No. 2018-1614

In the United States Court of Appeals for the Federal Circuit

SYNGENTA CROP PROTECTION, LLC,

Appellant,

v.

WILLOWOOD, LLC,

Appellee-Cross-Appellant.

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

BRIEF OF BIOTECHNOLOGY INNOVATION ORGANIZATION AND CROPLIFE INTERNATIONAL AS *AMICI CURIAE* IN SUPPORT OF APPELLANT SYNGENTA CROP PROTECTION, LLC

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FORM 9. Certificate of Interest **Form 9**
Rev. 10/17

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

Syngenta Crop Protection, LLC v. Willowood, LLC

Case No. 18-1614

CERTIFICATE OF INTEREST

Counsel for the:
☐ (petitioner) ☐ (appellant) ☐ (respondent) ☐ (appellee) ☒ (amicus) ☐ (name of party)

Biotechnology Innovation Organization and CropLife International

certifies the following (use "None" if applicable; use extra sheets if necessary):

1. Full Name of Party Represented by me	2. Name of Real Party in interest (Please only include any real party in interest NOT identified in Question 3) represented by me is:	3. Parent corporations and publicly held companies that own 10% or more of stock in the party
Biotechnology Innovation Organization	None	None
CropLife International	None	None

4. The names of all law firms and the partners or associates that appeared for the party or amicus now represented by me in the trial court or agency or are expected to appear in this court **(and who have not or will not enter an appearance in this case)** are:

None

5. The title and number of any case known to counsel to be pending in this or any other court or agency that will directly affect or be directly affected by this court's decision in the pending appeal. *See* Fed. Cir. R. 47. 4(a)(5) and 47.5(b). (The parties should attach continuation pages as necessary).

None

5/4/2018
Date

/s/ Jeffrey Kushan
Signature of counsel

Please Note: All questions must be answered

Jeffrey Kushan
Printed name of counsel

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STATEMENT OF INTEREST OF AMICI CURIAE

The Biotechnology Innovation Organization ("BIO") (formerly Biotechnology Industry Organization) is the principal trade association representing the biotechnology industry domestically and abroad. BIO has more than 1,000 members, which span the for-profit and non-profit sectors and range from small start-up companies and biotechnology centers to research universities and Fortune 500 companies. Approximately 90% of BIO's corporate members are small or midsize businesses that have annual revenues of under $25 million.

CropLife International ("CropLife") is a global federation representing the plant science industry as well as a network of regional and national associations in ninety-one countries. CropLife's member companies include BASF, Bayer CropScience, DuPont, Dow Agrosciences, FMC Corp., Monsanto, Sumitomo Chemical, and Syngenta. These companies are committed to sustainable agriculture through innovative research and development in the areas of crop protection, pest control, and seed and plant technologies that increase crop yields and enhance human and animal nutrition and food security, and decrease reliance on pesticides, herbicides, irrigation, and nutrients, thus benefitting the environment, farmers, and the public.

The members of BIO and CropLife are concerned that the district court's improper interpretation of § 271(g) will materially undermine their substantial investments in developing innovative manufacturing processes. Process patent

rights, and the rights conferred on owners of such patents by § 271(g), provide critically important market protections against foreign manufacturers who unfairly use those processes abroad, and are beyond the reach of U.S. patent laws. Process patents are particularly important to *amici's* members, because they are often the only form of protection available for many kinds of biotechnology products. Interpreting § 271(g) as the district court did to make it more difficult, if not impossible, for patentees to prove infringement would undermine Congress's intent to provide meaningful protection to process patent holders and thwart the stated goal of § 271 (g) to protect the continued growth of American businesses in the global economy.

