under § 271(g) even though the patented process at issue was carried out by multiple entities. Zoltek Corp. v. United States, 672 F.3d 1309, 1312, 1327 (Fed. Cir. 2012) (en banc).⁴

⁴ The patent at issue in *Zoltek* claimed a two-step process for creating carbon-fiber sheets for fighter-jet applications: (1) partially carbonizing fibers, and then (2) processing those

In framing its patent question, Willowood cites and relies heavily on this Court's decision in *Limelight*. Pet. i, 13–14 (citing *Limelight*, 572 U.S. at 915). Willowood, however, fails to address the limited scope of that decision, which neither addressed § 271(g) nor suggested that a single-entity requirement applies to Indeed, the sole question before this Court in Limelight was whether liability for induced infringement of a method claim under § 271(b) requires direct infringement by some entity, and this Court held that it does. Limelight, 572 U.S. at 920– Because the only form of direct infringement alleged in *Limelight* was under § 271(a), this Court proceeded to apply the single-entity requirement of § 271(a) as articulated by the Federal Circuit in Muniauction. Id. at 921–22 (citing Muniauction, 532) F.3d at 1329–30). This Court, however, was careful to explain it was "assuming without deciding that the Federal Circuit's decision in *Muniauction* is correct," because the question whether a single-entity requirement applies to § 271(a) was not before this Court. Id. at 922. Thus, contrary to Willowood's suggestion, this Court's decision in *Limelight* did not endorse the application of a single-entity requirement to § 271(a), let alone endorse the application of such a requirement to the separate and distinct provision for direct infringement under § 271(g).

fibers into sheets. *Zoltek*, 672 F.3d at 1312. The first step took place in Japan. *Id.* Thereafter, the fibers were imported into the United States, where the second step of the process took place. *Id.* Nonetheless, the Federal Circuit explained that "[i]f a private party had used Zoltek's patented process to create the resulting product, there would be liability for infringing Zoltek's patent right under . . . § 271(g)." *Id.* at 1323.

In short, Willowood does not identify any conflict or issues of significance with respect to the Federal Circuit's interpretation of § 271(g) that warrant this Court's review.

- B. The Federal Circuit Correctly Held that § 271(g) Does Not Impose a Single-Entity Requirement.
 - 1. The Plain Language of § 271(g) Confirms that It Does Not Impose a Single-Entity Requirement.

Willowood makes no attempt to identify support for a single-entity requirement in the plain language of § 271(g), because the plain language forecloses it. The language of a statute, "[u]nless otherwise defined, . . . will be interpreted as taking [its] ordinary, contemporary, common meaning." Bilski v. Kappos, 561 U.S. 593, 603 (2010) (quoting Diamond v. Diehr, 450 U.S. 175, 182 (1981)). Indeed, contrary to Willowood's position, this Court has "more than once" cautioned against reading into the patent laws "limitations and conditions" that Congress has not expressed. Diamond, 450 U.S. at 182.

Section 271(g) provides, in relevant part, that "[w]hoever without authority imports into the United States or offers to sell, sells, or uses within the United States a product which is made by a process patented in the United States shall be liable as an infringer." 35 U.S.C. § 271(g). As the Federal Circuit correctly recognized, "[t]his statutory language makes clear that the acts that give rise to liability under § 271(g) are the importation, offer for sale, sale, or use within this country of a product that was made by a process patented in the United States," and "[n]othing in this

statutory language suggests that liability arises from practicing the patented process." Pet. App. 26a–27a (emphasis in original). Thus, under § 271(g), it matters not who made the product by the patented process—one entity or multiple—only that the product is made by the patented process. *Id*.

