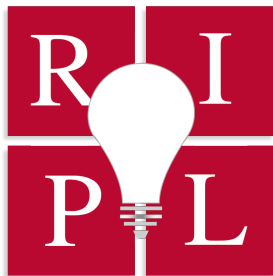


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PATENT INFRINGEMENT UNDER 35 U.S.C § 271(G) FOR GOODS MADE IN THE UNITED STATES

PETER A. HECKER

ABSTRACT

Section 271(g) filled a loophole that allowed companies to escape patent infringement by producing goods overseas and then importing them. In filling this loophole, Congress may have unintentionally broadened patent liability for the production and use of goods in the United States. This paper discusses important ramifications of this broadened language and encourages the Federal Circuit or Congress to clarify the extent of patent infringement under Section 271(g).

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Cite as Peter A. Hecker, Patent Infringement Under 35 U.S.C. § 271(g) for Goods Made in the United States, 19 UIC REV. INTELL. PROP. L. 64 (2019).

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PETER A. HECKER*

I. INTRODUCTION

Section 271 of 35 U.S.C. creates a cause of action for patent owners against patent infringement. Typically, patent owners sue under Section 271(a) for direct infringement when an infringing party makes, uses, or sells a product in the United States. Section 271(a) can also be used to prevent people from importing patented goods. Section 271(a) provides:

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.¹

Other subsections of the statute provide exceptions for infringement, and other avenues such as inducement and contributory infringement.² This paper, however, focuses only on direct infringement.

Another section, 271(g), creates direct infringement liability when products are made overseas by patented methods and then imported into the United States.³ In such a case, the product itself may not be patented, only the method of making it.

Section 271(g) also appears to broaden the scope of what constitutes infringement for activities taking place solely within the United States. This paper discusses this enlarged scope, and the unsettled state of the law. When courts apply a textual interpretation, Section 271(g) may reach downstream sellers and users of products unconnected with the manufacturer, provide parties with a decreased pleading standard, cover products otherwise made under a safe harbor statute, and reach some licensing situations that Section 271(a) does not cover. On the other hand, courts may limit Section 271(g)'s reach based on their perception of the statute's purpose. Because this area of the law is not developed, courts may set precedential opinions based on one set of facts without realizing the consequences of their precedent in other situations. For that reason, Congress, or at least the Federal Circuit should step in to clarify the scope of Section 271(g) on domestic manufacturing.

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¹ 35 U.S.C. § 271(a) (2010).

² See 35 U.S.C. § 271(b), (c).

³ 35 U.S.C. § 271(g) (1988).

II. § 271(G) BACKGROUND

Section 271(g) was enacted as the Process Patent Amendments Act of 1988. The purpose of the Act was to close a perceived loophole in the statutory scheme where a patentee previously had no cause of action if another person used their patented process outside the United States to make a product and then imported the product.⁴ Section 271(g) provides:

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.⁵

As such, a person may infringe a process patent by using or selling a product made by the process. Such use may be considered infringement even if the product itself is not patented.

Section 271(g) creates patent infringement for activities within the United States when a product is made by a patented process abroad. Section 271(g) also may apply to the use or sale of the product, if the product is made within the United States without being imported. For example, the phrase, “Whoever without authority . . . offers to sell, sells, or uses within the United States a product which is made by a process patented in the United States” admits no limitation to extraterritorial manufacturing, but by its face covers activities solely in the United States (as well as activities outside the United States).⁶

Thus, the text of 271(g) supplies a broader reading of what may be direct infringement than Section 271(a) alone. It not only expands the reach of patent liability to activities overseas that infringe a patent in the United States, but also may apply to activities inside the United States. Despite this textual language, however, it is not currently settled whether Section 271(g) actually applies to activities taking place solely within the United States, or whether Section 271(g) requires some sort of foreign manufacturing or importation.

⁴ *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).

⁵ 35 U.S.C. § 271(g).

⁶ *See, e.g.*, David L. Hitchcock & Craig Allen Nard, *The Process Patent Amendments Act: The Labyrinth*, 3 *FORDHAM INTEL. PROP., MEDIA & ENT. L.J.* 441, 441 (1993) (“the Act creates a cause of action for the importation into the United States or the sale or use within the United States of products made by a patented process and applies regardless of the location where the process is practiced (i.e. in the United States or in a foreign location).”).