BIO and CropLife have no direct stake in the result of this appeal and take no position on infringement of the patents at issue. Pursuant to Federal Rule of Appellate Procedure 29(a), BIO and CropLife each certify that no counsel for a party authored this brief in whole or in part, and no such counsel or party, nor any person other than the *amici* or its counsel, made a monetary contribution intended to fund the preparation or submission of this brief. This brief is solely the work of BIO and CropLife; it reflects the consensus view of BIO's members, but not necessarily the views of any individual member, and the consensus view of the individual member companies of CropLife, but not necessarily the views of its regional affiliates. Appellant Syngenta is a member of BIO and CropLife. Lists of BIO's and CropLife's members are available at https://www.bio.org/bio-member-directory

and https://croplife.org/about/members/, respectively. Pursuant to Federal Rule of Appellate Procedure 29(a) and Federal Circuit Rule 29(c), BIO and CropLife file concurrently herewith a motion for leave to file this brief.

INTRODUCTION

BIO's and CropLife's member companies heavily invest in development of innovative manufacturing processes to produce a wide range of products, including biofuels, food and animal feed additives, drugs, pigments, agrochemicals, enzymes, flavorants and fragrances, and other important industrial, medicinal and agricultural materials. Often, the products produced by such manufacturing processes are commodity products long known in the art and not patentable themselves. But advances in bioprocess engineering, analytical technology, and a rapidly-expanding understanding of molecular biology have made it possible to produce many staple products, in new ways, from new raw materials, at decreasingly lower cost and with less environmental impact than ever before.

In markets for commoditized products, proprietary process technology provides the main competitive advantage for BIO and CropLife members. Developing and implementing these innovative manufacturing processes requires significant research and investment. Those investments translate into significant and substantial commercial and societal benefits for U.S. companies and the American public. For example, a single facility for running advanced processes that transform corn husks, wheat stalks and other cellulosic materials into industrial ethanol was

estimated to generate an investment exceeding $200 million, 45 full time jobs, and hundreds of construction jobs, injecting over $2 million per year into the local community before add-on effects. It was further estimated that a single such facility replaces about 1 million barrels of imported oil per year, and reduces national CO_2 emissions by over 210,000 tons per year, equivalent to taking 40,000 cars off the road. *See* Katie Fletcher, *POET-DSM, DuPont, Abengoa begin commissioning cellulosic plants*, Ethanol Producing Magazine (June 11, 2014), http://www.ethanolproducer.com/articles/11153/poet-dsm-dupont-abengoa-begin-commissioning-cellulosic-plants.

In the pharmaceutical sector, proprietary manufacturing processes are no less important. This is particularly true in the case of biologic medicines, which are significantly more complex than small molecule drugs, requiring sophisticated manufacturing techniques for fermentation, aseptic processing, and storage, and necessitating a five-fold increase in critical testing to ensure quality. *See* Thomas Morrow & Linda H. Felcone, *Defining the Difference: What Makes Biologics Unique?*, Biotechnology Healthcare, Sept. 2004, at 26. A facility for producing a single drug can require years of construction and validation testing at a cost of hundreds of millions of dollars. Eli Lilly's Puerto Rico facility for producing Humalog®, for example, required five years before it could start production, at an investment exceeding $250 million in 2001 dollars. *See* Eli Lilly Humalog Manufacturing Facility, Carolina, *The 300,000 ft^2 facility produces the rapid acting*

insulin product Humalog, dispensed from the KwikPen, https://www.pharmaceutical-technology.com/projects/eli_lilly/. Bristol Myers Squibb's facility in Devens, Massachusetts started construction in 2006 and received FDA approval for the production of Orencia® in 2012; it required an investment of $750 million and provides more than 550 jobs. *See* Bristol-Myers Squibb Manufacturing Plant, Devens, Massachusetts, *Bristol-Myers Squibb was awarded $33m in tax credits by the state of Massachusetts, following legislation that changed the state's investment tax credit rules*, https://www.pharmaceutical-technology.com/projects/bristolmyers/.

Every biotechnology company allocates a significant part of its investments in process technology, including capital expenditures in brick-and-mortar facilities that cannot be retooled because they are specifically designed to practice particular biological or chemical processes. Given the need for large upfront investments in manufacturing technology, BIO and CropLife member companies generally need to commit to particular manufacturing processes early in the commercialization cycle. Purpose-built facilities take much time and money to construct, and once built to perform particular processes cannot be easily re-configured. Many facilities require regulatory approval and may only operate subject to federal establishment licenses and permits to perform manufacturing processes from which manufacturers cannot depart, because specific process steps can be critical to meeting the required product specifications and to maintaining a granted Biologics License Application before the FDA.