This is consistent with the well-established principle that Congress' use of the passive voice to set forth an action in a statutory provision indicates that Congress did not intend the provision to place limits on actors carrying out the action. For example, in Dean v. United States, this Court held that a statute that called for a sentencing enhancement if a firearm "is discharged" did not require the discharge to be carried out knowingly or intentionally, relying in part on Congress' use of the passive voice. 556 U.S. 568, 571–72 (2009). As this Court explained, Congress' use of "[t]he passive voice focuses on an event that occurs without respect to a specific actor It is whether something happened—not how or why it happened that matters." Id. at 572; see also Special Devices, Inc. v. OEA, Inc., 270 F.3d 1353, 1355 (Fed. Cir. 2001) (reasoning that Congress' use of the passive voice in on-sale bar provision indicated that "it does not matter who places the invention 'on sale'; it only matters that someone . . . placed it on sale"); A. Krishnakumar, Passive-Voice References in Statutory Interpretation, 76 Brook, L. Rev. 941 (2011).

Although Willowood repeatedly references the single-entity requirement of § 271(a), Willowood ignores that the reason the Federal Circuit has interpreted § 271(a) to require a single entity to practice all of the steps of a claimed method is because this provision sets forth the infringing conduct in the active voice, *i.e.*, liability attaches to "whoever without

authority *makes*, *uses*, . . . a patented invention." 35 U.S.C. § 271(a) (emphasis added); *see also BMC*, 498 F.3d at 1380; Pet. App. 27a–28a. Likewise, in § 271(g), Congress used the active voice to set forth the actions that give rise to liability: "[w]hosoever without authority imports . . . or offers to sell, sells, or uses within the United States a product." 35 U.S.C. § 271(g). But, significantly, Congress used the passive voice in § 271(g) to describe the product that the infringer imports, offers for sale, sells, or uses—"a product which is *made by a process* patented in the United States"—because it does not matter *who* makes the product. *Id.* (emphasis added).

The only argument that Willowood offers based on the statutory language is that § 271(a) refers to making, using, selling, or offering to sell a "patented invention" and that § 271(g) refers to a product made by a "patented" process. Pet. 21. According to Willowood, if § 271(a) is interpreted to include a single-entity requirement but not § 271(g), the term "patented" would somehow have different meanings in these provisions. *Id.* Any difference between these provisions, however, flows not from how they define the patented invention but from the fact that they attach liability to different activities carried out in connection with the patented invention. Put another way, the fact that § 271(a) proscribes the use of a patented process, whereas § 271(g) proscribes the importation, sale, offer for sale, and use of a product made by the patented process, does not suggest in any way that what is "patented" in the context of these provisions is different. Nor does it support imposing a single-entity requirement on § 271(g).

In short, Willowood does not, and cannot, identify any support in the plain language of § 271(g) to impose a single-entity requirement.

2. Other Sections of Title 35 Further Confirm that § 271(g) Does Not Impose a Single-Entity Requirement.

As the Federal Circuit correctly recognized, the language that Congress used in other provisions of the Patent Act under Title 35 reinforces the conclusion that a single-entity requirement does not apply to § 271(g). Pet. App. 29a–32a. "Where Congress includes particular language in one section of a statute but omits it in another section of the same Act, it is generally presumed that Congress acts intentionally and purposely in the disparate inclusion or exclusion." *Rodriguez v. United States*, 480 U.S. 522, 525 (1987); see also Lamar, Archer & Cofrin, LLP v. Appling, 138 S. Ct. 1752, 1761 (2018).

For example, § 271(f) creates liability for induced infringement when a party "supplies or causes to be supplied in or from the United States all or a substantial portion of the components of a patented invention . . . in such manner as to actively induce the combination of such components outside of the United States in a manner that would infringe the patent if such combination occurred within the United States." 35 U.S.C. § 271(f)(1) (emphasis added). Thus, if Congress wished to limit infringement under § 271(g) in a similar fashion to acts that would amount to infringement in a certain context if performed in the United States, it "kn[ew] precisely how to do so." Pet. App. 29a–30a (citing Limelight, 572 U.S. at 923). Congress, however, chose not to do so, even though it

enacted § 271(g) four years after § 271(f). *Id.* at 30a (citations omitted).

