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Contributor: **Melissa D. Schwaller**

Promega Corp. v. Life Tech., Inc., No. 2013-1011, -1029, -1376, 2014 U.S. App. LEXIS 23482 (Fed. Cir. Dec. 15, 2014)

Abstract

The Fed. Cir. reversed the district court's denial of LifeTech's summary judgment of invalidity of certain Promega patents and vacated the district court's grant of Promega's summary judgment motion of infringement of its patents. In doing so, the Court considered, among other things, the effect of the term "comprising" on enablement and the requirements for inducing infringement under 35 U.S.C. § 271(a) and § 271(f).

Invention

The invention at issue relates to the selection, amplification, and evaluation of the DNA sequences of multiple short tandem repeat ("STR") loci. STR loci are present in various numbers in different individuals. *Taq* polymerase can be used to amplify the number of copies of the DNA containing the STR loci in a sample to be analyzed. Primers that correspond to the sequences surrounding a particular locus are used in the amplification reaction. In order for successful amplification to occur, the primers must not react with the sequences surrounding other loci to be amplified in the reaction.

Background and Posture

Promega owns or has rights in various patents covering the amplification of DNA sequences in multiple STR loci. LifeTech produces genetic testing kits that include components that can be used to amplify multiple STR loci. LifeTech manufactures one component of the kits, *Taq* polymerase, in the United States, and ships the *Taq* polymerase to the United Kingdom for kit assembly and worldwide sale of the kits.

Promega sued LifeTech for infringement of four Promega patents (5,843,660; 6,221,598; 6,479,235; and 7,008,771) (hereinafter "the Promega patents") and one patent of which Promega was an exclusive licensee (RE 37,984) (hereinafter "the Tautz Patent").

The district court granted summary judgment that the Promega patents were enabled and non-obvious, granted JMOL that LifeTech did not actively induce infringement of the Promega and Tautz patents, and orally ruled that LifeTech was not licensed for all sales of the accused products.

Decision

Circuit Judge Chen wrote the opinion for a panel of Chief Judge Prost, Circuit Judge Mayer, and Circuit Judge Chen. Prost filed a dissent-in-part dissenting from the majority opinion regarding liability of LifeTech for active inducement of infringement.

The panel decided that the Promega patents are invalid and that LifeTech infringes the Tautz patent under 35 U.S.C. § 271(a) ("§ 271(a)") and § 271(f)(1).

Invalidity

Enablement and Obviousness

The asserted claims in the Promega patents were directed to STR loci combinations and included "comprising" claims. The "comprising" claims encompassed multiplex amplification reactions of STR loci as long as the recited STR loci were included. The "consisting" claims present in the patents encompassed only the recited STR loci.

One of the asserted claims was claim 23 of the '598 patent:

> 23. A kit for simultaneously analyzing short tandem repeat sequences in a set of short tandem repeat loci from one or more DNA samples, comprising: a single container containing oligonucleotide primers for each locus in a set or short tandem repeat loci which can be co-amplified, *comprising* HUMCSF1PO, HUMTPOX, and HUMTH01.

'598 patent, 40:22-28 (emphasis added).

It was undisputed that the addition of one more STR loci to an existing multiplex amplification set would involve undue experimentation because each STR locus responds differently in a PCR reaction with locus-specific primers. Promega itself stated that multiplex amplification of STR loci in the prior art "cannot be extended to predict the success of multiplexing unrelated combinations of loci" and that the prior art "clearly indicated[d] that each individual [STR] locus responds differently when subjected to the PCR using locus-specific primers." Promega Corp. v. Life Tech., Inc., No. 2013-1011, -1029, -1376, 2014 U.S. App. LEXIS 23482, at *19 (Fed. Cir. Dec. 15, 2014).

The Fed. Cir. determined that the STR loci in the "comprising" claims were not merely unrecited elements. Since the reaction with unrelated combinations of loci is unpredictable, the Fed. Cir. held that Promega's asserted claims are invalid for lack of enablement.

Infringement

Promega did not appeal the district court's grant of summary judgment of noninfringement of the asserted "consisting" claims. *Id.* at *6, n. 2. The Fed. Cir.

addressed the district court's granting of judgment as a matter of law ("JMOL") of active inducement of infringement of the Tautz patent. Claim 42 of the Tautz patent states:

> 42. A kit for analyzing polymorphism in at least one locus in a 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.

Tautz patent, 16:43-61.