III. SITUATIONS WHERE SECTION 271(G) IS RELEVANT TO DOMESTIC MANUFACTURING

District courts are split on the question of whether activities taking place solely in the United States can infringe 35 U.S.C. § 271(g).⁷ The courts' decisions have been largely context specific, and we discuss cases relevant to separate situations in turn.

A. Downstream Sellers

To my knowledge, *Shamrock Technologies v. Precision Micron Powders* is the first case to discuss the issue of domestically manufactured products under Section 271(g).⁸ In this unpublished decision issued in 1991, the Eastern District of New York held that the plain language of Section 271(g) prevented dismissal, under F.R.C.P. 12(b)(6), where a suit was brought against a downstream seller of a device made in the United States.

In *Shamrock*, Medical Sterilization, Inc. was the producer of a chemical called polytetrafluoroethylene (PTFE).⁹ In producing PTFE, Medical Sterilization was previously found to infringe a process patent held by Shamrock Technologies.¹⁰ The complaint at issue was then brought against Precision Micron Powders (PMP), asserting that PMP bought raw PTFE from Medical Sterilization, processed the PTFE, and then sold the processed PTFE.¹¹ Thus, this situation was one where PMP couldn't be held liable as a direct infringer under Section 271(a) because PMP did not practice the asserted process patent, and instead only sold a product made by the patent after it had been sold to them.¹² Therefore, the only way to hold PMP liable for direct infringement may have been through the broadened language of Section 271(g).

PMP sought to dismiss the case by arguing that based on the legislative history, Section 271(g) was enacted to create a cause of action against manufacturers and importers of infringing goods but not against domestic sellers of infringing goods.¹³ The court, however, stated that the plain language of the statute clearly states that whoever without authority sells within the United States a product made by a patented process shall be liable as an infringer.¹⁴ The court reasoned further that it

⁷ See §10:103, Applicability of § 271(g) to domestically manufactured products, 2 ANNOTATED PATENT DIGEST (2019) (citing cases on either side of the issue).

⁸ *Shamrock Techs., Inc. v. Precision Micron Powders, Inc.*, No. CV 91-0869, 1991 WL 335362 (E.D.N.Y. Aug. 8, 1991).

⁹ *Id.* at *1.

¹⁰ *Id.* (citing *Shamrock Techs., Inc. v. Med. Sterilization, Inc.*, 903 F.2d 789 (Fed. Cir. 1990)).

¹¹ *Shamrock*, 1991 WL 335362 at *1. Note that Section 271(g) has an exception for retail sellers, but PMP did not establish that its sales qualified PMP as a retail seller. *Id.* at *2, n.3.

¹² See *Hughes Aircraft Co. v. Nat'l Semiconductor Corp.*, 857 F. Supp. 691, 697 (N.D. Cal. 1994) ("It is well established that an individual who merely sells a product manufactured using an infringing process does not directly infringe the process patent within the meaning of 35 U.S.C. § 271(a).") (citing *Atlantic Thermoplastics Co. v. Faytex Corp.*, 970 F.2d 834, 836 (Fed. Cir. 1992); *Koratron Co. v. Lion Uniform, Inc.*, 449 F.2d 337, 338 (9th Cir. 1971)).

¹³ *Shamrock*, No. CV 91-0869, 1991 WL 335362 at *2.

¹⁴ *Id.* (citing § 271(g)).

did not need to examine any legislative history because the terms of the statute are unambiguous, and therefore the judicial inquiry was complete.¹⁵

One reason for the court's abruptness may have been its dedication to the *prima facie* text of the statute. However, the court also may have been concerned about letting off the president of PMP, Robert Luniewski, too easily. According to the complaint, Mr. Luniewski was not only a holder of a 50.5% share of PMP, but Mr. Luniewski was also the vice president at Medical Sterilization, the producer of PTFE, and had formerly worked at Shamrock where he became a co-inventor of the patent asserted against PMP by Shamrock.¹⁶ Overall, the court may have been worried that by incorporating PMP as a middleman broker, Mr. Luniewski was trying to insulate himself against liability for the patent he infringed by his other company, and the court may have thought this was unfair.

