No. 2018-1614

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-Appellees.

On Appeal from the United States District Court for the Middle District of North Carolina in case no. 15-cv-00274, Judge Catherine C. Eagles

BRIEF FOR THE UNITED STATES AS AMICUS CURIAE IN SUPPORT OF APPELLEES

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S. Rep. No. 100-346 (1988) 8, 15

Other Authorities:

Melville Nimmer & David Nimmer, *Nimmer on Copyright* (2017):

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Office of Pesticide Programs, U.S. Envtl. Prot. Agency:

Label Review Manual (rev. 2016), https://www.epa.gov/sites/production/files/2017-09/documents/lrm-complete-aug-2017.pdf.....7, 8, 21, 26

Pesticide Registration Manual: Introduction, https://www.epa.gov/pesticide-registration/pesticide-registration-manual-introduction#intro.....12

STATEMENT OF INTEREST AND SUMMARY OF ARGUMENT

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) allows pesticide manufacturers to obtain expedited "me-too" approval of generic pesticides, provided that the generic product is identical or substantially similar to a currently registered pesticide in composition and labeling or differs 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). FIFRA's expedited-review scheme thus encourages me-too applicants to copy brand-name labels, which ensures consistency in communicating important safety information to pesticide users.

The question in this case is whether a brand-name pesticide manufacturer can effectively prevent me-too competition by asserting copyright-infringement claims based on the label. This is an issue of first impression in the courts of appeals. The Court's resolution of the question will directly implicate the interests of the executive branch agencies that administer both FIFRA and the Copyright Act. The United States respectfully submits this amicus brief under Federal Rule of Appellate Procedure 29(a).

As the district court correctly recognized, "FIFRA contemplates that a 'me-too' applicant will copy from the original pesticide label in ways that would otherwise infringe a copyright." Appx33. But allowing brand-name pesticide manufacturers to obtain damages and injunctions under the Copyright Act against me-too applicants on that basis would effectively nullify FIFRA's me-too scheme. Contrary to Syngenta's

contention, moreover, a me-too applicant cannot easily avoid infringement by making the few modifications that FIFRA will permit under the me-too scheme. Indeed, Willowood tried to do so here, and Syngenta alleges that the resulting label still infringes its copyright because it is substantially similar to the original. *Cf. Copeland v. Bieber*, 789 F.3d 484, 488 (4th Cir. 2015) (discussing substantial-similarity test for copyright infringement). Congress would have understood, moreover, that requiring each of the many—sometimes hundreds—of generic manufacturers of a particular pesticide to find a new circumlocution for the same critical safety information would only impede the EPA's regulatory review and increase the risk of public confusion, user error, and harm to human health and the environment.

This Court should affirm the district court's holding that FIFRA's expedited-review scheme for generic pesticides precludes copyright-infringement claims against me-too applicants who do what FIFRA contemplates and copy the original label. This interpretation protects the purposes of FIFRA's expedited-review scheme without significantly undermining the purposes of the Copyright Act. And it is consistent with the Second Circuit's decision in *SmithKline Beecham Consumer Healthcare, LP v. Watson Pharmaceuticals, Inc.*, 211 F.3d 21 (2d Cir. 2000), which held that a generic drug manufacturer could not be liable for copyright infringement for using the same label as the pioneer drug, as required by the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act. The Second Circuit reasoned that those amendments "were intended to facilitate the introduction of generic competitors," but

"[i]f copyright law were to prevail, producers of generic drugs will always be delayed in—and quite often prohibited from—marketing the generic product, results at great odds with the purposes of the Hatch-Waxman Amendments." *Id.* at 28. That reasoning applies with particular force here because there can be dozens or even hundreds of generic pesticides for a given brand-name pesticide. *See* Appx3548.

Alternatively, the Court may resolve the dilemma by holding that the use of identical or substantially similar labels by generic manufacturers—as encouraged by FIFRA and EPA—is a non-infringing fair use of the copyrighted label under 17 U.S.C. § 107. This approach would protect the central purposes of FIFRA's expedited-review scheme by recognizing, consistent with the Copyright Act, that a me-too applicant who does only what FIFRA expressly encourages has engaged in a fair use of a copyrighted label.

STATEMENT OF THE CASE

A. Statutory Background

1. The Copyright Act

The Copyright Act protects "original works of authorship fixed in any tangible medium of expression." 17 U.S.C. § 102. The statute provides copyright owners with a set of exclusive rights, including "to reproduce the copyrighted work" and "to distribute copies … of the copyrighted work to the public." *Id.* § 106. Section 501(a) provides that "[a]nyone who violates any of the exclusive rights of the copyright owner as provided by section[] 106 … is an infringer of the copyright." *Id.* § 501(a).

"To establish a claim for copyright infringement, a plaintiff must prove that it owned a valid copyright and that the defendant copied the original elements of that copyright." *Building Graphics, Inc. v. Lennar Corp.*, 708 F.3d 573, 578 (4th Cir. 2013).[1] "Absent direct proof of copying, which is hard to come by, a plaintiff may prove copying indirectly, with evidence showing that the defendant had access to the copyrighted work and that the purported copy is 'substantially similar' to the original." *Copeland v. Bieber*, 789 F.3d 484, 488 (4th Cir. 2015); *Lyons P'ship LP v. Morris Costumes, Inc.*, 243 F.3d 789, 801 (4th Cir. 2001). The Copyright Act provides the copyright owner "with a potent arsenal of remedies," which include "an injunction to restrain the infringer from violating his rights, the impoundment and destruction of all reproductions of his work made in violation of his rights, a recovery of his actual damages and any additional profits realized by the infringer or a recovery of statutory damages, and attorneys fees." *Sony Corp. of Am. v. Universal City Studios, Inc.*, 464 U.S. 417, 433-34 (1984) (citing 17 U.S.C. §§ 502-505).

2. FIFRA

FIFRA prohibits the distribution or sale of "any pesticide that is not registered" by EPA. 7 U.S.C. § 136a(a).[2] FIFRA provides that EPA shall register a pesticide

[1] This Court applies copyright law as interpreted by the regional circuits, which is the Fourth Circuit here. *Amini Innovation Corp. v. Anthony Cal., Inc.*, 439 F.3d 1365, 1368 (Fed. Cir. 2006).

[2] The term "pesticide" includes the fungicides at issue here. 7 U.S.C. § 136(t), (u).

where the composition of the pesticide "warrant[s] the proposed claims for it"; "its labeling and other material required to be submitted comply with the requirements of this subchapter"; it will perform its intended function "without unreasonable adverse effects on the environment"; and, when used in accordance with accepted practice, "it will not generally cause unreasonable adverse effects on the environment." *Id.* § 136a(c)(5).[3]

To facilitate EPA's determination of whether those conditions are satisfied, Congress requires applicants to submit or cite to supporting data, which often includes extensive data developed by the applicant. 7 U.S.C. § 136a(c)(1)-(2); 40 C.F.R. §§ 152.42, 152.50, 152.80-152.99. In light of this substantial regulatory burden, FIFRA establishes an exclusivity period, under which the applicant maintains the sole right to use the data for at least ten years following registration, and compensation requirements after the exclusivity period. 7 U.S.C. § 136a(c)(1)(F)(i) (requiring written permission of original submitter for ten years following registration); *id.* § 136a(c)(1)(F)(ii) (providing for certain extensions); *id.* § 136a(c)(1)(F)(iii) (requiring compensation). *See Ruckleshaus v. Monsanto Co.*, 467 U.S. 986, 994-95 (1984) (describing FIFRA's exclusive-use and compensation periods).