As another example, § 287(b) makes inapplicable certain limits on the remedies for infringement under § 271(g) when the accused infringer "had knowledge before the infringement that a patented process was used to make the product the importation, use, offer for sale, or sale of which constitutes the infringement." 35 U.S.C. § 287(b)(1)(C) (2018) (emphasis added). The Federal Circuit correctly recognized that this language makes clear that infringement under § 271(g) occurs only after the use of the patented process. Pet. App. 31a. Because the practicing of the patented process is not the act that gives rise to liability under § 271(g), it is immaterial who practiced the patented process, whether a single entity or multiple entities. 5 Id. at 31a–32a.

Willowood largely does not dispute the Federal Circuit's comparative analysis of the language Congress used in 35 U.S.C. §§ 271(g), 271(f), and 287(b), and other provisions of Title 35. In fact, Willowood concedes that "the act of infringement under §271(g) occurs after [the] patented process has been used (i.e., [when] the product has been imported

⁵ Willowood faults the Federal Circuit for not addressing 35 U.S.C. § 287(b)(1)(A), which refers to a "person who . . . practiced the patented process," and argues that the reference to a "person" in the singular in this subsection reflects Congress' intent to impose a single-entity requirement. Pet. 24. This ignores, however, that § 287(b)(1) includes three subsections (A)-(C) in the disjunctive. As noted, the Federal Circuit did address subsection (C), which makes clear that a single person or entity need not practice the patented process. Pet. App. 31a-32a (discussing § 287(b)(1)(C)).

or sold)." Pet. 23. Instead, Willowood eschews the statutory language altogether and resorts to policy arguments based on its selective reading of the legislative history. *Id.* 22–24. As discussed in the next section, the legislative history does not support applying a single-entity requirement to § 271(g).

3. The Plain Language of § 271(g)
Forecloses Reliance on the
Legislative History, Which If
Anything Confirms that
§ 271(g) Does Not Impose a
Single-Entity Requirement.

Lacking support in the statutory text, Willowood relies almost exclusively on the legislative history, and mischaracterizes it, to argue that the singleentity requirement of § 271(a) should be read into § 271(g). Pet. 13–19. As a threshold matter, Willowood offers no basis to disregard unambiguous, plain language of § 271(g) in view of purported policy rationales that Willowood selectively gleans from the legislative history. Indeed, as this 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 U.S. 244, 260 (1945); see also United States v. Oregon, 366 U.S. 643, 648 (1961); Ex parte Collett, 337 U.S. 55, 61 (1949).

Even if it were appropriate to consider the legislative history, it only confirms that Congress did not intend to limit § 271(g) as Willowood suggests. For example, a Senate Report accompanying the bill that enacted § 271(g) explains that the purpose of the

statute is to provide a remedy "when someone, without authorization, uses or sells in the United States, or imports into the United States, a product made by [a] patented process." Pet. App. 32a (quoting S. Rep. No. 100-83, at 29 (1987)). As the Federal Circuit aptly noted, this report "makes clear that § 271(g) was enacted to 'extend protection [of process patents to products' resulting from practicing [the] patented process." Id. (quoting S. Rep. No. 100-83, at 46) (emphasis in original). The report further clarifies that § 271(g) "does not attempt to prevent the use of the process patent in another country" and that a "U.S. process patent holder [that] has not obtained a similar patent in the other country . . . has no right by virtue of his U.S. patent to prevent anyone from using process in that country." Id. at 32a-33a (quoting S. Rep. No. 100-83, at 30). Thus, as the Federal Circuit correctly recognized, because the legislative history confirms that "simply practicing a patented process ... does not come within the ambit of § 271(g)," it is "immaterial" that "there may be several entities involved in practicing the process." *Id.* at 33a.