Accordingly, because these costly manufacturing processes are often necessary for, or provide a more efficient means of, producing modern biotechnology products ranging from laundry detergent enzymes to lifesaving drugs, robust intellectual property protections are warranted. Patented process technology can give a manufacturing biotech company a critical advantage over its competitors, and because process technology is often applicable to more than one of a company's products, companies often count process patents among their most valuable business assets. For smaller, development-stage biotechnology companies that do not yet produce a product of their own, process patents on innovative platform technologies may be widely licensed in the industry and constitute the company's only source of revenue.

Section 271(g) is an essential tool for protecting these investments and promoting further innovation in process technologies. Congress specifically created this provision "to provide protection to process patent owners which is meaningful and not easily evaded." H.R. Rep. No. 100-60, at 13 (1987). The district court's incorrect interpretation of § 271(g) undermines this purpose and compromises the investments made by American manufacturers across industries. It imposes an undue, and potentially impossible, burden on a patentee that is not required by the plain language of the statute and creates an unfairness that disrupts the careful balance struck by Congress when enacting this provision.

ARGUMENT

I. Congress Did Not Write § 271(g) to Invoke a Single Entity Requirement for a Product Made by a Patented Process

In 1988, Congress passed the Process Patents Amendments Act to provide U.S. companies with meaningful patent protection against foreign manufacturers. H.R. Rep. No. 100-60, at 13. As part of that act, Congress created a new form of infringement, defined at § 271(g), which applies to "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." 35 U.S.C. § 271(g). Neither the plain language of § 271(g) nor its statutory context imposes a single entity requirement on making the product, as was done by the district court in this case.

A. Section § 271(g) Does Not Raise Issues of Divided Infringement and Imposes No Single Entity Requirement on Making the Subject Product

The "single-entity rule" for direct infringement was defined in *Akamai Techs., Inc. v. Limelight Networks, Inc.*, 797 F.3d 1020 (Fed. Cir. 2015) (en banc) (per curiam) ("*Akamai V*"). According to this rule, "[d]irect infringement under § 271(a) occurs where all steps of a claimed method are performed by or attributable to a single entity." *Id.* at 1022. The requirement that all steps be "attributable to" a single entity was established to address situations where different actors practiced different steps of a patented method. In such situations, infringement liability under § 271(a)

exists where the actors are in a "direction or control" relationship, or where they are parties to a joint enterprise. *Id*.

But, as this Court observed, "only method claims can raise an issue of divided infringement." *See, e.g., Akamai Techs., Inc. v. Limelight Networks, Inc.,* 786 F.3d 899, 910 (Fed. Cir. 2015) ("*Akamai IV*"), *vacated*, 612 F. App'x 617 (Fed. Cir. 2015), (discussing the origins of direct infringement under § 271(a) and inducement and contributory infringement under § 271(b) and § 271(c)). The unauthorized practice of a product claim, on the other hand, inherently satisfies the single entity requirement because there will always be an entity that completes (and thereby makes) the patented assembly, or that sells, uses, or imports it. *See Cross Med. Prods., Inc. v. Medtronic Sofamor Danek, Inc.*, 424 F.3d 1293, 1312 (Fed. Cir. 2005).