[3] FIFRA also provides for "conditional" registration of pesticides that are "identical or substantially similar" to a registered pesticide or "differ only in ways that would not significantly increase the risk of unreasonable adverse effects on the environment." 7 U.S.C. § 136a(c)(7)(A); Pub. L. No. 95-396, § 6, 92 Stat. 819, 825 (1978).

Congress established a highly reticulated scheme for pesticide labels, which must convey important safety information to pesticide users and are often dozens of pages in length. Congress required that each applicant submit "a complete copy of the labeling of the pesticide, a statement of all claims to be made for it, and any directions for its use." 7 U.S.C. § 136a(c)(1)(C); 40 C.F.R. § 152.50(e); *see* 7 U.S.C. § 136(p) (defining "labeling"). The information on the label must be "placed thereon with such conspicuousness … and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use." 7 U.S.C. § 136(q)(1)(E); *see generally Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 438 (2005). The label must contain the necessary "directions for use," 7 U.S.C. § 136(q)(1)(F), and any necessary "warning or caution statement" for the protection of health and the environment, *id.* § 136(q)(1)(G). The label must also include, among other things, "an ingredient statement," "a statement of the use classification," and, for highly toxic pesticides, "the skull and crossbones; … the word 'poison' prominently in red on a background of distinctly contrasting color; … and a statement of a practical treatment (first aid or otherwise) in case of poisoning by the pesticide." *Id.* § 136(q)(2)(A)-(D). FIFRA makes it unlawful to "use any registered pesticide in a manner inconsistent with its labeling." *Id.* § 136j(a)(2)(G); 40 C.F.R. § 156.10(i)(2)(ii).

EPA's regulations further detail the required contents and formatting of the label, including specific language that must be used depending on toxicity and use patterns. 40 C.F.R. § 156.10. EPA has published a manual with extensive guidance

on FIFRA's labeling requirements. Office of Pesticide Programs, U.S. Envtl. Prot. Agency, *Label Review Manual* (rev. 2016), https://www.epa.gov/sites/production/files/2017-09/documents/lrm-complete-aug-2017.pdf (*Manual*). As the manual explains, "[a] critical function of the label is to translate the results of the science evaluations into a set of conditions, directions, precautions, and restrictions that define who may use a pesticide, as well as where, how, how much, and how often it may be used." *Id.* at 1-2.

EPA reviews all of the relevant data and the proposed labeling for a completed application, 40 C.F.R. §§ 152.107, 152.108; assesses the potential risks and benefits; and makes a determination whether to approve the application, *id.* § 152.112; *see* 7 U.S.C. § 136a(c)(5). This process requires significant time and resources. 7 U.S.C. § 136w-8(b)(3) (tbl. 1) (providing review periods of fourteen to twenty-four months for pesticides with new active ingredients).

In 1988, Congress amended FIFRA to provide a simpler path for expedited registration of generic pesticides. Pub. L. No. 100-532, §§ 102, 103, 102 Stat. 2654, 2666-67 (1988). Codified at FIFRA section 136a(c)(3)(B), this provision requires EPA "as expeditiously as possible" to review and act on any application that

> proposes the initial or amended registration of an end-use pesticide that, if registered as proposed, would be identical or substantially similar in composition and labeling to a currently-registered pesticide identified in the application, or that 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). As a contemporaneous House Report explains, "[t]his expedited procedure is generally intended to hasten registration decisions on end-use pesticides that are identical or substantially similar to a currently registered pesticide." H.R. Rep. No. 100-939, at 31 (1988); *see also* S. Rep. No. 100-346, at 20 (1988) (describing expedited-review amendment as "provid[ing] for 'fast track' consideration of registration applications for products that are identical or substantially similar to already registered products").

Me-too applicants can take advantage of the expedited-review process, but they must satisfy the requirements for pesticide registration in section 136a(c)(5), including that the pesticide's "labeling … compl[ies] with the requirements" of FIFRA, or in section 136a(c)(7), which allows for conditional registration. 7 U.S.C. § 136a(c)(5), (c)(7); *see* 40 C.F.R. §§ 152.112, 152.113. Because the composition and labeling for the me-too pesticides must be identical or substantially similar to the currently registered pesticide or differ only in limited ways, EPA can make the determination that the registration criteria are satisfied on an expedited basis. For such pesticides, the EPA manual instructs the label reviewer to "ensure that the new product's use patterns, including any public health claims, are the same as those of the cited product." *Manual* 4-8. And in reviewing directions of use on a me-too label, the reviewer is instructed to "make a side-by-side comparison of the proposed set of use directions to the use directions on the label for the registered product(s)." *Id.* at 11-9.

In contrast to the up to two-year review period for pesticides with new active ingredients, FIFRA generally requires EPA to act on a me-too application within four months, 7 U.S.C. § 136w-8(b)(3) (tbl. 4), or, if there is no statutorily designated review period, within ninety days, *id.* § 136a(c)(3)(B)(ii)(II).

B. Factual Background

Plaintiff Syngenta Crop Protection, LLC markets its QUADRIS® and QUILT XCEL® fungicide products under EPA-approved labels, which it has registered with the Copyright Office. Appx276-277 (¶¶ 30, 32, 33, 35). Syngenta's product labels are approximately fifty and thirty pages long, respectively (Appx424-477, Appx481-509), and, as Syngenta explains (Br. 18-19), the labels "comprise narrative text and charts setting forth detailed directions for use, storage, and disposal; application rate information; precautions; first-aid instructions; and environmental, physical, and chemical hazards."

In 2013, defendants Willowood, LLC, Willowood USA, LLC, Willowood Azoxystrobin, LLC, and Willowood Limited (collectively, Willowood) filed me-too applications for two generic fungicide products, Azoxy 2SC and AzoxyProp Xtra, which correspond, in composition and labeling, to Syngenta's fungicides. *See* Appx278 (¶ 42); Appx714. Willowood's products and labels were approved by EPA in mid-2014. *See* Appx714.

In early 2015, Syngenta filed this lawsuit alleging patent and copyright infringement based on Willowood's pesticide compositions and labeling. With

respect to its copyright-infringement claim, Syngenta alleged that Willowood's labels infringe because they are "substantially similar" to Syngenta's labels. Appx290 (¶¶ 111-112); Appx289-292 (¶¶ 109-128); *see also* Appx284-286 (¶¶ 78-88).

After Syngenta filed its complaint, Willowood sought EPA approval to amend its labels to avoid the copyright-infringement claims. *See* Appx2980. Willowood's initial proposed amendments included formatting changes and limited substantive changes. *See* Appx3084-3200. EPA required several additional revisions to the labels (Appx2980, Appx3201-3339) to improve clarity and ensure satisfaction of FIFRA's standards. As the United States explained in our statement of interest filed in district court (Appx2980-2981), the revised labeling that EPA approved (Appx3341) differs only in minor respects from the previous Willowood labeling. Appx3444-3545 (demonstratives with comment bubbles describing changes between original and amended Willowood labels). Syngenta continues to assert that Willowood's labels infringe its copyright on the original labels despite these changes.

