LIFE TECHNOLOGIES v. PROMEGA, No. 14-1538 (U.S. February 22, 2017). Sotomayor, Kennedy, Ginsburg, Breyer, Kagan, Thomas, Alito. Appealed from Fed. Cir. (Judges Prost, Meyer, Chen).

Background:

Promega Corporation sued Life Tech for infringement under §271(f)(1) of patents directed to kits for coamplifying STR loci combinations. Of the kit's five components, one, the enzyme *Taq* polymerase, was manufactured by Life Tech in the U.S. and shipped to the U.K. to be combined with the other four components manufactured there.

§271(f)(1) recites, in part,

> supplies or causes to be supplied in or from the United States all or a substantial portion of the components of a patented invention, where such components are uncombined in whole or in part, in such manner as to actively induce the combination of such components outside of the United States

As to the §271(f)(1) liability, the district court granted Life Tech's motion for judgment as a matter of law, holding that "all or a substantial portion" did not encompass the single component made in the U.S. The Federal Circuit reversed, holding that a single important component could constitute a "substantial portion" under §271(f)(1), and the *Taq* polymerase was such a component.

Issue/Holding:

Did the Federal Circuit err in holding that supplying a single component of a multi-component invention from the United States for sale abroad exposes the manufacturer to liability for infringement? Yes, reversed.

Discussion:

The Court unanimously interpreted 35 U.S.C. §271(f)(1) to mean that the supply of a single component of a patented multicomponent invention for manufacture abroad does not give rise to infringement.

The Court first determined whether the term "substantial portion" is to be given qualitative or quantitative meaning. Because the dictionary definition of "substantial" did not provide any guidance, the Court looked to the text of the statute. Because the terms in §271(f)(1) neighboring "substantially," such as "all" and "portion," are quantitative, the Court held that the term "substantial portion" has a quantitative meaning. Promega suggested that there should be a case specific approach, which would require a determination for each claim whether the components at issue be given a quantitative or qualitative meaning. However, the Court declined to use this approach, stating that such an interpretation would lead to further ambiguity of the law.

Having determined that "substantial portion" would be measured quantitatively, the Court then decided whether a single component could be considered a substantial portion. The Court found that because §271(f)(1) consistently refers to "components," for example "all or a substantial portion of the *components* of a patented invention" where "such *components* are

uncombined," the term "substantial portion" was intended to mean more than one component. As such, the Court held that a single component would not be considered a "substantial portion" of a multi-component invention as defined in §271(f)(1).

The Court also pointed to §271(f)(2), which explicitly refers to a specific single "component" as further evidence that the term "components" in §271(f)(1) was intended to mean more than one.

Therefore, Life Tech was not liable because it only produced one of the five components required for the kits in the U.S.

In his concurring but separate opinion, Justice Alito (with Justice Thomas joining) noted that the main question of the case is to identify what number of components constitutes a "substantial portion," and not just establish that one component is not sufficient.

Claim 42 of RE 37,984 (Tautz Patent)

A kit for analyzing polymorphism in at least one locus in an DNA sample, comprising:
a) at least one vessel containing a mixture of primers constituting between 1 and 50 of said primer pairs;
b) a vessel containing a polymerizing enzyme suitable for performing a primer-directed polymerase chain reaction;
c) a vessel containing the deoxynucleotide triphosphates adenosine, guanine, cytosine and thymidine;
d) a vessel containing a buffer solution for performing a polymerase chain reaction;
e) a vessel containing a template DNA comprising i) a simple or cryptically simple nucleotide sequence having a repeat motif length of 3 to 10 nucleotides and ii) nucleotide sequences flanking said simple or cryptically simple nucleotide sequence that are effective for annealing at least one pair of said primers, for assaying positive performance of the method.

35 U.S.C. §271(f)(1)

Whoever without authority supplies or causes to be supplied in or from the United States all or a substantial portion of the components of a patented invention, where such components are uncombined in whole or in part, 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.

35 U.S.C. §271(f)(2)

Whoever without authority supplies or causes to be supplied in or from the United States any component of a patented invention that is especially made or especially adapted for use in the invention and not a staple article or commodity of commerce suitable for substantial noninfringing use, where such component is uncombined in whole or in part, knowing that such component is so made or adapted and intending that such component will be combined 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.