The same is true under the Process Patents Amendments Act, in which Congress created a form of direct infringement in § 271(g) that predicates infringement liability on the importation, use, sale, or offer for sale of a product that was made with a patented process.[1] Section 271(g) creates no liability for

[1] Courts have clarified that a "product" under § 271(g) means manufactured articles or substances, and does not extend to the importation of information or test results, for example. *See Bayer AG v. Housey Pharm., Inc.*, 340 F.3d 1367, 1373 (Fed. Cir. 2003) (holding that a product is a physical article that was manufactured, which does not include production of information); *Momenta Pharm., Inc. v. Teva Pharm. USA, Inc.*, 809 F.3d 610, 616 (Fed. Cir. 2015) ("'[M]ade' as used in § 271 (g) means 'manufacture,' and extends to the creation or transformation of a product, such as by

manufacturing the accused product. The application of a direction or control test, or a joint enterprise test, as a tool to establish who is liable for making the product is therefore irrelevant. And with respect to unauthorized importers, sellers, or commercial users of the accused product, the single entity rule will tend to be satisfied because it is hard to envision credible scenarios of "divided importation," "divided sale," or "divided use" of the manufactured product. In any event, should application of a direction or control or joint enterprise test ever be necessary under § 271(g), it would be to attribute the importation, sale or use, but not the "making," of the accused product to a single entity, because it is only those acts that can give rise to liability in the first place.

Thus, if satisfaction of the single entity rule is a prerequisite to direct infringement, the plain language of § 271(g) makes clear that such infringement consists of the importation, use, or sale, but not the making, of the product. The Court recognized as much during its initial *en banc* review of *Akamai*, when it concluded that § 271(g) "does not require that the process used to make the imported product be 'infringing' in a way that would satisfy section 271(a), such as being performed by a single entity." *See Akamai Techs., Inc. v. Limelight Networks, Inc.*, 692 F.3d 1301, 1314 (Fed. Cir. 2012) (en banc) (per curiam) ("*Akamai II*"), *rev'd on other grounds*, 134 S. Ct. 2111 (2014).

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synthesizing, combining components, or giving raw materials new properties," but does not extend to testing).

If Congress had wanted to impose a quasi-infringement requirement for the manufacturing of the accused product under § 271(g), it could have written the statute differently, and could have used qualifying language to restrict the scope of the subject product, as it did for other purposes. Section § 271(g) already includes two such restrictions:

> 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.

Id. These are the only restrictions that Congress chose to attach to a product made by a patented process under § 271(g) and it presumably intended no others.

The immediately preceding subsection of 35 U.S.C. § 271 confirms that Congress deliberately used language to invoke infringement under § 271(a) when appropriate and intended. 35 U.S.C. § 271(f) was enacted only 4 years before § 271(g), and it likewise predicates domestic infringement liability on certain foreign conduct. It provides that "whoever without authority" supplies a component "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." *Id*. (emphasis added). If Congress had intended for there to be a similar requirement for producing the infringing product of § 271(g), it would have specified that the foreign practice

of the process be done in a manner that "*would infringe* if it were done inside the United States," as it did in the related context of § 271(f) only four years earlier. If that had been the case, at least an argument could be made that divided foreign performance of the process would not "infringe" § 271(g) because it would not qualify as infringing performance of a process claim if it were done inside the United States. But unlike § 271(f), § 271(g) significantly did not choose such words and embodies no concept of "would-be infringement."

Other sections of the Process Patents Amendments Act reinforce that Congress did not intend to invoke an infringement requirement for making the subject product. Section 295, for example, establishes a presumption that a product "is made by a process patented in the United States" if a 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…." 35 U.S.C. § 295. As in § 271(g), Congress describes the product in terms that are indifferent as to who made it and under what circumstances. If Congress had intended to require patentees to prove infringement based on who made the product, it could, for example, have phrased the first requirement to say "that a substantial likelihood exists that the product was made in a manner that would infringe a process patent if performed in the United States."

Section 287(b) provides an additional example. This provision limits the scope of damages available against infringers under § 271(g), who import into the United States, or offer for sale, sell, or use in the United States, a product "before that person had notice of infringement with respect to that product." *See* 35 U.S.C. § 287(b)(2). Subsection (5)(A) defines notice of infringement to mean knowledge "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." *Id*. § 287(b)(5)(A); *see also*, *id*. § 287(b)(5)(B) (written notice from the patent holder "shall specify the patented process alleged to have been used"). Here again, Congress described the product without any reference as to who made it, and without invoking a concept that the foreign manufacturing would infringe a U.S. process patent but for the fact that it occurred abroad.