C. Prior Proceedings

The district court granted summary judgment to Willowood on Syngenta's copyright claims. Appx33-34.

The district court held that FIFRA "precludes copyright protection for the required elements of pesticide labels as against the labels of me-too registrants." Appx33 (citing *SmithKline Beecham Consumer Healthcare, LP v. Watson Pharm., Inc.*, 211 F.3d 21, 29 (2d Cir. 2000)). The court reasoned that "FIFRA contemplates that a

'me-too' applicant will copy from the original pesticide label in ways that would otherwise infringe a copyright." *Id.* The court observed that "[e]ven with some changes, use of the original pesticide label as a 'go by' for the new label will result in copyright infringement." Appx33-34. The court concluded, therefore, that "[i]n enacting FIFRA, Congress intended a narrow exception to copyright protection for the required elements of pesticide labels as against me-too registrants." Appx34.

Following a jury trial on the remaining claims, the district court entered final judgment, including dismissal of the copyright claims pursuant to the court's summary judgment order. Appx4. This appeal and cross-appeal followed.

ARGUMENT

I. FIFRA PRECLUDES SYNGENTA'S COPYRIGHT-INFRINGEMENT CLAIMS AGAINST WILLOWOOD'S "ME-TOO" PESTICIDE LABELS

Congress designed FIFRA's me-too registration scheme to facilitate and expedite the approval of generic pesticides. That scheme works because the generic pesticide labels must be "identical or substantially similar" to the original label or differ "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). The use of such similar labels allows EPA to expeditiously confirm that the me-too labeling "compl[ies] with the requirements of this subchapter," *id.* § 136a(c)(5)(B); *see also id.* § 136a(c)(7), and to approve the registration if the remaining statutory requirements

are satisfied. *See* Appx1165-1175 (declarations of senior EPA officials in other district court cases describing me-too labeling requirements and review process).

Pesticide labels are "of utmost importance" because they are "the primary mechanism to inform the end-user about how to use and apply the product to achieve the product's useful functions, as well as which precautions must be followed to protect both human health and the environment." Office of Pesticide Programs, U.S. Envtl. Prot. Agency, *Pesticide Registration Manual: Introduction*, https://www.epa.gov/pesticide-registration/pesticide-registration-manual-introduction#intro. Expeditious review of different labels for essentially the same products would be impracticable, particularly because there can be hundreds of me-too registrations for a single pesticide. Appx3547-3548 (letter of senior EPA official). Congress cannot have intended for each of these hundreds of registrants to try to find a different circumlocution to communicate the same critical warnings, preparation and application instructions, first aid information, and equipment requirements (to name a few label elements). *See* 7 U.S.C. § 136(q)(1)(E) (label must be "likely to be read and understood by the ordinary individual"). The resulting risk of confusion, and the attendant danger to the public health and environment, is plain. EPA has a strong interest in ensuring consistent labeling language for each pesticide, whenever and wherever the public encounters it. *See* Appx1171-1172. FIFRA facilitates that goal by requiring that generic pesticide makers use a label that is identical to, or differs only in insignificant ways from, the original EPA-approved label.

Imposing copyright liability on me-too manufacturers would thwart FIFRA's expedited-review scheme for generic pesticides. FIFRA's scheme, which depends on the similarity between already-approved and proposed labels, could not function if the me-too manufacturers were subject to the threat of litigation and the "potent arsenal of remedies" available under the Copyright Act, including injunctions, damages, and disgorgement. *Sony Corp. of Am. v. Universal City Studios, Inc.*, 464 U.S. 417, 433-34 (1984); 17 U.S.C. §§ 502-505. This Court should resolve the statutory tension, as the Second Circuit did in the analogous context of generic drug labels, *SmithKline Beecham Consumer Healthcare, LP v. Watson Pharm.*, 211 F.3d 21 (2d Cir. 2000), by holding that a me-too pesticide manufacturer cannot be held liable for copyright infringement for doing what Congress intended and copying the original label.

A. FIFRA's Expedited "Me-Too" Review Scheme Encourages Copying Of Pesticide Labels

Congress required EPA to "review and act on" a me-too application "as expeditiously as possible," 7 U.S.C. § 136a(c)(3)(B)(i), and expressly provided an abbreviated window for review, *id.* § 136a(c)(3)(B)(ii)(II)-(III). To make that expedited review possible, Congress encouraged me-too applicants to use labels that are identical or substantially similar to an already-approved label or that differ only in ways that would not significantly increase the risk of unreasonable environmental harm.

At the same time, a pesticide label—an original written work that may be dozens of pages long—qualifies as a "literary work" under the Copyright Act. 17 U.S.C. § 101 (definitions). There is no dispute that Willowood copied Syngenta's labels. That is how FIFRA works. And when a generic pesticide manufacturer uses an "identical or substantially similar" label as permitted under FIFRA section 136a(c)(3)(B)(i)(I) to obtain expedited review, that label will often satisfy the test for copyright infringement, *cf. Copeland v. Bieber*, 789 F.3d 484, 488 (4th Cir. 2015).

There is thus a substantial conflict between FIFRA's me-too expedited-review scheme and the remedial scheme of the Copyright Act. On Syngenta's understanding of the law, if a me-too pesticide manufacturer follows FIFRA's instructions and submits a label to EPA that is identical or substantially similar to the already-approved label, that manufacturer will face the threat of damages and an injunction under the Copyright Act from a brand-name manufacturer, which is unlikely to welcome the competition. That scheme is unworkable. Congress cannot have intended the Copyright Act's general remedial scheme to operate in the context of FIFRA's specific endorsement of me-too labels that copy already-approved labels.

Syngenta disputes that there is any conflict between the statutes, but its argument rests on a flawed premise. Relying primarily (Br. 26-27, 35-37, 40) on the second clause of section 136a(c)(3)(B)(i)(I), Syngenta argues that me-too labels need not be identical or substantially similar to already-registered pesticide labels because they can differ "in ways that would not significantly increase the risk of unreasonable

adverse effects on the environment." But Syngenta misunderstands the significant limitation in that clause.

That restrictive clause will not typically allow for differences in labeling that would avoid the risk of copyright liability. Indeed, in the legislative history, Congress referred to the expedited-review scheme as a "fast track" for "identical or substantially similar" pesticides. S. Rep. No. 100-346, at 20; *see also* H.R. Rep. No. 100-939, at 31. This shorthand description of the entire expedited-review scheme makes plain that Congress did not intend that prong to authorize substantial departures from an already-registered pesticide. Moreover, because the label is intended to communicate critical health and safety information in an easy-to-understand format, the exception for differences in labeling that "would not significantly increase" environmental risks has never been thought to authorize significant deviations from the already-approved label. The whole point of the scheme, after all, is to protect the public and the environment by ensuring that each approved pesticide carries essentially the same label, regardless of the registrant. And even where EPA permits the revision of a particular warning or instruction under that exception, sporadic edits of that kind to an otherwise copied label will not normally avoid a claim of overall "substantial similarity" for purposes of copyright infringement.