For its part, Willowood contends, based on its selective reading of the legislative history, that Congress enacted § 271(g) to "grant patent owners the same protection against overse[a]s infringers as they already enjoyed against domestic entities' under §271(a)" and that failing to apply a single-entity requirement to § 271(g) would purportedly expand the scope of protection under § 271(g) beyond what Congress intended. Pet. 13, 15 (quoting *Mycogen Plant Sci., Inv. v. Monsanto Co.*, 252 F.3d 1306, 1318

(Fed. Cir. 2001)).⁶ The problem with Willowood's reasoning is that it fails to square with the statute or its legislative history. As the Federal Circuit recognized, both "the statutory language and the legislative history . . . make clear that practicing a patented process abroad does not trigger liability under § 271(g) in the same manner that practicing a patented process domestically does under § 271(a)" and that Congress did not intend to "provide for identical rights" under these provisions. Pet. App. Indeed, infringement under § 271(g) is 33a. predicated on the importation, sale, offer for sale, or use within the United States of a product made by a patented process, whereas infringement under § 271(a) may flow from the use of any patented process, whether or not it results in a product. Thus, as the Federal Circuit correctly reasoned, "[t]he different scope of protection offered under § 271(a) and § 271(g) demonstrates that there is no inconsistency between the two sections" that would run afoul of congressional intent. *Id.* at 33a–34a.

In short, the plain language of § 271(g) forecloses Willowood's reliance on the legislative history, and even if it were appropriate to consider the legislative history, it confirms that a single-entity requirement does not apply to § 271(g).

⁶ In *Mycogen*, the Federal Circuit compared one aspect of § 271(a) and § 271(g) and concluded that liability under § 271(g) does not attach if the product made by the patented process was manufactured before the patent issued, just as liability under § 271(a) does not attach if an entity "practice[d] the process before the beginning of the patent term." *Mycogen*, 252 F.3d at 1317-18. Contrary to Willowood's assertion, *Mycogen* does not hold that § 271(a) and § 271(g) are, or must be interpreted to be, congruous in *all* respects.

4. The Federal Circuit's Decision Does Not Impermissibly Extend Syngenta's Patent Monopoly.

Failing with its legislative-history arguments, Willowood asserts a new argument that the Federal Circuit's interpretation of § 271(g) impermissibly extends Syngenta's patent protection beyond the expiration of its compound patents covering the azoxystrobin compound, citing this Court's decisions in Kimble v. Marvel Entm't, 576 U.S. 446 (2015) and Brulotte v. Thys Co., 379 U.S. 29 (1964). Pet. 19. As a threshold matter, this Court should decline to consider this argument because Willowood failed to raise it in its briefing before the district court and the Federal Circuit, and for that reason, neither the district court nor the Federal Circuit had any opportunity to address it. See Springfield v. Kibbe, 480 U.S. 257, 259-60 (1987) (per curiam) ("We ordinarily will not decide questions not raised or litigated in the lower courts.").

Moreover, Willowood's argument. if considered, misapprehends the law and the scope of protection afforded by Syngenta's patents. Brulotte rule, which this Court reaffirmed in Kimble, merely stands for the principle that a patentee may not misuse a patent granted to it by entering into a license agreement that requires payment of royalties for use of the invention after the expiration of the patent, thereby impermissibly extending its patent monopoly past patent expiration. Kimble, 576 U.S. at 453 (citing *Brulotte*, 379 U.S. at 30–31, 33). Nothing in *Kimble* or *Brulotte*, however, precludes a patentee from legitimately enforcing a process patent directed to a method of making a compound after a different,

earlier-filed patent directed to the compound expires. Notably, Willowood does not identify any case law applying *Kimble* or *Brulotte* in this fashion.

In short, this Court should deny review of the patent question Willowood raises in the Petition.

II. THIS COURT SHOULD DENY REVIEW OF THE COPYRIGHT QUESTION.

A. The Federal Circuit's Decision, Which Remanded to the District Court to Address Various Issues in the First Instance, Is Interlocutory in Nature and Not Ripe for this Court's Review.

