2018-1614; 2018-2044

United States Court of Appeals for the Federal Circuit

SYNGENTA CROP PROTECTION, LLC,

Plaintiff-Appellant,

v.

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

Defendants-Cross-Appellants.

On Appeal from the United States District Court for the
Middle District of North Carolina in Case No. 1:15-cv-00274-CCE-JEP
Honorable Catherine C. Eagles, Judge

CORRECTED
Brief of *Amici Curiae* on Behalf of 41 Companies Holding Generic EPA Pesticide Registrations*
In Support of Affirmance of the Judgment of the District Court

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UNITED STATES COURT OF APPEALS FOR THE FEDERAL COURT

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

Case No. 2018-1614; 2018-2044

CERTIFICATION OF INTEREST

Pursuant to Fed. Cir. R. 29 and 47.4, counsel for the amici curiae listed below certifies the following:

The full name of each party I represent (***each of which is a real party in interest***) and the parent corporation and publicly held companies that own 10% of more of stock in each party, are listed below.

1. / 2. **Full Name of Real Party of Interest Represented by me:**	3. **Parent Corporations and publicly held companies that own 10% or more stock in the party:**
Aceto Agricultural Chemicals Corp.	Aceto Corporation
Aceto Corporation	Aceto Corporation
AgLogic Chemical, LLC	None
Agro-Gor Corp.	None
Albaugh, LLC	None
Argite. LLC	None
Atticus, LLC	None
Axss Technical Holdings, LLC	None
Chemstarr, LLC	Tide Group China
Consus Chemicals, Inc.	None
Decco US Post-Harvest, Inc.	UPL Limited
Drexel Chemical Company	None
Ensystex, Inc.	None
Ensystex II, Inc.	None
Ensystex III, Inc.	None

Ensystex IV, Inc.	None
Extremis, LLC	None
GeneraTec, LLC	None
Gharda Chemicals International, Inc.	Gharda Chemicals, Limited
Helm Agro US, Inc.	Helm AG
LG Chem, Ltd.	None
MEY Corporation	None
PBI Gordon Corp.	None
Promika, LLC	None
Raymat Crop Science, Inc.;	None
Raymat Materials, Inc.	None
RedEagle International, LLC	None
RiceCo, LLC	UPL Limited
Rotam Agrochemical Company, Ltd.	Rotam Crop Sciences Ltd.
Rotam Ltd.	Rotam Crop Sciences Ltd
Rotam North America Inc.	Rotam Crop Sciences Ltd
Sharda CropChem Ltd.	Sharda CropChem Ltd.
Sharda USA, LLC	Sharda CropChem Ltd.
Summit Agro US, LLC	Sumitomo Corporation
Summit Agro North America Holding Corporation	Sumitomo Corporation
Tacoma AG, LLC	None
Tide International USA. Inc.	Tide Group China
Troy Corporation	None
United Phosphorus, Inc.	UPL Limited
UPL Delaware Inc.	UPL Limited
Woodstream Corporation	None

4. The names of all law firms and the partners or associates that appeared for the party now represented by me who appeared in the trial court or are expected to appear in this Court:

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5. The title and number of any case known to counsel to be pending in this or any other court or agency that will directly affect or be directly affected by this Court's decision in the pending appeal. *See* Fed. Cir. R. 47.4(a)(5) and 47.5(b): **None.**

/s/ James P. Rathvon
James P. Rathvon, Esquire

June 25, 2018

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Certification of Filing with Consent of Parties

Undersigned counsel for the amici curiae certifies that this brief is filed with the consent of all parties to the appeal.

Statement of Interest

Amici hold registrations issued by the U.S. Environmental Protection Agency ("EPA") under the Federal Insecticide, Fungicide and Rodenticide Act ("FIFRA") for generic versions of products that were originally registered by another company ("original registrants"). These registrations include both "manufacturing-use" and "end-use" products. A "manufacturing-use" registration is a registration for a technical grade, or concentrated form, of the pesticide active ingredient. Manufacturing-use products are not applied directly to control pests; rather, they are used to manufacture or formulate end-use products that are applied by ultimate end-users. Collectively, *amici* hold active EPA registrations for 1,961 pesticide products, including over 1,600 "end-use" products. The pesticide products registered by *amici* cover a broad spectrum and are labeled for a wide range of uses. Many *amici* are engaged in the registration and marketing of generic pesticide products for use in agriculture. These *amici* represent a sizable proportion of the entire generic agricultural pesticide industry. Other *amici* focus on the registration and sale of pesticides for use on turf and ornamentals, including nurseries, golf courses, and residential gardens and lawns; other *amici* focus on animal health products, and

others on commercial and structural pest control products (*e.g.*, termiticides, rodenticides, fumigants). One of the *amici* is in the business of registering and marketing of antimicrobials used in paints, packaging materials, and other products.

