



## INTELLECTUAL PROPERTY

# BIOTECH UPDATE

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## Section 271(g) Infringement Defenses Are Not Available In Patent Actions At The International Trade Commission

By: James Coughlan, Of Counsel, Kirkland & Ellis LLP<sup>1</sup>

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### Introduction

In 1988, the U.S. patent laws were amended to prohibit the sale or use of a product in the U.S. that was manufactured overseas by a patented process. Thus, a party who imports into the U.S. or offers to sell, sells, or uses within the U.S. a product made by a process patented in the United States may be an infringer.<sup>2</sup> However, the 1988 amendments also created two defenses to such infringement. A product is not "made by a process patented in the United States" if it: (1) is materially changed by subsequent processes; or (2) becomes a trivial and nonessential component of another product. These so-called "271(g) defenses" are often raised in

the ITC forum may have become more attractive for enforcing process patents, particularly pharmaceutical, biotech, and chemistry-related process patents that often encounter the 271(g) defenses.

### Patent Litigation at the ITC

Pursuant to 19 U.S.C. § 1337, the ITC offers an alternative forum to U.S. District Court for intellectual property owners seeking to enforce their rights in the U.S. against infringing imports. The ITC typically hears claims of patent or trademark infringement, but it also investigates allegations of copyright infringement, and unfair competition claims such as the misappropriation of trade secrets, passing off, and false advertising. The ITC is required by statute to complete its proceedings "at the earliest practicable time" and will generally render its final decision within 12 to 15 months after an action has been initiated.

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**the ITC forum may have become more attractive for enforcing process patents, particularly pharmaceutical, biotech, and chemistry-related process patents**

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actions involving pharmaceutical, biotech, or chemical process patents.

The U.S. Court of Appeals for the Federal Circuit recently affirmed the decision of the U.S. International Trade Commission that the 271(g) defenses are not available to accused infringers in ITC actions. Thus,

At the ITC, the party filing the complaint is referred to as the complainant and the defending party is referred to as the respondent. If a violation of section 337 is found, the ITC will typically issue a cease and desist order to bar the sale of the respondent's infringing articles that are in

## Section 271(g) Infringement Defenses

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inventory in the U.S. and a limited exclusion order directing that U.S. Customs bar the importation of additional infringing articles by the respondent. In certain circumstances, the ITC may also issue a general exclusion order to bar the entry of all infringing articles, regardless of their source. Damages are not available in ITC actions. An ITC determination can be appealed to the Federal Circuit.

### The ITC's Decision in *Abrasives*

In *Certain Abrasive Products Made Using a Process for Making Powder Preforms, and Products Containing Same*,<sup>3</sup> the patent owners alleged, *inter alia*, that the respondents' imported products were manufactured abroad by a process that infringed their U.S. patent. The respondents asserted the 271(g) defenses, but the patent owners argued that those defenses were not available in actions brought under section 337.

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**"...the defenses established in § 271(g) are not available in [section 337] actions."**

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The ITC agreed with the patent owners and barred the respondents from asserting the 271(g) defenses.<sup>4</sup> In its opinion, the ITC stated that section 271(g) was added to Title 35 as part of the Process Patents Amendments Act of 1988 ("the Act"), and the language of the Act makes clear that the 271(g) defenses were not intended to abrogate a remedy available under Sec. 337.<sup>5</sup>

In the ITC's view, the "plain meaning of the statute leaves no doubt that the Act was not intended to prevent a patent holder from obtaining a remedy pursuant to section 337."<sup>6</sup> Section 271(g) states that the exceptions to infringement contained in sections 271(g)(1) and (g)(2) are "for the purposes of this title [i.e., Title 35]." The ITC therefore reasoned that "the plain meaning of this statement is that 271(g)(1) and (g)(2) exceptions are not to be applied to section 337, which is found in Title 19, not Title 35."<sup>7</sup>

The Act that created section 271(g) also amended section 337. Accordingly, the ITC reasoned that Congress could have included the 271(g) defenses in Section 337, but did not because it did not intend for those defenses to apply to section 337.<sup>8</sup> Finally, the ITC noted that the legislative history of the Act states that it was not Congress' "intention for these provisions to limit in any way the ability of process patent owners to obtain relief from the U.S. International Trade Commission."<sup>9</sup>

