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Syngenta Confirms Section 271(g) Infringement Does Not Require Single Entity Perform All Steps of Patented Method

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Opinion also contains important holdings for labeling and copyright infringement in the context of the Federal Insecticide, Fungicide, and Rodenticide Act

In *Syngenta Crop Protection LLC v. Willowood LLC, et al*., the US Court of Appeals for the Federal Circuit held in a case of first impression that infringement liability under 35 U.S.C. § 271(g) does not require a single entity to perform all steps of the patented process. *See* No. 2018-1614 (Fed. Cir. Dec. 18, 2019) ("*Syngenta*"). The decision has broad impacts for process patent owners, including those who have process claims directed toward breeding new plant varieties. The Federal Circuit's decision strengthens process claims' usefulness against accused infringers who manufacture a patented product abroad and import it into the US. This decision also highlights the importance of protecting new plant varieties and breeding programs by seeking both composition and process claims.

35 U.S.C. § 271(g): broadened scope of patent protection for the global economy

Modern American patent law stems from the 1952 Patent Act. Section 271(a) identifies acts that constitute direct infringement, providing that:

> "whoever without authority makes, uses, offers to sell, or sells any patented invention, within the United States, or imports into the UnitedStates any patented invention during the term of the patent, therefore, infringes the patent."

In addition, §§ 271(b) and 271(c) define indirect infringement, creating vicarious liability for those who induce or contribute to acts of direct infringement. Although § 271(a) provided strong protection for patent owners against purely domestic infringement, the patent laws did not protect against infringing acts occurring outside of the US. (*See* § 271(a) ("*within the United States*").

This gap in protection was highlighted in the US Supreme Court's *Deepsouth Packing Co. v. Laitram Corp.* decision, which held that exporting components of a patented product for assembly abroad did not constitute direct infringement, reasoning that a patented system is made only after final assembly. *See* 406 U.S. 518, 529-32 (1972). Since final assembly was performed abroad, there could be no infringement under § 271(a).

As world trade and globalization continued to expand in the 1980s and 1990s, it became clear that patent owners in the US were more vulnerable than ever to infringers abroad. In response, US Congress broadened the scope of infringing activities through legislative amendments to the Patent Act, adding §§ 271(f) in 1984 and 271(g) in 1998. *See* Kastenmier, *"Section-By-Section Analysis of H.R. 6286, Patent Law Amendments Act of 1984,"* Congressional Record of October 1, 1984 at H10525 to H10529.

Section 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."

Thus anyone who imports into the US, or sells or uses in the US, a product made by a patented process – regardless of where the process was performed or where the product was assembled – is liable for infringement.

An issue of first impression: no single-entity requirement under § 271(g)

In *Syngenta*, the Federal Circuit further solidified the reach of protection under § 271(g) and resolved for the first time the question of whether § 271(g) requires that all steps of a patented process be performed by or at the direction or control of a single entity before infringement liability attaches.

Syngenta Crop Production LLC sued Willowood LLC (“Willowood LLC”), Willowood USA, LLC ("Willowood USA"), Willowood Azoxystrobin LLC and Willowood Limited ("Willowood China") (collectively, "Willowood"), asserting four patents directed to a fungicide compound and its manufacturing processes. The key product at issue was azoxystrobin, a fungicide commonly used in agriculture to control fungal growth on crops. The process patents were directed to a two-step method for manufacturing azoxystrobin and required using the chemical catalyst 1,4-diazabicyclo[2.2.2]octane to manufacture azoxystrobin.

Willowood China is a Hong Kong company that contracted for the manufacture of azoxystrobin in China and sold the fungicide to Willowood USA. Willowood USA and Willowood LLC then contracted with third parties to formulate azoxystrobin into Willowood's generic end-use fungicide products, which were marketed in the US. Before the expiration of Syngenta's compound and process patents, Willowood filed regulatory applications for its generic azoxystrobin product, triggering Syngenta to file the present suit for patent infringement.

If patent infringement claims were limited to § 271(a), Syngenta would have been powerless to enforce its process patents, since Willowood manufactured the fungicide outside of the US. Syngenta was able to assert its rights under § 271(g), which required Syngenta to prove that Willowood, without authority, imported into the US, sold, offered to sell or used within the US an azoxystrobin product made by Syngenta's patented process.

The district court rejected Syngenta's § 271(g) claims, finding that § 271(g) requires that all steps of the patented process be performed by a single entity. This requirement limits direct infringement liability only to circumstances "where all steps of a claimed method are performed by or attributable to a single entity." The district court believed that the single-entity requirement present for method claims under §§ 271(a) and (b) under cases such as *Limelight* and *BMC* carried over to § 271(g). *See Akamai Techs. v., Limelight Networks, Inc.*, 572 U.S. 915, 921-22 (2014) (*"Limelight"*); *BMC Res., Inc. v. Paymentech, L.P.*, 498 F.3d 1373, 1379–81 (Fed. Cir. 2007). In this case, Willowood China purchased azoxystrobin from a Chinese supplier, Tai He, and thus the district court found that Syngenta could not show whether Tai He performed all steps of the claimed process during its manufacture of azoxystrobin or whether Willowood directed Tai He and others to practice the claimed process.