Because the large majority of the pesticide registrations held by *amici* are for generic (also known as "me-too") products, *amici* have a strong interest in the issue of whether pesticide labels are entitled to copyright protection. A negative answer to this question – which would uphold the ruling of the District Court below and effectively reject the decision in *FMC Corp. v. Control Solutions Inc.*, 369 F. Supp.2d 539 (E.D. Pa. 2005) – would allow *amici* to lawfully conduct their generic pesticide businesses without incurring the costs, delays, risks, and challenges of trying to (re)write their labels so as to avoid copyright infringement claims. At the same time, it would preserve their ability to secure EPA approval of their me-too products. In contrast, a decision by this Court that reverses the ruling of the District Court below and finds that pesticide labels are entitled to copyright protection would reinforce the decision in *FMC v. CSI*. Such a ruling would have a significant adverse impact on *amici's* ability to conduct their generic pesticide businesses.

No party's counsel authored this brief in whole or in part. No party or party's counsel contributed money that was intended to fund preparing or submitting this brief. No person other than *amici curiae* contributed money that was intended to fund preparing or submitting this brief.

Introduction

Amici respectfully submit this brief in support of the ruling of the District Court below that FIFRA "precludes copyright protection for the required elements of pesticide labels as against the labels of me-too registrants." April 10, 2017 Order at 1. The District Court explained:

> FIFRA contemplates that a "me-too" applicant will copy from the original pesticide label in ways that would otherwise infringe a copyright. 7 U.S.C. § 136a(c)(3)(B)(i)(I). Even with some changes, use of the original pesticide label as a "go by" for the new label will result in copyright infringement. In enacting FIFRA, Congress intended a narrow exception to copyright infringement.

Id. at 1-2. In so ruling, the Court stated that it found the contrary ruling in *FMC Corp. v. Control Solutions, Inc.,* 369 F. Supp.2d 539, 555-71 (E.D. Pa. 2005) "unconvincing." *Id.* at 1. *Amici* urge this Court to strongly affirm the District Court's ruling.[1]

This brief explains why, in practical terms, granting copyright protection to pesticide labels poses costs, delays, risks, and challenges to entities, such as *amici*, engaged in the business of registering and marketing me-too pesticide products,

[1] For clarification, *amici* do not oppose the suggestion of *amicus curiae* New York Intellectual Property Law Association that this Court clarify that FIFRA's preclusion of copyright protection does not apply to decorative illustrations or other elements of trade dress that EPA generally allows the registrant to include on product labeling without pre-marketing review and approval by EPA.

effects that are contrary to the purposes of FIFRA to streamline pesticide registration procedures and increase competition.

Argument

FIFRA requires that all pesticides sold or distributed in the United States first be registered with EPA. 7 U.S.C. § 136a(a). To obtain a registration for a pesticide, the applicant must furnish, *inter alia*, both a proposed product label and test data concerning the pesticide. *Id*. § 136a(c)(1)(C) & (F). As to the requirement for test data, FIFRA provides that once data on a pesticide have been submitted (and any exclusive use period for those data has expired), subsequent applicants seeking to register a generic version of the same pesticide need not duplicate the data but, instead, may rely on the previously submitted data, so long as the applicant offers to compensate the original data submitter for this use. *Id*. § 136a(c)(1)(F)(iii). The Supreme Court has explained that the purposes of this data-sharing scheme are to discourage data duplication, streamline the registration of generic products, and thereby increase competition in pesticide markets. *Ruckelshaus v. Monsanto Co.*, 467 U.S. 986, 1014-15 (1984) ("the public purpose behind [FIFRA's] data-consideration provisions is clear from the legislative history, [*i.e.,* to] eliminate costly duplication of research and streamline the registration process *making new end-use products available to consumers more quickly* . . . thereby allowing greater competition among producers of end-use products") (emphasis added); *Thomas v.*

Union Carbide Agric. Prods. Co., 473 U.S. 568, 571 (1985) (data-sharing scheme intended "to streamline pesticide registration procedures, increase competition, and avoid unnecessary duplication of data-generation costs").