Additionally, the *Shamrock* court pointed in a footnote to legislative history favoring its position.¹⁷ For example, a House of Representatives report stated that the purpose of the section was to provide protection where previously there was "no remedy against parties who use or sell the product, regardless where it is made."¹⁸ Further, a Senate report stated that Section 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 was made (and the process used) in this country or in a foreign country."¹⁹

After *Shamrock*, the next case in which the issue of whether Section 271(g) applies to domestic sellers came up was *Hughes Aircraft v. National Semiconductor*.²⁰ In this 1994 decision, the Northern District of California held that Section 271(g) could *not* be applied to a downstream seller of a product made in the United States by another party.²¹ As such, the court granted summary judgment in favor of the defendant who merely incorporated the infringing product into its finished product.²²

This case did not involve the drama of *Shamrock*, where in reality the downstream seller was involved in the upstream production that infringed the patent. Here, instead, the defendant was part of the automobile producer General Motors ("GM").²³ GM apparently bought radios from a third party and installed them into its cars, whereas a subsidiary of the third party infringed a process patent by making semiconductors that were eventually incorporated into car radios.²⁴ The court found that the semiconductors incorporated in the car radios sold by GM did not fall into the *trivial and nonessential* defense of Section 271(g)(2) where they were merely incorporated as a part of a larger system, but grasped at the legislative history and purpose behind the enactment of Section 271(g) to avoid what the court appeared to view as an unfair result.²⁵ Here, the court reasoned that the Process Patent

¹⁵ *Id.* (citing *Demarest v. Manspeaker*, 498 U.S. 184, 190 (1991); *Burlington N. R.R. Co. v. Oklahoma Tax Comm'n*, 481 U.S. 429, 461 (1987)).

¹⁶ *Id.* at *1.

¹⁷ *Id.* at *2 n.4.

¹⁸ *Id.* (quoting H.R. Rep. No. 60, 100th Cong., 1st Sess., at 3 (1987)).

¹⁹ *Id.* (quoting S. Rep. No. 83, 100th Cong., 1st Sess. 46 (1987)).

²⁰ 857 F. Supp. 691 (N.D. Cal. 1994).

²¹ *Hughes Aircraft*, 857 F. Supp. at 698–99.

²² *Id.*

²³ *Id.* at 694.

²⁴ *Hughes Aircraft*, 857 F. Supp. at 698.

²⁵ *Id.*

Amendments Act of 1988 was enacted “to modernize our patent laws’ by providing ‘patent protection against the importation, and subsequent use or sale, of products made abroad.’”²⁶ This court did not cite to the same legislative history pages as the *Shamrock* court.

Overall, the court concluded that “[b]ased on its legislative history, it appears that the PPAA [Act] was designed to provide a remedy within the United States for United States process patent holders whose processes were being used in other countries to manufacture goods for importation into the United States, and therefore it did not appear designed to provide a basis for holding a domestic downstream seller liable “merely because it has incorporated an allegedly infringing good produced by a domestic, upstream manufacturer . . . into its finished product.”²⁷

The reasoning provided in *Hughes Aircraft* was later followed by another judge in the Northern District of California, who found the earlier analysis persuasive absent any controlling authority.²⁸ In the second case, *Boston Scientific v. Johnson & Johnson*, the court also found in favor of a downstream seller, and granted summary judgement on the seller’s behalf.²⁹ In this case, the court considered the first sale doctrine, in which an unconditional sale of a patented device exhausts the patentee’s right to control the purchaser’s use of the device.³⁰ If the first sale doctrine applied, it would have nullified any downstream sellers from patent infringement. However, the court concluded that the first sale doctrine did not apply because the case involved a conditional agreement.³¹

The District of Delaware came to similar holdings as the Northern District of California. In *British Telecommunications*, the court dismissed a complaint alleging that use of a fiber optic cable installed using a claimed process infringed Section 271(g).³² The court noted that the Federal Circuit had previously concluded that the statutory language was ambiguous in *Bayer v. Housey Pharms*.³³ The court then cited Donald Chisum in stating that “[s]ince a process patentee can already prevent the use of the patented process by domestic manufacturers, the primary effect will be on foreign-made goods,”³⁴ and cited legislative history to conclude that “the fundamental purpose underlying passage of the statute has absolutely no application” where the patented methods were being used in the United States.³⁵

One factor that may have influenced the *British Telecommunications* court was that it believed the plaintiffs still had a recourse under Section 271(a) because the defendants were the ones who were alleged to have installed the fiber optic cable

²⁶ *Id.* (quoting S. Rep. No. 83, 100th Cong., 1st Sess., 29-30 (1987)).