This Court has consistently denied review in cases that come before it in an interlocutory posture, where lower courts have not had an opportunity to develop the record and decide the merits of the issues presented. See Locomotive Firemen, 389 U.S. at 328 (denying certiorari because "the Court of Appeals [had] remanded the case" such that it was "not yet ripe for review by this Court"); see also Mount Soledad Mem'l Ass'n v. Trunk, 567 U.S. 944 (2012) (Alito, J., respecting the denial of certiorari) (denying certiorari due to interlocutory posture of case); Wrotten v. New York, 560 U.S. 959 (2010) (Sotomayor, J., respecting denial of certiorari) (same); Virginia Military Inst. v. United States, 508 U.S. 946 (1993) (Scalia, J., respecting denial of certiorari) (same).

Here, neither the district court nor the Federal Circuit has addressed the merits of Syngenta's copyright claims. In fact, although the district court concluded that FIFRA "precludes" "copyright protection for the required elements of pesticide

labels," it never identified what the "required" elements of Syngenta's labels are and instead dismissed Syngenta's copyright claims in their entirety. Pet. App. 40a–41a. Thus, the district court never reached the merits of the underlying copyright issues as they relate to portions of Syngenta's label that are *not* required. ⁷ *Id*.

For its part, the Federal Circuit declined to address the merits of these underlying copyright issues and remanded so that the district could develop a record and decide these issues in the first instance:

On remand, the district court should first discern whether the Copyright Act, as interpreted under existing copyright doctrines, would prohibit Willowood's use of any portion of Syngenta's label. The district court should, for instance, consider whether the fair-use doctrine or [other] limits on copyrightable subject matter, such as the merger doctrine, would eliminate infringement. Only if the district court concludes that the Copyright Act would in fact prohibit Willowood's conduct in a manner inconsistent with the purposes of FIFRA

⁷ Syngenta acknowledges that certain portions of a pesticide label may be suggested or mandated by the EPA (e.g., certain precautionary statements and hazard language), and Syngenta does not assert copyright infringement with respect to these portions. Pet. App. 24a n.5. But significant portions of Syngenta's labels include language, such as claims regarding product efficacy, that neither FIFRA nor the EPA requires in a label, let alone requires generic applicants to copy. See Bates v. Dow Agrosciences LLC, 544 U.S. 431, 440 (2005) (recounting FIFRA's legislative history and the EPA's implementation of FIFRA; finding FIFRA does not require the EPA to evaluate pesticide efficacy and that the "EPA's approval of a pesticide label does not reflect any determination on the part of EPA that the pesticide will be efficacious" (citations omitted)).

should it revisit the question of whether and to what extent FIFRA precludes Syngenta's copyright claims for any part of its pesticide labels.

Pet. App. 24a–25a. As the Federal Circuit recognized, the resolution of some or all of these issues on remand could obviate the need to resolve whether FIFRA precludes any aspect of Syngenta's copyright claims. *Id.* And if this Court were to grant review "at this stage, [it] would not have the benefit" of the district court's and Federal Circuit's "full consideration" of these issues. *Wrotten*, 560 U.S. at 959. Thus, as the Federal Circuit aptly put it, this Court should "decline to wield the blunt tool of preclusion before the full factual and legal contours of any latent problem have been examined." Pet. App. 25a.

- B. The Federal Circuit Correctly Held that FIFRA Does Not Preclude All Copyright Protection in Pesticide Labels.
 - 1. No Conflict Exists Between FIFRA and Copyright Law that Would Preclude All Copyright Protection in Pesticide Labels.

The Federal Circuit correctly determined that "FIFRA does not, on its face, require a [generic] metoo registrant to copy the label of a registered product" such that it would preclude all copyright protection in pesticide labels, as the district court held. Pet. App. 19a. As this Court has explained, "[w]here 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."