The Federal Circuit reversed. First, the court interpreted § 271(g) as written, explaining that "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." *Syngenta* at *23. Accordingly, whether that process is practiced by a single entity is immaterial to the infringement analysis.

Second, the court held that comparison to the language of other parts of § 271 supported its conclusion. The court rejected Willowood's extension argument based on § 271(a) and the *Limelight* decision because, as noted above, infringement under § 271(g) is not predicated on direct infringement of the patented process – a key distinction from application of § 271(a) to method claims. The court also applied the same logic to distinguish §271(f) from § 271(g), stating that if Congress had wanted to require a

single-entity requirement under 271(g) they "knew how to do so" given the single-entity requirement under 271(a) and 271(f). *Id.* at *29.

Third, the Federal Circuit noted that the legislative history 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 a process. *Id.*

As a result of the court's decision, patentees asserted rights under § 271(g) do not have to prove that a single entity, or one party exercising direction and control over other entities, was responsible for performing each step of the patented process.

Patentees benefit from the burden-shifting mechanism of § 295

The Federal Circuit also held that applying a single-entity requirement under § 271(g) would impose an undue evidentiary burden on patentees that was contrary to the intent of Congress. The legislative history of § 271(g) showed that Congress recognized "the great difficulties a patentee may have in proving that the patented process was used in the manufacture of a product in question" where the manufacture occurred abroad. *Id.* Part of Congress's solution is laid out in § 295, which shifts the burden of proof to the accused infringer to prove that the patented process was not used in manufacturing the accused product if there is a substantial likelihood that the infringing process was used and the patentee has been unable to make a definitive determination on its own. *See* 35 U.S.C. § 295. The court stated that 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." *Syngenta* at *29-30.

In this case, Syngenta accomplished the burden shift under § 295 by providing unrebutted expert testimony that "it would not be commercially reasonable to manufacture azoxystrobin" without infringement and showing that it had made "reasonable efforts" to discover Willowood's manufacturing process to no avail. For example, Willowood failed to provide any manufacturing records demonstrating it did not use the patented process. The mechanism of § 295 can be a powerful tool to put accused infringers on their heels, requiring them to prove a negative when patentees normally must carry the burden on infringement.

Additional copyright holding: FIFRA does not require that a generic product label copy that of a registered product + copyright infringement claims not preempted

Syngenta also alleged that Willowood's label on its generic product infringed Syngenta's copyright-protected label. The district court granted summary judgement to Willowood on the issue, holding that the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) creates an exception to copyright law for "the required elements of pesticide labels as against me-too registrants." This exception was created by the US Environmental Protection Agency to allow generic companies to copy otherwise protectable labels on the grounds that differences may adversely affect the environment by confusing users. Willowood claimed that the EPA required that Willowood copy Syngenta's label for these reasons and the district court granted summary judgement in favor of Willowood. However, the Federal Circuit found this decision to be premature since nothing in FIFRA explicitly requires a generic registrant to copy a label of a registered product, in contrast to the Hatch-Waxman Act’s requirement for generic drugs. *Id.* at *16.

The court found that there could only be a conflict between FIFRA and the Copyright Act if a copyrighted part of Syngenta's label was required for Willowood's product to be approved. As such, the district court needed to consider the merits of the copyright claims first, which have a similar exception under the fair use doctrine. Under that doctrine, the district court could easily access, 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. Instead of dismissing Syngenta's copyright claims, the district court was instructed to determine whether the presence of such elements in Willowood’s label would fairly constitute copyright infringement.

Take-home lessons for developers of new biological inventions and plant varieties

- For the strongest patent protection for new biological inventions, plant varieties or other replicating technologies, patentees should consider seeking protection of both composition claims directed to the final organism and process claims directed to the methods of creating, using and improving it. For example, inventors of new plant varieties should seek claims on breeding methods using the new variety. This strategy will best protect against foreign entities that breed with the variety abroad and import resulting plants into the US.
- Should the owner of a plant breeding process patent bring suit for patent infringement against an accused infringer who is suspected to have used the process, the patent owner should utilize the special notice provisions of § 287(b) and the burden-shifting mechanism of § 295 to force the accused infringer to produce evidence that they did notuse the patented process to generate the infringing plant.
- Entities with labeled plant varieties or other regulated agricultural products should consider the utility of copyright infringement claims as part of an overall enforcement strategy.

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