²⁷ *Id.* at 698–99.

²⁸ *Boston Sci. Corp. v. Johnson & Johnson*, 534 F. Supp. 2d 1062, 1080–81 (N.D. Cal. 2007).

²⁹ *See id.* at 1081.

³⁰ *Id.* at 1077 (quoting *LG Elecs., Inc. v. Bizcom Elecs., Inc.*, 453 F.3d 1364, 1369–70 (Fed. Cir. 2006)).

³¹ *Id.*

³² *British Telecomms. v. SBC Commc'ns Inc.*, No. CIV. 03-526 SLR, 2004 WL 5264272, at *1, *3 (D. Del. Feb. 24, 2004).

³³ *Id.* at *1 (citing *Bayer AG v. Housey Pharm., Inc.*, 340 F.3d 1367 (Fed. Cir. 2003)).

³⁴ *Id.* at *2 (quoting 9 Donald S. Chisum, *CHISUM ON PATENTS*, App. 25 at 67).

³⁵ *Id.* at *3.

using the patented process.³⁶ Therefore, it is possible that the court may not have taken the Section 271(g) question as seriously as if it had been the only section that could apply. This set the precedent for another case in the District of Delaware, *Asahi Glass v. Guardian Indus.*, which concluded that Section 271(g) did not apply to a downstream buyer who used a product made in the United States by a patented method.³⁷ The plaintiffs in *Asahi Glass* chose to sue its competitor under Section 271(g) rather than the supplier of the manufactured material under Section 271(a), likely because the plaintiffs used the same suppliers to purchase materials.³⁸ The court took note of this, and it is possible that the court saw this behavior as unfairly anticompetitive.

B. Motions to Dismiss: Pleading Without Evidence of an Overseas Manufacturer

Another, sometimes overlapping, context in which the domestic applicability of Section 271(g) has come up is in motions to dismiss when a complaint does not provide factual evidence of an overseas manufacturer. These complaints have generally been allowed to proceed even when plaintiffs do not include specific information about a foreign manufacturer.³⁹

For example, in *McRO v. Namco*, the Central District of California allowed a claim to proceed despite lack of information in the complaint about where an alleged product was made.⁴⁰ The court stated that the allegedly infringing process was either performed in the United States or outside the United States, that if it occurred inside the United States there would be infringement under at least Section 271(a), and that if it occurred outside the United States there would be infringement under Section 271(g); therefore, the defendant could not escape liability by being the only one who knew where infringing conduct occurred.⁴¹

In *McRO*, the court argued that the plain meaning of the statute is not limited to circumstances in which the manufacture of the product by an infringing process is performed abroad. Instead, it establishes liability for importation, or offers for sale, sales, or uses of products, and “[t]hose acts are listed in the disjunctive and are thus independent acts of infringement.”⁴² In other words, the statute creates liability for a person who imports a product made by an infringing process, and separately creates infringement for a person who offers for sale, sells, or uses a product made by an infringing process. There is no necessary connection between any of these acts within the Act’s plain meaning. The court argued further that although the statute was motivated by foreign manufacture, the statute in actuality was made equally

³⁶ *See id.* at *1, *4 n.1 (“Remember that Congress recognized that § 271(g) did not have to address the unauthorized domestic use of a patented process, because there were already remedies for such conduct.”).

³⁷ *Asahi Glass Co. v. Guardian Indus. Corp.*, 813 F. Supp. 2d 602, 608, 614 (D. Del. 2011).

³⁸ *Id.* at 614 n.13.

³⁹ *See, e.g., Kyowa Hakka Bio, Co. v. Ajinomoto Co.*, No. CV 17-313, 2018 WL 834583, at *8 (D. Del. Feb. 12, 2018).

