No. _____

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

PETITION FOR WRIT OF CERTIORARI AND APPENDIX VOLUME I OF II

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QUESTIONS PRESENTED

This Petition presents two questions for review:

1. Whether liability for patent infringement under 35 U.S.C. §271(g) requires that all steps of a patented process must be practiced by, or at least attributable to, a single entity, a requirement that this Court previously recognized is a prerequisite for infringement under 35 U.S.C. §§271(a) and (b) in *Limelight Networks, Inc. v. Akamai Technologies, Inc.*, 572 U.S. 915 (2014).

2. Whether, by requiring EPA to grant expedited review and approval of labels for generic pesticides that are "identical or substantially similar" to the previously approved labels for the same product, Congress intended to preclude claims of copyright infringement with respect to generic pesticide labels.

PARTIES TO THE PROCEEDING

Petitioners, who were defendants in the district court and respondents/cross-appellants in the court of appeals, are Willowood USA, LLC ("WW-USA"), Willowood, LLC ("WW-LLC"), Willowood Azoxystrobin, LLC ("WW-Azoxy"), and Willowood Limited ("WW-China")(collectively, "Willowood"). Respondent, Syngenta Crop Protection, LLC ("Syngenta"), was the plaintiff and appellant/cross-appellee below.

CORPORATE DISCLOSURE STATEMENT

WW-USA is not a publicly-traded entity. WW-USA's parent is Willowood USA Holdings, LLC, which is owned by Dream Acquisition, LLC, which is owned by Lariat Partners, LP. No publicly-held entity owns any WW-USA stock.

Neither WW-LLC nor WW-Azoxy are publicly-traded entities. WW-LLC and WW-Azoxy are wholly owned subsidiaries of WW-USA. No publicly-held entity owns any WW-LLC or WW-Azoxy stock.

WW-China is not a publicly-traded entity and has no parent entity. No publicly-held entity owns any WW-China stock.

RELATED CASES

Syngenta Crop Protection, LLC v. Willowood, LLC et al, No. 1:15-cv-274, U.S. District Court for the Middle District of North Carolina. Judgements on appeal entered March 24 and April 10, 2017.

Syngenta Crop Protection, LLC v. Willowood, LLC et al, Nos. 2018-1614 and 2018-2044, U.S. Court of Appeals for Federal Circuit. Judgement entered December 18, 2019.

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PETITION FOR A WRIT OF CERTIORARI

Petitioners respectfully petition for a writ of certiorari to review the judgment of the United States Court of Appeals for the Federal Circuit.

OPINIONS BELOW

The opinion of the Federal Circuit (App. 1a) is reported at 994 F.3d 1344 (Fed. Cir. 2019). The district court decisions at issue are unreported. (App. 40a; 42a).

JURISDICTION

The judgment of the Federal Circuit was entered on December 18, 2019. (App. 1a). This Court's jurisdiction is invoked under 28 U.S.C. §1254(1).

STATUTORY AND REGULATORY PROVISIONS INVOLVED

The relevant statutory and regulatory provisions are:

Section 271(g) of the Patent Act, 35 U.S.C. §271(g);

Section 136a(c)(3)(B)(i)(I) of the Federal Insecticide, Fungicide and Rodenticide Act, 7 U.S.C. §136a(c)(3)(B)(i)(I);

Sections 102, 105 and 501(a) of the Copyright Act, 17 U.S.C. §§102, 105 and 501(a); and

40 C.F.R. Parts 152 and 156.

STATEMENT OF CASE

This case presents questions of fundamental importance to the proper interpretation of the United States Patent Act and, more specifically, of this Court's construction of that statute in *Limelight Networks*. It also presents questions of fundamental importance to the proper interpretation and implementation of the Federal Insecticide, Fungicide and Rodenticide Act ("FIFRA") which governs the registration, sale, and use of pesticide products in the United States.

A. Factual and Procedural Background

On March 27, 2015, Syngenta sued Willowood[1] in the United States District Court for the Middle District of North Carolina, for infringement of four patents concerning the fungicide compound known as azoxystrobin. Two of the asserted patents claimed the azoxystrobin compound and expired in 2014, while the other two were directed to processes for manufacturing azoxystrobin. Syngenta also asserted copyright infringement claims against Willowood pertaining to the labels accompanying the defendants' generic azoxystrobin products. The district court's jurisdiction was predicated on 28 U.S.C. §§1331 and 1338, 17 U.S.C. §271 and 35 U.S.C. §501. Of the myriad of issues addressed by the courts below, this Petition seeks review of the Federal Circuit's holdings concerning (1) alleged infringement of one of the process patents, U.S. Patent No. 5,847,138 ("the '138

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[1] On February 15, 2019, WW-USA, WW-LLC, and WW-Azoxy filed for protection under the United States Bankruptcy Act in the United States Bankruptcy Court for the District of Colorado, Case No. 19-11079-KHT. On March 3, 2020, that court approved a plan of reorganization.

patent") and (2) Petitioners' alleged copyright infringement.

Syngenta uses azoxystrobin as an active ingredient in formulating a number of end-use fungicide products under various brand names, including QUADRIS® and QUILT EXCEL®. As required by FIFRA, both products are sold with detailed labels that provide directions for use, storage and disposal, as well as first-aid instructions and environmental physical and chemical hazard warnings. The QUADRIS label is comprised of more than fifty, pages of small-type texts and charts, while the QUILT EXCEL label includes twenty-nine pages. (App. 5a-6a, 501a).

WW-China is a Hong Kong company that contracts for the manufacture of azoxystrobin in China and sells the fungicide to WW-USA, a separate company based in Oregon. WW-USA and its wholly owned subsidiary WW-LLC contracted with third parties in the United States to formulate the azoxystrobin compound into generic end-use fungicide products, which they then marketed and sold in this country pursuant to registrations approved by the Environmental Protection Agency ("EPA"), under the names Azoxy 2SC and AzoxysProp Xtra, which correspond in composition and labeling to Syngenta's QUADRIS® and QUILT XCEL®, respectively. (App. 5a-6a).

B. Pre-Trial Rulings

1. Patent Infringement

Syngenta moved for summary judgment that Willowood infringed all four patents, including the '138 patent. The district court denied that motion

with respect to the '138 patent. (App. 51a-53a). The court found it to be undisputed that WW-Ltd purchased azoxystrobin from its Chinese supplier, Yangcheng Tai He Chemicals Corp ("Tai He"), and sold it to WW-USA, which then imported the azoxystrobin into the United States. (App. 51a-53a). The court found that it was also undisputed that the azoxystrobin was manufactured in China by performing both steps of the process claimed in the '138 patent. (App. 51a-53a). However, relying on this Court's opinion in *Limelight Networks*, the district court held that 35 U.S.C. §271(g) requires that all steps of the claimed process be performed by, or at least be attributable to, a single entity. (App. 51a-53a). The district court found genuine issues of material facts as to whether Tai He performed both steps of the process claimed by the '138 patent or whether Willowood directed Tai He and others to practice the claimed process. (App. 51a-53a). At trial, both sides presented evidence on this issue. The jury returned a verdict in favor of Willowood, finding that Syngenta did not prove that both steps of the claimed process were performed by, or were attributable to, Willowood or any other single entity. (App.15a).

2. Copyright Claims

Willowood filed a motion for summary judgment with respect to the copyright claims on the grounds that FIFRA precludes copyright protection for Syngenta's pesticide labels. (App. 9a). Willowood asserted that by directing EPA to "expeditiously" review and approve generic pesticide labels that are "identical or substantially similar" to brand-name labels (7 U.S.C. §136a(c)(3)(B)(i)(I) (App. 110a)), Congress intended to preclude copyright protection

for pesticide labels. (App. 9a). Willowood also argued that because much of the labels' text comprises instructions and warnings mandated by FIFRA and EPA regulations, and only limited means of expressing such information exist, extending copyright protection to Syngenta's labels would substantially constrain a generic company's ability to devise original label language and thus conflict with FIFRA's goals of encouraging and facilitating generic competition. (App. 10a).

Willowood also relied on *SmithKline Beecham Consumer Healthcare, L.P. v. Watson Pharm., Inc.*, 211 F.3d 21, 23 (2d Cir. 2000), in which the Second Circuit held that very similar provisions in the Hatch-Waxman Act governing generic drug labeling preclude assertion of copyright claims by drug manufacturers. (App. 10a). Alternatively, Willowood argued that its use of Syngenta's label language was protected by the copyright doctrines of merger and fair use because any language not specifically authored or required by the EPA is so "basic" and "commonplace in the industry" that it could not be protected by copyrights. (App. 10a).

The United States filed a Statement of Interest supporting Willowood's positions with regard to the copyright claims. The government emphasized that, in light of the plain language of 7 U.S.C. §136a(c)(3)(B)(i)(I), EPA has long encouraged generic labels to be identical to approved labels and has consistently interpreted FIFRA as precluding the application of copyright law to pesticide labels. (App. 11a). As the government has noted in this and other cases, EPA has registered thousands of generic products and most of their labels largely use language

that is identical or substantially similar to labels used by the original registrants. Therefore, as a practical matter, requiring every label of similar products to differ from previously approved labels could significantly limit the number of generic products that could be approved, since it would be difficult, especially for commonly used pesticides, for every individual label to avoid copyright infringement. (App. 488a).

In opposition, Syngenta argued that neither FIFRA nor EPA's regulations required Willowood to copy Syngenta's labels. Syngenta relied on *FMC Corp. v. Control Solutions, Inc.*, 369 F. Supp. 2d 539, 553-60 (E.D. Pa. 2005), which held that FIFRA does not preclude copyright protection for pesticide labels. (App. 10a).

The district court granted summary judgment in favor of Willowood and dismissed the copyright claims. (App. 40a). The court found the analysis in FMC to be "unconvincing," determining 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." (App.41a). The court concluded that because FIFRA contemplates copying by a generic applicant "in ways that would otherwise infringe a copyright.…Congress intended a narrow exception to copyright protection for the required elements" of fungicide labels. (App. 40a-41a).

C. Proceedings in the Federal Circuit

Syngenta appealed (among other issues) the district court's judgments entered in favor of Willowood with respect to the '138 patent and copyright claims. The Federal Circuit reversed the

trial court's ruling that §271(g) of the Patent Act requires all steps of patented processes be practiced by, or attributable to, a single entity. The Federal Circuit also reversed the district court's holding that FIFRA precludes copyright protection for pesticide labels.

1. Patent Infringement

The Federal Circuit recognized that §271(g) provides 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). (App. 26a). According to the Federal Circuit, it was "an issue of first impression" whether the single entity rule applies to §271(g) as it does to §§271(a) and (b). (App. 26a).

The Federal Circuit noted that, as with any statutory construction case, it must "begin with the language of the statute." (App. 26a). Because the language of §271(g) makes clear that the acts that give rise to liability are the importation, offer for sale, sale, or use within the United States of a product that was made by a process patented in the United States, the Federal Circuit held that "nothing in the statutory language suggests that liability arises from *practicing* the patented process…." (App. 27a)(emphasis in original). Rather, the court held, the focus is "only on acts with respect to *products* resulting from the patented process." (App. 27a)(emphasis in original). According to the appellate court, because the statutory language is clear that practicing a patented process abroad cannot create liability under §271(g), "whether that process is practiced by a single entity

is immaterial to the infringement analysis under that section." (App. 27a).

The Federal Circuit rejected Willowood's argument that this Court's decision in *Limelight Networks* required application of the single entity rule. (App. 28a). While the Federal Circuit agreed with Willowood that §271(g) involved a form of direct liability similar to §271(a), it concluded that liability does not arise from practicing the patented process, but rather from importing or selling the product resulting from that patented process. (App. 29a). *Limelight Networks*, the Federal Circuit held, was inapposite because the statute at issue – §271(b) – predicates induced infringement liability on the existence of direct infringement. (App. 29a). Because direct infringement under §271(a) requires a single entity to perform all of the claimed steps, this Court explained where "performance of all the patent's steps is not attributable to any one person….there has been no direct infringement," and consequently "no inducement of infringement under §271(b)." (App. 29a). By contrast, the Federal Circuit held that because liability under §271(g) is not predicated on direct infringement of the patented process, it would "not read into the patent laws limitations and conditions which the legislature has not expressed." (App. 29a). The Federal Circuit therefore reversed the district court's judgment that Willowood USA did not infringe the '138 patent under §271(g). (App. 35a).[2]

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[2] The Federal Circuit affirmed the jury's finding that WW-China did not import into the United States, or sell or offer for sale in the United States, the azoxystrobin at issue and therefore affirmed the trial court's judgment that WW-China did not infringe the '138 patent. (App. 35a).

2. Copyright Infringement

On appeal,[3] the Federal Circuit held that FIFRA does not *necessarily* preclude copyright protection for portions of Syngenta's azoxystrobin product labels, and therefore, the district court's holding that FIFRA precluded claims of copyright infringement was "premature." (App. 19a). The court relied heavily on the fact that FIFRA allows EPA to grant expedited approval for generic pesticide labels not only where the generic label is "identical or substantially similar" to the approved label, but alternatively, where the generic's label 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)(i)(I). According to the court, the alternative pathway for obtaining expedited approval for a generic label signifies that FIFRA does not *require* generic labels to be identical or substantially similar. (App. 21a).

On this basis, the court sought to distinguish the Second Circuit's decision in *SmithKline*. According to the Federal Circuit, the Copyright Act protects only against actual *copying* of protected elements of a protected work, whereas FIFRA's similarity requirement does not foreclose expedited review of an independently composed generic label that happens to address the same facts, concepts, and methods derived from the previously approved label. (App. 21a-22a). The court instructed that on remand, the district court should "first discern whether the Copyright Act, as interpreted under existing copyright doctrines [such as the doctrines of merger

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[3] On appeal, the United States again weighed in on behalf of Willowood, this time as *amicus curiae*. *See* App. 2a.

and fair use], would prohibit Willowood's use of any portion of Syngenta's label." "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 should it revisit the question of whether and to what extent FIFRA precludes Syngenta's copyright claims for any part of its pesticide labels." (App. 24a-25a).

REASONS FOR GRANTING PETITION

A. Patent Infringement

This Court recently took it as a given that a process patent may not be infringed under §271(a) unless each element of the patented process is practiced by, or attributable to, a single entity. *Limelight Networks*, 572 U.S. at 921-22. This Court then broadened that well-established principle by holding that the single entity rule applied to claims based on a party's alleged inducement to infringe a process patent under §271(b). *Id*. The Federal Circuit, however, rejected these fundamental propositions by finding Willowood liable for importing into, and selling, azoxystrobin products in the United States despite the fact that these products had been manufactured by multiple parties each practicing less than all steps of the '138 patent.

The Federal Circuit's ruling turns patent law on its head by imposing liability on a distributor of a product that is made by a non-infringing method. This broadening of protections for owners of process patents flies in the face of Congress' intent to simply close a loophole in the Patent Act where infringers could simply perform some or all of the steps of a patented process outside of the United States to avoid

infringement liability notwithstanding that the products manufactured by that patented process were later sold in the United States. While §271(g) closed this loophole, Congress did not intend to broaden the scope of process patents to cover the practice of less than all of the claimed steps of the patent. This, however, is exactly what the result will be if the Federal Circuit's decision is permitted to stand.

B. Copyright Infringement

The Federal Circuit's holding that FIFRA does not preclude copyright protection for pesticide labels effectively deletes FIFRA's express requirement that EPA "expeditiously" approve generic pesticide labels that are identical or substantially similar to previously approved labels. Given the length and complexity of pesticide labels, Congress could not possibly have permitted generic applicants to submit "identical or substantially similar" labels – and required EPA to approve such labels – without understanding that the only practical way to devise an identical or substantially similar label would be to copy the prior label. The Federal Circuit's decision thus violates one of the most basic tenets of statutory construction enunciated by this Court – that every provision of a statute should be construed in a way that gives it meaning.

As the government has repeatedly made clear (in this case and elsewhere), applying copyright protection to pesticide labels would thwart FIFRA's goals of encouraging and facilitating generic competition in the pesticide market and would upend EPA's longstanding interpretation and implementation of the statute, under which the agency has approved thousands of pesticide labels

that are identical or substantially similar to previously approved labels. The Federal Circuit decision also cannot be reconciled with the Second Circuit's decision in *SmithKline,* which construed an analogous statute governing drug labels to preclude copyright infringement claims against generic drug applicants. This Court should review the decision below in order to correct an elemental error of statutory construction committed by the Federal Circuit, thus giving full effect to FIFRA's language; to remove the uncertainty hanging over generic pesticide companies and EPA concerning a matter of fundamental importance; and address the conflict between the Federal and Second Circuits.

ARGUMENT

I. THIS COURT SHOULD REVERSE THE APPELLATE COURT'S HOLDING THAT THE SINGLE ENTITY RULE DOES NOT APPLY TO SECTION 271(g) OF THE PATENT ACT

This Court recently took it as a given that a process patent may not be infringed unless each element of the patented process is practiced by, or attributable to, a single entity. *See Limelight Networks*, 572 U.S. at 921-22. That is, if multiple steps are necessary to infringe a patented process, practicing less than all of those required steps does not constitute infringement. *See, e.g., Muniacution, Inc. v. Thomson Corp.*, 532 F.3d 1318 (2008). Yet, the Federal Circuit's decision imposes liability for these very acts by finding Willowood liable for importing into, and selling, azoxystrobin products in the United States despite the fact that patents claiming the azoxystrobin compound had expired and the specific

compound at issue had been manufactured by multiple parties practicing less than all of the patented steps. Such an inconsistent ruling should not be permitted to stand.

A. Failing to Apply the Single Entity Rule to §271(g) Would Impermissibly Expand the Scope of §271(g) Beyond Congress' Intent.

Direct infringement of a process patent requires a single party to practice every step of a claimed method. *Muniauction,* 532 F.3d at 1328. For if a single party practices less than all the steps of the patented process that party would simply be performing individual non-patented steps, and therefore, could not be liable for infringement.

Parties cannot, however, avoid liability for patent infringement simply by having third parties carry out one or more of the claimed steps on its behalf. Accordingly, where the actions of multiple parties combine to perform every step of a patented process, the patent is infringed if one party exercises "control or direction" over the entire process such that every step is attributable to that single entity. *Id.* at 1329. Consequently, in order to infringe on a multi-step process claim under §271(a), a single party must perform each step, or must control or direct other parties involved in practicing each step, of the patented process. *Id.* at 1330. This proposition has become known as the "single entity" rule.

In *Limelight Networks,* this Court expanded this principle by holding that liability for inducement to infringe under §271(b) must similarly be predicated on the actions of a single entity. 572 U.S. at 921-22.

To hold otherwise, this Court found, would deprive §271(b) of ascertainable standards and require courts to develop two parallel bodies of infringement law:

> The Federal Circuit's [decision to not apply the single entity rule deprives] § 271(b) of ascertainable standards. If a defendant can be held liable under §271(b) for inducing conduct that does not constitute infringement, then how can a court assess when a patent holder's rights have been invaded? What if a defendant pays another to perform just one step of a 12-step process, and no one performs the other steps, but that one step can be viewed as the most important step in the process? In that case the defendant has not encouraged infringement, but no principled reason prevents him from being held liable for inducement under the Federal Circuit's reasoning, which permits inducement liability when fewer than all of a method's steps have been performed within the meaning of the patent.

Id. at 922.

Notwithstanding this Court's application of the single entity rule to allegations of both direct and indirect infringement under §§271(a) and (b), the Federal Circuit held below that §271(g) does not require application of the single entity rule. As this Court is aware, however, §271(g) is simply another form of direct infringement enacted to close a loophole in the statutory scheme for the protection of process patent owners. *Ajinomoto Co. v. Archer-Daniels-*

Midland Co., 228 F.3d 1338, 1347 (Fed. Cir. 2000); *Eli Lilly & Co. v. Am. Cyanamid Co.*, 82 F.3d 1568, 1571-72 (Fed. Cir. 1996).

Prior to enactment of §271(g), the owner of a process patent had a remedy only if the unauthorized use of its patented process occurred entirely within the United States. *See, e.g., NTP, Inc. v. Research in Motion*, 418 F.3d 1282, 1317-18 (Fed. Cir. 2005). That same patent owner had no remedy, however, if those same individuals practiced some or all of the patented process abroad to manufacture products later imported into the United States for sale or use. *Id.* To close this loophole, §271(g) was enacted to "grant patent owners the same protection against oversees infringers as they already enjoyed against domestic entities" under §271(a). *Mycogen Plant Sci., Inc. v. Monsanto Co.*, 252 F.3d 1306, 1318 (Fed. Cir. 2001), *vacated on other grounds*, 535 U.S. 1109 (2002). The legislative history of §271(g) confirms this analysis:

> *…[T]he process patent bill [ultimately codified, in part, as 35 U.S.C. §271(g)] was crafted to apply equally to the use or sale of a product made by a process patented in this country whether the product (and the process) was used in this country or a foreign country.* The bill is prompted by the use of patented processes in other countries followed by the importation of the resulting products into this country. *The use of the process in this country is already an act of infringement under existing patent law, and such an infringing party would be subject to the jurisdiction of the U.S.*

> *courts. Thus, the inclusion of a domestic process patent infringement in the scope of a bill to extend protection to the products is regarded by the [Judiciary Committee] as a formality…, with little or no practical consequences in patent enforcement….*
>
> *[35 U.S.C. §217(g)] will prevent circumvention of a U.S. process patentee's rights through manufacture abroad and subsequent importation into the United States of products made by the patented process.*

S. REP. NO. 100-83, at 46–48 (1987)(emphasis added).

As the legislative history makes clear, although its emphasis is on the importation of products, the primary purpose of §271(g) is to preserve the force of the patented processes that create those products. *Synaptic Pharm. Corp. v. MDS Panlabs, Inc.*, 265 F. Supp. 2d 452, 460 (D. N.J. 2002).[4] Nothing in the legislative history, however, suggests that Congress intended to provide patent owners with broader protections for the unauthorized use of their patented processes outside the United States than within the United States. *Deepsouth Packing Co. v. Laitram Corp.*, 406 U.S. 518, 531

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[4] The Conference Report which accompanied H.R. 3, the bill that included the process patent provision when it was enacted, characterizes both the House and Senate versions of the bill as providing "that using, selling or importing a product made *in violation of* a U.S. process patent is an act of patent infringement." H.R. Conf. Rep. No. 576, 100th Cong., 2d Sess. 1085–86 (1988), *reprinted in* 1988 U.S.C.C.A.N. 2118–19 (emphasis added).

"We…require a clear and certain signal from Congress before approving the position of a litigant who…argues that the beachhead of [patent protection] is wider, and the area of public use is narrower, than courts had previously thought. ").

As Congress has not evidenced any intent to broaden the effect of the Patent Act, this Court should not permit expansion of the protections afforded by §271(g) to activities that are clearly not infringing under any other set of circumstances. But that is precisely what the Federal Circuit's interpretation of the statute does. Under §271(a), if multiple parties combine to perform every step of a patented process but those actions are *not* attributable to a single entity, their actions would *not* give rise to infringement liability. The same can be said for indirect infringement under §271(b). Under the Federal Circuit's interpretation of §271(g), however, if those *same parties* engaged in those *same actions*, liability will nonetheless be imposed on the distributor offering that product for sale in the United States notwithstanding the fact that the patented process had not been infringed. This result would be in clear contravention of §271(g)'s purpose to grant process patent holders a remedy (not a broader remedy) against oversees infringement of their patented processes where the resulting product is imported into the United States.

The Federal Circuit supported its expansion of the scope of §271(g) by focusing primarily on its language:

> [The language of §271(g)] 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. Nothing in this statutory language suggests that liability arises from *practicing* the patent process abroad. Rather, the focus is only on acts with respect to products resulting from the patented process. Thus, because the statutory language as a whole is clear that practicing a patented process abroad cannot create liability under §271(g), whether that process is practiced by a single entity is immaterial to the infringement analysis under that section.

(App. 26a-27a) (emphasis in original) (internal citations omitted). While the Federal Circuit correctly noted that §271(g) targets the importers and distributors of products made by a patented process, it failed to recognize that it was expanding the scope of process patents by imposing liability on parties where the patented process was not infringed. The dramatic effect of this decision can be seen here where the process claimed by the patent at issue is comprised of two steps, both of which were well known in the industry prior to issuance of the patent, yet, their practice by two separate entities acting independently of each other, is held to be infringing.

The '138 patent claims a process for the manufacture of azoxystrobin comprised of two steps – an etherification step followed by a condensation step. Both of these steps were well known in the industry and had been practiced for many years prior to issuance of the '138 patent. The jury found that two

separate entities performed each of these steps and that their performance could not be attributed to either Willowood or any other party. (App. 15a). Accordingly, Willowood was held to not infringe because the product that it imported into, and sold in, the United States was not made by a patented process, but rather, was manufactured by two separate entities each performing non-patented steps. The Federal Circuit's decision to impose liability on Willowood as a result of these actions turns patent law on its head by imposing liability on the distributor of a product that is made in a non-infringing manner.

B. The Federal Circuit's Holding Impermissibly Extends the Patent Owner's Monopoly Beyond the Expiration of the Patents Covering the Product at Issue.

In addition to the impermissible extension of §271(g)'s affect noted above, the Federal Circuit's decision violates *Kimble v. Marvel Entertainment*, 135 S. Ct. 2401 (2015), by impermissibly extending Syngenta's patent protection beyond the expiration date of the compound patents claiming azoxystrobin. In *Kimble*, this Court affirmed the over fifty-year old proposition first identified in *Brulotte v. Thys Co.*, 379 U.S. 29 (1964), that a patent license agreement requiring the payment of royalties for some period beyond the life of the licensed patent was unenforceable as a misuse of patent rights. In so holding, the Court noted that the United States patent system reflects a balance between fostering innovation and ensuring public access to discoveries. Consequently, once the statutory term of a patent monopoly ends, "the right to make or use the article,

free from restriction, passes to the public." *Kimble*, 135 S. Ct. at 2407. This Court elaborated on this point:

> In case after case, the Court has construed … laws [which] preclude measures that restrict free access to formerly patented … inventions. In one line of cases, we have struck down state statutes with that consequence. By virtue of federal law, we reasoned, "an article on which the patent has expired," like an unpatentable article, "is in the public domain and may be made and sold by whoever chooses to do so." In a related line of decisions, we have deemed unenforceable private contract provisions limiting free use of such inventions. ... Allowing even a single company to restrict its use of an expired or invalid patent, we explained, "would deprive ... the consuming public of the advantage to be derived" from free exploitation of the discovery. And to permit such a result, whether or not authorized "by express contract," would impermissibly undermine the patent laws.

Id.

Here, the products at issue had been protected by two separate patents claiming the azoxystrobin compound. Those patents expired, thus passing to the public, free from restriction, the right to import, make, use, sell, and offer for sale azoxystrobin in the United States. By imposing liability on Willowood for

importing and selling azoxystrobin in the United States notwithstanding that its manufacture did not result from infringement of any patent, the Federal Circuit has impermissibly extended Syngenta's patent monopoly beyond the term of the compound patents.

C. The Federal Circuit's Decision Applies Different Interpretations of the Same Statutory Provision Within §271.

The Federal Circuit's decision also leads to the impermissible application of different interpretations of the same term within §271. *See Ratzlaf v. United States*, 510 U.S. 135, 143 (1994)("A term appearing in several places in a statutory text is generally read the same way each time it appears."). In this regard, §271(a) refers to direct infringement as making, using, or selling "any patented invention" within the United States. As this Court has made clear, multiple parties who independently practice separate steps of a multi-step process are not making, using, or selling the "patented invention." Thus, if the term "patented" in §§271(a) and 271(g) is to be construed consistently, a process which would not be a direct infringement under §271(a) is not a "patented" process under §271(g). To hold otherwise would lead to the term "patented" having different meanings in §§271(a) and 271(g).

D. The Federal Circuit's Reliance on Other Provisions of the U.S. Patent Act to Support its Holding is Misplaced.

The Federal Circuit also improperly relied on §271(f) to support its holding.[5] Section 271(f) provides that the supply of components made in the United States for assembly outside the country constitutes infringement if "such combination occurred within the United States." The Federal Circuit pointed to this provision as evidence that if Congress intended to limit liability under §271(g) to instances where the patented process was practiced in a manner that would infringe the patent if practiced within the United States – such as by requiring a single entity to perform the entire process – it knew how to do so. (App. 29a-31a). A virtually identical argument, however, was rejected in *Limelight Networks*.

As noted above, by failing to require application of the single entity rule to §271(g), the Federal Circuit gave a process patent broader application than what was intended by Congress. As this Court held in *Limelight Networks*, "courts should not create liability for … non-infringing conduct where Congress has elected not to extend that concept." *Limelight Networks,* 572 U.S. at 923. Inclusion of certain language in §271(f) ("…if such combination occurred within the United States…") instead illustrates that "when Congress wishes to impose liability for [certain] activity that does not

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

constitute direct infringement, it knows precisely how to do so." *Id*. As Congress has not indicated a clear and certain signal that §271(g) was enacted to impose liability for what is otherwise non-infringing activity, the Federal Circuit's reliance on §271(f) is improper.

As set forth above, the legislative history makes clear that Congress simply intended to close a loophole in the Patent Act with the adoption of §271(g) so as to provide process patent owners with a means to prevent the use of their patented processes outside of the United States with the resulting products being distributed inside the United States. Congress did not set forth a clear and certain signal that it intended to broaden the scope of those process patents to preclude the non-infringing practice of certain steps of the claimed process by separate and independent parties. Yet, this is the exact result of the Federal Circuit's decision.

The Federal Circuit's additional reliance on §287(b) is also misplaced. The Federal Circuit, relying on §287(b)(1)(C), held that because the act of infringement under §271(g) occurs after a patented process has already been used (*i.e.*, the product has been imported or sold), it is "immaterial" whether that process is infringed. (App. 31a-32a). Willowood does not dispute that the actions giving rise to liability under §271(g) (*i.e.,* the importation or sale of the product made by the patented process) must occur after the product has been made. This does not change the fact that the Federal Circuit's decision broadens the scope of any process patent to provide protection to processes that do not infringe the patent, *e.g.*, where practicing the claimed process cannot be attributed to a single entity.

Moreover, the Federal Circuit failed to take stock of another clause of the same provision – §287(b)(1)(A) – which provides that modifications of remedies provided by §287(b) are not available to "any person who … practiced the patented process…." The fact that §287(b)(1)(A) limits the modifications of remedies provided in §287(b) to any "*person* who practiced the patented process" as opposed to any "*persons* who practiced the patented process" implies Congress' recognition that single entities practice patented processes, not multiple entities. Furthermore, Congress' use of the term "patented process" in §287(b)(1)(A) actually supports Willowood's position.

As set forth above, §271(a) provides that any person who, without authority, makes, uses, offers for sale, or sells a "patented" invention, infringes that patent. 35 U.S.C. §271(a). To hold that practicing a "patented" invention means one thing – application of the single entity rule – when construed in the context of §271(a), but that it means something different – single entity rule should not be applied – when construing §271(g) and/or §287(b)(1)(A) violates basic principles of statutory construction and turns patent law on its head by imposing liability where the patent has not been infringed. *Ratzlaf, supra.*

Here, the jury found that manufacture of the azoxystrobin imported and sold by Willowood was not attributable to any single entity. Accordingly, Willowood should not be held liable for patent infringement under §271(g) as the process claimed by the '138 patent was not infringed.

II. THIS COURT SHOULD REVERSE THE FEDERAL CIRCUIT'S HOLDING THAT FIFRA DOES NOT PRECLUDE COPYRIGHT CLAIMS AS TO PESTICIDE LABELS.

A. The FIFRA Statutory Scheme

FIFRA prohibits the distribution or sale of "any pesticide that is not registered" by EPA. 7 U.S.C. §136a(a) (App. 92a).[6] EPA shall register a pesticide when, among other things, "its labeling and other material required to be submitted comply with the requirements of this subchapter" and "it will not … cause unreasonable adverse effects on the environment." §136a(c)(5).

To facilitate EPA's determination of whether the substantive criteria are met, applicants must submit or cite to data supporting the environmental safety and efficacy of the pesticide. 7 U.S.C. §136a(c)(1)-(2); 40 C.F.R. 152.42, 152.50, 152.80-99.[7] FIFRA establishes an exclusivity period under which the applicant maintains the sole right to use any data it develops and submits for at least ten years following registration and requires payment of compensation for a generic applicant's reliance on such data. 7 U.S.C. §136a(c)(1)(F)(i) (App. 94a) (requiring written permission of original submitter for ten years following registration); §136a(c)(F)(iii) (requiring compensation). *See Ruckelshaus v.*

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[6] The term "pesticide" includes fungicides, such as azoxystrobin. *Id*. §136(t), (u) (App. 81a).

[7] Relevant sections of 40 C.F.R. Part 152 are reprinted at App. 209a *et seq*.

Monsanto Co., 467 U.S. 986, 994-95 (1984) (describing these provisions).

The EPA-approved labeling is an integral part of the registration. It is the primary means by which EPA establishes and enforces the terms of the registration and regulates the use of the pesticide. FIFRA makes it unlawful to "use any registered pesticide in a manner inconsistent with its labeling." §136j(a)(2)(G). Each applicant must submit "a complete copy of the labeling of the pesticide, a statement of all claims to be made for it, and any directions for use." §136a(c)(1)(C) (App. 93a); 40 C.F.R. §152.50(e) (App. 211a); *see* 7 U.S.C. §136(p) (App. 76a) (defining "labeling"). The information on the label must be "placed thereon in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use." §136(q)(1)(E). The label must contain the necessary "directions for use," §136(q)(1)(F), which likewise must "be stated in terms which can be easily read and understood by the average person likely to use or to supervise the use of the pesticide." 40 C.F.R. §156.10(i)(1)(i) (App. 256a).[8] The label also must include, among other things, any necessary "warning or caution statement" for the protection of health and the environment, §136(q)(1)(G); "an ingredient statement," a "statement of 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. §136(q)(2)(A)-(D).

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[8] A copy of 40 C.F.R. Part 156 is reprinted at App. 246a *et seq*.

EPA regulations prescribe in 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.[9] EPA has published a manual with extensive guidance on FIFRA's labeling requirements. Office of Pesticide Programs, U.S. Envt. Prot. Agency, Label Review Manual (rev. 2016) (https://www.epa.gov/pesticide-registration/pesticide-registration-manual (the "EPA Manual")). The EPA Manual states that 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, assesses the potential risks and benefits, and decides whether to approve the application. §§152.107 – 152.112 (App. 241a-242a); *see also* 7 U.S.C. §136a(c)(5) (App. 113a). 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 containing new active ingredients).

In 1988, Congress amended FIFRA to provide a simpler path for expedited registration of generic pesticides. Codified at §136a(c)(3)(B), FIFRA requires EPA "as expeditiously as possible" to review and act on any application for an end-use product that

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[9] Much of the label language and formatting is expressly required by EPA regulations (see App. 246a *et seq*.) or otherwise authored by EPA in documents such as the EPA Manual.

> 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. §136(a)(c)(3)(B)(i)(I) (App. 110a). Congress intended that these expedited procedures would "hasten" and provide "for 'fast track' consideration" of registration applications for end-use pesticide products that are identical or substantially similar to an already registered product. H.R. Rep. No. 100-939, at 31 (1988); S. Rep. No. 100-346, at 20 (1988). Applications for generic products and labeling that meet the criteria of this provision must be reviewed and approved within *ninety days* after receipt of a complete application (7 U.S.C. §136a(c)(3)(B)(ii)(II)) (App. 110a-111a), thus drastically reducing the two-year review time which the statute specifies for new active ingredients. These provisions are in keeping with one of the primary goals of Congress in enacting FIFRA – to encourage, promote, and facilitate generic competition in the pesticide market. *Ruckelshaus*, 467 U.S. at 1014.

Generic applicants (also known as "me-too" applicants) can take advantage of the expedited review process, but also must satisfy the requirements for pesticide registration in §136a(c)(5), including that the pesticide's labeling complies with FIFRA's requirements. 7 U.S.C. §136a(c)(7); *see*

40 C.F.R. §§152.112 and 152.113. As the labeling for the me-too pesticide (as well as the compound itself) must be identical or substantially similar to the currently registered pesticide or differ only in limited ways, EPA can decide whether the application meets the applicable requirements on an expedited basis. For these pesticides, the EPA directs 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." EPA Manual at 4-8. Further, in reviewing the directions of use on a me-too label, the reviewer must make only "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.*

B. The Federal Circuit's Holding that FIFRA Does Not Necessarily Preclude Copyright Protection for Pesticide Labels Effectively Repeals the Statute's Explicit Authorization of Labels that are "Identical or Substantially Similar" to Registered Labels.

One of this Court's most fundamental principles of statutory construction is that a statute should be construed so that effect is given to all its provisions, so that no part will be inoperative or superfluous, void, or insignificant. *Corley v. United States*, 556 U.S. 303, 314 (2009). The Federal Circuit's holding that FIFRA does not preclude application of copyright protection for pesticide labels violates this principle by effectively striking from the statute Congress' directive that EPA approve "identical or substantially similar" labels and its

commensurate grant of permission for generic applicants to submit such labels for approval.

The Federal Circuit thought it dispositive that FIFRA §136a(c)(3)(B)(i)(I) requires expedited EPA review not just if the product's composition and labeling is "identical or substantially similar" but also if they would differ "only in ways that would not significantly increase the risk of unreasonable adverse effects on the environment." (App 21a). The Federal Circuit reasoned that in light of this second pathway for expedited review, the statute does not require me-too labels to be copied. By the Court's reasoning, however, the second pathway for expedited approval is not just one alternative; it effectively eliminates the first pathway, which specifically *directs* EPA to expeditiously approve generic labels that are "identical or substantially similar," and therefore necessarily contemplates copying of previously approved labels.

In the Federal Circuit's view, "FIFRA's similarity requirement does not foreclose expedited review for an *independently composed* label that relies solely on *unprotected* facts, concepts, and methods derived from the registered label." (App. 21a) (emphasis in original). This reasoning is untethered to reality, however, because Willowood could not reasonably be expected to "independently compose" a generic label that would be identical to Syngenta's label. Even a cursory review of the azoxystrobin labels at issue here shows why there is no realistic way for a me-too applicant to devise a label that is "identical" to an already approved label *without copying*. Syngenta's label for Azoxy 2.08SC, for example, is over 50 pages long and contains primarily

technical and scientific information and instructions. (App. 501a). Absent purposeful copying, the likelihood that Willowood could come up with an "identical label" is vanishingly small.

Rather than giving effect to both pathways for expedited label approval that FIFRA authorizes, the Federal Circuit effectively construed the second pathway as nullifying, rather than supplementing, the first. This violation of basic tenets of statutory construction as applied to an important environmental regulatory statute warrants reversal.

C. Allowing Copyright Infringement Claims Against Pesticide Labels Would be Contrary to FIFRA's Fundamental Goals of Promoting Generic Competition and Would Upend Decades of EPA's Implementation of the Statute.

This Court has twice found that in enacting FIFRA, Congress intended to encourage competition, reduce barriers to entry for generic products, and streamline EPA's review process for me-too applications. *Ruckelshaus*, at 1015; *Thomas v. Union Carbide Agric. Prods. Co.*, 473 U.S. 568, 571 (1985). FIFRA §136a(c)(3)(B)(i)(I) is a linchpin in furthering those goals by allowing me-too applicants to submit, and directing EPA to approve, generic product labels that are "identical or substantially similar" to registered labels. (App. 110a). Consequently, as the government has noted in this and other cases, EPA has long encouraged me-too applicants to submit product labels that are in fact identical to registered labels, and interpreted FIFRA as permitting label copying. Fifteen years ago, a district court held that

FIFRA does not preclude copyright protection for me-too labels. *FMC*, 369 F. Supp. 2d at 569. That court, however, was significantly influenced by the fact that the EPA failed to appear in support of the generic applicant's position. *Id*. at 570. But on many occasions thereafter – including in this case – the EPA has made plain that it interprets FIFRA as precluding copyright infringement. Less than three months after *FMC* was decided, EPA informed a trade association why "[i]t has been the practice of [EPA] since…1978 to strongly encourage 'me-too' product labels to be identical or substantially similar to the labels of the products on which their registrations are based." (App. 480a). As me-too applicants continued to submit proposed labels that were copied from previously approved labels, brand-name companies continued to threaten and initiate copyright infringement actions. In cases brought in 2006 and 2009, senior EPA officials submitted detailed declarations explaining why the agency views application of copyright law to pesticide labels to be antithetical to FIFRA's statutory scheme and in direct conflict with EPA's interpretation and implementation of the statute. (App. 483a; 491a).

In this case, the EPA again weighed in before the district court and the Federal Circuit, explaining why the FIFRA 'me too' standard, which is intended to streamline review and registration of me too products, "endorses label copying…." (App. 10a). As the EPA has stated in this case and elsewhere, allowing copyright infringement claims conflict not just with the plain language of FIFRA §136a(c)(3)(i)(I), and its' pro-competitive goals; it would also vitiate FIFRA's bedrock purpose of protecting human health and the environment

because variability in label language for substantially identical products significantly increases the risk of confusion among users, and hence the risk of pesticide misuse. (App. 490a).

The United States also has pointed out that in many cases there may be hundreds of EPA-approved generic versions of a particular product. For example, EPA has registered more than 650 generic versions of the pesticide 2,4-D alone. (App. 489a). Even if there were numerous ways to express the technical information and instructions contained in a pesticide label, application of copyright laws to every label would mean that numerous generic labels must convey the same basic information while avoiding infringement not only of the original registrant's label, but of every previously approved generic label. Not only would this serve no purpose, but as the government has noted, it would severely increase the risk of confusion on the part of end-users, thus increasing the risk of environmental harm and personal injury – completely contrary to FIFRA's purpose.

The Federal Circuit concluded that these practical concerns do not necessarily create a conflict between FIFRA and the Copyright Act because me-too applicants can invoke traditional copyright defenses like merger (which can defeat copyright claims when an underlying fact, procedure, or idea can be expressed in so few ways that 'protection of the expression would effectively accord protection to the idea itself") or the fair use doctrine. (App. 21a). But subjecting me-too applicants to the threat of copyright infringement litigation in which they would have the burden to prove various defenses does not comport

with FIFRA's pro-competitive and pro-environmental goals. The success of these defenses would be highly fact-dependent in each case. The uncertainty of success and substantial cost associated with defending copyright claims would act as significant deterrents to copy a registered label. The generic would be faced with the Hobson's choice of either taking the risk that its copied label will be invalidated under copyright law – and thus its ability to sell the pesticide product derailed until it rewrites the label to EPA's satisfaction – or attempt to write an original product label and thus defer its entry into the market even though FIFRA does not require it to do so. In short, the potential availability of affirmative defenses to copyright infringement does not resolve the conflict between copyright protection on the one hand and FIFRA's plain statutory language and fundamental goals on the other.

The facts of this case bear this out. After Syngenta filed suit, Willowood attempted to revise the language and formatting of its azoxystrobin labels in an effort to avoid Syngenta's copyright claims. Although EPA eventually approved revised labels, the process was neither quick nor easy. In fact, EPA rejected many proposed revisions submitted by Willowood to ensure compliance with FIFRA's substantive requirements. (App. 23a-24a). Most significantly, even after EPA approved revised label language, Syngenta persisted in alleging that the EPA-approved revised language infringed its copyrights.

EPA plainly lacks the expertise to review me-too labels in relation to copyright law. Consequently, no generic could be confident that any label approved

by EPA is non-infringing unless and until a copyright claim is adjudicated. It is nonsensical to believe that Congress would require EPA to spend the time and effort to "expeditiously" approve an identical label that might subsequently be nullified under copyright law.

D. This Court's Review is Warranted Because the Federal Circuit's Decision Cannot be Reconciled With the Second Circuit's Decision in *SmithKline*.

In *SmithKline,* the Second Circuit held that the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act, which direct copying of drug labels by generic producers in order to facilitate generic drug competition, preclude copyright infringement claims with respect to such labels. *SmithKline*, 211 F.3d at 25. The Second Circuit recognized that Congress could not have required generic drug labels be to be identical to registered labels "without requiring labels that will often violate copyrights." *Id*. at 28-29. It concluded: "Certainly, 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 of 'substantial similarity.'" *Id*. at 27. The Second Circuit also explained in the generic drug context that "[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 also delay the introduction of the

generic product without advancing public health and safety …." *Id.*

The Second Circuit's reasoning in the drug context applies with equal force to pesticide labels. The Federal Circuit sought to distinguish *SmithKline* on the grounds that the Hatch Waxman Act *requires* generic drug labels to be identical. (App. 22a). But the Second Circuit's reasoning is equally applicable here because FIFRA *permits* me-too applicants to submit identical labels and *requires* EPA to approve such labels. Consequently, the drafters of FIFRA, no less than the drafters of the Hatch-Waxman Act, would have understood that identical or substantially similar pesticide labels might otherwise be subject to copyright infringement claims. Application of copyright law to pesticide labels, no less than drug labels, would delay the process of approving generic products, drain the resources of the EPA, create enormous problems for successive generic producers who would have to avoid infringing copyrighted labels, and would conflict with FIFRA's primary goals of environmental protection by creating potential confusion among end users as a result of numerous labels conveying the same information in varying language and formats.

For the foregoing reasons, the Petition should be granted so that this Court can resolve the conflict between the Federal Circuit's decision in this and the Second Circuit's decision in *SmithKline*.

Respectfully submitted,

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[ENTERED: December 18, 2019]

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

2018-1614, 2018-2044

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

Decided: December 18, 2019

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Before REYNA, TARANTO, and STOLL, *Circuit Judges*.

REYNA, *Circuit Judge*.

Syngenta Crop Protection, LLC, sued Willowood, LLC, Willowood USA, LLC, Willowood Azoxystrobin, LLC, and Willowood Limited in the U.S. District Court for the Middle District of North Carolina for copyright infringement and patent infringement, asserting four patents directed to a fungicide compound and its manufacturing processes. Prior to trial, the district court dismissed the copyright infringement claims, determining them to be precluded by the Federal Insecticide Fungicide and Rodenticide Act. The district court granted-in-part and denied-in-part Syngenta Crop Protection, LLC's summary judgment motion with respect to patent infringement. The district court also denied-in-part the defendants' motion to exclude expert testimony on damages.

After a jury trial, the district court entered judgment in favor of Willowood Limited on all patent infringement claims; in favor of all defendants on infringement of one patent at issue; and against Willowood, LLC, and Willowood USA, LLC, on infringement of the remaining three patents. The district court denied Syngenta Crop Protection, LLC's motions for judgment as a matter of law. Syngenta Crop Protection, LLC, appeals the district court's

denials of its motions for judgment as a matter of law and its final judgment. Defendants conditionally cross-appeal the district court's partial denial of their motion to exclude expert testimony on damages. For the reasons explained below, we affirm-in-part, reverse-in-part, vacate-in-part, and remand for further proceedings consistent with this opinion.

BACKGROUND

I. The Asserted Patents

Syngenta Crop Protection, LLC, ("Syngenta") is the assignee of U.S. Patent Nos. 5,602,076 ("the '076 patent"), 5,633,256 ("the '256 patent"), 5,847,138 ("the '138 patent"), and 8,124,761 ("the '761 patent"). The '076 patent is entitled "Certain Fungicides, Pesticides and Plant Growth Regulants." The '256 patent is entitled "Certain Pyrimidinyloxy-phenyl Acrylates, Derivatives Thereof and Their Fungicidal Use." The '076 and '256 patents (collectively, "the Compound Patents") expired on February 11, 2014. The Compound Patents are directed to a group of chemical compounds, including azoxystrobin, a fungicide commonly used in agriculture to control fungal growth on crops. J.A. 7; Appellant's Br. 9.

The '138 patent is entitled "Chemical Process" and expired on December 8, 2015. The '138 patent is directed to a two-step process for manufacturing azoxystrobin that includes an etherification step followed by a condensation step. Appellant's Br. 12; J.A. 6672. The etherification step produces an intermediate compound that is then used in the condensation step to produce azoxystrobin. J.A. 6672.

The '761 patent is entitled "Processes for the Preparation of Azoxystrobin Using DABCO as a

Catalyst and Novel Intermediates Used in the Processes" and does not expire until April 15, 2029. The '761 patent is directed to a process of using the chemical catalyst 1,4-diazabicyclo[2.2.2]octane ("DABCO") during the condensation step to manufacture azoxystrobin. '761 patent col. 1 ll. 20–25; J.A. 6682–83. Each claim of the '761 patent requires at least "the presence of between 0.1 and 2 mol % of [DABCO]." '761 patent col. 20 ll. 1–2, 25–26.

II. The Asserted Copyrights

Syngenta uses azoxystrobin as an active ingredient in formulating its fungicide end-use products. Appellant's Br. 7. Syngenta markets and sells these end-use products under several brand names, including QUADRIS® and QUILT XCEL®. *Id.* Both products are sold with detailed labels that provide directions for use, storage, and disposal, as well as first-aid instructions and environmental, physical, and chemical hazard warnings. *Id.* at 19. The QUADRIS® label comprises fifty-four pages of small-type text and charts. J.A. 276; 424–77. The QUILT XCEL® label comprises twenty-nine pages of small-type text and charts. J.A. 276; 481–509. Syngenta registered these two labels with the U.S. Copyright Office on March 25, 2015. Appellant's Br. 19; J.A. 276–77, 479.

III. District Court Proceedings

On March 27, 2015, Syngenta brought suit against Willowood, LLC ("Willowood LLC"), Willowood USA, LLC ("Willowood USA"), and Willowood Limited ("Willowood China") (collectively,

"Willowood")[1] for patent and copyright infringement. Willowood China is a Hong Kong company that contracts for the manufacture of azoxystrobin in China and sells the fungicide to Willowood USA, its Oregon-based affiliate. Willowood USA and Willowood LLC contract with third parties to formulate azoxystrobin into Willowood's generic end-use fungicide products, and market and sell azoxystrobin and those end-use products in the United States. Shortly before the expiration of the Compound Patents, Willowood filed applications with the Environmental Protection Agency ("EPA") to register its Azoxy 2SC and AzoxyProp Xtra generic products, which correspond in composition and labeling to Syngenta's QUADRIS® and QUILT XCEL® fungicides, respectively. J.A. 278, 714; Appellant's Br. 19.

Syngenta asserted in its suit that Willowood's Azoxy 2SC and AzoxyProp Xtra products infringed claims 1–4 and 12–14 of the '076 patent, claims 1–3, 5, and 7 of the '256 patent, claims 6 and 12–14 of the '138 patent, and claims 1, 3–5, and 9–10 of the '761 patent. J.A. 1617–1619, 1627. Syngenta also asserted that Willowood infringed Syngenta's registered copyrights in its QUADRIS® and QUILT XCEL® labels by copying those labels for Willowood's Azoxy 2SC and AzoxyProp Xtra product labels. J.A. 289–91.

A. Pre-Trial Motions

On October 31, 2016, both parties filed motions for summary judgment. Syngenta moved for summary judgment that all asserted claims of the

[1] Syngenta also sued Willowood Azoxystrobin, LLC, but does not appeal the district court's rulings concerning this entity. Appellant's Br. 6 n.1.

four patents were infringed by Willowood. Willowood cross-moved for summary judgment, seeking dismissal of Syngenta's copyright claims and its claim of infringement of the '761 patent.

1. Patent Infringement Claims

The district court granted summary judgment against Willowood USA for direct infringement of the Compound Patents on the basis of Willowood's concession that Willowood USA imported five kilograms of azoxystrobin into the United States in 2013, prior to the Compound Patents' expiration. *Syngenta Crop Prot., LLC v. Willowood, LLC*, No. 1:15-CV-274, 2017 WL 1133378, at *2 (M.D.N.C. Mar. 24, 2017) ("*Summary Judgment Order*"); *see also* J.A. 1617–18. The district court also granted summary judgment against Willowood LLC for induced infringement of the Compound Patents on the basis of Willowood's concession that Willowood LLC contributed to and induced the formulation and testing of Willowood's Azoxy 2SC and AzoxyProp Xtra products by third parties using the same imported five kilograms of azoxystrobin. *Summary Judgment Order*, 2017 WL 1133378, at *2–3; *see also* J.A. 1618. The district court, however, denied summary judgment against Willowood China for direct infringement of the Compound Patents. *Summary Judgment Order*, 2017 WL 1133378, at *2. The district court found a genuine dispute of material fact as to whether Willowood China's sale of five kilograms of azoxystrobin to Willowood USA took place in China or within the United States as required under 35 U.S.C. § 271(a). *Id.*

The district court next denied summary judgment as to infringement of the '138 patent. *Id.* at

*5. The district court found that it was undisputed that Willowood China purchases azoxystrobin from its Chinese supplier, Yangcheng Tai He Chemicals Corp. ("Tai He"), and sells it to Willowood USA, which then imports the azoxystrobin into the United States. *Id.* at *4; *see also* J.A. 1619. The district court found that it was also undisputed that the azoxystrobin in question was manufactured in China by performing both steps of the process claimed in the '138 patent. *Summary Judgment Order*, 2017 WL 1133378, at *4. Relying on our decision in *Akamai Technologies., Inc. v. Limelight Networks, Inc.*, the district court determined that 35 U.S.C. § 271(g) requires that all steps of a claimed process be performed by or attributable to a single entity. *Id.* at *5 (citing 797 F.3d 1020, 1022 (Fed. Cir. 2015)). On this basis, the district court found a genuine dispute of material fact as to whether Tai He performed both steps of the process claimed by the '138 patent during its manufacture of azoxystrobin or whether Willowood directed Tai He and others to practice the claimed process. *Id.* at *4–5.

With respect to the '761 patent, both parties agreed that the issue of infringement turned on whether the azoxystrobin that Willowood China purchases and Willowood USA imports was manufactured using DABCO at concentrations within the claimed range of 0.1 and 2 mol %. *Summary Judgment Order*, 2017 WL 1133378, at *6; J.A. 1627. The district court denied summary judgment on this issue, finding a genuine dispute of material fact as to whether Willowood's suppliers used DABCO within the claimed range in the manufacturing process. *See Summary Judgment Order*, 2017 WL 1133378, at *7.

The district court next granted Syngenta's motion to shift the burden of proof to Willowood under 35 U.S.C. § 295 on the claim of infringement of the '761 patent. The district court found that Syngenta demonstrated a substantial likelihood of infringement, rejecting Willowood's argument that neither Tai He nor any of its intermediaries manufacture azoxystrobin using DABCO within the claimed range. *Id.* at *7–8. The district court credited the testimony of Syngenta's expert, who testified that it would not be commercially reasonable to manufacture azoxystrobin using DABCO outside the claimed range. *Id.* at *8. The district court noted that Willowood's expert did not rebut this testimony, and Willowood's only rebuttal witness, the president of Tai He, had "credibility issues." *Id.* The district court also determined that Willowood did not produce any manufacturing records demonstrating that DABCO was not used or describing what process was used instead. *Id.* at *8, *10. The district court further found that Syngenta made reasonable efforts to discover Tai He's actual manufacturing process, but was unsuccessful because of Willowood's failure to cooperate. *Id.* at *9–10. Finding both elements of § 295 satisfied, the district court shifted the burden to Willowood to prove non-infringement of the '761 patent. *Id.* at *11.

2. Copyright Infringement Claims

In its cross-motion for summary judgment, Willowood argued that Syngenta's copyright claims should be dismissed because the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA") precludes copyright protection for Syngenta's labels. J.A. 730–37. Willowood asserted that FIFRA requires generic

fungicide products to have labels that are "identical or substantially similar" to brand-name labels. J.A. 730–31. Willowood further contended that because much of its labels' text comprises instructions and warnings mandated by FIFRA and EPA regulations, and only limited means of expressing such information exist, extending copyright protection to Syngenta's labels "would make subsequent labeling practically impossible." J.A. 731 & n.14, 733–35 (citing *SmithKline Beecham Consumer Healthcare, L.P. v. Watson Pharm. Inc.*, 211 F.3d 21, 23 (2d Cir. 2000)).

Willowood also argued that any language that is not required by the EPA is nonetheless uncopyrightable because it is so "basic" and "commonplace in the industry," that it merges with the ideas the language is meant to convey. J.A. 732. In the alternative, Willowood argued that its use of some of the language from Syngenta labels constituted permissible fair use. J.A. 737–40.

In response, Syngenta argued that nothing in FIFRA or EPA regulations authorizes or requires Willowood to copy verbatim Syngenta's labels. J.A. 2806. Syngenta asserted that pursuant to FIFRA's legislative scheme, the EPA requires only generic products—not label language—to be identical or substantially similar to their brand-name counterparts, and then only to the extent that a generic applicant seeks expedited review by the EPA. *Id.* In support of its arguments, Syngenta relied heavily on *FMC Corp. v. Control Solutions., Inc.*, a decision from the Eastern District of Pennsylvania, which held that FIFRA does not preclude copyright protection for pesticide labels because "verbatim or nearly wholesale copying of another registrant's label

is unnecessary to obtain expedited review by the EPA of a label." 369 F. Supp. 2d 539, 553–60 (E.D. Pa. 2005); *see* J.A. 2806.

The United States filed a statement of interest on this issue, presenting four arguments in support of Willowood's position. J.A. 2969–3005. First, according to the government, FIFRA "endorses" copying by generic applicants and furthers Congress's intent of expediting market access for generic fungicide manufacturers. J.A. 2970, 2983–91. Second, the government asserted that Syngenta granted Willowood an implied license to copy its labels by participating in FIFRA's labeling scheme. J.A. 2970, 2991–94. Third, the government argued that Willowood's labels are protected under the doctrine of merger, which permits copying of material that can only be expressed in a limited number of ways. J.A. 2971, 2994–98. Lastly, the government argued that Willowood's labels are also protected under the doctrine of fair use. J.A. 2971, 2998–3005.

The district court agreed with Willowood and the United States, and issued a short order granting summary judgment against Syngenta and dismissing its copyright infringement claims. J.A. 33–34. The district court stated that it found the analysis in *FMC* "unconvincing," and determined 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." *Id.* The district court concluded that because FIFRA contemplates copying by a generic applicant "in ways that would otherwise infringe a copyright, . . . Congress intended a narrow exception to copyright protection for the required elements" of fungicide

labels. *Id.* The district court did not otherwise address the arguments presented on this issue.

3. Willowood's Motion to Exclude

On April 10, 2017, Willowood filed a motion to exclude the testimony of Syngenta's damages expert. J.A. 3838–67; *see also* J.A. 37. Willowood did not object to the expert's methodology; rather, Willowood contended that the expert's choice of benchmarks was based on unreliable facts or data. J.A. 44. Willowood argued that the expert's damages calculation was speculative and unreliable because he based his analysis on products unrelated to azoxystrobin and Syngenta's "wildly inaccurate" budgets. J.A. 48; *see also* J.A. 3851–3861. Willowood also argued that Syngenta's expert did not properly apportion damages for infringement of the '761 patent because the expert relied on the same methodology that he used to calculate damages for infringement of the '138 patent, even though the '138 patent claims two steps of the manufacturing process (etherification and condensation) while the '761 patent claims only one step (condensation). J.A. 3861–3865.

The district court denied Willowood's motion to exclude with respect to the Compound Patents, determining that Syngenta's expert relied on "sufficient facts and data applied using a reasonable method in a justifiable manner" based on a hypothetical non-infringing market with a similar product as a benchmark. J.A. 35. The district court approved the expert's choice of using an herbicide product as a benchmark, explaining that both products created similar barriers to generic access to the markets, were sold in similar markets, protected the same crops, had comparable life cycles, and were

both leading products for Syngenta. J.A. 47, 50. With respect to using Syngenta's budgets as benchmarks, the district court found that the expert accounted for any errors in budgeting, and explained that any inaccuracies went to the weight of the evidence instead of its admissibility. J.A. 49.

The district court, however, granted Willowood's motion to exclude Syngenta's expert's testimony with respect to the '138 and '761 patents, finding that the expert did not provide an adequate explanation for his choice of bench-marks. The district court found that in contrast to the benchmarks chosen for the Compound Patents, the expert provided "scant analysis for why non-azoxystrobin fungicides" were a proper benchmark and no evidence of similarities between the products and their markets. J.A. 53–54. The district court also excluded testimony on lost profits with respect to the '761 patent, explaining that the expert failed to address but-for causation or account for existing non-infringing alternatives in his calculations. J.A. 55–58.

B. Trial and Post-Trial Motions

The district court held a seven-day trial beginning on September 5, 2017. With respect to the Compound Patents, the only issues at trial were whether Willowood China imported into the United States or sold to Willowood USA within the United States the five-kilogram sample of azoxystrobin. Syngenta argued that Willowood China imported azoxystrobin into the United States by arranging for its entry into the country. J.A. 6961. Syngenta also argued that Willowood China's sale of the azoxystrobin necessarily occurred within the United States because Willowood USA is located within the

United States. *Id.* Willowood argued in response that Willowood China did not infringe the Compound Patents because the shipment of five-kilogram sample of azoxystrobin was marked "f.o.b. China,"[2] meaning that title to the azoxystrobin passed from Willowood China to Willowood USA overseas. J.A. 6961. After presenting its case, Syngenta moved for a judgment as a matter of law ("JMOL") on this issue.

The district court denied Syngenta's JMOL motion, and the jury returned a specific verdict in favor of Willowood China, finding that Syngenta did not prove that Willowood China imported azoxystrobin into the United States or sold azoxystrobin within the United States. J.A. 266. The jury awarded Syngenta $75,600 in damages for infringement of the Compound Patents by Willowood USA and Willowood LLC. Syngenta renewed its motion for JMOL after the verdict, which the district court again denied. J.A. 6523; Appellant's Br. 12.

With respect to the '138 patent, the only issue at trial was whether both steps of the claimed process were performed by a single entity or attributable to Willowood as the directing or controlling entity. J.A. 240–241; 266; Appellant's Br. 13. Syngenta presented evidence that Willowood directed or controlled Tai He's manufacturing process, and that Tai He performed both claimed steps. Appellant's Br. 13–15. In rebuttal, Willowood presented evidence that Tai He did not perform the etherification step when

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[2] "F.o.b" stands for "free on board" and designates a method of shipment whereby legal title passes from the seller to the buyer once goods are delivered at a designated location. *Litecubes, LLC v. N. Light Prod., Inc.*, 523 F.3d 1353, 1358 n.1 (Fed. Cir. 2008).

manufacturing Willowood's azoxystrobin. *See* J.A. 8232–8241; J.A. 7682 at 63:22–64:11; Appellant's Br. 15. The jury returned a specific verdict in favor of Willowood 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. J.A. 266.

