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## PATENTS

## Is One the Only Lonely Number? *Life Technologies v. Promega* and the Impact on Substantiality Requirements in the Patent Context and Beyond



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In *Life Technologies Corp. v. Promega Corp.*, 137 S. Ct. 734 (2017), the U.S. Supreme Court held that the domestic supply of one component of a multi-component invention assembled outside of the U.S. does not suffice to warrant liability for patent infringement. Specifically, the Court held that a single component cannot meet the statutory requirement that a “substantial portion” of the components be supplied from the U.S. Because the Court did not provide guidance on what percentage or number of components does suffice to constitute a “substantial portion,” and merely found that one is not enough, questions remain as to where the line will be drawn going forward.

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This article discusses the aftermath of *Life Technologies* in patent law, explores how courts have interpreted “substantial portion” requirements in other areas of law, and considers whether this ruling may impact future assessments of substantiality in all contexts.

### Supreme Court's Decision in *Life Technologies v. Promega*

Promega Corp. sued Life Technologies Corp. for patent infringement concerning a toolkit for genetic testing. The kit, which is used to amplify small samples of DNA for forensic analysis and clinical and research purposes, has five components. The Supreme Court considered whether the manufacture of only one component—the *Taq* polymerase—within the U.S. sufficed to render Life Technologies liable for infringement under 35 U.S.C. § 271(f)(1) when the remaining components were manufactured and the combination of all components took place abroad.

Section 271(f)(1) provides for patent liability if “all or a substantial portion of the components of a patented invention” are supplied in the U.S. The Court noted that the term “substantial” was ambiguous and could mean “qualitative importance” or “quantitatively large size.” However, the Court held that “substantial portion” in Section 271(f)(1) required a quantitative assessment of the number of components supplied domestically, and rejected the U.S. Court of Appeals for the Federal Circuit's previous qualitative assessment of importance of the component in question. In so ruling, the Court focused on the surrounding words in the statute.

While the Court made clear that one component cannot be a “substantial portion” of the components, the Court did not set a minimum number of components or percentage of components that must be supplied from the U.S. to warrant liability. In fact, in his concurring opinion, Justice Samuel A. Alito commented that he did not read the majority decision to suggest that “any number greater than one is sufficient,” noting instead that “today's opinion establishes that more than one

component is necessary, but does not address *how much* more.”

## “Substantial Proportion” in Patent Law After *Life Technologies*

The Federal Circuit may be the first to apply the *Life Technologies* quantitative test on remand of the same case. Specifically, Promega has argued that Life Technologies is liable for manufacturing two of five components—40 percent—for certain accused kits. Plaintiff-Cross Appellant Promega’s Statement of Position on Remand at 22-26, *Promega Corp. v. Life Techs. Corp.*, Nos. 2013-1011, 1029, 1376 (Fed. Cir. Mar. 29, 2017), ECF No. 112. Life Technologies, however, has argued that Promega did not present sufficient evidence to quantify damages for these kits and that “[t]his case is over.” Defendants-Appellants Life Technologies’ Statement of Position on Remand at 3, 15-25, *Promega*, Nos. 2013-1011, 1029, 1376 (Fed. Cir. Mar. 29, 2017), ECF No. 108. The Federal Circuit has not yet issued a substantive ruling on remand.

While the Federal Circuit and/or district courts will be tasked with delineating what percentages or absolute numbers of components constitute a “substantial portion” under Section 271(f)(1), there may not be a single percentage that applies as a bright line minimum for substantiality. Indeed, the Federal Circuit could find on remand that the provision of 40 percent of components was sufficiently “substantial” under the Supreme Court’s definition on remand. However, since the Supreme Court has already held that the provision of one component can never suffice, the Court has effectively already found that even in a two-component invention, the provision of 50 percent of components is insufficient under Section 271(f)(1).

In the meantime, two district courts have since declined to find liability under Section 271(f)(1) for the export of 100 percent of a *single* component invention, relying upon the discussion in *Life Technologies* about the need for components to be “combined” to warrant liability. *Regents of the Univ. of California v. California Berry Cultivars, LLC*, No. 16-cv-02477-VC (N.D. Cal. April 27, 2017), ECF No. 240 (no liability for infringing a plant patent by allegedly causing a strawberry plant to be supplied to Spain); *Natural Alternatives Int’l, Inc. v. Creative Compounds*, No. 16-cv-02146-H-AGS (S.D. Cal. Mar. 14, 2017), ECF No. 34 (no liability for exporting a dietary supplement that allegedly comprised the entire invention).