⁴⁰ *McRO, Inc. v. Namco Bandai Games Am., Inc.*, 23 F. Supp. 3d 1113, 1118–23 (C.D. Cal. 2013).

⁴¹ *Id.* at 1121.

⁴² *Id.* at 1118–19.

applicable to domestic manufacture to comply with the General Agreement on Tariff and Trade nondiscrimination rules.⁴³

Similarly, in *Kyowa Hakka* the District of Delaware held that a complaint “need not allege facts that the offending process was practiced for a product manufactured outside the United States or that Defendants imported that product.”⁴⁴

Another case that held similarly is *United General Supply*.⁴⁵ In this Western District of Louisiana case, plaintiffs used Form 18, formerly authorized by F.R.C.P. 84, to plead infringement.⁴⁶ Form 18 merely stated that “[t]he defendant has infringed and is still infringing the Letters Patent by making, selling, and using [products] that embody the patented invention,” without specifying any details about where;⁴⁷ however, this Form has since been abandoned in favor of the more stringent *Iqbal/Twombly* pleading standard.⁴⁸ The court concluded that such pleading was sufficient because of the disjunctive language and plain meaning of the statute.⁴⁹

On the other hand, in *Zond*, the District of Massachusetts concluded that Section 271(g) does not apply to domestically-manufactured goods, but the court still allowed the case to proceed because the complaint included a statement that defendants’ customers use, sell, offer for sale, *and import* defendants’ infringing products.⁵⁰ The allegation of importation satisfied Form 18’s requirements.⁵¹ The plaintiff alleged that the defendants must be utilizing their patented technology in their manufacturing process.⁵² The court stated that normally an allegation that simply mirrors the legal standard would be deficient, but Form 18 was satisfied by the allegation of importation.⁵³

Overall, it is difficult to conceive of a Section 271(g) allegation such as the one in *Zond* being allowed to proceed without facts supporting a plausibility of a foreign manufacturer under the *Iqbal/Twombly* standard, now that Form 18 has been abrogated. However, in districts where Section 271(g) may apply to domestic manufacturing, a plaintiff may still be able to plead less facts to proceed with a Section 271(g) allegation if the court follows reasoning such as that in *McRO*. Therefore, the domestic applicability of Section 271(g) may lower a pleading standard.

⁴³ *Id.* at 1120 n.4.

⁴⁴ *Kyowa Hakka*, 2018 WL 834583, at *9.

⁴⁵ *United Gen. Supply Co. v. 2nds in Bldg. Materials, Inc.*, No. CV 15-1975, 2017 WL 524720 (W.D. La. Feb. 7, 2017).

⁴⁶ *Id.* at *3; see also Jason E. Stach & Jonathan J. Fagan, *Life After Form 18: A One-Year Retrospective on Pleading Direct Infringement*, IP LITIGATOR (2017), <https://www.finnegan.com/en/insights/life-after-form-18-a-one-year-retrospective-on-pleading-direct.html> (discussing pleading requirements using Form 18 and its abrogation by the Judicial Conference of the United States).

⁴⁷ See FED. R. CIV. P. 84 (2007) (abrogated 2015) (Form 18).

⁴⁸ See Stach & Fagan, *supra* note 46.

⁴⁹ *United Gen. Supply*, 2017 WL 524720, at *3.

⁵⁰ *Zond, Inc. v. SK Hynix Inc.*, No. CIV.A. 13-11570-RGS, 2014 WL 346008, at *4 (D. Mass. Jan. 31, 2014).

⁵¹ *Id.*

⁵² *Id.* at *1.

⁵³ *Id.* at *4.

C. Selling or Using Products Made Under a Safe Harbor Provision

Another situation in which Section 271(g), but not Section 271(a), may apply is when a safe harbor provision such as that found in 35 U.S.C. § 271(e)(1) applies. Section 271(e)(1) contains what is known as the FDA safe harbor provision, and states:

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* . . . 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.⁵⁴

Based on this provision, activities reasonably related to seeking approval of a generic drug are protected from constituting infringement.⁵⁵ This would include producing a drug for approval by the FDA of a generic drug application, or Abbreviated New Drug Application (ANDA).