Congress has been consistent in how it describes an infringing product under § 271(g), requiring only that it be made by a patented process, without reference to who made it, and accounting in the statute itself for the possibility that the identity of the foreign manufacturer might not become known at all. *See* § 287(b)(4)(A)(iii) (referring to "the manufacturer, or *if the manufacturer is not known*, to the supplier of the product"); § 287(b)(5)(C)(ii) (same)(emphasis added). Congress presumably knew what it is doing when it defined this new form of infringement. *See Limelight Networks, Inc. v. Akamai Techs., Inc.*, 134 S. Ct. 2111, 2118 (2014) (when Congress wishes to impose liability for infringement, it knows precisely how to do so).

Accordingly, this Court should decline to redefine infringement under § 271(g) by importing elements of proof that Congress reserved for other forms of infringement liability, such as § 271(a) and (f).

B. The Statutory Context of § 271(g) Indicates That No Underlying Act of Direct Infringement is Required

In the 1952 Patent Act, Congress created a statutory scheme that distinguishes between direct infringement under § 271(a), and indirect infringement by another under § 271(b) or (c). Congress "carefully crafted subsections (b) and (c) to expressly define the only ways in which individuals not completing an infringing act under § 271(a) could nevertheless be liable, rejecting myriad other possibilities that existed in common law at the time…." *Akamai II*, 692 F.3d at 1337 (Linn, dissenting); *see also Akamai IV*, 786 F.3d at 905 ("Presented with numerous conflicting theories of joint liability that existed in the common law prior to 1952, Congress enacted specific rules for inducement and contributory liability in § 271(b) and (c), respectively."). Congress envisioned both forms of indirect infringement to require a predicate act of direct infringement under § 271(a). *See Limelight*, 134 S. Ct. at 2119 ("the nature of the rights created by the Patent Act defeats the notion that Congress could have intended to permit inducement liability where there is not underlying direct infringement."); *see also Akamai II*, 692 F.3d at 1337 (Linn, dissenting) (Section 271(a) defines "infringement" as that term is used in § 271(b)

and (c) (citing H.R. Rep. No. 82-1023 at 9 (1952) ("Section 271, paragraph (a) is a declaration of what constitutes infringement.")).

Section 271(g) was not enacted against this kind of common law backdrop, and was not intended by Congress to codify preexisting common law rules related to vicarious or joint liability. Instead, § 271(g) was enacted more than 30 years after the Patent Act of 1952 to close a loop hole in the existing statutory scheme for direct infringement. Before this legislation, infringement of a process patent could only occur when the process was performed in the United States, meaning that a product could be made overseas using the patented process and then imported into, sold and used in the United States without any recourse for the patentee. *See* H.R. Rep. No. 100-60, at 3, 5-6. Congress concluded that "[t]here is no policy justification for encouraging such overseas production and concurrent violation of United States intellectual property rights. The courts cannot solve this defect. The Congress can." *Id*. at 6.

Congress accordingly enacted § 271(g) as a new form of infringement. In doing so, "the fact that § 271(e), (f), and (g) identify acts not falling under § 271(a) that are to be treated as infringement confirms that, when Congress intended to cover acts not encompassed within the traditional definition of infringement, it knew how to create an alternative definition thereof." *Akamai II*, 692 F.3d at 1343 (Linn, dissenting). Within this statutory context, it is clear that Congress did not write

§ 271(g) to require an underlying act of direct infringement, as it did when it wrote § 271(b) and (c).

II. Properly Construed, § 271(g) Does Not Give Patentees Greater Rights Than Those Available Under § 271(a), Or Impose Any Greater Unfairness On Potential Infringers

Willowood argued below to the district court that without a single entity infringement requirement for the manufacture of a product made by a patented process, § 271(g) would provide patentees with greater recourse than § 271(a), which does not extend to a patented process performed by multiple, unrelated entities. *See* Def's Opp'n to Pl's Mot. For Partial Summ. J. at 15-16, ECF No. 105. This argument fails to acknowledge the limitations Congress placed on infringement in § 271(g), along with corresponding amendments to § 287 that limit the available remedies.