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); Zenith Elecs. Corp. v. Exzec, Inc., 182 F.3d 1340, 1347 (Fed. Cir. 1999).

Willowood's argument that FIFRAentirely precludes copyright protection in pesticide labels rests on the false premise that FIFRA requires generic applicants to copy the original registrant's label. In relevant part, FIFRA § 136a provides for expedited review of an application for a generic pesticide when the proposed product, as compared to the currently registered product, (1) "would be identical or substantially similar in composition and labeling," or (2) "would differ in composition and labeling from such currently registered pesticide only in ways that significantly increase would not the unreasonable adverse effects on the environment." 7 U.S.C. \S 136a(c)(3)(B)(i)(I) (emphasis added). As the Federal Circuit correctly recognized, this statutory language does not require a generic applicant to "ensure that its product label is identical to a registered label; nor does it require applicants to otherwise derive the elements of its label from that of the registered label." Pet. App. 21a. Indeed, the text of § 136a expressly provides for expedited review of applications that "differ in . . . labeling" so long as the differences "do not significantly increase the risk of unreasonable adverse effects to the environment." $\S 136a(c)(3)(B)(i)(I)$ (emphasis added).

Willowood asserts that the Federal Circuit failed to give meaning to the clause in § 136a that provides for expedited review of labels that are "identical or substantially similar," which according to Willowood indicates that the statute "necessarily contemplates

copying of previously approved labels." Pet. 30. But the fact that FIFRA may contemplate the submission of copied labels under certain circumstances does not mean that FIFRA requires or authorizes generic applicants to copy. Giving full force to both FIFRA and copyright law, it simply means that a generic applicant may submit a label that is identical or substantially similar to that of a registered pesticide, as contemplated by FIFRA, but may not disregard any copyrights the original registrant holds in the label. See POM Wonderful LLC v. Coca-Cola Co., 573 U.S. 102, 118 (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."). To be sure, there may be circumstances where it is entirely appropriate for a generic applicant to copy an original registrant's label, such where the applicant has sought and generic authorization to copy from the original registrant.

Alternatively, the generic applicant may independently create its label, which would not violate the original registrant's copyrights even if the label it creates is ultimately substantially similar to the original registrant's. See Selle v. Gibb, 741 F.2d 896, 901 (7th Cir. 1984) ("[N]o matter how similar the two works may be (even to the point of identity), if the defendant did not copy the accused work, there is no [copyright] infringement."); Keeler Brass Co. v. Cont'l Brass Co., 862 F.2d 1063, 1065 (4th Cir. 1988) (explaining that a defendant may rebut copying "with evidence of independent creation"); App. 21a.

In short, Willowood does not identify any conflict between FIFRA and copyright law that would preclude all copyright protection in pesticide labels.

2. Willowood's Policy Arguments Are Unfounded and Best Directed to Congress, Not This Court.

Unable to identify any clear conflict between FIFRA and copyright law in the statutory text, Willowood turns to speculative policy arguments that are best directed to Congress, not this Court. See Azar, 139 S. Ct. at 1815 (explaining "courts aren't free to rewrite clear statutes under the banner of our own policy concerns" and that those who dislike Congress' policy choices "must take [their] complaints there"); Patsy v. Bd. of Regents of State of Fla., 457 U.S. 496, 508 (1982) (declining to judicially impose requirement in statute that "would usurp policy judgments that Congress has reserved for itself").