Assuming a situation where the composition of the drug itself is covered by a patent, a person making, selling, using the drug would normally infringe under Section 271(a). However, because of the FDA safe harbor provision, such activities would not infringe if they are reasonably related to an ANDA because the drug itself is a *patented invention* under Section 271(e)(1).

Likewise, if there is a patent for a method of making the drug, making the drug would also normally constitute infringement under Section 271(a), and possibly under Section 271(g), but not if it was related to an ANDA in view of the FDA safe harbor provision. In such a case, the method of making the drug is considered the *patented invention* under Section 271(e)(1). On the other hand, using or selling the drug made by the patented method may not fall in the scope of the safe harbor provision because the drug itself would be sold or made, not the *patented invention* of making it. This situation would fall within the purview of Section 271(g), because Section 271(g) includes use of a product made by a patented method. This situation would fall outside the scope of Section 271(a), because Section 271(a) covers only making, using, offering to sell, selling, and importing a patented invention, not a product made by a patented invention.

In the situation where a drug made by a patented method is sold or used outside the scope of the safe harbor provision, a finding of infringement may fall on whether Section 271(g) applies to domestic manufacturing, if the drug was made in the United States. In such a case, if Section 271(g) does *not* apply to domestic manufacturing, making the drug in the United States could be considered a loophole, whereas making the drug outside the United States would constitute infringement.

The courts do not appear to have decided this issue for this set of facts. The closest case to being on point is likely *Momenta Pharmaceuticals*, which involved a generic drug manufacturer in the United States. The District of Massachusetts did not discuss all of the issues described above, but concluded that Section 271(g) was inapplicable because there was no suggestion of the drug being manufactured

⁵⁴ 35 U.S.C. § 271(e)(1) (emphasis added).

⁵⁵ See *Momenta Pharm., Inc. v. Amphastar Pharm., Inc.*, 686 F.3d 1348, 1356 (Fed. Cir. 2012).

abroad.⁵⁶ The court cited *Cardiac Pacemakers*, where the Federal Circuit stated that “§ 271(g) requires importation or sale of the product of a patented process practiced abroad, before infringement can be established under that provision.”⁵⁷ It should be noted, however, that this statement in *Cardiac Pacemakers* was a dissenting opinion which has been characterized as dicta.⁵⁸

On appeal, the Federal Circuit in *Momenta Pharmaceuticals* bypassed a decision on whether Section 271(g) should apply to the domestically manufactured goods in this case by concluding that the patent was not directed to a method of making the drug, because the patent covered subject matter more along the lines of a quality control method.⁵⁹ Because the method was directed to a quality control method instead of a method of making, the patent was outside the purview of Section 271(g), and the court did not need to decide whether Section 271(g) could apply to the domestically manufactured products in the case. However, Judge Dyk, in a dissenting opinion, stated that “[w]hile the primary purpose of § 271(g) was to impose infringement liability for products shipped to the United States but made abroad by a United States patented process, the plain language of § 271(g) admits of no such geographic limitation.”⁶⁰

D. Licensing Arrangements

A final situation in which the applicability of Section 271(g) to solely domestic activities may be found in some licensing scenarios. For example, a patent license may authorize the making of a product by a patented method, but not selling that product. In such a case, the downstream use or sale would be irrelevant under Section 271(a), but a violation of the terms of the agreement by selling the product may trigger Section 271(g) depending on whether that section applies if the product was made in the United States. Because the Federal Circuit has concluded that Section 271(g) could be violated even when the use of a patented process abroad is authorized,⁶¹ it seems likely that a court would hold that Section 271(g) would apply in this situation if it considers Section 271(g) relevant to domestic manufacturing.

In another example, a patent license may authorize all would-be infringement under Sections 271(a) but not 271(g). Such a case may occur if a patent owner wants to stop imports but fails to realize that Section 271(g) may apply domestically.

⁵⁶ *Momenta Pharm., Inc. v. Amphastar Pharm., Inc.*, 962 F. Supp. 2d 348, 353 (D. Mass. 2013), *aff'd in part, vacated in part, remanded sub nom.* *Momenta Pharm., Inc. v. Teva Pharm. USA Inc.*, 809 F.3d 610 (Fed. Cir. 2015).