A single entity rule is not necessary to ensure that § 271(g) does not overpower § 271(a). Liability under § 271(g) is constrained by numerous, complex limitations that do not apply to § 271(a). *See* 35 U.S.C. § 271(g)(1)-(2); § 287(b). For example, the provision does not apply at all if the product is materially changed by subsequent processing or it becomes a trivial or nonessential component of another product. *Id*., § 271(g). Section 271(g) also precludes recovery against retailers and consumers or other non-commercial users of a product made by a patented process, unless no adequate remedy is otherwise available. *Id*. Section 287 further allows a court to shield from liability anyone who makes a good faith attempt to determine whether a

product is made by a patented process, before importing, using, offering for sale, or selling that product in the United States. *See* § 287(b)(3),(4) (describing the process for making a request for disclosure to known manufacturers of the product). None of these limitations exists for infringement under § 271(a).

In addition, while remedies for infringement of a process patent under § 271(a) are not limited by a notice requirement, Congress intentionally imposed a "harsh" notice requirement on § 271(g). *See* S. Rep. No. 100-83, at 52 (1987) ("The Committee intends that this harsher standard [for product patents] apply…."). For infringement under § 271(g), damages can only be obtained once a defendant has actual knowledge or notice of infringement, and a patentee may forfeit any damages against a non-manufacturing defendant by failing to give proper written notice of infringement. *See id*., § 287(b)(2). This notice requirement "goes far beyond the norm for product patent cases (or for that matter process patent infringement cases under existing law)…." S. Rep. No. 100-83, at 43. Even after a patentee provides written notice to an accused infringer, that infringer may be shielded from liability if it transmits the notice to the manufacturer and receives a written assurance in response that the identified patents are not infringed. *See* § 287(b)(5).

Section 271(g) also does not create unfair extraterritorial liability for innocent foreign manufacturers who might unwittingly participate in the practice of a process subject to a U.S patent. Manufacturing is not a defined act of infringement under § 271(g) at all, which is limited only to importing, or selling, offering for sale, or

using a product in the United States. For example, if a foreign business uses the patented process to make widgets in Shanghai, sells these widgets FOB origin to an independent wholesaler, and these widgets subsequently find their way into the United States, then the patentee has no cause of action under § 271(g) against the original manufacturer. According to the specified acts of infringement in § 271(g), an action can only be brought against the importer, domestic distributor or domestic commercial user. These domestic actors, in turn, benefit from the numerous special protections against unfair liability described above that do not exist under § 271(a). As well, the importer or domestic distributor can further limit its liability through its contractual relationships with foreign suppliers or manufacturers 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." S. Rep. No. 100-83, at 39.

III. A Single Entity Requirement Would Impose an Undue, If Not Impossible, Evidentiary Burden on Patentees

It can be very difficult to detect the unauthorized use of a patented process, even in the United States, and it becomes that much harder when manufacturing happens abroad. Foreign manufacturers, if they can be identified at all, may refuse to comply with requests for information for any variety of reasons, without suffering any consequences because they are not defendants in the infringement suit or

otherwise subject to jurisdiction of the U.S. courts. *See, e.g., Pfizer Inc. v. F&S Alloys and Minerals Corp.,* 856 F. Supp. 808 (S.D.N.Y. 1994) (noting that accused foreign manufacturer dismissed from the case steadfastly refused, because of a confidentiality agreement with another overseas company, to divulge the process used to make a product sold by defendant in the United States); *Nutrinova Nutrition Specialties and Food Ingredients GmBH v. Int'l Trade Comm'n*, 224 F.3d 1356 (Fed. Cir. 2000) (noting that the accused foreign manufacturer refused to comply with a request to permit a plant inspection, claiming that it might violate Chinese law).