With respect to the '761 patent, the only issue at trial was whether during manufacture of Willowood's azoxystrobin, the condensation step was performed using the DABCO catalyst within the range claimed by the '761 patent. J.A. 248–50; Appellant's Br. 17. The burden of proof was on Willowood pursuant to the district court's order under 35 U.S.C. § 295. *Summary Judgment Order*, 2017 WL 1133378, at *11. After presenting its case, Syngenta moved for JMOL on this issue, which the district court denied. J.A. 7045; Appellant's Br. 18. After trial, the jury returned a specific verdict in favor of Syngenta that "the Defendants" did not prove that DABCO was not used as claimed. J.A. 267. The jury awarded $900,000 in damages to Syngenta for infringement of the '761 patent "by the Defendants." *Id.*

After trial, the parties submitted proposed final judgments to the district court. J.A. 6489. At that point, a dispute arose between the parties as to whether the jury found that Willowood China infringed the '761 patent. In resolving the dispute, the district court noted that the jury found with respect to the Compound Patents that Willowood China did not import azoxystrobin into the United States or sell azoxystrobin within the United States. *Id.* The district court explained that "[n]either party asked the court to submit a separate issue as to Willowood

China's infringement of the '138 patent or the '761 patent," and concluded that "the parties implicitly agreed to resolve Willowood China's liability for the ['138 and '761 patents] based on the answer to the importation question which was first on the verdict sheet." *Id.* The district court concluded that "[t]here is no evidentiary basis" for finding that Willowood China infringed the '761 patent. *Id.*

On November 20, 2017, the district court entered final judgment. The district court entered judgment in favor of Willowood China on "all claims" and in favor of all Willowood defendants on the claim of infringement of the '138 patent. J.A. 3. The district court entered judgment against Willowood USA and Willowood LLC on the claims of infringement of the Compound Patents and the '761 patent. *Id.* After the district court entered final judgment, Syngenta renewed its JMOL motion with respect to Willowood China's infringement. J.A. 6522–6523; Appellant's Br. 18. Syngenta contended that Willowood waived its argument that Willowood China did not infringe the '761 patent by not objecting to the wording of the jury verdict form. J.A. 6522. The district court denied Syngenta's renewed JMOL motion. J.A. 91.

Syngenta appeals the district court's dismissal of its copyright claims, the district court's conclusion that § 271(g) requires every step of a claimed process to be performed by or attributable to a single entity, the jury's verdict that Willowood did not infringe the '138 patent even with the single entity requirement imposed on § 271(g), and the district court's judgment that Willowood China did not infringe any of the asserted patents. Willowood conditionally cross-appeals the district court's partial

denial of its motion to exclude the testimony of Syngenta's damages expert. We have jurisdiction under 28 U.S.C. § 1295(a)(1).

DISCUSSION

I. Standard of Review

We review a district court's decisions on motions for summary judgment and JMOL under the law of the regional circuit, in this case the Fourth Circuit. *Supernus Pharm., Inc. v. Iancu*, 913 F.3d 1351, 1356 (Fed. Cir. 2019); *Mohsenzadeh v. Lee*, 790 F.3d 1377, 1381 (Fed. Cir. 2015). The Fourth Circuit reviews the grant of a motion for summary judgment de novo, viewing all evidence in the light most favorable to the non-moving party. *Amdocs (Israel) Ltd. v. Openet Telecom, Inc.*, 761 F.3d 1329, 1337–38 (Fed. Cir. 2014) (citing *Ramos v. S. Maryland Elec. Co–op., Inc.*, 996 F.2d 52, 53 (4th Cir. 1993)). The Fourth Circuit reviews a district court's post-verdict JMOL decisions de novo, determining whether the jury's verdict is supported by substantial evidence. *LifeNet Health v. LifeCell Corp.*, 837 F.3d 1316, 1322 (Fed. Cir. 2016) (citing *Carolina Trucks & Equip., Inc. v. Volvo Trucks of N. Am.*, 492 F.3d 484, 488 (4th Cir. 2007)). The Fourth Circuit reviews a district court's pre-verdict grant of JMOL de novo, viewing all evidence in light most favorable to the non-moving party and considering whether a reasonable jury could find for the non-moving party. *ActiveVideo*, 694 F.3d at 1319 (citing *Brown v. CSX Transp.*, 18 F.3d 245, 248 (4th Cir. 1994)).

We review questions of patent law under Federal Circuit law. *Ericsson, Inc. v. D-Link Sys., Inc.*, 773 F.3d 1201, 1214 (Fed. Cir. 2014). We review

a jury's findings on questions of fact, such as infringement and damages, for substantial evidence. *Power Integrations, Inc. v. Fairchild Semiconductor Int'l, Inc.*, 711 F.3d 1348, 1377 (Fed. Cir. 2013). We review a district court's decisions concerning damages methodologies for abuse of discretion. *ActiveVideo Networks, Inc. v. Verizon Commc'ns, Inc.*, 694 F.3d 1312, 1332 (Fed. Cir. 2012) (citing *Lucent Techs., Inc. v. Gateway, Inc.*, 580 F.3d 1301, 1310 (Fed. Cir. 2009)).

We apply copyright law as interpreted by the regional circuit. *Amini Innovation Corp. v. Anthony Cal., Inc.*, 439 F.3d 1365, 1368 (Fed. Cir. 2006). Interpretation of the rights granted by the Copyright Act is a question of law that the Fourth Circuit reviews de novo. *See Rosciszewski v. Arete Assocs., Inc.*, 1 F.3d 225, 229 (4th Cir. 1993).

We also review a district court's rulings on admission of expert testimony under the law of the regional circuit. *ePlus, Inc. v. Lawson Software, Inc.*, 700 F.3d 509, 516 (Fed. Cir. 2012). The Fourth Circuit reviews such evidentiary rulings for abuse of discretion. *Id.* (citing *Kopf v. Skyrm*, 993 F.2d 374, 378 (4th Cir. 1993)).

We review questions of statutory interpretation de novo. *Mohsenzadeh*, 790 F.3d at 1381 (citing *AD Global Fund, LLC v. United States*, 481 F.3d 1351, 1353 (Fed. Cir. 2007)). If two statutory provisions 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 *Regional Rail Reorganization Act*

Cases, 419 U.S. 102, 133-34 (1974)) (internal quotation marks omitted).

II. Syngenta's Copyright Claims

Syngenta challenges the district court's summary judgment order dismissing its copyright claims in their entirety. The dismissal was based on the court's holding that FIFRA "precludes copyright protection for the required elements of pesticide labels as against the labels of me-too [*i.e.* generic[3]] registrants." J.A. 33. We conclude that this determination was premature. Because the text of 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. This determination requires this court to review the merits of Syngenta's copyright claims, which the district court did not reach. Thus, we remand for the court to do so in the first instance.

When evaluating the "alleged preclusion of a cause of action under one federal statute by the provisions of another federal statute," we rely on traditional rules of statutory interpretation. *POM Wonderful LLC v. Coca-Cola Co.*, 573 U.S. 102, 111 (2014). Among these principles is the presumption

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[3] Consistent with terminology used by the EPA, the parties and the district court use the term "me-too" to refer to applications requesting registration of generic pesticide products pursuant to FIFRA's criteria for expedited review. *See* EPA, PRIA Glossary, https://www.epa.gov/pria-fees/pria-glossary (last visited December 9, 2019).

that a later-enacted statute does not impliedly repeal, even in part, an earlier one. *Id.* (citing *Carcieri v. Salazar*, 555 U.S. 379, 395 (2009)). Thus, where the later-enacted statute does not cover the whole subject of the earlier one and is not "clearly intended as a substitute," an implied repeal will only be found where provisions in the two statutes are in "irreconcilable conflict"—a stringent standard that renders implicit repeals a "rarity." *Nat'l Ass'n of Home Builders v. Defs. of Wildlife*, 551 U.S. 644, 662-63 (2007); *J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc.*, 534 U.S. 124, 142 (2001). In the absence of such conflict, statutory provisions acting upon the same subject should be interpreted and applied in a way that "gives effect to each" and "preserves the purposes of both." *United States v. Borden Co.*, 308 U.S. 188, 198 (1939); *Zenith Elecs. Corp. v. Exzec, Inc.*, 182 F.3d 1340, 1347 (Fed. Cir. 1999).

Here, the Copyright Act prohibits parties from reproducing the protected elements of a valid copyright without authorization, except where such actions would constitute fair use. *See Harper & Row Publishers, Inc. v. Nation Enterprises*, 471 U.S. 539, 547 (1985); *Lyons P'ship, L.P. v. Morris Costumes, Inc.*, 243 F.3d 789, 801 (4th Cir. 2001); *Ale House Mgmt., Inc. v. Raleigh Ale House, Inc.*, 205 F.3d 137, 143 (4th Cir. 2000). At the same time, FIFRA provides for expedited EPA review of applications for generic pesticide products when the proposed "me-too" 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" "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) (emphasis added).

In finding that FIFRA precluded copyright claims against me-too applicants, the district court relied on its understanding that "FIFRA contemplates that a 'me-too' applicant will copy from the original pesticide label in ways that would otherwise infringe a copyright." J.A. 33. But while use of FIFRA's expedited generic pathway is premised on similarity to a registered product, the text of § 136 does not require a me-too 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. Rather, the statute provides for expedited review so long as any differences between the proposed and registered products "would not significantly increase the risk of unreasonable adverse effects on the environment"—a substantive criterion evaluated by the EPA under its technical expertise. 7 U.S.C. § 136a(c)(3)(B)(i)(I).

This is significant because copyright infringement requires, at a minimum, some *copying* of *protected elements* from the copyrighted work, which does not include "any idea, procedure, process, system, method of operation, concept, principle, or discovery" embodied by the work. 17 U.S.C. § 102(b); *Lyons P'ship,* 243 F.3d at 801. FIFRA's similarity requirement does not foreclose expedited review for an *independently composed* label that relies solely on *unprotected* facts, concepts, and methods derived from the registered label.

In this respect, the asserted conflict between the Copyright Act and FIFRA differs from the conflict

between the Copyright Act and the Hatch-Waxman Act that was addressed in *SmithKline*, a decision cited by the district court and Willowood. *SmithKline Beecham Consumer Healthcare, L.P. v. Watson Pharms., Inc.*, 211 F.3d 21 (2d Cir. 2000). There, the Second Circuit found that the Hatch-Waxman Act "not only permit[s] but *require[s]* producers of generic drugs *to use the same labeling* as was approved for, and is used in, the sale of the pioneer drug."[4] *Id.* at 25 (emphasis added). In these circumstances, the court concluded that generic applicants faced a double-bind: "if [the plaintiff's] copyright claim has merit, then [the defendant] cannot realistically use the ANDA process to sell its [generic product] because it will either have to change the label and lose FDA approval or be enjoined from using a label that infringes [the plaintiff's] copyright." *Id.* at 27. Thus, the court found it "obvious" that Congress intended for the Hatch-Waxman Act to "trump the copyright laws." *Id.* at 29. Here, in contrast, FIFRA's express allowance for differences between the proposed and registered labels allows me-too applicants to avoid this conflict by using an independently created label.

Willowood and 41 Companies Holding Generic EPA Pesticide Registrations ("Generics Amici") counter that there are nonetheless practical and regulatory constraints that frustrate their reasonable attempts to comply with the requirements of both the

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[4] The Hatch-Waxman Act requires that, except for changes related to the manufacturer name or approved difference in the drug, "[a]n abbreviated application for a new drug shall contain . . . (v) *information to show* that the *labeling* proposed for the new drug *is the same as* the labeling approved for the listed drug . . . ." 21 U.S.C. § 355(j)(2)(A) (emphases added).

Copyright Act and expedited review under FIFRA. We disagree that these concerns alone warrant preclusion. To begin with, Generics Amici contend there are "only so many ways to express the *same* instructions and warnings" contained in many portions of these pesticide labels, such that any attempt to capture the pertinent information will inevitably require using substantially the same expressions. Generics Amici Br. at 8 (emphasis in original); *see also* Appellee's Br. at 23-25. But this is precisely the type of problem addressed by the traditional copyright doctrine of merger, under which courts have declined to protect against copying when an underlying fact, procedure, or idea can be expressed in so few ways that "protection of the expression would effectively accord protection to the idea itself." *Kregos v. Associated Press*, 937 F.2d 700, 705 (2d Cir. 1991); *see also Morrissey v. Procter & Gamble Co.*, 379 F.2d 675, 678 (1st Cir. 1967) ("When the uncopyrightable subject matter is very narrow, so that the topic necessarily requires, if not only one form of expression, at best only a limited number, to permit copyrighting would mean that a party or parties, by copyrighting a mere handful of forms, could exhaust all possibilities of future use of the substance." (internal citations and quotation marks omitted)). Thus, copyright law has its own solution for the constraints inherent in the expression of certain information contained in pesticide labels.

Willowood raises a more difficult problem with respect to portions of a registered label for which the EPA has allegedly required me-too applicants to copy otherwise protectable elements from the registered label on the grounds that any differences may adversely affect the environment by confusing

users.[5] For example, Willowood contends that when it sought to revise the directions for use in its own label from the four-column table format used by Syngenta to a narrative form, the EPA required Willowood to reinstate the information in a table, essentially requiring Willowood to copy Syngenta's format. Appellee's Br. at 24 (citing J.A. 3129-3200 (Azoxy 2.08 SC Label); J.A. 3201-3339 (AzoxProp Xtra label)). But this is a predicament appropriately addressed, at least in the first instance, under copyright law's own "equitable rule of reason": the fair use doctrine. *Sony Corp. of Am. v. Universal City Studios, Inc.*, 464 U.S. 417, 448 (1984) (quoting H. Rep. No. 94–1476, at 65–66, *reprinted in* 1976 U.S.C.C.A.N. 5659, 5679). Under that established framework, the district court can assess, based on factors such as the character of the allegedly creative elements, their substantiality in the context of the labels as a whole, and the nature and effect of their use by Willowood, whether the presence of those elements in Willowood's generic labels would fairly constitute infringement in violation of the Copyright Act.[6]

Thus, we vacate the district court's grant of summary judgment on Syngenta's copyright claims and remand for further consideration. On remand,

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[5] This is distinct from portions of the registered label where the language was originally mandated or suggested by the EPA. Syngenta has disclaimed any copyright protection over those label elements. Appellant's Reply Br. at 11.

[6] The Copyright Act expressly identifies the following non-exhaustive factors to be considered in assessing fair use: "(1) the purpose and character of the use . . . ; (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." 17 U.S.C. § 107.

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 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 should it revisit the question of whether and to what extent FIFRA precludes Syngenta's copyright claims for any part of its pesticide labels. It is possible that after a full assessment of the requirements of copyright law and FIFRA as applied in this case, there may come to light a truly irreconcilable conflict between Copyright Act liability and implementation of FIFRA. In the absence of a clear facial conflict, however, we decline to wield the blunt tool of preclusion before the full factual and legal contours of any latent problem have been examined.

III. Infringement Under 35 U.S.C. § 271(g)

Syngenta next challenges the district court's interpretation of 35 U.S.C. § 271(g). The district court interpreted § 271(g) to require that all steps of a patented process be performed by or at the direction or control of a single entity before infringement liability under that section can attach. *Summary Judgment Order*, 2017 WL 1133378, at *5. Syngenta contends that the district court's interpretation of § 271(g) is contrary to the plain language of the statute and Congress's intent expressed in the legislative history. Appellant's Br. 41–46. The amici add to this argument by asserting that the district

court's interpretation is inconsistent with the broader context of the statute as a whole and the purpose behind § 271(g), and creates an impossible evidentiary burden on the patent owner. *See* Amicus NYPLA Br. 10–14; Amici Biotechnology & CropLife Br. 8–14; 17–23. This is an issue of first impression. We conclude that the district court erred by imposing a single-entity requirement under § 271(g).

"As in all statutory construction cases, we begin with the language of the statute." *Barnhart v. Sigmon Coal Co.*, 534 U.S. 438, 450 (2002). The meaning of statutory language "is determined by reference to the language itself, the specific context in which that language is used, and the broader context of the statute as a whole." *Robinson v. Shell Oil Co.*, 519 U.S. 337, 340 (1997). If the statutory language does not clearly resolve the disputed issue, we also consider the legislative history to determine Congressional intent. *Burlington N. R. Co. v. Oklahoma Tax Comm'n*, 481 U.S. 454, 461 (1987); *In re Swanson*, 540 F.3d 1368, 1376 (Fed. Cir. 2008) (citing *Timex V.I. v. United States*, 157 F.3d 879, 882 (Fed. Cir. 1998), and *Deluxe Corp. v. United States*, 885 F.2d 848, 850 (Fed. Cir. 1989)).

The resolution of this issue turns on the nature of the infringing acts covered by § 271(g). 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) (2012). This 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. *Id.* Nothing in this statutory language suggests that liability arises from *practicing* the patented process abroad. Rather, the focus is only on acts with respect to *products* resulting from the patented process. Thus, because the statutory language as a whole is clear that practicing a patented process abroad cannot create liability under § 271(g), whether that process is practiced by a single entity is immaterial to the infringement analysis under that section.

The context of the statute as a whole also supports our conclusion. Section 271(a) states that "whoever without authority makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States any patented invention during the term of the patent therefor, infringes the patent." 35 U.S.C. § 271(a). Derived from this statutory language is the single-entity requirement under § 271(a), which limits direct infringement liability only to circumstances "where all steps of a claimed method are performed by or attributable to a single entity." *Akamai Techs.*, 797 F.3d at 1022; *BMC Res., Inc. v. Paymentech, L.P.*, 498 F.3d 1373, 1379–81 (Fed. Cir. 2007).

On the basis of this court's § 271(a) jurisprudence, the district court concluded that § 271(g) similarly imposes a single-entity requirement on the performance of a patented process. *Summary Judgment Order*, 2017 WL 1133378, at *5 (citing *Akamai*, 797 F.3d at 1022). This conclusion was erroneous because infringement liability under the two sections is distinct. In contrast to § 271(g), the act that gives rise to liability under § 271(a) occurs when

"a party . . . make[s], use[s], sell[s], or offer[s] to sell the patented invention, meaning the entire patented invention." *BMC*, 498 F.3d at 1380. Under this precedent, direct infringement under § 271(a) of a process patent occurs only when a single party practices every step of the claimed process. *Id.*; *see also* 35 U.S.C. § 271(a) (infringement occurs when "*whoever* without authority *makes, uses, offers to sell, or sells . . . or imports . . .* any patented invention" (emphasis added)). As discussed above, however, liability under § 271(g) is not predicated on practicing the claimed process, but rather on importing, offering for sale, selling, or using a product. *See* 35 U.S.C. § 271(g) (infringement occurs when "*whoever* without authority *imports . . . or offers to sell, sells, or uses . . . a product*" (emphasis added)). Thus, the single-entity requirement, which is necessary for direct infringement liability under § 271(a), has no application to acts that do not constitute infringement under § 271(g).

On the same basis we reject Willowood's argument that the Supreme Court's *Limelight* decision requires us to apply the single-entity rule to § 271(g). Willowood asserts that the Court in that case applied "the single entity rule to allegations of both direct and indirect infringement under [§] 271(a) and (b)." Appellee's Br. 29 (citing *Limelight Networks, Inc. v. Akamai Techs., Inc.*, 572 U.S. 915, 921–22 (2014)). Willowood argues that because "§ 271(g) is simply another form of direct infringement," we are bound by the *Limelight* decision to apply the single-entity rule to § 271(g). *Id.* We disagree.

Willowood fundamentally misunderstands the nature of the act that gives rise to liability under

§ 271(g). Although § 271(g) may involve a form of direct liability, that liability does not arise from practicing a patented process abroad. *Limelight* is further inapposite because the statute at issue in *Limelight*—§ 271(b)—predicates induced infringement liability on the existence of direct infringement. 35 U.S.C. § 271(b) ("Whoever actively induces *infringement* of a patent shall be liable as an infringer." (emphasis added)); *Limelight*, 572 U.S. at 921. Because direct infringement under § 271(a) requires a single entity to perform all of the claimed steps, the Supreme Court explained that where "performance of all the patent's steps is not attributable to any one person[,] . . . . there has been no direct infringement," and consequently "no inducement of infringement under § 271(b)." *Id.* at 922. By contrast, infringement liability under § 271(g) is not predicated on direct infringement of the patented process, and we will "not read into the patent laws limitations and conditions which the legislature has not expressed." *Diamond v. Diehr*, 450 U.S. 175, 182 (1981) (quoting *Diamond v. Chakrabarty*, 447 U.S. 303, 308 (1980)).

Section 271(f) reinforces our conclusion. Section 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) (2012) (emphasis added). If Congress intended to limit liability under § 271(g) to instances where the patented process was practiced

in a manner that would infringe the patent if such practice occurred within the United States—such as it did by requiring a single entity to perform the entire process under § 271(a)—it "kn[ew] precisely how to do so." *Limelight*, 572 U.S. at 923. Congress, however, did not do so, even though § 271(g) was enacted four years after § 271(f). *See Microsoft Corp. v. AT & T Corp.*, 550 U.S. 437, 441 (2007); *Kinik Co. v. Int'l Trade Comm'n*, 362 F.3d 1359, 1362 (Fed. Cir. 2004). "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) (quoting *Russello v. United States*, 464 U.S. 16, 23 (1983)) (internal alterations and quotation marks omitted). The Supreme Court has warned that "courts should not create liability for . . . non-infringing conduct where Congress has elected not to extend that concept." *Limelight*, 572 U.S. 923. We heed this warning.

Willowood asserts that the inclusion of the phrase "if such combination occurred within the United States" in § 271(f) but not in § 271(g) demonstrates that Congress did not intend for § 271(g) to extend the scope of patent protection outside the United States to include conduct that would not constitute direct infringement domestically—such as the divided practice of a patented process by more than one entity. Appellee's Br. 41–42. We agree with this proposition but reject Willowood's conclusion that the absence of that phrase necessitates the application of the single-entity requirement to § 271(g). As explained above, practicing a patented process abroad does not give

rise to infringement liability under § 271(g). Thus, our conclusion that a single entity need not perform every step of a patented process abroad under § 271(g) does not extend patent protection to cover extraterritorial conduct that would not otherwise trigger liability within the United States. Rather, it is Willowood who asks us to impermissibly apply § 271(g) to extraterritorial conduct by attempting to shift the focus of the statute from domestic acts of importation, offer for sale, sale, or use of a product to cover a foreign act of practicing a patented process. *See WesternGeco LLC v. ION Geophysical Corp.*, 138 S. Ct. 2129, 2137 (2018) ("If the conduct relevant to the statute's focus . . . . occurred in another country, 'then the case involves an impermissible extraterritorial application regardless of any other conduct that occurred in U.S. territory.'" (quoting *RJR Nabisco, Inc. v. European Cmty.*, 136 S. Ct. 2090, 2094 (2016))). We are not inclined to do so.

Other sections of Title 35 add support to our conclusion that infringement under § 271(g) is not predicated on a single entity practicing a patented process abroad. For example, § 287(b), which limits available damages under § 271(g), states that "[t]he modifications of remedies provided in this subsection shall not be available to any [infringer under § 271(g)] who . . . 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) (2012) (emphasis added). This language makes clear that the act of infringement under § 271(g) occurs *after* a patented process has already been used. Thus, because practicing a patented process does not trigger liability under § 271(g), it is immaterial

whether that process is practiced by more than a single entity. Additionally, § 287(b) limits available remedies under § 271(g) in certain circumstances where the manufacturer of a product made by a patented process "is not known." *See* 35 U.S.C. §§ 287(b)(3)(B)(iii); 287(b)(4)(A)(iii); 287(b)(5)(C)(i) (2012). It would not have made sense for Congress to make infringement liability under § 271(g) contingent on a single entity practicing a patented process while expressly providing limitations on that liability where it is unknown which manufacturer—or how many—practiced the process.

The legislative history is instructive. A Senate Report accompanying the Process Patents Amendments Act of 1987, the bill that enacted § 271(g), states 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 their patented process." S. Rep. 100-83, at 29 (1987). The Report makes clear that § 271(g) was enacted to "extend protection to the *products*" resulting from practicing a patented process and to "prevent circumvention of a U.S. process patentee's rights through manufacture abroad and *subsequent importation into the United States of products* made by the patented process." *Id.* at 46, 48 (emphasis added); *see also id.* at 30 (stating that § 271(g) would "protect against the entry into the U.S. marketplace of goods made abroad without authorization from the inventor"). Even Willowood concedes that the legislative history's clear "focus is on the importation of products," rather than on the use of a patented process. Appellee's Br. 31 The Report also clarifies that § 271(g) "does not attempt to prevent *the use of*

the process in another country." S. Rep. 100-83, at 30 (emphasis added); *see also id.* at 48. The Report explains that a "U.S. process patentholder [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 the process in that country." S. Rep. 100-83, at 30. Thus, because simply practicing a patented process abroad does not come within the ambit of § 271(g), that there may be several entities involved in practicing the process is immaterial to the infringement analysis under § 271(g).

Willowood argues that in enacting § 271(g), Congress intended to provide patentees with "the same protection against overse[a]s infringers as they already enjoyed against domestic entities." Appellee's Br. 30 (quoting *Mycogen Plant Sci., Inc. v. Monsanto Co.*, 252 F.3d 1306, 1318 (Fed. Cir. 2001), *judgment vacated on other grounds*, 535 U.S. 1109 (2002)) (emphasis removed). On this basis, Willowood contends that because direct infringement of a process patent under § 271(a) requires the same entity to perform all of the claimed steps, the same must be true under § 271(g). *Id.* at 30–31. We disagree.

The statutory language and legislative history described above 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). Section 271(a) covers all patented processes, whether or not they result in a product. Infringement under § 271(g) instead requires importation, sale, offer for sale, or use within the United States of a product made by a patented process. The different scope of

protection offered under § 271(a) and § 271(g) demonstrates that there is no inconsistency between the two sections. The legislative history further demonstrates that Congress did not enact § 271(g) to provide for identical rights to those enjoyed by patentees under § 271(a) with respect to process patents. Rather, Congress made clear that § 271(g) "is prompted by the use of patented processes in other countries *followed by the importation of the resulting products into this country*," and simply "extend[s] protection to the products" made by such processes. S. Rep. 100-83 at 46.

Lastly, applying a single-entity requirement to the practice of a patented process under § 271(g) would impose an undue evidentiary burden on patentees that is contrary to the intent of Congress. Congress recognized "the great difficulties a patentee may have in proving that the patented process was used in the manufacture of the product in question" where the manufacture occurred abroad. *Id.* at 57. As a solution, Congress provided for a rebuttable presumption in § 295 that shifted the burden to the accused infringer to prove that the patented process was not used in manufacturing the accused products. *See* 35 U.S.C. § 295. Congress would not have on the one hand recognized the difficulty in determining *how* a product was manufactured, and on the other hand concluded that determining *who* manufactured the product would be an easy exercise so as to require patentees to prove that a single manufacturer practiced the claimed process.

We hold that in light of the plain language of the statute, the broader context of the statutory scheme as a whole, and the legislative history,

§ 271(g) does not require a single entity to perform all of the steps of a patented process for infringement liability to arise from the importation into the United States or offer to sell, sale, or use within the United States of a product made by a process patented in the United States.

It is undisputed that Willowood USA imported into the United States an azoxystrobin compound that was manufactured abroad using the process patented by the '138 patent. *Summary Judgment Order*, 2017 WL 1133378, at *5. We therefore reverse the district court's judgment that Willowood USA did not infringe the '138 patent under § 271(g). The jury found, however, that Willowood China did not import into the United States or sell or offer for sale in the United States the azoxystrobin compound at issue, and as discussed below, substantial evidence supports this finding. We therefore affirm the district court's judgment that Willowood China did not infringe the '138 patent under § 271(g). Because neither the jury nor the district court made any findings concerning Willowood LLC's role, if any, with respect to the azoxystrobin compound made using the process claimed in the '138 patent, we vacate the district court's judgement that Willowood LLC did not infringe the '138 patent under § 271(g) and remand for further proceedings.

IV. Infringement by Willowood China

Syngenta argues that the district court erred as a matter of law by denying its JMOL motion and entering judgment in favor of Willowood China on the issues of infringement of the Compound Patents and

the '761 patent.[7] Syngenta contends that substantial evidence does not support the jury's verdict that Willowood China did not sell or import azoxystrobin within the United States. Syngenta points to evidence it presented that Willowood China "agreed to be 'the exclusive seller'" of Tai He's azoxystrobin within the United States and continued to sell azoxystrobin to Willowood USA after 2013. Appellant's Br. 63. Syngenta argues that the fact that Willowood China's sale of azoxystrobin to Willowood USA was made "f.o.b. China" is not determinative, because "a sale can take place in more than one location." Appellant's Reply Br. 36. Syngenta also contends that Willowood China imported azoxystrobin into the United States, pointing to evidence in the record that Willowood China coordinates the shipping from China to the United States, pays freight charges, and makes delivery arrangements. Appellant's Br. 63; Appellant's Reply Br. 34–35. We are not persuaded by Syngenta's arguments.

The question before us is not whether substantial evidence supports Syngenta's position but whether substantial evidence supports the jury's verdict. *See Regents of Univ. of California v. Broad Inst., Inc.*, 903 F.3d 1286, 1294 (Fed. Cir. 2018) ("We do not reweigh the evidence. It is not our role to ask whether substantial evidence supports fact-findings not made . . . , but instead whether such evidence

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[7] On the issue of Willowood China's alleged infringement of the Compound Patents, Syngenta appeals both the district court's denial of its motion for summary judgment and its post-verdict motion for JMOL. *See* Appellant's Br. 58–68. A district court's denial of summary judgment is not appealable after a trial on the merits. *Ortiz v. Jordan*, 562 U.S. 180, 183–84 (2011); *Function Media, L.L.C. v. Google, Inc.*, 708 F.3d 1310, 1322 (Fed. Cir. 2013). We therefore limit our review to Syngenta's appeal of the district court's denial of JMOL.

supports the findings that were in fact made."). Here, the jury heard evidence that because the shipment of azoxystrobin was marked "f.o.b. China," legal title passed from Willowood China to Willowood USA in Hong Kong. *See* J.A. 6794. The jury also heard evidence that Willowood USA is responsible for clearing the shipments of azoxystrobin through customs in United States and for registering the fungicide with the EPA. J.A. 6795. In addition, Willowood presented testimony that Willowood USA reimburses Willowood China for the freight charges, and the jury saw Willowood's invoices stating that Willowood USA assumes the entire liability for the shipment of azoxystrobin from China to the United States. *See id.*; J.A. 8225–27.[8] We conclude that this is substantial evidence that supports the jury's findings that Willowood China did not infringe the Compound Patents because it sold azoxystrobin in China and did not import azoxystrobin into the United States.

Syngenta also contends that even if Willowood China did not infringe the Compound Patents, the jury found that Willowood China infringed the '761 patent. Syngenta points to the jury's finding that "the Defendants" did not prove that Willowood's azoxystrobin was not manufactured using DABCO within the range claimed by the '761 patent and the jury's award of damages for infringement of the '761 patent by "the Defendants." Appellant's Br. 68 (citing J.A. 267). Syngenta asserts that "the Defendants"

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[8] Willowood's counsel confirmed at Oral Argument that Willowood USA is the importer of record and assumes the risk of shipment. Oral Arg. at 22:29–22:31, http://oralarguments.cafc.uscourts.gov/de-fault.aspx?fl=2018-1614.mp3 ("The importer of record is Willowood USA."); *id.* at 23:16–23:19 ("Willowood USA assumes liability.").

referred to all Willowood entities collectively, including Willowood China, and contends that Willowood waived any argument to the contrary by failing to object to the wording of the jury verdict form. *Id.* at 68, 71–72; *see also* Appellant's Reply Br. 39–42. Syngenta argues that the question on the jury verdict form regarding Willowood China's importation or sale of azoxystrobin applied only to the issue of infringement of the Compound Patents, not the '761 patent, and the district court erred by linking the two issues. Appellant's Br. 69–72; Appellant's Reply Br. 39–42.

We disagree.[9] As we discussed above, substantial evidence supports the jury's finding that Willowood China did not import azoxystrobin into the United States or sell or offer for sale azoxystrobin within the United States. The district court was thus correct to find that Willowood China did not infringe the '761 patent. J.A. 6489. To the extent there was any ambiguity in the jury verdict form, we have held that district courts enjoy "broad discretion to interpret an ambiguous verdict form, because district courts witness and participate directly in the jury trial process." *Telcordia Techs., Inc. v. Cisco Sys., Inc.*, 612 F.3d 1365, 1378 (Fed. Cir. 2010); *see also Prism Techs. LLC v. Sprint Spectrum L.P.*, 849 F.3d 1360, 1377 (Fed. Cir. 2017).

In light of the foregoing, we conclude that the district court did not err by denying Syngenta's JMOL motion with respect to infringement of the Compound

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[9] We reject Syngenta's waiver argument because we "have the discretion to consider issues not raised below 'as justice may require.'" *Ninestar Tech. Co. v. Int'l Trade Comm'n*, 667 F.3d 1373, 1382 (Fed. Cir. 2012) (quoting *Hormel v. Helvering*, 312 U.S. 552, 555–59 (1941)).

Patents and the '761 patent and entering judgment in favor of Willowood China on these issues.

V. Willowood's Cross-Appeal

Willowood conditionally cross-appeals the district court's denial of its motion to exclude the testimony of Syngenta's expert concerning damages for infringement of the Compound Patents. Cross-Appellant's Br. 56–66. Syngenta responds that Willowood's cross-appeal is procedurally improper because it does not seek to expand the scope of the judgment below. Appellant's Resp. Br. 49–51. We need not decide these issues because Willowood's cross-appeal is conditional on our reversal of the judgment concerning the Compound Patents, and we affirm the district court in that respect.

CONCLUSION

We have considered the parties' remaining arguments and find them unpersuasive. We conclude that the district court did not provide an adequate analysis of the potential conflict between FIFRA and the Copyright Act for us to determine whether such a conflict truly exists. We also conclude that the district court erred by imposing a single-entity requirement on the performance of a patented process under § 271(g). We agree with the district court in all other respects. We therefore affirm-in-part, reverse-in-part, vacate-in-part, and remand for further proceedings consistent with this opinion.

AFFIRMED-IN-PART, REVERSED-IN-PART, VACATED-IN-PART, AND REMANDED

COSTS

Each party shall bear its own costs.

[ENTERED: April 10, 2017]

IN THE UNITED STATES DISTRICT COURT FOR THE MIDDLE DISTRICT OF NORTH CAROLINA

SYNGENTA CROP PROTECTION, LLC,	)	
Plaintiff,	)	
v.	)	1:15-CV-00274
WILLOWOOD, LLC, et al.,	)	
Defendant.	)	

ORDER

Syngenta Crop Protection, LLC has sued four affiliated companies, denominated collectively here as Willowood, claiming patent and copyright infringement. Because the Federal Insecticide Fungicide and Rodenticide Act (FIFRA) precludes copyright protection for the required elements of pesticide labels as against the labels of me-too registrants, the Court will grant summary judgment to Willowood on Syngenta's copyright claims. *Cf. SmithKline Beecham Consumer Healthcare, LP. v.Watson Pharm., Inc.,* 211 F.3d 21, 29 (2d Cir. 2000) (holding that the Hatch-Waxman Act precludes copyright protections for prescription drug labels as against generic drug manufacturers).

The Court appreciates the analysis of *FMC Corp. v. Control Solutions, Inc.*, 369 F. Supp. 2d 539, 555-71 (E.D. Pa. 2005), but finds it unconvincing. 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. *See* 17 U.S.C. § 106; *Lyons P'ship, L.P. v. Morris Costumes, Inc.*, 243 F.3d 789, 801 (4th Cir. 2001) (discussing substantially similar standard for copyright infringement). In enacting FIFRA, Congress intended a narrow exception to copyright protection for the required elements of pesticide labels as against me-too registrants.

Syngenta has moved to exclude an expert report from Steven Schatzow and declarations from Gerald Simmons, Lois Rossi, Debra Edwards, and Janelle Kay, all offered by Willowood in its defense of Syngenta's copyright claims. Because the Court is granting the summary judgment motion on legal grounds unrelated to the proffered evidence, the Court has not considered this evidence and concludes that these evidentiary motions are moot.

It is **ORDERED** that the Willowood's motion for summary judgment, Doc. 87, is **GRANTED in part** as to Counts V and VI and Syngenta's copyright claims are dismissed. It is further **ORDERED** that Syngenta's motions to exclude Mr. Schatzow's report, Doc. 90, and certain declarations, Doc. 106, are **DENIED as moot**.

This the 10th day of April, 2017.

/s/
UNITED STATES DISTRICT JUDGE

[ENTERED: March 24, 2017]

IN THE UNITED STATES DISTRICT COURT FOR THE MIDDLE DISTRICT OF NORTH CAROLINA

SYNGENTA CROP PROTECTION, LLC,	)	
Plaintiff,	)	
v.	)	1:15-CV-274
WILLOWOOD, LLC, et al.,	)	
Defendants.	)	

MEMORANDUM OPINION AND ORDER

Catherine C. Eagles, District Judge.

Syngenta Crop Protection, LLC has sued four affiliated companies denominated collectively here as Willowood,[1] alleging patent and copyright infringement. Syngenta contends Willowood has infringed its patents in connection with the manufacture and sale of Willowood's Azoxy 2SC, AzoxyProp Xtra, and Tebustrobin SC products and has infringed its copyrights by verbatim copying of Syngenta product labels. Syngenta seeks partial summary judgment on Counts I through IV, asserting that its 5,602,076 Patent, 5,633,256 Patent, 5,847,138 Patent, and 8,124,761 Patent are valid and that Willowood infringed the patents. Syngenta makes

[1] The defendants are Willowood, LLC; Willowood USA, LLC; Willowood Azoxystrobin, LLC; and Willowood Limited. Where it is necessary to distinguish between the defendants, these companies are referenced individually as W-LLC, W-USA, and W-Ltd.

related evidentiary objections to opinion testimony by the defendant's expert Dr. Mark A. Lipton.[2] Willowood seeks summary judgment on Count IV, asserting that its products do not infringe the '761 Patent as a matter of law, and on Counts V and VI, asserting that Syngenta does not have a valid copyright and that its copying constituted fair use.

The Court will grant in part and deny in part Syngenta's motion for summary judgment and will deny Willowood's motion for summary judgment as to Count IV. The Court retains under advisement Willowood's motion for summary judgment as to Counts V and VI, which will be resolved by separate order.

I. Facts

The following facts are undisputed. Syngenta holds several patents protecting azoxystrobin, a fungicidal compound used to protect various crops, and the process for making it.[3] The '076 and '256 Patents expired on February 11, 2014, and the '138 Patent expired on December 8, 2015. Doc. 96-1 ¶¶ 29, 30. The '761 Patent will expire in April 2029. *Id.* at ¶ 31. Willowood sells generic versions of crop-protection

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[2] Syngenta has objected to other expert testimony and related declarations, which the Court will address in separate orders.

[3] *See* Doc. 12 at ¶¶ 20-21; Doc. 96-1 at ¶¶ 29-31; Doc. 1-8 (the '076 Patent); Doc. 1-9 (the '256 Patent); Doc. 1-10 (the '138 Patent); Doc. 1-11 (the '761 Patent). All citations in this opinion are to the ECF docket and page numbers, or where appropriate internal paragraph designations, except for deposition transcripts, where citations are to the ECF docket number and the deposition page and line numbers provided by the court reporter.

products, including the generic azoxystrobin fungicides Azoxy 2SC and AzoxyProp Xtra. Doc. 12 at ¶¶ 73, 75; Doc 16 at ¶¶ 4, 8. Willowood and Syngenta use azoxystrobin technical, a relatively pure form of the chemical compound azoxystrobin, as the active ingredient in their azoxystrobin fungicides. Doc. 96-1 ¶¶ 34-35; Doc. 12 at ¶ 37 (admitting allegation in Doc, 1 at ¶ 37).

II. Count I (the '076 Patent) and Count II (the '256 Patent)

Syngenta moves for summary judgment on these two counts, contending that the evidence shows that the two patents are valid and that Willowood infringed the patents. The Court views the evidence in the light most favorable to Willowood, the non-moving party, as is appropriate at summary judgment.

a. Validity

Patents are "presumed valid," 35 U.S.C. § 282(a), unless the defendant can show invalidity by clear and convincing evidence. *Microsoft Corp. v. i4i Ltd. P'ship*, 564 U.S. 91, 95 (2011); *Insite Vision Inc. v. Sandoz, Inc.*, 783 F.3d 853, 858 (Fed. Cir. 2015). Willowood presents no evidence of invalidity for either the '076 or '256 Patents. Doc. 137 at 17:13-18:15. The Court will grant summary judgment for Syngenta on this issue.

b. Infringement

i. Relevant Facts

The '076 and '256 Patents claim a group of chemical compounds, which include azoxystrobin. Docs. 1-8, 1-9; Doc. 96-1 at ¶¶ 74, 87. In 2013, W-Ltd

bought five kilograms of azoxystrobin technical from its Chinese supplier, Yangcheng Tai He Chemicals Corp., ("Tai He"), and sold it to W-USA. *See* Doc. 137 at 41:12-:15; Doc. 105 at 6-7 n.3; Doc. 15 at ¶ 6. W-USA imported the five kilograms of azoxystrobin technical into the United States before the expiration of the two patents. Doc. 96-7 at 3; Doc. 96-9 at 5, 6. W-LLC commissioned Adjuvants Unlimited, Inc. to formulate fungicides using azoxystrobin technical and to create product samples. *See* Doc. 137 at 26:3-:7. W-LLC then commissioned Analytical & Regulatory Chemistry, Inc. (ARC) to analyze the product samples for its EPA applications. Doc. 96-7 at 3; Doc. 96-10 at 41:21-42:10. Before performing these studies, and before importing the azoxystrobin technical, Willowood knew of the '076 and '256 Patents and knew that these activities would likely infringe the patents. *See* Doc. 96-7 at 3; Doc. 96-10 at 305:11-:18.

ii. Direct Infringement by W-USA and W-Ltd

Anyone who "makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States any patented invention" without the patent holder's permission has infringed the patent. 35 U.S.C. § 271(a).

Willowood concedes that in 2013. W-USA infringed the '076 and '256 Patents by importing five kilograms of azoxystrobin technical into the United States. Doc. 96-9 at 5, 6. The Court will grant summary judgment against W-USA on these two counts.

Willowood also concedes that W-Ltd sold azoxystrobin technical to W-USA, which is located in Roseburg, Oregon. *See* Doc. 15 at ¶ 6; Doc. 16 at ¶ 3. Willowood asserts that the sale did not infringe because the shipment of azoxystrobin technical "FOB China" by W-Ltd, a Hong Kong company, was not a sale "within the United States" under § 271(a). *See* Doc. 15 at ¶ 3, 6; Doc. 137 at 18:16-:19.

Free on board or "FOB" is a shipping term that indicates when in the delivery process title transfers from the buyer to the seller. *Litecubes*, *LLC v. N. Light Prods.*, *Inc.*, 523 F.3d 1353, 1.358 n. 1 (Fed. Cir. 2008). "FOB China" means that title transferred to the buyer, W-USA, when the seller, W-Ltd, conveyed the goods to the shipper in China. *See id.* at 1358 n.1, 1369.

In analyzing where a sale took place, the Court should not "exalt form over substance. *Id.* at 1370 (quoting *N. Am. Philips Corp. v. Am. Vending Sales*, *Inc.*, 35 F.3d 1576, 1579 (Fed. Cir. 1994)). When other factors indicate an intention to sell infringing products to customers in the United States, shipment FOB a location abroad neither limits the place of sale to the location from which the goods were shipped nor precludes liability under § 271. *SEB S.A. v. Montgomery Ward & Co., Inc.*, 594 F.3d 1360, 1375 (Fed. Cir. 2010), *aff'd sub nom. Glob.-Tech Appliances*, *Inc. v. SEB S.A.*, 563 U.S. 754 (2011); *see also Transocean Offshore Deepwater Drilling*, *Inc.*, *v. Maersk Contractors USA*, *Inc.*, 617 F.3d 1296, 1310-11 (Fed. Cir. 2010). To determine the location of the sale, the fact-finder can consider the location, of the buyer and seller, *N. Am. Philips*, 35 F.3d at 1579, "where the products were shipped from and where the

products were shipped to." *SEB*, 594 F.3d at 1375, "the transfer of tangible property," *Transocean*, 617 F.3d at 1311, and "the agreement by which such a transfer t[ook] place." *Id.*; *see also Litecubes*, 523 F.3d at 1369.

Here, the seller, W-Ltd, was in Hong Kong, Doc. 15 at ¶ 3, while the buyer, W-USA, was in the United States. Doc. 16 at ¶ 3. W-Ltd shipped the azoxystrobin technical FOB China to W-USA, for delivery in the United States. *See id.* at ¶ 8; Doc. 15 at ¶ 6. There is a genuine issue of material fact on whether the sale took place in the United States, *See SEB*, 594 F.3d at 1375 (approving instructions to the jury to consider evidence including FOB terms, invoices with U.S. companies, and delivery to the United States to determine the location of the sale). Summary judgment will be denied as to whether W-Ltd infringed.

iii. Indirect Infringement by W-LLC

"Whoever actively induces infringement of a patent shall be liable as an infringer." 35 U.S.C. § 271(b). Induced infringement requires (1) "active steps taken to encourage direct infringement," *Takeda Pharm. U.S.A., Inc. v. W.-Ward Pharm. Corp.*, 785 F.3d 625, 630 (Fed. Cir. 2015) (quotation omitted), and (2) knowledge or willful blindness that the induced acts constitute patent infringement. *Glob.-Tech Appliances*, 563 U.S. at 766, 768. An active step sufficient for induced infringement includes causing, urging, encouraging, or aiding another to infringe the patent. *Takeda Pharm.*, 785 F.3d at 631

n.3 (citing *Tegal Corp. v. Tokyo Electron Co., Ltd.*, 248 F.3d 1376, 1379 (Fed. Cir. 2001)).

W-LLC commissioned Adjuvants to formulate azoxystrobin fungicides from the imported azoxystrobin technical and commissioned ARC to analyze samples of the resulting end products. Doc. 137 at 20:9-: 19, 26:3-:7; Doc. 96-10 at 41:21-42:10. W-LLC knew that this use of azoxystrobin technical by Adjuvants and ARC would infringe Syngenta's patents. Doc. 96-10 at 305:5-:18. By commissioning Adjuvants and ARC to undertake formulation and analysis that required using azoxystrobin technical, W-LLC actively induced infringement of the '076 and '256 Patents. The Court will grant summary judgment in favor of Syngenta against W-LLC.

III. Count III (the '138 Patent)

a. Validity

Syngenta moves for summary judgment as to the validity of the '138 Patent, which protects a chemical process used to produce azoxystrobin technical. Willowood proffers Dr. Lipton's expert opinion as evidence that the '138 Patent is invalid due to obviousness, *see* 35 U.S.C. § 103, and asserts that summary judgment should be denied, Syngenta contends that Willowood's evidence of obviousness is insufficient to raise a disputed question of material fact and moves to exclude Dr. Lipton's analysis. As noted *supra*, the burden to show invalidity is on the challenger, and therefore Willowood must show by clear and convincing evidence that at the time of the invention, the patent's claimed subject matter was obvious to a person of ordinary skill in the art.

Plantronics, *Inc. v. Aliph*, *Inc.*, 724 F.3d 1343, 1353 (Fed. Cir. 2013). To prove obviousness, the defendant must explicitly provide "[a] reason for combining disparate prior art references." *InTouch Techs.*, *Inc. v. VGO Commc'ns*, *Inc.*, 751 F.3d 1327, 1351 (Fed. Cir. 2014); *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 418 (2007) (requiring that arguments explicitly provide an "articulated reasoning with some rational underpinning" to make the asserted combinations (quoting *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006))).

In evaluating obviousness, an expert should take steps "to guard against slipping into use of hindsight and to resist the temptation to read into the prior art the teachings of the invention in issue." *Graham v. John Deere Co. of Kan. City*, 383 U.S. 1, 36 (1966) (quotation omitted); *see KSR Int'l*, 550 U.S. at 421 (noting a factfinder "must be cautious of arguments reliant upon *ex post* reasoning"); *Insite Vision*, 783 F.3d at 859. In this case, Dr. Lipton stated several times that "the substance of claim 6" was the "starting point" of his obviousness analysis. Doc. 96-15 at 142:8-:21, 144:5-:6. He explicitly admitted that he started with Claim Six and worked backwards. Doc. 96-15 at 140:7-:19.

Relying on *Interactive Gift Express*, *Inc. v. CompuServe Inc.*, 256 F.3d 1323, 1331 (Fed. Cir. 2001), Willowood contends that "an analysis of claim validity must start with the claim itself." Doc. 102 at 13. However, *Interactive* involved claim construction, not validity, and it does not justify a hindsight analysis. *See* 256 F.3d at 1331. Willowood also asserts that Dr. Lipton only started with Claim Six to identify

prior art and to understand the invention. *See* MPEP § 2145(X)(A) (9th ed. Nov. 2015). However, his deposition belies this assertion:

> Q: So as part of your invalidity analysis you assume that someone of ordinary skill would be interested, in the first instance, in making compound (XV) from compound (X), correct?
>
> A: Since that is the substance of claim 6, that's my starting point.

Doc. 96-15 at 142:16-:21. Willowood points to no explanation from Dr. Lipton indicating that he had a reason beyond the '138 Patent to assume that a person of ordinary skill would be motivated to attempt the intermediate combinations of prior art necessary to achieve the '138 Patent's process. Dr. Lipton analyzed obviousness using the "patent itself as [a] roadmap" and "did not articulate reasons why a person of ordinary skill in the art at the time of the invention would combine" particular prior art references. *InTouch Techs.*, 751 F.3d at 1351; *see* Doc. 96-15 at 146:11-:20.

Because of the hindsight embedded in his analysis and the lack of reasons for combining the relevant prior art, Dr. Lipton's expert opinion is not the product of a reliable method and will not help the jury determine obviousness. *See* Fed. R. Evid. 702; *InTouch Techs.*, 751 F.3d at 1351-52. The Court will grant Syngenta's motion to exclude this evidence. Without any additional evidence on the validity of the '138 Patent, Willowood cannot meet, its burden to

demonstrate obviousness.[4] The Court will grant summary judgment for Syngenta on the issue of the validity of the '138 Patent.

b. Infringement

The '138 Patent claims a process for preparing a group of compounds, including azoxystrobin, by performing an etherification step followed by a condensation step. *See* Doc. 96-1 at ¶¶ 94-99, 111-13; Doc. 1-10 at 16-17. It is undisputed that W-Ltd buys azoxystrobin technical from Tai He and sells it to W-USA, and that W-USA imports the azoxystrobin technical into the U.S. and uses it to formulate its end products, which W-LLC sells to the public. Doc. 96-10 at 64:4-:15, 278:4-:14; Doc. 96-8 at 3. It further is undisputed that the azoxystrobin technical that W-Ltd buys from Tai He is made overseas by a process that contains the etherification and condensation

[4] Willowood suggested at oral argument that even without Dr. Lipton's testimony, it can prove invalidity through the prosecution history. Doc. 137 at 60:10-:16 (suggesting that the prosecution history alone could convince the jury of obviousness). *But see* Doc. 137 at 50:10-:15 (conceding that Dr. Lipton's testimony is the only evidence of obviousness). Willowood has since filed the prosecution history. Doc. 133-1. Willowood has not identified the relevant portions of the history in its briefing or explained how it supports obviousness. The Court will not scour the record to locate evidentiary support. *Hughes v. B/E Aerospace, Inc.*, No. 1:12CV717, 2014 WL 906220, at *1 n.1 (M.D.N.C. Mar. 7, 2014) ("A party should not expect a court to do the work that it elected not to do."); *see also Ritchie v. Glidden Co.*, 242 F.3d 713, 723 (7th Cir. 2001) ("[A] court is not required to scour the record in search of evidence to defeat a motion for summary judgment" (quotation omitted)). Since it was not raised in the briefing, Syngenta has not had an opportunity to address Willowood's argument. Consequently the Court has not considered the prosecution history.

steps set forth in the '138 patent. *See* Doc. 99-9 at 23, 28;[5] Doc. 99-8 at 4-5, 7; Doc. 137 at 40:9-41:10.

It is an act of infringement to "import[ ] into the United States or offer[ ] to sell, sell[ ], or use[ ] within the United States a product which is made by a process patented in the United States." 35 U.S.C. § 271(g). Syngenta contends that it is entitled to summary judgment on infringement because the Willowood entities infringed the "138 Patent, under § 271(g) by importing into the United States azoxystrobin technical made by the claimed process, using it to formulate end products, and selling the azoxystrobin technical and resulting end products in the United States. Willowood asserts that § 271(g) requires that a single entity perform the patented process and that the evidence here shows that no single entity performed all the steps claimed in the '138 Patent.

The Federal Circuit has not decided whether the single entity requirement applies to claims of infringement under § 271(g), and there do not appear to be district court decisions on this question. While there are arguments both ways, the Court concludes that the single-entity rule in § 271(a) should also apply in § 271(g) infringement actions.

The single-entity rule requires that "all steps of a claimed method are performed by or attributable to a single entity." *See Akamai Techs., Inc., v. Limelight Networks, Inc.*, 797 F.3d 1020, 1022 (Fed. Cir. 2015) (en banc) (per curiam). If more than one actor is involved in practicing the steps, "the acts of one are

[5] The parties have submitted much of the evidence in this case under seal, subject to motions to seal. The Court will resolve those motions to seal by separate order.

attributable to the other such that a single entity is responsible for the infringement .... in two sets of circumstances; (1) where that entity directs or controls others' performance, and (2) where the actors form a joint enterprise." *Id*.

Here, there is a factual dispute as to whether all steps of the process claimed by the '138 Patent are performed by or attributable to a single entity. Syngenta has evidence that Tai He either performed all of the claimed steps of the '138 Patent, *e.g.*, Doc. 99-9 at 23, 28 (stating that the etherification and condensation steps are "carried out at" Tai He), or alternatively that Willowood arranged for Tai He and other entities to manufacture azoxystrobin according to the patented process. Doc. 99-8 at 4-5; Doc. 96-10 at 229:2-:8, 252:12-253:8. Willowood points to conflicting evidence indicating that Tai He controls its own process, acts independently from Willowood, and contracts at arms-length with other companies, who perform portions of the manufacturing process. Doc, 105-4 at 20:5-21:18.

Finding a disputed question of material fact, the Court will deny Syngenta's motion for summary judgment as to the infringement of the '138 Patent.

IV. Count IV (the '761 Patent)

The '761 Patent claims a process for making azoxystrobin technical that uses DABCO,[6] a catalyst, at concentrations between 0.1 and 2 mol % for the condensation step. Doc. 1-11 at 2; Doc. 96-1 at ¶ 31. Syngenta moves for summary judgment on the issue of validity. Syngenta and Willowood both move for

[6] DABCO stands for 1, 4-diazabicyclo[2.2.2]octane. Doc. 1-11 at 3.

summary judgment as to the infringement of the '761 Patent,

a. Validity

To meet its burden to show invalidity, Willowood offers Dr. Lipton's expert testimony to show that the '761 Patent was obvious in light of Weintritt, an earlier patent application. In turn, Syngenta moves to exclude this testimony, contending that hindsight bias infected Dr. Lipton's analysis and that he parrots Willowood's counsel, rather than presenting his own opinion and analysis. Syngenta further contends that Dr. Lipton's opinions are insufficient to establish invalidity based on obviousness.

i. Admissibility of Dr. Lipton's Opinion.

In contrast with Dr. Lipton's invalidity analysis for the '138 Patent, where he started with the patent's claim and worked backwards. Dr. Lipton's obviousness analysis for the '761 patent starts with the prior art reference. His report describes why a person of ordinary skill in the art would want to minimize the amount of catalyst from that claimed in the Weintritt reference. *See* Doc. 96-3 at ¶¶ 36, 39 (noting researchers are motivated to decrease the amount of catalyst used to lower costs and health hazards).[7]

Dr. Lipton attests that he performed his own analysis. Doc. 96-15 at 38:18-:20 ("I arrived at a decision about invalidity based on discussions with counsel and my own reading of the patents."); *see also* Doc. 96-15 at 35:12-:15. In his deposition, he was

[7] In his report, Dr. Lipton refers to Weintritt as the '723 Patent. Doc. 96-3 at ¶ 18.

responsive to counsel's questions and demonstrated a firm understanding of his report. *See* Doc. 96-15. His report explains the patent's chemistry, the role of a catalyst in a chemical reaction, and how manipulation of the catalyst affects the reaction. Doc. 96-3 at ¶¶ 33-40. Every indication is that the opinions expressed in his report are his own, and those opinions will not be excluded. *Cf Numatics*, *Inc. v. Balluff. Inc.*, 66 F. Supp. 3d 934, 941-43, 945 (E.D. Mich. 2014) (excluding opinion after the expert admitted that he signed a report written by the lawyer and showed a lack of understanding both of the facts and relevant legal standards).

Syngenta has not identified any evidence of hindsight bias in Dr. Lipton's analysis. Rather. Syngenta disputes his understanding of the teachings of the Weintritt reference. *See* Doc. 96-2 at ¶ 53 (Dr. Joseph Fortunak's testimony that "Weintritt would have discouraged ... using DABCO at even lower amounts"). This is a question of fact underlying the obviousness analysis. *Apple Inc. v. Samsung Elecs. Co.*, *Ltd.*, 839 F.3d 1034, 1051 (Fed. Cir. 2016) (en banc), *pet. for cert. filed*, No. 16-1102 (U.S. Mar. 10, 2017).

Dr. Lipton's report also includes verbatim an invalidity claims chart provided to him by counsel. Doc. 96-15 at 37:2-39:5; *see* Doc. 96-3 at pp. 21-26. The Court does not decide here whether this chart will be admissible at trial.

ii. Obviousness

Obviousness "is a question of law based on underlying questions of fact." *Plantronics*, 724 F.3d at 1353 (quotation omitted); *Apple Inc.*, 839 F.3d at 1051 ("What a prior art reference teaches and whether a

skilled artisan would have been motivated to combine references are questions of fact."). As noted *supra*, Willowood must show obviousness by clear and convincing evidence.

As evidence of obviousness, Willowood offers Dr. Tipton's testimony that, based on Weintritt, a person of ordinary skill in the art would have been motivated to test smaller amounts of DABCO in the reaction, *see* Doc. 105-6 at ¶¶ 36-40, and the proximity of the '761 Patent's claimed range to the range described by Weintritt. *Compare* Doc. 96-34 at 8 (claiming use of DABCO from 2 to 40 mol %) *with* Doc. 1-11 at 2 (claiming use of DABCO between .1 and 2 mol %). This evidence conflicts with Syngenta's evidence, including Dr. Fortunak's testimony on what Weintritt teaches. *See* Doc. 96-2 at ¶ 53.

There is a disputed question of material fact underlying obviousness. The Court will deny Syngenta's motion for summary judgment as to validity of the '761 patent.

b. Infringement of the '761 Patent

Syngenta and Willowood both move for summary judgment on the issue of infringement of the '761 Patent. They agree that if the azoxystrobin technical used by Willowood was made with DABCO within the claimed range, then Willowood infringes the '761 Patent by importing it, using it to make its end products, and selling those end products. Conversely, they agree that if DABCO is not used or is used outside the claimed range, then the products do not infringe. Doc. 137 at 67:10-:22. In its motion for summary judgment, Syngenta contends that Willowood should bear the burden to prove non-

infringement under § 295. Syngenta also moves to exclude certain laboratory tests offered by Willowood as inadmissible. Willowood opposes these motions. Each party contends that either way, the Court should grant summary judgment in its favor.

i. Evidence of Infringement and Non-Infringement

Willowood provides testimony from Tai He's president, Wu Xiaolong, stating that neither Tai He nor its intermediaries use DABCO to manufacture azoxystrobin technical. Doc. 88-5. Willowood also provides analyses from JDM Research and Product Safety Laboratories (PSL), which show that their azoxystrobin technical contains no DABCO.[8] Doc. 99-10 at 2 (JDM); Doc. 88-4 at 10 (PSL). This evidence, if believed, is sufficient to prove non-infringement.

In turn, Syngenta presents tests from two laboratories, CAC Shanghai and JDM Research,[9] which detected DABCO in Willowood's azoxystrobin technical. Doc. 99-1 at ¶¶ 129-133; Doc. 99-4 at 270:2-271:20, 273:19-275:11, and its own analysis that Willowood's Azoxy 2SC contains DABCO. Doc. 96-1 at ¶ 128. This is well sufficient to prove that DABCO was used.

Whether Syngenta has sufficient evidence showing that DABCO is used within the infringing

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[8] As discussed *infra*, Willowood also offers inadmissible evidence from EAG, which shows that a form of azoxystrobin tested before the condensation step contained no DABCO.

[9] There appears to be some confusion about what the JDM results show and both sides offer the JDM tests to support their position. *See* Doc. 96-1 at ¶ 52 & n.31 (Dr. Fortunak relying on Mr. Heinze's testimony that JDM detected DABCO); Doc. 99-2 at ¶¶ 21-23 (Dr. Lipton explaining Mr. Heinze's confusion and that JDM did not detect DABCO).

amount is a closer question. Syngenta relies on Dr. Fortunak's analysis that it would not be commercially reasonable for Tai He to manufacture azoxystrobin technical using DABCO outside the range claimed by the "761 Patent. Doc. 96-1 at ¶ 138; Doc. 88-2 at 100:13-101:15. Dr. Fortunak is a Professor of Chemistry and Pharmaceutical Sciences at Howard University. Doc. 96-1 at ¶ 6. He has extensive experience in relevant product development, including transferring process technology to commercial scale production. *See id.* at ¶¶ 5-20. He appears qualified to offer such an opinion. While on the edge, the Court concludes that this creates a disputed question of material fact as to whether DABCO was used in an infringing amount.[10]

There is a genuine dispute of material fact as to whether DABCO is used in the manufacture of Willowood's azoxystrobin technical and if so, in what amount. Thus, the Court will deny both motions for summary judgment.

ii. Barden-Shifting under § 295

Syngenta and Willowood disagree on which party should bear the burden of proof on the claim of infringement of the '761 Patent. Ordinarily, the plaintiff bears the burden to show infringement, but when "the accused infringer is in a far better position to determine the actual manufacturing process than the patentee," the patent statute authorizes shifting the burden to the accused infringer to show non-infringement. *Creative Compounds, LLC v. Starmark*

[10] If the Court is mistaken in this conclusion, it provides a further reason to shift the burden of proof. *See* discussion *infra* at pp. 16-24.