⁵⁷ *Id.* (quoting *Cardiac Pacemakers, Inc. v. St. Jude Med., Inc.*, 576 F.3d 1348, 1369 (Fed. Cir. 2009) (Newman, J., dissenting)).

⁵⁸ §10:103, *Applicability of § 271(g) to domestically manufactured products*, 2 ANNOTATED PATENT DIGEST (2019).

⁵⁹ *See Momenta Pharm.*, 809 F.3d at 615 n.3.

⁶⁰ *Id.* at 622 n.1 (Dyk, J., dissenting).

⁶¹ *See* Timothy R. Holbrook, *Extraterritoriality in U.S. Patent Law*, 49 WM. & MARY L. REV. 2119, 2149 (2008) (citing *Ajinomoto*, 228 F.3d at 1338).

IV. THEMES

We have seen that there are certain scenarios in which Section 271(g), but not Section 271(a), may apply to activities solely within the United States. If Section 271(g) applies to activities in the United States, it may have broader implications than merely redundantly covering ground already included under Section 271(a). Perhaps the implication with the biggest impact is whether or not Section 271(g) applies to downstream sellers or users of goods made by a patented process in the United States.⁶² This is important because if it does, it may reach customers and users of goods who have no idea they have purchased a product made upstream by some disconnected manufacturer, even if the manufacturer owns or licenses the patent. District courts are split on whether Section 271(g) may apply to situations with no international component, and the Federal Circuit or Congress should get involved to clear this up.

One issue with the piecemeal litigation that occurs in district courts is that they do not have or necessarily consider the overall picture. As we have seen, the applicability of Section 271(g) to domestic manufacturing and use is context specific and may occur in diverse situations. In one case, a court may set a precedent by ruling based on one set of facts that Section 271(g) is inapplicable. This case may then be followed merely because of its precedent by another court with a completely separate set of facts not considered by the first court.

For example, in *Hughes Aircraft*, the Northern District of California held that Section 271(g) was inapplicable to a defendant who merely bought a product made by an infringing process and incorporated it into a larger product.⁶³ The ruling in *Hughes Aircraft* was later followed by the same court in a second case, *Boston Scientific*, without much analysis beyond noting the *Hughes Aircraft* precedent.⁶⁴ If the second case had been based on a different set of facts, one wonders whether the court would have followed the *Hughes Aircraft* precedent as readily. For example, in *Shamrock*, the Eastern District of New York concluded that Section 271(g) could apply to a downstream seller who in reality was involved in the upstream production that infringed the patent, but might have otherwise escaped infringement under Section 271(a).⁶⁵ If the *Shamrock* decision had occurred after *Hughes Aircraft* and followed that precedent, the *Shamrock* court might have made what some would believe to be an unfair ruling in allowing a person involved in the manufacturing of a product by a patented method to escape some degree of liability and make a profit by incorporating a second entity to sell the product downstream. Thus, these early cases play an important role in setting precedents for later cases that may be based on different facts.

Patent prosecutors and litigators can take advantage of the current ambiguity in the law surrounding Section 271(g). For example, patent prosecutors may wish to pursue patent claims directed to methods of making products of interest, even if they already have patent claims covering the products themselves. Litigators may wish to file suits alleging Section 271(g) along with Section 271(a) even when they believe

⁶² See Timothy R. Holbrook, *Method Patent Exceptionalism*, 102 IOWA L. REV. 1001, 1015 (2017).

⁶³ See *Hughes Aircraft*, 857 F. Supp. at 699.

⁶⁴ See *Bos. Sci. Corp.*, 534 F. Supp. 2d at 1080–81.

⁶⁵ See *Shamrock*, 1991 WL 335362, at *1–*2.

Section 271(a) would cover the infringing activity, because Section 271(g) may widen the scope of what is considered infringement. Finally, in areas where district courts have held that Section 271(g) can be applied to downstream sellers, Section 271(g) can be a potent weapon for asserting a direct infringement claim against an otherwise unsuspecting party. Both litigators asserting patents and would-be defendants should be aware of this possibility.