Syngenta has no answer, moreover, to the broader point that Congress wanted and expected me-too applicants to copy the original EPA-approved labels. FIFRA expressly contemplates that me-too labels will be "identical" or "substantially similar"

to the original label. Expedited regulatory review of me-too applications is possible only if the composition and label of a generic pesticide is, in broad terms, the same as the pesticide and label that EPA originally approved. In this sense, the scheme is exactly like the Hatch-Waxman scheme for generic drugs: after a period of regulatory exclusivity for the innovating manufacturer, and following the expiration or invalidation of any relevant patents, generic competitors are encouraged to enter the market with the same product and label.

Syngenta argues that substantial similarity "merely serves as a proxy to demonstrate copying," and suggests that an alleged infringer should have the burden of "showing that it independently created its work." Br. 39 (emphases omitted). That argument, again, misses the point of the expedited-review scheme, which is to *encourage* copying and avoid the independent creation of labels. And, for all the reasons discussed, even "independently created" labels for similar products would likely be similar to pre-existing labels after EPA review and consultation because they must satisfy all of the statutory and regulatory labeling requirements for the particular pesticide in question.

B. Copyright Liability Does Not Attach To FIFRA's "Me-Too" Labels That Are Substantially Similar To Copyrighted Labels

This Court can resolve the statutory tension and preserve the purposes of both FIFRA and the Copyright Act by holding that a me-too pesticide manufacturer is not liable for copyright infringement to the extent that FIFRA encourages its label to be

identical or substantially similar to the original.[4] The Second Circuit reached the same conclusion—that copyright law yields—in a case involving the analogous conflict between the Copyright Act and the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act, which require that the labeling for a generic drug be "the same as the labeling approved" for the brand-name drug. *SmithKline Beecham*, 211 F.3d at 23 (quoting 21 U.S.C. § 355(j)(2)(A)(v)).

In the event of a conflict between two statutes, the "first principle … is to give effect to each federal law." *Zenith Elecs. Corp. v. Exzec, Inc.*, 182 F.3d 1340, 1347 (Fed. Cir. 1999); *see also United States v. Borden Co.*, 308 U.S. 188, 198 (1939). Where Congress has not "clearly indicate[d] which of two statutes is to prevail in event of conflict," this Court's "responsibility is to interpret and apply them in a way that preserves the purposes of both and fosters harmony between them." *Zenith Elecs. Corp.*, 182 F.3d at 1347 (quotation marks omitted). In addition, it is a basic principle of statutory construction that the specific will control the general. *Thiess v. Witt*, 100 F.3d 915, 919 (Fed. Cir. 1996) ("Specific terms prevail over the general in the same or another statute which otherwise might be controlling." (quoting *D. Ginsberg & Sons, Inc. v. Popkin*, 285 U.S. 204, 208 (1932)).[5]

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[4] There may be elements of a label that FIFRA does not require, for example, artistic designs or logos, and FIFRA would not preclude any copyright claims based on those elements. *See* NYIPLA Amicus Br. at 19, 23-24 (examples and illustrations).

[5] Syngenta (Br. 31-34) and amicus NYIPLA (Br. 15-18) note that Congress did not create an express exception to copyright law in FIFRA. But that simply restates

The specific purpose of FIFRA's expedited-review scheme for generic pesticides would be undermined if me-too labels were subject to copyright claims. The expedited-review scheme was "intended to hasten registration decisions on end-use pesticides that are identical or substantially similar to a currently registered pesticide." H.R. Rep. No. 100-939, at 31. That is possible where generic labels are highly similar to already-approved labels, allowing EPA reviewers to determine expeditiously that FIFRA's labeling requirements are satisfied. This is important because there can be hundreds of generic pesticides for a given brand-name product. *See* Appx3548.

Congress would have understood that EPA cannot provide the expedited review contemplated by section 136a(c)(3)(B)(i)(I) "without requiring labels that will often violate copyrights." *SmithKline Beecham*, 211 F.3d at 28. As the Second Circuit explained in the generic drug context, "[i]f labels that were 'substantially similar' to copyrighted labels on pioneer drugs had to be avoided, the administrative process of approving a new label would, … drain the resources of the FDA and generic producer—not to mention the problem of successive generic producers avoiding infringement of multiple copyrighted labels." *Id.* "Avoiding such infringement would

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the reason for this litigation: judicial reconciliation of two statutes where Congress did not foresee the conflict or did not expressly provide for its resolution. NYIPLA's reliance (Br. 16-17) on *POM Wonderful LLC v. Coca-Cola Co.*, 134 S. Ct. 2228 (2014), for the proper resolution of that conflict is misplaced. There, the Supreme Court discussed relevant tools of statutory construction, but it did not (and could not) dictate the outcome in cases involving different statutory conflicts.

also delay the introduction of the generic product without advancing public health and safety to any perceptible degree." *Id.*

In contrast, rejecting Sygenta's copyright-infringement claim would not significantly undermine "the ultimate aim" of copyright laws, which is "to stimulate artistic creativity for the general public good." *Twentieth Century Music Corp. v. Aiken*, 422 U.S. 151, 156 (1975); *Atari Games Corp. v. Nintendo of Am. Inc.*, 975 F.2d 832, 842 (Fed. Cir. 1992). It is true for pesticide manufacturers, as for pharmaceutical companies, that "[t]he creativity of the author is focused not only on pleasing … ultimate consumers but also on obtaining the administrative approval of labeling necessary to" the approval of the product and "the patent and exclusivity periods free from competition that follow." *SmithKline Beecham*, 211 F.3d at 28-29. Rejecting Syngenta's copyright claim raises no risk that registrants "will so fear the copying of labels by future generic [pesticide] producers that some pioneer producers—or even one of them—will lack the incentive to create labeling needed for [EPA] approval." *Id.* at 29.

Congress has already provided that a pesticide will be protected from competition during FIFRA's ten-year period of data exclusivity under section 136a(c)(1)(F)(i), and the term of any applicable patents. There is no support for the idea that Congress wanted to extend that exclusive-use period for the nearly century-long term of the copyright for a corporate product label. 17 U.S.C. § 302. As the Second Circuit emphasized, the copyright owner will retain all of its other rights under

the Copyright Act, including to "pursue copyright claims against potential infringers in other circumstances," *SmithKline Beecham*, 211 F.3d at 29—for example, the use of visual artwork such as a logo, the use of the label by another pioneer pesticide manufacturer, or the reproduction of the label in a book.