Labs., 651 F.3d 1303, 1314-15 (Fed. Cir. 2011) (citation omitted). Section 295 provides:

> [I]f the court finds—
>
> > (1) that a substantial likelihood exists that the product was made by the patented process, and
> >
> > (2) that the plaintiff has made a reasonable effort to determine the process actually used in the production of the product and was unable to so determine,
>
> the product shall be presumed to have been so made, and the burden of establishing that the product was not made by the process shall be on the party asserting that it was not so made.

35 U.S.C. § 295.

Syngenta asserts that it has satisfied both prongs of the § 295 test, showing a substantial likelihood that Willowood's azoxystrobin technical was made with an infringing amount of DABCO and that it has made reasonable efforts to determine the actual process, without success. Willowood disagrees, emphasizing that Syngenta's evidence is insufficient and that Willowood disclosed the non-infringing manufacturing process for their azoxystrobin technical. The Court finds that Syngenta has shown both a substantial likelihood and reasonable efforts, and the Court will shift the burden to Willowood to show non-infringement at trial.

The Court has discretion to determine when § 295 "will be brought into play." *Nutrinova Nutrition Specialties & Food Ingredients GmbH v. Int'l Trade Comm'n.* 224 F.3d 1356, 1360 (Fed. Cir. 2000); *West v. Jewelry Innovations*, *Inc.*, No. C 07-1812 JF (HRL), 2009 WL 1010848, at *7 (N.D. Cal. Apr. 14, 2009) ("A district court may rule on a § 295 motion at any stage of the proceedings."). It is appropriate to consider this burden-shifting provision now: discovery has closed; the Court has the benefit of summary judgment briefing; and resolution of the issue now will allow for better trial preparation by the parties.

1. Substantial Likelihood

As the patent holder, Syngenta must show a substantial likelihood that the azoxystrobin technical imported and sold by Willowood was made by the patented process before burden-shifting is appropriate. 35 U.S.C. § 295(1). The patent holder must "present evidence that would support a reasonable conclusion that the imported product was made by the patented process;" but need not show that the patented method is the "only commercially practical method of manufacture." *West*, 2009 WL 1010848, at *8. This requires something less than proving the issue at trial by a preponderance of the evidence, but more than a slight possibility. *Id.* (citation omitted); *LG Display Co., Ltd. v. AU Optronics Corp.*, 709 F. Supp. 2d 311, 335 (D. Del. 2010); *see also Aventis Pharm.*, *Inc. v. Barr Labs.*, *Inc.*, 411 F. Supp. 2d 490, 510 (D.N.J.), aff'd, 208 Fed.Appx. 842 (Fed. Cir.) (per curiam), *and aff'd*, 208 Fed.Appx. 843 (Fed. Cir. 2006) (examining evidence for a "persuasive showing of substantial likelihood").

As discussed *supra*, Syngenta presents persuasive evidence that the azoxystrobin technical imported by Willowood was manufactured using DABCO during the condensation phase, including internal and external testing by several laboratories and admissions by Willowood. Its evidence that DABCO was used in an infringing amount—Dr. Fortunak's opinion about commercial reasonableness—is less strong. Nonetheless, given Dr. Fortunak's experience and qualifications, his opinion is adequate to make a "persuasive showing of substantial likelihood" *Aventis*, 411 F. Supp. 2d at 510. This is especially so in light of Willowood's failure to rebut Dr. Fortunak's opinion[11] and the absence of evidence that anyone actually manufactures azoxystrobin using DABCO by a method different than that claimed by the '761 Patent. Doc. 137 at 85:16-86:5.

While Willowood offers testimony from Tai He's president, Mr. Wu, that neither Tai He nor any of its intermediaries use DABCO to make azoxystrobin technical, Doc. 88-5, his testimony has credibility issues.[12] Moreover, Mr. Wu did not provide any manufacturing or batch records to confirm his

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[11] Willowood's expert, Dr. Lipton, has not offered any opinion on the commercial benefits and burdens of producing azoxystrobin according to particular methods. *See* Doc. 96-15 at 66:14-70:16, 121:20-122:2; Doc. 110-5 at 17:11-18:2, 19:1-:11.

[12] For example, Mr. Wu's testimony on other production matters contradicts manufacturing documents from Tai He. *Compare* Doc. 99-6 at 20:9-:12 (stating Guoshang creates intermediate from etherification step) *and* at 93:24-94:2 (stating condensation step is not performed at Tai He) *with* Doc. 99-9 at 23, 28 (noting the etherification and condensation steps are "carried out at" Tai He) *and* Doc. 96-10 at 246:10-247:8 (discussing email stating Tai He performs the etherification and condensation steps).

testimony, even though he was asked for them and admitted they existed. *See* Doc. 96-13 at 87:6-88:4; Doc. 88-7. Nor has Willowood provided a non-infringing explanation for how DABCO and its by-products could be detected in its end products or the samples of azoxystrobin technical.

Because Syngenta offers significant persuasive evidence of the presence of DABCO, consistent with the use of the patented process, and expert testimony opining that the patented process is used, the Court finds Syngenta has shown a substantial likelihood that Willowood's azoxystrobin technical is made with the process claimed by the '761 Patent.

2. Reasonable Efforts

Syngenta contends that it made reasonable efforts to discover Tai He's process for producing azoxystrobin technical, but that it has been thwarted by Willowood's lack of full cooperation and its inability to get information from Tai He, a Chinese company. To show "reasonable efforts," the patentee must follow "all of the avenues of discovery likely to uncover the defendant's [or manufacturer's] process, including written discovery requests, facility inspections, first-hand observation of the process, independent testing of process samples, the use of experts, and depositions of the defendant's [or manufacturer's] officials." *LG Display Co.*, 709 F. Supp. 2d at 335 (quotation omitted).

Syngenta tested Willowood's azoxystrobin technical and the Azoxy 2SC end product, employed experts, and deposed representatives from Willowood. *See*, *e.g.*, Doc. 99-1 at ¶¶ 128-31; Doc. 96-10. Syngenta also attempted to obtain production documents and

information from Willowood and Tai He. *See*, *e.g.*, Docs. 88-5, 88-6.

On December 17, 2015, Syngenta submitted several interrogatories and requests for production to Willowood, seeking information on the manufacture of Willowood's azoxystrobin technical. Doc. 96-5 at 12-13, 16; Doc. 96-6 at 11, 14. Willowood provided two documents describing Tai He's process, one that had been submitted to the EPA and one from its manufacturer Tai He. Docs. 99-9, 99-8. Syngenta followed up on March 1, 2016, asking Willowood to clarify what catalyst was used in the process or to state whether no catalyst was used. Doc. 96-28 at 2-3. Willowood responded that, to the best of its knowledge, DABCO was not used, but that it bought the azoxystrobin technical from Tai He. Doc. 96-29 at 2-3. On June 15, 2016, Syngenta requested that Willowood provide all communications between Willowood and Tai He and any agreements between the two companies not yet provided. Doc. 110-14 at 2-4. Willowood asserted that it had no written communications with Tai He, because they corresponded only in person, via telephone, or via a chat program that did not save correspondence. Doc. 110-15 at 2.

Finally, on July 26, 2016, following Willowood's decision to depose Mr. Wu at the end of the discovery period, Syngenta told Willowood it would need several categories of documents, including on the manufacturing process, from Tai He before the deposition so that the deposition would not be "significantly one-sided." Doc. 88-6 at 2. Willowood forwarded the request for documents to Tai He on July 28, 2016. Doc, 88-7 at 2-3. Shortly before the

deposition on August 31, 2016, Doc. 99-6 at 3, and after the date originally established for the close of fact discovery on July 29, 2016, Doc. 48 at 2, Willowood provided another Tai He document describing the manufacturing process. *See* Doc. 99-17.

At his deposition, Mr. Wu testified that Tai He and its intermediaries make azoxystrobin technical without the use of DABCO. Doc. 88-5. He also affirmed that Tai He has production records with the ratios and quantities of materials used in the manufacturing process, *see* Doc. 96-13 at 87:6-88:4, but that no one associated with Willowood informed him that Syngenta was asking for those documents, apart from sharing the July 28 letter about a month before his deposition. *Id*. at 55:9-56:4. He did not produce any of these documents at his deposition, despite being aware that Syngenta had asked for them.

The Court finds that these efforts by Syngenta to discover how Willowood's azoxystrobin technical is made were reasonable. While Syngenta did not seek discovery directly from Tai He. Willowood itself admitted that it "is extremely difficult, if not impossible...to compel the Manufacturer [in China] to produce any documents," Doc. 75 at ¶ 11, and Mr. Wu appeared for his deposition voluntarily at the request of Willowood, not under compulsion by law. Willowood had to obtain an extension of the discovery schedule in order to take Mr. Wu's deposition, which the Court allowed over Syngenta's objection, *see* Docs. 75, 78; Text Order 08/22/2016, and which prevented any follow-up discovery directly from Tai He. Moreover, given Tai He's location in China, requesting voluntary facility inspections or observing

the process firsthand are unlikely possibilities for discovering information.

"Reasonable efforts" under § 295 do not require fruitless discovery attempts overseas or motions to compel against a party, like Willowood, who says it does not have the documents. *See Kemin Foods v. Pigmentos Vegetales Del Centro S.A. de C. V.*, No. 4:02-cv-40327, 2004 U.S. Dist. Lexis 17206, at *34-35, 45-47 (S.D. Iowa Aug. 27, 2004) (finding reasonable efforts and shifting the burden despite some cooperation by the defendant and no motions to compel). Moreover, Syngenta did not know that Tai He had additional production records not shared with Willowood until Mr. Wu's late deposition, a month after the close of fact discovery. *See id.* at *34-35 (applying § 295, noting *inter alia* that the defendant's failure to produce production documents creates problems for patent holder in proving infringement). Here, Syngenta repeatedly requested that Willowood provide the information, it conducted its own tests, employed experts, and it asked Tai He for the production records; this establishes that Syngenta has made reasonable efforts to obtain the information.

The Court further finds that despite these reasonable efforts, Syngenta has not been able to determine the process actually used in the production of the product, particularly as to the amount of DABCO used. As discussed above, Willowood provided some information about the manufacturing process for its azoxystrobin technical. Docs. 99-8, 99-9, 99-17. However, this information has been inconsistent. *Compare* Doc. 99-9 at 14, 28 (noting the condensation step is "carried out at" Tai He) *with* Doc.

99-6 at 93:8-94:2 (stating Tai He oversees the condensation step, performed by Guangda). It does not explain the presence of DABCO in Willowood's end products or samples of azoxystrobin technical, and it is incomplete given the relevant production records held but not provided by Tai He. *See* Doc. 96-13 at 87:20-88:4; *see also Kemin Foods*, 2004 U.S. Dist. LEXIS 17206, at *43 (applying § 295 when patent holder "was left with a host of inconsistent observations, unexplained solvents, and constantly changing representations").

Willowood contends that it cooperated with discovery and provided Syngenta with relevant information about the process. Yet, Mr. Wu testified that no one associated with Willowood told him Syngenta was requesting documents from Tai He until a short time before the close of the planned discovery period. Doc, 96-13 at 54:5-:20. This does not indicate full cooperation and, regardless, Willowood was in a better position than Syngenta to obtain the relevant production records. *See Creative Compounds*, 651 F.3d at 1314-15. In any event, the plain language of § 295 indicates that Syngenta's, and not Willowood's, actions are determinative to the "reasonable efforts" question.

Willowood also contends that it has given Syngenta information about the manufacturing process showing that DABCO is not used, and that the burden should not be shifted merely because Syngenta does not like Willowood's evidence. Certainly Willowood is correct that the burden should not be shifted where discovery indicates a non-infringing process. *See Nutrinova*, 224 F.3d at 1360. Here, however, Syngenta has produced significant

evidence that DABCO is used, and Willowood has not suggested a non-infringing reason for the appearance of DABCO in Syngenta's tests. Nor has it made Tai He's production records available to Syngenta.

Because Syngenta has shown a substantial likelihood of infringement and made reasonable but unsuccessful discovery efforts to obtain Tai He's production records, the Court will shift the burden under § 295 to Willowood to show non-infringement of the '761 Patent.

iii. Syngenta's Motion to Exclude Lab Analyses and Expert Testimony

The '761 Patent claims a process to make azoxystrobin technical using DABCO as a catalyst. As previously discussed, Willowood contends that Tai He uses a different process, without DABCO, to make its azoxystrobin technical and that its importation of Tai He's azoxystrobin technical did not infringe the '761 Patent. To support this contention, it offers test reports from Product Safety Laboratories (PSL) and EAG Laboratories (EAG) on the absence of DABCO in azoxystrobin technical and testimony from Dr. Lipton explaining the test reports. *See* Doc. 99-2 at ¶¶ 24-26, pp. 24-110. Syngenta asserts that the Court should exclude test reports from PSL and EAG and Dr. Lipton's interpretation of those reports under *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), because the testing was fundamentally flawed and will not assist the trier of fact.

1. The EAG Test and Dr. Lipton's Related Testimony

Willowood admits that EAG did not test azoxystrobin technical, but rather a form of azoxystrobin from a stage of manufacturing before the condensation reaction, when DABCO is added under the '761 Patent's claimed process. Doc. 102 at 17; *see* Doc. 96-4 at ¶ 26. In other words, EAG tested for DABCO at a point during the process when DABCO would not have yet been added. The absence of DABCO is hardly surprising under those circumstances. To the extent Willowood offers the EAG test to show that the absence of DABCO before the condensation step tends to prove that Willowood did not infringe the '761 Patent's claimed process, the Court will exclude the test and Dr. Lipton's related testimony.

Willowood suggests that the EAG test shows that DABCO was not present before the condensation step, and that this may be otherwise relevant. Doc. 137 at 125:11-126:2. Syngenta contends that even if this is so, it would tend to confuse the jury and be unfairly prejudicial. *See* Fed. R. Evid. 403. If and when Willowood decides to offer the EAG test into evidence at trial, it shall advise the Court outside the presence of the jury.

2. The PSL Test

PSL analyzed azoxystrobin technical from Tai He's completed process. Its finding that the sample did not contain DABCO is relevant to the issue of whether Tai He's manufacturing process infringes the '761 Patent. Based on its own testing, Syngenta contends that PSL's test lacked sufficient sensitivity to detect DABCO. However, Dr. Lipton critiques the reliability

and methodology of Syngenta's tests and testifies that PSL performed its analysis "to a very high level of confidence." *See* Doc. 99-2 at ¶¶ 13-20, 24. Syngenta has not challenged his qualifications to offer this opinion.

The jury should determine the appropriate weight to be given to PSL's test and Dr. Lipton's testimony explaining the PSL test. *See i4i Ltd. P'ship v. Microsoft Corp.*, 598 F.3d 831, 852 (Fed. Cir. 2010), *aff'd*, 564 U.S. 91 (2011). The Court will deny the motion to exclude as to the PSL test and Dr. Lipton's corresponding opinion because they are relevant to whether the process for making Willowood's azoxystrobin technical infringes on the '761 Patent and they are based on sufficient data and reliable methods to reach the jury. *See* Fed. R. Evid. 702.

V. Counts V and VI: Copyright Claims

Willowood moves for summary judgment on Syngenta's claims for copyright violation. The Court will rule by separate order on this aspect of Willowood's motion, along with Syngenta's motion to exclude certain evidence offered by Willowood in support of summary judgment on these claims.

VI. Conclusion

For the reasons stated, the Court will grant summary judgment in favor of Syngenta as to validity of the '076, '256, and '138 Patents; will grant Syngenta's motion as to infringement of the '076 and '256 Patents by Willowood USA and Willowood, LLC and deny it as to Willowood Limited; will deny Syngenta's motion as to infringement of the '138 patent and as to validity and infringement of the '761 patent; and will deny Willowood's motion as to the infringement of the '761 patent. The Court will also

grant in part, deny in part, and otherwise defer Syngenta's motion to exclude as to Dr. Lipton's testimony, as stated herein.

Willowood's motion on Syngenta's copyright claims will be resolved by separate order. The Court will also resolve by separate order Syngenta's remaining motions to exclude certain evidence proffered by Willowood related to the copyright claim, *see* Docs. 90, 106, and damages. *See* Doc. 90.

It is **ORDERED** that the plaintiff's motion for summary judgment, Doc. 93, is **GRANTED in part and DENIED in part** and the defendants' motion for summary judgment, Doc. 87, is **DENIED in part and is otherwise retained under advisement**, as follows:

1. Counts I and II: The Court grants summary judgment in favor of Syngenta as to validity for the '076 and '256 Patents and in favor of Syngenta as to infringement of the '076 and '256 Patents by Willowood, LLC and Willowood USA, LLC. The Court denies summary judgement as to infringement by Willowood Limited. The issues remaining for trial are infringement by Willowood Limited, willfulness, and damages.

2. Count III: The Court grants summary judgment to Syngenta as to validity of the '138 Patent and denies summary judgment as to infringement. The issues of infringement, willfulness, and damages remain for trial.

3. Count IV: The Court denies Syngenta's motion for summary judgment on validity and infringement of the '761 Patent and

denies Willowood's motion for summary judgment on infringement. The Court grants Syngenta's request to shift the burden to prove non-infringement to Willowood under § 295. All issues related to Count IV remain for trial.

4. Counts V and VI: The Court retains under advisement the part of Willowood's motion for summary judgment directed towards Syngenta's copyright claims and will rule on this aspect of the motion by separate order.

It is further **ORDERED** that the plaintiff's motion to exclude certain expert opinions. Doc. 90, is **GRANTED in part, DENIED in part, and DEFERRED in part** and is **otherwise retained under advisement** as follows:

1. The Court grants the motion to exclude Dr. Lipton's testimony about the validity of the '138 Patent. Subject to developments at trial, the Court also grants the motion to exclude the EAG test and Dr. Lipton's related testimony. The Court defers until trial the question of admissibility of the claims chart for the '761 Patent in Dr. Lipton's report. Otherwise, the Court denies the motion directed towards Dr. Lipton's testimony.

2. The Court retains under advisement the remaining issues raised by the motion, relating to testimony of Mr. Steven Schatzow and. Mr. John C. Jarosz.

This the 24th day of March, 2017.

/s/
UNITED STATES DISTRICT JUDGE

7 U.S.C.A. § 136

§ 136. Definitions

Effective: August 3, 1996

For purposes of this subchapter--

(a) Active ingredient

The term "active ingredient" means--

(1) in the case of a pesticide other than a plant regulator, defoliant, desiccant, or nitrogen stabilizer, an ingredient which will prevent, destroy, repel, or mitigate any pest;

(2) in the case of a plant regulator, an ingredient which, through physiological action, will accelerate or retard the rate of growth or rate of maturation or otherwise alter the behavior of ornamental or crop plants or the product thereof;

(3) in the case of a defoliant, an ingredient which will cause the leaves or foliage to drop from a plant;

(4) in the case of a desiccant, an ingredient which will artificially accelerate the drying of plant tissue; and

(5) in the case of a nitrogen stabilizer, an ingredient which will prevent or hinder the process of nitrification, denitrification, ammonia volatilization, or urease production through action affecting soil bacteria.

(b) Administrator

The term "Administrator" means the Administrator of the Environmental Protection Agency.

(c) Adulterated

The term "adulterated" applies to any pesticide if--

(1) its strength or purity falls below the professed standard of quality as expressed on its labeling under which it is sold;

(2) any substance has been substituted wholly or in part for the pesticide; or

(3) any valuable constituent of the pesticide has been wholly or in part abstracted.

(d) Animal

The term "animal" means all vertebrate and invertebrate species, including but not limited to man and other mammals, birds, fish, and shellfish.

(e) Certified applicator, etc.

(1) Certified applicator

The term "certified applicator" means any individual who is certified under section 136i of this title as authorized to use or supervise the use of any pesticide which is classified for restricted use. Any applicator who holds or applies registered pesticides, or uses dilutions of registered pesticides consistent with subsection (ee), only to provide a service of controlling pests without delivering any unapplied pesticide to any person so served is not deemed to be a seller or distributor of pesticides under this subchapter.

(2) Private applicator

The term "private applicator" means a certified applicator who uses or supervises the use of any pesticide which is classified for restricted use for

purposes of producing any agricultural commodity on property owned or rented by the applicator or the applicator's employer or (if applied without compensation other than trading of personal services between producers of agricultural commodities) on the property of another person.

(3) Commercial applicator

The term "commercial applicator" means an applicator (whether or not the applicator is a private applicator with respect to some uses) who uses or supervises the use of any pesticide which is classified for restricted use for any purpose or on any property other than as provided by paragraph (2).

(4) Under the direct supervision of a certified applicator

Unless otherwise prescribed by its labeling, a pesticide shall be considered to be applied under the direct supervision of a certified applicator if it is applied by a competent person acting under the instructions and control of a certified applicator who is available if and when needed, even though such certified applicator is not physically present at the time and place the pesticide is applied.

(f) Defoliant

The term "defoliant" means any substance or mixture of substances intended for causing the leaves or foliage to drop from a plant, with or without causing abscission.

(g) Desiccant

The term "desiccant" means any substance or mixture of substances intended for artificially accelerating the drying of plant tissue.

(h) Device

The term "device" means any instrument or contrivance (other than a firearm) which is intended for trapping, destroying, repelling, or mitigating any pest or any other form of plant or animal life (other than man and other than bacteria, virus, or other microorganism on or in living man or other living animals); but not including equipment used for the application of pesticides when sold separately therefrom.

(i) District court

The term "district court" means a United States district court, the District Court of Guam, the District Court of the Virgin Islands, and the highest court of American Samoa.

(j) Environment

The term "environment" includes water, air, land, and all plants and man and other animals living therein, and the interrelationships which exist among these.

(k) Fungus

The term "fungus" means any non-chlorophyll-bearing thallophyte (that is, any non-chlorophyll-bearing plant of a lower order than mosses and liverworts), as for example, rust, smut, mildew, mold, yeast, and bacteria, except those on or in living man or other animals and those on or in processed food, beverages, or pharmaceuticals.

(l) Imminent hazard

The term "imminent hazard" means a situation which exists when the continued use of a pesticide during the time required for cancellation proceeding would be likely to result in unreasonable adverse effects on

the environment or will involve unreasonable hazard to the survival of a species declared endangered or threatened by the Secretary pursuant to the Endangered Species Act of 1973.

(m) Inert ingredient

The term "inert ingredient" means an ingredient which is not active.

(n) Ingredient statement

The term "ingredient statement" means a statement which contains--

(1) the name and percentage of each active ingredient, and the total percentage of all inert ingredients, in the pesticide; and

(2) if the pesticide contains arsenic in any form, a statement of the percentages of total and water soluble arsenic, calculated as elementary arsenic.

(o) Insect

The term "insect" means any of the numerous small invertebrate animals generally having the body more or less obviously segmented, for the most part belonging to the class insecta, comprising six-legged, usually winged forms, as for example, beetles, bugs, bees, flies, and to other allied classes of arthropods whose members are wingless and usually have more than six legs, as for example, spiders, mites, ticks, centipedes, and wood lice.

(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.

(r) Nematode

The term "nematode" means invertebrate animals of the phylum nemathelminthes and class nematoda, that is, unsegmented round worms with elongated, fusiform, or saclike bodies covered with cuticle, and

inhabiting soil, water, plants, or plant parts; may also be called nemas or eelworms.

(s) Person

The term "person" means any individual, partnership, association, corporation, or any organized group of persons whether incorporated or not.

(t) Pest

The term "pest" means (1) any insect, rodent, nematode, fungus, weed, or (2) any other form of terrestrial or aquatic plant or animal life or virus, bacteria, or other micro-organism (except viruses, bacteria, or other micro-organisms on or in living man or other living animals) which the Administrator declares to be a pest under section 136w(c)(1) of this title.

(u) Pesticide

The term "pesticide" means (1) any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest, (2) any substance or mixture of substances intended for use as a plant regulator, defoliant, or desiccant, and (3) any nitrogen stabilizer, except that the term "pesticide" shall not include any article that is a "new animal drug" within the meaning of section 321(w) of Title 21, that has been determined by the Secretary of Health and Human Services not to be a new animal drug by a regulation establishing conditions of use for the article, or that is an animal feed within the meaning of section 321(x) of Title 21 bearing or containing a new animal drug. The term "pesticide" does not include liquid chemical sterilant products (including any sterilant or subordinate disinfectant claims on such products) for use on a critical or semi-

critical device, as defined in section 321 of Title 21. For purposes of the preceding sentence, the term "critical device" includes any device which is introduced directly into the human body, either into or in contact with the bloodstream or normally sterile areas of the body and the term "semi-critical device" includes any device which contacts intact mucous membranes but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body.

(v) Plant regulator

The term "plant regulator" means any substance or mixture of substances intended, through physiological action, for accelerating or retarding the rate of growth or rate of maturation, or for otherwise altering the behavior of plants or the produce thereof, but shall not include substances to the extent that they are intended as plant nutrients, trace elements, nutritional chemicals, plant inoculants, and soil amendments. Also, the term "plant regulator" shall not be required to include any of such of those nutrient mixtures or soil amendments as are commonly known as vitamin-hormone horticultural products, intended for improvement, maintenance, survival, health, and propagation of plants, and as are not for pest destruction and are nontoxic, nonpoisonous in the undiluted packaged concentration.

(w) Producer and produce

The term "producer" means the person who manufactures, prepares, compounds, propagates, or processes any pesticide or device or active ingredient used in producing a pesticide. The term "produce" means to manufacture, prepare, compound,

propagate, or process any pesticide or device or active ingredient used in producing a pesticide. The dilution by individuals of formulated pesticides for their own use and according to the directions on registered labels shall not of itself result in such individuals being included in the definition of "producer" for the purposes of this subchapter.

(x) Protect health and the environment

The terms "protect health and the environment" and "protection of health and the environment" mean protection against any unreasonable adverse effects on the environment.

(y) Registrant

The term "registrant" means a person who has registered any pesticide pursuant to the provisions of this subchapter.

(z) Registration

The term "registration" includes reregistration.

(aa) State

The term "State" means a State, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, the Trust Territory of the Pacific Islands, and American Samoa.

(bb) Unreasonable adverse effects on the environment

The term "unreasonable adverse effects on the environment" means (1) any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide, or (2) a human dietary risk from residues that result from a use of a

pesticide in or on any food inconsistent with the standard under section 346a of Title 21. The Administrator shall consider the risks and benefits of public health pesticides separate from the risks and benefits of other pesticides. In weighing any regulatory action concerning a public health pesticide under this subchapter, the Administrator shall weigh any risks of the pesticide against the health risks such as the diseases transmitted by the vector to be controlled by the pesticide.

(cc) Weed

The term "weed" means any plant which grows where not wanted.

(dd) Establishment

The term "establishment" means any place where a pesticide or device or active ingredient used in producing a pesticide is produced, or held, for distribution or sale.

(ee) To use any registered pesticide in a manner inconsistent with its labeling

The term "to use any registered pesticide in a manner inconsistent with its labeling" means to use any registered pesticide in a manner not permitted by the labeling, except that the term shall not include (1) applying a pesticide at any dosage, concentration, or frequency less than that specified on the labeling unless the labeling specifically prohibits deviation from the specified dosage, concentration, or frequency, (2) applying a pesticide against any target pest not specified on the labeling if the application is to the crop, animal, or site specified on the labeling, unless the Administrator has required that the labeling specifically state that the pesticide may be

used only for the pests specified on the labeling after the Administrator has determined that the use of the pesticide against other pests would cause an unreasonable adverse effect on the environment, (3) employing any method of application not prohibited by the labeling unless the labeling specifically states that the product may be applied only by the methods specified on the labeling, (4) mixing a pesticide or pesticides with a fertilizer when such mixture is not prohibited by the labeling, (5) any use of a pesticide in conformance with section 136c, 136p, or 136v of this title, or (6) any use of a pesticide in a manner that the Administrator determines to be consistent with the purposes of this subchapter. After March 31, 1979, the term shall not include the use of a pesticide for agricultural or forestry purposes at a dilution less than label dosage unless before or after that date the Administrator issues a regulation or advisory opinion consistent with the study provided for in section 27(b) of the Federal Pesticide Act of 1978, which regulation or advisory opinion specifically requires the use of definite amounts of dilution.

(ff) Outstanding data requirement

(1) In general

The term "outstanding data requirement" means a requirement for any study, information, or data that is necessary to make a determination under section 136a(c)(5) of this title and which study, information, or data--

(A) has not been submitted to the Administrator; or

(B) if submitted to the Administrator, the Administrator has determined must be

resubmitted because it is not valid, complete, or adequate to make a determination under section 136a(c)(5) of this title and the regulations and guidelines issued under such section.

(2) Factors

In making a determination under paragraph (1)(B) respecting a study, the Administrator shall examine, at a minimum, relevant protocols, documentation of the conduct and analysis of the study, and the results of the study to determine whether the study and the results of the study fulfill the data requirement for which the study was submitted to the Administrator.

(gg) To distribute or sell

The term "to distribute or sell" means to distribute, sell, offer for sale, hold for distribution, hold for sale, hold for shipment, ship, deliver for shipment, release for shipment, or receive and (having so received) deliver or offer to deliver. The term does not include the holding or application of registered pesticides or use dilutions thereof by any applicator who provides a service of controlling pests without delivering any unapplied pesticide to any person so served.

(hh) Nitrogen stabilizer

The term "nitrogen stabilizer" means any substance or mixture of substances intended for preventing or hindering the process of nitrification, denitrification, ammonia volatilization, or urease production through action upon soil bacteria. Such term shall not include--

(1) dicyandiamide;

(2) ammonium thiosulfate; or

(3) any substance or mixture of substances.[1] --

(A) that was not registered pursuant to section 136a of this title prior to January 1, 1992; and

(B) that was in commercial agronomic use prior to January 1, 1992, with respect to which after January 1, 1992, the distributor or seller of the substance or mixture has made no specific claim of prevention or hindering of the process of nitrification, denitrification, ammonia volatilization[2] urease production regardless of the actual use or purpose for, or future use or purpose for, the substance or mixture.

Statements made in materials required to be submitted to any State legislative or regulatory authority, or required by such authority to be included in the labeling or other literature accompanying any such substance or mixture shall not be deemed a specific claim within the meaning of this subsection.

(jj)[3] Maintenance applicator

The term "maintenance applicator" means any individual who, in the principal course of such individual's employment, uses, or supervises the use of, a pesticide not classified for restricted use (other than a ready to use consumer products pesticide); for the purpose of providing structural pest control or lawn pest control including janitors, general maintenance personnel, sanitation personnel, and

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[1] So in original. Probably should not have a period.

[2] So in original. Probably should be followed by ", or".

[3] So in original. No subsec. (ii) has been enacted.

grounds maintenance personnel. The term "maintenance applicator" does not include private applicators as defined in subsection (e)(2); individuals who use antimicrobial pesticides, sanitizers or disinfectants; individuals employed by Federal, State, and local governments or any political subdivisions thereof, or individuals who use pesticides not classified for restricted use in or around their homes, boats, sod farms, nurseries, greenhouses, or other noncommercial property.

(kk) Service technician

The term "service technician" means any individual who uses or supervises the use of pesticides (other than a ready to use consumer products pesticide) for the purpose of providing structural pest control or lawn pest control on the property of another for a fee. The term "service technician" does not include individuals who use antimicrobial pesticides, sanitizers or disinfectants; or who otherwise apply ready to use consumer products pesticides.

(ll) Minor use

The term "minor use" means the use of a pesticide on an animal, on a commercial agricultural crop or site, or for the protection of public health where--

(1) the total United States acreage for the crop is less than 300,000 acres, as determined by the Secretary of Agriculture; or

(2) the Administrator, in consultation with the Secretary of Agriculture, determines that, based on information provided by an applicant for registration or a registrant, the use does not provide sufficient economic incentive to support

the initial registration or continuing registration of a pesticide for such use and--

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

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

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

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

The status as a minor use under this subsection shall continue as long as the Administrator has not determined that, based on existing data, such use may cause an unreasonable adverse effect on the environment and the use otherwise qualifies for such status.

(mm) Antimicrobial pesticide

(1) In general

The term "antimicrobial pesticide" means a pesticide that--

(A) is intended to--

(i) disinfect, sanitize, reduce, or mitigate growth or development of microbiological organisms; or

(ii) protect inanimate objects, industrial processes or systems, surfaces, water, or other chemical substances from

contamination, fouling, or deterioration caused by bacteria, viruses, fungi, protozoa, algae, or slime; and

(B) in the intended use is exempt from, or otherwise not subject to, a tolerance under section 346a of Title 21 or a food additive regulation under section 348 of Title 21.

(2) Excluded products

The term "antimicrobial pesticide" does not include--

(A) a wood preservative or antifouling paint product for which a claim of pesticidal activity other than or in addition to an activity described in paragraph (1) is made;

(B) an agricultural fungicide product; or

(C) an aquatic herbicide product.

(3) Included products

The term "antimicrobial pesticide" does include any other chemical sterilant product (other than liquid chemical sterilant products exempt under subsection (u)), any other disinfectant product, any other industrial microbiocide product, and any other preservative product that is not excluded by paragraph (2).

(nn) Public health pesticide

The term "public health pesticide" means any minor use pesticide product registered for use and used predominantly in public health programs for vector control or for other recognized health protection uses, including the prevention or mitigation of viruses,

bacteria, or other microorganisms (other than viruses, bacteria, or other microorganisms on or in living man or other living animal) that pose a threat to public health.

(oo) Vector

The term "vector" means any organism capable of transmitting the causative agent of human disease or capable of producing human discomfort or injury, including mosquitoes, flies, fleas, cockroaches, or other insects and ticks, mites, or rats.

7 U.S.C.A. § 136a

§ 136a. Registration of pesticides

Effective: December 20, 2018

(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.

(b) Exemptions

A pesticide which is not registered with the Administrator may be transferred if--

(1) the transfer is from one registered establishment to another registered establishment operated by the same producer solely for packaging at the second establishment or for use as a constituent part of another pesticide produced at the second establishment; or

(2) the transfer is pursuant to and in accordance with the requirements of an experimental use permit.

(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.

(iii) Except as otherwise provided in clause (i), with respect to data submitted after December 31, 1969, by an applicant or registrant to support an application for registration, experimental use permit, or amendment adding a new use to an existing registration, to support or maintain in effect an existing registration, or for reregistration, the Administrator may, without the permission of the original data submitter, consider any such item of data in support of an application by any other person

(hereinafter in this subparagraph referred to as the "applicant") within the fifteen-year period following the date the data were originally submitted only if the applicant has made an offer to compensate the original data submitter and submitted such offer to the Administrator accompanied by evidence of delivery to the original data submitter of the offer. The terms and amount of compensation may be fixed by agreement between the original data submitter and the applicant, or, failing such agreement, binding arbitration under this subparagraph. If, at the end of ninety days after the date of delivery to the original data submitter of the offer to compensate, the original data submitter and the applicant have neither agreed on the amount and terms of compensation nor on a procedure for reaching an agreement on the amount and terms of compensation, either person may initiate binding arbitration proceedings by requesting the Federal Mediation and Conciliation Service to appoint an arbitrator from the roster of arbitrators maintained by such Service. The procedure and rules of the Service shall be applicable to the selection of such arbitrator and to such arbitration proceedings, and the findings and determination of the arbitrator shall be final and conclusive, and no official or court of the United States shall have power or jurisdiction to review any such findings and determination, except for fraud, misrepresentation, or other

misconduct by one of the parties to the arbitration or the arbitrator where there is a verified complaint with supporting affidavits attesting to specific instances of such fraud, misrepresentation, or other misconduct. The parties to the arbitration shall share equally in the payment of the fee and expenses of the arbitrator. If the Administrator determines that an original data submitter has failed to participate in a procedure for reaching an agreement or in an arbitration proceeding as required by this subparagraph, or failed to comply with the terms of an agreement or arbitration decision concerning compensation under this subparagraph, the original data submitter shall forfeit the right to compensation for the use of the data in support of the application. Notwithstanding any other provision of this subchapter, if the Administrator determines that an applicant has failed to participate in a procedure for reaching an agreement or in an arbitration proceeding as required by this subparagraph, or failed to comply with the terms of an agreement or arbitration decision concerning compensation under this subparagraph, the Administrator shall deny the application or cancel the registration of the pesticide in support of which the data were used without further hearing. Before the Administrator takes action under either of the preceding two sentences, the Administrator shall furnish to the affected person, by certified mail,

notice of intent to take action and allow fifteen days from the date of delivery of the notice for the affected person to respond. If a registration is denied or canceled under this subparagraph, the Administrator may make such order as the Administrator deems appropriate concerning the continued sale and use of existing stocks of such pesticide. Registration action by the Administrator shall not be delayed pending the fixing of compensation.

(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.

(v) The period of exclusive use provided under clause (ii) shall not take effect until 1 year after August 3, 1996, except where an applicant or registrant is applying for the registration of a pesticide containing an active ingredient not previously registered.

(vi) With respect to data submitted after August 3, 1996, by an applicant or registrant to support an amendment adding a new use to an existing registration that does not retain any period of exclusive use, if such data relates solely to a minor use of

a pesticide, such data shall not, without the written permission of the original data submitter, be considered by the Administrator to support an application for a minor use by another person during the period of 10 years following the date of submission of such data. The applicant or registrant at the time the new minor use is requested shall notify the Administrator that to the best of their knowledge the exclusive use period for the pesticide has expired and that the data pertaining solely to the minor use of a pesticide is eligible for the provisions of this paragraph. If the minor use registration which is supported by data submitted pursuant to this subsection is voluntarily canceled or if such data are subsequently used to support a nonminor use, the data shall no longer be subject to the exclusive use provisions of this clause but shall instead be considered by the Administrator in accordance with the provisions of clause (i), as appropriate.

(G) If the applicant is requesting that the registration or amendment to the registration of a pesticide be expedited, an explanation of the basis for the request must be submitted, in accordance with paragraph (10) of this subsection.

(2) Data in support of registration

(A) In general

The Administrator shall publish guidelines specifying the kinds of information which will

be required to support the registration of a pesticide and shall revise such guidelines from time to time. If thereafter the Administrator requires any additional kind of information under subparagraph (B) of this paragraph, the Administrator shall permit sufficient time for applicants to obtain such additional information. The Administrator, in establishing standards for data requirements for the registration of pesticides with respect to minor uses, shall make such standards commensurate with the anticipated extent of use, pattern of use, the public health and agricultural need for such minor use, and the level and degree of potential beneficial or adverse effects on man and the environment. The Administrator shall not require a person to submit, in relation to a registration or reregistration of a pesticide for minor agricultural use under this subchapter, any field residue data from a geographic area where the pesticide will not be registered for such use. In the development of these standards, the Administrator shall consider the economic factors of potential national volume of use, extent of distribution, and the impact of the cost of meeting the requirements on the incentives for any potential registrant to undertake the development of the required data. Except as provided by section 136h of this title, within 30 days after the Administrator registers a pesticide under this subchapter the Administrator shall make available to the public the data called for in the registration statement together with such other scientific

information as the Administrator deems relevant to the Administrator's decision.

(B) Additional data

(i) If the Administrator determines that additional data are required to maintain in effect an existing registration of a pesticide, the Administrator shall notify all existing registrants of the pesticide to which the determination relates and provide a list of such registrants to any interested person.

(ii) Each registrant of such pesticide shall provide evidence within ninety days after receipt of notification that it is taking appropriate steps to secure the additional data that are required. Two or more registrants may agree to develop jointly, or to share in the cost of developing, such data if they agree and advise the Administrator of their intent within ninety days after notification. Any registrant who agrees to share in the cost of producing the data shall be entitled to examine and rely upon such data in support of maintenance of such registration. The Administrator shall issue a notice of intent to suspend the registration of a pesticide in accordance with the procedures prescribed by clause (iv) if a registrant fails to comply with this clause.

(iii) If, at the end of sixty days after advising the Administrator of their agreement to develop jointly, or share in the cost of developing, data, the registrants have not further agreed on the terms of the

data development arrangement or on a procedure for reaching such agreement, any of such registrants may initiate binding arbitration proceedings by requesting the Federal Mediation and Conciliation Service to appoint an arbitrator from the roster of arbitrators maintained by such Service. The procedure and rules of the Service shall be applicable to the selection of such arbitrator and to such arbitration proceedings, and the findings and determination of the arbitrator shall be final and conclusive, and no official or court of the United States shall have power or jurisdiction to review any such findings and determination, except for fraud, misrepresentation, or other misconduct by one of the parties to the arbitration or the arbitrator where there is a verified complaint with supporting affidavits attesting to specific instances of such fraud, misrepresentation, or other misconduct. All parties to the arbitration shall share equally in the payment of the fee and expenses of the arbitrator. The Administrator shall issue a notice of intent to suspend the registration of a pesticide in accordance with the procedures prescribed by clause (iv) if a registrant fails to comply with this clause.

(iv) Notwithstanding any other provision of this subchapter, if the Administrator determines that a registrant, within the time required by the Administrator, has failed to take appropriate steps to secure the data required under this subparagraph, to participate in a procedure for reaching

agreement concerning a joint data development arrangement under this subparagraph or in an arbitration proceeding as required by this subparagraph, or to comply with the terms of an agreement or arbitration decision concerning a joint data development arrangement under this subparagraph, the Administrator may issue a notice of intent to suspend such registrant's registration of the pesticide for which additional data is required. The Administrator may include in the notice of intent to suspend such provisions as the Administrator deems appropriate concerning the continued sale and use of existing stocks of such pesticide. Any suspension proposed under this subparagraph shall become final and effective at the end of thirty days from receipt by the registrant of the notice of intent to suspend, unless during that time a request for hearing is made by a person adversely affected by the notice or the registrant has satisfied the Administrator that the registrant has complied fully with the requirements that served as a basis for the notice of intent to suspend. If a hearing is requested, a hearing shall be conducted under section 136d(d) of this title. The only matters for resolution at that hearing shall be whether the registrant has failed to take the action that served as the basis for the notice of intent to suspend the registration of the pesticide for which additional data is required, and whether the Administrator's

determination with respect to the disposition of existing stocks is consistent with this subchapter. If a hearing is held, a decision after completion of such hearing shall be final. Notwithstanding any other provision of this subchapter, a hearing shall be held and a determination made within seventy-five days after receipt of a request for such hearing. Any registration suspended under this subparagraph shall be reinstated by the Administrator if the Administrator determines that the registrant has complied fully with the requirements that served as a basis for the suspension of the registration.

(v) Any data submitted under this subparagraph shall be subject to the provisions of paragraph (1)(D). Whenever such data are submitted jointly by two or more registrants, an agent shall be agreed on at the time of the joint submission to handle any subsequent data compensation matters for the joint submitters of such data.

(vi) Upon the request of a registrant the Administrator shall, in the case of a minor use, extend the deadline for the production of residue chemistry data under this subparagraph for data required solely to support that minor use until the final deadline for submission of data under section 136a-1 of this title for the other uses of the pesticide established as of August 3, 1996, if--

(I) the data to support other uses of the pesticide on a food are being provided;

(II) the registrant, in submitting a request for such an extension, provides a schedule, including interim dates to measure progress, to assure that the data production will be completed before the expiration of the extension period;

(III) the Administrator has determined that such extension will not significantly delay the Administrator's schedule for issuing a reregistration eligibility determination required under section 136a-1 of this title; and

(IV) the Administrator has determined that based on existing data, such extension would not significantly increase the risk of any unreasonable adverse effect on the environment. If the Administrator grants an extension under this clause, the Administrator shall monitor the development of the data and shall ensure that the registrant is meeting the schedule for the production of the data. If the Administrator determines that the registrant is not meeting or has not met the schedule for the production of such data, the Administrator may proceed in accordance with clause (iv) regarding the continued registration of the affected products with the minor use and shall inform the public of such action. Notwithstanding the provisions of this

clause, the Administrator may take action to modify or revoke the extension under this clause if the Administrator determines that the extension for the minor use may cause an unreasonable adverse effect on the environment. In such circumstance, the Administrator shall provide, in writing to the registrant, a notice revoking the extension of time for submission of data. Such data shall instead be due in accordance with the date established by the Administrator for the submission of the data.

(vii) If the registrant does not commit to support a specific minor use of the pesticide, but is supporting and providing data in a timely and adequate fashion to support uses of the pesticide on a food, or if all uses of the pesticide are nonfood uses and the registrant does not commit to support a specific minor use of the pesticide but is supporting and providing data in a timely and adequate fashion to support other nonfood uses of the pesticide, the Administrator, at the written request of the registrant, shall not take any action pursuant to this clause in regard to such unsupported minor use until the final deadline established as of August 3, 1996, for the submission of data under section 136a-1 of this title for the supported uses identified pursuant to this clause unless the Administrator determines that the absence of the data is significant enough to cause

human health or environmental concerns. On the basis of such determination, the Administrator may refuse the request for extension by the registrant. Upon receipt of the request from the registrant, the Administrator shall publish in the Federal Register a notice of the receipt of the request and the effective date upon which the uses not being supported will be voluntarily deleted from the registration pursuant to section 136d(f)(1) of this title. If the Administrator grants an extension under this clause, the Administrator shall monitor the development of the data for the uses being supported and shall ensure that the registrant is meeting the schedule for the production of such data. If the Administrator determines that the registrant is not meeting or has not met the schedule for the production of such data, the Administrator may proceed in accordance with clause (iv) of this subparagraph regarding the continued registration of the affected products with the minor and other uses and shall inform the public of such action in accordance with section 136d(f)(2) of this title. Notwithstanding the provisions of this clause, the Administrator may deny, modify, or revoke the temporary extension under this subparagraph if the Administrator determines that the continuation of the minor use may cause an unreasonable adverse effect on the environment. In the event of modification or revocation, the Administrator shall provide, in writing, to

the registrant a notice revoking the temporary extension and establish a new effective date by which the minor use shall be deleted from the registration.

(viii)(I) If data required to support registration of a pesticide under subparagraph (A) is requested by a Federal or State regulatory authority, the Administrator shall, to the extent practicable, coordinate data requirements, test protocols, timetables, and standards of review and reduce burdens and redundancy caused to the registrant by multiple requirements on the registrant.

(II) The Administrator may enter into a cooperative agreement with a State to carry out subclause (I).

(III) Not later than 1 year after August 3, 1996, the Administrator shall develop a process to identify and assist in alleviating future disparities between Federal and State data requirements.

(C) Simplified procedures

Within nine months after September 30, 1978, the Administrator shall, by regulation, prescribe simplified procedures for the registration of pesticides, which shall include the provisions of subparagraph (D) of this paragraph.

(D) Exemption

No applicant for registration of a pesticide who proposes to purchase a registered pesticide

from another producer in order to formulate such purchased pesticide into the pesticide that is the subject of the application shall be required to--

(i) submit or cite data pertaining to such purchased product; or

(ii) offer to pay reasonable compensation otherwise required by paragraph (1)(D) of this subsection for the use of any such data.

(E) Minor use waiver

In handling the registration of a pesticide for a minor use, the Administrator may waive otherwise applicable data requirements if the Administrator determines that the absence of such data will not prevent the Administrator from determining--

(i) the incremental risk presented by the minor use of the pesticide; and

(ii) that such risk, if any, would not be an unreasonable adverse effect on the environment.

(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.

(C) Minor use registration

(i) The Administrator shall, as expeditiously as possible, review and act on any complete application--

(I) that proposes the initial registration of a new pesticide active ingredient if the active ingredient is proposed to be registered solely for minor uses, or proposes a registration amendment solely for minor uses to an existing registration; or

(II) for a registration or a registration amendment that proposes significant minor uses.

(ii) For the purposes of clause (i)--

(I) the term "as expeditiously as possible" means that the Administrator shall, to the greatest extent practicable, complete a review and evaluation of all data, submitted with a complete application, within 12 months after the submission of the complete application, and the failure of the Administrator to complete such a review and evaluation under clause (i) shall not be subject to judicial review; and

(II) the term "significant minor uses" means 3 or more minor uses proposed for every nonminor use, a minor use that would, in the judgment of the Administrator, serve as a replacement for any use which has been canceled in the 5 years preceding the receipt of the application, or a minor use that in the opinion of the Administrator would avoid the reissuance of an emergency exemption under section 136p of this title for that minor use.

(D) Adequate time for submission of minor use data

If a registrant makes a request for a minor use waiver, regarding data required by the Administrator, pursuant to paragraph (2)(E), and if the Administrator denies in whole or in part such data waiver request, the registrant shall have a full-time period for providing such data. For purposes of this subparagraph, the term "full-time period" means the time period originally established by the Administrator for submission of such data, beginning with the date of receipt by the registrant of the Administrator's notice of denial.

(4) Notice of application

The Administrator shall publish in the Federal Register, promptly after receipt of the statement and other data required pursuant to paragraphs (1) and (2), a notice of each application for registration of any pesticide if it contains any new active ingredient or if it would entail a changed

use pattern. The notice shall provide for a period of 30 days in which any Federal agency or any other interested person may comment.

(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.

(8) Interim administrative review

Notwithstanding any other provision of this subchapter, the Administrator may not initiate a public interim administrative review process to develop a risk-benefit evaluation of the ingredients of a pesticide or any of its uses prior to initiating a formal action to cancel, suspend, or deny registration of such pesticide, required under this subchapter, unless such interim administrative process is based on a validated test or other significant evidence raising prudent concerns of unreasonable adverse risk to man or to the environment. Notice of the definition of the terms "validated test" and "other significant

evidence" as used herein shall be published by the Administrator in the Federal Register.

(9) Labeling

(A) Additional statements

Subject to subparagraphs (B) and (C), it shall not be a violation of this subchapter for a registrant to modify the labeling of an antimicrobial pesticide product to include relevant information on product efficacy, product composition, container composition or design, or other characteristics that do not relate to any pesticidal claim or pesticidal activity.

(B) Requirements

Proposed labeling information under subparagraph (A) shall not be false or misleading, shall not conflict with or detract from any statement required by law or the Administrator as a condition of registration, and shall be substantiated on the request of the Administrator.

(C) Notification and disapproval

(i) Notification

A registration may be modified under subparagraph (A) if--

(I) the registrant notifies the Administrator in writing not later than 60 days prior to distribution or sale of a product bearing the modified labeling; and

(II) the Administrator does not disapprove of the modification under clause (ii).

(ii) Disapproval

Not later than 30 days after receipt of a notification under clause (i), the Administrator may disapprove the modification by sending the registrant notification in writing stating that the proposed language is not acceptable and stating the reasons why the Administrator finds the proposed modification unacceptable.

(iii) Restriction on sale

A registrant may not sell or distribute a product bearing a disapproved modification.

(iv) Objection

A registrant may file an objection in writing to a disapproval under clause (ii) not later than 30 days after receipt of notification of the disapproval.

(v) Final action

A decision by the Administrator following receipt and consideration of an objection filed under clause (iv) shall be considered a final agency action.

(D) Use dilution

The label or labeling required under this subchapter for an antimicrobial pesticide that is or may be diluted for use may have a different statement of caution or protective

measures for use of the recommended diluted solution of the pesticide than for use of a concentrate of the pesticide if the Administrator determines that--

(i) adequate data have been submitted to support the statement proposed for the diluted solution uses; and

(ii) the label or labeling provides adequate protection for exposure to the diluted solution of the pesticide.

(10) Expedited registration of pesticides

(A) Not later than 1 year after August 3, 1996, the Administrator shall, utilizing public comment, develop procedures and guidelines, and expedite the review of an application for registration of a pesticide or an amendment to a registration that satisfies such guidelines.

(B) Any application for registration or an amendment, including biological and conventional pesticides, will be considered for expedited review under this paragraph. An application for registration or an amendment shall qualify for expedited review if use of the pesticide proposed by the application may reasonably be expected to accomplish 1 or more of the following:

(i) Reduce the risks of pesticides to human health.

(ii) Reduce the risks of pesticides to nontarget organisms.

(iii) Reduce the potential for contamination of groundwater, surface water, or other valued environmental resources.

(iv) Broaden the adoption of integrated pest management strategies, or make such strategies more available or more effective.

(C) The Administrator, not later than 30 days after receipt of an application for expedited review, shall notify the applicant whether the application is complete. If it is found to be incomplete, the Administrator may either reject the request for expedited review or ask the applicant for additional information to satisfy the guidelines developed under subparagraph (A).

(11) Interagency working group

(A) Definition of covered agency

In this paragraph, the term "covered agency" means any of the following:

(i) The Department of Agriculture.

(ii) The Department of Commerce.

(iii) The Department of the Interior.

(iv) The Council on Environmental Quality.

(v) The Environmental Protection Agency.

(B) Establishment

The Administrator shall establish an interagency working group, to be comprised of representatives from each covered agency, to provide recommendations regarding, and to

implement a strategy for improving, the consultation process required under section 7 of the Endangered Species Act of 1973 (16 U.S.C. 1536) for pesticide registration and registration review.

(C) Duties

The interagency working group established under subparagraph (B) shall--

(i) analyze relevant Federal law (including regulations) and case law for purposes of providing an outline of the legal and regulatory framework for the consultation process referred to in that subparagraph, including--

(I) requirements under this subchapter and the Endangered Species Act of 1973 (16 U.S.C. 1531 et seq.);

(II) Federal case law regarding the intersection of this subchapter and the Endangered Species Act of 1973 (16 U.S.C. 1531 et seq.); and

(III) Federal regulations relating to the pesticide consultation process;

(ii) provide advice regarding methods of--

(I) defining the scope of actions of the covered agencies that are subject to the consultation requirement referred to in subparagraph (B); and

(II) properly identifying and classifying effects of actions of the covered agencies

with respect to that consultation requirement;

(iii) identify the obligations and limitations under Federal law of each covered agency for purposes of providing a legal and regulatory framework for developing the recommendations referred to in subparagraph (B);

(iv) review practices for the consultation referred to in subparagraph (B) to identify problem areas, areas for improvement, and best practices for conducting that consultation among the covered agencies;

(v) develop scientific and policy approaches to increase the accuracy and timeliness of the process for that consultation, in accordance with requirements of this subchapter and the Endangered Species Act of 1973 (16 U.S.C. 1531 et seq.), including--

(I) processes to efficiently share data and coordinate analyses among the Department of Agriculture, the Department of Commerce, the Department of the Interior, and the Environmental Protection Agency;

(II) a streamlined process for identifying which actions require no consultation, informal consultation, or formal consultation;

(III) an approach that will provide clarity with respect to what constitutes the best scientific and commercial data

available in the fields of pesticide use and ecological risk assessment, pursuant to section 7(a)(2) of the Endangered Species Act of 1973 (16 U.S.C. 1536(a)(2)); and

(IV) approaches that enable the Environmental Protection Agency to better assist the Department of the Interior and the Department of Commerce in carrying out obligations under that section in a timely and efficient manner; and

(vi) propose and implement a strategy to implement approaches to consultations under the Endangered Species Act of 1973 (16 U.S.C. 1531 et seq.) and document that strategy in a memorandum of understanding, revised regulations, or another appropriate format to promote durable cooperation among the covered agencies.

(D) Reports

(i) Progress reports

(I) In general

Not later than 18 months after December 20, 2018, the Administrator, in coordination with the head of each other covered agency, shall submit to the Committee on Agriculture of the House of Representatives and the Committee on Agriculture, Nutrition, and Forestry of the Senate a report describing the

progress of the working group in developing the recommendations under subparagraph (B).

(II) Requirements

The report under this clause shall--

(aa) reflect the perspectives of each covered agency; and

(bb) identify areas of new consensus and continuing topics of disagreement and debate.

(ii) Results

(I) In general

Not later than 1 year after December 20, 2018, the Administrator, in coordination with the head of each other covered agency, shall submit to the Committee on Agriculture of the House of Representatives and the Committee on Agriculture, Nutrition, and Forestry of the Senate a report describing--

(aa) the recommendations developed under subparagraph (B); and

(bb) plans for implementation of those recommendations.

(II) Requirements

The report under this clause shall--

(aa) reflect the perspectives of each covered agency; and

(bb) identify areas of consensus and continuing topics of disagreement and debate, if any.

(iii) Implementation

Not later than 1 year after the date of submission of the report under clause (i), the Administrator, in coordination with the head of each other covered agency, shall submit to the Committee on Agriculture of the House of Representatives and the Committee on Agriculture, Nutrition, and Forestry of the Senate a report describing--

(I) the implementation of the recommendations referred to in that clause;

(II) the extent to which that implementation improved the consultation process referred to in subparagraph (B); and

(III) any additional recommendations for improvements to the process described in subparagraph (B).

(iv) Other reports

Not later than the date that is 180 days after the date of submission of the report under clause (iii), and not less frequently than once every 180 days thereafter during the 5-year period beginning on that date, the Administrator, in coordination with the head of each other covered agency, shall submit to the Committee on Agriculture of the House of Representatives and the

Committee on Agriculture, Nutrition, and Forestry of the Senate a report describing--

(I) the implementation of the recommendations referred to in that clause;

(II) the extent to which that implementation improved the consultation process referred to in subparagraph (B); and

(III) any additional recommendations for improvements to the process described in subparagraph (B).

(E) Consultation with private sector

In carrying out the duties under this paragraph, the working group shall, as appropriate--

(i) consult with, representatives of interested industry stakeholders and nongovernmental organizations; and

(ii) take into consideration factors, such as actual and potential differences in interest between, and the views of, those stakeholders and organizations.

(F) Federal Advisory Committee Act

The Federal Advisory Committee Act (5 U.S.C. App.) shall not apply to the working group established under this paragraph.

(G) Savings clause

Nothing in this paragraph supersedes any provision of--

(i) this subchapter; or

(ii) the Endangered Species Act of 1973 (16 U.S.C. 1531 et seq.), including the requirements under section 7 of that Act (16 U.S.C. 1536).

(d) Classification of pesticides

(1) Classification for general use, restricted use, or both

(A) As a part of the registration of a pesticide the Administrator shall classify it as being for general use or for restricted use. If the Administrator determines that some of the uses for which the pesticide is registered should be for general use and that other uses for which it is registered should be for restricted use, the Administrator shall classify it for both general use and restricted use. Pesticide uses may be classified by regulation on the initial classification, and registered pesticides may be classified prior to reregistration. If some of the uses of the pesticide are classified for general use, and other uses are classified for restricted use, the directions relating to its general uses shall be clearly separated and distinguished from those directions relating to its restricted uses. The Administrator may require that its packaging and labeling for restricted uses shall be clearly distinguishable from its packaging and labeling for general uses.

(B) If the Administrator determines that the pesticide, when applied in accordance with its directions for use, warnings and cautions and

for the uses for which it is registered, or for one or more of such uses, or in accordance with a widespread and commonly recognized practice, will not generally cause unreasonable adverse effects on the environment, the Administrator will classify the pesticide, or the particular use or uses of the pesticide to which the determination applies, for general use.

(C) If the Administrator determines that the pesticide, when applied in accordance with its directions for use, warnings and cautions and for the uses for which it is registered, or for one or more of such uses, or in accordance with a widespread and commonly recognized practice, may generally cause, without additional regulatory restrictions, unreasonable adverse effects on the environment, including injury to the applicator, the Administrator shall classify the pesticide, or the particular use or uses to which the determination applies, for restricted use:

(i) If the Administrator classifies a pesticide, or one or more uses of such pesticide, for restricted use because of a determination that the acute dermal or inhalation toxicity of the pesticide presents a hazard to the applicator or other persons, the pesticide shall be applied for any use to which the restricted classification applies only by or under the direct supervision of a certified applicator.

(ii) If the Administrator classifies a pesticide, or one or more uses of such pesticide, for restricted use because of a determination

that its use without additional regulatory restriction may cause unreasonable adverse effects on the environment, the pesticide shall be applied for any use to which the determination applies only by or under the direct supervision of a certified applicator, or subject to such other restrictions as the Administrator may provide by regulation. Any such regulation shall be reviewable in the appropriate court of appeals upon petition of a person adversely affected filed within 60 days of the publication of the regulation in final form.

(2) Change in classification

If the Administrator determines that a change in the classification of any use of a pesticide from general use to restricted use is necessary to prevent unreasonable adverse effects on the environment, the Administrator shall notify the registrant of such pesticide of such determination at least forty-five days before making the change and shall publish the proposed change in the Federal Register. The registrant, or other interested person with the concurrence of the registrant, may seek relief from such determination under section 136d(b) of this title.

(3) Change in classification from restricted use to general use

The registrant of any pesticide with one or more uses classified for restricted use may petition the Administrator to change any such classification from restricted to general use. Such petition shall set out the basis for the registrant's position that restricted use classification is unnecessary because

classification of the pesticide for general use would not cause unreasonable adverse effects on the environment. The Administrator, within sixty days after receiving such petition, shall notify the registrant whether the petition has been granted or denied. Any denial shall contain an explanation therefor and any such denial shall be subject to judicial review under section 136n of this title.

(e) Products with same formulation and claims

Products which have the same formulation, are manufactured by the same person, the labeling of which contains the same claims, and the labels of which bear a designation identifying the product as the same pesticide may be registered as a single pesticide; and additional names and labels shall be added to the registration by supplemental statements.

(f) Miscellaneous

(1) Effect of change of labeling or formulation

If the labeling or formulation for a pesticide is changed, the registration shall be amended to reflect such change if the Administrator determines that the change will not violate any provision of this subchapter.

(2) Registration not a defense

In no event shall registration of an article be construed as a defense for the commission of any offense under this subchapter. As long as no cancellation proceedings are in effect registration of a pesticide shall be prima facie evidence that the pesticide, its labeling and packaging comply with the registration provisions of the subchapter.

(3) Authority to consult other Federal agencies

In connection with consideration of any registration or application for registration under this section, the Administrator may consult with any other Federal agency.

(4) Mixtures of nitrogen stabilizers and fertilizer products

Any mixture or other combination of--

(A) 1 or more nitrogen stabilizers registered under this subchapter; and

(B) 1 or more fertilizer products,

shall not be subject to the provisions of this section or sections 136a-1, 136c, 136e, 136m, and 136*o*(a)(2) of this title if the mixture or other combination is accompanied by the labeling required under this subchapter for the nitrogen stabilizer contained in the mixture or other combination, the mixture or combination is mixed or combined in accordance with such labeling, and the mixture or combination does not contain any active ingredient other than the nitrogen stabilizer.