As noted, in order to obtain (or amend) an EPA registration for a pesticide, the applicant must also submit a proposed label. 7 U.S.C. § 136a(c)(1)(C). When EPA approves the registration, EPA also approves the product label, often conditioned on the applicant making revisions to the label and submitting a final version for EPA's stamped approval. The final, EPA-approved label sets forth the terms and conditions by which the user may legally handle and apply the product. It is unlawful to use any pesticide in a manner inconsistent with its labeling. 7 U.S.C. § 136j(a)(2)(G).

Most components of pesticide labels are prescribed by EPA, and many words and phrases used therein are specified by regulation. *See generally* 40 C.F.R. pt. 156. Other portions of the label are not specified in advance but rather are based on the particular properties of, and hazards posed by, the pesticide. For example, the directions for use of a pesticide product, which are often lengthy, are determined on a case-by-case basis.

In the experience of *amici*, once EPA has determined the appropriate directions for use, warnings, precautions, and other information on a pesticide label, EPA *wants* substantially similar products, *i.e.*, generic versions of the already-

registered product, to bear the same or a very similar label. Indeed, in the experience of *amici*, EPA has long encouraged applicants for generic pesticide products to propose a label that is substantially similar or identical to the label of the already-registered comparable product. EPA has explained that consistency of labels among similar products reduces the likelihood of confusion and product misuse on the part of ultimate consumers. Having consistent label language for similar products also reduces the workload on EPA in reviewing registration applications for similar products.

Accordingly, submitting a proposed label that is substantially similar or identical to the label of the already-approved comparable product streamlines the registration process, consistent with the pro-competitive purpose of FIFRA. This practice is also consistent with the express provisions of FIFRA, including FIFRA § 3(c)(3)(B), 7 U.S.C. § 136a(c)(3)(B) (providing for expedited approval of end-use products bearing substantially similar or identical label to that of a currently-registered product) and FIFRA § 3(c)(7)(A), 7 U.S.C. § 136a(c)(7)(A) (authorizing conditional registration of a generic product with proposed use "identical or substantially similar to any currently registered pesticide and use thereof").

In light of the foregoing, it was the experience of *amici* that proposed labels for generic products should closely mirror or copy substantial portions of the label for the comparable, existing pesticide. This ensured that EPA would accept their

proposed label with very few comments or revisions, and thus facilitated EPA's timely review and approval of their registration applications.

In 2005, however, a federal district court in Pennsylvania ruled that pesticide labels are entitled to copyright protection and, accordingly, it enjoined a company from marketing its generic products for the pesticide at issue using infringing labels. *FMC v. CSI*, *supra*. In the wake of the *FMC* decision, many *amici* initiated steps to avoid pesticide label copyright infringement claims for at least some of their existing and/or new generic labels.

This is not easily done. On the one hand, *amici* have sought to change the wording and presentation of the use instructions, warnings, and other information on the label sufficiently to avoid copyright infringement liability. However, there are no bright line tests or other standards by which a company can determine whether and when a label has been sufficiently changed to eliminate copyright liability. Thus, even after making changes to the label, *amici* are left uncertain whether they could still be vulnerable to copyright infringement claims.

One the other hand, in order to secure EPA approval of the proposed label revisions, *amici* also have to ensure that the revisions do not change the *meaning* of the use instructions, warnings, and other information on the label, or make them more difficult for the end user to understand and follow. If a revision does any of these things, EPA will reject it and require the applicant to submit a new revised

label. Accordingly, some *amici* have experienced delays in obtaining EPA approval of registrations or amended registrations because of issues over label revisions that depart from the label for an already-approved comparable product.