Syngenta relies extensively (Br. 2-4, 21-22, 25-30, 33-35, 37), on a different district court's holding in *FMC Corp. v. Control Solutions, Inc.*, 369 F. Supp. 2d 539 (E.D. Pa. 2005), that FIFRA does not preclude a copyright-infringement claim against a me-too label. Despite Syngenta's characterization of the decision as "longstanding precedent" (Br. 2), a single district court decision from another circuit does not establish controlling law nationwide. And the district court here correctly explained that *FMC*'s analysis is "unconvincing" on its own terms. Appx33.[6]

The district court in *FMC* misunderstood both FIFRA and the Copyright Act. As to FIFRA, the court erroneously concluded that there was "no evidence, statute or regulation that permits or authorizes" what the court termed "direct infringement or plagiarism" of a label. *FMC*, 369 F. Supp. 2d at 558. In fact, as already discussed, Congress expressly contemplated that me-too labels "would be identical or substantially similar … to a currently-registered pesticide." 7 U.S.C. § 136a(c)(3)(B)(i)(I). Similarly, the *FMC* court also faulted the defendant for failing to

[6] The United States did not participate in *FMC*. *See* 369 F. Supp. 2d at 568-69 (noting that "there was no evidence from or on behalf of the EPA to advance the notion that the EPA requires generic or me-too applicants to copy the label language").

offer "any support for its proposition … that applicants likely would be forced by the EPA back to using the exact form of wording as is in the already registered label." 369 F. Supp. 2d at 558. But as Willowood's attempt to modify its labels demonstrates, EPA does require substantial similarity between the currently approved and me-too labeling. *See* Appx2980-2981 (statement of interest).

As to the Copyright Act, the court in *FMC* appears to have believed that a substantially similar label would not infringe the copyright. 369 F. Supp. 2d at 558 (rejecting argument that requiring different labels would make expedited EPA review "an impossibility" because "EPA has been able to comply with the regulatory expedited time requirements when approving a me-too label application that consisted of language drafted to merely be substantially—and substantively—similar without being a near-verbatim copy").[7] But that is wrong: substantial similarity is the test for copyright infringement.

The court in *FMC* was also too quick to distinguish *SmithKline Beecham*. *FMC*, 369 F. Supp. 2d at 568-71. *FMC* failed to appreciate the strong similarities between

[7] *FMC* suggests (in an analysis Syngenta adopts (Br. 27-31)) that EPA's Manual "does not require the pesticide label to be identical or substantially similar." 369 F. Supp. 2d at 559. First, this fails to account for *statutory* language encouraging "identical or substantially similar" labeling. 7 U.S.C. § 136a(c)(3)(B)(i)(I). But it is also clear from the Manual that the label for a me-too pesticide should be the same or substantially similar to an already-approved label. *Manual* 4-8 ("The label reviewer must also ensure that the new product's use patterns, including any public health claims, are *the same* as those of the cited product." (emphasis added)); *id.* at 11-9 (describing side-by-side use directions comparison for me-too labels).

FIFRA's me-too registration process and the Hatch-Waxman Amendments scheme for generic drug products, both of which were enacted after the 1976 Copyright Act. To be sure, the Hatch-Waxman Amendments require generic drug labeling to be "the same as the labeling approved for the listed drug." 21 U.S.C. § 355(j)(2)(A)(v). And the Second Circuit reasoned that "[c]ertainly, a legislative drafter would believe that a sameness requirement would lead to the creation of works that would easily fall within the copyright law's infringement test of 'substantial similarity.'" *SmithKline Beecham*, 211 F.3d at 27. The same logic, however, applies equally to FIFRA's endorsement of "identical or substantially similar" labeling. 7 U.S.C. § 136a(c)(3)(B)(i)(I). A legislative drafter would understand that substantially similar labeling was likely to be found infringing.

II. THE DISTRICT COURT'S JUDGMENT CAN BE AFFIRMED ON THE ALTERNATIVE GROUND THAT WILLOWOOD'S "ME-TOO" LABELS ARE A NON-INFRINGING FAIR USE OF SYNGENTA'S LABELS

For the foregoing reasons, the Court should affirm the dismissal of Syngenta's copyright claims on the ground that FIFRA precludes copyright liability for doing what the statute contemplates. The Court may alternatively affirm the dismissal of those claims under the fair use doctrine, which is supported by the record and was briefed below. *See Banner v. United States*, 238 F.3d 1348, 1355 (Fed. Cir. 2001).

Section 107 of the Copyright Act provides that "the fair use of a copyrighted work … for purposes such as criticism, comment, news reporting, teaching (including

multiple copies for classroom use), scholarship, or research, is not an infringement of copyright." 17 U.S.C. § 107.

> In determining whether the use made of a work in any particular case is a fair use the factors to be considered shall include—
>
> (1) the purpose and character of the use, including whether such use is of a commercial nature or is for nonprofit educational purposes;
>
> (2) the nature of the copyrighted work;
>
> (3) the amount and substantiality of the portion used in relation to the copyrighted work as a whole; and
>
> (4) the effect of the use upon the potential market for or value of the copyrighted work.

Id. The Supreme Court has made clear that 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." *Campbell v. Acuff-Rose Music, Inc.,* 510 U.S. 569, 577 (1994); *Harper & Row Publishers, Inc. v. Nation Enters.*, 471 U.S. 539, 549 (1985) ("Section 107 requires a case-by-case determination whether a particular use is fair, and the statute notes four nonexclusive factors to be considered.").

The Court should hold that, on the facts of this case, Willowood's use of Syngenta's copyrighted work as authorized by FIFRA is a fair use. That conclusion is correct for all of the reasons discussed above: Willowood used Syngenta's copyrighted material as required by the EPA to satisfy FIFRA's criteria for expedited review of labels that are similar to already-approved labels. That FIFRA specifically encourages the use of identical or substantially similar labels supports a finding of fair

use. Construing the non-exclusive language of section 107 to encompass these circumstances would allow section 107 to serve its traditional role as safety valve for the intersection between copyright law and other social goals.

In any event, an analysis of the individual section 107 factors confirms that Willowood's use was a fair one.

1. Purpose and character of the use

The first factor is neutral, or favors Syngenta only slightly. On the one hand, there can be little dispute that Willowood's use of Syngenta's labeling "is of a commercial nature," which weighs against fair use. *Campbell*, 510 U.S. at 578; *Harper & Row, Publishers, Inc.*, 471 U.S. at 562. Similarly, Willowood's use is not "transformative." *Campbell*, 510 U.S. at 579 (transformative work "adds something new, with a further purpose or different character").

On the other hand, the Supreme Court has made clear that courts "cannot ignore [the defendant's] stated purpose" in copying because "the propriety of the defendant's conduct" is relevant to the character of the use. *Harper & Row*, 471 U.S. at 562 (quoting 4 Melville Nimmer & David Nimmer, *Nimmer on Copyright* § 13.05[A][1][d] (2017)). Willowood copied Syngenta's labels as contemplated by FIFRA's me-too registration scheme, which encourages using identical or substantially similar labeling. The fact that the copying was encouraged by FIFRA substantially mitigates the commercial and non-transformative use at issue here.

2. The nature of the work

The second factor, the nature of the copyrighted work, weighs in favor of a finding of fair use. "The law generally recognizes a greater need to disseminate factual works than works of fiction or fantasy." *Harper & Row*, 471 U.S. at 563; *see also Campbell*, 510 U.S. at 586. Thus, "the more informational or functional the [copyright holder's] work, the broader should be the scope of the fair use defense." 4 *Nimmer* § 13.05[A][2][a]. Syngenta's labels are primarily factual works intended to instruct consumers how to safely use its pesticides. *Feist Publ'ns, Inc. v. Rural Tel. Serv. Co.*, 499 U.S. 340, 350-51 (1991). While there may be some creative expression in the labels, they are principally technical disclosures—the labels reflect the underlying data, which drive the necessary warning statements and other information—and the copyright interest is thin. *Cf. SmithKline Beecham*, 211 F.3d at 29 n.5 ("SmithKline's copyright claim is arguably weaker than even the typical commercial labeling case, because the copyrighted text was submitted to obtain FDA approval and consequent market exclusivity.").