(g) Registration review

(1) General rule

(A) Periodic review

(i) In general

The registrations of pesticides are to be periodically reviewed.

(ii) Regulations

In accordance with this subparagraph, the Administrator shall by regulation establish a procedure for accomplishing the periodic review of registrations.

(iii) Initial registration review

The Administrator shall complete the registration review of each pesticide or pesticide case, which may be composed of 1 or more active ingredients and the products associated with the active ingredients, not later than the later of--

(I) October 1, 2022; or

(II) the date that is 15 years after the date on which the first pesticide containing a new active ingredient is registered.

(iv) Subsequent registration review

Not later than 15 years after the date on which the initial registration review is completed under clause (iii) and each 15 years thereafter, the Administrator shall complete a subsequent registration review for each pesticide or pesticide case.

(v) Cancellation

No registration shall be canceled as a result of the registration review process unless the Administrator follows the procedures and substantive requirements of section 136d of this title.

(B) Docketing

(i) In general

Subject to clause (ii), after meeting with 1 or more individuals that are not government employees to discuss matters relating to a registration review, the Administrator shall place in the docket minutes of the meeting, a list of attendees, and any documents exchanged at the meeting, not later than the earlier of--

(I) the date that is 45 days after the meeting; or

(II) the date of issuance of the registration review decision.

(ii) Protected information

The Administrator shall identify, but not include in the docket, any confidential business information the disclosure of which is prohibited by section 136h of this title.

(C) Limitation

Nothing in this subsection shall prohibit the Administrator from undertaking any other review of a pesticide pursuant to this subchapter.

(2) Data

(A) Submission required

The Administrator shall use the authority in subsection (c)(2)(B) to require the submission of data when such data are necessary for a registration review.

(B) Data submission, compensation, and exemption

For purposes of this subsection, the provisions of subsections (c)(1), (c)(2)(B), and (c)(2)(D) shall be utilized for and be applicable to any data required for registration review.

(h) Registration requirements for antimicrobial pesticides

(1) Evaluation of process

To the maximum extent practicable consistent with the degrees of risk presented by an antimicrobial pesticide and the type of review appropriate to evaluate the risks, the Administrator shall identify and evaluate reforms to the antimicrobial registration process that would reduce review periods existing as of August 3, 1996, for antimicrobial pesticide product registration applications and applications for amended registration of antimicrobial pesticide products, including--

(A) new antimicrobial active ingredients;

(B) new antimicrobial end-use products;

(C) substantially similar or identical antimicrobial pesticides; and

(D) amendments to antimicrobial pesticide registrations.

(2) Review time period reduction goal

Each reform identified under paragraph (1) shall be designed to achieve the goal of reducing the review period following submission of a complete

application, consistent with the degree of risk, to a period of not more than--

(A) 540 days for a new antimicrobial active ingredient pesticide registration;

(B) 270 days for a new antimicrobial use of a registered active ingredient;

(C) 120 days for any other new antimicrobial product;

(D) 90 days for a substantially similar or identical antimicrobial product;

(E) 90 days for an amendment to an antimicrobial registration that does not require scientific review of data; and

(F) 120 days for an amendment to an antimicrobial registration that requires scientific review of data and that is not otherwise described in this paragraph.

(3) Implementation

(A) Proposed rulemaking

(i) Issuance

Not later than 270 days after August 3, 1996, the Administrator shall publish in the Federal Register proposed regulations to accelerate and improve the review of antimicrobial pesticide products designed to implement, to the extent practicable, the goals set forth in paragraph (2).

(ii) Requirements

Proposed regulations issued under clause (i) shall--

(I) define the various classes of antimicrobial use patterns, including household, industrial, and institutional disinfectants and sanitizing pesticides, preservatives, water treatment, and pulp and paper mill additives, and other such products intended to disinfect, sanitize, reduce, or mitigate growth or development of microbiological organisms, or protect inanimate objects, industrial processes or systems, surfaces, water, or other chemical substances from contamination, fouling, or deterioration caused by bacteria, viruses, fungi, protozoa, algae, or slime;

(II) differentiate the types of review undertaken for antimicrobial pesticides;

(III) conform the degree and type of review to the risks and benefits presented by antimicrobial pesticides and the function of review under this subchapter, considering the use patterns of the product, toxicity, expected exposure, and product type;

(IV) ensure that the registration process is sufficient to maintain antimicrobial pesticide efficacy and that antimicrobial pesticide products continue to meet product performance standards and effectiveness levels for each type of label claim made; and

(V) implement effective and reliable deadlines for process management.

(iii) Comments

In developing the proposed regulations, the Administrator shall solicit the views from registrants and other affected parties to maximize the effectiveness of the rule development process.

(B) Final regulations

(i) Issuance

The Administrator shall issue final regulations not later than 240 days after the close of the comment period for the proposed regulations.

(ii) Failure to meet goal

If a goal described in paragraph (2) is not met by the final regulations, the Administrator shall identify the goal, explain why the goal was not attained, describe the element of the regulations included instead, and identify future steps to attain the goal.

(iii) Requirements

In issuing final regulations, the Administrator shall--

(I) consider the establishment of a certification process for regulatory actions involving risks that can be responsibly managed, consistent with the degree of risk, in the most cost-efficient manner;

(II) consider the establishment of a certification process by approved laboratories as an adjunct to the review process;

(III) use all appropriate and cost-effective review mechanisms, including--

(aa) expanded use of notification and non-notification procedures;

(bb) revised procedures for application review; and

(cc) allocation of appropriate resources to ensure streamlined management of antimicrobial pesticide registrations; and

(IV) clarify criteria for determination of the completeness of an application.

(C) Expedited review

This subsection does not affect the requirements or extend the deadlines or review periods contained in subsection (c)(3).

(D) Alternative review periods

If the final regulations to carry out this paragraph are not effective 630 days after August 3, 1996, until the final regulations become effective, the review period, beginning on the date of receipt by the Agency of a complete application, shall be--

(i) 2 years for a new antimicrobial active ingredient pesticide registration;

(ii) 1 year for a new antimicrobial use of a registered active ingredient;

(iii) 180 days for any other new antimicrobial product;

(iv) 90 days for a substantially similar or identical antimicrobial product;

(v) 90 days for an amendment to an antimicrobial registration that does not require scientific review of data; and

(vi) 120 days for an amendment to an antimicrobial registration that requires scientific review of data and that is not otherwise described in this subparagraph.

(E) Wood preservatives

An application for the registration, or for an amendment to the registration, of a wood preservative product for which a claim of pesticidal activity listed in section 136(mm) of this title is made (regardless of any other pesticidal claim that is made with respect to the product) shall be reviewed by the Administrator within the same period as that established under this paragraph for an antimicrobial pesticide product application, consistent with the degree of risk posed by the use of the wood preservative product, if the application requires the applicant to satisfy the same data requirements as are required to support an application for a wood preservative product that is an antimicrobial pesticide.

(F) Notification

(i) In general

Subject to clause (iii), the Administrator shall notify an applicant whether an application has been granted or denied not later than the final day of the appropriate review period under this paragraph, unless the applicant and the Administrator agree to a later date.

(ii) Final decision

If the Administrator fails to notify an applicant within the period of time required under clause (i), the failure shall be considered an agency action unlawfully withheld or unreasonably delayed for purposes of judicial review under chapter 7 of Title 5.

(iii) Exemption

This subparagraph does not apply to an application for an antimicrobial pesticide that is filed under subsection (c)(3) (B) prior to 90 days after August 3, 1996.

(iv) Limitation

Notwithstanding clause (ii), the failure of the Administrator to notify an applicant for an amendment to a registration for an antimicrobial pesticide shall not be judicially reviewable in a Federal or State court if the amendment requires scientific review of data within--

(I) the time period specified in subparagraph (D)(vi), in the absence of a final regulation under subparagraph (B); or

(II) the time period specified in paragraph (2)(F), if adopted in a final regulation under subparagraph (B).

(4) Annual report

(A) Submission

Beginning on August 3, 1996, and ending on the date that the goals under paragraph (2) are achieved, the Administrator shall, not later than March 1 of each year, prepare and submit an annual report to the Committee on Agriculture of the House of Representatives and the Committee on Agriculture, Nutrition, and Forestry of the Senate.

(B) Requirements

A report submitted under subparagraph (A) shall include a description of--

(i) measures taken to reduce the backlog of pending registration applications;

(ii) progress toward achieving reforms under this subsection; and

(iii) recommendations to improve the activities of the Agency pertaining to antimicrobial registrations.

17 U.S.C.A. § 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.A. § 105

§ 105. Subject matter of copyright: United States Government works

Effective: December 20, 2019

(a) In general.--Copyright protection under this title is not available for any work of the United States Government, but the United States Government is not precluded from receiving and holding copyrights transferred to it by assignment, bequest, or otherwise.

(b) Copyright protection of certain of works.--Subject to subsection (c), the covered author of a covered work owns the copyright to that covered work.

(c)[1] **Use by Federal Government.**--The Secretary of Defense may direct the covered author of a covered work to provide the Federal Government with an irrevocable, royalty-free, world-wide, nonexclusive license to reproduce, distribute, perform, or display such covered work for purposes of the United States Government.

(c)[1] **Definitions.**--In this section:

(1) The term "covered author" means a civilian member of the faculty of a covered institution.

(2) The term "covered institution" means the following:

(A) National Defense University.

(B) United States Military Academy.

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[1] So in original. Two subsecs. (c) were enacted.

(C) Army War College.

(D) United States Army Command and General Staff College.

(E) United States Naval Academy.

(F) Naval War College.

(G) Naval Post Graduate School.

(H) Marine Corps University.

(I) United States Air Force Academy.

(J) Air University.

(K) Defense Language Institute.

(L) United States Coast Guard Academy.

(3) The term "covered work" means a literary work produced by a covered author in the course of employment at a covered institution for publication by a scholarly press or journal.

17 U.S.C.A. § 501

§ 501. Infringement of copyright

Effective: December 20, 2019

(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.

(b) The legal or beneficial owner of an exclusive right under a copyright is entitled, subject to the requirements of section 411, to institute an action for any infringement of that particular right committed while he or she is the owner of it. The court may require such owner to serve written notice of the action with a copy of the complaint upon any person shown, by the records of the Copyright Office or otherwise, to have or claim an interest in the copyright, and shall require that such notice be served upon any person whose interest is likely to be affected by a decision in the case. The court may require the joinder, and shall permit the intervention, of any

person having or claiming an interest in the copyright.

(c) For any secondary transmission by a cable system that embodies a performance or a display of a work which is actionable as an act of infringement under subsection (c) of section 111, a television broadcast station holding a copyright or other license to transmit or perform the same version of that work shall, for purposes of subsection (b) of this section, be treated as a legal or beneficial owner if such secondary transmission occurs within the local service area of that television station.

(d) For any secondary transmission by a cable system that is actionable as an act of infringement pursuant to section 111(c) (3), the following shall also have standing to sue: (i) the primary transmitter whose transmission has been altered by the cable system; and (ii) any broadcast station within whose local service area the secondary transmission occurs.

(e) With respect to any secondary transmission that is made by a satellite carrier of a performance or display of a work embodied in a primary transmission and is actionable as an act of infringement under section 119(a)(3), a network station holding a copyright or other license to transmit or perform the same version of that work shall, for purposes of subsection (b) of this section, be treated as a legal or beneficial owner if such secondary transmission occurs within the local service area of that station.

(f)(1) With respect to any secondary transmission that is made by a satellite carrier of a performance or display of a work embodied in a primary transmission and is actionable as an act of infringement under

section 122, a television broadcast station holding a copyright or other license to transmit or perform the same version of that work shall, for purposes of subsection (b) of this section, be treated as a legal or beneficial owner if such secondary transmission occurs within the local market of that station.

(2) A television broadcast station may file a civil action against any satellite carrier that has refused to carry television broadcast signals, as required under section 122(a)(2), to enforce that television broadcast station's rights under section 338(a) of the Communications Act of 1934.

21 U.S.C.A. § 355

§ 355. New drugs

Effective: October 24, 2018

(a) Necessity of effective approval of application

No person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application filed pursuant to subsection (b) or (j) is effective with respect to such drug.

(b) Filing application; contents

(1) Any person may file with the Secretary an application with respect to any drug subject to the provisions of subsection (a). Such person shall submit to the Secretary as a part of the application (A) full reports of investigations which have been made to show whether or not such drug is safe for use and whether such drug is effective in use; (B) a full list of the articles used as components of such drug; (C) a full statement of the composition of such drug; (D) a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug; (E) such samples of such drug and of the articles used as components thereof as the Secretary may require; (F) specimens of the labeling proposed to be used for such drug, and (G) any assessments required under section 355c of this title. The applicant shall file with the application the patent number and the expiration date of any patent which claims the drug for which the applicant submitted the application or which claims a method of using such drug and with

respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug. If an application is filed under this subsection for a drug and a patent which claims such drug or a method of using such drug is issued after the filing date but before approval of the application, the applicant shall amend the application to include the information required by the preceding sentence. Upon approval of the application, the Secretary shall publish information submitted under the two preceding sentences. The Secretary shall, in consultation with the Director of the National Institutes of Health and with representatives of the drug manufacturing industry, review and develop guidance, as appropriate, on the inclusion of women and minorities in clinical trials required by clause (A).

(2) An application submitted under paragraph (1) for a drug for which the investigations described in clause (A) of such paragraph and relied upon by the applicant for approval of the application were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted shall also include--

* * *

(A) information on design of the investigation and adequate reports of basic information, certified by the applicant to be accurate reports, necessary to assess the safety of the drug for use in clinical investigation; and

(B) adequate information on the chemistry and manufacturing of the drug, controls available for the drug, and primary data tabulations from animal or human studies.

(3)(A) At any time, the Secretary may prohibit the sponsor of an investigation from conducting the investigation (referred to in this paragraph as a "clinical hold") if the Secretary makes a determination described in subparagraph (B). The Secretary shall specify the basis for the clinical hold, including the specific information available to the Secretary which served as the basis for such clinical hold, and confirm such determination in writing.

(B) For purposes of subparagraph (A), a determination described in this subparagraph with respect to a clinical hold is that--

(i) the drug involved represents an unreasonable risk to the safety of the persons who are the subjects of the clinical investigation, taking into account the qualifications of the clinical investigators, information about the drug, the design of the clinical investigation, the condition for which the drug is to be investigated, and the health status of the subjects involved; or

(ii) the clinical hold should be issued for such other reasons as the Secretary may by regulation establish (including reasons established by regulation before November 21, 1997).

(C) Any written request to the Secretary from the sponsor of an investigation that a clinical hold be removed shall receive a decision, in

writing and specifying the reasons therefor, within 30 days after receipt of such request. Any such request shall include sufficient information to support the removal of such clinical hold.

(4) Regulations under paragraph (1) shall provide that such exemption shall be conditioned upon the manufacturer, or the sponsor of the investigation, requiring that experts using such drugs for investigational purposes certify to such manufacturer or sponsor that they will inform any human beings to whom such drugs, or any controls used in connection therewith, are being administered, or their representatives, that such drugs are being used for investigational purposes and will obtain the consent of such human beings or their representatives, except where it is not feasible, it is contrary to the best interests of such human beings, or the proposed clinical testing poses no more than minimal risk to such human beings and includes appropriate safeguards as prescribed to protect the rights, safety, and welfare of such human beings. Nothing in this subsection shall be construed to require any clinical investigator to submit directly to the Secretary reports on the investigational use of drugs. The Secretary shall update such regulations to require inclusion in the informed consent documents and process a statement that clinical trial information for such clinical investigation has been or will be submitted for inclusion in the registry data bank pursuant to subsection (j) of section 282 of Title 42.

(j) Abbreviated new drug applications

(1) Any person may file with the Secretary an abbreviated application for the approval of a new drug.

(2)(A) An abbreviated application for a new drug shall contain--

(i) information to show that the conditions of use prescribed, recommended, or suggested in the labeling proposed for the new drug have been previously approved for a drug listed under paragraph (7) (hereinafter in this subsection referred to as a "listed drug");

(ii)(I) if the listed drug referred to in clause (i) has only one active ingredient, information to show that the active ingredient of the new drug is the same as that of the listed drug;

(II) if the listed drug referred to in clause (i) has more than one active ingredient, information to show that the active ingredients of the new drug are the same as those of the listed drug, or

(III) if the listed drug referred to in clause (i) has more than one active ingredient and if one of the active ingredients of the new drug is different and the application is filed pursuant to the approval of a petition filed under subparagraph (C), information to show that the other active ingredients of the new drug are the same as the active

ingredients of the listed drug, information to show that the different active ingredient is an active ingredient of a listed drug or of a drug which does not meet the requirements of section 321(p) of this title, and such other information respecting the different active ingredient with respect to which the petition was filed as the Secretary may require;

(iii) information to show that the route of administration, the dosage form, and the strength of the new drug are the same as those of the listed drug referred to in clause (i) or, if the route of administration, the dosage form, or the strength of the new drug is different and the application is filed pursuant to the approval of a petition filed under subparagraph (C), such information respecting the route of administration, dosage form, or strength with respect to which the petition was filed as the Secretary may require;

(iv) information to show that the new drug is bioequivalent to the listed drug referred to in clause (i), except that if the application is filed pursuant to the approval of a petition filed under subparagraph (C), information to show that the active ingredients of the new drug are of the same pharmacological or therapeutic class as those of the listed drug referred to in clause (i) and the new drug can be expected to have the same therapeutic effect as the listed

drug when administered to patients for a condition of use referred to in clause (i);

(v) information to show that the labeling proposed for the new drug is the same as the labeling approved for the listed drug referred to in clause (i) except for changes required because of differences approved under a petition filed under subparagraph (C) or because the new drug and the listed drug are produced or distributed by different manufacturers;

(vi) the items specified in clauses (B) through (F) of subsection (b)(1);

(vii) a certification, in the opinion of the applicant and to the best of his knowledge, with respect to each patent which claims the listed drug referred to in clause (i) or which claims a use for such listed drug for which the applicant is seeking approval under this subsection and for which information is required to be filed under subsection (b) or (c)--

(I) that such patent information has not been filed,

(II) that such patent has expired,

(III) of the date on which such patent will expire, or

(IV) that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted; and

(viii) if with respect to the listed drug referred to in clause (i) information was filed under subsection (b) or (c) for a method of use patent which does not claim a use for which the applicant is seeking approval under this subsection, a statement that the method of use patent does not claim such a use.

The Secretary may not require that an abbreviated application contain information in addition to that required by clauses (i) through (viii).

(B) Notice of opinion that patent is invalid or will not be infringed

(i) Agreement to give notice

An applicant that makes a certification described in subparagraph (A)(vii)(IV) shall include in the application a statement that the applicant will give notice as required by this subparagraph.

(ii) Timing of notice

An applicant that makes a certification described in subparagraph (A)(vii)(IV) shall give notice as required under this subparagraph--

(I) if the certification is in the application, not later than 20 days after the date of the postmark on the notice with which the Secretary informs the applicant that the application has been filed; or

(II) if the certification is in an amendment or supplement to the application, at the time at which the applicant submits the amendment or supplement, regardless of whether the applicant has already given notice with respect to another such certification contained in the application or in an amendment or supplement to the application.

(iii) Recipients of notice

An applicant required under this subparagraph to give notice shall give notice to--

(I) each owner of the patent that is the subject of the certification (or a representative of the owner designated to receive such a notice); and

(II) the holder of the approved application under subsection (b) for the drug that is claimed by the patent or a use of which is claimed by the patent (or a representative of the holder designated to receive such a notice).

(iv) Contents of notice

A notice required under this subparagraph shall--

(I) state that an application that contains data from bioavailability or bioequivalence studies has been submitted under this subsection for the drug with respect to which the

certification is made to obtain approval to engage in the commercial manufacture, use, or sale of the drug before the expiration of the patent referred to in the certification; and

(II) include a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed.

(C) If a person wants to submit an abbreviated application for a new drug which has a different active ingredient or whose route of administration, dosage form, or strength differ from that of a listed drug, such person shall submit a petition to the Secretary seeking permission to file such an application. The Secretary shall approve or disapprove a petition submitted under this subparagraph within ninety days of the date the petition is submitted. The Secretary shall approve such a petition unless the Secretary finds--

(i) that investigations must be conducted to show the safety and effectiveness of the drug or of any of its active ingredients, the route of administration, the dosage form, or strength which differ from the listed drug; or

(ii) that any drug with a different active ingredient may not be adequately evaluated for approval as safe and effective on the basis of the information required to be submitted in an abbreviated application.

(D)(i) An applicant may not amend or supplement an application to seek approval of

a drug referring to a different listed drug from the listed drug identified in the application as submitted to the Secretary.

(ii) With respect to the drug for which an application is submitted, nothing in this subsection prohibits an applicant from amending or supplementing the application to seek approval of a different strength.

(iii) Within 60 days after December 8, 2003, the Secretary shall issue guidance defining the term "listed drug" for purposes of this subparagraph.

(3)(A) The Secretary shall issue guidance for the individuals who review applications submitted under paragraph (1), which shall relate to promptness in conducting the review, technical excellence, lack of bias and conflict of interest, and knowledge of regulatory and scientific standards, and which shall apply equally to all individuals who review such applications.

(B) The Secretary shall meet with a sponsor of an investigation or an applicant for approval for a drug under this subsection if the sponsor or applicant makes a reasonable written request for a meeting for the purpose of reaching agreement on the design and size of bioavailability and bioequivalence studies needed for approval of such application. The sponsor or applicant shall provide information necessary for discussion and agreement on the design and size of such studies. Minutes of any such meeting shall be prepared by the

Secretary and made available to the sponsor or applicant.

(C) Any agreement regarding the parameters of design and size of bioavailability and bioequivalence studies of a drug under this paragraph that is reached between the Secretary and a sponsor or applicant shall be reduced to writing and made part of the administrative record by the Secretary. Such agreement shall not be changed after the testing begins, except--

> **(i)** with the written agreement of the sponsor or applicant; or
>
> **(ii)** pursuant to a decision, made in accordance with subparagraph (D) by the director of the reviewing division, that a substantial scientific issue essential to determining the safety or effectiveness of the drug has been identified after the testing has begun.

(D) A decision under subparagraph (C)(ii) by the director shall be in writing and the Secretary shall provide to the sponsor or applicant an opportunity for a meeting at which the director and the sponsor or applicant will be present and at which the director will document the scientific issue involved.

(E) The written decisions of the reviewing division shall be binding upon, and may not directly or indirectly be changed by, the field or compliance office personnel unless such field or compliance office personnel demonstrate to the

reviewing division why such decision should be modified.

(F) No action by the reviewing division may be delayed because of the unavailability of information from or action by field personnel unless the reviewing division determines that a delay is necessary to assure the marketing of a safe and effective drug.

(G) For purposes of this paragraph, the reviewing division is the division responsible for the review of an application for approval of a drug under this subsection (including scientific matters, chemistry, manufacturing, and controls).

(4) Subject to paragraph (5), the Secretary shall approve an application for a drug unless the Secretary finds--

(A) the methods used in, or the facilities and controls used for, the manufacture, processing, and packing of the drug are inadequate to assure and preserve its identity, strength, quality, and purity;

(B) information submitted with the application is insufficient to show that each of the proposed conditions of use have been previously approved for the listed drug referred to in the application;

(C)(i) if the listed drug has only one active ingredient, information submitted with the application is insufficient to show that the active ingredient is the same as that of the listed drug;

(ii) if the listed drug has more than one active ingredient, information submitted with the application is insufficient to show that the active ingredients are the same as the active ingredients of the listed drug, or

(iii) if the listed drug has more than one active ingredient and if the application is for a drug which has an active ingredient different from the listed drug, information submitted with the application is insufficient to show--

(I) that the other active ingredients are the same as the active ingredients of the listed drug, or

(II) that the different active ingredient is an active ingredient of a listed drug or a drug which does not meet the requirements of section 321(p) of this title,

or no petition to file an application for the drug with the different ingredient was approved under paragraph (2)(C);

(D)(i) if the application is for a drug whose route of administration, dosage form, or strength of the drug is the same as the route of administration, dosage form, or strength of the listed drug referred to in the application, information submitted in the application is insufficient to show that the route of administration, dosage form, or strength is the same as that of the listed drug, or

(ii) if the application is for a drug whose route of administration, dosage form, or

strength of the drug is different from that of the listed drug referred to in the application, no petition to file an application for the drug with the different route of administration, dosage form, or strength was approved under paragraph (2)(C);

(E) if the application was filed pursuant to the approval of a petition under paragraph (2)(C), the application did not contain the information required by the Secretary respecting the active ingredient, route of administration, dosage form, or strength which is not the same;

(F) information submitted in the application is insufficient to show that the drug is bioequivalent to the listed drug referred to in the application or, if the application was filed pursuant to a petition approved under paragraph (2)(C), information submitted in the application is insufficient to show that the active ingredients of the new drug are of the same pharmacological or therapeutic class as those of the listed drug referred to in paragraph (2)(A)(i) and that the new drug can be expected to have the same therapeutic effect as the listed drug when administered to patients for a condition of use referred to in such paragraph;

(G) information submitted in the application is insufficient to show that the labeling proposed for the drug is the same as the labeling approved for the listed drug referred to in the application except for changes required because of differences approved under a petition filed under paragraph (2)(C) or because the drug

and the listed drug are produced or distributed by different manufacturers;

(H) information submitted in the application or any other information available to the Secretary shows that (i) the inactive ingredients of the drug are unsafe for use under the conditions prescribed, recommended, or suggested in the labeling proposed for the drug, or (ii) the composition of the drug is unsafe under such conditions because of the type or quantity of inactive ingredients included or the manner in which the inactive ingredients are included;

(I) the approval under subsection (c) of the listed drug referred to in the application under this subsection has been withdrawn or suspended for grounds described in the first sentence of subsection (e), the Secretary has published a notice of opportunity for hearing to withdraw approval of the listed drug under subsection (c) for grounds described in the first sentence of subsection (e), the approval under this subsection of the listed drug referred to in the application under this subsection has been withdrawn or suspended under paragraph (6), or the Secretary has determined that the listed drug has been withdrawn from sale for safety or effectiveness reasons;

(J) the application does not meet any other requirement of paragraph (2)(A); or

(K) the application contains an untrue statement of material fact.

(5)(A) Within one hundred and eighty days of the initial receipt of an application under paragraph

(2) or within such additional period as may be agreed upon by the Secretary and the applicant, the Secretary shall approve or disapprove the application.

(B) The approval of an application submitted under paragraph (2) shall be made effective on the last applicable date determined by applying the following to each certification made under paragraph (2)(A)(vii):

(i) If the applicant only made a certification described in subclause (I) or (II) of paragraph (2)(A)(vii) or in both such subclauses, the approval may be made effective immediately.

(ii) If the applicant made a certification described in subclause (III) of paragraph (2)(A)(vii), the approval may be made effective on the date certified under subclause (III).

(iii) If the applicant made a certification described in subclause (IV) of paragraph (2)(A)(vii), the approval shall be made effective immediately unless, before the expiration of 45 days after the date on which the notice described in paragraph (2)(B) is received, an action is brought for infringement of the patent that is the subject of the certification and for which information was submitted to the Secretary under subsection (b)(1) or (c)(2) before the date on which the application (excluding an amendment or supplement to the application), which the Secretary later

determines to be substantially complete, was submitted. If such an action is brought before the expiration of such days, the approval shall be made effective upon the expiration of the thirty-month period beginning on the date of the receipt of the notice provided under paragraph (2)(B)(i) or such shorter or longer period as the court may order because either party to the action failed to reasonably cooperate in expediting the action, except that--

(I) if before the expiration of such period the district court decides that the patent is invalid or not infringed (including any substantive determination that there is no cause of action for patent infringement or invalidity), the approval shall be made effective on--

(aa) the date on which the court enters judgment reflecting the decision; or

(bb) the date of a settlement order or consent decree signed and entered by the court stating that the patent that is the subject of the certification is invalid or not infringed;

(II) if before the expiration of such period the district court decides that the patent has been infringed--

(aa) if the judgment of the district court is appealed, the approval shall be made effective on--

(AA) the date on which the court of appeals decides that the patent is invalid or not infringed (including any substantive determination that there is no cause of action for patent infringement or invalidity); or

(BB) the date of a settlement order or consent decree signed and entered by the court of appeals stating that the patent that is the subject of the certification is invalid or not infringed; or

(bb) if the judgment of the district court is not appealed or is affirmed, the approval shall be made effective on the date specified by the district court in a court order under section 271(e)(4)(A) of Title 35;

(III) if before the expiration of such period the court grants a preliminary injunction prohibiting the applicant from engaging in the commercial manufacture or sale of the drug until the court decides the issues of patent validity and infringement and if the court decides that such patent is invalid or not infringed, the approval shall be made effective as provided in subclause (I); or

(IV) if before the expiration of such period the court grants a preliminary

injunction prohibiting the applicant from engaging in the commercial manufacture or sale of the drug until the court decides the issues of patent validity and infringement and if the court decides that such patent has been infringed, the approval shall be made effective as provided in subclause (II).

In such an action, each of the parties shall reasonably cooperate in expediting the action.

(iv) 180-day exclusivity period

(I) Effectiveness of application

Subject to subparagraph (D), if the application contains a certification described in paragraph (2)(A)(vii)(IV) and is for a drug for which a first applicant has submitted an application containing such a certification, the application shall be made effective on the date that is 180 days after the date of the first commercial marketing of the drug (including the commercial marketing of the listed drug) by any first applicant.

(II) Definitions

In this paragraph:

(aa) 180-day exclusivity period

The term "180-day exclusivity period" means the 180-day period ending on the day before the date on which an

application submitted by an applicant other than a first applicant could become effective under this clause.

(bb) First applicant

As used in this subsection, the term "first applicant" means an applicant that, on the first day on which a substantially complete application containing a certification described in paragraph (2)(A)(vii)(IV) is submitted for approval of a drug, submits a substantially complete application that contains and lawfully maintains a certification described in paragraph (2)(A)(vii)(IV) for the drug.

(cc) Substantially complete application

As used in this subsection, the term "substantially complete application" means an application under this subsection that on its face is sufficiently complete to permit a substantive review and contains all the information required by paragraph (2)(A).

(dd) Tentative approval

(AA) In general

The term "tentative approval" means notification to an applicant by the Secretary that an application under this subsection

meets the requirements of paragraph (2)(A), but cannot receive effective approval because the application does not meet the requirements of this subparagraph, there is a period of exclusivity for the listed drug under subparagraph (F) or section 355a of this title, or there is a 7-year period of exclusivity for the listed drug under section 360cc of this title.

(BB) Limitation

A drug that is granted tentative approval by the Secretary is not an approved drug and shall not have an effective approval until the Secretary issues an approval after any necessary additional review of the application.

(v) 180-day exclusivity period for competitive generic therapies

(I) Effectiveness of application

Subject to subparagraph (D)(iv), if the application is for a drug that is the same as a competitive generic therapy for which any first approved applicant has commenced commercial marketing, the application shall be made effective on the date that is 180 days after the date of the first commercial marketing of the competitive generic therapy (including the commercial marketing of the listed drug) by any first approved applicant.

(II) Limitation

The exclusivity period under subclause (I) shall not apply with respect to a competitive generic therapy that has previously received an exclusivity period under subclause (I).

(III) Definitions

In this clause and subparagraph (D)(iv):

(aa) The term "competitive generic therapy" means a drug--

(AA) that is designated as a competitive generic therapy under section 356h of this title; and

(BB) for which there are no unexpired patents or exclusivities on the list of products described in section 355(j) (7)(A) of this title at the time of submission.

(bb) The term "first approved applicant" means any applicant that has submitted an application that--

(AA) is for a competitive generic therapy that is approved on the first day on which any application for such competitive generic therapy is approved;

(BB) is not eligible for a 180-day exclusivity period under clause (iv) for the drug that is the subject of the application for the competitive generic therapy; and

(CC) is not for a drug for which all drug versions have forfeited eligibility for a 180-day exclusivity period under clause (iv) pursuant to subparagraph (D).

(C) Civil action to obtain patent certainty

(i) Declaratory judgment absent infringement action

(I) In general

No action may be brought under section 2201 of Title 28, by an applicant under paragraph (2) for a declaratory judgment with respect to a patent which is the subject of the certification referred to in subparagraph (B)(iii) unless--

(aa) the 45-day period referred to in such subparagraph has expired;

(bb) neither the owner of such patent nor the holder of the approved application under subsection (b) for the drug that is claimed by the patent or a use of which is claimed by the patent brought a civil action against the applicant for infringement of the patent before the expiration of such period; and

(cc) in any case in which the notice provided under paragraph (2)(B) relates to noninfringement, the notice was accompanied by a document described in subclause (III).

(II) Filing of civil action

If the conditions described in items (aa), (bb), and as applicable, (cc) of subclause (I) have been met, the applicant referred to in such subclause may, in accordance with section 2201 of Title 28, bring a civil action under such section against the owner or holder referred to in such subclause (but not against any owner or holder that has brought such a civil action against the applicant, unless that civil action was dismissed without prejudice) for a declaratory judgment that the patent is invalid or will not be infringed by the drug for which the applicant seeks approval, except that such civil action may be brought for a declaratory judgment that the patent will not be infringed only in a case in which the condition described in subclause (I)(cc) is applicable. A civil action referred to in this subclause shall be brought in the judicial district where the defendant has its principal place of business or a regular and established place of business.

(III) Offer of confidential access to application

For purposes of subclause (I)(cc), the document described in this subclause is a document providing an offer of confidential access to the application that is in the custody of the applicant under paragraph (2) for the purpose of

determining whether an action referred to in subparagraph (B)(iii) should be brought. The document providing the offer of confidential access shall contain such restrictions as to persons entitled to access, and on the use and disposition of any information accessed, as would apply had a protective order been entered for the purpose of protecting trade secrets and other confidential business information. A request for access to an application under an offer of confidential access shall be considered acceptance of the offer of confidential access with the restrictions as to persons entitled to access, and on the use and disposition of any information accessed, contained in the offer of confidential access, and those restrictions and other terms of the offer of confidential access shall be considered terms of an enforceable contract. Any person provided an offer of confidential access shall review the application for the sole and limited purpose of evaluating possible infringement of the patent that is the subject of the certification under paragraph (2)(A)(vii)(IV) and for no other purpose, and may not disclose information of no relevance to any issue of patent infringement to any person other than a person provided an offer of confidential access. Further, the application may be redacted by the applicant to remove any

information of no relevance to any issue of patent infringement.

(ii) Counterclaim to infringement action

(I) In general

If an owner of the patent or the holder of the approved application under subsection (b) for the drug that is claimed by the patent or a use of which is claimed by the patent brings a patent infringement action against the applicant, the applicant may assert a counterclaim seeking an order requiring the holder to correct or delete the patent information submitted by the holder under subsection (b) or (c) on the ground that the patent does not claim either--

(aa) the drug for which the application was approved; or

(bb) an approved method of using the drug.

(II) No independent cause of action

Subclause (I) does not authorize the assertion of a claim described in subclause (I) in any civil action or proceeding other than a counterclaim described in subclause (I).

(iii) No damages

An applicant shall not be entitled to damages in a civil action under clause (i) or a counterclaim under clause (ii).

(D) Forfeiture of 180-day exclusivity period

(i) Definition of forfeiture event

In this subparagraph, the term "forfeiture event", with respect to an application under this subsection, means the occurrence of any of the following:

(I) Failure to market

The first applicant fails to market the drug by the later of--

(aa) the earlier of the date that is--

(AA) 75 days after the date on which the approval of the application of the first applicant is made effective under subparagraph (B)(iii); or

(BB) 30 months after the date of submission of the application of the first applicant; or

(bb) with respect to the first applicant or any other applicant (which other applicant has received tentative approval), the date that is 75 days after the date as of which, as to each of the patents with respect to which the first applicant submitted and lawfully maintained a certification qualifying the first applicant for the 180-day exclusivity period under subparagraph (B)(iv), at least 1 of the following has occurred:

(AA) In an infringement action brought against that applicant with respect to the patent or in a declaratory judgment action brought by that applicant with respect to the patent, a court enters a final decision from which no appeal (other than a petition to the Supreme Court for a writ of certiorari) has been or can be taken that the patent is invalid or not infringed.

(BB) In an infringement action or a declaratory judgment action described in subitem (AA), a court signs a settlement order or consent decree that enters a final judgment that includes a finding that the patent is invalid or not infringed.

(CC) The patent information submitted under subsection (b) or (c) is withdrawn by the holder of the application approved under subsection (b).

(II) Withdrawal of application

The first applicant withdraws the application or the Secretary considers the application to have been withdrawn as a result of a determination by the Secretary that the application does not meet the requirements for approval under paragraph (4).

(III) Amendment of certification

The first applicant amends or withdraws the certification for all of the patents with respect to which that applicant submitted a certification qualifying the applicant for the 180-day exclusivity period.

(IV) Failure to obtain tentative approval

The first applicant fails to obtain tentative approval of the application within 30 months after the date on which the application is filed, unless the failure is caused by a change in or a review of the requirements for approval of the application imposed after the date on which the application is filed.

(V) Agreement with another applicant, the listed drug application holder, or a patent owner

The first applicant enters into an agreement with another applicant under this subsection for the drug, the holder of the application for the listed drug, or an owner of the patent that is the subject of the certification under paragraph (2)(A)(vii)(IV), the Federal Trade Commission or the Attorney General files a complaint, and there is a final decision of the Federal Trade Commission or the court with regard to the complaint from which no appeal (other than a petition to the Supreme

Court for a writ of certiorari) has been or can be taken that the agreement has violated the antitrust laws (as defined in section 12 of Title 15, except that the term includes section 45 of Title 15 to the extent that that section applies to unfair methods of competition).

(VI) Expiration of all patents

All of the patents as to which the applicant submitted a certification qualifying it for the 180-day exclusivity period have expired.

(ii) Forfeiture

The 180-day exclusivity period described in subparagraph (B)(iv) shall be forfeited by a first applicant if a forfeiture event occurs with respect to that first applicant.

(iii) Subsequent applicant

If all first applicants forfeit the 180-day exclusivity period under clause (ii)--

(I) approval of any application containing a certification described in paragraph (2)(A)(vii)(IV) shall be made effective in accordance with subparagraph (B)(iii); and

(II) no applicant shall be eligible for a 180-day exclusivity period.

(iv) Special forfeiture rule for competitive generic therapy

The 180-day exclusivity period described in subparagraph (B)(v) shall be forfeited by a

first approved applicant if the applicant fails to market the competitive generic therapy within 75 days after the date on which the approval of the first approved applicant's application for the competitive generic therapy is made effective.

(E) If the Secretary decides to disapprove an application, the Secretary shall give the applicant notice of an opportunity for a hearing before the Secretary on the question of whether such application is approvable. If the applicant elects to accept the opportunity for hearing by written request within thirty days after such notice, such hearing shall commence not more than ninety days after the expiration of such thirty days unless the Secretary and the applicant otherwise agree. Any such hearing shall thereafter be conducted on an expedited basis and the Secretary's order thereon shall be issued within ninety days after the date fixed by the Secretary for filing final briefs.

(F)(i) If an application (other than an abbreviated new drug application) submitted under subsection (b) for a drug, no active ingredient (including any ester or salt of the active ingredient) of which has been approved in any other application under subsection (b), was approved during the period beginning January 1, 1982, and ending on September 24, 1984, the Secretary may not make the approval of an application submitted under this subsection which refers to the drug for which the subsection (b) application was submitted effective before the expiration of ten years from

the date of the approval of the application under subsection (b).

(ii) If an application submitted under subsection (b) for a drug, no active ingredient (including any ester or salt of the active ingredient) of which has been approved in any other application under subsection (b), is approved after September 24, 1984, no application may be submitted under this subsection which refers to the drug for which the subsection (b) application was submitted before the expiration of five years from the date of the approval of the application under subsection (b), except that such an application may be submitted under this subsection after the expiration of four years from the date of the approval of the subsection (b) application if it contains a certification of patent invalidity or noninfringement described in subclause (IV) of paragraph (2)(A)(vii). The approval of such an application shall be made effective in accordance with subparagraph (B) except that, if an action for patent infringement is commenced during the one-year period beginning forty-eight months after the date of the approval of the subsection (b) application, the thirty-month period referred to in subparagraph (B)(iii) shall be extended by such amount of time (if any) which is required for seven and one-half years to have elapsed from the date of approval of the subsection (b) application.

(iii) If an application submitted under subsection (b) for a drug, which includes an active ingredient (including any ester or salt of the active ingredient) that has been approved in another application approved under subsection (b), is approved after September 24, 1984, and if such application contains reports of new clinical investigations (other than bioavailability studies) essential to the approval of the application and conducted or sponsored by the applicant, the Secretary may not make the approval of an application submitted under this subsection for the conditions of approval of such drug in the subsection (b) application effective before the expiration of three years from the date of the approval of the application under subsection (b) for such drug.

(iv) If a supplement to an application approved under subsection (b) is approved after September 24, 1984, and the supplement contains reports of new clinical investigations (other than bioavailability studies) essential to the approval of the supplement and conducted or sponsored by the person submitting the supplement, the Secretary may not make the approval of an application submitted under this subsection for a change approved in the supplement effective before the expiration of three years from the date of the approval of the supplement under subsection (b).

(v) If an application (or supplement to an application) submitted under subsection (b) for a drug, which includes an active ingredient (including any ester or salt of the active ingredient) that has been approved in another application under subsection (b), was approved during the period beginning January 1, 1982, and ending on September 24, 1984, the Secretary may not make the approval of an application submitted under this subsection which refers to the drug for which the subsection (b) application was submitted or which refers to a change approved in a supplement to the subsection (b) application effective before the expiration of two years from September 24, 1984.

(6) If a drug approved under this subsection refers in its approved application to a drug the approval of which was withdrawn or suspended for grounds described in the first sentence of subsection (e) or was withdrawn or suspended under this paragraph or which, as determined by the Secretary, has been withdrawn from sale for safety or effectiveness reasons, the approval of the drug under this subsection shall be withdrawn or suspended--

(A) for the same period as the withdrawal or suspension under subsection (e) or this paragraph, or

(B) if the listed drug has been withdrawn from sale, for the period of withdrawal from sale or, if earlier, the period ending on the date the

Secretary determines that the withdrawal from sale is not for safety or effectiveness reasons.

(7)(A)(i) Within sixty days of September 24, 1984, the Secretary shall publish and make available to the public--

(I) a list in alphabetical order of the official and proprietary name of each drug which has been approved for safety and effectiveness under subsection (c) before September 24, 1984;

(II) the date of approval if the drug is approved after 1981 and the number of the application which was approved; and

(III) whether in vitro or in vivo bioequivalence studies, or both such studies, are required for applications filed under this subsection which will refer to the drug published.

(ii) Every thirty days after the publication of the first list under clause (i) the Secretary shall revise the list to include each drug which has been approved for safety and effectiveness under subsection (c) or approved under this subsection during the thirty-day period.

(iii) When patent information submitted under subsection (b) or (c) respecting a drug included on the list is to be published by the Secretary, the Secretary shall, in revisions made under clause (ii), include such information for such drug.

(B) A drug approved for safety and effectiveness under subsection (c) or approved under this subsection shall, for purposes of this subsection, be considered to have been published under subparagraph (A) on the date of its approval or September 24, 1984, whichever is later.

(C) If the approval of a drug was withdrawn or suspended for grounds described in the first sentence of subsection (e) or was withdrawn or suspended under paragraph (6) or if the Secretary determines that a drug has been withdrawn from sale for safety or effectiveness reasons, it may not be published in the list under subparagraph (A) or, if the withdrawal or suspension occurred after its publication in such list, it shall be immediately removed from such list--

(i) for the same period as the withdrawal or suspension under subsection (e) or paragraph (6), or

(ii) if the listed drug has been withdrawn from sale, for the period of withdrawal from sale or, if earlier, the period ending on the date the Secretary determines that the withdrawal from sale is not for safety or effectiveness reasons.

A notice of the removal shall be published in the Federal Register.

(8) For purposes of this subsection:

(A)(i) The term "bioavailability" means the rate and extent to which the active ingredient

or therapeutic ingredient is absorbed from a drug and becomes available at the site of drug action.

(ii) For a drug that is not intended to be absorbed into the bloodstream, the Secretary may assess bioavailability by scientifically valid measurements intended to reflect the rate and extent to which the active ingredient or therapeutic ingredient becomes available at the site of drug action.

(B) A drug shall be considered to be bioequivalent to a listed drug if--

(i) the rate and extent of absorption of the drug do not show a significant difference from the rate and extent of absorption of the listed drug when administered at the same molar dose of the therapeutic ingredient under similar experimental conditions in either a single dose or multiple doses; or

(ii) the extent of absorption of the drug does not show a significant difference from the extent of absorption of the listed drug when administered at the same molar dose of the therapeutic ingredient under similar experimental conditions in either a single dose or multiple doses and the difference from the listed drug in the rate of absorption of the drug is intentional, is reflected in its proposed labeling, is not essential to the attainment of effective body drug concentrations on chronic use, and is considered medically insignificant for the drug.

(C) For a drug that is not intended to be absorbed into the bloodstream, the Secretary may establish alternative, scientifically valid methods to show bioequivalence if the alternative methods are expected to detect a significant difference between the drug and the listed drug in safety and therapeutic effect.

(9) The Secretary shall, with respect to each application submitted under this subsection, maintain a record of--

(A) the name of the applicant,

(B) the name of the drug covered by the application,

(C) the name of each person to whom the review of the chemistry of the application was assigned and the date of such assignment, and

(D) the name of each person to whom the bioequivalence review for such application was assigned and the date of such assignment.

The information the Secretary is required to maintain under this paragraph with respect to an application submitted under this subsection shall be made available to the public after the approval of such application.

(10)(A) If the proposed labeling of a drug that is the subject of an application under this subsection differs from the listed drug due to a labeling revision described under clause (i), the drug that is the subject of such application shall, notwithstanding any other provision of this chapter, be eligible for approval and shall not be

considered misbranded under section 352 of this title if--

(i) the application is otherwise eligible for approval under this subsection but for expiration of patent, an exclusivity period, or of a delay in approval described in paragraph (5)(B)(iii), and a revision to the labeling of the listed drug has been approved by the Secretary within 60 days of such expiration;

(ii) the labeling revision described under clause (i) does not include a change to the "Warnings" section of the labeling;

(iii) the sponsor of the application under this subsection agrees to submit revised labeling of the drug that is the subject of such application not later than 60 days after the notification of any changes to such labeling required by the Secretary; and

(iv) such application otherwise meets the applicable requirements for approval under this subsection.

(B) If, after a labeling revision described in subparagraph (A)(i), the Secretary determines that the continued presence in interstate commerce of the labeling of the listed drug (as in effect before the revision described in subparagraph (A)(i)) adversely impacts the safe use of the drug, no application under this subsection shall be eligible for approval with such labeling.

(11)(A) Subject to subparagraph (B), the Secretary shall prioritize the review of, and act

within 8 months of the date of the submission of, an original abbreviated new drug application submitted for review under this subsection that is for a drug--

> **(i)** for which there are not more than 3 approved drug products listed under paragraph (7) and for which there are no blocking patents and exclusivities; or
>
> **(ii)** that has been included on the list under section 356e of this title.

(B) To qualify for priority review under this paragraph, not later than 60 days prior to the submission of an application described in subparagraph (A) or that the Secretary may prioritize pursuant to subparagraph (D), the applicant shall provide complete, accurate information regarding facilities involved in manufacturing processes and testing of the drug that is the subject of the application, including facilities in corresponding Type II active pharmaceutical ingredients drug master files referenced in an application and sites or organizations involved in bioequivalence and clinical studies used to support the application, to enable the Secretary to make a determination regarding whether an inspection of a facility is necessary. Such information shall include the relevant (as determined by the Secretary) sections of such application, which shall be unchanged relative to the date of the submission of such application, except to the extent that a change is made to such information to exclude a facility that was not used to generate data to meet any

application requirements for such submission and that is not the only facility intended to conduct one or more unit operations in commercial production. Information provided by an applicant under this subparagraph shall not be considered the submission of an application under this subsection.

(C) The Secretary may expedite an inspection or reinspection under section 374 of this title of an establishment that proposes to manufacture a drug described in subparagraph (A).

(D) Nothing in this paragraph shall prevent the Secretary from prioritizing the review of other applications as the Secretary determines appropriate.

(12) The Secretary shall publish on the internet website of the Food and Drug Administration, and update at least once every 6 months, a list of all drugs approved under subsection (c) for which all patents and periods of exclusivity under this chapter have expired and for which no application has been approved under this subsection.

(13) Upon the request of an applicant regarding one or more specified pending applications under this subsection, the Secretary shall, as appropriate, provide review status updates indicating the categorical status of the applications by each relevant review discipline.

(k) Records and reports; required information; regulations and orders; access to records

(1) In the case of any drug for which an approval of an application filed under subsection (b) or (j) is in effect, the applicant shall establish and

maintain such records, and make such reports to the Secretary, of data relating to clinical experience and other data or information, received or otherwise obtained by such applicant with respect to such drug, as the Secretary may by general regulation, or by order with respect to such application, prescribe on the basis of a finding that such records and reports are necessary in order to enable the Secretary to determine, or facilitate a determination, whether there is or may be ground for invoking subsection (e). Regulations and orders issued under this subsection and under subsection (i) shall have due regard for the professional ethics of the medical profession and the interests of patients and shall provide, where the Secretary deems it to be appropriate, for the examination, upon request, by the persons to whom such regulations or orders are applicable, of similar information received or otherwise obtained by the Secretary.

(2) Every person required under this section to maintain records, and every person in charge or custody thereof, shall, upon request of an officer or employee designated by the Secretary, permit such officer or employee at all reasonable times to have access to and copy and verify such records.

* * *

35 U.S.C.A. § 271

§ 271. Infringement of patent

Effective: March 23, 2010

(a) Except as otherwise provided in this title, whoever without authority makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States any patented invention during the term of the patent therefor, infringes the patent.

(b) Whoever actively induces infringement of a patent shall be liable as an infringer.

(c) Whoever offers to sell or sells within the United States or imports into the United States a component of a patented machine, manufacture, combination or composition, or a material or apparatus for use in practicing a patented process, constituting a material part of the invention, knowing the same to be especially made or especially adapted for use in an infringement of such patent, and not a staple article or commodity of commerce suitable for substantial noninfringing use, shall be liable as a contributory infringer.

(d) No patent owner otherwise entitled to relief for infringement or contributory infringement of a patent shall be denied relief or deemed guilty of misuse or illegal extension of the patent right by reason of his having done one or more of the following: (1) derived revenue from acts which if performed by another without his consent would constitute contributory infringement of the patent; (2) licensed or authorized another to perform acts which if performed without his consent would constitute contributory infringement of

the patent; (3) sought to enforce his patent rights against infringement or contributory infringement; (4) refused to license or use any rights to the patent; or (5) conditioned the license of any rights to the patent or the sale of the patented product on the acquisition of a license to rights in another patent or purchase of a separate product, unless, in view of the circumstances, the patent owner has market power in the relevant market for the patent or patented product on which the license or sale is conditioned.

(e)(1) It shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention (other than a new animal drug or veterinary biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act and the Act of March 4, 1913) which is primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology, or other processes involving site specific genetic manipulation techniques) solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products.

(2) It shall be an act of infringement to submit--

(A) an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act or described in section 505(b)(2) of such Act for a drug claimed in a patent or the use of which is claimed in a patent,

(B) an application under section 512 of such Act or under the Act of March 4, 1913 (21 U.S.C. 151-158) for a drug or veterinary

biological product which is not primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology, or other processes involving site specific genetic manipulation techniques and which is claimed in a patent or the use of which is claimed in a patent, or

(C)(i) with respect to a patent that is identified in the list of patents described in section 351(l)(3) of the Public Health Service Act (including as provided under section 351(l)(7) of such Act), an application seeking approval of a biological product, or

(ii) if the applicant for the application fails to provide the application and information required under section 351(l)(2)(A) of such Act, an application seeking approval of a biological product for a patent that could be identified pursuant to section 351(l)(3)(A)(i) of such Act,

if the purpose of such submission is to obtain approval under such Act to engage in the commercial manufacture, use, or sale of a drug, veterinary biological product, or biological product claimed in a patent or the use of which is claimed in a patent before the expiration of such patent.

(3) In any action for patent infringement brought under this section, no injunctive or other relief may be granted which would prohibit the making, using, offering to sell, or selling within the United States or importing into the United States of a patented invention under paragraph (1).

(4) For an act of infringement described in paragraph (2)--

(A) the court shall order the effective date of any approval of the drug or veterinary biological product involved in the infringement to be a date which is not earlier than the date of the expiration of the patent which has been infringed,

(B) injunctive relief may be granted against an infringer to prevent the commercial manufacture, use, offer to sell, or sale within the United States or importation into the United States of an approved drug, veterinary biological product, or biological product,

(C) damages or other monetary relief may be awarded against an infringer only if there has been commercial manufacture, use, offer to sell, or sale within the United States or importation into the United States of an approved drug, veterinary biological product, or biological product, and

(D) the court shall order a permanent injunction prohibiting any infringement of the patent by the biological product involved in the infringement until a date which is not earlier than the date of the expiration of the patent that has been infringed under paragraph (2)(C), provided the patent is the subject of a final court decision, as defined in section 351(k)(6) of the Public Health Service Act, in an action for infringement of the patent under section 351(l)(6) of such Act, and the biological

product has not yet been approved because of section 351(k)(7) of such Act.

The remedies prescribed by subparagraphs (A), (B), (C), and (D) are the only remedies which may be granted by a court for an act of infringement described in paragraph (2), except that a court may award attorney fees under section 285.

(5) Where a person has filed an application described in paragraph (2) that includes a certification under subsection (b)(2)(A) (iv) or (j)(2)(A)(vii)(IV) of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355), and neither the owner of the patent that is the subject of the certification nor the holder of the approved application under subsection (b) of such section for the drug that is claimed by the patent or a use of which is claimed by the patent brought an action for infringement of such patent before the expiration of 45 days after the date on which the notice given under subsection (b)(3) or (j)(2)(B) of such section was received, the courts of the United States shall, to the extent consistent with the Constitution, have subject matter jurisdiction in any action brought by such person under section 2201 of title 28 for a declaratory judgment that such patent is invalid or not infringed.

(6)(A) Subparagraph (B) applies, in lieu of paragraph (4), in the case of a patent--

> **(i)** that is identified, as applicable, in the list of patents described in section 351(l)(4) of the Public Health Service Act or the lists of patents described in section 351(l)(5)(B)

of such Act with respect to a biological product; and

(ii) for which an action for infringement of the patent with respect to the biological product--

(I) was brought after the expiration of the 30-day period described in subparagraph (A) or (B), as applicable, of section 351(l)(6) of such Act; or

(II) was brought before the expiration of the 30-day period described in subclause (I), but which was dismissed without prejudice or was not prosecuted to judgment in good faith.

(B) In an action for infringement of a patent described in subparagraph (A), the sole and exclusive remedy that may be granted by a court, upon a finding that the making, using, offering to sell, selling, or importation into the United States of the biological product that is the subject of the action infringed the patent, shall be a reasonable royalty.

(C) The owner of a patent that should have been included in the list described in section 351(l)(3)(A) of the Public Health Service Act, including as provided under section 351(l)(7) of such Act for a biological product, but was not timely included in such list, may not bring an action under this section for infringement of the patent with respect to the biological product.

(f)(1) Whoever without authority supplies or causes to be supplied in or from the United States all or a substantial portion of the components of a patented invention, where such components are uncombined in whole or in part, 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, shall be liable as an infringer.

(2) Whoever without authority supplies or causes to be supplied in or from the United States any component of a patented invention that is especially made or especially adapted for use in the invention and not a staple article or commodity of commerce suitable for substantial noninfringing use, where such component is uncombined in whole or in part, knowing that such component is so made or adapted and intending that such component will be combined outside of the United States in a manner that would infringe the patent if such combination occurred within the United States, shall be liable as an infringer.

(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. In an action for infringement of a process patent, no remedy may be granted for infringement on account of the noncommercial use or retail sale of a product unless there is no adequate remedy under this title for infringement on account of the importation or other use, offer to sell, or sale of that

product. A product which is made by a patented process will, for purposes of this title, not be considered to be so made after--

(1) it is materially changed by subsequent processes; or

(2) it becomes a trivial and nonessential component of another product.

(h) As used in this section, the term "whoever" includes any State, any instrumentality of a State, and any officer or employee of a State or instrumentality of a State acting in his 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.

(i) As used in this section, an "offer for sale" or an "offer to sell" by a person other than the patentee, or any designee of the patentee, is that in which the sale will occur before the expiration of the term of the patent.

35 U.S.C.A. § 287

§ 287. Limitation on damages and other remedies; marking and notice

(a) Patentees, and persons making, offering for sale, or selling within the United States any patented article for or under them, or importing any patented article into the United States, may give notice to the public that the same is patented, either by fixing thereon the word "patent" or the abbreviation "pat.", together with the number of the patent, or by fixing thereon the word "patent" or the abbreviation "pat." together with an address of a posting on the Internet, accessible to the public without charge for accessing the address, that associates the patented article with the number of the patent, or when, from the character of the article, this can not be done, by fixing to it, or to the package wherein one or more of them is contained, a label containing a like notice. In the event of failure so to mark, no damages shall be recovered by the patentee in any action for infringement, except on proof that the infringer was notified of the infringement and continued to infringe thereafter, in which event damages may be recovered only for infringement occurring after such notice. Filing of an action for infringement shall constitute such notice.

(b)(1) An infringer under section 271(g) shall be subject to all the provisions of this title relating to damages and injunctions except to the extent those remedies are modified by this subsection or section 9006 of the Process Patent Amendments Act of 1988. The modifications of remedies provided in this subsection shall not be available to any person who--

(A) practiced the patented process;

(B) owns or controls, or is owned or controlled by, the person who practiced the patented process; or

(C) 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.

(2) No remedies for infringement under section 271(g) shall be available with respect to any product in the possession of, or in transit to, the person subject to liability under such section before that person had notice of infringement with respect to that product. The person subject to liability shall bear the burden of proving any such possession or transit.

(3)(A) In making a determination with respect to the remedy in an action brought for infringement under section 271(g), the court shall consider--

(i) the good faith demonstrated by the defendant with respect to a request for disclosure,

(ii) the good faith demonstrated by the plaintiff with respect to a request for disclosure, and

(iii) the need to restore the exclusive rights secured by the patent.

(B) For purposes of subparagraph (A), the following are evidence of good faith:

(i) a request for disclosure made by the defendant;

(ii) a response within a reasonable time by the person receiving the request for disclosure; and

(iii) the submission of the response by the defendant to the manufacturer, or if the manufacturer is not known, to the supplier, of the product to be purchased by the defendant, together with a request for a written statement that the process claimed in any patent disclosed in the response is not used to produce such product.

The failure to perform any acts described in the preceding sentence is evidence of absence of good faith unless there are mitigating circumstances. Mitigating circumstances include the case in which, due to the nature of the product, the number of sources for the product, or like commercial circumstances, a request for disclosure is not necessary or practicable to avoid infringement.

(4)(A) For purposes of this subsection, a "request for disclosure" means a written request made to a person then engaged in the manufacture of a product to identify all process patents owned by or licensed to that person, as of the time of the request, that the person then reasonably believes could be asserted to be infringed under section 271(g) if that product were imported into, or sold, offered for sale, or used in, the United States by an unauthorized person. A request for disclosure is further limited to a request--

(i) which is made by a person regularly engaged in the United States in the sale of the same type of products as those manufactured by the person to whom the request is directed, or which includes facts showing that the person making the request plans to engage in the sale of such products in the United States;

(ii) which is made by such person before the person's first importation, use, offer for sale, or sale of units of the product produced by an infringing process and before the person had notice of infringement with respect to the product; and

(iii) which includes a representation by the person making the request that such person will promptly submit the patents identified pursuant to the request to the manufacturer, or if the manufacturer is not known, to the supplier, of the product to be purchased by the person making the request, and will request from that manufacturer or supplier a written statement that none of the processes claimed in those patents is used in the manufacture of the product.

(B) In the case of a request for disclosure received by a person to whom a patent is licensed, that person shall either identify the patent or promptly notify the licensor of the request for disclosure.

(C) A person who has marked, in the manner prescribed by subsection (a), the number of the

process patent on all products made by the patented process which have been offered for sale or sold by that person in the United States, or imported by the person into the United States, before a request for disclosure is received is not required to respond to the request for disclosure. For purposes of the preceding sentence, the term "all products" does not include products made before the effective date of the Process Patent Amendments Act of 1988.

(5)(A) For purposes of this subsection, notice of infringement means actual knowledge, or receipt by a person of a written notification, or a combination thereof, of information sufficient to persuade a reasonable person that it is likely that a product was made by a process patented in the United States.

(B) A written notification from the patent holder charging a person with infringement shall specify the patented process alleged to have been used and the reasons for a good faith belief that such process was used. The patent holder shall include in the notification such information as is reasonably necessary to explain fairly the patent holder's belief, except that the patent holder is not required to disclose any trade secret information.

(C) A person who receives a written notification described in subparagraph (B) or a written response to a request for disclosure described in paragraph (4) shall be deemed to have notice of infringement with respect to any patent referred to in such written notification

or response unless that person, absent mitigating circumstances--

(i) promptly transmits the written notification or response to the manufacturer or, if the manufacturer is not known, to the supplier, of the product purchased or to be purchased by that person; and

(ii) receives a written statement from the manufacturer or supplier which on its face sets forth a well grounded factual basis for a belief that the identified patents are not infringed.

(D) For purposes of this subsection, a person who obtains a product made by a process patented in the United States in a quantity which is abnormally large in relation to the volume of business of such person or an efficient inventory level shall be rebuttably presumed to have actual knowledge that the product was made by such patented process.

(6) A person who receives a response to a request for disclosure under this subsection shall pay to the person to whom the request was made a reasonable fee to cover actual costs incurred in complying with the request, which may not exceed the cost of a commercially available automated patent search of the matter involved, but in no case more than $500.

(c)(1) With respect to a medical practitioner's performance of a medical activity that constitutes an infringement under section 271(a) or (b), the provisions of sections 281, 283, 284, and 285 shall not apply against the medical practitioner or against a

related health care entity with respect to such medical activity.