Even if likely foreign activities are detected and notice of such activities reaches foreign manufacturers, such foreign manufacturers may be under no obligation to comply with rules pertaining to the preservation and production of evidence. Active concealment, even spoliation, may go unsanctioned. This is not a hypothetical concern. For example, when the accused manufacturer in *Nutrinova* finally permitted the patentee to inspect its manufacturing facility, the inspectors "noticed that the walls had been freshly painted, which caused Nutrinova to speculate that the paint was necessary to cover up a recent conversion of the plant from use of one ASK manufacturing process to use of another one." *Id*. at 1358. This suspicion was reinforced after testing product samples taken from the plant, which did not match product samples obtained earlier in the case. *Id*.

When Congress enacted § 271(g), it was keenly aware of the difficulty of proving how a product is made, particularly overseas. *See* S. Rep. No. 100-83, at 57

(acknowledging "the great difficulties a patentee may have in proving that the patented process was used"); H.R. Rep. No. 100-60, at 16 (acknowledging "a great difficulty a patentee may have in proving that a patented process was actually used"). In an effort to provide patentees with meaningful protection when faced with these evidentiary challenges, Congress went so far as to create a presumption under § 295 that a product was made by a patented process, if the patentee can show a substantial likelihood exists that the product was so made and that it made a reasonable effort to determine the process actually used. 35 U.S.C. § 295. Even with this presumption, patentees are faced with insurmountable challenges to proving infringement. *See, e.g., Nutrinova*, 224 F.3d at 1361 (affirming ALJ's determination that patentee failed to establish that it was entitled to the presumption of § 295).

Establishing liability under § 271(g), with all of its carve-outs, limitations, and notice requirements, is difficult enough as it is without applying a single entity requirement to foreign manufacturing. If establishing the likely existence of tools, machinery, and hardware adapted to running a U.S.-patented manufacturing process in a foreign country is challenging, it is surely even more challenging to establish the relationships, understandings, and agreements between foreign participants to such processes. Requiring a patentee to delve into the relationships of foreign participants in foreign enterprises could be highly problematic, not just as a matter of proof, but also because foreign law could be quite different in the way it defines vicarious liability or mutual liability of participants in a joint enterprise. Adding the

burden of flushing out the foreign business relationships between foreign manufacturers to see if they meet U.S. jurisprudential conceptions of single entity infringement goes beyond what is reasonable or what Congress possibly could have intended when it passed this statute to enhance protection of process patents.

It is possible that the district court may have assumed that foreign production of export goods follows traditional industrial models of centralized, vertically integrated, single-site manufacturing, where it may be possible to identify "who is in charge" of the production process. But as a general rule, this notion defies reality, especially in foreign, emerging countries, where manufacturing of export articles is often highly dispersed, with production and assembly of component parts being contracted and subcontracted through extensive supply networks, sometimes down to the level of village workshops. It would make no sense for Congress to provide relief from the evidentiary challenges of proving foreign performance of a manufacturing process by establishing the presumption of § 295, but then impose on a patentee the full burden of ferreting out inscrutable business relationships between participating foreign entities that may be transient or unknown. If Congress had been of the view that a single-entity rule should apply under § 271(g) – or that it mattered at all who made the product – it could have created a corresponding presumption in the patentee's favor, as it did for establishing how the product was made.

Congress recognized the inherent difficulty in proving how a product was made overseas by a patented process. Even in instances where tell-tale characteristics of the imported product establish beyond doubt that it was made by the patented process, a patentee would have no recourse under the district court's interpretation of § 271(g) unless it can also prove who performed the process. Imposing this single entity requirement creates an undue, if not impossible, burden on the patentee, which is inconsistent with the statutory framework Congress created to provide a cause of action against products made by foreign manufacturers.

IV. Imposing a Single Entity Requirement On § 271(g) Would Undermine the Purpose of the Provision and Eliminate Meaningful Protection for Patentees

The legislative history is clear that Congress passed § 271(g) to close a loop hole that left U.S. patentees without recourse when a product was made overseas using a patented process. *See* H.R. Rep. No. 100-60, at 3, 5-6; S. Rep. 100-83, at 30. The resulting legislation was "a carefully crafted compromise reached between [legislators] and a wide variety of parties interested in process patent legislation." S. Rep. No. 100-83, at 29. Imposing a new, single entity requirement on § 271(g), making it difficult if not impossible for a patentee to prove infringement, would disrupt the careful balance Congress intended to achieve.