This conclusion is supported by the doctrine of merger, which "provides that, when there are a limited number of ways to express an idea, the idea is said to 'merge' with its expression, and the expression becomes unprotected." *Oracle Am., Inc. v. Google Inc.*, 750 F.3d 1339, 1359 (Fed. Cir. 2014); *see* NYIPLA Br. 21-22. In light of the limited options available to Syngenta in creating its label, merger principles are likely to preclude copyright liability for many discrete label elements, such as the lists

of ingredients (Appx424), descriptions of protective equipment required (Appx425), and mixing instructions (Appx437). Other parts of Syngenta's label are not protected by copyright because they are required by EPA and do not originate with Syngenta. *See, e.g.*, *Manual* 3-2 (requiring phrase "Keep Out Of Reach Of Children"). To be sure, merger, which this Court has characterized as an affirmative defense to infringement, *Oracle Am., Inc.*, 750 F.3d at 1358, is distinct from fair use doctrine, which provides that a fair use "is not an infringement of copyright," 17 U.S.C. § 107. Other aspects of Syngenta's labels include copyrightable expression, but the fact that Syngenta's labels are replete with uncopyrightable subject matter underscores that the nature of the copyrighted work—functional labels designed to meet stringent statutory and regulatory requirements—weighs in favor of fair use.

3. The amount and substantiality of the portion used

The third factor, which "asks whether the amount and substantiality of the portion used in relation to the copyrighted work as a whole … are reasonable in relation to the purpose of the copying," *Campbell*, 510 U.S. at 586 (quotation marks and citations omitted), weighs somewhat in favor of fair use. In addition to quantity, this factor requires consideration of "the quality and importance of the copyrighted materials used, that is, whether the portion of the copyrighted material was the heart of the copyrighted work." *A.V. ex rel. Vanderhye v. iParadigms, LLC*, 562 F.3d 630, 642 (4th Cir. 2009) (quotation marks and citations omitted). While "[c]opying an entire

work weighs against finding a fair use, … it does not *preclude* a finding of fair use." *Id.* (alterations in original).

Willowood copied a significant portion of Syngenta's labels, but it did so consistent with FIFRA's scheme and as required by EPA. When Willowood attempted to modify its labels, EPA approved only limited changes. *See* Appx2980-2981. The purpose of Willowood's copying was to comply with FIFRA's expedited review requirements and the EPA's mandate. And because EPA allowed only minor deviations from the original, the substantial amount of material Willowood copied was justified by the need to comply with the labeling laws as interpreted by EPA. Willowood has "not helped themselves overmuch," *Campbell*, 510 at 587, and this factor somewhat supports a fair use finding, or is neutral.

4. The effect on the potential market

The last factor, the effect of the use upon the potential market, weighs in favor of fair use. The Supreme Court has suggested that this factor is the "single most important element of fair use," *Harper & Row*, 471 U.S. at 566, "considering that a primary goal of copyright is to ensure that authors [have] the opportunity to realize rewards in order to encourage them to create." *A.V. ex rel. Vanderhye*, 562 F.3d at 642 (quotation marks omitted). By contrast, "a use that has no demonstrable effect upon the potential market for, or the value of, the copyrighted work need not be prohibited in order to protect the author's incentive to create." *Id.* at 642-43 (quoting *Sony Corp.*, 464 U.S. at 450).

The commercial purpose of a pesticide label is in the registration of the underlying product. But even assuming that Syngenta's labels themselves have some market value, for reasons similar to those discussed above, this factor supports fair use. The objective in creating pesticide labeling is to obtain EPA registration of the pesticide. The value in the labeling is driven by EPA registration and subsequent sales of the pesticide. As the Second Circuit noted in *SmithKline Beecham*, 211 F.3d at 29, "[i]t is simply not conceivable" that permitting generic registrants to draw upon pioneering drug labels will result in "even one" pioneer drug producer "lack[ing] the incentive to create labeling needed for FDA approval." Moreover, allowing original registrants to use copyright law to limit entry to the pesticide market beyond the period of exclusive data-use provided in the statute would undermine Congress's intent to facilitate market-entry of generic pesticides. If the copyrights are used that way, "the tail threatens to wag the dog—proprietors at times seize on copyright protection for the label in order to leverage their thin copyright protection over the text … on the label into a monopoly on the typically uncopyrightable product to which it is attached." *Id.* at 29 n.5 (quoting 1 *Nimmer* § 2.08[G][2], at 2-138). Such an outcome would frustrate FIFRA's expedited-review scheme.

In short, if the Court reaches the question of fair use, it should hold that Willowood's copying of the labels as contemplated by FIFRA to obtain EPA registration was a fair use of Syngenta's copyrighted works.

CONCLUSION

For the foregoing reasons, the judgment of the district court on the copyright claims should be affirmed.

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

This brief complies with the type-volume limit of Federal Rule of Appellate Procedure 29(a)(5) and Federal Circuit Rule 32(a) because it contains 6,934 words. This brief also complies with the typeface and type-style requirements of Federal Rule of Appellate Procedure 32(a)(5)-(6) because it was prepared using Microsoft Word 2013 in Garamond 14-point font, a proportionally spaced typeface.

s/ Megan Barbero
Megan Barbero

CERTIFICATE OF SERVICE

I hereby certify that on June 13, 2018, I electronically filed the foregoing brief with the Clerk of the Court for the United States Court of Appeals for the Federal Circuit by using the appellate CM/ECF system. Participants in the case are registered CM/ECF users, and service will be accomplished by the appellate CM/ECF system.

s/ Megan Barbero
Megan Barbero

ADDENDUM

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7 U.S.C. § 136(p)-(q)

(p) Label and labeling

(1) Label

The term "label" means the written, printed, or graphic matter on, or attached to, the pesticide or device or any of its containers or wrappers.

(2) Labeling

The term "labeling" means all labels and all other written, printed, or graphic matter—

(A) accompanying the pesticide or device at any time; or

(B) to which reference is made on the label or in literature accompanying the pesticide or device, except to current official publications of the Environmental Protection Agency, the United States Departments of Agriculture and Interior, the Department of Health and Human Services, State experiment stations, State agricultural colleges, and other similar Federal or State institutions or agencies authorized by law to conduct research in the field of pesticides.