(2) For the purposes of this subsection:

(A) the term "medical activity" means the performance of a medical or surgical procedure on a body, but shall not include (i) the use of a patented machine, manufacture, or composition of matter in violation of such patent, (ii) the practice of a patented use of a composition of matter in violation of such patent, or (iii) the practice of a process in violation of a biotechnology patent.

(B) the term "medical practitioner" means any natural person who is licensed by a State to provide the medical activity described in subsection (c)(1) or who is acting under the direction of such person in the performance of the medical activity.

(C) the term "related health care entity" shall mean an entity with which a medical practitioner has a professional affiliation under which the medical practitioner performs the medical activity, including but not limited to a nursing home, hospital, university, medical school, health maintenance organization, group medical practice, or a medical clinic.

(D) the term "professional affiliation" shall mean staff privileges, medical staff membership, employment or contractual relationship, partnership or ownership interest, academic appointment, or other affiliation under which a medical practitioner provides the medical

activity on behalf of, or in association with, the health care entity.

(E) the term "body" shall mean a human body, organ or cadaver, or a nonhuman animal used in medical research or instruction directly relating to the treatment of humans.

(F) the term "patented use of a composition of matter" does not include a claim for a method of performing a medical or surgical procedure on a body that recites the use of a composition of matter where the use of that composition of matter does not directly contribute to achievement of the objective of the claimed method.

(G) the term "State" shall mean any State or territory of the United States, the District of Columbia, and the Commonwealth of Puerto Rico.

(3) This subsection does not apply to the activities of any person, or employee or agent of such person (regardless of whether such person is a tax exempt organization under section 501(c) of the Internal Revenue Code), who is engaged in the commercial development, manufacture, sale, importation, or distribution of a machine, manufacture, or composition of matter or the provision of pharmacy or clinical laboratory services (other than clinical laboratory services provided in a physician's office), where such activities are:

(A) directly related to the commercial development, manufacture, sale, importation, or distribution of a machine, manufacture, or composition of matter or the provision of

pharmacy or clinical laboratory services (other than clinical laboratory services provided in a physician's office), and

(B) regulated under the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act, or the Clinical Laboratories Improvement Act.

(4) This subsection shall not apply to any patent issued based on an application which has an effective filing date before September 30, 1996.

40 C.F.R. § 152.42

§ 152.42 Application for new registration.

Any person seeking to obtain a registration for a new pesticide product must submit an application for registration, containing the information specified in § 152.50. An application for new registration must be approved by the Agency before the product may legally be distributed or sold, except as provided by § 152.30.

40 C.F.R. § 152.50

§ 152.50 Contents of application.

Effective: February 10, 2009

Each application for registration or amended registration must include the following information, as applicable:

(a) Application form. An application form must be completed and submitted to the Agency. Application forms are provided by the Agency, with instructions as to the number of copies required and proper completion.

(b) Identity of the applicant—

(1) Name. The applicant must identify himself. An applicant not residing in the United States must also designate an agent in accordance with paragraph (b)(3) of this section to act on behalf of the applicant on all registration matters.

(2) Address of record. The applicant must provide an address in the United States for correspondence purposes. The U.S. address provided will be considered the applicant's address of record, and

EPA will send all correspondence concerning the application and any subsequent registration to that address. It is the responsibility of the applicant and any registrant under § 152.122 to ensure that the Agency has a current and accurate address.

(3) Authorized agent. An applicant may designate a person residing in the United States to act as his agent. If an applicant wishes to designate an agent, he must send the Agency a letter stating the name and United States address of his agent. The applicant must notify the Agency if he changes his designated agent. This relationship may be terminated at any time by the applicant by notifying the Agency in writing.

(4) Company number. If an applicant has been assigned a company number by the Agency, the application must reference that number.

(c) Summary of the application. Each application must include a list of the data submitted with the application, together with a brief description of the results of the studies. The list of data submitted may be the same as the list required by § 158.32 or § 161.32, as applicable, of this chapter. The summary must state that it is releasable to the public after registration in accordance with § 152.119.

(d) Identity of the product. The product for which application is being submitted must be identified. The following information is required:

(1) The product name;

(2) The trade name(s) (if different); and

(3) The EPA Registration Number, if currently registered.

(e) Draft labeling. Each application for new registration must be accompanied by five legible copies of draft labeling (typescript or mock-up). Each application for amended registration that proposes to make any changes in the product labeling must be accompanied by five legible copies of draft labeling incorporating the proposed labeling changes. If the proposed labeling change affects only a portion of the labeling, such as the use directions, the applicant may submit five copies of that portion of the label which is the subject of the amendment. Upon request, an applicant for amended registration must submit a complete label to consolidate amendments.

(f) Registration data requirements.

(1) An applicant must submit materials to demonstrate that he has complied with the FIFRA sec. 3(c)(1)(F) and subpart E of this part with respect to satisfaction of data requirements, to enable the Agency to make the determination required by FIFRA sec. 3(c)(5)(B). Required items are described in subpart E of this part.

(2) An applicant must furnish any data specified in part 158 or part 161 of this chapter, as applicable, of this chapter which are required by the Agency to determine that the product meets the registration standards of FIFRA sec. 3(c)(5) or (7). Each study must comply with:

(i) Section 158.32 of this chapter, with respect to format of data submission.

(ii) Section 158.33 of this chapter, with respect to studies for which a claim of trade secret or confidential business information is made.

(iii) Section 158.34 of this chapter, with respect to flagging for potential adverse effects.

(iv) Section 160.12 of this chapter, with respect to a statement whether studies were conducted in accordance with Good Laboratory Practices of part 160.

(3) An applicant shall furnish with his application any factual information of which he is aware regarding unreasonable adverse effects of the pesticide on man or the environment, which would be required to be reported under FIFRA sec. 6(a)(2) if the product were registered.

(g) Certification relating to child-resistant packaging. If the product meets the criteria for child-resistant packaging, the applicant must submit a certification that the product will be distributed or sold only in child-resistant packaging. Refer to part 157 of this chapter for the criteria and certification requirements.

(h) Request for classification. If an applicant wishes to request a classification different from that established by the Agency, he must submit a request for such classification and information supporting the request.

(i) Statement concerning tolerances.

(1) If the proposed labeling bears instructions for use of the pesticide on food or feed crops, or if the intended use of the pesticide results or may be expected to result, directly or indirectly, in pesticide chemical residues in or on food or feed (including residues of any active ingredient, inert ingredient, metabolite, or degradation product),

the applicant must submit a statement indicating whether such residues are authorized by a tolerance or exemption from the requirement of a tolerance issued under section 408 of the Federal Food, Drug and Cosmetic Act (FFDCA).

(2) If such residues have not been authorized, the application must be accompanied by a petition for establishment of appropriate tolerances or exemptions from the requirement of a tolerance, in accordance with part 180 of this chapter.

(j) Fees.

(1) The applicant shall identify the appropriate fee category in the schedule provided for by FIFRA sec. 33, and shall submit the fee for that category as prescribed by the latest EPA notice of section 33 fees.

(2) If FIFRA sec. 33 is not in effect, the applicant shall submit any fees required by subpart U of this part, if applicable.

40 C.F.R. § 152.80

§ 152.80 General.

Effective: February 10, 2009

This subpart E describes the information that an applicant must submit with his application for registration or amended registration to comply (and for the Agency to determine compliance) with the provisions of FIFRA sec. 3(c)(1)(F). This subpart also describes the procedures by which data submitters may challenge registration actions which allegedly failed to comply with these procedures. If the Agency determines that an applicant has failed to comply

with the requirements and procedures in this subpart, the application may be denied. If the Agency determines, after registration has been issued, that an applicant failed to comply with these procedures and requirements, the Agency may issue a notice of intent to cancel the product's registration.

40 C.F.R. § 152.81

§ 152.81 Applicability.

Effective: April 7, 2014

(a) Except as provided in paragraph (b) of this section, the requirements of this subpart apply to:

(1) Each application for registration of a new product.

(2) Each application for amended registration of a currently registered product.

(3) Each submission in response to a Data Call–In under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) section 3(c)(2)(B)[1] for an existing registration, including but not limited to, a product subject to reregistration under FIFRA section 4[2] or registration review under FIFRA section 3(g)[3]. If the Data Call–In establishes procedures for protection of data submitters' rights, recipients must comply with the specific requirements of the Data Call–In rather than the generic procedures set forth in §§ 152.85 through 152.96.

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[1] See 7 USCA § 136a(c)(2)(B).

[2] See 7 USCA § 136a–1.

[3] See 7 USCA § 136(g).

(b) This subpart does not apply to any of the following:

(1) An application for registration submitted to a State under FIFRA section 24(c).[4]

(2) An application for an experimental use permit (EUP) under FIFRA section 5[5].

(3) An application for an emergency exemption under FIFRA section 18.[6]

(4) A request for cancellation of a registration, or a request for deletion of one or more existing uses, under FIFRA section 6(f).[7]

(5) A modification to registration of a currently registered product that may be accomplished under the notification or non-notification provisions of § 152.46 and any procedures issued thereunder. Notwithstanding the preceding sentence, compliance with this subpart is required if the Administrator has, by written notice under § 152.46, determined that the modification may not be accomplished by notification or non-notification.

(6) Any type of amendment if the Administrator determines, by written finding, that Agency consideration of data would not be necessary in order to approve the amendment under FIFRA section 3(c)(5).[8]

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[4] See 7 USCA § 136v.

[5] See 7 USCA § 136c.

[6] See 7 USCA § 136p.

[7] See 7 USCA § 136d.

[8] See 7 USCA § 136a–1(c)(5).

(7) Compliance with Agency regulations, adjudicatory hearing decisions, notices, or other Agency announcements that unless the registration is amended in the manner the Agency proposes, the product's registration will be suspended or canceled, or that a hearing will be held under FIFRA section 6.[9] However, this paragraph does not apply to amendments designed to avoid cancellation or suspension threatened under FIFRA section 3(c)(2)(B)[10] or because of failure to submit data.

40 C.F.R. § 152.82

§ 152.82 Definitions.

Effective: April 7, 2014

For the purposes of this subpart, the definitions set forth in the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), in § 152.3, and in this section apply. In addition, the term "exclusive use study" shall have the meaning set forth in § 152.83.

Data gap means the absence of any valid study or studies in the Agency's files which would satisfy a specific data requirement for a particular pesticide product.

Data Submitters List means the current Agency list, entitled "Pesticide Data Submitters by Chemical," of persons who have submitted data to the Agency.

Original data submitter means the person who possesses all rights to exclusive use or compensation

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[9] See 7 USCA § 136(d).

[10] See 7 USCA § 136a(c)(2)(B).

under FIFRA section 3(c)(1)(F) in a study originally submitted in support of an application for registration, amended registration, reregistration, or experimental use permit, or to maintain an existing registration in effect. The term includes the person who originally submitted the study, any person to whom the rights under FIFRA section 3(c)(1)(F) have been transferred, or the authorized representative of a group of joint data developers.

Valid study means a study that has been conducted in accordance with the Good Laboratory Practice standards of 40 CFR part 160 or generally accepted scientific methodology and that EPA has not determined to be invalid.

40 C.F.R. § 152.83

§ 152.83 Definition of exclusive use study.

Effective: April 7, 2014

A study is an exclusive use study if it meets the conditions of either paragraph (a) or paragraph (b) of this section.

(a) Initial exclusive use period. A study submitted to support the registration of a product containing a new active ingredient (new chemical) or a new combination of active ingredients (new combination) is an exclusive use study if all the following conditions are met:

(1) The study pertains to a new active ingredient (new chemical) or new combination of active ingredients (new combination) first registered after September 30, 1978.

(2) The study was submitted in support of, or as a condition of approval of, the application resulting in the first registration of a product containing such new chemical or new combination, or an application to amend such registration to add a new use.

(3) Less than 10 years have passed (or up to 13 years, if the period of exclusive use protection has been extended under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) section 3(c)(1)(F)(ii)) since the issuance of the registration for which the data were submitted.

(4) The study was not submitted to satisfy a data requirement imposed under FIFRA section 3(c)(2)(B).

(b) Exclusive use period for certain minor use data. A study submitted by an applicant or registrant to support an amendment adding a new minor use to an existing registration that does not retain any period of exclusive use under paragraph (b)(1) of this section is an exclusive study under FIFRA section 3(c)(1)(F)(vi) if all the following conditions are met:

(1) The study relates solely to a minor use of a pesticide.

(2) The applicant or registrant at the time the new use is requested has notified the Administrator that any exclusive use period for the pesticide has expired and that the study is eligible for exclusive use treatment.

(3) Less than 10 years have passed since the study was submitted to EPA.

(4) The study was not submitted to satisfy a data requirement imposed under FIFRA section 3(c)(2)(B).

(5) The minor use supported by the data has not been voluntarily canceled nor have such data been used to support a non-minor use.

40 C.F.R. § 152.84

§ 152.84 When materials must be submitted to the Agency.

Effective: April 7, 2014

Information and materials required by this subpart must be submitted at the time of application, unless the application is determined not to be subject to the requirements of this subpart.

40 C.F.R. § 152.85

§ 152.85 Formulators' exemption.

Effective: December 26, 2007

(a) Statutory provision. FIFRA section 3(c)(2)(D) excuses an applicant from the requirement to submit or cite data pertaining to any pesticide contained in his product that is derived solely from one or more EPA–registered products which the applicant purchases from another person. This provision is commonly referred to as the formulators' exemption.

(b) Applicability of the formulators' exemption.

(1) The formulators' exemption applies only to data concerning the purchased product or its ingredients. These data may include, but are not

limited to, product chemistry, toxicology, residue chemistry, exposure, environmental fate, and ecological effects.

(2) The data to which the formulators' exemption applies usually will concern the safety of one or more of the product's active ingredients, specifically, those active ingredients which are contained in the purchased product. In general, data for which the required test substance is the technical grade of the active ingredient, the pure active ingredient, the radiolabeled pure active ingredient, or a typical end-use product are eligible for the formulators' exemption.

(3) The formulators' exemption generally does not apply to data on the applicant's product itself, including the safety or efficacy of the product, unless the composition of the product is identical to the purchased product. In general, data for which the required test substance is the product proposed for registration are not eligible for the formulators' exemption.

(c) Limitation of the formulators' exemption. EPA interprets FIFRA section 3(c)(2)(D) as allowing an applicant to use the formulators' exemption with respect to data concerning an ingredient of his product only if:

(1) The application indicates that the ingredient's presence in the product is attributable solely to the purchase from another person of an identified, registered product containing that ingredient and the use of the purchased product in formulating the product; and

(2) The purchased product is a registered manufacturing-use product whose label does not prohibit its use for making an end-use product labeled for any use for which the applicant's product will be labeled; or

(3) The purchased product is a registered end-use product labeled for each use for which the applicant's product will be labeled.

(d) Claiming eligibility for the exemption.

(1) If the product contains one or more ingredients eligible for the formulators' exemption, the applicant need not comply with the requirements of §§ 152.90 through 152.96 with respect to any data requirement pertaining to such ingredient, provided that he submits to the Agency a certification statement containing the following information (a form for this purpose is available from the Agency):

(i) Identification of the applicant, and of the product by EPA registration number or file symbol.

(ii) Identification of each ingredient in the pesticide that is eligible for the formulators' exemption, and the EPA registration number of the product that is the source of that ingredient.

(iii) A statement that the listed ingredients meet the requirements for the formulators' exemption.

(iv) A statement that the applicant has submitted (either previously or with the current application) a complete, accurate and current Confidential Statement of Formula.

(v) The name, title and signature of the applicant or his authorized representative and the date of signature.

(2) An applicant for amended registration is not required to submit a new formulators' exemption statement, if the current statement in Agency files is complete and accurate.

(e) Approval of registration. Notwithstanding FIFRA section 3(c)(2)(D), EPA will not approve an application unless there are available to EPA for its review all data that are necessary to make the required risk/benefit finding under FIFRA section 3(c) (5) or section 3(c)(7).

40 C.F.R. § 152.86

§ 152.86 The cite-all method.

Effective: April 7, 2014

An applicant may comply with this subpart by citing all data in Agency files that are pertinent to its consideration of the requested registration under FIFRA section 3(c)(5), in accordance with the procedures in this section, as applicable.

(a) Exclusive use studies. The applicant must certify to the Agency that he has obtained, from each person listed on the Data Submitters List as an exclusive use data submitter for the chemical in question, a written authorization that contains at least the following information:

(1) Identification of the applicant to whom the authorization is granted;

(2) Authorization to the applicant to use all pertinent studies in satisfaction of data requirements for the application in question; and

(3) The signature and title of the original data submitter or his authorized representative and date of the authorization.

If the Agency identifies any exclusive use data submitter not on the Data Submitters List, the applicant will be required prior to registration to obtain the necessary written authorization from such person.

(b) Other studies. The applicant must certify to the Agency that, with respect to each other person on the Data Submitters List for the chemical in question:

(1) He has obtained from that person a written authorization that contains the information required by paragraphs (a) (1) through (3) of this section; or

(2) He has furnished to that person:

(i) A notification of his intent to apply for registration, including the name of the proposed product, and a list of the product's active ingredients;

(ii) An offer to pay the person compensation to the extent required by FIFRA section 3(c)(1)(F) for any data on which the application relies;

(iii) An offer to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of any study; and

(iv) The applicant's name, address, and contact information, including telephone number and email address.

(c) General offer to pay statement. The applicant must submit to the Agency the following general offer to pay statement: [Name of applicant] hereby offers and agrees to pay compensation to other persons, with regard to the approval of this application, to the extent required by FIFRA section 3(c)(1)(F) of the Federal Insecticide, Fungicide and Rodenticide Act.

(d) Acknowledgement of reliance on data. Each application filed under this section shall include an acknowledgement that for purposes of FIFRA section 3(c)(1)(F) the application relies on the following data:

(1) All data submitted with or specifically cited in the application; and

(2) Each other item of data in the Agency's files which:

(i) Concerns the properties or effects of the applicant's product, of any product which is identical or substantially similar to the applicant's product, or of one or more of the active ingredients in the applicant's product; and

(ii) Is one of the types of data that EPA would require to be submitted if the application sought the initial registration under FIFRA section 3(c)(5) of a product with composition and intended uses identical or substantially similar to the applicant's product, under the data requirements in effect on the date EPA approves the applicant's present application.

40 C.F.R. § 152.90

§ 152.90 The selective method.

Effective: April 7, 2014

An applicant may comply with this subpart by listing the specific data requirements that apply to his product, its active ingredients, and use patterns, and demonstrating his compliance for each data requirement by submitting or citing individual studies, or by demonstrating that no study has previously been submitted to the Agency. This section summarizes the procedures that an applicant must follow if he chooses the selective method of demonstrating compliance. Sections 152.91 through 152.96 contain specific procedures for citing or submitting a study or claiming a data gap.

(a) List of data requirements.

(1) Each applicant must submit a list of the data requirements that would apply to his pesticide, its active ingredients, and its use patterns, if the product were being proposed for registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) section 3(c)(5) for the first time.

(2) The applicant must list the applicable requirements, as prescribed by part 158 of this chapter, as applicable. All required (R) studies, and any studies that could be conditionally required (CR) based upon composition, use pattern, or the results of required studies, are to be listed. The applicant need not list data requirements pertaining to any ingredient which qualifies for the formulators' exemption.

(b) Methods of demonstrating compliance. The applicant must state for each data requirement on the list required by paragraph (a) of this section which of the following methods of compliance with the requirement he is using, and shall provide the supporting documentation specified in the referenced section.

(1) Existence of or granting of a data waiver. Refer to § 152.91.

(2) Submission of a new valid study. Refer to § 152.92.

(3) Citation of a specific valid study previously submitted to the Agency by the applicant or another person, with any necessary written authorizations or offers to pay. Refer to § 152.93.

(4) Citation of a public literature study. Refer to § 152.94.

(5) Citation of all pertinent studies previously submitted to the Agency, with any necessary written authorizations or offers to pay. Refer to § 152.95.

(6) Claim of data gap. Refer to § 152.96.

40 C.F.R. § 152.91

§ 152.91 Waiver of a data requirement.

Effective: April 7, 2014

The applicant may demonstrate compliance for a data requirement by documenting the existence of a waiver in accordance with paragraph (a) of this section, or by being granted a new waiver requested in accordance with paragraph (b) of this section.

(a) Request for an extension of an existing waiver. An applicant may claim that a waiver previously granted by the Agency also applies to a data requirement for the product. To document this claim, the applicant must provide a reference to the Agency record that describes the previously granted waiver, such as an Agency list of waivers or an applicable Reregistration Eligibility Decision (RED) document or registration review decision document, and explain why that waiver should apply to the product.

(b) Request for a new waiver. An applicant who requests a waiver to satisfy a data requirement must submit the information specified in 40 CFR 158.45 or 40 CFR 161.45.

(c) Effect of denial of waiver request. A decision by the Agency to deny a written request for a new waiver or an extension of an existing waiver is a final Agency action. Following denial, the applicant must choose another method of satisfying the data requirement.

40 C.F.R. § 152.92

§ 152.92 Submission of a new valid study.

An applicant may demonstrate compliance for a data requirement by submitting a valid study that has not previously been submitted to the Agency. A study previously submitted to the Agency should not be resubmitted but should be cited in accordance with § 152.93.

40 C.F.R. § 152.93

§ 152.93 Citation of a previously submitted valid study.

Effective: April 7, 2014

An applicant may demonstrate compliance for a data requirement by citing a valid study previously submitted to the Agency. The study is not to be submitted to the Agency with the application.

(a) Study originally submitted by the applicant. If the applicant certifies that he is the original data submitter, no documentation other than the citation is necessary.

(b) Study previously submitted by another person. If the applicant is not the original data submitter, the applicant may cite the study only in accordance with paragraphs (b) (1) through (3) of this section.

(1) Citation with authorization of original data submitter. The applicant may cite any valid study for which he has obtained the written authorization of the original data submitter. The applicant must obtain written authorization to cite any study that is an exclusive use study. The applicant must certify that he has obtained from the original data submitter a written authorization that contains at least the following information:

(i) Identification of the applicant to whom the authorization is granted;

(ii) Identification by title, EPA Accession Number or Master Record Identification Number, and date of submission, of the study or studies for which the authorization is granted;

(iii) Authorization to the applicant to use the specified study in satisfaction of the data requirement for the application in question; and

(iv) The signature and title of the original data submitter or his authorized representative, and date of the authorization.

(2) Citation with offer to pay compensation to the original data submitter. The applicant may cite any valid study that is not subject to the exclusive use provisions of FIFRA section 3(c)(1)(F)(i) without written authorization from the original data submitter if the applicant certifies to the Agency that he has furnished to the original data submitter:

(i) A notification of the applicant's intent to apply for registration, including the proposed product name and a list of the product's active ingredients;

(ii) Identification of the specific data requirement involved and of the study for which the offer to pay is made (by title, EPA Accession Number or Master Record Identification Number, and date of submission, if possible);

(iii) An offer to pay the person compensation to the extent required by FIFRA section 3©(1)(F);

(iv) An offer to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study; and

(v) The applicant's name, address, and contact information, including a telephone number and email address.

(3) Citation without authorization or offer to pay. The applicant may cite any valid study without written authorization from, or offer to pay to, the original data submitter if the study was originally submitted to the Agency on or before the date that is 15 years before the date of the application for which it is cited, and the study is not an exclusive use study, as defined in § 152.83©.

40 C.F.R. § 152.94

§ 152.94 Citation of a public literature study or study generated at government expense.

Effective: February 10, 2009

(a) An applicant may demonstrate compliance for a data requirement by citing, and submitting to the Agency, one of the following:

(1) A valid study from the public literature.

(2) A valid study generated by, or at the expense of, any government (Federal, State, or local) agency.

(b) In no circumstances does submission of a public literature study or government-generated study confer any rights on the data submitter to exclusive use of data or compensation under FIFRA section 3(c)(1)(F).

40 C.F.R. § 152.95

§ 152.95 Citation of all studies in the Agency's files pertinent to a specific data requirement.

Effective: April 7, 2014

An applicant normally may demonstrate compliance for a data requirement by citation of all studies in the Agency's files pertinent to that data requirement. The applicant who selects this cite-all option must submit to the Agency:

(a) A general offer to pay statement having the same wording as that specified in § 152.86(c) except that the offer to pay may be limited to apply only to data pertinent to the specific data requirement(s) for which the cite-all method of support has been selected;

(b) A certification that:

(1) For each person who is included on the Data Submitters List as an original data submitter of exclusive use data for the active ingredient in question, the applicant has obtained a written authorization containing the information required by § 152.86(a) for the use the any exclusive use study that would be pertinent to the applicant's product; and

(2) For each person included on the current Data Submitters List as an original data submitter of data that are not exclusive use for the active ingredient in question, the applicant has furnished:

(i) A notification of the applicant's intent to apply for registration, including the name of

the proposed product, and a list of the product's active ingredients;

(ii) Identification of the specific data requirement(s) for which the offer to pay for data is being made; (iii) An offer to pay the person compensation to the extent required by FIFRA section 3(c)(1)(F);

(iv) An offer to commence negotiations to determine the amount and terms of compensation, if any, to be paid for use of any study; and

(v) The applicant's name, address, and contact information, including a telephone number and email address.

(c) An acknowledgment having the same wording as that specified in § 152.86(d), except that it may be limited to apply only to data pertinent to the specific data requirement(s) for which the cite-all method of support has been selected.

40 C.F.R. § 152.96

§ 152.96 Claim of data gap.

Effective: April 7, 2014

(a) When a data gap may be claimed. Except as provided in paragraph (b) of this section, an applicant may defer his obligation to satisfy an applicable data requirement until the Agency requires the data if no other person has previously submitted to the Agency a valid study that would satisfy the data requirement in question.

(b) When a data gap may not be claimed—

(1) Product containing a new active ingredient. An applicant for registration of a product containing a new active ingredient may not defer his obligation by claiming a data gap unless he can demonstrate to the Agency's satisfaction that the data requirement was imposed so recently that insufficient time has elapsed for the study to have been completed and that, in the public interest, the product should be registered during the limited period of time required to complete the study. Refer to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) section 3(c)(7)(C).

(2) Product not containing a new active ingredient. An applicant for registration of a product under FIFRA sections 3(c) (7)(A) or (B) (a product not containing a new active ingredient) may not defer his obligation by claiming a data gap if the data are:

(i) Data needed to determine whether the product is identical or substantially similar to another currently registered product or differs only in ways that would substantially increase the risk of unreasonable adverse effects on the environment.

(ii) Efficacy data specific to the product, if required to be submitted to the Agency.

(iii) If a new use is proposed for a product that is identical or substantially similar to an existing product, data to demonstrate whether the new use would substantially increase the risk of unreasonable adverse effects on the environment.

(c) Approval of application with a data gap claim—

(1) In accordance with § 152.115(a), any registration that is approved based upon a data gap claim shall be conditioned on the submission of the data no later than the time that the data are required to be submitted for similar products already registered.

(2) Notwithstanding paragraph (c)(1) of this section, the Agency will not approve an application if it determines that the data for which a data gap claim has been made are needed to determine if the product meets the requirements of FIFRA sections 3(c)(5) or (7).

40 C.F.R. § 152.97

§ 152.97 Rights and obligations regarding the Data Submitters List.

Effective: April 7, 2014

(a) Each original data submitter shall have the right to be included on the Agency's Data Submitters List.

(b) Each original data submitter who wishes to have his name added to the current Data Submitters List must submit to the Agency the following information:

(1) Name and current address.

(2) Chemical name, common name (if any) and Chemical Abstracts Service (CAS) number (if any) of the active ingredients(s), with respect to which he is an original data submitter.

(3) For each such active ingredient, the type(s) of study he has previously submitted (identified by

reference to data/ information requirements listed in part 158 of this chapter), the date of submission, and the EPA registration number, file symbol, or other identifying reference for which it was submitted.

(c) Each applicant not already included on the Data Submitters List for a particular active ingredient must inform the Agency at the time of the submission of a relevant study whether he wishes to be included on the Data Submitters List for that pesticide.

40 C.F.R. § 152.98

§ 152.98 Procedures for transfer of exclusive use or compensation rights to another person.

Effective: February 10, 2009

A person who possesses rights to exclusive use or compensation under FIFRA section 3(c)(1)(F) may transfer such rights to another person in accordance with this section.

(a) The original data submitter must submit to the Agency a transfer document that contains the following information:

(1) The name, address and state of incorporation (if any) of the original data submitter (the transferor);

(2) The name, address and state of incorporation (if any) of the person to whom the data rights are being transferred (the transferee);

(3) Identification of each item of data transferred including:

(i) The name of the study or item of data;

(ii) Whether the study is an exclusive use study, and, if so, when the period of exclusive use protection expires;

(iii) The name of the person or laboratory that conducted the study;

(iv) The date the study was submitted to the Agency;

(v) The EPA document number assigned to the item of data (the Master Record Identification Number or Accession Number), if known. If not known, the EPA administrative number (such as the EPA Registration Number, petition number, file symbol, or permit number) with which the item of data was submitted, such that the Agency can identify the item of data.

(vi) A statement that the transferor transfers irrevocably to the transferee all rights, titles, and interest in the items of data named;

(vii) A statement that the transferor and transferee understand that any false statement may be punishable under 18 U.S.C. 1001; and

(viii) The names, signatures and titles of the transferor and transferee, and the date signed.

(b) In addition, the original data submitter must submit to the Agency a notarized statement affirming that:

(1) The person signing the transfer agreement is authorized by the original data submitter to bind the data submitter;

(2) No court order prohibits the transfer, and any required court approvals have been obtained; and

(3) The transfer is authorized under Federal, State, and local law and relevant corporate charters, bylaws or partnership agreements.

(c) The Agency will acknowledge the transfer of the data by notifying both transferor and transferee, and will state the effective date of the transfer. Thereafter the transferee will be considered to be the original data submitter of the items of data transferred for all purposes under FIFRA section 3(c)(1)(F), unless a new transfer agreement is submitted to the Agency.

40 C.F.R. § 152.99

§ 152.99 Petitions to cancel registration.

Effective: April 7, 2014

An original data submitter may petition the Agency to deny or cancel the registration of a product in accordance with this section if he has submitted to the Agency a valid study which, he claims, satisfies a data requirement that an applicant purportedly has failed to satisfy.

(a) Grounds for petition.

(1) If an applicant has offered to pay compensation to an original data submitter of a study (either specifically or by filing a general offer to pay statement), the original data submitter may petition the Agency to deny or cancel the registration to which the offer related on any of the following grounds:

(i) The applicant has failed to participate in an agreed-upon procedure for reaching an agreement on the amount and terms of compensation. The petitioner shall submit a copy of the agreed-upon procedure and describe the applicant's failure to participate in the procedure.

(ii) The applicant has failed to comply with the terms of an agreement on compensation. The petitioner shall submit a copy of the agreement, and shall describe how the applicant has failed to comply with the agreement.

(iii) The applicant has failed to participate in an arbitration proceeding. The petitioner shall submit evidence of such failure. (iv) The applicant has failed to comply with the terms of an arbitration decision. The petitioner shall submit a copy of the arbitration decision, and describe how the applicant has failed to comply with the decision.

(2) When no offer to pay has been made, the petitioner shall state in his petition the basis for the challenge, and describe how the failure of the applicant to comply with the procedures of this subpart has deprived him of the rights accorded him under FIFRA section 3(c)(1)(F). Possible grounds for challenge include, but are not limited to, the following:

(i) The applicant has failed to list a data requirement applicable to his product, or has failed to demonstrate compliance with all applicable data requirements.

(ii) The applicant has submitted or cited a study that is not valid.

(iii) The applicant has submitted or cited a study that does not satisfy the data requirement for which it was submitted or cited.

(iv) The applicant has falsely or improperly claimed that a data gap existed at the time of his application.

(v) The applicant has submitted or cited a study originally submitted by the petitioner, without the required authorization or offer to pay.

(b) Procedure for petition to the Agency—

(1) Time for filing. A petition under paragraph (a)(1) of this section may be filed at any time that the circumstances warrant. A petition under paragraph (a)(2) of this section must be filed within one year after the Agency makes public the issuance of the registration.

(2) Notice to affected registrant. At the same time that the petitioner files his petition with the Agency, the petitioner shall send a copy to the affected applicant or registrant by certified mail or by any other method that provides evidence of delivery. The affected applicant or registrant shall have 60 days from the date of receipt of the petition to submit written comments to the Agency.

(c) Disposition of petitions. The Agency will consider the material submitted by the petitioner and the response, if any, by the affected applicant or registrant.

(1) If the Agency determines that the petition is without merit, it will inform the petitioner and the

affected applicant or registrant that the petition is denied. Denial of a petition is a final Agency action.

(2) If the Agency determines that an applicant has acted in any way described by paragraph (a)(1) of this section, the Agency will notify the petitioner and the affected applicant or registrant that it intends to deny or cancel the registration of the product in support of which the data were cited. The affected applicant or registrant will have 15 days from the date of delivery of this notice to respond. If the Agency determines, after considering any response, that the affected applicant or registrant has acted in the ways described by paragraph (a)(1) of this section, the Agency will deny or cancel the registration without further hearing. Refer to FIFRA section 3(c)(1)(F)(ii). Denial or cancellation of a registration is a final Agency action.

(3) Except as provided in paragraph (c)(2) of this section, if the Agency determines that an applicant for registration of a product has acted in any way that deprives an original data submitter of rights under FIFRA section 3(c)(1)(F), the Agency will take steps to deny the application or cancel the registration, as appropriate. The procedures in FIFRA section 3(c)(6) or section 6(b) shall be followed. Denial or cancellation is a final Agency action.

(d) Hearing. Any hearing will be conducted in accordance with the procedures in 40 CFR part 164. The only matter for resolution at the hearing shall be whether the registrant failed to comply with the requirements and procedures of FIFRA section 3(c)(1)

(F) or of this subpart, in the manner described by the petitioner. A decision following a hearing shall be final.

40 C.F.R. § 152.107

§ 152.107 Review of data.

Effective: December 26, 2007

(a) The Agency normally will review data submitted with an application that have not previously been submitted to the Agency. (b) The Agency normally will review other data submitted or cited by an applicant only:

(1) As part of the process of reregistering currently registered products;

(2) When acting on an application for registration of a product containing a new active ingredient;

(3) If such data have been flagged in accordance with § 158.34 or § 161.34 of this chapter; or

(4) When the Agency determines that it would otherwise serve the public interest.

(c) If the Agency finds that it needs additional data in order to determine whether the product may be registered, it will notify the applicant as early as possible in the review process.

40 C.F.R. § 152.108

§ 152.108 Review of labeling.

The Agency will review all draft labeling submitted with the application. If an applicant for amended registration submits only that portion of the labeling

proposed for amendment, the Agency may review the entire label, as revised by the proposed changes, in deciding whether to approve the amendment. The Agency will not approve final printed labeling, but will selectively review it for compliance.

40 C.F.R. § 152.112

§ 152.112 Approval of registration under FIFRA sec. 3(c)(5).

Effective: February 10, 2009

EPA will approve an application under the criteria of FIFRA sec. 3(c)(5) only if:

(a) The Agency has determined that the application is complete and is accompanied by all materials required by the Act and this part, including, but not limited to, evidence of compliance with subpart E of this part;

(b) The Agency has reviewed all relevant data in the possession of the Agency (see §§ 152.107 and 152.111);

(c) The Agency has determined that no additional data are necessary to make the determinations required by FIFRA sec. 3(c) (5) with respect to the pesticide product which is the subject of the application;

(d) The Agency has determined that the composition of the product is such as to warrant the proposed efficacy claims for it, if efficacy data are required to be submitted for the product by part 158 or part 161 of this chapter, as applicable.

(e) The Agency has determined that the product will perform its intended function without unreasonable

adverse effects on the environment, and that, when used in accordance with widespread and commonly recognized practice, the product will not generally cause unreasonable adverse effects on the environment;

(f) The Agency has determined that the product is not misbranded as that term is defined in FIFRA sec. 2(q) and part 156 of this chapter, and its labeling and packaging comply with the applicable requirements of the Act, this part, and parts 156 and 157 of this chapter;

(g) If the proposed labeling bears directions for use on food, animal feed, or food or feed crops, or if the intended use of the pesticide results or may reasonably be expected to result, directly or indirectly, in pesticide residues (including residues of any active or inert ingredient of the product, or of any metabolite or degradation product thereof) in or on food or animal feed, all necessary tolerances, exemptions from the requirement of a tolerance, and food additive regulations have been issued under FFDCA sec. 408, and

(h) If the product, in addition to being a pesticide, is a drug within the meaning of FFDCA sec. 201(q), the Agency has been notified by the Food and Drug Administration (FDA) that the product complies with any requirements imposed by FDA.

40 C.F.R. § 152.113

§ 152.113 Approval of registration under FIFRA sec. 3(c)(7)—Products that do not contain a new active ingredient.

(a) Except as provided in paragraph (b) of this section, the Agency may approve an application for

registration or amended registration of a pesticide product, each of whose active ingredients is contained in one or more other registered pesticide products, only if the Agency has determined that:

(1) It possesses all data necessary to make the determinations required by FIFRA sec. 3(c)(7)(A) or (B) with respect to the pesticide product which is the subject of the application (including, at a minimum, data needed to characterize any incremental risk that would result from approval of the application);

(2) Approval of the application would not significantly increase the risk of any unreasonable adverse effect on the environment; and

(3) The criteria of § 152.112(a), (d), and (f) through (h) have been satisfied.

(b) Notwithstanding the provisions of paragraph (a) of this section, the Agency will not approve the conditional registration of any pesticide under FIFRA sec. 3(c)(7)(A) unless the Agency has determined that the applicant's product and its proposed use are identical or substantially similar to a currently registered pesticide and use, or that the pesticide and its proposed use differ only in ways that would not significantly increase the risk of unreasonable adverse effects on the environment.

(c) Notwithstanding the provisions of paragraph (a) of this section, the Agency will not approve the conditional registration of any pesticide product for a new use under FIFRA sec. 3(c)(7)(B) if:

(1) The pesticide is the subject of a special review, based on a use of the product that results in human dietary exposure; and

(2) The proposed new use involves use on a major food or feed crop, or involves use on a minor food or feed crop for which there is available an effective alternative registered pesticide which does not meet the risk criteria associated with human dietary exposure. The determination of available and effective alternatives shall be made with the concurrence of the Secretary of Agriculture.

40 C.F.R. § 156.3

§ 156.3 Definitions.

Effective: December 29, 2008

Terms used in this part have the same meaning as in the Act and part 152 of this chapter. In addition, as used in this part, the following terms shall have the meanings set forth below.

Dilutable means that the pesticide product's labeling allows or requires the pesticide product to be mixed with a liquid diluent prior to application or use.

Transport vehicle means a cargo-carrying vehicle such as an automobile, van, tractor, truck, semitrailer, tank car or rail car used for the transportation of cargo by any mode.

40 C.F.R. § 156.10

§ 156.10 Labeling requirements.

Effective: February 10, 2009

(a) General—

(1) Contents of the label. Every pesticide product shall bear a label containing the information specified by the Act and the regulations in this part. The contents of a label must show clearly and prominently the following:

(i) The name, brand, or trademark under which the product is sold as prescribed in paragraph (b) of this section;

(ii) The name and address of the producer, registrant, or person for whom produced as prescribed in paragraph (c) of this section;

(iii) The net contents as prescribed in paragraph (d) of this section;

(iv) The product registration number as prescribed in paragraph (e) of this section;

(v) The producing establishment number as prescribed in paragraph (f) of this section;

(vi) An ingredient statement as prescribed in paragraph (g) of this section;

(vii) Hazard and precautionary statements as prescribed in subpart D of this part for human and domestic animal hazards and subpart E of this part for environmental hazards.

(viii) The directions for use as prescribed in paragraph (i) of this section; and

(ix) The use classification(s) as prescribed in paragraph (j) of this section.

(2) Prominence and legibility.

(i) All words, statements, graphic representations, designs or other information required on the labeling by the Act or the regulations in this part must be clearly legible to a person with normal vision, and must be placed with such conspicuousness (as compared with other words, statements, designs, or graphic matter on the labeling) and expressed in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

(ii) All required label text must:

(A) Be set in 6–point or larger type;

(B) Appear on a clear contrasting background; and

(C) Not be obscured or crowded.

(3) Language to be used. All required label or labeling text shall appear in the English language. However, the Agency may require or the applicant may propose additional text in other languages as is considered necessary to protect the public. When additional text in another language is necessary, all labeling requirements will be applied equally to both the English and other-language versions of the labeling.

(4) Placement of Label—

(i) General. The label shall appear on or be securely attached to the immediate container of the pesticide product. For purposes of this section, and the misbranding provisions of the Act, "securely attached" shall mean that a label can reasonably be expected to remain affixed during the foreseeable conditions and period of use. If the immediate container is enclosed within a wrapper or outside container through which the label cannot be clearly read, the label must also be securely attached to such outside wrapper or container, if it is a part of the package as customarily distributed or sold.

(ii) Tank cars and other bulk containers—

(A) Transportation. While a pesticide product is in transit, the appropriate provisions of 49 CFR parts 170–189, concerning the transportation of hazardous materials, and specifically those provisions concerning the labeling, marking and

placarding of hazardous materials and the vehicles carrying them, define the basic Federal requirements. In addition, when any registered pesticide product is transported in a tank car, tank truck or other mobile or portable bulk container, a copy of the accepted label must be attached to the shipping papers, and left with the consignee at the time of delivery.

(B) Storage. When pesticide products are stored in bulk containers, whether mobile or stationary, which remain in the custody of the user, a copy of the label of labeling, including all appropriate directions for use, shall be securely attached to the container in the immediate vicinity of the discharge control valve.

(5) False or misleading statements. Pursuant to section 2(q)(1)(A) of the Act, a pesticide or a device declared subject to the Act pursuant to § 152.500, is misbranded if its labeling is false or misleading in any particular including both pesticidal and non-pesticidal claims. Examples of statements or representations in the labeling which constitute misbranding include:

(i) A false or misleading statement concerning the composition of the product;

(ii) A false or misleading statement concerning the effectiveness of the product as a pesticide or device;

(iii) A false or misleading statement about the value of the product for purposes other than as a pesticide or device;

(iv) A false or misleading comparison with other pesticides or devices;

(v) Any statement directly or indirectly implying that the pesticide or device is recommended or endorsed by any agency of the Federal Government;

(vi) The name of a pesticide which contains two or more principal active ingredients if the name suggests one or more but not all such principal active ingredients even though the names of the other ingredients are stated elsewhere in the labeling;

(vii) A true statement used in such a way as to give a false or misleading impression to the purchaser;

(viii) Label disclaimers which negate or detract from labeling statements required under the Act and these regulations;

(ix) Claims as to the safety of the pesticide or its ingredients, including statements such as "safe," "nonpoisonous," "noninjurious," "harmless" or "nontoxic to humans and pets" with or without such a qualifying phrase as "when used as directed"; and

(x) Non-numerical and/or comparative statements on the safety of the product, including but not limited to:

(A) "Contains all natural ingredients";

(B) "Among the least toxic chemicals known";

(C) "Pollution approved".

(6) Final printed labeling.

(i) Except as provided in paragraph (a)(6)(ii) of this section, final printed labeling must be submitted and accepted prior to registration. However, final printed labeling need not be submitted until draft label texts have been provisionally accepted by the Agency.

(ii) Clearly legible reproductions or photo reductions will be accepted for unusual labels such as those silk-screened directly onto glass or metal containers or large bag or drum labels. Such reproductions must be of microfilm reproduction quality.

(b) Name, brand, or trademark.

(1) The name, brand, or trademark under which the pesticide product is sold shall appear on the front panel of the label.

(2) No name, brand, or trademark may appear on the label which:

(i) Is false or misleading, or

(ii) Has not been approved by the Administrator through registration or supplemental registration as an additional name pursuant to § 152.132.

(c) Name and address of producer, registrant, or person for whom produced. An unqualified name and address given on the label shall be considered as the name and address of the producer. If the registrant's name appears on the label and the registrant is not the producer, or if the name of the person for whom the pesticide was produced appears on the label, it

must be qualified by appropriate wording such as "Packed for * * *," "Distributed by * * *," or "Sold by * * * " to show that the name is not that of the producer.

(d) Net weight or measure of contents.

(1) The net weight or measure of content shall be exclusive of wrappers or other materials and shall be the average content unless explicitly stated as a minimum quantity.

(2) If the pesticide is a liquid, the net content statement shall be in terms of liquid measure at 68° F (20°C) and shall be expressed in conventional American units of fluid ounces, pints, quarts, and gallons.

(3) If the pesticide is solid or semisolid, viscous or pressurized, or is a mixture of liquid and solid, the net content statement shall be in terms of weight expressed as avoirdupois pounds and ounces.

(4) In all cases, net content shall be stated in terms of the largest suitable units, i.e., "1 pound 10 ounces" rather than "26 ounces."

(5) In addition to the required units specified, net content may be expressed in metric units.

(6) Variation above minimum content or around an average is permissible only to the extent that it represents deviation unavoidable in good manufacturing practice. Variation below a stated minimum is not permitted. In no case shall the average content of the packages in a shipment fall below the stated average content.

(7) For a pesticide product packaged in a refillable container, an appropriately sized area on the label

may be left blank to allow the net weight or measure of content to be marked in by the refiller according to 40 CFR 165.65(h) or 165.70(i) prior to distribution or sale of the pesticide. As required in paragraph (a)(1)(iii) of this section, the net contents must be shown clearly and prominently on the label.

(e) Product registration number. The registration number assigned to the pesticide product at the time of registration shall appear on the label, preceded by the phrase "EPA Registration No.," or the phrase "EPA Reg. No." The registration number shall be set in type of a size and style similar to other print on that part of the label on which it appears and shall run parallel to it. The registration number and the required identifying phrase shall not appear in such a manner as to suggest or imply recommendation or endorsement of the product by the Agency.

(f) Producing establishment's registration number. The producing establishment registration number preceded by the phrase "EPA Est.", of the final establishment at which the product was produced may appear in any suitable location on the label or immediate container. It must appear on the wrapper or outside container of the package if the EPA establishment registration number on the immediate container cannot be clearly read through such wrapper or container. For a pesticide product packaged in a refillable container, an appropriately sized area on the label may be left blank after the phrase "EPA Est." to allow the EPA establishment registration number to be marked in by the refiller according to 40 CFR 165.65(h) or 165.70(i) prior to distribution or sale of the pesticide.

(g) Ingredient statement—

(1) General. The label of each pesticide product must bear a statement which contains the name and percentage by weight of each active ingredient, the total percentage by weight of all inert ingredients; and if the pesticide contains arsenic in any form, a statement of the percentages of total and water-soluble arsenic calculated as elemental arsenic. The active ingredients must be designated by the term "active ingredients" and the inert ingredients by the term "inert ingredients," or the singular forms of these terms when appropriate. Both terms shall be in the same type size, be aligned to the same margin and be equally prominent. The statement "Inert Ingredients, none" is not required for pesticides which contain 100 percent active ingredients. Unless the ingredient statement is a complete analysis of the pesticide, the term "analysis" shall not be used as a heading for the ingredient statement.

(2) Position of ingredient statement.

(i) The ingredient statement is normally required on the front panel of the label. If there is an outside container or wrapper through which the ingredient statement cannot be clearly read, the ingredient statement must also appear on such outside container or wrapper. If the size or form of the package makes it impracticable to place the ingredient statement on the front panel of the label, permission may be granted for the ingredient statement to appear elsewhere.

(ii) The text of the ingredient statement must run parallel with other text on the panel on which it appears, and must be clearly distinguishable from and must not be placed in the body of other text.

(3) Names to be used in ingredient statement. The name used for each ingredient shall be the accepted common name, if there is one, followed by the chemical name. The common name may be used alone only if it is well known. If no common name has been established, the chemical name alone shall be used. In no case will the use of a trademark or proprietary name be permitted unless such name has been accepted as a common name by the Administrator under the authority of section 25(c)(6).

(4) Statements of percentages. The percentages of ingredients shall be stated in terms of weight-to-weight. The sum of percentages of the active and the inert ingredients shall be 100. Percentages shall not be expressed by a range of values such as "22–25%." If the uses of the pesticide product are expressed as weight of active ingredient per unit area, a statement of the weight of active ingredient per unit volume of the pesticide formulation shall also appear in the ingredient statement.

(5) Accuracy of stated percentages. The percentages given shall be as precise as possible reflecting good manufacturing practice. If there may be unavoidable variation between manufacturing batches, the value stated for each active ingredient shall be the lowest percentage which may be present.

(6) Deterioration. Pesticides which change in chemical composition significantly must meet the following labeling requirements:

(i) In cases where it is determined that a pesticide formulation changes chemical composition significantly, the product must bear the following statement in a prominent position on the label: "Not for sale or use after [date]."

(ii) The product must meet all label claims up to the expiration time indicated on the label.

(7) Inert ingredients. The Administrator may require the name of any inert ingredient(s) to be listed in the ingredient statement if he determines that such ingredient(s) may pose a hazard to man or the environment.

(h) [Reserved]

(i) Directions for Use—

(1) General requirements—

(i) Adequacy and clarity of directions. Directions for use must be stated in terms which can be easily read and understood by the average person likely to use or to supervise the use of the pesticide. When followed, directions must be adequate to protect the public from fraud and from personal injury and to prevent unreasonable adverse effects on the environment.

(ii) Placement of directions for use. Directions may appear on any portion of the label provided that they are conspicuous enough to be easily

read by the user of the pesticide product. Directions for use may appear on printed or graphic matter which accompanies the pesticide provided that:

(A) If required by the Agency, such printed or graphic matter is securely attached to each package of the pesticide, or placed within the outside wrapper or bag;

(B) The label bears a reference to the directions for use in accompanying leaflets or circulars, such as "See directions in the enclosed circular:" and

(C) The Administrator determines that it is not necessary for such directions to appear on the label.

(iii) Exceptions to requirement for direction for use.

(A) Detailed directions for use may be omitted from labeling of pesticides which are intended for use only by manufacturers of products other than pesticide products in their regular manufacturing processes, provided that:

(1) The label clearly shows that the product is intended for use only in manufacturing processes and specifies the type(s) of products involved.

(2) Adequate information such as technical data sheets or bulletins, is available to the trade specifying the type of product involved and its proper use in manufacturing processes;

(3) The product will not come into the hands of the general public except after incorporation into finished products; and

(4) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment.

(B) Detailed directions for use may be omitted from the labeling of pesticide products for which sale is limited to physicians, veterinarians, or druggists, provided that:

(1) The label clearly states that the product is for use only by physicians or veterinarians;

(2) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment; and

(3) The product is also a drug and regulated under the provisions of the Federal Food, Drug and Cosmetic Act.

(C) Detailed directions for use may be omitted from the labeling of pesticide products which are intended for use only by formulators in preparing pesticides for sale to the public, provided that:

(1) There is information readily available to the formulators on the composition, toxicity, methods of use, applicable restrictions or limitations,

and effectiveness of the product for pesticide purposes;

(2) The label clearly states that the product is intended for use only in manufacturing, formulating, mixing, or repacking for use as a pesticide and specifies the type(s) of pesticide products involved;

(3) The product as finally manufactured, formulated, mixed, or repackaged is registered; and

(4) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment.

(2) Contents of Directions for Use. The directions for use shall include the following, under the headings "Directions for Use":

(i) The statement of use classification as prescribed in paragraph (j) of this section immediately under the heading "Directions for Use."

(ii) Immediately below the statement of use classification, the statement "It is a violation of Federal law to use this product in a manner inconsistent with its labeling."

(iii) The site(s) of application, as for example the crops, animals, areas, or objects to be treated.

(iv) The target pest(s) associated with each site.

(v) The dosage rate associated with each site and pest.

(vi) The method of application, including instructions for dilution, if required, and type(s) of application apparatus or equipment required.

(vii) The frequency and timing of applications necessary to obtain effective results without causing unreasonable adverse effects on the environment.

(viii) Worker protection statements meeting the requirements of subpart K of this part.

(ix) Specific directions concerning the storage, residue removal and disposal of the pesticide and its container, in accordance with subpart H of this part. These instructions must be grouped and appear under the heading, "Storage and Disposal." This heading must be set in type of the same minimum sizes as required for the child hazard warning. (See table in § 156.60(b))

(x) Any limitations or restrictions on use required to prevent unreasonable adverse effects, such as:

(A) Required intervals between application and harvest of food or feed crops.

(B) Rotational crop restrictions.

(C) Warnings as required against use on certain crops, animals, objects, or in or adjacent to certain areas.

(D) For total release foggers as defined in § 156.78(d)(1), the following statements must be included in the "Directions for Use."

DO NOT use more than one fogger per room. DO NOT use in small, enclosed spaces such as closets, cabinets, or under counters or tables. Do not use in a room 5 ft.x5 ft. or smaller; instead, allow fog to enter from other rooms. Turn off ALL ignition sources such as pilot lights (shut off gas valves), other open flames, or running electrical appliances that cycle off and on (i.e., refrigerators, thermostats, etc.). Call your gas utility or management company if you need assistance with your pilot lights."

(E) For restricted use pesticides, a statement that the pesticide may be applied under the direct supervision of a certified applicator who is not physically present at the site of application but nonetheless available to the person applying the pesticide, unless the Agency has determined that the pesticide may only be applied under the direct supervision of a certified applicator who is physically present.

(F) Other pertinent information which the Administrator determines to be necessary for the protection of man and the environment.

(j) Statement of use classification. Any pesticide product for which some uses are classified for general use and others for restricted use shall be separately

labeled according to the labeling standards set forth in this subsection, and shall be marketed as separate products with different registration numbers, one bearing directions only for general use(s) and the other bearing directions for restricted use(s) except that, if a product has both restricted use(s) and general use(s), both of these uses may appear on a product labeled for restricted use. Such products shall be subject to the provisions of paragraph (j)(2) of this section.

(1) General Use Classification. Pesticide products bearing directions for use(s) classified general shall be labeled with the exact words "General Classification" immediately below the heading "Directions for Use." And reference to the general classification that suggests or implies that the general utility of the pesticide extends beyond those purposes and uses contained in the Directions for Use will be considered a false or misleading statement under the statutory definitions of misbranding.

(2) Restricted Use Classification. Pesticide products bearing direction for use(s) classified restricted shall bear statements of restricted use classification on the front panel as described below:

(i) Front panel statement of restricted use classification.

(A) At the top of the front panel of the label, set in type of the same minimum sizes as required for human hazard signal words (see table in paragraph (h)(1)(iv) of this section), and appearing with sufficient

prominence relative to other text and graphic material on the front panel to make it unlikely to be overlooked under customary conditions of purchase and use, the statement "Restricted Use Pesticide" shall appear.

(B) Directly below this statement on the front panel, a summary statement of the terms of restriction imposed as a precondition to registration shall appear. If use is restricted to certified applicators, the following statement is required: "For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's certification." If, however, other regulatory restrictions are imposed, the Administrator will define the appropriate wording for the terms of restriction by regulation.

40 C.F.R. § 156.60

§ 156.60 General.

Each product label is required to bear hazard and precautionary statements for humans and domestic animals (if applicable) as prescribed in this subpart. Hazard statements describe the type of hazard that may occur, while precautionary statements will either direct or inform the user of actions to take to avoid the hazard or mitigate its effects.

(a) Location of statements—

(1) Front panel statements. The signal word, child hazard warning, and, in certain cases, the first aid

statement are required to appear on the front panel of the label, and also in any supplemental labeling intended to accompany the product in distribution or sale.

(2) Statements elsewhere on label. Hazard and precautionary statements not required on the front panel may appear on other panels of the label, and may be required also in supplemental labeling. These include, but are not limited to, the human hazard and precautionary statements, domestic animal statements if applicable, a Note to Physician, and physical or chemical hazard statements.

(b) Placement and prominence—

(1) Front panel statements. All required front panel warning statements shall be grouped together on the label, and shall appear with sufficient prominence relative to other front panel text and graphic material to make them unlikely to be overlooked under customary conditions of purchase and use. The table below shows the minimum type size requirements for the front panel warning statements for various front panel sizes.

Type Sizes for Front Panel Warning Statements

Size of Label Front Panel (Square Inches)	Point Size
Signal Word (All Capital Letters)	Child Hazard Warning

5 and under	6	6
Over 5 to 10	10	6
Over 10 to 15	12	8
Over 15 to 30	14	10
Over 30	18	12

(2) Other required statements. All other hazard and precautionary statements must be at least 6 point type.

40 C.F.R. § 156.62

§ 156.62 Toxicity Category.

This section establishes four Toxicity Categories for acute hazards of pesticide products, Category I being the highest toxicity category. Most human hazard, precautionary statements, and human personal protective equipment statements are based upon the Toxicity Category of the pesticide product as sold or distributed. In addition, toxicity categories may be used for regulatory purposes other than labeling, such as classification for restricted use and requirements for child-resistant packaging. In certain cases, statements based upon the Toxicity Category of the product as diluted for use are also permitted. A Toxicity Category is assigned for each of five types of acute exposure, as specified in the table in this paragraph.

Acute Toxicity Categories for Pesticide Products

Hazard Indicators	I	II	III	IV
Oral LD_{50}	Up to and including 50 mg/kg	>50 thru 500 mg/kg	>500 thru 5,000 mg/kg	>5000 mg/kg
Dermal LD_{50}	Up to and including 200 mg/kg	>200 thru 2000 mg/kg	>200 thru 20,000 mg/kg	>20,000 mg/kg
Inhalation LC_{50}	Up to and including 0.2 mg/liter	>0.2 thru 2 mg/liter	>2 thru 20 mg/liter	>20 mg/liter
Eye Irritation	Corrosive; corneal opacity not reversible within 7 days	Corneal opacity reversible within 7 days; irritation persisting for 7 days	No corneal opacity; irritation reversible within 7 days	No irritation
Skin Irritation	Corrosive	Severe irritation at 72 hours	Moderate irritation at 72 hours	Mild or slight irritation at 72 hours

40 C.F.R. § 156.64

§ 156.64 Signal word.

(a) Requirement. Except as provided in paragraph (a)(4), each pesticide product must bear on the front panel a signal word, reflecting the highest Toxicity Category (Category I is the highest toxicity category) to which the product is assigned by any of the five routes of exposure in § 156.62. The signal word must also appear together with the heading for the human precautionary statement section of the labeling (see § 156.70).

(1) Toxicity Category I. Any pesticide product meeting the criteria of Toxicity Category I for any route of exposure must bear on the front panel the signal word "DANGER." In addition, if the product is assigned to Toxicity Category I on the basis of its oral, inhalation or dermal toxicity (as distinct from skin and eye irritation), the word "Poison" must appear in red on a background of distinctly contrasting color, and the skull and crossbones symbol must appear in immediate proximity to the word "Poison."

(2) Toxicity Category II. Any pesticide product meeting the criteria of Toxicity Category II as the highest category by any route of exposure must bear on the front panel the signal word "WARNING."

(3) Toxicity Category III. Any pesticide product meeting the criteria of Toxicity Category III as the highest category by any route of exposure must bear on the front panel the signal word "CAUTION."

(4) Toxicity Category IV. A pesticide product meeting the criteria of Toxicity Category IV by all

routes of exposure is not required to bear a signal word. If a signal word is used, it must be "CAUTION."

(b) Use of signal words. In no case may a product:

(1) Bear a signal word reflecting a higher Toxicity Category than indicated by the route of exposure of highest toxicity, unless the Agency determines that such labeling is necessary to prevent unreasonable adverse effects on man or the environment;

(2) Bear a signal word reflecting a lesser Toxicity Category associated with a diluted product. Although precautionary statements for use dilutions may be included on label, the signal word must reflect the toxicity of the product as distributed or sold; or

(3) Bear different signal words on different parts of the label.

40 C.F.R. § 156.66

§ 156.66 Child hazard warning.

(a) Each pesticide product must bear on the front panel of the label the statement "Keep Out of Reach of Children." That statement, or any alternative statement approved by EPA, must appear on a separate line in close proximity to the signal word, if required. The statement is required on Toxicity Category IV products that do not otherwise require a signal word.

(b) In its discretion, EPA may waive the requirement, or require or permit an alternative child hazard warning, if:

(1) The applicant can demonstrate that the likelihood of exposure of children to the pesticide during distribution, marketing, storage or use is remote (for example, an industrial use product); or

(2) The pesticide is approved for use on children (for example, an insect repellent).

(c) EPA may approve an alternative child hazard warning that more appropriately reflects the nature of the pesticide product to which children may be exposed (for example, an impregnated pet collar). In this case, EPA may also approve placement on other than the front panel.

40 C.F.R. § 156.68

§ 156.68 First aid statement.

(a) Product as sold and distributed. Each product must bear a first aid statement if the product has systemic effects in Category I, II, or III, or skin or eye irritation effects in Category I or II.

(b) Product as diluted for use. If the product labeling bears directions for dilution with water prior to use, the label may also include a statement describing how the first aid measures may be modified for the diluted product. Such a statement must reflect the Toxicity Category(ies) of the diluted product, based upon data for the route of exposure (or calculations if appropriate). If the labeling provides for a range of use dilutions, only that use dilution representing the highest concentration allowed by labeling may be used as the basis for a statement pertaining to the diluted product. The statement for a diluted product may not substitute for the statement for the

concentrate, but augments the information provided for the concentrate.

(c) Heading. The heading of the statement may be "First Aid" or "Statement of Practical Treatment."

(d) Location of first aid statement. The first aid statement must appear on the front panel of the label of all products assigned to Toxicity Category I by any route of exposure. Upon review, the Agency may permit reasonable variations in the placement of the first aid statement if a reference such as "See first aid statement on back panel" appears on the front panel. The first aid statement for products assigned to Toxicity Categories II or III may appear on any panel of the label.

40 C.F.R. § 156.70

§ 156.70 Precautionary statements for human hazards.

(a) Requirement. Human hazard and precautionary statements as required must appear together on the label or labeling under the general heading "Precautionary Statements" and under appropriate subheadings similar to "Humans and Domestic Animals," "Environmental Hazards" (see subpart E of this part) and "Physical or Chemical Hazards." The phrase "and Domestic Animals" may be omitted from the heading if domestic animals will not be exposed to the product.

(b) Content of statements. When data or other information show that an acute hazard may exist to humans or domestic animals, the label must bear precautionary statements describing the particular

hazard, the route(s) of exposure and the precautions to be taken to avoid accident, injury or toxic effect or to mitigate the effect. The precautionary paragraph must be immediately preceded by the appropriate signal word.