LifeTech's accused infringing products are genetic testing kits including components for multiplex amplification of STR loci in DNA. The components in the kits include a primer mix, *Taq* polymerase, PCR reaction mix including nucleotides, a buffer solution, and control DNA. *Id*. at *10. The *Taq* polymerase is manufactured in the United States and sent to a LifeTech manufacturing facility in the United Kingdom for assembly of the kit. *Id*. The kits are sold worldwide. *Id*.

The Fed. Cir. determined LifeTech's genetic testing kits made, used, or sold in the U.S. infringed the Tautz patent under § 271(a) based on LifeTech's admissions and evidence in the record.

The district court granted JMOL that Promega failed to prove infringement under § 271(f)(1).

§ 271(f)(1) states:

> 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)(1) (emphasis added).

The Fed. Cir. asked whether "actively induce the combination" required a third party or just intent to cause the patented combination outside of the United States. The Fed. Cir. discussed the legislative history of § 271(f)(1) and stated "it is unlikely that Congress intended § 271(f)(1) to hold companies liable for shipping components overseas to third parties, but not for shipping those same components overseas to themselves or their foreign subsidiaries." *Id.* at *35. Therefore, the Fed. Cir. determined that LifeTech actively induced the combination of the *Taq* polymerase into the kit.

The Fed. Cir. also asked whether a "substantial portion of the components of a patented invention" requires at least two components be supplied from the United States. The Fed. Cir. stated that the meaning of the individual words "substantial portion" suggested that "'a single or important component can be a substantial portion of the components' of a patented invention." *Id.* at *37. LifeTech unsuccessfully argued that there must be at least two components based on the language in § 271(f)(1), "where such components are uncombined in whole or in part". *Id.* at *38. The Fed. Cir. noted that "such components" refer to "the components of a patented invention" and not to what is supplied, *i.e.*, all or a substantial portion of the components. *Id.* at *37-38.

The Fed. Cir. determined that in this case, the *Taq* polymerase is a "substantial portion" of LifeTech's genetic testing kits. The *Taq* polymerase is responsible for amplifying the DNA sequences through PCR. The genetic testing kits could not function in the absence of the *Taq* polymerase because there would not be enough DNA to test. LifeTech admitted that the *Taq* polymerase was one of the "main" and "major" components of the kits. *Id.* at *44.

The Fed. Cir. thus determined that there was substantial evidence to support the jury's finding that LifeTech infringed the Tautz patent under § 271(a) and § 271(f)(1).

Chief Judge Prost's Dissent

Chief Judge Prost stated that § 271(f)(1) requires that "actively induce the combination" requires inducement of another. She asserted that the Supreme Court has twice held that inducement liability in § 271(b) requires a third party. She also noted that the en banc Fed. Cir. has made similar statements. Chief Judge Prost stated "[i]t is a 'standard principle of statutory construction that identical words and phrases within the same statute should normally be given the same meaning." *Id.* at *52.

Chief Judge Prost addressed the majority's statement that it does not make sense for Congress to hold companies liable for shipping components to third parties overseas while allowing them to ship components to themselves or subsidiaries. She stated that "it is hardly our role as judges to surmise or divine what Congress may or may not have foreseen or desired, and to act as its surrogate." *Id.* at *53. Chief Judge Prost also stated that the Supreme Court has cautioned against judicial decisions to cause a law to have an extraterritorial effect.

Practice Pointers

Practitioners should remember that the entire scope of the subject matter of the claim must be enabled. Practitioners should be aware that the "comprising" language although typically acceptable when used in the preamble, in certain circumstances "expands the claims at a key limitation in order to cover what are indisputably advances in this unpredictable art" and thus may not be construed as merely being "unrecited elements". *Id.* at *27.

Practitioners should be careful when arguing for non-obviousness that they do not make statements that are detrimental to enablement. When asserting invalidity of claims in litigation, practitioners should search for these type of statements.

This case also confirms that an entity can actively induce itself to infringe claims under § 271(f)(1) of a U.S. patent by sending a portion of the components of a claimed invention outside of the U.S. for assembly. Practitioners should advise their clients of this pitfall. If only one component is manufactured in the U.S. and shipped abroad, infringement still can be found under § 271(f)(1) as long as it is a substantial portion of the components of the patented invention. Those practitioners attempting to prove infringement in litigation should utilize these arguments when applicable.

Melissa D. Schwaller is Counsel with the law firm of Ramey & Browning, PLLC in Houston Texas. She has a Ph.D. in Biochemistry and her practice is focused on patent preparation and prosecution, patent litigation, trademark prosecution, freedom-to-operate analysis and opinion drafting.