The difficulty of changing labels to avoid copyright liability while keeping the meaning of the label information the same is heightened by the fact that a pesticide label conveys basic factual information on how to use the product safely. There are only so many ways to express the *same* instructions and warnings. Common techniques used by *amici* in their attempts to thread the needle between revising label language to try to avoid copyright infringement claims while, at the same time, not changing the meaning of label language include: using synonyms (*e.g.* substituting "pail" for "bucket"); changing sentences from active to passive voice (or vice versa); converting charts (*e.g.*, those listing rates, times, and frequencies of application to different crops) into tables (or vice versa); reordering the information on charts and tables; and reordering sections, paragraphs, or sentences containing the same information.

Another complication facing *amici* in attempting to avoid copyright claims is that, for some popular pesticides (*e.g.,* glyphosate, the active ingredient in Monsanto's Roundup®), there are many scores of substantially similar products. For these pesticides, *amici* have found that it is not possible as a practical matter to draft a label that meets EPA requirements that does not also mirror very closely the

label of one or more already-registered products. In such cases, *amici* focus their efforts on minimizing the potential for copyright infringement claims from the brand-name registrant(s), and hope that registrants of similar generic products will not assert claims.

The work of rewriting labels to minimize copyright liability while at the same time meeting EPA requirements is challenging, time-consuming, and serves no independent business purpose. From the viewpoint of *amici*, rewriting labels to avoid copyright infringement claims is a waste of time, attention and resources that could be used productively elsewhere. To minimize the diversion of internal resources, some *amici* have hired consultants or even law firms to prepare revised labels, steps which have added to the out-of-pocket costs associated with these *amici* obtaining and maintaining their generic pesticide registrations.

Over the past decade, several *amici* have been contacted by original registrants threatening legal action because of alleged label copyright infringement. In a few instances, a law suit was filed. In all instances to date, *amici* have been able to reach a settlement with the original registrant involving an agreement to revise the offending label(s) by a date certain.

Amici are extremely concerned that original registrants will be even more aggressive in asserting copyright infringement claims if this Court reverses the District Court and rules that pesticide labels are protected by copyright. Such a

ruling would pose a serious threat to the ability of *amici* to carry on their generic pesticide businesses and obtain EPA's approval of labels for generic pesticide products. To avoid copyright liability in the face of such a ruling, *amici* would have to redouble their efforts at revising their existing labels, and preparing labels for all new products, so that the labels do not closely resemble the label of any already-approved comparable product. However, as noted, there are no clear standards by which *amici* can determine whether the revisions they make will be sufficient to eliminate copyright liability, thus leaving *amici* in legal jeopardy. At the same time, to secure EPA approval, *amici* must ensure that each revised label conveys the same basic use instructions, warnings, and other information as the label of the already-registered product(s) – and does so in a way that meets EPA standards, and is clear and readily understandable to users.

This may be an impossible task. At a minimum, a ruling by this Court that pesticide labels are protected by copyright would impose significant costs and registration delays on *amici* and other generic registrants, and encourage additional label copyright infringement litigation. At worse, such a ruling could place *amici* in a Catch-22 situation in which it is nearly impossible to register a generic product because of the conflicting label requirements imposed by EPA and copyright law.

Conclusion

For all the foregoing reasons, *amici* urge this Court to strongly affirm the District Court's ruling that FIFRA "precludes copyright protection for the required elements of pesticide labels as against the labels of me-too registrants."

Respectfully submitted this 25th day of June, 2018

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CERTIFICATE OF SERVICE

I hereby certify that on this 25th day of June, 2018, I caused the foregoing to be electronically filed with the Clerk of the Court for the United States Court of Appeals for the Federal Circuit through the Court's CM/ECF system.

Participants in the case are registered CM/ECF users and will be served by the appellate CM/ECF system.

/s/ James P. Rathvon
James P. Rathvon, Esquire

June 25, 2018

CERTIFICATE OF COMPLIANCE

1. This document complies with the type-volume limit of Fed. R. App. P. 32(a)(7)(B) and Fed. R. App. P. 29(a)(5) because, excluding the parts of the document exempted by Fed. R. App. P. 32(f), this document contains 2,366 words.

2. This document complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type style requirements of Fed. R. App. P. 32(a)(6) because this document was prepared in a proportionally spaced typeface using Microsoft Word 2013 in 14 point font in the Times New Roman style.

/s/ James P. Rathvon
James P. Rathvon, Esquire

June 25, 2018