(c) Typical precautionary statements. The table below presents typical hazard and precautionary statements. Specific statements pertaining to the hazards of the product and its uses must be approved by the Agency. With Agency approval, statements may be augmented to reflect the hazards and precautions associated with the product as diluted for use. Refer to § 156.68(b) for requirements for use dilution statements.

Typical Human Hazard and Precautionary Statements

Toxicity Category	Systemic effects (oral, dermal, inhalation toxicity)	Irritation effects (skin and eye)	Sensitizer (There are no categories of sensitization.)
I	Fatal (poisonous) if swallowed [inhaled or absorbed through skin]. Do not breathe vapor [dust or spray mist]. Do	Corrosive, causes eye and skin damage [or skin irritation]. Do not get in eyes on skin, or on clothing. Wear	If product is sensitizer; Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals.

	not get in eyes, on skin, or on clothing. [Front panel first aid statement required.]	goggles or face shield and rubber gloves when handling. Harmful or fatal if swallowed. [Front panel first paid statement required.
II	May be fatal if swallowed, [inhaled or absorbed through the skin]. Do not breathe vapors [dust or spay mist]. Do not get in eyes, on skin or on clothing. [Appropriate first aid statement required.]	Causes eye [and skin] irritation. Do not get in eyes, on skin, or on clothing. Harmful if swallowed. [Appropriate first aid statement required.]
III	Harmful if swallowed [inhaled or	Avoid contact with

	absorbed through the skin]. Avoid breathing vapors [dust or spray mist]. Avoid contact with skin [eyes or clothing]. [Appropriate first aid statement required.	skin, eyes or clothing.
IV	No precaution-ary statements required	No precaution-ary statements required.

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40 C.F.R. § 156.78

§ 156.78 Precautionary statements for physical or chemical hazards.

(a) Requirement. Warning statements on the flammability or explosive characteristics of the pesticide product are required if a product meets the criteria in this section. Warning statements pertaining to other physical/chemical hazards (e.g., oxidizing potential, conductivity, chemical reactions leading to production of toxic substances) may be required on a case-by-case basis.

(b) Pressurized products. The table below sets out the required flammability label statements for pressurized products.

Flammability Statements for Pressurized Products

Flash point/flame extension of product	Required labeling statement
—Flash point at or below 20° F OR —Flashback at any valve opening	Extremely flammable. Contents under pressure. Keep away from fire, sparks, and heated surfaces. Do not puncture or incinerate container. Exposure to temperatures above 130° F may cause bursting.
—Flash point >20° F to 80° F OR —Flame extension more than 18 in. long at a distance of 6 in from the flame	Flammable. Contents under pressure. Keep away from heat, sparks and open flame. Do not puncture or incinerate container. Exposure to temperatures above 130° F may cause bursting.
All other pressurized products	Contents under pressure. Do not use or store near heat or open flame. Do not puncture or incinerate container. Exposure to temperatures above 130° F may cause bursting.

(c) Non-pressurized products. The table below sets out the required flammability label statements for non-pressurized products.

Flammability Statements for Non-Pressurized Products

Flash point	Required labeling statement
At or below 20° F	Extremely flammable. Keep away from fire, sparks and heated surfaces.
Greater than 20° F to 80° F	Flammable. Keep away from heat and open flame.
Greater than 80° F to 150° F	Combustible. Do not use or store near heat or open flame.

(d) Total release fogger products.

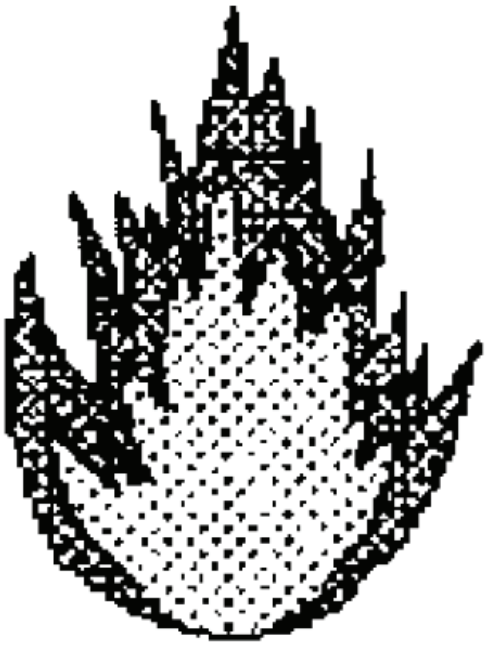
(1) A total release fogger is defined as a pesticide product in a pressurized container designed to automatically release the total contents in one operation, for the purpose of creating a permeating fog within a confined space to deliver the pesticide throughout the space.

(2) If a pesticide product is a total release fogger containing a propellant with a flash point at or below 20° F, then the following special instructions must be added to the "Physical and Chemical Hazards" warning statement, in addition to any flammability statement required by paragraph (b) of this section:

This product contains a highly flammable ingredient. It may cause a fire or explosion if not

used properly. Follow the Directions for Use on this label very carefully.

(3) A graphic symbol depicting fire, such as illustrated in this paragraph, or an equivalent symbol, must be displayed along with the required language adjoining the "Physical and Chemical Hazards" warning statement. The graphic symbol must be no smaller than twice the size of the first character of the human hazard signal word.



Highly Flammable Ingredient

Ingrediente Altamente Inflamable

40 C.F.R. § 156.80

§ 156.80 General.

(a) Requirement. Each product is required to bear hazard and precautionary statements for environmental hazards, including hazards to non-target organisms, as prescribed in this subpart. Hazard statements describe the type of hazard that may be present, while precautionary statements direct or inform the user of actions to take to avoid the hazard or mitigate its effects.

(b) Location of statements. Environmental hazard and precautionary statements may appear on any panel of the label and may be required also in supplemental labeling. The environmental hazard statements must appear together under the heading "Environmental Hazards." Typically the statements are grouped as a sub-category within the "Precautionary Statements" section of the labeling.

(c) Type size. All environmental hazard and precautionary statements must be at least 6 point type.

40 C.F.R. § 156.85

§ 156.85 Non-target organisms.

(a) Requirement. Where a hazard exists to non-target organisms, EPA may require precautionary statements of the nature of the hazard and the appropriate precautions to avoid potential accident, injury, or damage.

(b) Examples. The statements in this paragraph illustrate the types of hazard statements that EPA

may require and the circumstances under which they are typically required. These statements are not comprehensive; other statements may be required if more appropriate to the formulation or use.

(1) If a pesticide intended for outdoor use contains an active ingredient with a mammalian acute oral LD50 of 100 mg/kg or less, the statement, "This pesticide is toxic to wildlife" is required.

(2) If a pesticide intended for outdoor use contains an active ingredient with a fish acute LC50 of 1 ppm or less, the statement, "This pesticide is toxic to fish" is required.

(3) If a pesticide intended for outdoor use contains an active ingredient with an avian acute oral LD50 of 100 mg/kg or less, or a subacute dietary LC50 of 500 ppm or less, the statement, "This pesticide is toxic to wildlife" is required.

(4) If either accident history or field studies demonstrate that the use of the pesticide may result in fatality to birds, fish or mammals, the statement, "This pesticide is extremely toxic to wildlife (fish)" is required.

(5) If a product is intended for or involves foliar application to agricultural crops, forests or shade trees, or mosquito abatement treatments, and contains a pesticide toxic to pollinating insects, the label must bear appropriate label cautions.

(6) If a product is intended for outdoor use other than aquatic applications, the label must bear the caution, "Keep out of lakes, ponds or streams. Do not contaminate water by cleaning of equipment or disposal of wastes."

40 C.F.R. § 156.140

§ 156.140 Identification of container types.

Effective: December 29, 2008

For products other than plant-incorporated protectants, the following statements, as applicable, must be placed on the label or container. The information may be located on any part of the container except the closure. If the statements are placed on the container, they must be durably marked on the container. Durable marking includes, but is not limited to etching, embossing, ink jetting, stamping, heat stamping, mechanically attaching a plate, molding, or marking with durable ink.

(a) Nonrefillable container. For nonrefillable containers, the statements in paragraphs (a)(1) through (a)(4) of this section are required except as provided in paragraphs (a)(5), (c), (d), and (e) of this section. If placed on the label, the statements in paragraphs (a)(1) through (a)(3) of this section must be under an appropriate heading under the heading "Storage and Disposal." If any of the statements in paragraphs (a)(1) through (a)(3) of this section are placed on the container, an appropriate referral statement such as "See container for recycling [or other descriptive word] information." must be placed on the label under the heading "Storage and Disposal."

(1) Statement identifying a nonrefillable container. The following phrase is required: "Nonrefillable container."

(2) Reuse statement. One of the following statements is required. Products with labels that

allow household/residential use must use the statement in paragraph (a)(2)(i) or (a)(2)(iii) of this section. All other products must use the statement in paragraph (a)(2)(i), (a)(2)(ii), or (a)(2)(iii) of this section.

(i) "Do not reuse or refill this container."

(ii) "Do not reuse this container to hold materials other than pesticides or dilute pesticides (rinsate). After emptying and cleaning, it may be allowable to temporarily hold rinsate or other pesticide-related materials in the container. Contact your state regulatory agency to determine allowable practices in your state."

(iii) The following statement may be used if a product is "ready-to-use" and its directions for use allow a different product (that is a similar, but concentrated formulation) to be poured into the container and diluted by the end user: "Do not reuse or refill this container unless the directions for use allow a different (concentrated) product to be diluted in the container."

(3) Recycling or reconditioning statement. One of the following statements is required:

(i) "Offer for recycling if available."

(ii) "Once cleaned, some agricultural plastic pesticide containers can be taken to a container collection site or picked up for recycling. To find the nearest site, contact your chemical dealer or manufacturer or contact [a pesticide container recycling organization] at [phone

number] or [web site]. For example, this statement could be "Once cleaned, some agricultural plastic pesticide containers can be taken to a container collection site or picked up for recycling. To find the nearest site, contact your chemical dealer or manufacturer or contact the Ag Container Recycling Council (ACRC) at 1–877–952–2272 (toll-free) or www.acrecycle.org."

(iii) A recycling statement approved by EPA and published in an EPA document, such as a Pesticide Registration Notice.

(iv) An alternative recycling statement that has been reviewed and approved by EPA.

(v) "Offer for reconditioning if appropriate."

(4) Batch code. A lot number, or other code used by the registrant or producer to identify the batch of the pesticide product which is distributed and sold is required.

(5) Exemptions. Pesticide products in the following types of nonrefillable containers, and their packaging, are exempt from the requirements in paragraphs (a)(1) and (a)(2) of this section:

(i) Aerosol cans.

(ii) Devices as defined in § 152.500 of this chapter.

(iii) One-time use caulking tubes and other one-time use squeezable tube containers for paste, gel, or other similar substances.

(iv) Foil packets for water soluble packaging, repellent wipes, and other one-time use products.

(v) One-time use portion control packets, such as polyethylene sleeve packages, or rodenticide placepacks.

(vi) One-time use bait stations.

(vii) One-time use cages for repellent or trapping strips.

(viii) Pet collars or animal ear tags, such as cattle ear tags.

(ix) One-time use semiochemical dispersion devices.

(x) Any container that is destroyed by the use of the product contained.

(xi) Any container that would be destroyed if reuse of the container were attempted.

(b) Refillable container. For refillable containers, one of the following statements is required, except as provided in paragraphs (c), (d), and (e) of this section. If placed on the label, the statement must be under the heading "Storage and Disposal." If the statement is placed on the container, an appropriate referral statement, such as "Refilling limitations are on the container." Must be placed under the heading "Storage and Disposal."

(1) "Refillable Container. Refill this container with pesticide only. Do not reuse this container for any other purpose."

(2) "Refillable Container. Refill this container with [common chemical name] only. Do not reuse this container for any other purpose."

(c) Modification. EPA may, on its own initiative or based on data or information submitted by any person, modify or waive the requirements of this section or permit or require alternative labeling statements.

(d) Exemption for articles. Pesticidal articles that are not exempted from FIFRA regulation by § 152.25(a) of this chapter are exempt from the requirements of this section.

(e) Exemption for transport vehicles. Transport vehicles are exempt from the requirements of this section.

40 C.F.R. § 156.144

§ 156.144 Residue removal instructions—general.

Effective: December 29, 2008

(a) General. Except as provided by paragraphs (c) through (g) of this section, the label of each pesticide product must include the applicable instructions for removing pesticide residues from the container prior to container disposal that are specified in § 156.146 and § 156.156. The residue removal instructions are required for both nonrefillable and refillable containers.

(b) Placement of residue removal statements. All residue removal instructions must be placed under the heading "Storage and Disposal."

(c) Exemption for residential/household use products. Residential/household use pesticide products are exempt from the residue removal instruction requirements in this section through § 156.156.

(d) Modification. EPA may, on its own initiative or based on data submitted by any person, modify or waive the requirements of this section through § 156.156, or permit or require alternative labeling statements.

(e) Exemption for gases. Pesticide products that are gaseous at atmospheric temperature and pressure are exempt from the residue removal instruction requirements in this section through § 156.156.

(f) Exemption for articles. Pesticidal articles that are not exempted from FIFRA regulation by § 152.25(a) of this chapter are exempt from the residue removal instruction requirements in this section through § 156.156.

(g) Exemption for transport vehicles. Transport vehicles are exempt from the requirements in this section through § 156.156.

40 C.F.R. § 156.146

§ 156.146 Residue removal instructions for nonrefillable containers—rigid containers with dilutable pesticides.

Effective: October 16, 2006

The label of each dilutable (liquid or solid) pesticide product packaged in a rigid nonrefillable container must include the following residue removal instructions as appropriate.

(a) Timing of the residue removal procedure. One of the following statements must immediately precede the instructions required in paragraph (b) of this section and must be consistent with the instructions in paragraphs (b) and (c) of this section:

(1) "Clean container promptly after emptying."

(2) "Triple rinse or pressure rinse container (or equivalent) promptly after emptying."

(3) "Triple rinse container (or equivalent) promptly after emptying."

(b) Triple rinse instructions. The label of each dilutable pesticide product packaged in rigid nonrefillable containers must include one of the following sets of instructions.

(1) For liquid dilutable pesticide products in containers small enough to shake, use the following instructions: "Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank and drain for 10 seconds after the flow begins to drip. Fill the container 1/4 full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times."

(2) For solid dilutable pesticide products in containers small enough to shake, use the following instructions: "Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank. Fill the container 1/4 full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times."

(3) For containers that are too large to shake, use the following instructions: "Triple rinse as follows:

Empty remaining contents into application equipment or a mix tank. Fill the container 1/4 full with water. Replace and tighten closures. Tip container on its side and roll it back and forth, ensuring at least one complete revolution, for 30 seconds. Stand the container on its end and tip it back and forth several times. Turn the container over onto its other end and tip it back and forth several times. Empty the rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Repeat this procedure two more times."

(c) Pressure rinse instructions. The label of each dilutable pesticide product packaged in rigid nonrefillable containers may include one of the following sets of instructions, and one of them must be used if the statement in paragraph (a)(2) of this section is used. If one of these statements is included on the label, it must immediately follow the triple rinse instructions specified in paragraph (b) of this section.

(1) For liquid dilutable pesticide products, use the following label instruction: "Pressure rinse as follows: Empty the remaining contents into application equipment or a mix tank and continue to drain for 10 seconds after the flow begins to drip. Hold container upside down over application equipment or mix tank or collect rinsate for later use or disposal. Insert pressure rinsing nozzle in the side of the container, and rinse at about 40 PSI for at least 30 seconds. Drain for 10 seconds after the flow begins to drip."

(2) For solid dilutable pesticide products, use the following label instruction: "Pressure rinse as

follows: Empty the remaining contents into application equipment or a mix tank. Hold container upside down over application equipment or mix tank or collect rinsate for later use or disposal. Insert pressure rinsing nozzle in the side of the container, and rinse at about 40 PSI for at least 30 seconds. Drain for 10 seconds after the flow begins to drip."

(d) Non-water diluent.

(1) A registrant who wishes to require users to clean a container with a diluent other than water (e.g., solvents) must submit to EPA a written request to modify the residue removal instructions of this section. The registrant may not distribute or sell the pesticide with the modified residue removal instructions until EPA approves the request in writing.

(2) The registrant must indicate why a non-water diluent is necessary for efficient residue removal, and must propose residue removal instructions and disposal instructions that are appropriate for the characteristics and formulation of the pesticide product and non-water diluent. The proposed residue removal instructions must identify the diluent. If the Directions for Use permit the application of a mixture of the pesticide and the non-water diluent, the instructions may allow the rinsate to be added to the application equipment or mix tank. If the Directions for Use do not identify the nonwatery diluent as an allowable addition to the pesticide, the instructions must require collection and storage of the rinsate in a rinsate collection system.

(3) EPA may approve the request if EPA finds that the proposed instructions are necessary and appropriate.

40 C.F.R. § 156.156

§ 156.156 Residue removal instructions for refillable containers.

Effective: October 16, 2006

The label of each pesticide product packaged in a refillable container must include the residue removal instructions in this section. Instructions must be given for all pesticide products that are distributed or sold in refillable containers, including those that do not require dilution prior to application.

(a) Timing of the residue removal procedure. One of the following statements must immediately precede the instructions required in paragraph (b) of this section and must be consistent with the instructions in paragraph (b) of this section:

(1) "Cleaning the container before final disposal is the responsibility of the person disposing of the container. Cleaning before refilling is the responsibility of the refiller."

(2) "Pressure rinsing the container before final disposal is the responsibility of the person disposing of the container. Cleaning before refilling is the responsibility of the refiller."

(b) Residue removal instructions prior to container disposal.

(1) Instructions for cleaning each refillable container prior to disposal are required. The residue removal instructions must be appropriate for the characteristics and formulation of the pesticide product and must be adequate to protect human health and the environment.

(2) Subject to meeting the standard in paragraph (b)(1) of this section, the statement on residue removal instructions could include any one of the following:

(i) The refilling residue removal procedure developed by the registrant for the pesticide product.

(ii) Standard industry practices for cleaning refillable containers.

(iii) For pesticides that require dilution prior to application, the following statement: "To clean the container before final disposal, empty the remaining contents from this container into application equipment or a mix tank. Fill the container about 10 percent full with water. Agitate vigorously or recirculate water with the pump for 2 minutes. Pour or pump rinsate into application equipment or rinsate collection system. Repeat this rinsing procedure two more times."

(iv) Any other statement the registrant considers appropriate.

40 C.F.R. § 156.159

§ 156.159 Compliance date.

Effective: December 7, 2010

Any pesticide product released for shipment by a registrant after August 16, 2011 must bear a label that complies with §§ 156.10(d)(7), 156.10(f), 156.10(i)(2)(ix), 156.140, 156.144, 156.146 and 156.156.

40 C.F.R. § 156.200

§ 156.200 Scope and applicability.

Effective: February 10, 2009

(a) Scope.

(1) This subpart prescribes statements that must be placed on the pesticide label and in pesticide labeling. These statements incorporate by reference the Worker Protection Standard, part 170 of this chapter. The requirements addressed in these statements are designed to reduce the risk of illness or injury resulting from workers' and pesticide handlers' occupational exposures to pesticides used in the production of agricultural plants on agricultural establishments as defined in § 170.3 of this chapter. These statements refer to specific workplace practices designed to reduce or eliminate exposure and to respond to emergencies that may arise from the exposures that may occur.

(2) This subpart prescribes interim requirements that must be placed on the pesticide label and in

pesticide labeling. These interim requirements pertain to restricted-entry intervals, personal protective equipment, and notification. On a case-by-case basis, these interim requirements will be reviewed and may be revised during reregistration or other agency review processes.

(b) Applicability.

(1) The requirements of this subpart apply to each pesticide product that bears directions for use in the production of any agricultural plant on any agricultural establishment as defined in § 170.3 of this chapter, or whose labeling reasonably permits such use.

(2) The requirements of this subpart do not apply to a product that bears directions solely for uses excepted by § 170.202(b) of this chapter.

(c) Effective dates. No product to which this subpart applies shall be distributed or sold without amended labeling by any registrant after April 21, 1994, or by any person after October 23, 1995.

40 C.F.R. § 156.203

§ 156.203 Definitions.

Effective: February 10, 2009

Terms in this subpart have the same meanings as they do in the Federal Insecticide, Fungicide, and Rodenticide Act, as amended. In addition, the following terms, as used in this subpart, shall have the meanings stated below:

Fumigant means any pesticide product that is a vapor or gas or forms a vapor or gas on application and

whose method of pesticidal action is through the gaseous state.

Restricted-entry interval or REI means the time after the end of a pesticide application during which entry to the treated area is restricted.

40 C.F.R. § 156.204

§ 156.204 Modification and waiver of requirements.

Effective: February 10, 2009

(a) Modification on Special Review. If the Agency concludes in accordance with § 154.25(c) of this chapter that a pesticide should be placed in Special Review because the pesticide meets or exceeds the criteria for human health effects of § 154.7(a)(1)(2) or (6) of this chapter, the Agency may modify the personal protective equipment required for handlers or early-entry workers or both, the restricted-entry intervals, or the notification to workers requirements.

(b) Other modifications. The Agency, pursuant to this subpart and authorities granted in FIFRA sections 3, 6, and 12, may, on its initiative or based on data submitted by any person, modify or waive the requirements of this subpart, or permit or require alternative labeling statements. Supporting data may be either data conducted according to Subdivisions U or K of the Pesticide Assessments guidelines or data from medical, epidemiological, or health effects studies. A registrant who wishes to modify any of the statements required in §§ 156.206, 156.208, 156.210, or 156.212 must submit an application for amended registration unless specifically directed otherwise by the Agency.

40 C.F.R. § 156.206

§ 156.206 General statements.

Effective: February 10, 2009

(a) Application restrictions. Each product shall bear the statement: "Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application." This statement shall be near the beginning of the DIRECTIONS FOR USE section of the labeling under the heading AGRICULTURAL USE REQUIREMENTS.

(b) 40 CFR part 170 reference statement.

(1) Each product shall bear the reference statement: "Use this product only in accordance with its labeling and with the Worker Protection Standard, 40 CFR part 170." This statement shall be placed on the product label under the heading AGRICULTURAL USE REQUIREMENTS.

(2) Each product shall bear the statement: "This standard contains requirements for the protection of agricultural workers on farms, forests, nurseries, and greenhouses, and handlers of agricultural pesticides. It contains requirements for training, decontamination, notification, and emergency assistance. It also contains specific instructions and exceptions pertaining to the statements on this label [in this labeling] about [use any of the following that are applicable] personal protective equipment, restricted-entry interval, and notification to workers." These statements shall be placed immediately following the reference statement required by paragraph

(b)(1) of this section, or they shall be placed in the supplemental product labeling under the heading AGRICULTURAL USE REQUIREMENTS.

(3) If the statements in paragraph (b)(2) of this section are included in supplemental labeling rather than on the label of the pesticide container, the container label must contain this statement immediately following the statement required in paragraph (b)(1) of this section: "Refer to supplemental labeling entitled AGRICULTURAL USE REQUIREMENTS in the DIRECTIONS FOR USE section of the labeling for information about this standard."

(4) If the statements in paragraph (b)(2) of this section are included in supplemental labeling, they must be preceded immediately by the statement in paragraph (b)(1) of this section under the heading AGRICULTURAL USE REQUIREMENTS in the labeling.

(c) Product-type identification.

(1) If the product contains an organophosphate (i.e., an organophosphorus ester that inhibits cholinesterase) or an N-methyl carbamate (i.e., an N-methyl carbamic acid ester that inhibits cholinesterase), the label shall so state. The statement shall be associated with the product name or product-type identification or shall be in the STATEMENT OF PRACTICAL TREATMENT or FIRST AID section of the label.

(2) If the product is a fumigant, the label shall so state. The identification shall appear:

(i) As part of the product name; or

(ii) Close to the product name, as part of the product-type identification or as a separate phrase or sentence.

(d) State restrictions. Each product shall bear the statement: "For any requirements specific to your State, consult the agency in your State responsible for pesticide regulation." This statement shall be under the heading AGRICULTURAL USE REQUIREMENTS in the labeling.

(e) Spanish warning statements. If the product is classified as toxicity category I or toxicity category II according to the criteria in § 156.62, the signal word shall appear in Spanish in addition to English followed by the statement, "Si Usted no entiende la etiqueta, busque a alguien para que se la explique a Usted en detalle. (If you do not understand the label, find some one to explain it to you in detail.)" The Spanish signal word "PELIGRO" shall be used for products in toxicity category I, and the Spanish signal word "AVISO" shall be used for products in toxicity category II. These statements shall appear on the label close to the English signal word.

40 C.F.R. § 156.208

§ 156.208 Restricted-entry statements.

Effective: February 10, 2009

(a) Requirement. Each product with a restricted-entry interval shall bear the following statement: "Do not enter or allow worker entry into treated areas during the restricted-entry interval (REI)." This statement shall be under the heading AGRICULTURAL USE REQUIREMENTS in the labeling.

(b) Location of specific restricted-entry interval statements.

(1) If a product has one specific restricted-entry interval applicable to all registered uses of the product on agricultural plants, the restricted-entry interval for the product shall appear as a continuation of the statement required in paragraph (a) of this section and shall appear as follows: "of X hours" or "of X days" or "until the acceptable exposure level of X ppm or mg/m 3 is reached."

(2) If different restricted-entry intervals have been established for some crops or some uses of a product, the restricted-entry statement in paragraph (b)(1) of this section shall be associated on the labeling of the product with the directions for use for each crop each use to which it applies, immediately preceded or immediately followed by the words "Restricted-entry interval" (or the letters "REI").

(c) Restricted-entry interval based on toxicity of active ingredient—

(1) Determination of toxicity category. A restricted-entry interval shall be established based on the acute toxicity of the active ingredients in the product. For the purpose of setting the restricted-entry interval, the toxicity category of each active ingredient in the product shall be determined by comparing the obtainable data on the acute dermal toxicity, eye irritation effects, and skin irritation effects of the ingredient to the criteria of § 156.62. The most toxic of the applicable toxicity categories that are obtainable

for each active ingredient shall be used to determine the restricted-entry interval for that product. If no acute dermal toxicity data are obtainable, data on acute oral toxicity also shall be considered in this comparison. If no applicable acute toxicity data are obtainable on the active ingredient, the toxicity category corresponding to the signal word of any registered manufacturing-use product that is the source of the active ingredient in the end-use product shall be used. If no acute toxicity data are obtainable on the active ingredients and no toxicity category of a registered manufacturing-use product is obtainable, the toxicity category of the end-use product (corresponding to the signal word on its labeling) shall be used.

(2) Restricted-entry interval for sole active ingredient products.

(i) If the product contains only one active ingredient and it is in toxicity category I by the criteria in paragraph (c)(1) of this section, the restricted-entry interval shall be 48 hours. If, in addition, the active ingredient is an organophosphorus ester that inhibits cholinesterase and that may be applied outdoors in an area where the average annual rainfall for the application site is less than 25 inches per year, the following statement shall be added to the restricted-entry interval statement: "(72 hours in outdoor areas where average annual rainfall is less than 25 inches a year)."

(ii) If the product contains only one active ingredient and it is in toxicity category II by the

criteria in paragraph (c)(1) of this section, the restricted-entry interval shall be 24 hours.

(iii) If the product contains only active ingredients that are in toxicity category III or IV by the criteria in paragraph (c)(1) of this section, the restricted-entry interval shall be 12 hours.

(3) Restricted-entry interval for multiple active ingredient products. If the product contains more than one active ingredient, the restricted-entry interval (including any associated statement concerning use in arid areas under paragraph (c)(2)(i) of this section) shall be based on the active ingredient that requires the longest restricted-entry interval as determined by the criteria in this section.

(d) Exception for fumigants. The criteria for determining restricted-entry intervals in paragraph (c) of this section shall not apply to any product that is a fumigant. For fumigants, any existing restricted-entry interval (hours, days, or acceptable exposure level) shall be retained. Entry restrictions for fumigants have been or shall be established on a case-by-case basis at the time of registration, reregistration, or other Agency review process.

(e) Existing product-specific restricted-entry intervals.

(1) A product-specific restricted-entry interval, based on data collected in accordance with § 158.1070 or § 161.390 of this chapter and Subdivision K of the Pesticide Assessment Guidelines, shall supersede any restricted-entry

interval applicable to the product under paragraph (c) of this section.

(2) Product-specific restricted-entry intervals established for pesticide products or pesticide uses that are not covered by part 170 of this chapter shall remain in effect and shall not be placed under the heading AGRICULTURAL USE REQUIREMENTS in the labeling.

(f) Existing interim restricted-entry intervals.

(1) An interim restricted-entry interval established by the Agency before the effective date of this subpart will continue to apply unless a longer restricted-entry interval is required by paragraph (c) of this section.

(2) Existing interim restricted-entry intervals established by the Agency for pesticide products or pesticide uses not covered by part 170 of this chapter shall remain in effect and shall not be placed under the heading AGRICULTURAL USE REQUIREMENTS in the labeling.

40 C.F.R. § 156.210

§ 156.210 Notification-to-workers statements.

Effective: February 10, 2009

(a) Requirement. Each product that meets the requirements of paragraph (b) of this section shall bear the posting and oral notification statements prescribed below. The statements shall be in the DIRECTIONS FOR USE section of the labeling under the heading AGRICULTURAL USE REQUIREMENTS.

(b) Notification to workers of pesticide application.

(1) Each product that contains any active ingredient classified as toxicity category I for either acute dermal toxicity or skin irritation potential under the criteria in § 156.62 shall bear the statement: "Notify workers of the application by warning them orally and by posting warning signs at entrances to treated areas." If no acute dermal toxicity data are obtainable, data on acute oral toxicity of the active ingredient shall be considered instead. If no data on acute dermal toxicity, skin irritation potential, or acute oral toxicity are obtainable on the active ingredient, the toxicity category corresponding to the signal word of any registered manufacturing-use product that is the source of the active ingredient in the end-use product shall be used. If none of the applicable acute toxicity data are obtainable on the active ingredient and no toxicity category of the registered manufacturing-use product is obtainable, the toxicity category of the end-use product corresponding to the product's signal word shall be used.

(2) Each product that is a fumigant and is registered for use in a greenhouse (or whose labeling allows use in a greenhouse) shall bear the statement: "For greenhouse applications, notify workers of the application by warning them orally and by posting warning signs outside all entrances to the greenhouse."

40 C.F.R. § 156.212

§ 156.212 Personal protective equipment statements.

Effective: February 10, 2009

(a) Requirement. Each product shall bear the personal protective equipment statements prescribed in paragraphs (d) through (j) of this section.

(b) Exceptions.

(1) If personal protective equipment were required for a product before the effective date of this subpart, the existing requirements shall be retained on the labeling wherever they are more specific or more protective (as specified in EPA guidance materials) than the requirements in the table in paragraph (e) of this section.

(2) Any existing labeling statement that prohibits the use of gloves or boots overrides the corresponding requirement in paragraph (e) of this section and must be retained on the labeling.

(3) If the product labeling contains uses that are not covered by part 170 of this chapter, the registrant may adopt the personal protective equipment required in this section for those uses. However, if the personal protective equipment required in this section would not be sufficiently protective or would be onerously overprotective for uses not covered by part 170 of this chapter, the registrant must continue to apply the existing personal protective equipment requirements to those uses. The labeling must indicate which personal protective equipment requirements apply to uses covered by part 170 of this chapter

and which personal protective equipment requirements apply to other uses.

(c) Location of personal protective equipment statements—

(1) Personal protective equipment statements for pesticide handlers. Personal protective equipment statements for pesticide handlers shall be in the HAZARDS TO HUMANS (AND DOMESTIC ANIMALS) section of the labeling. The required statements may be combined to avoid redundancy as long as the requirements and conditions under which they apply are identified.

(2) Personal protective equipment statements for early-entry workers. Personal protective equipment statements for early-entry workers shall be placed in the DIRECTIONS FOR USE section of the labeling under the heading AGRICULTURAL USE REQUIREMENTS and immediately after the restricted-entry statement required in § 156.208(a).

(d) Personal protective equipment statements for pesticide handlers.

(1) The table in paragraph (e) of this section specifies minimum requirements for personal protective equipment (as defined in § 170.240 of this chapter) and work clothing for pesticide handlers. This personal protective equipment requirement applies to any product that presents a hazard through any route of exposure identified in the table (acute dermal toxicity, skin irritation potential, acute inhalation toxicity, and eye irritation potential).

(2) The requirement for personal protective equipment is based on the acute toxicity category of the end-use product for each route of exposure as defined by § 156.62. If data to determine the acute dermal toxicity or the acute inhalation toxicity are not obtainable, the acute oral toxicity shall be used as a surrogate to determine the personal protective equipment requirements for that route of exposure. If data to determine the acute toxicity of the product by a specific route of exposure (including acute oral toxicity in lieu of acute dermal or acute inhalation toxicity) are not obtainable, the toxicity category corresponding to the signal word of the end-use product shall be used to determine personal protective equipment requirements for that route of exposure. If the signal word is "CAUTION," toxicity category III will be used.

(3) The minimum personal protective equipment and work clothing requirements specified in this section shall be included in a statement such as the following: "Applicators and other handlers must wear: (body protection statement); (glove statement, if applicable); (footwear statement, if applicable); (protective eyewear statement, if applicable); (respirator statement, if applicable)." The format of statements given in this paragraph is optional, but it is recommended for clarity.

(e) Summary of personal protective equipment requirements. The following table 1 summarizes the personal protective equipment requirements by route of exposure and toxicity category:

Table 1—Minimum Personal Protective Equipment (PPE) and Work Clothing for Handling Activities

	Toxicity Category of End-Use Product			
Route of Exposure	**I**	**II**	**III**	**IV**
Dermal Toxicity or Skin Irritation	Coveralls worn over long-sleeved shirt and long pants	Coveralls worn over short-sleeved shirt and short pants	Long-sleeved shirt and long pants	Long-sleeved shirt and long pants
Potential[1]				
	Socks	Socks	Socks	Socks
	Chemical-resistant footwear	Chemical-resistant footwear	Shoes	Shoes
	Chemical-resistant gloves[2]	Chemical-resistant gloves[2]	Chemical-resistant gloves[2]	No minimum[4]
Inhalation Toxicity	Respiratory	Respiratory	No minimum[4]	No minimum[4]

[1] If dermal toxicity and skin irritation potential are in different toxicity categories, protection shall be based on the more toxic (lower numbered) category.

[2] For labeling language for chemical-resistant gloves, see paragraph (f) of this section.

[4] Although no minimum PPE is required by this section for this toxicity category and route of exposure, the Agency may require PPE on a product-specific basis.

	protection device[3]	protection device[3]		
Eye Irritation Potential	Protective eyewear	Protective eyewear	No minimum[4]	No minimum[4]

(f) Chemical-resistant gloves labeling statements for pesticide handlers. If the table in paragraph (e) of this section indicates that chemical-resistant gloves are required, the glove statement shall be as specified in paragraph (f)(2), (3), (4), or (5) of this section.

(1) Exception. The registrant shall specify a glove type other than that selected through the criteria in paragraphs (f)(2) through (5) of this section if information available to the registrant indicates that such a glove type is more appropriate or more protective than the glove type specified in this section. The statement must specify the particular types of chemical-resistant glove (such as nitrile, butyl, neoprene, and/or barrier-laminate).

(2) Solid formulations. For products formulated and applied as solids or formulated as solids and diluted solely with water for application, the glove statement shall specify: "waterproof gloves."

(3) Aqueous-based formulations. For products formulated and applied as a water-based liquid or formulated as a water-based liquid and diluted solely with water for application, the glove statement may specify: "waterproof gloves" instead of the statement in paragraph (f)(4) of this section.

[3] For labeling language for respiratory protection device, see paragraphs (g) and (h) of this section.

(4) Other liquid formulations. For products formulated or diluted with liquids other than water, the glove statement shall specify: "chemical-resistant (such as nitrile or butyl) gloves."

(5) Gaseous formulations and applications. For products formulated or applied as gases, any existing glove statement established before the effective date of this subpart, including any glove prohibition statement, will continue to apply. If no glove statement or glove prohibition now exists, the glove statement shall specify "chemical-resistant (such as nitrile or butyl) gloves."

(g) Existing respirator requirement for pesticide handlers on product labeling—

(1) General requirement. If a statement placed on a product's labeling before the effective date of this subpart indicates that respiratory protection is required, that requirement for protection shall be retained. The statement must specify, or be amended to specify, one of the following respirator types and the appropriate MSHA/NIOSH approval number prefix:

(i) Dust/mist filtering respirator with MSHA/NIOSH/ approval number prefix TC–21C; or

(ii) Respirator with an organic-vapor-removing cartridge and a prefilter approved for pesticides with MSHA/NIOSH approval number prefix TC–23C or with a canister approved for pesticides with MSHA/NIOSH approval number prefix TC–14G; or

(iii) Supplied-air respirator with MSHA/NIOSH approval number prefix TC–19C or self-contained breathing apparatus (SCBA) with MSHA/NIOSH approval number TC–13F.

(2) Respirator type already specified on labeling. If the existing respiratory protection requirement specifies a respirator type, it shall be retained. The respirator statement must be revised, if necessary, to conform to the wording in paragraph (g)(1) of this section.

(3) Respirator type not already specified on labeling. If the existing respiratory protection requirement on product labeling does not specify a respirator type as listed in paragraph (g)(1) of this section, the specific respirator type shall be that required in the criteria in paragraphs (g)(3)(ii) through (vi) of this section.

(i) Exception. The registrant shall specify a different type of respiratory protection device if information, such as vapor pressure value, is available to the registrant to indicate that the type of respiratory protection device selected through the criteria in paragraphs (g)(3)(ii) through (vi) of this section would not be adequately protective, or might increase risks to the user unnecessarily.

(ii) Gases applied outdoors. For products that are formulated or applied as a gas (space and soil fumigants) and that may be used outdoors, the respiratory protection statement shall be: "For handling activities outdoors, use either a respirator with an organic-vapor-removing cartridge with a prefilter approved for

pesticides (MSHA/NIOSH approval number prefix TC–23C), or a canister approved for pesticides (MSHA/NIOSH approval number prefix TC–14G)."

(iii) Gases used in enclosed areas. For products that are formulated or applied as a gas (space and soil fumigants) and that may be used in greenhouses or other enclosed areas, the respiratory protection statement shall specify: "For handling activities in enclosed areas, use either a supplied-air respirator with MSHA/NIOSH approval number prefix TC–19C, or a self-contained breathing apparatus (SCBA) with MSHA/NIOSH approval number TC–13F."

(iv) Solids. For products that are formulated and applied as solids, the respiratory protection statement shall specify: "dust/mist filtering respirator (MSHA/NIOSH approval number prefix TC–21C)."

(v) Liquids in toxicity category I. For products that are formulated or applied as liquids, and, as formulated, have an acute inhalation toxicity (or its surrogate as specified in paragraph (d)(2) of this section) in category I, the respiratory protection statement shall specify: "either a respirator with an organic-vapor-removing cartridge with a prefilter approved for pesticides (MSHA/NIOSH approval number prefix TC–23C), or a canister approved for pesticides (MSHA/NIOSH approval number prefix 14G)."

(vi) Liquids in toxicity category II. For products that are formulated or applied as liquids, and, as formulated, have an acute inhalation toxicity (or its surrogate as specified in paragraph (d)(2) of this section) in category II, the respiratory protection statement shall specify: "For handling activities during (select uses applicable to the product: airblast, mistblower, pressure greater than 40 p.s.i. with fine droplets, smoke, mist, fog, aerosol or direct overhead) exposures, wear either a respirator with an organic-vapor-removing cartridge with a prefilter approved for pesticides (MSHA/NIOSH approval number prefix TC–23C), or a canister approved for pesticides (MSHA/NIOSH approval number prefix 14G). For all other exposures, wear a dust/mist filtering respirator (MSHA/NIOSH approval number prefix TC–21C)."

(h) New respirator requirement established for pesticide handlers in this part—

(1) General requirement. If the table in paragraph (e) of this section indicates a respiratory protection device is required, and existing product labeling has no respiratory protection requirement, the registrant shall add a respiratory protection statement that specifies a: "dust/mist filtering respirator (MSHA/NIOSH approval number prefix TC–21C)."

(2) Exception. The registrant shall specify a different type of respiratory protection device if information, such as vapor pressure value, is available to the registrant to indicate that the type of respiratory protection device required in

paragraph (h)(1) of this section would not be adequately protective or might increase risks to the user unnecessarily.

(i) Additional personal protective equipment requirements for pesticide handlers. In addition to the minimum personal protective equipment and work clothing requirements given in the table in paragraph (e) of this section, the labeling statement for any product in toxicity category I or II on the basis of dermal toxicity or skin irritation potential (or their surrogate as specified in paragraph (d)(2) of this section), shall include the following personal protective equipment instructions, additions, or substitutions as applicable:

(1) If the product is not ready-to-use and there is no existing requirement for a chemical-resistant suit, the following statement shall be included: "Mixers/Loaders: add a chemical-resistant apron."

(2) If the application of the product may result in overhead exposure to any handler (for example, applicator exposure during airblast spraying of orchards or flagger exposure during aerial application), the following statement shall be included: "Overhead Exposure: wear chemical-resistant headgear."

(3) If any type of equipment other than the product container may be used to mix, load, or apply the product, and there is no requirement for a chemical-resistant protective suit, the following statement shall be included: "For Cleaning Equipment: add a chemical-resistant apron."

(j) Personal protective equipment for early-entry workers. This paragraph specifies minimum requirements for personal protective equipment (as defined in § 170.240 of this chapter) and work clothing for early-entry workers.

(1) For all pesticide products, add the statement: "For early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil, or water, wear: (list the body protection, glove, footwear, protective eyewear, and protective headgear, if applicable, statements specified for applicators and other handlers, but omit any respiratory protection statement)."

(2) If the body protection statement in the personal protective equipment requirement for handlers specifies a long-sleeved shirt and long pants, "coveralls" must be specified in the statement of personal protective equipment for early-entry workers.

(3) If there is no statement requiring gloves and no prohibition against gloves for applicators and other handlers under the heading HAZARDS TO HUMANS (AND DOMESTIC ANIMALS) in the labeling, add a requirement for "waterproof gloves" in the statement of personal protective equipment for early-entry workers.

S. REP. 100-83, S. Rep. No. 83, 100TH Cong., 1ST Sess. 1987, 1987 WL 967478 (Leg.Hist.)

PROCESS PATENTS AMENDMENTS ACT OF 1987

SENATE REPORT NO. 100–83

June 23, 1987

Mr. BIDEN, from the Committee on the Judiciary, submitted the following REPORT

[To accompany S. 1200]

The Committee on Judiciary, to which was referred the bill (S. 1200) to amend Title 35, United States Code, with respect to patented processes, patent misuse and licensee challenges to patent validity, having considered the same, reports favorably thereon with an amendment in the nature of a substitute and recommends that the bill (as amended) do pass.

CONTENTS

I. PURPOSE

The purpose of the proposed legislation, as amended, is to improve the rights of patent owners and certain aspects of the patent law by providing patent owners the new right to sue for damages and seek an injunction in Federal district court when someone without authorization, uses or sells in the United States, or import-into the United States a product made by their patented process by reforming the doctrine of patent misuse so it will not be used to

restrict the rights of patent owners when their licensing practices do not violate the antitrust laws; by clarifying the rights of parties with respect to patent licensing agreements; and by extending the patent on the pharmaceutical product gemfibrozil for a period of a years.

II. TEXT OF BILL S. 1200

To amend title 35, United States Code, with respect to patented processes, patent misuse and licensee challenges to patent validity.

IN THE SENATE OF THE UNITED STATES

MAY 14 (legislative day, MAY 13), 1987

Mr. DECONCINI (for himself, Mr. HATCH, and Mr. LAUTENBERG) introduced the following bill; which was read twice and referred to the Committee on the Judiciary

JUNE 5, 1987

Reported by Mr. BYRD (for Mr. BIDEN), with an amendment and amendment to the title

[Strike out all after the enacting clause and insert the part printed in italic]

A BILL

To amend title 35, United States Code, with respect to patented processes, patent misuse and licensee challenges to patent validity.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

TITLE I—PROCESS PATENT AMENDMENTS ACT OF 1987

SECTION 1. SHORT TITLE.

That this Act may be cited as the "Process Patent Amendments Act of 1987".

SEC. 2. RIGHTS OF OWNERS OF PATENTED PROCESSES.

Section 154 is amended by inserting after "United States," the following: "and, if the invention is a process, of the right to exclude others from using or selling throughout the United States, or importing into the United States, products made by that process,".

SEC. 3. INFRINGEMENT FOR IMPORTATION, SALE, OR USE.

Section 271 is amended by adding at the end the following now subsection:

"(g) Whoever without authority imports into the United States or 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, sale, or use of the product occurs during the term of such process patent. In an action for infringement of a process patent, no remedy may be granted for infringement on account of the noncommercial use or retail sale of a product unless there is no adequate remedy under this title for infringement on account of the importation or other use or sale of that product. A product which is made by a patented process will, for purposes of this title, not be considered to be so made after—

"(1) it is materially changed by subsequent processes; or

"(2) it becomes a minor or nonessential component of another product.".

SEC. 4. DAMAGES FOR INFRINGEMENT.

(a) LIMITATIONS AND OTHER REMEDIES.—Section 287 is amended—

(1) in the section heading by striking "**Limitation on damages**" and inserting "**Limitation on damages and other remedies**";

(2) by inserting "(a)" before "Patentees"; and

(3) by adding at the end the following:

"(b)(1) An infringer under section 271(g) shall be subject to all the provisions of this title relating to damages and injunctions except to the extent those remedies are modified by this subsection or section 6 of the Process Patent Amendments Act of 1987. The modifications of remedies provided in this subsection shall not be available to any person who—

"(A) practiced the patented process;

"(B) owns or controls, or is owned or controlled by, the person who practiced the patented process; or

"(C) had knowledge before the infringement that a patented process was used to make the product the importation, use, or sale of which constitutes the infringement.

"(2) No remedies for infringement under section 271(g) of this title shall be available with

respect to any product in the possession of, or in transit to the infringer, or which the infringer has made a binding commitment to purchase and which has been partially or wholly manufactured, before the infringer had notice of infringement as defined in paragraph (5). The infringer shall bear the burden of proving any such possession, transit, binding commitment or manufacture. If the court finds that (i) the infringer maintained or ordered an abnormally large amount of infringing product, or (ii) the product was acquired or ordered by the infringer to take advantage of the limitation on remedies provided by this paragraph, the court shall limit the application of this paragraph to that portion of the product supply which is not subject to such a finding.

"(3)(A) In making a determination with respect to remedy in an action brought for infringement under section 271(g), the court shall consider—

> "(i) the good faith and reasonable business practices demonstrated by the defendant;
>
> "(ii) the good faith demonstrated by the plaintiff with respect to the request for disclosure as provided in paragraph (4); and
>
> "(iii) the need to restore the exclusive rights secured by the patent.

"(B) For purposes of paragraph (3)(A), the following are evidence of good faith—a request for disclosure by a party, a response by the party receiving the request for disclosure within sixty days, and submission of the

response by the party who received the disclosed information to the manufacturer, or if not known, the supplier with a request for a written statement that the process claimed in the disclosed patent is not used. The failure to perform any such acts is evidence of absence of good faith unless there are mitigating circumstances. Mitigating circumstances shall include the case in which, due to the nature of the product, the number of sources for products, or like commercial circumstances, a request for disclosure is not necessary or practicable to avoid infringement.

"(4) For purposes of paragraph (3), a 'request for disclosure' means a written request made to a party then engaged in the manufacture of a product to identify all process patents owned by or licensed to the party as of the time of the request that the party then reasonably believes could be asserted to be infringed under section 271(g) if that product were imported into, or sold or used in, the United States by an unauthorized party. A request for disclosure is further limited to a request—

"(i) made by a party regularly engaged in the United States in the sale of the same type of products as the party to whom the request is directed, or a request which includes facts showing that the requester plans to engage in the sale of such products in the United States;

"(ii) made prior to such party's first importation, use or sale of units of the

product produced by an infringing process and prior to notice of infringement; and

"(iii) which includes a representation by the requesting party that it will promptly submit the patents identified to the manufacturer, or if not known, the supplier of the product to be purchased by the requester and will request from that manufacturer or supplier a written statement that none of the processes claimed in those patents is used in the manufacture of the product.

"(5)(A) For the purposes of this subsection, notice of infringement means actual knowledge, or receipt by a party of a written notification or a combination thereof, of information sufficient to persuade a reasonable person that it is likely that the product was made by an infringing process and not by a noninfringing process.

"(B) A written notification from the patent holder charging a party with infringement shall, in order to be a valid notification under paragraph (A), specify the patent alleged to have been used and the reasons for belief that such process, and not others, was used in the production of the product.

"(C) A party who receives a notification as described in (B) and fails to thereafter seek information from the manufacturer, or if not known, the supplier as to whether the allegations in the statement are true shall, absent mitigating circumstances, be deemed to have notice of infringement.

"(D) A party who fails to make the submission referred to in subsection (b)(4)(iii) shall be deemed to have notice of infringement.

"(E) Filing of an action for infrangement shall constitute notice of infringement only if the pleadings or other papers filed in the action meet the requirements of (A).".

(b) TECHNICAL AMENDMENT.—The item relating to section 287 in the table of sections for chapter 29 is amended to read as follows:

"287. Limitations on damages and other remedies; marking and notice.".

SEC. 5. PRESUMPTION IN INFRINGEMENT ACTIONS.

(a) IN GENERAL.—Chapter 29 is amended by adding at the end the following:

"§ **295. Presumption: Product made by patented process**

"In actions alleging infringement of a process patent based on the importation, sale, or use of a product which is made from a process patented in the United States, if the court finds

"(1) that there is evidence establishing a substantial likelihood that the product was made by the patented process; and "(2) that the claimant has made a reasonable effort to determine the process actually used in the production of the product and was unable so to determine,

the product shall be presumed to have been so made, and the burden of establishing that the product was

not made by the process shall be on the party asserting that it was not so made.".

(b) CONFORMING AMENDMENT.—The table of sections for chapter 29 is amended by adding after the item relating to section 294 the following:

"205. Presumption: Product made by patented process.".

SEC. 6. EFFECTIVE DATE.

(a)(1) IN GENERAL.—The amendments made by this title shall apply only to products made or imported after the date of the enactment of this Act.

(2) EXCEPTIONS. This Act shall not abridge or affect the right of any person or any successor in business of such person to continue to use, sell, or import any specific product already in substantial and continuous sale or use by such person in the United States on May 15, 1987, or for which substantial preparation by such person for such sale or use was made before such date, to the extent equitable for the protection of commercial investments made or business commenced in the United States before such date. This paragraph shall not apply to any person or any successor in business of such person using, selling, or importing a product produced by a patented process that is the subject of a patent process enforcement action commenced before January 1, 1987, including actions before the International Trade Commission, that is pending or in which an order has been entered.

(b) RETENTION OF OTHER REMEDIES.—The amendments made by this title shall not deprive

a patent owner of any remedies available under subsection (a) through (f) of section 271 of title 35, United States Code, under section 337 of the Tariff Act of 1930, or under any other provision of law.

SEC. 7. REPORTS TO CONGRESS.

(a) CONTENTS.—The Secretary of Commerce shall, not later than the end of each one-year period described in subsection (b), report to the Congress on the effect of the amendments made by this title on the importation of ingredients to be used for manufacturing products in the United States in those domestic industries that submit complaints to the Department of Commerce, during that one-year period, alleging that their legitimate sources of supply have been adversely affected by the amendments made by this title.

(b) WHEN SUBMITTED.—A report described in subsection (a) shall be submitted with respect to each of the five one-year periods which occur successively beginning on the date of the enactment of this Act and ending five years after that date.

TITLE II—PATENT MISUSE DOCTRINE REFORM

Section 271 of title 35, United States Code, is amended—

(1) by redesignating subsection (c) as paragraph (1) of subsection (c);

(2) by redesignating subsection (d) as paragraph

(2) of subsection (c); and

(3) by inserting after subsection (d) the following new subsection:

"(d) No patent owner otherwise entitled to relief for infringement or contributory infringement of a patent shall be denied relief or deemed guilty of misuse or illegal extension of the patent right by reason of his or her licensing practices or actions or inactions relating to his or her patent, unless such practices or actions, in view of the circumstances in which such practices or actions are employed, violate the antitrust laws.".

TITLE III—LICENSEE CHALLENGES TO PATENT VALIDITY

SEC. 301. Chapter 29 of title 35, United States Code, is amended by adding at the end thereof the following new section:

"**§ 295. Licensee challenges to patent validity**

"(a) A licensee shall not be estopped from asserting in a judicial action the invalidity of any patent for which the licensee has obtained a license. Any agreement between the parties to a patent license agreement which purports to bar the licensee from asserting the invalidity of any licensed patent shall be unenforceable as to that provision.

"(b) Any patent license agreement may provide for a party or parties to the agreement to terminate the license if the licensee asserts in a judicial action the invalidity of the licensed patent, and, if the licensee has such a right to terminate, the agreement may further provide that the licensee's obligations under the agreement shall continue until a final and unappealable determination of invalidity is reached

or until the license is terminated. Such agreement shall not be unenforceable as to such provisions on the grounds that such provisions are contrary to Federal law or policy.".

SEC. 302. The table of sections for chapter 29 of title 35, United States Code is amended by adding at the end thereof the following new item:

"295. Licensee challenges to patent validity.".

That this Act may be cited as the "Process Patent Amendments Act of 1987".

TITLE I—PROCESS PATENT AMENDMENTS ACT OF 1987

SEC. 101. RIGHTS OF OWNERS OF PATENTED PROCESSES.

Section 154 of title 35, United States Code, is amended by inserting after "United States," the following: "and, if the invention is a process, of the right to exclude others from using or selling throughout the United States, or importing into the United States, products made by that process,".

SEC. 102. INFRINGEMENT FOR IMPORTATION, SALE, OR USE.

Section 271 of title 35, United States Code, is amended by adding at the end the following new subsection:

"*(g) Whoever without authority imports into the United States or 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, sale, or use of the product occurs during*

the term of such process patent. In an action for infringement of a process patent, no remedy may be granted for infringement on account of the noncommercial use or retail sale of a product unless there is no adequate remedy under this title for infringement on account of the importation or other use or sale of that product. A product which is made by a patented process will, for purposes of this title, not be considered to be so made after—

"(1) it is materially changed by subsequent processes; or

"(2) it becomes a trivial and nonessential component of another product.".

SEC. 103. DAMAGES FOR INFRINGEMENT.

(a) LIMITATIONS AND OTHER REMEDIES.—Section 287 of title 35, United States Code, is amended—

(1) in the section heading, by striking "LIMITATION ON DAMAGES" and inserting "LIMITATION ON DAMAGES AND OTHER REMEDIES";

(2) by inserting "(a)" before "Patentees"; and

(3) by adding at the end the following:

"(b)(1) An infringer under section 271(g) shall be subject to all the provisions of this title relating to damages and injunctions except to the extent those remedies are modified by this subsection or section 105 of the Process Patent Amendments Act of 1987. The modifications of remedies provided in this subsection shall not be available to any person who—

"*(A) practiced the patented process*;

"*(B) owns or controls, or is owned or controlled by, the person who practiced the patented process; or*

"*(C) had knowledge before the infringement that a patented process was used to make the product the importation, use, or sale of which constitutes the infringement.*

"*(2) No remedies for infringement under section 271(g) of this title shall be available with respect to any product in the possession of, or in transit to the party, or which the party has made a binding commitment to purchase and which has been partially or wholly manufactured, before the party had notice of infringement as defined in paragraph (5). The party shall bear the burden of proving any such possession, transit, binding commitment, or manufacture. If the court finds that (A) the party maintained or ordered an abnormally large amount of infringing product, or (B) the product was acquired or ordered by the party to take advantage of the limitation on remedies provided by this paragraph, the court shall limit the application of this paragraph to that portion of the product supply which is not subject to such a finding.*

"*(3)(A) In making a determination with respect to the remedy in an action brought for infringement under section 271(g), the court shall consider—*

"*(i) the good faith and reasonable business practices demonstrated by the defendant*,

"(ii) the good faith demonstrated by the plaintiff with respect to the request for disclosure as provided in paragraph (4), and

"(iii) the need to restore the exclusive rights secured by the patent.

"(B) For purposes of subparagraph (A), the following are evidence of good faith: a request for disclosure by a party, a response by the party receiving the request for disclosure within 60 days, and submission of the response by the party who received the disclosed information to the manufacturer, or if not known, the supplier with a request for a written statement that the process claimed in the disclosed patent is not used. The failure to perform any such acts is evidence of absence of good faith unless there are mitigating circumstances. Mitigating circumstances shall include the case in which, due to the nature of the product, the number of sources for products, or like commercial circumstances, a request for disclosure is not necessary or practicable to avoid infringement.

"(4) For purposes of paragraph (3), a 'request for disclosure' means a written request made to a party then engaged in the manufacture of a product to identify all process patents owned by or licensed to the party as of the time of the request that the party then reasonably believes could be asserted to be infringed under section 271(g) if that product were imported into, or sold or used in, the United States by an unauthorized party. A request for disclosure is further limited to a request—

"(A) made by a party regularly engaged in the United States in the sale of the same type of products as the party to whom the request is directed, or a request which includes facts showing that the requester plans to engage in the sale of such products in the United States;

"(B) made prior to such party's first importation, use, or sale of units of the product produced by an infringing process and prior to notice of infringement; and

"(C) which includes a representation by the requesting party that it will promptly submit the patents identified to the manufacturer, or if not known, the supplier of the product to be purchased by the requestor, and will request from that manufacturer or supplier a written statement that none of the processes claimed in those patents is used in the manufacture of the product.

"(5)(A) For the purpose of this subsection, notice of infringement means actual knowledge, or receipt by a party of a written notification, or a combination thereof, of information sufficient to persuade a reasonable person that it is likely that a product was made by a patented process.

"(B) A written notification from the patent holder charging a party with infringement shall specify the patent alleged to have been used and the reasons for a good faith belief that such process was used. If the patent holder has actual knowledge of any commercially feasible process other than the patented process which is capable of producing

the allegedly infringing product, the notification shall set forth such information with respect to the other processes only as is reasonably necessary to fairly explain the patent holder's belief and is not required to disclose any trade secret information.

"(C) A party who receives a written notification as described in the first sentence of such subparagraph (B) and fails to thereafter seek information from the manufacturer, or if not known, the supplier, as to whether the allegations in the notification are true shall, absent mitigating circumstances, be deemed to have notice of infringement. This provision shall apply even though the notification does not establish notice of infringement under subparagraph (A).

"*(D) A party who fails to make the submission referred to in subsection (b)(4)(C) shall be deemed to have notice of infringement..*

"*(E) Filing of an action for infringement shall constitute notice of infringement only if the pleadings or other papers filed in the action meet the requirements of subparagraph (A).*".

(b) TECHNICAL AMENDMENT.—The item relating to section 287 of title 35, United States Code, in the table of sections for chapter 29 of such title is amended to read as follows:

"*287. Limitations on damages and other remedies; marking and notice.*".

SEC. 104. PRESUMPTION IN INFRINGEMENT ACTIONS.

(a) IN GENERAL.—Chapter 29 of title 35, United States Code, is amended by adding at the end the following:

"§ 295. Presumption: Product made by patented process

"In actions alleging infringement of a process patent based on the importation, sale, or use of a product which is made from a process patented in the United States, if the court finds—

> *"(1) that there is evidence establishing a substantial likelihood that the product was made by the patented process, and*
>
> *"(2) that the claimant has made a reasonable effort to determine the process actually used in the production of the product and was unable so to determine,*

the product shall be presumed to have been so made, and the burden of establishing that the product was not made by the process shall be on the party asserting that it was not so made.".

(b) CONFORMING AMENDMENT.—The table of sections for chapter 29 of title 35, United States Code, is amended by adding after the item relating to section 294 the following:

"*295. Presumption: Product made by patented process.*".

SEC. 105. EFFECTIVE DATE*.*

(a)(1) IN GENERAL.—The amendments made by this title shall apply only to products made or imported after the date of the enactment of this Act.

(2) EXCEPTIONS.—This title shall not abridge or affect the right of any person or any

successor in business of such person to continue to use, sell, or import any specific product already in substantial and continuous sale or use by such person in the United States on May 15, 1987, or for which substantial preparation by such person for such sale or use was made before such date, to the extent equitable for the protection of commercial investments made or business commenced in the United States before such date. This paragraph shall not apply to any person or any successor in business of such person using, selling, or importing a product produced by a patented process that is the subject of a patent process enforcement action commenced before January 1, 1987, before the International Trade Commission, that is pending or in which an order has been entered.

(b) RETENTION OF OTHER REMEDIES.—The amendments made by this title shall not deprive a patent owner of any remedies available under subsections (a) through (f) of section 271 of title 35, United States Code, under section 337 of the Tariff Act of 1930, or under any other provision of law.

***SEC. 106. REPORTS TO CONGRESS**.*

(a) CONTENTS.—The Secretary of Commerce shall, not later than the end of each 1-year period described in subsection (b), report to the Congress on the effect of the amendments made by this title on the importation of ingredients to be used for manufacturing products in the United States in those domestic industries that submit complaints to the Department of Commerce, during that 1-year period, alleging that their legitimate sources of supply have been adversely affected by the amendments made by this title.

(b) WHEN SUBMITTED.—A report described in subsection (a) shall be submitted with respect to each of the five 1-year periods which occur successively beginning on the date of the enactment of this Act and ending five years after that date.

TITLE II—PATENT MISUSE DOCTRINE REFORM

SEC. 201. INFRINGEMENT OF PATENT.

Section 271 of title 35, United States Code, is amended—

(1) by redesignating subsection (c) as subsection (c)(1) of subsection (c);

(2) by redesignating subsection (d) as paragraph (2) of such subsection (c); and

(3) by inserting after subsection (c) the following new subsection:

"(d) No patent owner otherwise entitled to relief for infringement or contributory infringement of a patent shall be denied relief or deemed guilty of misuse or illegal extension of the patent right by reason of his or her licensing practices or actions or inactions relating to his or her patent, unless such practices or actions or inactions, in view of the circumstances in which such practices or actions or inactions are employed, violate the antitrust laws.".

TITLE III—LICENSEE CHALLENGES TO PATENT VALIDITY

SEC. 301. LICENSEE CHALLENGES.