(q) Misbranded

(1) A pesticide is misbranded if—

(A) its labeling bears any statement, design, or graphic representation relative thereto or to its ingredients which is false or misleading in any particular;

(B) it is contained in a package or other container or wrapping which does not conform to the standards established by the Administrator pursuant to section 136w(c)(3) of this title;

(C) it is an imitation of, or is offered for sale under the name of, another pesticide;

(D) its label does not bear the registration number assigned under section 136e of this title to each establishment in which it was produced;

(E) any word, statement, or other information required by or under authority of this subchapter to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or graphic matter in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use;

(F) the labeling accompanying it does not contain directions for use which are necessary for effecting the purpose for which the product is intended and if

complied with, together with any requirements imposed under section 136a(d) of this title, are adequate to protect health and the environment;

(G) the label does not contain a warning or caution statement which may be necessary and if complied with, together with any requirements imposed under section 136a(d) of this title, is adequate to protect health and the environment; or

(H) in the case of a pesticide not registered in accordance with section 136a of this title and intended for export, the label does not contain, in words prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or graphic matter in the labeling) as to render it likely to be noted by the ordinary individual under customary conditions of purchase and use, the following: "Not Registered for Use in the United States of America".

(2) A pesticide is misbranded if—

(A) the label does not bear an ingredient statement on that part of the immediate container (and on the outside container or wrapper of the retail package, if there be one, through which the ingredient statement on the immediate container cannot be clearly read) which is presented or displayed under customary conditions of purchase, except that a pesticide is not misbranded under this subparagraph if—

(i) the size or form of the immediate container, or the outside container or wrapper of the retail package, makes it impracticable to place the ingredient statement on the part which is presented or displayed under customary conditions of purchase; and

(ii) the ingredient statement appears prominently on another part of the immediate container, or outside container or wrapper, permitted by the Administrator;

(B) the labeling does not contain a statement of the use classification under which the product is registered;

(C) there is not affixed to its container, and to the outside container or wrapper of the retail package, if there be one, through which the required information on the immediate container cannot be clearly read, a label bearing—

(i) the name and address of the producer, registrant, or person for whom produced;

(ii) the name, brand, or trademark under which the pesticide is sold;

(iii) the net weight or measure of the content, except that the Administrator may permit reasonable variations; and

(iv) when required by regulation of the Administrator to effectuate the purposes of this subchapter, the registration number assigned to the pesticide under this subchapter, and the use classification; and

(D) the pesticide contains any substance or substances in quantities highly toxic to man, unless the label shall bear, in addition to any other matter required by this subchapter—

(i) the skull and crossbones;

(ii) the word "poison" prominently in red on a background of distinctly contrasting color; and

(iii) a statement of a practical treatment (first aid or otherwise) in case of poisoning by the pesticide.

7 U.S.C. § 136a (excerpts)

§ 136a. Registration of pesticides

(a) Requirement of registration

Except as provided by this subchapter, no person in any State may distribute or sell to any person any pesticide that is not registered under this subchapter. To the extent necessary to prevent unreasonable adverse effects on the environment, the Administrator may by regulation limit the distribution, sale, or use in any State of any pesticide that is not registered under this subchapter and that is not the subject of an experimental use permit under section 136c of this title or an emergency exemption under section 136p of this title.

…

(c) Procedure for registration

(1) Statement required

Each applicant for registration of a pesticide shall file with the Administrator a statement which includes—

(A) the name and address of the applicant and of any other person whose name will appear on the labeling;

(B) the name of the pesticide;

(C) a complete copy of the labeling of the pesticide, a statement of all claims to be made for it, and any directions for its use;

(D) the complete formula of the pesticide;

(E) a request that the pesticide be classified for general use or for restricted use, or for both; and

(F) except as otherwise provided in paragraph (2)(D), if requested by the Administrator, a full description of the tests made and the results thereof upon which the claims are based, or alternatively a citation to data that appear in the public literature or that previously had been submitted to the Administrator and that the Administrator may consider in accordance with the following provisions:

(i) With respect to pesticides containing active ingredients that are initially registered under this subchapter after September 30, 1978, data submitted to support the application for the original registration of the pesticide, or an application for an amendment adding any new use to the registration and that pertains solely to such new use, shall not, without the written permission of the original data submitter, be considered by the Administrator to support an application by another person during a period of ten years following the date the Administrator first registers the pesticide, except that such permission shall not be required in the case of defensive data.

(ii) The period of exclusive data use provided under clause (i) shall be extended 1 additional year for each 3 minor uses registered after August 3, 1996, and within 7 years of the commencement of the exclusive use period, up to a total of 3 additional years for all minor uses registered by the Administrator if the Administrator, in consultation with the Secretary of Agriculture, determines that, based on information provided by an applicant for registration or a registrant, that—

(I) there are insufficient efficacious alternative registered pesticides available for the use;

(II) the alternatives to the minor use pesticide pose greater risks to the environment or human health;

(III) the minor use pesticide plays or will play a significant part in managing pest resistance; or

(IV) the minor use pesticide plays or will play a significant part in an integrated pest management program.

The registration of a pesticide for a minor use on a crop grouping established by the Administrator shall be considered for purposes of this clause 1 minor use for each representative crop for which data are provided in the crop grouping. Any additional exclusive use period under this clause shall be modified as appropriate or terminated if the registrant voluntarily cancels the product or deletes from the registration the minor uses which formed the basis for the extension of the additional exclusive use period or if the Administrator determines that the registrant is not actually marketing the product for such minor uses.

…

(iv) After expiration of any period of exclusive use and any period for which compensation is required for the use of an item of data under clauses (i), (ii), and (iii), the Administrator may consider such item of data in support of an application by any other applicant without the permission of the original data submitter and without an offer having been received to compensate the original data submitter for the use of such item of data.

…

(3) Application

(A) In general

The Administrator shall review the data after receipt of the application and shall, as expeditiously as possible, either register the pesticide in accordance with paragraph (5), or notify the applicant of the Administrator's determination that it does not comply with the provisions of the subchapter in accordance with paragraph (6).

(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, would be identical or substantially similar in composition and labeling to a currently-registered pesticide identified in the application, or that 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; or

(II) proposes an amendment to the registration of a registered pesticide that does not require scientific review of data.

(ii) In expediting the review of an application for an action described in clause (i), the Administrator shall—

(I) review the application in accordance with section 136w-8(f)(4)(B) of this title and, if the application is found to be incomplete, reject the application;

(II) not later than the applicable decision review time established pursuant to section 136w-8(f)(4)(B) of this title, or, if no review time is established, not later than 90 days after receiving a complete application, notify the registrant if the application has been granted or denied; and

(III) if the application is denied, notify the registrant in writing of the specific reasons for the denial of the application.

…

(5) Approval of registration

The Administrator shall register a pesticide if the Administrator determines that, when considered with any restrictions imposed under subsection (d)—

(A) its composition is such as to warrant the proposed claims for it;

(B) its labeling and other material required to be submitted comply with the requirements of this subchapter;

(C) it will perform its intended function without unreasonable adverse effects on the environment; and

(D) when used in accordance with widespread and commonly recognized practice it will not generally cause unreasonable adverse effects on the environment.

The Administrator shall not make any lack of essentiality a criterion for denying registration of any pesticide. Where two pesticides meet the requirements of this paragraph, one should not be registered in preference to the other. In considering an application for the registration of a pesticide, the Administrator may waive data requirements pertaining to efficacy, in which event the Administrator may register the pesticide without determining that the pesticide's composition is such as to warrant proposed claims of efficacy. If a pesticide is found to be efficacious by any State under section 136v(c) of this title, a presumption is established that the Administrator shall waive data requirements pertaining to efficacy for use of the pesticide in such State.