### The Federal Circuit Decision

On appeal, the Federal Circuit agreed with the ITC that "the defenses established in § 271(g) are not available in [section 337] actions."<sup>10</sup> The court determined that the ITC's decision was supported by the statute's language and its legislative history and also noted the deference the ITC is typically given in interpreting section 337.<sup>11</sup>

### Impact on Patent Litigation

As a result of this decision by the Federal Circuit, the ITC forum may have become a more attractive forum to owners of process patents, particularly pharmaceutical, biotech, and chemistry-related process patents that most often encounter the 271(g) defenses. ITC decisions on patent matters have no *res judicata* or collateral estoppel effect in District Court, even if the ITC decision is subsequently affirmed by the Federal Circuit.<sup>12</sup> Thus, a respondent found to infringe at the ITC can assert the 271(g) defenses to avoid liability in a District Court action for monetary damages. Whether any conflict arises, and if so what is the result, between an ITC exclusion order and an Article III judgement of no infringement is an open question.

## Patent Challenges By A Licensee In Good Standing: *Gen-Probe v. Vysis*

By: Min Wang

Declaratory judgment actions provide an attractive option for accused infringers to obtain certainty while controlling the timing and, to some extent, the forum of a patent litigation. But the right to bring suit under the Declaratory Judgment Act arises only where there is an "actual controversy"<sup>1</sup> as shown by the "totality of the circumstances."<sup>2</sup> In patent cases, courts focus not only on the conduct of the patentee but also on the conduct of the putative infringer. An actual controversy requires "both (1) an explicit threat or other action by the patentee, which creates a reasonable apprehension on the part of the declaratory judgment plaintiff that it will face an infringement suit, and (2) present activity which could constitute infringement or concrete steps taken with the intent to conduct such activity."<sup>3</sup>

As with most fact-intensive questions that depend on the "totality of the circumstances," the showing required for declaratory judgment jurisdiction is often litigated and even more often debated. In an important recent decision, the Federal Circuit addressed whether a licensee in good standing can show the required reasonable apprehension to support a declaratory judgment action challenging the validity or scope of a licensed patent. In *Gen-Probe Inc. v. Vysis, Inc.*, 359 F.3d 1376 (Fed. Cir. 2004), the court answered this question in the negative, dismissing Gen-Probe's declaratory judgment action because Gen-Probe was a licensee in good standing and, therefore, could have no apprehension of suit.

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**"This license, unless materially breached, obliterated any reasonable apprehension of a lawsuit ...."**

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The patent in the *Gen-Probe* case claimed methods and kits for use in nucleic acid

diagnostic assays for the HIV and hepatitis C virus. Shortly after the patent issued, Vysis orally informed Gen-Probe that Gen-Probe might be infringing the patent and later exchanged letters with Gen-Probe stating that the patent should be "of interest" to Gen-Probe and that it "may apply" to certain Gen-Probe technology. Gen-Probe took a license under the patent in conjunction with the settlement of an unrelated litigation.

Gen-Probe was not, however, content to continue as licensee. It wanted to challenge Vysis' patent, while maintaining its license. Before filing the declaratory judgment action, Gen-Probe wrote to Vysis declaring its intent to maintain the *status quo* under the license: "[b]ased on present circumstances, Gen-Probe and its allied parties expect to fulfill their obligations under the licenses during the pendency of the litigation."<sup>4</sup> Consistent with its stated intent, Gen-Probe fulfilled its obligations and continued to pay royalties (under protest) under the license agreement.