(a) IN GENERAL.—Chapter 29 of title 35, United States Code, as amended by section 104 of this

Act, is further amended by adding at the end thereof the following new section:

"§ *296. Licensee challenges to patent validity*

"(a) A licensee shall not be estopped from asserting in a judicial action the invalidity of any patent for which the licensee has obtained a license. Any agreement between the parties to a patent license agreement which purports to bar the licensee from asserting the invalidity of any licensed patent shall be unenforceable as to that provision.

"(b) Any patent license agreement may provide for a party or parties to the agreement to terminate the license if the licensee asserts, in a judicial action, the invalidity of the licensed patent, and, if the licensee has such a right to terminate, the agreement may further provide that the licensee's obligations under the agreement shall continue until a final and unappealable determination of invalidity is reached or until the license is terminated. Such agreement shall not be unenforceable as to such provisions on the grounds that such provisions are contrary to Federal law or policy.".

(b) TECHNICAL AMENDMENT.—The table of sections for chapter 29 of title 35, United States Code, as amended by section 104 of this Act, is further amended by adding at the end thereof the following new item:

"*296. Licensee challenges to patent validity.*".

TITLE IV—PHARMACEUTICAL PATENT TERM RESTORATION ACT AMENDMENTS

SEC. 401. (a) Title 35, United States Code, is amended by adding the following new section:

"§ ***155B. Patent Term Restoration***

"(a) Notwithstanding section 154 of this title, the term of a patent which encompasses within its scope a composition of matter which is a new drug shall be extended for a period of 5 years, and such patent shall have the effect as if originally issued with such extended term, if—

"(1) such composition has been subjected to a regulatory review by the Federal Food and Drug Administration pursuant to the Federal Food, Drug, and Cosmetic Act,

"(2) the Federal Food and Drug Administration has approved a new drug application after receipt of a letter from the applicant stating that a Phase IV clinical study that had been requested as a condition for approval has been undertaken,

"(3) the Phase IV clinical study has covered at least 5 years with the study term commencing prior to the introduction of the Drug Price Competition and Patent Term Restoration Act of 1984 and ending subsequent to the enactment of such Act,

"(4) such Phase IV clinical study has been completed, and a supplemental new drug application to expand the permitted indications and usage in the labeling of the new drug based upon such Phase IV clinical study has been submitted to the Federal Food and Drug Administration,

"(5) the Federal Food and Drug Administration has either approved the

supplemental new drug application or the original patent term is within 90 days of

expiration, and

"(6) the Federal Food and Drug Administration has not made a final determination that the supplemental new drug application is approved or disapproved.

If, however, the term of a patent is extended because the Federal Food and Drug Administration has not made a final determination that the supplemental new drug application is approved or disapproved prior to 90 days before the expiration of the patent, such patent extension shall immediately terminate if the Federal Food and Drug Administration makes a final determination disapproving the supplemental new drug application.

"(b)(1) The patentee, his heirs, successors, or assigns shall notify the Commissioner of Patents and Trademarks within 30 days after the date of enactment of this section, or within 30 days after the date of the approval of the supplemental new drug application if such approval does not occur before enactment of this section, or within 30 days after the date which is 90 days from the expiration of the original patent term if the Federal Food and Drug Administration has not made a final determination that the supplemental new drug application is approved or disapproved by such date, of the number of the patent to be extended.

"(2) On receipt of such notice, the Commissioner shall promptly issue to the owner of record of the patent a certificate of extension, under seal, stating the fact and length of the extension

and identifying the composition of matter to which such extension is applicable. Such certificate shall be recorded in the official file of the patent extended and such certificate shall be considered as part of the original patent, and an appropriate notice shall be published in the Official Gazette of the Patent and Trademark Office. If, subsequent to a notification that it is within 90 days of the expiration of the patent and that the Federal Food and Drug Administration has not made a final determination that the supplemental new drug application is approved or disapproved, a final determination is made by the Federal Food and Drug Administration that the supplemental new drug application is disapproved, the patentee, his heirs, successors, or assigns shall, within 2 days, notify the Commissioner of Patents and Trademarks of such final determination. On receipt of such notice and if the patent has been extended pursuant to the terms hereof, the Commissioner shall promptly issue a certificate of termination of extension, under seal, stating the fact that the patent is terminated, effective the date of the final determination that the supplemental new drug application is disapproved, and identifying the composition of matter to which such termination of extension is applicable. Such certificate shall be recorded in the official file of the patent terminated and such certificate shall be considered as a part of the original patent, and an appropriate notice shall be published in the Official Gazette of the Patent and Trademark Office.".

(b) The analysis for chapter 14 of such title 35 is amended by adding at the end the following:

"*155B. Patent term restoration*.".

Amend the title to read as follows: "A bill to amend title 35, United States Code, with respect to patented processes, patent misuse, license challenges to patent validity, and patent term restoration.".

III. TITLE I—PROCESS PATENT AMENDMENTS ACT OF 1987

A. PURPOSE OF AMENDMENT

As amended, title I of S. 1200 provides patent owners the new right to sue for damages and seek an injunction in Federal district court when someone, without authorization, uses or sells in the United States, or imports into the United States a product made by their patented process.

B. HISTORY OF LEGISLATION

The importance of strengthening process patent protection was first recognized in 1966 by President Johnson's Commission on the Patent System; then in 1979 by President Carter's Domestic Policy Review on Industrial Innovation, and again in 1985 by President Reagan's Commission on Industrial Competitiveness. More recently, it was included in President Reagan's competitiveness initiative of 1987 and strongly endorsed by the President's Commission on Industrial Competitiveness in 1984.

The Process Patent Amendments Act of 1987, title I of S. 1200, is the result of a carefully crafted compromise reached between Senators DeConcini, Hatch, Lautenberg and a wide variety of parties interested in process patent legislation. On April 22, 1987, the Patents, Copyrights and Trademarks Subcommittee held a hearing on predecessors to this bill, S. 568, which was introduced in the 100th

Congress by Senators Hatch and DeConcini and S. 573, which was introduced by Senator Lautenberg. Hearings on Process Patent legislation was also held in both the 98th and 99th Congresses. S. 568 contained the same language as S. 1543, which passed the Judiciary Committee and the Senate unanimously during the 99th Congress. On May 13, 1987 the Patents Subcommittee reported S. 568 with an amendment in the nature of a substitute which was then introduced as title I of S. 1200 on May 14, 1987 by Senators DeConcini, Hatch, and Lautenberg. S. 1200 as amended passed the Judiciary Committee unanimously on June 4, 1987. The Judiciary Committee will include S. 1200 in the Senate Omnibus Trade Act of 1987.

C. DISCUSSION

America's leading position in technology innovation throughout the world is credited in large part to the stimulus of its patent system, which stems ultimately from Article I, Section 8, clause 8 of the Constitution which states, "The Congress shall have Power ... To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries ..." In the past two decades, however, it has become necessary to modernize our patent laws. As compared with those of our major trading partners, the inadequate protection contained in U.S. process patent law has emerged as a major factor in the dynamics of global innovation and economic competition. In contrast to Japan and nearly all of the Western European nations, the United States does not provide patent protection against the importation, and subsequent use or sale,

of products made abroad without authorization using a process patented in the United States except for a limited form of protection is afforded under the trade laws (19 U.S.C. 1337a) enforced by the International Trade Commission (ITC).

The U.S. patent laws recognize three basic types of inventions for which patents may be obtained: products, methods of use, and methods of manufacture. Patents on the last are also known as process patents, that is, patents on process inventions. A process patent covers a process for making a product, which may or may not be patented itself. Process patents promise to be increasingly important to a number of industries in the coming years, especially in the areas of industrial and pharmaceutical chemicals, optical fibres, and above all in the fields of biotechnology and bioengineering research. Biotechnology companies are often built around a new process for artificial manufacture of a substance that occurs in nature and is therefore itself unpatentable. A well known example is the Genentech Corporation of California, whose principal assets since its founding in 1976 have been process patents on revolutionary new ways of making human insulin and growth hormone.

Under our current patent laws, a patent on a process gives the patentholder the right to exclude others from using that process in the United States without authorization from the patentholder. The other two standard aspects of the patent right—the exclusive right to make or sell the invention—are not directly applicable to a patented process. S. 1200 proposes to also cover the importation. use or sale in the United States of products resulting from the

process. The bill does not attempt to prevent the use of the process in another country. If the U.S. process patentholder has not obtained a similar patent in the other country, he has no right by virtue of his U.S. patent to prevent anyone from using the process in that country. However, if the U.S. patentholder does have a patent in the other country as well, he may seek remedy in the courts of that country. S. 1200 would protect against the entry into the U.S. marketplace of goods made abroad without authorization from the inventor who has a process patent in this country. The patent is on the process alone, but the entry of the goods made elsewhere by that process clearly encroaches on the rights of the patent owner.

The principle of process patent protection is also incorporated in the European Patent Convention, the Community Patent Convention, and the World Intellectual Property Organization (W.I.P.O.) Treaty on Harmonization. The following excerpt from a recent memorandum on process patent law prepared by the International Bureau of W.I.P.O. elaborates on the rationale for including products obtained from a patented process in the scope of the protection afforded by the process patent:

The extension (to the product of the process) seems to be an exception to the principle that the protection conferred by a patent or another title of protection for an invention is defined by the object of the invention. In the case of a process invention, a strict application of the said principle would mean that the owner of a process patent could only exclude others from using the patented process. The legal provisions which extend process protection to

products obtained by the patented process are based on practical economic considerations. A process which leads to a specific product presents an economic value only through the product. However, it is not always possible to obtain a patent for the product; for example, the product may not be new or may—although new—lack inventive step. The invention of a new and inventive process for the production of such a product which is not patentable constitutes an important technological advance but the reward granted through a process patent is not important because—without an extension to the product—the process patent would be difficult to enforce (since infringement of the process is difficult to prove) and could even be circumvented by use of the process in another country where the process is protected. In order to make patent protection of a process meaningful, it is therefore necessary to consider the patented process and the resulting product as a whole, with the consequence that process protection is automatically extended to the resulting product even if the said product has not been claimed.[1]

FOREIGN PROCESS PATENT LEGISLATION

Importation, use and sale in the United States of products produced by processes patented in this country severely diminishes the value of such patents. This practice must be effectively countered by changes in the patent laws to protect the legitimate interests of U.S. inventors. Expanding the scope of our laws to bring them into conformity with the

[1] "Extension of Patent Protection of a Process to the Products obtained by that Process; Proof of Infringement of a Process Patent." Memorandum by the International Bureau of WIPO, March 12, 1986, pp. 3-4.

European Patent Convention and the national laws of many industrialized countries is necessary to protect the continued growth of American business. The following chart summarizes the protection offered to process patent holders in the group B or development market economy countries. In addition, some typical examples of foreign laws in this area are helpful for comparison. As the chart and summaries indicate, most countries' patent laws are structured so that the direct product of a patented process is also included within the scope of the patent. Nearly one-half of those countries make importation an act of infringement. [Charts and summaries follow:]

PROCESS PATENT PROTECTION IN GROUP B COUNTRIES

Country	Process patent protects its direct product	Important constitutes infringement	Presumption in favor of process patentee
??[1].....	Yes……..		Yes.[2]
??[1].....	Yes[3] [4]…..	Yes	
??.....	Yes[3] [4]…..		
??[5].....	Yes……..	Yes	
??.....	Yes……..	Yes	
??.....	Yes……..	Yes	
??[1].....	Yes……..	Yes	
Federal Republic of Germany[1]…...	Yes……..		Yes.[2]

Great Britain[1]…	Yes……..	Yes	
Greece…….	Yes……..	Yes……...	Yes.[2]
Holy See[6]			
Iceland…….	Yes……..	Yes	
Iceland…….	Unclear[37]		
Italy[1]…….……	Yes……..		Yes.[2]
Japan…….....	Yes……..	Yes…….	Yes.
Liechtenstein[1 8]…	Yes……..		Yes.
Liechtenstein[1 9]…	Yes[4]		
Monaco[5]			
Netherlands[1]…	Yes……..		Yes.[2]
New Zealand…	Yes[4]		
Norway…….	Yes……..	Yes	
Portugal…….	Yes……..	Yes	
San Marino[10]…..	Yes……..		Yes.[2]
South Africa……	Yes……..		Yes.
Spain	Yes……..	Yes	
Sweden[1]	Yes……..	Yes…….	Yes.[2]
Switzerland[1]…..	Yes……..		Yes.
Turkey[9]			
United States of America			

FN1. EPC member.

FN2. Applies to new substances only. FN3. No clear statutory provision.

FN4. Apparently applies in at least some situations.

FN5. Registration in Cyprus of a United Kingdom patent confers the same right in Cyprus.

FN6. No patent law.

FN7. Claims are permitted, but legal issues are apparently unsettled.

FN8. Liechtenstein and Switzerland constitute a single territory for patent purposes.

FN9. No copy of the national law was available.

FN10. Industrial property rights acquired in Italy are valid in San Marino and vice versa.

DENMARK

SECTION 3

(1) The exclusive right conferred by a patent shall imply that no one except the proprietor of the patent may without permission exploit the invention:

(i) by making, offering, putting on the market or using a product which is the subject-matter of the patent, or by importing or stocking the product for these purposes;

(ii) by using a process which is the subject-matter of the patent or by offering the process for use in this country if the person offering the process knows, or it is obvious in the circumstances, that the use of the process is prohibited without the consent of the proprietor of the patent;

(iii) by offering, putting on the market or using a product obtained by a process which is the subject-matter of the patent or by importing or stocking the product for these purposes.

FRANCE

CHAPTER THREE.—RIGHTS AND OBLIGATIONS ATTACHED TO THE PATENT

Article 28.—1. The scope of protection conferred by a patent shall be determined by the terms of the claims. The description of the invention and the drawings, however, shall serve to construe the claims.

2. Where a patent relates to a process, the protection conferred by the patent shall extend to the products directly obtained by that process.

Article 29.—A patent confers the right to prohibit any other person, without the consent of the proprietor of the patent:

(a) from making, offering, putting on the market, using, or importing or storing for such purposes the product to which the patent relates;

(b) from using a process to which the patent relates, or, where such other person knows, or where it is obvious in the circumstances, that the use of the process is prohibited without the consent of the proprietor of the patent, from offering the process for use within French territory;

(c) from offering, putting on the market, using, or importing or storing for such purposes the product obtained directly by the process to which the patent relates.

GREAT BRITAIN

STATUTES, REGULATIONS, AND TREATIES

Patents Act 1977

Infringement

60.—(1) Subject to the provisions of this section, a person infringes a patent for an invention if, but only if, while the patent is in force, he does any of the following things in the United Kingdom in relation to the invention without the consent of the proprietor of the patent, that is to say—

(a) where the invention is a product, he makes, disposes of, offers to dispose of, uses or imports the product or keeps it whether for disposal or otherwise;

(b) where the invention is a process, he uses the process or he offers it for use in the United Kingdom when he knows, or it is obvious to a reasonable person in the circumstances, that its use there without the consent of the proprietor would be an infringement of the patent;

(c) where the invention is a process, he disposes of, offers to dispose of, uses or imports any product obtained directly by means of that process or keeps any such product whether for disposal or otherwise.

§ 5.—No-one may make an occupation of the following without the consent of the patentee:—1. Manufacturing, importing or offering for sale an article which is patented or prepared by a patented method; or 2. Using the patented method.—The following is however, permissible having no regard for a Patent:— a) The use of articles accompanying or

connected with means of transport from other countries when these come to this country for limited periods, and b) The continued use of articles arrived by and belonging to means of transport which have been purchased abroad for Icelandic currency or for an Icelandic vessel which has broken down at sea and been repaired abroad.

ITALY

§ 2.—The patent concerning a new industrial method or process confers upon the patentee the exclusive use thereof.

The exclusive use includes also commercializing the product directly obtained by the new industrial method or process. If the product is a new one, every identical product is presumed to have been obtained, unless there is evidence to the contrary, but the method or process which is the subject of the patent.

JAPAN

3. "Working" in respect of an invention in this Law shall mean the following acts:

(1) In an invention of a thing, acts of manufacturing, using transferring, leasing, exhibiting for the purpose of transfer or lease, or importing the thing;

(2) In an invention of a process, acts of using the process.

(3) In an invention of a process of manufacturing a thing acts of using, transferring, leasing, exhibiting for the purpose of transfer or leave, or importing the thing produced by the process in addition to those as mentioned in the preceding items.

PORTUGAL

Article 214. A penalty of 500 to 10,000 escudos, to which may be added imprisonment for a period of from one to six months, will be imposed on those who, during the period of legal protection, should prejudice the owner of a patent in the exercise of his right in any of the following ways:

1. Manufacturing, without license from the title holder, the articles or products covered by the patent;

2. Employing, without the said license, the means and processes or using new applications of means and processes forming the subject of the patent;

3. Importing, selling, offering for sale, putting in circulation or concealing, in bad faith, products obtained in any of the ways referred to.

SWEDEN

SECTION 3

The exclusive right conferred by a patent implies, with the exceptions stated below, that no one except the proprietor of the patent may, without the proprietor's consent, use the invention by

(1) making, offering, putting on the market or using a product protected by the patent or importing or possessing such product for these purposes;

(2) using a process which is protected by the patent or, while knowing, or it being obvious from the circumstances, that the use of the process is prohibited without the consent of the proprietor of

the patent, offering the process for use in this country;

Statutes, Regulations and Treaties

(3) offering, putting on the market, or using products made by a process protected by the patent or importing or possessing the product for these purposes.

SWITZERLAND

If the invention concerns a process, the effects of the patent shall extend to the immediate products of the process.

SECTION 67

If the invention concerns a process for the manufacture of a new product, every product of the same composition shall be presumed to have been made by the patented process until proof to the contrary has been adduced.

Subsection 1 shall apply by analogy in the case of a process for the manufacture of a known product if the patentee shows prima facie evidence of infringement of the patent.

WEST GERMANY

PART NINE.—INFRINGEMENT OF PATENT

Article 74

(1) A person who uses an invention contrary to the provisions of Articles 6, 7 and 8 may be sued by the injured party to enjoin such use.

(2) A person making such use intentionally or negligently shall be liable for compensation to the

injured party for the damage suffered therefrom. If the infringer has acted with only slight negligence, the court may fix, in lieu of compensation, an indemnity being between the damage to the injured party and the profit which has accrued to the infringer.

(3) In the case of an invention whose subject matter is a process for the production of a new substance, any substance of the same nature shall, in the absence of proof to the contrary, be deemed to have been produced by the patented process.

NEED FOR MODERNIZATION OF U.S. PROCESS PATENT LAW

The United States has historically given different treatment to product and process patents, while so many other industrialized countries give uniform, full protection to both. The Commissioner of Patents and Trademarks, Donald Quigg, has suggested that the U.S. patent system is older than many of the European systems and that the ultimate historical origin of the omission of process patent protection may have been simply that in earlier commercial eras processes had not become so significant as they are in the present high-technology milieu. At the same time, adjacent European countries would become more aware more quickly of importations of products made outside by processes patented in the receiving country.

Many industrial countries, Japan and Germany for example, have only recently adopted product patent protection in the pharmaceutical area, having previously confined patent protection on drugs to the processes used to make them, in the interest of

promoting wider and easier availability of medicines for their populations. Thus when a new medicine comes on the market, competitors would only have to find a new way to produce it and could go on the market immediately, without waiting for any patent on the medicine itself to expire. Because it was the only form of protection allowed for pharmaceutical products, broader process patent protection was developed in those countries, covering not only domestic use of the process, but also importation, use or sale of the products obtained from the process. On the other hand, when Germany and Japan (in 1967 and 1975 respectively) broadened their laws to cover pharmaceutical product patents, they did not eliminate patent protection of processes and their resulting products.

Most countries that provide process patent protection extending to the products have also established a rebuttable presumption shifting the burden of proof to the defendant if the plaintiff presents evidence meeting some threshold of reasonable likelihood that the product was made by the patented process (France and Sweden are the only exceptions). However, many of these countries add a limitation that this presumption is only available in the case of processes for making "new" products. By contrast, as discussed further below and in the sectional analysis, S. 1200 allows the rebuttable presumption in any process patent infringement action under the bill, on the theory that every genuinely novel and useful (hence patentable) process invention deserves the full protection of the law, regardless of whether the resulting product is new or not. The example of the biotechnology industry is relevant here, in its efforts to develop recombinant

DNA processes to produce already existing natural substances such as growth hormones. Another point of difference, again discussed at length below, is the limitation in the process patent laws of most industrialized nations to products made "directly" from the process; Japan and Sweden are the only exceptions to this rule. S. 1200 introduces a new phrase, "materially changed by subsequent processes; or ... becomes a trivial and nonessential component of another product," to serve the same general purpose of restricting the scope of the bill to exclude ultimate products that, because of intervening manufacturing steps, cease to have a reasonable nexus with the patented process.

An integral part of the debate on strengthening U.S. process patent protection has been the alternative remedy under the trade laws against importation. of products made abroad using a process patented in the United States (Section 337a of the Tariff Act of 1930, 19 U.S.C. 1337a). Section 337 originated in 1922 as an antidote to a range of unfair methods of competition in import trade. It was not widely used until the 1974 strengthening amendments providing for more timely and effective remedies, the principal change being that the ITC was given full authority to order remedies, subject only to veto by the President for policy reasons. In process patent cases brought before the ITC, the available remedies under section 337a are exclusion of the goods from entry, and, if the goods have already entered, cease and desist orders against particular firms that have received them.

In order to obtain these remedies from the ITC, the complainants must show that their patented

processes were used in manufacturing the imported products, that an efficiently and economically operated industry utilizing the patent exists in the United States, and that the imported product had the effect or tendency of destroying or substantially injuring the domestic industry. After making these findings, the ITC must in addition decide that enjoining the importation of the infringing goods is in the public interest. Only then can the ITC provide relief to the process patentholder; and even then, its decision is subject to a binding Presidential veto.

The ITC, unlike a Federal court in a patent infringement suit, can award no damages. Payment of damages to the patentholder has the effect of compensating inventors and penalizing infringers for the economic injury due to the infringement, and also acts as a deterrent against future infringements. Furthermore, the tests that must be met to win an ITC order excluding the infringing products are more elaborate than in a Federal court action where all that is necessary is to show infringement. The requirement in the ITC proceeding to show that the importation of infringing goods is causing substantial injury to an efficiently run domestic industry requires the patentowner to show more than infringement. The patentee must show that there is an industry in the United States which generally means that the patentholder must practice a patented process commercially in the United States before he may enforce it. Morever, the industry must be efficiently and economically operated. The patentee also must show sufficent harm to justify relief. These requirements utilize an approach that has never been a part of our patent system. Instead, our system is based on the conviction that the public is well served

by the disclosure of the invention in return for a limited period of the exclusivity for the inventor, even if the latter chooses not to commercialize the invention during this period.

A hypothetical example illustrates this difference. Suppose an American company has obtained a process patent. The issued patent discloses the details of its new process for all the world to see. But for one reason or another, the American company has not yet been able to begin marketing the product. In that situation, the company may be unable to prove the existence of establishment of a domestic industry, and therefore unable to stop foreign pirates who use the published process and import the resulting products for sale in this country. A similar predicament might beset a university that obtains a process patent but is still involved in negotiations with potential licensees. To be sure, there may be some scope in a Section 337 investigation for treating impairment for prevention of a domestic patentholder's efforts to establish an industry here as substantial injury. But this whole issue simply does not arise in an ordinary infringement suit under the patent laws, where the only question is whether a valid patent has been infringed.

Even where the process patent has engendered an efficiently run domestic industry, the patentholder has the additional burden of showing that the industry has been injured by the entry of infringing articles. This circumstance was illustrated in the recent *Corning* case against Sumitomo before the ITC (In the Matter of Certain Optical Waveguide Fibers; Investigation No. 337- TA-189). Corning succeeded in establishing that its patents were valid and were

being infringed by Sumitomo's imported products. Further, it proved that two legitimate domestic industries, efficiently and economically operated, had grown under the Corning patents. However, because the ITC found that Sumitomo's infringing imports did not substantially injure either of those domestic industries, it found no violation of Section 337, and Corning was unable to obtain any relief.

Finally, in the best of circumstances, where the full ITC remedy is obtained, the patentholder is saddled with an expensive and burdensome proceeding, with no prospect of having his injury compensated, only brought to a hold prospectively. By the same token, the ITC remedy has little deterrent value. Foreign manufacturers are not punished for simply infringing U.S. process patents by importing their products into the country until they are enjoined, with no further penalty. Still, the ITC forum will remain a useful supplement in process patent infringement situations after S. 1200 is enacted. The ITC can provide speedy and comprehensive injunctive relief (covering many ports of entry in a single proceeding) while the patentholder awaits the outcome of the trial in the federal court to obtain damages.

In fact, measures under consideration within the Senate Trade Bill incorporate S. 486, introduced by Senator Lautenberg and others, which would lower some of the standards that must be met in an ITC process patent infringement investigation, such as eliminating the injury requirement. None of these proposals, however, are conceived by their advocates as being a substitute for achieving the needed modernization of the patent laws themselves that allows infringement by importation of goods made

abroad using a patented process. Commissioner Quigg concurs with this view in his statements on the issue: "Although ITC proceedings are an important adjunct to enforcement of patent rights, they should not be the sole remedy available to process patentholders against competition from offshore manufacturers.[2] Commissioner Quigg has also stated:

> ... I think it is important to keep 337, because that is a short-term compact operation which the patent owner can use to prevent the market from slipping away to foreign manufacturers. Patent litigation in the Federal courts is a more prolonged thing. It is not likely that you would be able to get a preliminary injunction during the litigation, and therefore the 337 approach does have a benefit for U.S. patentholders.[3]

It is worth noting that the ITC itself has in the past recommended that a distinction be maintained between the patent-type protection for process inventions that is sought in S. 1200 and the trade-type protection currently afforded by ITC adjudications in process patent proceedings. The Commission has asserted that its principal expertise is in micro-economic analysis of industrial competitiveness and the trade situation, factors that would not necessarily have a bearing on the pure issues of patent validity and enforcement considered in straight infringement cases before the federal courts. Some experts analyzing process patent

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[2] "Process Patents," Hearings on S. 1543 before the Senate Judiciary Subcommittee on Patents, Copyrights and Trademarks, 99th Congress, 1st Session, p. 12.

[3] Ibid., p. 43.

legislation, on the other hand, maintain that the ITC remedy in its current form is adequate and the appropriate way of addressing the problem of infringing importations. They point out that ITC exercises *in rem* rather than *in personam* jurisdiction: its orders go only to the goods themselves that are being imported and used or sold here. These experts contend that this focus on the goods is fair because once the goods have passed beyond the hands of the original manufacturer, the persons handling them can no longer be assumed to be knowledgeable of the process used to make the goods. This situation differs from the analogous one involving product patents, because in a case involving product patents, the person holding the goods actually has in hand everything necessary to ascertain whether there is infringement of a patent. A comparison of the tangible item with the description and diagrams in the patent itself may well reveal an infringement. In the process patent situation, the persons holding the goods after they have left the manufacturer do not have in their hands the specific infringing element, the process by which the product was made at some point in the past, and it is not always possible to deduce the exact process that was used by an analysis of the product at hand.

IMPLEMENTATION OF PROCESS PATENT LEGISLATION

In approving S. 1200, the Committee rejects the view that the U.S. purchaser from an overseas manufacturer who makes goods using a process patented in the United States has no responsibility for the patent infringement involved. On the whole, it should be the burden of business entrepreneurs who

purchase goods to check beforehand for possible infringement, whether of product or process patents. They do so, now in the case of product patents, and S. 1200 will encourage them to do so with respect to process patents. It is reasonable to expect that the more conscientious and legitimate importers would indeed concern themselves to a greater degree with the question of whether the goods they are importing infringe a U.S. patent, if S. 1200 is enacted, because such importers may find themselves otherwise emmeshed in litigation that may be more expensive than the importation is worth to them.

The primary target of the U.S. process patentholder will naturally be the manufacturer, who is practicing the process and importing the resulting goods into the United States. If that manufacturer is subject to the jurisdiction of the U.S. courts then it would be the preferred defendant because of its direct knowledge of the process. Since the manufacturer may not be subject to jurisdiction, S. 1200 also allows the patentholder to sue the persons receiving the goods in this country in the belief that they may be in the best position, apart from the manufacturer, to determine how the goods were made. The U.S. purchaser may protect itself in a number of ways: by specifying in the contract how the goods are to be made, or by eliciting a contractual commitment from the foreign manufacturer either to come into the U.S. courts itself to defend an infringement suit or to indemnify the purchaser against such a suit. See also Section 2-312(3), Uniform Commercial Code (implied warranty against patent infringement).

At the same time, the Committee is sensitive to the special difficulties that may attend a charge of

process patent infringement for persons who import, use or sell the products but do not themselves practice the process. The Committee is also sensitive to the concern that the bill might be abused for aggressive business purposes to harass U.S. competitors whose operations depend on importing goods from overseas. S. 1200 is intended to be a strong disincentive to the importation, use or sale of products that are made by an infringing process, but it should not simply be a weapon for patent-holders to use indiscriminately to try to stop all entry of products that compete with products made by their patented process. Only goods made by an unauthorized use of the patented process should be threatened by the bill. With a view to addressing those concerns about potential abuse by patentholders, and undue burdens on defendants in actions brought under S. 1200, the Committee devised a system of damage limitations for different classes of defendants, incorporated a new procedure encouraging advance communications between process patent owners and purchasers or importers of goods in order to encourage infringement avoidance, and established a notice requirement structured to insure that the alleged infringer receives enough information to allow a reasonable assessment of whether the goods are being manufactured by a process patented in the United States.

The Committee-approved bill envisions three types of infringers:

(1) The manufacturer who uses the process without authorization who is fully liable under the bill if he engaged in importing, using or selling the resulting product in the United States.

(2) An infringing importer, user or seller who had knowledge before the infringement that a patented process was used by the manufacturer to make the product which the importer or retailer uses or sells is fully liable under the bill and is not able to utilize the modifications of damages and other remedies available under the bill for innocent infringers.

(3) An innocent (i.e. unknowing) infringing retailer or importer, user or seller who does not himself use the process, is entitled to take advantage of the limitations on damages and other remedies available under S. 1200.

As was mentioned earlier, S. 568 is the same as S. 1543 of the 99th Congress, which unanimously passed this Committee and the Senate but which failed to become enacted during the hectic closing hours of Congress last year. S. 1200 follows the same general philosophy as S. 568. In S. 568 and in S. 573, damages only lay for infringements that occurred after notice. Moreover, such damages were limited by an 18-month grace period for retailers and a 6-month grace period for non-retailers with respect to the disposal of inventory. During those time periods, damages would have been limited to reasonable royalties in order to give the notice recipient sufficient time to dispose of inventory and make rational business decisions without unnecessarily exposing himself to potentially damaging risks.

Those 6-and 18-month periods were criticized by some as "compulsory licenses." The Committee did not interpret reasonable royalties for inventory for a limited period of time to constitute even an extremely loose conception of a compulsory license. In fact, the phrase "compulsory license" implies an ongoing right

of the licenses to do business in perpetuity without permission from the patent owner. Such a right has no place in U.S. patent law, and no such right was contemplated in S. 1543 or S. 568. Nevertheless, the Committee changed the legislation in order to accommodate the concerns of the parties who raise this issue. Thus, S. 1200 does not contain any such mention of time periods nor does it require any payment to the patentholder with respect to inventory disposal. Instead, S. 103(a)(2) provides that there are no remedies for infringement under this bill for product in possession, in transit to, or for which there is a binding commitment to purchase and which has been wholly or partially manufactured prior to notice of infringement.

However, if the notice recipient maintained or ordered an abnormally large amount of infringing product, the amount of product constituting the excessive inventory is subject to an infringement action. This Committee continues to believe that the aforementioned 6-and 18-month inventory provisions of S. 1543 and S. 568 are reasonable. Thus, we would encourage the courts to presume that a party who maintains or orders an amount of infringing product that cannot be used or sold after notice within 18 months by retailers or 6 months by non-retailers, is either maintaining an abnormally large inventory or is attempting to take advantage of the limitations of this bill. Such a finding would still permit the use or sale of 6 and 18 months of product without liability, but would put an infringer at risk for the amount of product in excess. Similarly, we encourage the courts to presume that the 6-and 18-month inventories are reasonable and that a party should not be subject to liability for such an inventory unless he was

otherwise attempting to take advantage of this section or lost this limitation for other reasons, such as lack of good faith or actual knowledge.

Under S. 1200, a party planning to import a product which is the same as a currently produced product may make a request for disclosure to the current manufacturer. This request asks the manufacturer to list all process patents owned by or licensed to the manufacturer as of the time of the request that the manufacturer then reasonably believes could be asserted to be infringed. In the normal case, the manufacturer will respond to the request with a list of process patent numbers, and the potential infringer will use this information to advise his supplier of what processes to avoid using. Failure to present the information received from a request for disclosure to the supplier will result in a finding that the potential infringer had notice of infringement, such that remedies for infringement will be available with respect to any goods imported beyond that time.

Defending against patent infringement charges is a normal burden of doing business in America and around the world in the technologically sophisticated commercial conditions of the 1980's. The limitations on damages in S. 1200, combined with the advance disclosure procedure, should eliminate the possibility of aggressive use of process patent infringement charges to harass innocent purchasers (whether in fact infringing or not). The remedy limitation here is not to be construed as a compulsory license, nor as a precedent for other areas of patent law or types of patent infringement. The Committee finds the "grace period" policy to be justified only in the context of a bill intended to strengthen process patent protection. It is justified because of the elusive

character of process inventions, from the standpoint of infringers who are involved only with the resulting products and not with the use of the process itself. From the beginning of congressional consideration of process patent reform in 1983 all proponents of the legislation have accepted the restriction of the scope of the bill to exclude innocent (i.e. unknown) infringing activity that occurs before the infringer is on notice. The remedy limitations are simply a mechanism for realizing this principle in practice by allowing the unknowing infringers, once notice is established, to sell a reasonable amount of inventory accumulated prior to notice with limitations on their exposure to damages. The temporary grace periods have as their sole purpose to allow the infringer to rid himself of products he had purchased and fulfill business commitments made prior to the time he had notice of the infringement of a U.S. process patent, and to either close down his business in this time or to find an alternative source of supply that does not infringe the patent. The remedy limitation is only available once for a given product: if the importer, wholesaler or distributor chooses to shift to a different supplier, he will be fully liable from the time of notice should the process patentholder bring another action against him with respect to the same product. Of course, the importer or retailer must be an innocent infringer, i.e. not have knowledge that the products were made by the patented process, to be eligible for the remedy limitation.

Similarly, the treatment of retailers should not be construed as an unlimited compulsory license, but as a temporary reprieve to allow them to move to non-infringing suppliers and liquidate their inventory without disrupting their businesses. Infringers fall

into this category only if they obtain the illicit goods from a party in the United States who does not use the patented process. If a retailer has resources to send agents to other countries to seek suppliers, then he should be able and willing to exercise more vigilance. By using the request for disclosure procedure, he may seek out legitimate manufacturers who do not avail themselves of processes patented in this country to make products intended for export to this country. However, the Committee recognizes that in some cases, it may not be useful for retailers to avail themselves of the request for disclosure opportunity. Therefore, S. 1200 clarifies that while it is generally evidence of good faith when a party requests disclosure, the failure to request disclosure is not absence of good faith if there are mitigating circumstances. For example, for many retailers, due to the nature of the product, the number of sources for products, or like commercial circumstances, a request for disclosure may not be necessary or practicable as a means to avoid infringement. The rationale in S. 1200 is to shelter only purchasers who are remote from the manufacturer and not in the position to protect themselves in contracts with the party who is actually using the process.

While this new request for disclosure procedure will assist in avoiding intimidation of potential innocent infringers, it should be noted that the problem of using patents for illegitimate purposes of harassment is neither new nor limited to process patents. The Committee notes that the courts are not powerless to deal with the problem. For example, the federal judiciary, under Rule 11 of the revised Federal Rules of Civil Procedures, has lately taken a more stringent attitude toward an attorney's responsibility

to investigate the soundness of a complaint before filing it. And the patent law itself allows the court, in an appropriate case, to order a patent owner to pay his adversary's attorney's fees and other expenses.

An additional safeguard against abuse of S. 1200 is the requirement that the notification from the patent holder charging the party with infringement must provide a specificity of information that will permit the accused party to make a reasonable business decision as to whether to continue his activities or seek a new source for the product. Notice of infringement occurs when the alleged infringer has a combination of information sufficient to persuade a reasonable person that it is likely that a product was made by a patented process. This combination of information will include actual knowledge which may be acquired from the request for disclosure procedure, the information contained in the notification from the patent holder and any other information known to the accused relevant to the issue of infringement. In issuing a notification, the patentholder must specify the patent alleged to have been used and the reasons for a goodfaith belief that such process was used. If the patent holder has actual knowledge of any commercially feasible process other than the patented process which is capable of producing the allegedly infringing product, the notification shall set forth such information with respect to the other processes only as in reasonably necessary to fairly explain the patent holder's belief and is not required to disclose any trade secret information. Thus, even if the patentholder decides to bring suit, unless his filing includes this information, he will be deemed to have served notice. Neither a vague unspecified claim of infringement, nor even a lawsuit embodying such a

claim would suffice for notice of infringement; only a specific claim articulating the reasons for believing the patented process has been used, would expose the defendant to damage liability. The Committee anticipates that the difficulty of making this kind of showing will tend to discourage use of the new cause of action for the purpose of "business aggression."

Once the recipient of notice knows the exact patent or patents in question, and the reasons indicating that the process they cover was used in manufacturing the goods, he will be able to evaluate the claim, confer with the foreign manufacturer (or other supplier) and decide whether to discontinue importing goods or defend an infringement claim. The proposed notice requirements goes far beyond the norm for product patent cases (or for that matter process patent infringement cases under existing law) but the higher threshold is justified here, in the Committee's judgement, because of the special difficulties that may arise from the fact that the process was used by a party other than the defendant. The notice provision of S. 1200 is not intended as a precedent for other areas of patent protection. Despite its greater stringency, the Committee expects that the serving of notice will still fulfill its traditional role of avoiding the need for litigation in many situations.

Beside the extended notice requirement and damages limitations, S. 1200 includes two further protections for potential defendants: a grandfather clause stating that the bill shall not abridge or affect the right of any person to continue to use, sell or import products already in substantial and continuous sale or use in the United States on May 15, 1987, and a provision calling on the Department

of Commerce to report annually to Congress during the first 5 years after enactment on the effect of S. 1200 on any domestic industries that submit formal complaints about interruption of legitimate sources of supply.

In reference specifically to the concerns voiced by the generic drug industry about the effects of S. 1200 on their overseas supplies, one potentially valuable resource is the Food and Drug Administration. It is the Committee's understanding that whenever a generic drug company applies for FDA approval of a new generic medicine, the FDA begins a Drug Master File (DMF) collecting among other things information from the supplier about the processes involved in generating the materials sold to and subsequently used by the generic company. The DMF is a confidential file, not available to the public or even to the generic company for inspection. The DMF is complied from information supplied directly to the FDA from the manufacturer and from inspections by FDA personnel in the factories of the manufacturer. However, if the file can be obtained by the U.S. courts under a protective order without violating any other provisions of law, it could be used to assist the court in resolving whether the patented process was used in making the goods in question. It might alleviate the need to rely on indirect forms of evidence, such as chemical analysis, to trace the process used.

The debate on the presumption clause in Section (4) of the bill goes back to the 98th Congress. At that time the Judiciary Committee reported a process patent measure without including the presumption in the text of the bill but indicating

instead in the report that the Committee expected the courts to apply a presumption where warranted.[4] In the present Congress, the Committee decided to accede to the strong recommendations of the Administration and the industry advocates of the bill to include presumption in the statute itself.

The presumption would place the burden of proof on the defendant to come forward with evidence that the goods in question were not made by using the plaintiff's patented process after the plaintiff has made a reasonable but unsuccessful effort to ascertain the process actually used, and further has established a substantial likelihood that the goods were made by that process. The presumption mechanism stems from the basic principle behind the bill, that the U.S. purchaser of the goods is in the best position to make the arrangements necessary with foreign manufacturers and suppliers to assure that U.S. process patents are not violated. The Committee envisions that the plaintiff would make informal inquiries to the foreign manufacturer of the product (if identifiable) or make reasonable attempts to use the discovery procedures available in the foreign countries. Certainly, the presumption clause attempts to strike a balance. Presumptions should not be casually established. To ensure that an unfair burden is not imposed on importers and distributors of noninfringing products, any provision dealing with this subject should, at a minimum, require the patentee to demonstrate, on the basis of available evidence, that a substantial likelihood exists that the product was produced by the patented process and, further, that a reasonable but unsuccessful effort was

[4] Senate Report 98-663, 98th Congress, 2nd Session, p. 6.

made to determine that the process was actually used in the production of the product. To establish a substantial likelihood, for example, a patentee might show that the patented process was the only known method, or the only commercially practical method, for producing the product, or that physical evidence, such as the exact chemical composition of the product, indicates the use of the patented process. A reasonable effort requirement could easily be satisfied in the United States through our discovery procedures. For a foreign manufacturer the patentee would have to take some reasonable step, such as writing to the manufacturer, to determine how the product was made and to have been unsuccessful in this regard. The reasonableness of the effort would depend on the facts of the case but should generally avoid the need for such measures as letters rogatory or suits in a foreign country. Exactly how much evidence will be needed in particular situations to satisfy the "substantial likelihood" condition will depend on the circumstances. However, the patentee's burden would be less than that of proving successfully at trial by a fair preponderance of the evidence that a product in question was in fact made by the patented process but would be more than a slight possibility that the product was so made.

Most of our trading partners that extend process patent protection to the products made by the processes do also provide for a rebuttable presumption for shift in the process burden of proof. But many of them also limit the application of the new presumption to processes for making "new" products. The drawbacks of this approach may be illustrated by the recombinant DNA processes for producing naturally occurring substances, which cannot themselves be

patented and which are in no sense "new." Thus, this approach would deprive some of the most important process innovators of the value of the presumption. The Committee rejects this approach because there is no clear justification for discriminating against certain types of process inventions. In order to secure a patent, a new process must be deemed useful, novel and unobvious—the same criteria that are applied to product inventions. If a process invention satisfies these criteria, then it is in the interests of society to have it publicly disclosed in return for a limited period of exclusivity for the inventor, regardless of whether the process leads to a "new" or "old" product. A good example of the latter was presented to the House Judiciary Committee during a hearing on this issue by Genentech Corporation; a new, more economical process they have developed in conjunction with Lubrizol Corporation for producing Vitamin C.[5] Enactment of S. 1200 would help Genentech protect itself against an influx of Vitamin C produced abroad by means of their economical new process, and produced all the more cheaply because the foreign manufacturer had no R&D expenses in procuring the process. But under the "new product" approach, Genentech would not benefit from the presumption clause in bringing suits for such infringement of its process.

Most of the foreign patent statutes that extend process protection to the product resulting from the

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[5] Statement of Thomas D. Kiley, Esq., Vice President, Corporate Development, Genentech, Inc., before the House Judiciary Subcommittee on Courts, Civil Liberties and the Administration of Justice, February 19, 1986 (Hearing on "Intellectual Property and Trade." 99th Congress, Serial Number 60).

process also include the limitation that the product must be made "directly" from the process. The significance of this qualification is discussed at length in the section-by-section analysis. The basic point is that if a final product has undergone a material change after being initially produced by the patented process, then it should no longer be covered within the scope of protection offered by S. 1200.

Some parties urged the Committee to include the word "directly" in the statutory language of the bill, making the U.S. law conform to the norm of industrialized nations and insuring that process patent protection does not become too broad. A number of industry advocates of the bill on the other hand were concerned that including the word "directly" might unduly restrict the scope of the bill if it were interpreted narrowly to exclude products that had been altered in trivial ways after the stage of manufacture where the patented process was used. The Committee concluded that both parties were seeking the same balance, and reached the decision to exclude products that had been "materially changed by subsequent processes; or ... become a trivial and nonessential component of another product." Inevitably the courts will have to assess the permutations of this issue of proximity to or distance from the process on a case-by-case basis. The section-by-section analysis offers guidance and examples for the interpretation of this provision.

Because of our obligations under the GATT treaty to refrain from trade discrimination, the process patent bill was crafted to apply equally to the use or sale of a product made by a process patented in this country whether the product was made (and the

process used) in this country or in a foreign country. As explained earlier, the bill is prompted by the use of patented processes in other countries followed by the importation of the resulting products into this country. The use of the process in this country is already an act of infringement under existing patent law, and such an infringing party would be subject to the jurisdiction of the U.S. courts. Thus the inclusion of domestic process patent infringement in the scope of a bill to extend protection to the products is regarded by the Committee as a formality to conform to the GATT, with little or no practical consequences in patent enforcement. The American Bar Association suggested in a letter to the Committee[6] that an alteration should be made in the presumption clause to make clear that if a suit is brought under the bill against a purchaser of goods made domestically by infringing a process patent, then the presumption is not applicable since there is no obstacle to obtaining discovery to determine the process used to make the goods. The Committee accepts the ABA's reasoning that the presumption should not be operative in this situation, but concludes that no change in the language of the bill is necessary. The presumption would never apply in the situation of domestic process patent infringement because a reasonable effort on the part of the plaintiff would require obtaining discovery against the manufacturer who is actually practicing the process in this country and who is therefore subject to the U.S. courts' jurisdiction, as

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[6] Letter from Jan Jancin, Jr., President, ABA Section of Patent, Trademark and Copyright Law, to Senator Mathias, March 10, 1986. Printed in "Process Patents," Hearing on S. 1543 before the Senate Judiciary Subcommittee on Patents, Copyrights and Trademarks, 99th Congress, 1st Session, pp. 266-8.

might not be the case with foreign manufacturers. In any case, the Committee does not expect or intend the bill to be used to sue purchasers of the product, when the infringing manufacturer can be sued instead.

Concerns were raised, at a Senate hearing and elsewhere, that process patent legislation would undermine the Drug Price Competition and Patent Term Restoration Act, which became law in the 98th Congress (P.L. 98-417). Generally, this law combined an expedited procedure for FDA approval of generic imitation on brand-name drugs. The generic companies contended that if their supply of raw materials from overseas sources is reduced by process patent infringement suits, then the goals of P.L. 98-417 would be undermined. With the protections built into the substitute approved by the Committee, the generic pharmaceutical industry now supports S. 1200. It should be recognized, in particular, that the grandfather clause gives an exception for the many new generic medicines that have been approved or whose applications have been submitted to the FDA during the period between enactment of P.L. 98-417 (signed into law on September 24, 1984) and May 15, 1987.

Once the patent on a brand-name drug has expired, anyone is free to make, use or sell the product (assuming FDA clearance), but if there is an unexpired patented process for making the drug, then other parties must find a different way to make it. Again, in order to obtain a patent, the process must be novel, useful and unobvious, an invention whose disclosure would benefit the public as envisioned in the Constitution. To obtain a process patent on a useful, new way to make a medicine is not to prolong

or "evergreen" the product patent on the medicine itself, even if the patentholder for the process and original product is the same inventor. No responsible critic of S. 1200 has ever maintained that goods made abroad by a process patented in the United States should be allowed to come into the United States to benefit competitors of the process patent-owner. To the extent that this is happening at present, S. 1200 is indeed intended to cut off such lines of supply, and to expose the beneficiaries, after adequate notice, to damage liability for their actions. The only issue has been whether the bill could also be used to cut off other, legitimate supplies from overseas, and in response to this concern the Committee has fashioned an elaborate system of pre-disclosure safeguards and limitations.

D. SECTION-BY-SECTION ANALYSIS

SECTION 101

Section 101 amends Section 154 of title 35, United States Code, by adding to the present rights held by the patent owner, the right to exclude others from using or selling throughout the United States, or importing into the United States, products made by a patented process.

SECTION 102

Section 102 amends Section 271 of title 35, United States Code, by adding a new subsection (g). This subsection provides that whoever without authority imports in the United States or sells or uses within the United States a product which is made by a process patented in United States is liable as an infringer.

Since a process patentee can already prevent the use of the patented process by domestic manufacturers, the primary effect will be on foreign-made goods. These amendments will not give extraterritorial effect to U.S. law. U.S. patents will not prevent foreign manufacturers from using abroad the process covered by the U.S. patent, so long as the products they make thereby are sold and used abroad. But the amendments will prevent circumvention of a U.S. process patentee's rights through manufacture abroad and subsequent importation into the United States of products made by the patented process.

Specifically, the Committee does not intend that it shall be an act of infringement to import a product which is made by a process patented in the United States "solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use or sale of drugs." See 271(e)(1) of title 35, United States Code. Congress previously decided that certain actions do not constitute patent infringements and this Act does not change that prior policy decision.

The bill provides that no remedy may be granted for infringement resulting from the noncommercial use or retail sale of a product unless there is no adequate remedy on account of the importation or other use or sale of that product. The purpose of this provision is to protect retail sellers and the consumers who purchase products at retail for personal use and consumption from damages for infringement if adequate relief is obtainable from more involved parties.

The Committee intends the limitations on remedies against "noncommercial users" to be for the protection of those purchasers who enjoy personal use and consumption of the product produced by the allegedly infringing process, such as the patient who consumes a drug product or a home gardener who sprays a pesticide. The Committee does not intend this protection to be enjoyed by a party who uses a product produced by an allegedly infringing process in the production of another product, or who otherwise engages in further manufacturing, processing, or other industrial or business use of the product, other than that which may fall under the provision of Sec. 287(b)(2).

It should be noted that many of the "products" produced by patented biotechnology processes are themselves "used" in the manufacture of another product which is introduced into commerce. Consider a process patent held on a method for preparing a plasmid or other vector. The use of the plasmid or vector to insert a new gene into a living cell, instructing the cell to produce an important human protein (such as insulin or interferon) which will then be separated from the fermentation mash, purified, and packaged into single dosage forms, is a commercial use and is ineligible for the limited protection granted to non-commercial uses. The field of biotechnology is particularly susceptible to commercial "uses" without sales. For example, a patent may cover a process for producing a microorganism using recombinant DNA technology. The microorganism is then used to produce a particular commercial end-product of great value. The bill's provisions limiting remedies against users are not intended to apply to such commercial uses. The

Committee believes that without expeditious remedies against use-based infringement, merely stopping importation and non-retail sale of the microorganism after its entry into the country fails to prevent commercial use of the microorganism.

An understanding of the statement that "A product which is made by a patented process will, for purposes of this title, not be considered to be so made after—(1) it is materially changed by subsequent processes; or (2) it becomes a trivial and nonessential component of another product" is critical to understanding the scope of this legislation. The Committee intends a specific two- hase test to be implemented.

Many foreign patent statutes extending process protection to the product resulting from the process include the limitation that the patented product be made "directly" from the process. They use the word "directly" to exclude as an infringement the importation, use or sale of a product which is materially changed from the product resulting from the patented process by subsequent steps or processes. An example of the problem the Committee is addressing in this section is the extraction of minerals from the earth. These minerals may later be used to manufacture materials, which are still later embodied in components, which are in turn used in the assembly of the product in question. In this instance, the minerals have been "materially changed" within the meaning of this section.

The Committee agrees that once a product has been materially changed, then subsequent purchasers, users and sellers should no longer be liable for process patent infringement. However, the

Committee decided against including the word "directly" in the statute out of concern that the word "directly" might have been construed too broadly and possibly exempt too many products that have been altered in insignificant ways after manufacture by the patented process. These products ought to be treated as infringing under the bill. The Committee expects the courts to exercise careful judgement in distinguishing those products that are too far removed from the patented process, and those that have been changed only in insignificant ways. The Committee believes that the courts will be in a better position to settle such issues without the standard of "directly" constraining their judgment.

The inclusion in the standard of the words "trivial and nonessential component" will further assist the court in distinguishing products that are too far removed from the patented process.

In order to give the courts Congressional guidance in what may be a difficult determination, the Committee notes that the bill would establish the following two-phased test:

1. A product will be considered made by the patented process regardless of any subsequent changes if it would not be possible or commercially viable to make that product but for the use of the patented process. In judging commercial viability, the courts shall use a flexible standard which is appropriate to the competitive circumstances.

2. A product will be considered to have been made by a patented process if the additional processing steps which are not covered by the patent do not change the physical or chemical properties of

the product in a manner which changes the basic utility of the product by the patented process. However, a change in the physical or chemical properties of a product, even though minor, may be "material" if the change relates to a physical or chemical property which is an important feature of the product produced by the patented process. Usually, a change in the physical form of a product (e.g. the granules to powder, solid to liquid) or minor chemical conversion, (e.g., conversion to a salt, base, acid, hydrate, ester, or addition or removal of a protection group) would not be a "material" change.

It is only those who import, use or sell a product after it has been materially changed or has become a trivial or nonessential component of another product who may avoid liability for process patent infringement. Even with that general guidance, the courts may frequently find themselves in a quandary on this most important phrase. There will be cases where the product has clearly been materially changed or become trivial and nonessential, under the two-phase test, and others where it clearly has not; however, many instances will be less clear. Some examples may help provide additional resources to the courts:

A metal strip with certain unique properties is produced by a U.S. patented process. A foreign competitor makes the strip using the process, then turns the strip into a core, puts the core in a transformer and imports the transformer into the United States. Even if there were other commercially or economically viable non-infringing processes for making the strip, this is still a clearcut case of infringement of the process patent that this Act is

intended to prevent because the subsequent changes would not be considered material. Similarly, taking that metal strip and hear treating or annealing it in a magnetic field would not change the product as to avoid infringement.

If the patented process produces chemical X, any person importing, using or selling chemical X is liable for infringement.

If new entity, chemical Y, is produced from chemical X as the result of a material change, the court must also consider the other phase of the test before deciding if Y is infringing or non-infringing:

If the only way to have arrived at Y is to have used the patented process at some step, e.g., producing X as an intermediate, Y is infringing.

If there is more than one way to have arrived a Y, but the patented process is the only commercially viable way to have done so, Y is infringing.

If there are commercially viable non-infringing processes to have arrived at X, the connection between the patented process for producing chemical X and the ultimate product, chemical Y, is broken, and Y would be a non-infringing product having satisfied both phases of the test.

In the biotechnology field it is well known that naturally occurring organisms contain within them particular genetic sequences composed of unique structural characteristics. The patented process may be for the process of preparing a DNA molecule comprising a specific genetic sequence. A foreign manufacturer uses the patented process to prepare the DNA molecule which is the product of the

patented process. The foreign manufacturer inserts the DNA molecule into a plasmid or other vector and the plasmid or other vecot containing the DNA molecule is, inturn, inserted into a host organism; for example, a bacterium. The plasmid-containing host organism still containing the specific genetic sequence undergoes expression to produce the desired polypeptide. Even if a different organism was created by this biotech procedure, if it would not have been possible or commercially viable to make the different organism and product expressed therefrom but for the patented process, the product will be considered to have been made by the patented process.

In the semiconductor industry, a manufacturer may have a process patent for forming a semiconductor structure in a semiconductor substrate. Subsequent processing to complete and finish the component does not materially change the semiconductor substrate in which the semiconductor structure formed. In addition, a court could determine that the cost of a semiconductor component was trivial in relation to the cost of the whole product, but if that same component is essential to the intended function of the whole product then it would be covered by this title.

The Committees recognizes the concern raised concerning possible overreach. One example is a process patent for extracting minerals from the earth. There is no intent that the minerals, eventually refined, with the product ending up as a component of an automobile which is imported into this country, should subject the importer to an infringement action. However, this must be distinguished from the importation of the mined minerals themselves.

Similarly, this must be distinguished from the case wherein the patent covers a process for making shock absorber. Even if that shock absorber is put into a much larger and more expensive product, e.g., an automobile, the patent owner could still sue the importer of that automobile. Although injunctive relief might not be appropriate under those circumstances, some damage relief would be appropriate, based, for example, on an apportionment of the contribution of the infringing part to the value of the whole product in which it is incorporated. Of course, the importer and wholesaler have other rights under this bill to limit liability, and the retailer may avail himself of other provision of this bill and have no liability for retail sales. Finally, there is no intent whatsoever for the innocent consumer to even be subject to suit.

SECTION 103

Section 103 amends Section 287 of title 35 by adding a new subsection (b) with five subparagraphs, which introduces limitations on the remedies available to a process patentholder when infringement is based on importation, sale or use of a patented process and conditions associated with the eligibility of the modification of remedies.

Paragraph (b)(1) provides that the modification of remedies outlined in subsection (b) are not available to three categories of infringers. For these three categories of infringers, all of the provision of title 35 relating to damages and injunctions apply. Paragraphs (b)(1) (A) through (C) define those infringers who are not entitled to any diminution of the monetary and injunctive remedies normally available to a patentholder. They include the party

who actually carries out the process, or who controls or is controlled by that party. Thus, those who are closely connected with carrying out the process in the manner outlined, are fully liable for any direct acts of infringement they commit in the United States, as well as for any acts of inducement of infringement or contributory infringement committed through control inside or outside the territorial limits of this country. The bill is not intended to reward infringers who close their eyes to facts that a reasonable person would see. Similarly, it is not intended that a party should be permitted to qualify for reduction of or immunity from liability by intentionally avoiding the acquisition of knowledge.

Existing section 287 of title 35 states that damages for patent infringement may be recovered by the patentholder either from the time he marks his patented article with the patent number, or if he fails to mark, from the time he serves notice to the infringer. However, the courts have held that these prerequisites for damages apply only to product patents, and that persons who infringe a process patent by using the process in this country are fully liable from the beginning of the activity without notice from or marking by the patent owner. The Committee intends that this harsher standard apply also with respect to process patent infringers who use the process and engage in importing, using or selling the products in the United States. This would apply in a situation, for example, where a foreign manufacturer who uses a process patented in the United States but not in the country of manufacture, itself imports the products for use or sale here. In that situation, the foreign manufacturer would be liable for damages from the outset of the infringing activity

even without receiving notice of infringement from the patent owner. Similarly, any party who knowingly imports, uses or sells products made without authority by a process patented in this country is fully liable for damages running from the time he begins knowingly engaging in such activity. On the other hand, a foreign manufacturer is not liable under the bill if he merely uses the process abroad (again assuming the U.S. inventor has not also patented the process in the foreign country) and sells the product there with no knowledge that the buyer will subsequently import the product here.

Paragraph (2) specifies that with regard to infringers not excluded under paragraph (1), the patentholder has no remedy for infringement with respect to any product which was in the possession of, or in transit to the party, of for which the party has made a binding commitment to purchase and which has been partially or wholly manufactured before the party had notice of infringement. The Committee intends that with respect to an infringer not excluded under paragraph (1), the patentholder has no remedy for infringement with respect to pre-notice inventory. However, if the court finds that the party maintained or ordered an abnormally large amount of infringing product, or the product was acquired or ordered by the party to take advantage of the limitation on remedies provisions, the court shall limit the application of the modification of remedies provisions to the reasonable portion of the inventory. For the purpose of this paragraph, an abnormally large inventory on hand or on order shall be presumed to exist if it cannot be sold in the normal course of the infringer's business in 18 months if the infringer is a retailer or in 6 months in any other case. Thus, courts should presume that

maintaining or ordering an amount of infringing product that cannot be used and sold after notice of infringement within 18 months by retailers and 6 months by non-retailers is either maintaining an abnormally large inventory or an attempt to take advantage of the limitations of this bill. Such a finding would still permit the use or sale of 6 and 18 months of product without liability, but would put an infringer at risk for the amount of product in excess. Similarly, the Committee encourages the courts to presume that the 6 and 18 month inventories are reasonable and that a party should not be subject to liability for such an inventory unless he was otherwise attempting to take advantage of this section or lost this limitation for other reasons, such as lack of good faith or actual knowledge.

Paragraph (3) provides that in an action brought for infringement under section 271(g) of title 35, United States Code, the court shall take into consideration the good faith and reasonable business demonstrated by the defendant, the good faith demonstrated by the plaintiff with respect to the request for disclosure discussed below, and the need to restore the exclusive rights of the patent-holder through an adequate remedy.

During the discussions and testimony leading to the adoption of this bill, the non-manufacturing groups likely to use or sell imported products stressed their need and desire to obtain information to assist them in avoiding infringement. A procedure to assist these groups in attaining this information is necessary because an importer of a product from a foreign manufacturer is ordinarily unable to obtain specific information from his supplier regarding the

process used in manufacturing the imported product. The groups representing patentholders agreed to a procedure under which manufacturers would provide a listing of the patent numbers of process patents owned by or licensed to the manufacturer as of the time of the request that the manufacturer then reasonably believes could be asserted to be infringed in connection with the production of its product.

The request for disclosure procedure is explained is paragraph (4). The first step—the actual request for information is a formal request made by a party who is engaged in, or intends to become engaged in, the sale of a particular product. The request is directed to one or more other parties who are then engaged in the manufacture of the product, no the expectation they are most likely to hold pertinent process patents. Such a request should be made before the requester actually commences any activity which could result in infringement, and it should be made in all cases except those in which, because of the nature of the product, the number of parties to whom a request would need to be directed, or like circumstances. a request for disclosure would be impracticable or unnecessary. For example, due to the nature of the product or the number of sources for products, it may not be practicable for retailers to use this procedure to avoid infringement.

An illustration of the situation in which a request would be impracticable would be one in which a party intends to import a table that is simple and undistinguished, and the party knows that similar tables are made by many other companies. Since requests would have to be directed to a large number of companies and there is nothing unusual about the

table to be imported, a request for disclosure is very unlikely to produce meaningful information. It is impracticable. However, if the subject table had a distinctive construction, and a similar one was being manufactured by only a few companies, the importer would be expected to request disclosure.

A request for disclosure is unnecessary when the party who would otherwise make it already has the information sought, for example, when a prior request was previously made to the same source and it is clear no additional patents have arisen since the earlier request. Of course, a court should be reluctant to conclude that a request was "unnecessary" when, in fact, the product is found to be made by an infringing process, and a request for disclosure might have avoided the infringement.

The second step in the procedure is the patentees's response to the request. The patentee is expected to provide a complete good faith response, identifying all process patents owned by or licensed to him that he reasonably believes could be used to make his own product. It is understood that the patentee's response will depend largely on the information available to him at the time the request is made. For example, it is also possible that the manufacturer may acquire additional relevant patents subsequent to the request for disclosure. The manufacturer is not precluded from making, indeed is encouraged to make, supplemental responses if the acquisition of additional information warrants it.

The request for disclosure must include a representation by the requesting party that it will submit the response to its manufacturer, or if not known, to its supplier, with the request for assurance

that none of the processes of the disclosed patents is used in the manufacturer of the product.