Congress was particularly concerned that "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." S. Rep. No. 100-83, at 29. One

widely publicized example at the time involved Corning Glass Works, which discovered that a Japanese competitor was selling fiber glass cables in the United States that were made in Japan using a patented process that Corning Glass Works had spent more than $200 million to develop. *See* Calvin Sims, *Wounded By Patent Piracy … Vexed By Tape Technology; U.S. Laws Offer Less Protection Than Those Of Major Trading Partners*, N.Y. Times, May 13, 1987, https://www.nytimes.com/1987/05/13/business/wounded-patent-piracy-vexed-tape-technology-us-laws-offer-less-protection-than.html. Corning Glass Works had no recourse under the then-current U.S. statutory framework, despite the fact that other industrialized nations provided more protection for patented processes under their individual laws. *See id.*; *see also* H.R. Rep. No. 100-60, at 10-11. Congress enacted § 271(g) to address precisely this kind of problem, and thereby protect the legitimate interests of U.S. inventors by expanding the scope of U.S. patent laws to bring them into conformity with those of other countries, which Congress deemed necessary "to protect the continued growth of American business." *See* S. Rep. No. 100-83, at 31; *see also* H.R. Rep. No. 100-60, at 3 ("the unfettered ability of others to import, sell or use a product made by the patented process, severely diminishes the value of a U.S. process patent. It also results in the loss of American jobs, particularly in new technology areas.").

Imposing a single entity requirement on making the product in § 271(g) would undermine this purpose, making it harder for patentees to enforce their U.S. patent

rights and easier for foreign manufacturers to again misappropriate the processes U.S. manufacturers are required to publish in their U.S. patents. Foreign economies can then capture the value-added gain from more efficient manufacturing, to the detriment of U.S. patentees and the U.S. economy when competing manufactured goods made by those processes are imported and sold in the U.S. market.

As a result, domestic manufacturers will be deprived of the exclusive rights in their inventions, promised to them by the quid pro quo of the patent system. *See J.E.M. AG Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc.*, 534 U.S. 124, 142 (2001) ("The disclosure required by the Patent Act is 'the quid pro quo of the right to exclude.'") (citation omitted). Without this promised benefit of patent exclusivity, domestic manufacturers may be compelled to maintain their processes as trade secrets instead of relying on ineffective patent protection, undermining the very purpose of the patent laws to promote the progress of science by encouraging the disclosure of such innovations, and thereby diminishing the United States' status as a leader in innovation. *See* S. Rep. No. 100-83, at 29 (crediting "America's leading position in technology innovation… in large part to the stimulus of its patent system," which derives from Article I, Section 8 of the Constitution). Surely this was not the result intended by Congress.

CONCLUSION

For these reasons, BIO and CropLife respectfully request that the Court reverse the district court's improper interpretation of § 271(g) and hold that that there is no requirement under this statute that a patentee prove that a product was made by a single entity using a patented process.

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Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on this 4th day of May, 2018, I caused the foregoing to be electronically filed with the Clerk of the Court for the United States Court of Appeals for the Federal Circuit through the Court's CM/ECF system.

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

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CERTIFICATE OF COMPLIANCE WITH TYPE-VOLUME LIMITATION, TYPEFACE REQUIREMENTS AND TYPE STYLE REQUIREMENTS

1. This brief complies with the type-volume limitation of Federal Rule of Appellate Procedure 32(a)(7)(B) or Federal Rule of Appellate Procedure 28.1(e). The brief contains 5708 words, excluding the parts of the brief exempted by Federal Rule of Appellate Procedure 27(d)(2).

2. This brief complies with the typeface requirements of Federal Rule of Appellate Procedure 32(a)(5) and the type style requirements of Federal Rule of Appellate Procedure 32(a)(6). The brief has been prepared in a proportionally spaced typeface using Microsoft Word in a 14 point Times New Roman font.

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