(6) Denial of registration

If the Administrator determines that the requirements of paragraph (5) for registration are not satisfied, the Administrator shall notify the applicant for registration of the Administrator's determination and of the Administrator's reasons (including the factual basis) therefor, and that, unless the applicant corrects the conditions and notifies the Administrator thereof during the 30-day period beginning with the day after the date on which the applicant receives the notice, the Administrator may refuse to register the pesticide. Whenever the Administrator refuses to register a pesticide, the Administrator shall notify the applicant of the Administrator's decision and of the Administrator's reasons (including the factual basis) therefor. The Administrator shall promptly publish in the Federal Register notice of such denial of registration and the reasons therefor. Upon such notification, the applicant for registration or other interested person with the concurrence of the applicant shall have the same remedies as provided for in section 136d of this title.

(7) Registration under special circumstances

Notwithstanding the provisions of paragraph (5)—

(A) The Administrator may conditionally register or amend the registration of a pesticide if the Administrator determines that (i) the pesticide and proposed use are identical or substantially similar to any currently registered pesticide and use thereof, or differ only in ways that would not significantly increase the risk of unreasonable adverse effects on the environment, and (ii) approving the registration or amendment in the manner proposed by the applicant would not significantly increase the risk of any unreasonable adverse effect on the environment. An applicant seeking conditional registration or amended registration under this subparagraph shall submit such data as would be required to obtain registration of a similar pesticide under paragraph (5). If the applicant is unable to submit an item of data because it has not yet been generated, the Administrator may register or amend the registration of the pesticide under such conditions as will require the submission of such data not later than the time such data are required to be submitted with respect to similar pesticides already registered under this subchapter.

(B) The Administrator may conditionally amend the registration of a pesticide to permit additional uses of such pesticide notwithstanding that data concerning the pesticide may be insufficient to support an unconditional amendment, if the Administrator determines that (i) the applicant has submitted satisfactory data pertaining to the proposed additional use, and (ii) amending the registration in the manner proposed by the applicant would not

significantly increase the risk of any unreasonable adverse effect on the environment. Notwithstanding the foregoing provisions of this subparagraph, no registration of a pesticide may be amended to permit an additional use of such pesticide if the Administrator has issued a notice stating that such pesticide, or any ingredient thereof, meets or exceeds risk criteria associated in whole or in part with human dietary exposure enumerated in regulations issued under this subchapter, and during the pendency of any risk-benefit evaluation initiated by such notice, if (I) the additional use of such pesticide involves a major food or feed crop, or (II) the additional use of such pesticide involves a minor food or feed crop and the Administrator determines, with the concurrence of the Secretary of Agriculture, there is available an effective alternative pesticide that does not meet or exceed such risk criteria. An applicant seeking amended registration under this subparagraph shall submit such data as would be required to obtain registration of a similar pesticide under paragraph (5). If the applicant is unable to submit an item of data (other than data pertaining to the proposed additional use) because it has not yet been generated, the Administrator may amend the registration under such conditions as will require the submission of such data not later than the time such data are required to be submitted with respect to similar pesticides already registered under this subchapter.

(C) The Administrator may conditionally register a pesticide containing an active ingredient not contained in any currently registered pesticide for a period reasonably sufficient for the generation and submission of required data (which are lacking because a period reasonably sufficient for generation of the data has not elapsed since the Administrator first imposed the data requirement) on the condition that by the end of such period the Administrator receives such data and the data do not meet or exceed risk criteria enumerated in regulations issued under this subchapter, and on such other conditions as the Administrator may prescribe. A conditional registration under this subparagraph shall be granted only if the Administrator determines that use of the pesticide during such period will not cause any unreasonable adverse effect on the environment, and that use of the pesticide is in the public interest.

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17 U.S.C. § 102

§ 102. Subject matter of copyright: In general

(a) Copyright protection subsists, in accordance with this title, in original works of authorship fixed in any tangible medium of expression, now known or later

developed, from which they can be perceived, reproduced, or otherwise communicated, either directly or with the aid of a machine or device. Works of authorship include the following categories:

(1) literary works;

(2) musical works, including any accompanying words;

(3) dramatic works, including any accompanying music;

(4) pantomimes and choreographic works;

(5) pictorial, graphic, and sculptural works;

(6) motion pictures and other audiovisual works;

(7) sound recordings; and

(8) architectural works.

(b) In no case does copyright protection for an original work of authorship extend to any idea, procedure, process, system, method of operation, concept, principle, or discovery, regardless of the form in which it is described, explained, illustrated, or embodied in such work.

17 U.S.C. § 106

§ 106. Exclusive rights in copyrighted works

Subject to sections 107 through 122, the owner of copyright under this title has the exclusive rights to do and to authorize any of the following:

(1) to reproduce the copyrighted work in copies or phonorecords;

(2) to prepare derivative works based upon the copyrighted work;

(3) to distribute copies or phonorecords of the copyrighted work to the public by sale or other transfer of ownership, or by rental, lease, or lending;

(4) in the case of literary, musical, dramatic, and choreographic works, pantomimes, and motion pictures and other audiovisual works, to perform the copyrighted work publicly;

(5) in the case of literary, musical, dramatic, and choreographic works, pantomimes, and pictorial, graphic, or sculptural works, including the individual images of a motion picture or other audiovisual work, to display the copyrighted work publicly; and

(6) in the case of sound recordings, to perform the copyrighted work publicly by means of a digital audio transmission.

17 U.S.C. § 107

§ 107. Limitations on exclusive rights: Fair use

Notwithstanding the provisions of sections 106 and 106A, the fair use of a copyrighted work, including such use by reproduction in copies or phonorecords or by any other means specified by that section, for purposes such as criticism, comment, news reporting, teaching (including multiple copies for classroom use), scholarship, or research, is not an infringement of copyright. In determining whether the use made of a work in any particular case is a fair use the factors to be considered shall include—

(1) the purpose and character of the use, including whether such use is of a commercial nature or is for nonprofit educational purposes;

(2) the nature of the copyrighted work;

(3) the amount and substantiality of the portion used in relation to the copyrighted work as a whole; and

(4) the effect of the use upon the potential market for or value of the copyrighted work.

The fact that a work is unpublished shall not itself bar a finding of fair use if such finding is made upon consideration of all the above factors.

17 U.S.C. § 501(a)

§ 501. Infringement of copyright

(a) Anyone who violates any of the exclusive rights of the copyright owner as provided by sections 106 through 122 or of the author as provided in section 106A(a), or who imports copies or phonorecords into the United States in violation of section 602, is an infringer of the copyright or right of the author, as the case may be. For purposes of this chapter (other than section 506), any reference to copyright shall be deemed to include the rights conferred by section 106A(a). As used in this subsection, the term "anyone" includes any State, any instrumentality of a State, and any officer or employee of a State or instrumentality of a State acting in his or her official capacity. Any State, and any such instrumentality, officer, or employee, shall be subject to the provisions of this title in the same manner and to the same extent as any nongovernmental entity.