According to Willowood, allowing copyright protection in pesticide labels would frustrate FIFRA's alleged pro-competitive goals by making it more difficult and expensive for generic applicants to prepare labels that both meet the EPA's standards and respect the original registrant's copyrights. To be sure, the notion that pesticide labels are entitled to copyright protection is not new. More than fifteen years ago, the court in *FMC* held that FIFRA does not conflict with, or preclude, copyright protection in pesticide labels, consistent with the Federal Circuit's decision here. FMC Corp. v. Control Sols., Inc., 369 F. Supp. 2d 539 (E.D. Pa. 2005). Yet, Willowood identifies no actual evidence of any anticompetitive effect as a result of that decision in the years since. Cf. Melendez-Diaz v. Mass., 557 U.S. 305, 325 (2009) "Perhaps the best indication that the sky will not fall . . . is that it has not done so already.").

ignores Moreover, Willowood that FIFRA principally furthers competition by providing generic applicants a pathway to obtain expedited review and approval of a generic version of a registered pesticide and enter a market already built by the original registrant, without devoting substantial resources to product development, testing, and generation of data to support an EPA registration. Thus, to the extent that FIFRA has a pro-competitive purpose, it achieves that purpose short of allowing generic applicants to ignore copyright laws and entirely free-ride off of the efforts of original registrants by copying their labels. Indeed, taken to its logical extreme, Willowood's reasoning would mean that generic applicants could disregard any intellectual property that an original registrant holds in its product, including any patent and trademark rights, because respecting those rights arguably would frustrate generic competition.

Willowood's arguments based on FIFRA's purported policy goals also wrongly assume that a generic applicant must copy the original registrant's label. Rather, a generic applicant may avoid copyright concerns by not copying the original registrant's label and instead *independently* creating its own label. Again, because copyright infringement is premised on copying, an independently created label, even one that is substantially similar to the original registrant's label, would not infringe the original registrant's copyright. See Selle, 741 F.2d at 901; Keeler, 862 F.2d at 1065; App. 21a.

For similar reasons, Willowood's argument that there are purportedly only a limited number of ways to express the information in a pesticide label lacks merit, because even assuming that were true, a generic applicant is free to independently create its label. Pet. 33. Moreover, as the Federal Circuit correctly found, such concerns can be addressed by applying traditional copyright doctrines, such as merger and fair use, to challenged aspects of a pesticide label; they do not justify precluding all copyright protection in pesticide labels, as Willowood asks this Court to do. Pet. App. 23a–24a.

Further, Willowood asserts that to promote FIFRA's purported policy goals, the EPA has encouraged the copying of registered labels, but Willowood notably stops short of asserting that the EPA has required copying. Pet. 31–32. To be sure, Willowood identifies no actual EPA policy, let alone would require copying the original registrant's label without authorization. Willowood's assertion that the "EPA plainly lacks the expertise to review me-too labels in relation to copyright" likewise misses the mark, because no one is suggesting that the EPA is, or should be, charged with evaluating compliance with copyright laws. Id. at 34. Rather, the responsibility lies with generic applicants to create labels that satisfy the EPA's requirements while also respecting copyright laws, and with the original registrant to enforce its copyrights.

In short, Willowood's arguments based on FIFRA's purported policy goals do not warrant usurping Congress' role to create a judicial exception to copyright protection for generic pesticide labels.

3. The Federal Circuit's Decision Addressing FIFRA Does Not Conflict with the Second Circuit's Decision in **SmithKline** Addressing a **Facially** Different Hatch-Waxman Provision.

The Second Circuit's decision in SmithKline holding that a Hatch-Waxman provision precludes copyright protection in drug labels does not conflict with the Federal Circuit's holding that FIFRA does not preclude copyright protection in pesticide labels. 21a–22a (distinguishing Beecham Consumer Healthcare, LP. v. Pharm., Inc., 211 F.3d 21, 29 (2d Cir. 2000)); FMC, 369 F. Supp. 2d at 568-71 (same). Indeed, this case is easily reconciled with *SmithKline* by comparing the language of the statutory provisions at issue. On the one hand, FIFRA places the burden on the EPA and expressly requires it to accept and expedite review of even those applications that <u>differ</u> in labeling. On the other hand, the Hatch-Waxman provision at issue in SmithKline places the burden on the generic applicant and expressly requires the applicant to show that the labeling is the same to obtain expedited FDA review.