The District Court denied Vysis' motion to dismiss for lack of subject matter jurisdiction, ruling that the oral notification, letters from Vysis, and the history of litigation between the parties supported a reasonable apprehension of suit under the patent at issue. The Federal Circuit disagreed. The subsequent entry into the license agreement, an enforceable covenant not to sue, removed any basis for apprehending suit based on the pre-license events:

[T]he license insulated Gen-Probe from an infringement suit instituted by Vysis.... This license, unless materially breached, obliterated any reasonable apprehension of a lawsuit based on the prior circumstances cited by the district court for jurisdiction.<sup>5</sup>

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Nor did events following entry into the license agreement support a reasonable apprehension of suit under the patent since Gen-Probe had confirmed its desire to remain, and had in fact remained, a licensee in good standing throughout.<sup>6</sup>

**“a licensee must, at a minimum, stop paying royalties...before bringing suit to challenge the validity or scope of the licensed patent”**

The *Gen-Probe* court identified *C.R. Bard, Inc. v. Schwartz*, 716 F.2d 874 (Fed. Cir. 1983) as the closest precedent. In *Bard*, the Federal Circuit had stated, “a patent license need not be terminated before a patent licensee may bring a declaratory judgment suit.”<sup>7</sup> The *Gen-Probe* court distinguished *Bard* as relying on two critical circumstances: first, the licensee had ceased payment of royalties, constituting a material breach of the license agreement; and second, the patentee had filed suit in state court for recovery of the royalties, manifesting the patentee's willingness to enforce the patent. In contrast, Gen-Probe did not cease paying royalties or materially breach the license

agreement, and Vysis did not file a breach of contract action.

Under *Gen-Probe*, “a licensee must, at a minimum, stop paying royalties (and thereby materially breach the agreement) before bringing suit to challenge the validity or scope of the licensed patent.”<sup>8</sup> The Federal Circuit reasoned that a license, unless materially breached, eliminates any reasonable apprehension of a lawsuit.

The Federal Circuit supported its decision on policy grounds, explaining that the contrary result would be undesirable because it would discourage patentees from granting licenses. In granting a license, a patentee forgoes its statutory right to exclude infringements (usually) in exchange for payment of royalties by the licensee. If a licensee in good standing were allowed to challenge a patent, the licensee could do so while the license places a cap on damages if the challenge fails. This, according to the court, would force the patentee to bear all of the risk and discourage licensing by patentees.

NOTES

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Section 271(g) Infringement Defenses

- 1 The author is a former investigative attorney at the ITC's Office of Unfair Import Investigations and judicial law clerk to the Hon. Marion T. Bennett, U.S. Court of Appeals for the Federal Circuit.
- 2 See 35 U.S.C. § 271(g).
- 3 Inv. No 337-TA-449, Comm'n Op. (July 26, 2002) (“*Abrasives*”)
- 4 *Id.* at 2-4.
- 5 *Id.* at 2.
- 6 *Id.* at 3.
- 7 *Id.*
- 8 *Id.*
- 9 *Id.* at 3-4.
- 10 *Kinik Co. v. International Trade Comm'n*, 362 F.3d 1359, 1363 (Fed. Cir. 2004)
- 11 *Id.* at 1362-63.
- 12 See *Texas Instruments Inc. v. Cypress Semiconductor Corp.*, 90 F.3d 1558, 1569 (Fed. Cir. 1996) (quoting S.Rep.No. 1298, 93d Cong., 2d Sess. 196 (1974), *U.S. Code Cong. & Admin. News* 1974, 7186, 7329) (“The Commission's findings neither purport to be, nor can they be, regarded as binding interpretations of the U.S. patent laws in particular factual contexts. Therefore, it seems clear that any disposition of a Commission action by a Federal Court should not have a *res judicata* or collateral estoppel effect in cases before such courts.”).

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Patent Challenges By A Licensee In Good Standing

- 1 28 U.S.C. § 2201(a).
- 2 *Spectronics Corp. v. H.B. Fuller Co., Inc.*, 940 F.2d 631, 634 (Fed. Cir. 1991).
- 3 *BP Chemicals Ltd., v. Union Carbide Corp.*, 4 F.3d 975, 978 (Fed. Cir. 1993).
- 4 *Gen-Probe*, 359 F.3d at 1379.
- 5 *Id.* at 1381 (internal citations omitted).
- 6 *Id.* at 1380-81.
- 7 *C.R. Bard, Inc. v. Schwartz*, 715 F.2d 874, 875 (Fed. Cir. 1983).
- 8 *Gen-Probe*, 359 F.3d at 1381.