## “Substantial Portion” Quantified in Other Contexts

“Substantial portion” requirements are used frequently outside of patent law, and by one court’s count, this phrase appears 51 times in the United States Code. *15192 Thirteen Mile Rd., Inc. v. City of Warren*, 626 F. Supp. 803, 820 n.19 (E.D. Mich. 1985) (collecting statutes). While there is little developed jurisprudence on the minimum needed to meet “substantial portion” requirements, courts have considered the meaning of this requirement in connection with the Civil Rights Act of 1964, the Jones Act, and various local ordinances.

### *Civil Rights Act*

Title II of the Civil Rights Act of 1964 includes an “interstate commerce” provision for restaurants where “a

*substantial portion* of the food . . . has moved in commerce.” The Supreme Court found that a restaurant where 46 percent of the food came from out-of-state satisfied the requisite “substantial portion” in *Katzenbach v. McClung*, 379 U.S. 294, 296-97 (1964), as did establishments where “three of the four food items” served, i.e., 75 percent, “contain[ed] ingredients originating outside of the State,” in *Daniel v. Paul*, 395 U.S. 298, 305 (1969). However, lower courts have noted that the Supreme Court did not set a “minimum test of substantiality,” and instead interpreted this “to mean anything more than a minimal or insignificant amount.” See, e.g., *United States v. Lansdowne Swim Club*, 713 F. Supp. 785, 794-95 (E.D. Pa. 1989), (quoting *Gregory v. Meyer*, 376 F.2d 509, 511 n.1 (5th Cir. 1967)). One court even found the “substantial portion” provision was satisfied where “many of the purchases . . . include a cold drink,” and the “primary cold drinks . . . [were] ‘Coca-Cola’ . . . which contain an essential ingredient that has moved in commerce.” *Id.* This characterization of the out-of-state ingredient as “essential” seems to impart a qualitative assessment, which the Supreme Court rejected in *Life Technologies*.

### *Jones Act*

The Jones Act provides a negligence cause of action for “seaman” injured in the course of employment, 46 U.S.C. App. § 688(a), and the Supreme Court has defined “seamen” as having “a connection with a vessel in navigation that is substantial in both duration and nature.” *Chandris, Inc. v. Latsis*, 515 U.S. 347, 370 (1995). This substantiality requirement has been interpreted to exclude workers spending less than about 30 percent of time in service on a vessel. *Id.* at 356-58, 371; see also *Grab v. Boh Bros. Constr. Co., LLC*, 506 F. App’x 271, 277 (5th Cir. 2013). However, 100 percent of time in service spent on a vessel has also been deemed insufficient where the time in service (here, four weeks total) was deemed too brief. *Brown v. Trinity Catering, Inc.*, No. 06-5756, 2007 BL 203990, at \*6 (E.D. La. Dec. 11, 2007).

### *Local Ordinances*

Local ordinances governing the zoning and licensing of a sexually-oriented business (SOB) often utilize a “substantial portion” requirement to categorize a business based upon the amount of adult merchandise. In some instances, the ordinance includes a presumption that more than 25 percent of the retail value of the inventory being adult-oriented constitutes a “substantial portion”; however, at least one case proceeded against a store with less than 25 percent of its retail being adult items. See, e.g., *St. Louis Cty. v. B.A.P., Inc.*, 25 S.W.3d 629, 630-31 (Mo. Ct. App. 2000) (reversing judgment that store was not a SOB). Under similar ordinances which did not include a specific minimum, one court found a store’s 50-80 percent adult content was sufficiently “substantial,” *Dandy Co. v. Civil City of South Bend*, 401 N.E.2d 1380, 1385-86 (Ind. Ct. App. 1980) (affirming entry of preliminary injunction), and another court found the adult merchandise to be sufficiently “substantial or significant” where the business offered 8,242 adult items, even though this represented only 12 percent of total products. See *VIP of Berlin, LLC v. Town of Berlin*, 593 F.3d 179, 183 (2d Cir. 2010).

## Summary

To date, assessments of “substantial portion” requirements have been dependent on both the surround-

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ing statutory framework as well as courts' discretion. However, the Supreme Court's guidance in *Life Technologies* to focus on quantitative, rather than qualitative, assessments may impact future determinations of substantiality even beyond patent law.

Moreover, within the realm of quantitative assessments, courts may continue to avoid defining absolute thresholds and may instead continue to factor case-specific considerations into the equation.