The requirement of "notice of infringement" embodied in various paragraphs of subsection (b), is intended to balance the interests of process patentees and parties who are infringing by using or selling the product, in good faith, without knowledge of the process used to produce it. The Committee does not intend that "notice" be a device through which infringers can escape liability by deliberately avoiding knowledge or failing to appreciate the significance of information available to them. What should be kept in mind is that no liability attaches in any event unless infringement of the patentee's rights has occurred: "notice" simply defines the point in time when someone who is, in fact, an infringer has sufficient information to make it reasonable to initiate the period of his accountability.

As stated in subparagraph (5)(A), the accumulation through actual knowledge, or receipt by a party of a written notification, or a combination thereof, of information will put the infringer on notice when, in the aggregate, it is sufficient to persuade a reasonable person that it is likely a patented process was or is being used. It is important to note that the issue to be resolved with respect to "notice of infringement" is not whether there are sufficient facts recited in the notification or known to the party notified to support the conclusion that there is infringement but rather only whether infringement is "likely." This is significantly less demanding than the "preponderance of evidence" standard a patentholder would face in proving infringement at trial. What is required is simply enough to bring home to the

infringer the presence of an appreciable likelihood of infringement, sufficient to make it reasonable to hold him accountable when he chooses to continue his activities.

Subparagraph (5)(B) relates to written notification addressed to the accused infringer by the patentholder. The written notification shall specify the patented process that is alleged to have been used and the reasons supporting a good faith belief that such process was used. If the patentholder has actual knowledge of other commercial processes for producing the particular product, the notification should set forth such information with respect to such processes only as is reasonably necessary to fairly explain the patent holder's belief and is not required to disclose any trade secret information.

Subparagraph (C) provides that a party who receives a written notification of infringement shall be deemed to have notice of infringement if he fails to seek responsive information from the manufacturer (or, if not known, the supplier) of the product he is using or selling, unless there are mitigating circumstances. The notification need only meet the first sentence of subparagraph (B) to trigger that requirement and that result; obviously it is unnecessary to provide the manufacturer with information tending to negate the use of other processes, since the manufacturer knows directly what process he is using. Similarly, this provision applies even though the notification does not contain enough information to constitute "notice of infringement."

A non-manufacturing party receiving a notification alleging infringement has an obligation to

take reasonable steps to determine it there is any basis for the allegation and cannot evade liability by remaining ignorant of facts which might establish a likelihood of infringement. Any knowledge which a purchaser may acquire as a result of such inquiries will contribute to satisfying "notice of infringement", which can be satisfied by a combination of the information contained in a notification from the patent holder and any other information known to the party charged with infringement.

Since making an effective inquiry is not costly, and it has the potential of stopping, curtailing or avoiding infringement of the patent holder's rights, only the most compelling reasons should be accepted as excusing a failure by the recipient of a notification to submit it to his manufacturer/supplier for verification. An example of such "mitigating circumstances" would be death or incapacity of the person who was intended to make the submission or an inability to locate the manufacturer/supplier due to his no longer being in business or in circumstances where the product has passed through many hands.

For similar reasons, subparagraph (D) provides that a party who receives a response to a request for disclosure and who fails promptly to submit it to the manufacturer/supplier with a request for a written statement that none of the patented processes is used, is deemed to have notice of infringement. Submission of the response to a request for disclosure to the requester's manufacturer/supplier is mandated because that manufacturer knows the process being used and therefore is in the best position to avoid infringement or provide evidence that the patented process is not being used, if that is the case.

The mere act of submitting the patentee's response or notification to the manufacturer does not, however, automatically absolve a party from having notice of infringement. The Committee has not attempted to, and could not, spell out in detail all circumstances in which the infringer should be found to have notice. Nevertheless, the Committee expects the court to consider, in determining the presence or absence of notice, the information received (or lack thereof) by the importer from his manufacturer/supplier. For example, a party who sends to his manufacturer/supplier a notification of infringement or a response to a request for disclosure, and who does not receive from that manufacturer/supplier an adequate assurance that the patented process is not being used, and sufficient supporting information to make an assurance credible should almost certainly be found to have notice of infringement should he choose to continue to deal in the goods of that supplier/ manufacturer.

Subparagraph (E) provides that filing of an action for infringement shall constitute notice of infringement only if the pleadings or other papers filed in the action meet the requirements of subparagraph (A), i.e. contain sufficient information to persuade a reasonable person that it is likely the product was made by a patented process. The Committee recognizes, however, that it may not always be clearcut when sufficient information exists to constitute "notice of infringement", and that patentholders may properly and lawfully bring suit irrespective of whether that technical requirement is met. Neither "notice of infringement" nor "notification" is a prerequisite for a legally sufficient complaint for patent infringement.

Even if "notice of infringement" is not satisfied by the initial papers filed in the action, this subparagraph recognizes that it may be satisfied at a later time by other papers filed in the action, including discovery obtained from the accused infringer or third parties, additional information provided by the patentholder, expert witness statements or the like. As discussed earlier, remedies for infringement will not begin to accrue until the standard for notice of infringement is met, even if a legal action has already begun.

SECTION 104

Section 104 adds a new Section 295 to title 35, to establish in carefully defined circumstances, a rebuttable presumption that a product that could have been made by use of a patented process was in fact so made. This presumption addresses the great difficulties a patentee may have in proving that the patented process was used in the manufacture of the product in question where the manufacturer is not subject to the service of process in the United States. The burden of overcoming this presumption will be on the alleged infringer, regardless of whether the infringement charge is based on use, importation, or subsequent sale of the infringing article. While the defendant may not necessarily have in its possession the means necessary to rebut the presumption, it is likely to be in a far better position than the patentee to obtain them. Importers, for example, because of their relationships with foreign manufacturers, may be able to exert pressure on such manufacturers to produce the necessary information. Users and sellers who purchase possibly infringing articles from importers may be able to exert similar pressure on

those importers, who would in turn influence foreign manufacturers. Of course, purchasers would retain whatever rights to indemnification they may have under contract or applicable State law.

Presumptions of manufacture by a patented process, however, should not be casually established. Importers and subsequent purchasers may be unable to obtain the information needed to overcome such presumptions when the products in question were not made by patented processes. At a minimum, the existence of the presumption will require a party who uses, sell, or imports a product that might have been made by a patented process to exercise greater care in business dealings to avoid increased liability. To minimize the risk of aggressive litigation intended to discourage firms from carrying competing products, the presumption will be available under Section 295 only when two conditions are satisfied.

First, the patentee must demonstrate on the basis of the evidence that is available that a 'substantial likelihood' exists that the product was made by the patented process. Such evidence could include chemical analysis of the product or indications or "marks" on the product itself, as well as expert testimony regarding known methods of production at costs that would justify sale of the product at the prices being charged. Exactly how much evidence will be needed in particular situations to satisfy the "substantial likelihood" condition will depend on the circumstances, However, the patentee's burden would be less than that of proving successfully at trial by a fair preponderance of the evidence that a product in question was in fact made by the patented process but would be more than a

slight possibility that the product was so made. Second, the patentee must show that he or she has made a reasonable effort to determine what process was used in the manufacture of the product in question and was unable to do so. The reasonableness of the effort would include the use of discovery procedures under the Federal Rules of Civil Procedure or other good-faith methods, such as requesting the information from the manufacturer, if not subject to U.S. jurisdiction. These limitations on the availability of the presumption should make it available to patent owners who might otherwise be left with no remedy against an infringer, and should also adequately safeguard the rights of competitors.

The Committee notes that the rebuttable presumption would be inapplicable if the defendant has used the process in the United States, or has derived the products directly or indirectly from a manufacturer who used the process in the United States. In these circumstances, the discovery provisions of the Federal Rules of Civil Procedure and the equitable powers of Federal courts should be sufficient to allow the plaintiff to ascertain what process was employed. In this regard, the Committee trusts the courts to issue protective orders, in appropriate circumstances to prevent disclosure of the trade secrets and confidential business data of the parties. For example, the Committee expects protective orders to be used in encouraging foreign manufacturers to supply information pertinent to a process patent infringement suit revolving around goods made by such manufacturers. If information is obtained under a protective order that definitely determines the process used to make the goods in question, the presumption, would not be applicable.

Once the plaintiff has been found to be entitled to the presumption, the burden of producing evidence to establish that the product was not made by the process shifts to the defendant. Courts will continue to determine which party has the ultimate burden of persuasion and what amount of proof is necessary.

SECTION 105

Section 105(a) contains a grandfather clause exempting commercial arrangements that have been or were about to be entered into prior to May 15, 1987. The special importance of this provision for the generic pharmaceutical industry was mentioned in the Statement. Since the Drug Price Competition and Patent Term Restoration Act of 1984, over 100 abbreviated new drug applications (ANDA's) for generic medicines have been approved by the FDA The Committee firmly believes it would be inequitable if process patent legislation were to interfere with the marketing of these newly approved generic drugs, or with other ANDA's that were pending but not yet approved on May 15, 1987, if substantial commercial investments had been made in them prior to that date.

That is, if a generic pharmaceutical company has made substantial commercial investment in preparing and filing an ANDA and is awaiting FDA approval as of May 15, 1987, or if the company had been granted an approval before that date and starts to market a generic medicine in the United States, the pharmaceutical products that the company imports, uses and sells in connection with the ANDA are protected under the grandfather clause. The generic company may expand or contract its business with these products, shift to different suppliers as

necessary and continue to come under the protection of the grandfather clause.

Apart from this particularly sensitive area, the Committee envisions that the courts will interpret the scope of the grandfather clause in the individual cases brought before them with a view to the qualifying language "to the extent equitable" in the provision. Ordinarily, a party whose business before the grandfather date involved infringing activity should be able to continue to import, use or sell the product as necessary to maintain the same level of business, but not to expand such business by increasing the volume of products that he is using or selling, unless of course he has prospectively committed himself to such increases in a contract made prior to the grandfather date.

An important variation of this restriction could be illustrated as follows. If an importer contracts prior to May 15, 1987 to receive a certain volume of goods every month for the next 5 years, and a certain retailer contracts to purchase the goods from him during that period, both of these arrangements fall within the grandfather clause exempting them from the scope of the bill. If the retailer only contracts to purchase the goods for 3 years and the importer turns to another retailer afterwards, again the bill should not apply to the second retailer during the remaining 2 years of the importers contract, even though no contract with the second retailer existed prior to May 15, 1987, because the goods in question were contracted for by the importer before that date. However, if in this situation, the importer expands the volume of the goods he is importing, then the grandfather clause does not exempt him with respect

to units beyond what he contracted for before the grandfather date.

In addition, the Committee does not intend that it shall be an act of infringement to import a product which is made by a process patented in the United States "solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use or sale of a drug. See Sec. 271(e)(1) of title 35, United States Code. Congress previously decided that certain actions do not constitute patent infringements and this Act does not change that prior policy decision.

The Committee intends to provide the courts with flexibility to achieve an equitable solution in situations where the infringer has made a substantial investment necessary to sell or use the infringing product before this date. In that case, the investment was made during a time when use or sale of the product was not unlawful. The grandfather clause is modeled after 35 U.S.C. 252, and Section 107(d) of P.L. 98-662 (98 Stat. 3384) which Congress has provided for fundamentally the same purpose.

The Committee intends three other restrictions on the scope of the grandfather clause. The phrase "successors in business" does not include parties to whom the grandfathered infringer may license the goods; the phrase is meant only to allow the infringer who sells his business to pass on also its grandfathered status to the buyer of the business.

Secondly, the grandfather clause does not apply to any business whose product had already been the subject of International Trade Commission

litigation before January 1, 1987. The Committee has included the grandfather exception for those parties who reasonably relied upon the law as it was when they made their investments so that they should not be penalized for such good faith reliances and should be allowed, to the extent equitable, to recoup those investments made in the United States. However, when the product has already been the subject of ITC litigation, there are no good faith reliances since the patent owner has already indicated his clear intention to enforce his process patent in any and all appropriate forums, and investments therefore occur at the alleged infringer's own risk. It is not the Committee's intention to deny patentholders the right to pursue process patent infringement actions in U.S. courts against alleged infringers who made commercial investments during the prosecution of the ITC suit.

Thirdly, the grandfather clause applies to products being purchased, imported, used or sold as part of an ongoing business operation before the grandfather date only with respect to the process of manufacture used at that time to make such products. If the manufacturer of the products later shifts to a different process, such as a process developed and patented in the United States well after the grandfather date which the manufacturer in question has not been authorized to use, then units of the product made by this latter process are not protected by the grandfather clause, even if the U.S. wholesaler, importer or distributor had contracted with the manufacturer before the grandfather date for continued supply of the product. In order to keep products under the umbrella of the grandfather clause while fulfilling such a contract, the

manufacturer would have to make them by the process contemplated at the time of contracting (or May 15, 1987). This example, incidentally makes plain that importers, wholesalers and distributors who come under the grandfather clause with respect to some product still would have a strong incentive to make a request for disclosure to all manufacturers in the United States who are marketing that same product in order to insure their eligibility for the remedy limitations in the event that their supplying manufacturer shifts to a different process at some point in the future and so disengages the protection of the grandfather clause.

Section 105(b) makes clear that the bill does not affect any remedies patent owners have under existing law. The new remedies for process patent owners provided by the bill are subject to general limitations which do not apply in suits under existing law by process patent owners against parties manufacturing in the United States. For example, the bill requires notice of infringement to persuade a reasonable person that it is likely that the product was made by a patented process. The bill limits remedies available with respect to products already in the possession of or in transit to the infringer, or which the infringer already has made a binding commitment to purchase. The bill encourages parties to request disclosure of the identity of certain process patents. The bill provides that a product which is made by a patented process will not be considered so made after it is materially changed by subsequent processes; or it becomes a trivial and nonessential component of another product, there is no intention to impose any of these limitations on owners of product patents or on owners of process patents in suits they

are able to bring under existing law. Neither is there any intention for these provision to limit in any way the ability of process patent owners to obtain relief from the U.S. International Trade Commission.

SECTION 106

Section 106 instructs the Department of Commerce to report annually to Congress on the effect of the bill on any U.S. industries that submit formal complaints that they have lost legitimate sources of supply. Such reports will assist Congress in the unexpected event that the bill has a drastic adverse effect on some domestic industry, requiring emergency remedial measures.

IV. TITLE II—PATENT MISUSE DOCTRINE REFORM

A. PURPOSE OF AMENDMENT

As amended, title II of S. 1200 provides that a patent owner's licensing practices cannot be found to constitute patent misuse unless such practices violate antitrust laws.

B. HISTORY OF LEGISLATION

Legislation was first introduced in the 98th Congress (S. 1841, title IV) to reform the patent misuse doctrine as part of the administration's National Productivity and Innovation Act. Hearings on the bill reflected extensive support of and no opposition to title IV: the chairman of the ABA Patent Law Section, the president of Intellectual Property Owners, Inc. and the president of the American Intellectual Property Law Association supported enactment of title IV. *Patent Law Improvements Act, 1984, Hearings on S. 1535 and S. 1834*, before the

Senate Committee on the Judiciary, 98th Congress, 2d Sess. 44, 52, 91, 105 (1984). However, concern over the specific language of the proposal was expressed and, ultimately, the Congress went on to approve and enact only title I of the bill as the National Cooperative Research Act of 1984 (the so-called "Joint R&D Venture Bill"), Public Law 98-462.

In the 100th Congress legislation was again introduced to reform the law of patent misuse. S. 635, Section 115, 100th Congress, 1st Sess. General patent law oversight hearings were held by the Subcommittee on Patents, Copyrights and Trademarks, and testimony received during those hearings again supported enactment of patent misuse reform legislation.

In a statement submitted for the record by Ronald T. Reiling on behalf of Digital Equipment, Reiling highlights the need for misuse legislation in the current technological age:

These misuse doctrines are inappropriate to this era when intellectual property rights are essential components of technological and economic growth and international competitiveness. The current misuse doctrines hinder development and distribution of technological advances by requiring only that a court fine "some" anticompetitive effect.

Reiling's observations are echoed in a statement submitted to the Subcommittee on Patents, Copyrights and Trademarks by Robert Kline, President of the American Intellectual Property Law Association. In a letter dated June 4, 1987, Kline outlines the AIPLA concerns with the current doctrine:

> The "misuse" doctrine is a counterproductive legal fiction. It negatively affects virtually every license agreement involving technology developed or used in the United States. The doctrine reduces the incentive to innovate. This doctrine does not increase or stimulate competition.

Kline continues by detailing improvements in S. 1200:

> S. 1200 is a clear and straight forward solution to the "patent misuse" problem. It would merely require and ensure that economic analysis has been conducted before a court would be able, properly, to refuse to enforce a valid patent on anti- competitive grounds.

During Subcommittee consideration of S. 635, a proposal was made to change the language listing specific conduct by patent owners to which the law would apply to a more generic and easily applied approach that had been recommended in earlier testimony by the AIPLA witness. Chairman DeConcini adopted this amended language in an original bill circulated to the Subcommittee, and, on May 13, 1987, the Subcommittee unanimously approved that bill, containing the present title II on reform of the misuse doctrine. This original bill was then introduced by Chairman DeConcini on May 14, 1987 as S. 1200. *See* Cong. Rec. S6480-86 (May 14, 1987 daily ed.)

The Committee on the Judiciary met and considered the bill on June 4, 1987, and voted favorably to report the legislation. The Committee intends by adoption of this bill to clarify the law of patent misuse and to put intellectual property rights on an equal footing with other property with respect

to license, sale, and other agreements concerning the distribution of property rights.

C. DISCUSSION

The doctrine of patent misuse is a judicially created doctrine. It constitutes a defense to a patent infringement suit and provides that a patent owner may not enforce its patents if it has engaged in conduct deemed "misuse," at least until the patentee's conduct constituting misuse has ceased and its effects purged. Misuse thus renders the patent unenforceable, not void.

One branch of the misuse doctrine involves conduct alleged to constitute fraud on or inequitable conduct before the Patent Office. This part of the doctrine remains unaffected by title II.

The second branch of the misuse doctrine, to which this legislation is addressed, has its root in judicial interpretations that find misuse present because of alleged anticompetitive extensions of the owner's patent rights. For example, while misuse may be found where the antitrust laws have been violated, it may also be found where the patent owner's conduct has not violated the antitrust laws, has not demonstrated anticompetitive effect, and has not even injured the infringing party who raises misuse as a defense.

In recent years the need for reform of the law of patent misuse has gained increasing recognition. Commentators have repeatedly criticized the doctrine, and reform was initially proposed in title IV of S. 1841, the National Productivity and Innovation Act, introduced by Senator Thurmond in the 98th Congress. Hearings on this earlier proposal revealed

extensive support for reform of the patent misuse doctrine.

In 1984 hearings before the Subcommittee on Patents, Copyrights and Trademarks, Bernarr R. Pravel of the American Intellectual Property Law Association (AIPLA) testified that reform of the law of patent misuse would encourage and promote the efficient use of newly created technology. Mr. Pravel stated:

> Very often, the creators and owners of advances in technology in the form of intellectual property are not able to fully develop its commercial applications. In these cases, the most effective, and often the only, method of bringing this technology to the market place is for its owner to license it to another with the ability to do so. However, despite the practical benefits of licensing to the industrial innovation process, courts have sometimes found intellectual property licensing practices to be unlawful without fully considering the effect of the practices on competition.

Recent statements by the U.S. Department of Justice and American Bar Association Section of Antitrust Law also emphasize the need for reform. In a letter to the Subcommittee on Patents, Copyrights and Trademarks dated June 4, 1987, John R. Bolton, Assistant Attorney General of the U.S. Department of Justice, stated that:

> The Department believes that legislation in the misuse area is both important and timely, and thus strongly support this legislation. Because the sanction of misuse is harsh ... patent owners can be expected to avoid entering into patent licensing

> arrangements that they fear may be deemed to constitute patent misuse. In order to reassure creators of new technology that the courts will not interfere with procompetitive patent licensing, the misuse doctrine must not be applied in a manner that condemns competitively desirable licensing.

Robert P. Taylor of the American Bar Association Section of Antitrust Law stated in a letter to the Subcommittee of May 11, 1987, that:

> This change is needed to promote and encourage the licensing of new technology. In many situations, the misuse doctrine in its present form forces the owner of new technology to choose between either not licensing at all or licensing under circumstances which place at risk the enforceability of his property and contractual rights to that technology ... It also means that creative and innovative licensing schemes are rarely if ever used, because any license provision that is even slightly questionable is likely to place the entire patent at risk whenever an enforcement proceeding is brought.

Some courts have themselves questioned the soundness of the patent misuse doctrine. The Justice Department has urged its reform: Deputy Assistant Attorney General Roger Andewelt articulated a firm foundation for concluding that the misuse doctrine has been applied in a manner inconsistent with sound economic principles in his speech before the Bar Association for the District of Columbia on November 3, 1982. And recent law review commentary has condemned certain applications of the misuse doctrine as inherently anticompetitive. 46 U. Pitts. L. Rev. 209 (1984).

The lack of clarity and predictability in application of the patent misuse law doctrine and that doctrine's potential for impeding pro-competitive arrangements, are major causes for concern. Title II addresses this concern by providing that conduct shall only be found to be misuse when that conduct violates the antitrust law. As Donald W. Banner of the organization Intellectual Property Owners, Inc. observed in his 1984 testimony before the Subcommittee, the proposed reform would "add predictability to the law governing licensing practices" and "eliminate a hodgepodge of arbitrary rules developed by courts during the era when courts were hostile to licensing." Mr. Banner continued: "By providing more certainty to the permissible scope of licensing practices, the bill would increase the value of patents to patent owners. This would strengthen the incentives that patents provide to engage in research and development."

ORIGIN AND DEVELOPMENT OF THE PATENT MISUSE DOCTRINE

Patent misuse is a judicially created doctrine that allows a patent owner's overextension of his or her patent rights to be asserted as a defense in an action by the patent owner to enforce the patent. If the patent owner is held to have overextended, or "misused" patent rights, equity may bar the owner from enforcing the patent as long as the misuse continues. *Morton Salt Co.* v. *G.S. Suppiger Co.*, 314 U.S. 488 (1942).

The doctrine of patent misuse originally emerged as a judicial response to the patent owner's practice of conditioning the sale or license of patented inventions upon the purchase or license of additional

products. This practice was at first approved by courts, including the United States Supreme Court. In *Henry* v. *A.B. Dick Co.*, 224 U.S. 1 (1912) the Court upheld a patent owner's practice of requiring, as a condition to sale of a patented invention (mimeograph machine), that the invention be used only with certain supplies (ink) provided by the patent owner.

By 1917, however, the Court's attitude had changed. Citing the enactment of Section 3 of the Clayton Act as evidence that such conditional sales were against public policy, the Court held that the conditions to sale were unenforceable regardless of whether they violated the Clayton Act. In *Motion Picture Patents Co.* v. *Universal Film Manufacturing Co.*, 243 U.S. 502 (1917), the owner of a patent for a film feeder used in the projection of motion pictures sought to license the feeder on the condition that the licensee show only films leased from persons approved by the patent owner. The patented film feeder was dramatically superior to other film feeders on the market, giving the patent owner significant market power. The Court refused to enforce the patent, finding that imposing the condition would extend the patent owner's power beyond the scope of its patent rights. *Id.* at 518.

Cases following *Motion Picture Patents* continued to expand the doctrine of patent misuse. In the *Morton Salt Co.* case, where the term "patent misuse" appears for the first time, the Supreme Court held that the misuse defense was available even to a person who knowingly infringed a valid patent and was not affected by the conduct held to be misuse. The patent owner in *Morton Salt* had licensed its patented sale machine upon the condition that the licensee use

the machine with salt tablets purchased from the patent owner. According to the Court, this use of the patent exceeded the limited grant of the Patent Act, the patent owner had misused the patent, and the owner therefore was not entitled to the protection of the Act. 314 U.S. at 491. The Court found it unnecessary to determine whether the patent owner's action had violated the antitrust law. 314 U.S. at 494.

In *Morton Salt*, as in *Motion Picture Patents*, the Court ignored the antitrust issues presented and based its decision on public policy grounds. From this origin courts have developed the principle that a claim of patent misuse need not be supported by a showing of violation of the antitrust laws. *See, e.g., Zenith Radio Corp.* v. *Hazeltine Research, Inc.*, 395 U.S. 100, 140-41 (1960); *Duplan Corp.* v. *Deering Milliken, Inc.*, 444 F. Supp. 648 (D.S.C. 1977), *aff'd* in relevant part, 594 F.2d 979 (4th Cir. 1979). In most courts, the *Morton Salt* principles, interpreted as they were in *Zenith Radio* and *Duplan*, remain the established law of patent misuse. See Section of Antitrust Law of the American Bar Association, Antitrust Law Developments (2d) 488-89 (1984), and cases cited therein.

Recently, however, the Seventh Circuit challenged the reasoning of *Motion Picture Patents, Morton Salt*, and the line of cases following these decisions. In *USM Corporation* v. *SPS Technologies, Inc.*, 694 F.2d 505 (7th Cir. 1982), *cert. denied*, 462 U.S. 1107 (1983), the court of appeals, in dicta, questioned whether the reasoning of *Motion Picture Patents* accurately characterized the economic effect of practices held to constitute patent misuse. At issue in *USM Corporation* was whether the inclusion of a

different royalty schedule in a license agreement constitutes patent misuse. Citing the facts of several prior findings of patent misuse, including *Brulotte* v. *Thys Co.*, 379 U.S. 29 (1964) (patent license extending licensee fees beyong license period), *Zenith Radio Corp.* v. *Hazeltine Research, Inc.*, 395 U.S. 100, 133-40 (1969) (patent royalties measured by the sale of unpatented products containing the patented item), and *Stewart* v. *Mo-Trim, Inc.*, 192, U.S.P.Q. 410 (S.D. Ohio 1975) (licensees required not to make items competing with the patented item), Judge Posner noted that:

> As an original matter one might question whether any of these practices really "extends" the patentee. The patentee who insists on limiting the freedom of his purchaser or licensee ... will have to compensate the purchaser for the restriction by charging a lower price for the use of the patent True, a tie-in can be a method of price discrimination. It enables the patent owner to vary the amount he charges for the use of the patent by the intensity of each user's demand for the patent ....
>
> But since ... there is no principle that patent owners may not engage in price discrimination, it is unclear who one form of discrimination, the tie-in, alone is forbidden.

Id. at 510-11.

In addition, the *USM Corporation* court questioned the appropriateness of the law showing of anticompetitive effect required to establish patent misuse. The court suggested that patent misuse claims could be tested under standard antitrust

principles, stating that, "Our law is not rich in alternative concepts of monopolistic abuse and it is rather late in the day to try to develop one without in the process subjecting the rights of patent holders to debilitating uncertainty. *Id.* at 512.

D. SECTION-BY-SECTION ANALYSIS

Subsections (1) and (2) provide for conforming changes to Section 271 of title 35, United States Code. Subsection (3) provides for the addition of language to Section 271 addressing patent misuse. This language provides that no patent owner shall be denied relief or deemed guilty of misuse or illegal extension of the patent right by reason of his or her licensing practices, actions or inactions relating to his or her patent, unless such conduct violates the antitrust laws.

The term "patentowner" is intended to include all persons with the rights commonly held by a patentowner, including a licensee of a patent who is engaged in the sublicensing of the patent.

Title II includes contributory infringement as well as infringement, to make clear that a party charged with contributory infringement under 35 U.S.C. § 271(c) must also show conduct violating the antitrust laws to support the affirmative defense of patent misuse.

The reference to "illegal extension of the patent right" as well as "misuse" recognizes the differing formulations of activity deemed to be "misuse" and that misuse is often characterized as illegal extension of the patent right. Such reference to "illegal extension" is not meant, by itself, to alter or expand in any way the existing law of patent misuse.

The terms "licensing practices," "actions," and "inactions" are intended to include omissions as well as affirmative acts. The refusal to license or failure to take action is intended to be included within the meaning of "licensing practices or actions or inactions."

The broad reference to the patentowner's "actions or inactions relating to his or her patent"—in addition to "licensing practices"—indicates that the provisions of the subsection are not limited in application to licensing practices, but extend to all actions taken by the patentowner with respect to his patent, including the sale of patented products as well as the license of patent rights. The phrase "actions or inactions relating to his or her patent" includes the patentowner's sale of a product that embodies the patent.

E. JUSTICE DEPARTMENT VIEWS

U.S. DEPARTMENT OF JUSTICE,

OFFICE OF LEGISLATIVE AND INTER-GOVERNMENTAL AFFAIRS,

Washington, DC, June 4, 1987.

Hon. DENNIS DECONCINI,

Chairman, Subcommittee on Patents, Copyrights and Trademarks, Committee on the Judiciary, U.S. Senate, Washington, DC.

DEAR MR. CHAIRMAN: In response to your request, the Department of Justice has reviewed the patent misuse title of S. 1200, a bill to amend title 35, United States Code. This title would clarify and

reform the doctrine of patent misuse. It is similar in purpose and effect to pending legislation introduced on behalf of the Administration as part of its overall trade and competitiveness package (S. 539), and separately introduced by Senators Thurmond and Cochran as part of S. 635. The patent misuse title of S. 1200 would prohibit the courts from depriving patent holders of their exclusive property rights in their inventions because of alleged misuse of these rights unless their conduct violates the antitrust laws. The Department believes that legislation in the patent misuse area is both important and timely, and thus strongly supports this legislation.

Misuse is a judicially created doctrine founded in the courts' equitable powers. It frequently is used to attack patent licensing practices that are alleged to be undesirable from a public policy standpoint. Because the sanction for misuse is harsh—for example, a patent is unenforceable against anyone until the misuse has ceased and its effects purged from the marketplace—patent owners can be expected to avoid entering into patent licensing arrangements that they fear may be deemed to constitute patent misuse. In order to reassure creators of new technology that the courts will not interfere with procompetitive patent licensing, the misuse doctrine must not be applied in a manner that condemns competitively desirable licensing.

Unfortunately, misuse has been applied as a per se doctrine prohibiting conduct that careful analysis demonstrates is not necessarily anticompetitive and, in fact, often is procompetitive. Reform of the misuse doctrine is needed: Congress should make clear that licensing practices may be

condemned as misuse on competitive grounds only if sound antitrust analysis demonstrates that those practices are indeed anticompetitive.[7]

Title II of S. 1200 states simply that "No patent owner otherwise entitled to relief for infringement or contributory infringement of a patent shall be denied relief or deemed guilty of misuse or illegal extension of the patent right by reason of his or her licensing practices or actions or inactions relating to his or her patent, unless such practices or actions, in view of the circumstances in which such practices or actions are employed, violate the antitrust laws."[8] The Administration's proposal is to the same effect, but would go into more detail by listing five specific types of practices related to patent licensing that could not be the basis for a finding of misuse unless such conduct, in view of the circumstances, violated the antitrust laws. It would also require any other allegation that a patentee had misused its rights by "otherwise [using] the patent allegedly to suppress

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[7] While reform of the misuse doctrine to track antitrust analysis would have substantial benefits, improvements in the manner in which intellectual property licensing arrangements are considered under the antitrust laws are also crucial to encouraging innovation and productivity. Congress has before it proposals for improvements in this area, including a proposal of the Administration (see S. 438, H.R. 557, S. 539, S. 635). We hope that legislation in the misuse area will be accompanied by passage of such complementary legislation.

We also support the inclusion in S. 1200 of legislation clarifying licensor and licensee rights in the event of licensee challenge to patent validity.

[8] This new language would constitute 35 U.S.C. § 271(d). Existing subsections (c) and (d) of that section would be redesignated as paragraphs (c)(1) and (c)(2) respectively.

competition" to be evaluated under antitrust law standards.

Title II of S. 1200 would appear to accomplish the same result as the Administration's more detailed proposal. Both would make clear that licensing conduct may not be condemned as misuse on grounds related to competition unless analysis under antitrust standards demonstrates such conduct to be anticompetitive.[9] Accordingly, should Congress decide to take the more generalized approach embodied in Title II of S. 1200, the Department would enthusiastically support the legislation.[10]

We very much appreciate your interest and efforts in reporting legislation designed to encourage the development of new technologies by ensuring that

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[9] Title II is virtually identical to language suggested to the Subcommittee in 1984 by the American Intellectual Property Law Association (AIPLA). AIPLA noted that its suggested language "would not alter existing law with respect to the misuse doctrine as it applies to improper practices not related to competition (e.g., fraud on the Patent and Trademark Office and the like)." Supplemental Statement of Bernarr R. Pravel, President, AIPLA. Before the Subcommittee on Patents, Copyrights and Trademarks, Committee on the Judiciary, United States Senate, April 23, 1984, on S. 1841 (Titles III and IV) at 6-7. The Administration's proposal similarly would not alter existing law with respect to such practices.

[10] We understand that you intend to conform the language of proposed new section 271(d) by adding the words "or inactions" after the word "actions" where they do not already appear. By requiring an antitrust evaluation of licensing practices or actions or inactions relating to a patent, the legislation would make quite clear that neither licensing nor refusals to license could be condemned as misuse absent a finding of an antitrust violation. "[Refusal] to license the patent to any person" is one of the specific types of practices listed in the Administration's proposal. See section 115 of S. 635.

procompetitive patent licensing is not unreasonably discouraged by the misuse doctrine. If we can be of further assistance in this regard, please feel free to call on us.

The Office of Management and Budget has advised this Department there is no objection to the submission of this report from the standpoint of the Administration's program.

Sincerely,

JOHN R. BOLTON,

Assistant Attorney General.

V. TITLE III—LICENSEE CHALLENGES TO PATENT VALIDITY

A. PURPOSE OF AMENDMENT

As amended, title III of S. 1200 provides that a licensee cannot be estopped from challenging the validity of a patent to which it is licensed. It further provides that the parties to a licensing contract may define their respective rights regarding termination of a license and payment of royalties if the validity of the licensed patent is challenged.

B. HISTORY OF LEGISLATION

Legislation to address the concerns surrounding challenges to patent validity was introduced in the 98th Congress in S. 1535, a bill to amend title 35, United States Code, to increase the effectiveness of the patent laws and for other purposes. It would have allowed either the licensee or the licensor to terminate the license once the licensee asserts invalidity in a judicial action. However, the

licensee would have had to continue to pay royalties directly to the licensor unless the license was terminated. Upon termination by either party, further unlicensed practice of the patented invention would subject the former licensee to the infringement provisions of the patent laws.

During hearings held before the Senate Judiciary Subcommittee on Patents, Copyrights and Trademarks (Serial No. J-98-107, 4/3/84) then Assistant Secretary and Commissioner of Patents and Trademarks, Gerald Mossinghoff, agreed that a clarification of the *Lear* decision was needed:

> A fairer balance between the rights of licensor and those of the licensee is needed without compromising the public interest. New section 295(b) proposed by section 10 would achieve this balance with a number of straightforward principles. Either the licensor or the licensee could terminate the license once the licensee asserts invalidity in a judicial action. However, the licensee would have to continue to pay royalties directly to the licensor unless the unlicensed practice of the patented invention would subject the former licensee to the infringement provisions of the patent laws.

However, at that time, Commissioner Mossinghoff also noted the need for some changes in the legislation:

> We believe the statute should not be drafted in the form of section 10, which would increase Federal interference in patent licensing. We believe the correct approach is to do exactly the opposite. Parties should be properly able to

> negotiate contracts containing provisions, for instance, that a licensor or licensee could terminate if the licensee challenged the validity of the license in a judicial proceeding.

Though S. 1535 was approved by the Judiciary Committee, it was not ultimately enacted into law.

Former Chairman Mossinghoff's suggestions were included in Title III of an original bill circulated by Chairman DeConcini to members of the Subcommittee on Patents, Copyrights and Trademarks. On May 13, 1987 the Subcommittee unanimously approved this bill containing Title III on the reform of licensee challenges. This original bill was then introduced by Chairman DeConcini on May 14, 1987 as S. 1200. See Cong. Rec. S. 6480-06 (May 14, 1987 daily ed.).

The Committee on the Judiciary met and considered the bill on June 4, 1987, and voted favorably to report the legislation.

C. STATEMENT

Since the United States Supreme Court decision in *Lear v. Adkins*, 395 U.S. 653 (1969) there has been considerable uncertainty in the area of patent license validity. In particular, there has been confusion as to the rights of licensees and licensors in a patent license agreement where the validity of the patent is challenged in litigation. Numerous law review articles have been written in an attempt to sort out the case law including *Unmuzzling the Patent Licensee: Chaos in the Wake of Lear* v. *Adkins*, 59 J. Pat Offic. Society 475 (1977).

In the *Lear* case, an inventor, Adkins, alleged breach of a patent licensing agreement against the

licensee, Lear. Lear then challenged the validity of the patent and refused to pay royalties. In this case, the Supreme Court overturned the licensee estoppel doctrine and assured a licensee the right to challenge the validity of the patent. The Court recognized the public interest in freedom from invalid patents and that the licensee is the party most able and most likely to challenge validity.

Prior to *Lear*, a licensee was precluded from questioning the validity of any patent under which it was licensed, i.e. license estoppel. The theory underlying this doctrine is that a licensee should not be permitted to enjoy the benefit afforded by the agreement while simultaneously urging that the patent is void. However, the result of *Lear* was that the licensee was able to attack patent validity under conditions competitively unfair to the licensor. For example, a licensee can negotiate the best license terms available, accept a contract, and then question patent validity without relinquishing the license.

Under the current case law, the following hypothetical could occur. The licensee negotiates successfully with the patent owner for the right to practice the patented invention. A royalty is agreed upon. The licensee then brings a declaratory judgment action against the patentowner to have the patent declared invalid. The court allows the licensee to pay the royalties owing into an escrow account during the pendency of the case. If the patent is declared invalid, the licensee continues to use the invention and retain the royalties paid into the escrow account. If the patent is declared valid, the licensee continues to use the invention; he has not breached the license agreement so the patentowner has no

ground to prevent it. The patentowner receives the royalties from the escrow account but these are royalties already owing under the license. The licensee risks nothing and stands to lose nothing, except attorneys fees, in this situation.

In a statement before the Senate Judiciary Subcommittee on Patents, Copyrights and Trademarks during its February 17, 1987 General Oversight Hearing on Patent and Trademark Law, American Intellectual Property Law Association President, Robert Kline highlighted these problems:

> The unfairness of the current state of the law is especially relevant when the licensor is an individual inventor and the licensee is a large corporation. This is often the case and was in *Lear*. If a patent owner does not have the resources to utilize his invention, he must license it to another who possesses those resources. That licensee is able to bear the cost of litigation where the licensor is often hardpressed to do so.

As this explanation illustrates, the patent owner is in a no win situation. If the licensee has the exclusive right to use the invention, during the legal challenge the patent owner is deprived of all royalty income during this period.

D. SECTION-BY-SECTION ANALYSIS

Section 1 of this title adds a new section with two subsections to Chapter 29 of title 35, United States Code. Subsection (2) provides that a licensee shall not be estopped from asserting the invalidity of a patent to which it is licensed, and that any provision in an agreement between the parties that purports to bar such an assertion shall be unenforceable. Thus, it

codifies the holding of *Lear v. Adkins* that a licensee cannot be estopped, by agreement or otherwise, from contesting the validity of a patent to which it is licensed.

Subsection (b) provides that a patent license agreement may contain provisions allowing termination if the licensee challenges its validity in a judicial proceeding. It further provides that if the licensee has a right to terminate, the agreement also may provide for the licensee's obligations under the agreement to continue until the patent is finally declared invalid or until the license is terminated. Under the subsection (b) such provisions will be enforceable as long as they are consistent with federal patent law or policy.

This issue, namely, the rights of the parties with respect to termination of a license and payment of royalties if the licensee challenges the validity of the licensed patent is one over which courts have differed in the years since the *Lear* decision. New section 295(b) would give the parties broad discretion to define these rights during the license negotiation process. It makes clear that the parties may provide for termination by licensor and-or licensee in the event of such a challenge, and, if the licensee has a right to terminate, for the licensee's obligations to continue pending adjudication of validity. In this way, patent licensors can bargain for provisions they feel necessary to assure the realization of their rights in an invention, while licensees can bargain for provisions they feel necessary to protect their interests if they choose to challenge patent validity.

Subsection (b) also clarifies the issue of whether it is equitable to allow the parties to agree

that the licensor should receive royalties during litigation which results in the patent being held invalid. Some courts have interpreted *Lear* to require that royalties owing during the period of litigation should not go to the licensor after a finding of invalidity. The Court of Appeals for the Federal Circuit (CAFC) *Cordis Corporation* v. *Medtronics, Inc.* 780 F.2d 991(1985) held, inter alia, that *Lear* does not provide authority for courts to establish escrow accounts to hold royalty payments until after the case has been decided. The CAFC did not decide the issue of whether royalties paid after the complaint in a case in which the patent was held invalid should be returned to the licensee or retained by the licensor. The CAFC cited *Nebraska Engineering Corp.* v. *Shivvers* 557 F2d 1257, (8th Cir.1977) as standing for the proposition that royalties paid after the complaint may have to be returned to the plaintiff. A more thorough explanation of the equities surrounding this issue is found in *REC Corporation* v. *Applied Digital Systems Inc., RCA Corporation* v. *Hazeltime Corp., Lear Siegler* v. *RCA Corporation*, 217 USPQ 241 (Dist. Ct. Delaware 1983):

> The opinion in the *Lear* case does not reach the issue which is presented here: when a licensee elects to pay royalties while litigating the validity of the patent, he may, if successful, recover those royalties. I conclude "no". When a licensee continues to pay royalties after filing a declaratory judgment action, it does so because it believes that course is in its best interest. As Prof. McCarthy has pointed out, a licensee "hedges" its bet by continuing the payment of royalties and thereby continues to derive benefits from the license even while attacking the patent. McCarthy,

> *"Unmuzzling" the Patent Licensee: Chaos in the Wake of Lear v. Adkins*, 59 J. Pat. Off. Socy 475, 528-33 (1977). First, the license assures that the licensee will be able to continue its use of the patented invention during the litigation and, if it loses, thereafter. It has neither of these assurances if it chooses to cease paying and terminate the license. Moreover, continued payment assures the licensee that its use pendente lite and thereafter, if he is unsuccessful, will be at the license royalty rate, thereby providing insurance against the possibility of a higher court determined "reasonable royalty" or a higher negotiated rate in a new license. Finally, continued payment provides insurance against the possibility of an award of attorney's fees or treble damages in the event the challenge of the patent is unfruitful. Given the fact that the licensee reaps these benefits from the payment of royalties under the license while litigating, I believe equity is on the side of the patentee when recoupment is sought after a finding of patent invalidity. Moreover, I perceive no inconsistency between a result consistent with this equity and the policy considerations which underlie *Lear*. Since I find no special circumstances favoring recovery of royalties by Lear Siegler, judgement will be entered for RCA on this claim.

The Committee believes that subsection (b) settles the issue in an equitable manner by allowing an agreement between a licensee and licensor to stipulate that royalty payments shall continue until a final determination of invalidity is reached or until the license is terminated.

VI. TITLE IV—PHARMACEUTICAL PATENT TERM RESTORATION ACT AMENDMENTS

A. PURPOSE OF AMENDMENT

As amended, title IV of S. 1200 extends the patent on the pharmaceutical product gemfibrozil for a period of 5 years.

B. STATEMENT

The Committee believes that patent term extension is extraordinary relief, but that the circumstances surrounding gemfibrozil are sufficiently unique to warrant extension. Further, the Committee believes that this action will set no precedent justifying the extension of patents on other drug products.

The unique circumstances involving gemfibrozil are as follows. First, gemfibrozil was approved by the Food and Drug Administration (under the brand name "Lopid") in 1981 for the limited claim of treating triglycerides among adult patients with a risk of pancreatitis, but approval was contingent upon a Phase IV study involving effectiveness and long-term safety. At the time, Warner-Lambert, the patent holder, was engaged in a primary heart attack prevention study conducted by the Helsinki Heart Council in Helsinki, Finland. (Finland has the highest death rate from coronary disease.) The 1981 approval by the FDA specified that "satisfactory completion of the ongoing Finnish study" would meet the Phase IV study requirements. Without the additional study, gemfibrozil could not have been marketed for any purpose.

Second, the Finnish study was more extensive and would take longer than any previous Phase IV

study. It involved basic medical research and endeavored to establish the basic medical hypothesis regarding cholesterol that raising the level of high density lipids helps protect against arteriosclerosis and heart attacks. Warner-Lambert financed the double-blind study, which was administered by officials of the Helsinki Heart Council.

Third, after the Finnish study was begun, the Drug Price Competition and Patent Term Restoration Act of 1984 (the "Act") was introduced and enacted. That legislation changed the regulatory environment for human pharmaceuticals. At the time of the 1981 FDA approval, Warner-Lambert reasonably expected at least five more years of market exclusivity for Lopid following the expiration of its patent on July 4, 1989. Enactment of the Act affected the period of market exclusivity for Lopid. Title IV restores the minimum period of protection that Warner-Lambert could have reasonably expected in 1981 and does so in a manner that eliminates any precedential value.

C. SECTION-BY-SECTION ANALYSIS

Section 1 of this title amends Title 35 of the United States Code.

Subsection (a) of section one adds a new section 155B entitled "Patent Term Restoration," which section is divided into two subsections.

Subsection (a) of new section 155B extends for five years the patent on a composition of matter which is a "new drug" if five conditions are met.

First, the composition which is covered by the patent must have been subjected to a regulatory review by the Federal Food and Drug Administration (FDA).

Second, such composition must have been approved by the FDA in a new drug application after the receipt of a letter from the applicant stating that the Phase IV clinical study requested by the agency as a condition of approval of the composition has been undertaken.

Third, the Phase IV study must have covered at least five years. This means that the period which elapsed from the time the first patient entered in the study (i.e.), the commencement of the study term) until the last patient completed the study (i.e., the ending of the study term) was at least 5 years. For example, in the case of gemfibrozil, the Phase IV study began when the first patient entered the study on November 3, 1980, and ended when the last patient completed the study on March 21, 1987. In addition, the Phase IV study must have been commenced prior to the introduction of the Drug Price Competition and Patent Term Restoration Act of 1984 and ended subsequent to the enactment of that Act. The Drug Price Competition and Patent Term Restoration Act of 1984 was introduced as S. 1538 on June 23, 1983 and ultimately became Public Law 98-417 of September 24, 1984.

Fourth, the Phase IV study must be completed and a supplemental new drug application (NDA) to expand the permitted indications and usage in the labeling of the new drug based upon such Phase IV clinical study must have been submitted to the FDA. The requirement of an expansion of the indications and usage of the composition is satisfied by any change in the permitted "indications and usage" section of the existing package insert of the drug, as those terms are defined in 21 Code of Federal

Regulations 201.57(c), reflecting a decrease in the incidence of morbidity or mortality for hyperlipidemic patients as shown by the results of the Phase IV study.

Finally, the supplemental NDA must either have been approved or, if the FDA has not made a final determination as to the approvability of the application, the patent must be within ninety days of expiration.

If the patent is extended because the FDA has not made a final determination regarding the approvability of the supplemental NDA prior to ninety days before the patent expires, the patent extension shall immediately terminate if the FDA subsequently makes a final determination disapproving the supplemental NDA.

Subsection (b) of new section 155B requires the holder of the rights to the patent of a qualifying drug to inform the Commissioner of Patents of the number of the patent covering the composition. The notification must take place within the earlier of:

—30 days after enactment of the section if approval of supplemental NDA occurs before enactment of this section;

—30 days after the approval of the supplemental NDA if such approval does not occur before enactment of the section; or

—Between the 90th and 60th day prior to the expiration of the patent if the FDA has not made a final determination as to the approvability of the application before the 90th day prior to expiration.

Upon receipt of such notification from the patent holder, subsection (b) of new section 155B then requires the Commissioner of Patents to issue a certificate of extension for the qualifying composition of matter patent. The certificate of patent extension must be recorded in the official file of the patent extended and is to be considered part of the original patent. In the case of a patent extension granted on the basis that the FDA had not made a final determination as to the approvability of the application, the subsection requires the holder of the rights to the patent to notify the Commission of patents within 2 days if the FDA makes a final determination to disapprove the supplemental NDA. This provision would not be invoked by the customary interim FDA letters saying that the supplemental NDA is incomplete or unapprovable without further information or labeling changes, but would be invoked if the FDA states with finality that the supplemental NDA is disapproved for lack of proof of effectiveness.

Upon receipt of such notification, the Commissioner must promptly issue a certificate of termination of extension, stating that the patent extension is terminated as of the date of the FDA's disapproval of the supplemental NDA as a final agency action. Such certificate of termination must be recorded in the official file of the patent extension terminated.

Subsection (b) of section 1 amends the title to read as follows:

> A bill to amend title 35, United States Code, with respect to patented processes, patent misuse, license challenges to patent validity, and patent term restoration.

VII. REGULATORY IMPACT STATEMENT

In compliance with paragraph 11(b), Rule XXVI of the Standing Rules of the Senate, the Committee has concluded that no significant additional regulatory impact would be incurred in carrying out the provisions of this legislation; there would not be additional impact on the personal privacy of companies or individuals; and there would be no additional paperwork impact.

VIII. COST OF LEGISLATION

U.S. CONGRESS,
CONGRESSIONAL BUDGET OFFICE,
Washington, DC, June 15, 1987.
Hon. JOSEPH R. BIDEN, Jr.,
Chairman, Committee on the Judiciary,
U.S. Senate, Washington, DC.

DEAR MR. CHAIRMAN: The Congressional Budget Office has reviewed S. 1200, the Process Patent Amendments Act of 1987, as ordered reported by the Senate Committee on the Judiciary, June 5, 1987. Based on information from the Patent and Trademark Office, CBO estimates that enactment of this bill would not result in significant additional costs to the federal government and will not affect the budgets of state or local governments.

Title I of S. 1200 would extend to patent owners the right to exclude others from using or selling in the United States, or importing into the United States, a product made by a patented process. If this bill is enacted, the holder of a process patent would be allowed, with certain restrictions, to seek damages for patent infringements. After certain court findings,

the product would be presumed to have been made by a patented process, and the burden of proving otherwise would fall on the alleged infringer. The bill would also require the Secretary of Commerce to submit to the Congress annual reports for five years on the effectiveness of the amendments included in Title I.

Title II provides that no patent owner can be denied relief for infringement because of his or her licensing practices or actions, unless such practices or actions violate the antitrust laws. Title III declares unenforceable any agreement between the parties to a patent license agreement that would prevent the licensee from asserting the invalidity of a patent. Title IV establishes procedures for restoring the term of patents for certain new drugs by extending their term for five years.

If you wish further details on this estimate, we will be pleased to provide them. With best wishes,

Sincerely,

EDWARD M. GRAMLICH, *Acting Director*.

IX. CHANGES IN EXISTING LAW

In compliance with paragraph 12, Rule XXVI of the Standing Rules of the Senate, changes in existing law made by S. 1200, as reported, are shown as follows (new matter is printed in italic, and existing law in which no change is proposed is shown in roman):

TITLE 35, UNITED STATES CODE

* * * * * * *

PART II—PATENTABILITY OF INVENTIONS AND GRANT OF PATENTS

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CHAPTER 14—ISSUE OF PATENT

Subsection 154. Contents and Terms of Patent

Every patent shall contain a short title of the invention and a grant to the patentee, his heirs or assigns, for the term of seventeen years, subject to the payment of fees as provided for in this title, of the right to exclude others from making, using, or selling, the invention throughout the United States, *and, if the invention is a process, of the right to exclude others from using or selling throughout the United States, or importing into the United States, products made by that process*, referring to the specification for the particulars thereof. A copy of the specification and drawings shall be annexed to the patent and be a part thereof.

* * * * * * *

Subsection 155B. Patent Term Restoration

(a) Notwithstanding section 154 of this title, the term of a patent which encompasses within its scope a composition of matter which is a new drug shall be extended for a period of 5 years, and such patent shall have the effect as if originally issued with such extended term, if—

(1) such composition has been subjected to a regulatory review by the Federal Food and Drug

Administration pursuant to the Federal Food, Drug, and Cosmetic Act,

(2) the Federal Food and Drug Administration has approved a new drug application after receipt of a letter from the applicant stating that a Phase IV clinical study that had been requested as a condition for approval has been undertaken,

(3) the Phase IV clinical study has covered at least 5 years with the study term commencing prior to the introduction of the Drug Price Competition and Patent Term Restoration Act of 1984 and ending subsequent to the enactment of such Act,

(4) such Phase IV clinical study has been completed, and a supplemental new drug application to expand the permitted indications and usage in the labeling of the new drug based upon such Phase IV clinical study has been submitted to the Federal Food and Drug Administration,

(5) the Federal Food and Drug Administration has either approved the supplemental new drug application or the original patent term is within 90 days of expiration, and

(6) the Federal Food and Drug Administration has not made a final determination that the supplemental new drug application is approved or disapproved.

If, however, the term of a patent is extended because the Federal Food and Drug Administration has not made a final determination that the supplemental new

drug application is approved or disapproved prior to 90 days before the expiration of the patent, such patent extension shall immediately terminate if the Federal Food and Drug Administration makes a final determination disapproving the supplemental new drug application.

(b)(1) The patentee, his heirs, successors, or assigns shall notify the Commissioner of Patents and Trademarks within 30 days after the date of enactment of this section, or within 30 days after the date of the approval of the supplemental new drug application if such approval does not occur before enactment of this section, or within 30 days after the date which is 90 days from the expiration of the original patent term if the Federal Food and Drug Administration has not made a final determination that the supplemental new drug application is approved or disapproved by such date, of the number of the patent to be extended.

(2) On receipt of such notice, the Commissioner shall promptly issue to the owner of record of the patent a certificate of extension, under seal, stating the fact and length of the extension and identifying the composition of matter to which such extension is applicable. Such certificate shall be recorded in the official file of the patent extended and such certificate shall be considered as part of the original patent, and an appropriate notice shall be published in the Official Gazette of the Patent and Trademark Office. If, subsequent to a notification that it is within 90 days of the expiration of the patent and that the Federal Food and Drug Administration has not made a final determination that the supplemental new drug application is approved or disapproved, a final

determination is made by the Federal Food and Drug Administration that the supplemental new drug application is disapproved, the patentee, his heirs, successors, or assigns shall, within 2 days, notify the Commissioner of Patents and Trademarks of such final determination. On receipt of such notice and if the patent has been extended pursuant to the terms hereof, the Commissioner shall promptly issue a certificate of termination of extension, under seal, stating the fact that the patent is terminated, effective the date of the final determination that the supplemental new drug application is disapproved, and identifying the composition of matter to which such termination of extension is applicable. Such certificate shall be recorded in the official file of the patent terminated and such certificate shall be considered as a part of the original patent, and an appropriate notice shall be published in the Official Gazette of the Patent and Trademark Office.

PART III—PATENTS AND PROTECTION OF PATENT RIGHTS

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CHAPTER 28—INFRINGEMENT OF PATENTS

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Subsection 271. Infringement of Patent

(a) * * *

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(c)*(1)* Whoever sells a component of a patented machine, manufacture, combination or composition, or a material or apparatus for use in practicing a patented process, constituting a material part of the

invention, knowing the same to be especially made or especially adapted for use in an infringement of such patent, and not a staple article or commodity of commerce suitable for substantial noninfringing use, shall be liable as a contributory infringer.

(2) No patent owner otherwise entitled to relief for infringement or contributory infringement of a patent shall be denied relief or deemed guilty of misuse or illegal extension of the patent right by reason of his having one or more of the following: (1) derived revenue from acts which if performed by another without his consent would constitute contributory infringement of the patent; (2) licensed or authorized another to perform acts which if performed without his consent would constitute contributory infringement of the patent; (3) sought to enforce his patent rights against infringement or contributory infringement.

(d) No patent owner otherwise entitled to relief for infringement or contributory infringement of a patent shall be denied relief or deemed guilty of misuse or illegal extension of the patent right by reason of his or her licensing practices or actions or inactions relating to his or her patent, unless such practices or actions or inactions, in view of the circumstances in which such practices or actions or inactions are employed, violate the antitrust laws.

(e) * * *

* * * * * * *

(g) Whoever without authority imports into the United States or 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, sale, or use of the product occurs during the term of such process patent. In an action for infringement of a process patent, no remedy may be granted for infringement on account of the noncommercial use or retail sale of a product unless there is no adequate remedy under this title for infringement on account of the importation or other use or sale of that product. A product which is made by a patented process will, for purposes of this title, not be considered to be so made after—

(1) it is materially changed by subsequent processes;

(2) it becomes a trivial and nonessential component of another product.

CHAPTER 29—REMEDIES FOR INFRINGEMENT OF PATENT, AND OTHER ACTIONS

* * * * * * *

Subsection 287. Limitation on Damages *and Other Remedies*; Marking and Notice

(a) Patentees, and persons making or selling any patented article for or under them, may give notice to the public that the same is patented, either by fixing thereon the word "patent" or the abbreviation "pat.", together with the number of the patent, or when, from the character of the article, this can not be done, by fixing to it, or to the package wherein one or more of them is contained, a label containing a like notice. In the event of failure so to mark, no damages shall be recovered by the patentee in any action for infringement, except on proof that the infringer was notified of the infringement and

continued to infringe thereafter, in which event damages may be recovered only for infringement occurring after such notice. Filing of an action for infringement shall constitute such notice.

(b)(1) An infringer under section 271(g) shall be subject to all the provisions of this title relating to damages and injunctions except to the extent those remedies are modified by this subsection or section 105 of the Process Patent Amendments Act of 1987. The modifications of remedies provided in this subsection shall not be available to any person who—

(A) practices the patented process;

(B) owns or controls, or is owned or controlled by, the person who practiced the patented process; or

(C) had knowledge before the infringement that a patented process was used to make the product the importation, use, or sale of which constitutes the infringement.

(2) No remedies for infringement under section 271(g) of this title shall be available with respect to any product in the possession of, or in transit to the party, or which the party has made a binding commitment to purchase and which has been partially or wholly manufactured, before the party had notice of infringement as defined in paragraph (5). The party shall bear the burden of proving any such possession, transit, binding commitment, or manufacture. If the court finds that (A) the party maintained or ordered an abnormally large amount of infringing product, or (B) the product was acquired or ordered by the party to take advantage of the limitation on remedies provided by this paragraph, the court shall limit the

application of this paragraph to that portion of the product supply which is not subject to such a finding.

(3)(A) In making a determination with respect to the remedy in an action brought for infringement under section 271(g), the court shall consider—

> *(i) the good faith and reasonable business practices demonstrated by the defendant,*
>
> *(ii) the good faith demonstrated by the plaintiff with respect to the request for disclosure as provided in paragraph (4), and*
>
> *(iii) the need to restore the exclusive rights secured by the patent.*
>
> *(B) For purposes of subparagraph (A), the following are evidence of good faith: a request for disclosure by a party, a response by the party receiving the request for disclosure within 60 days, and submission of the response by the party who received the disclosed information to the manufacture, or if not known, the supplier with a request for a written statement that the process claimed in the disclosed patent is not used. The failure to perform any such acts is evidence of absence of good faith unless there are mitigating circumstances. Mitigating circumstances shall include the case in which, due to the nature of the product, the number of sources for products, or like commercial circumstances, a request for disclosure is not necessary or practicable to avoid infringement.*

(4) For purposes of paragraph (3), a "request for disclosure" means a written request made to a party

then engaged in the manufacture of a product to identify all process patents owned by or licensed to the party as of the time of the request that the party then reasonably believes could be asserted to be infringed under section 271(g) if that product were imported into, or sold or used in, the United States by an unauthorized party. A request for disclosure is further limited to a request—

> *(A) made by a party regularly engaged in the United States in the sale of the same type of products as the party to whom the request is directed, or a request which includes facts showing that the requester plans to engage in the sale of such products in the United States*;
>
> *(B) made prior to such party's first importation, use, or sale of units of the product produced by an infringing process and prior to notice of infringement; and*
>
> *(C) which includes a representation by the requesting party that it will promptly submit the patents identified to the manufacturer, or if not known, the supplier of the product to be purchased by the requester, and will request from that manufacturer or supplier a written statement that none of the processes claimed in those patents is used in the manufacture of the product.*

(5)(A) For the purpose of this subsection, notice of infringement means actual knowledge, or receipt by a party of a written notification, or a combination thereof, of information sufficient to persuade a reasonable person that it is likely that a product was made by a patented process.

(B) A written notification from the patent holder charging a party with infringement shall specify the patent alleged to have been used and the reasons for a good faith belief that process was used. If the patent holder has actual knowledge of any commercially feasible process other than the patented process which is capable of producing the allegedly infringing product, the notification shall set forth such information with respect to the other processes only as is reasonably necessary to fairly explain the patent holder's belief and is not required to disclose any trade secret information.

(C) A party who receives a written notification as described in the first sentence of such subparagraph (B) and fails to thereafter seek information from the manufacturer, or if not known, the supplier, as to whether the allegations in the notification are true shall, absent mitigating circumstances, be deemed to have notice of infringement. This provision shall apply even though the notification does not establish notice of infringement under subparagraph (A).

(D) A party who fails to make the submission referred to in subsection (b)(4)(C) shall be deemed to have notice of infringement.

(E) Filing of an action for infringement shall constitute notice of infringement only if the pleadings or other papers filed in the action meet the requirements of subparagraph (A).

Subsection 295. Presumption: Product Made by Patented Process

In actions alleging infringement of a process patent based on the importation, sale, or use of a

product which is made from a process patented in the United States, if the court finds—

> *(1) that there is evidence establishing a substantial likelihood that the product was made by the patented process, and*
>
> *(2) that the claimant has made a reasonable effort to determine the process actually used in the production of the product and was unable so to determine, the product shall be presumed to have been so made, and the burden of establishing that the product was not made by the process shall be on the party asserting that it was not so made.*

Subsection 296. Licensee Challenges to Patent Validity

(a) A licensee shall not be estopped from asserting in a judicial action the invalidity of any patent for which the licensee has obtained a license. Any agreement between the parties to a patent license agreement which purports to bar the licensee from asserting the invalidity of any licensed patent shall be unenforceable as to that provision.

(b) Any patent license agreement may provide for a party or party or parties to the agreement to terminate the license if the licensee asserts, in a judicial action, the invalidity of the licensed patent, and, if the licensee has such a right to terminate, the agreement may further provide that the licensee's obligations under the agreement shall continue until a final and unappealable determination of invalidity is reached or until the license is terminated. Such agreement shall not be unenforceable as to such provisions on the grounds that such provisions are contrary to Federal law or policy.