Hatch-Waxman	FIFRA
"An abbreviated	$"The \ Administrator \ shall,$
application for a new	as expeditiously as
$drug shall \dots show$	possible, review and act
that the <i>labeling</i>	$on\ any\ application\ \dots$
proposed for the new	that would <u>differ</u> in
drug is the <u>same</u> as the	composition and labeling
labeling approved for	from such currently-
the listed drug"	registered pesticide only
	in ways that would not
21 U.S.C. § 355(j)(2)	significantly increase the
(A)(v) (emphasis	risk of unreasonable
added).	adverse effects on the
	environment."
	7 U.S.C. § 136a(c)(3)(B)
	(i)(I) (emphasis added).

Notably, in discussing the sameness requirement of the Hatch-Waxman provision, the Second Circuit explained that any flexibility it offered was "narrow and intended to prevent misstatements" such as allowing a generic applicant to change references in the label to the name/address of the manufacturer or the color of a product. SmithKline, 211 F.3d at 28 (citing H. Rep. No. 98-857 at 22 (1984)). Indeed, in that case, the FDA had rejected the generic applicant's label because it did not "copy verbatim substantially all of the text" from the registered label. Id. at 24. Conversely, FIFRA offers relatively wide latitude for generic applicants to independently create and submit labels that differ from the registered label. Pet. App. 21a-22a. Thus, as the Federal Circuit correctly recognized, the Second Circuit's reasoning in SmithKline does not apply to FIFRA. Id.

In short, this Court should deny review of the copyright question Willowood raises in the petition.

III. THE PENDING BANKRUPTCY PROCEEDINGS MAKE THIS CASE A POOR VEHICLE.

The pending bankruptcy proceedings, which Willowood briefly mentions in footnote 1 of the Petition, make this case a poor vehicle for addressing the questions presented. On February 15, 2019, Petitioners WW-USA, WW-LLC, and WW-Azoxy (among other Willowood entities) filed for bankruptcy under Chapter 11 of the Bankruptcy Act in the U.S. Bankruptcy Court for the District of Colorado. Pet. 2 The bankruptcy court approved a plan of reorganization on March 3, 2020. Id.Petitioner that has not filed for bankruptcy as part of these proceedings is WW-China, and Willowood has maintained that at least Syngenta's claims of infringement of the '138 patent, which form the basis of the first question presented, do not apply to WW-China. Thus, once the bankruptcy proceedings are completed, the questions presented in the Petition may become, in whole or in part, moot.

Further, in light of the bankruptcy filings, the district court proceedings are currently subject to an automatic stay of litigation under 11 U.S.C. § 362. Syngenta has moved the bankruptcy court to lift the stay, and the Willowood Debtors have opposed. At the same time, in a disclosure filed with the bankruptcy court, Willowood explained that non-party "Generic Crop Science LLC, which purchased substantially all of the [Willowood] Debtors' assets pursuant to a sale approved by [the bankruptcy court] on April 17, 2019 . . ., has agreed to fund [Willowood's counsel's]

professional fees and expenses" in connection with this appeal. Supplemental Disclosure of Compensation of Attorney for the Debtors, *In re Willowood USA Holdings, LLC* (No. 19-11079-KHT) (Bankr. D. Colo. Mar. 4, 2020). It is unclear what interests this non-party buyer has with respect to the issues raised in the Petition, why it is funding this appeal, or how its interests may change were this Court to grant review or as the bankruptcy proceedings progress.

IV. CONCLUSION

For the foregoing reasons, this Court should deny the petition for a writ of certiorari.

Respectfully submitted,

RUSSELL E. LEVINE, P.C.

Counsel of Record
HARI SANTHANAM
KIRKLAND & ELLIS LLP
300 North LaSalle Street
Chicago, Illinois 60654
(312) 862-2000
rlevine@kirkland.com

June 25, 2020