

Keywords: 35 U.S.C. § 112, 1st paragraph; enablement; comprising; consists

General: The Fed. Circuit invalidates claims under 35 U.S.C. § 112, 1st paragraph, finding that the specification does not enable a skilled artisan to practice the full breadth of ‘comprising’ claim scope.

Promega Corp. v. Life Tech. Corp.

2013-1011, -1029, -1376 (Fed. Cir. 2014)

I. Facts

DNA is a double-stranded molecule that encodes genetic instructions for living organisms. DNA includes repeating nucleotide sequences called short tandem repeats (STRs). These STRs are found in regions of the DNA strand called STR loci.

STR loci occur frequently in the human genome. The number of repeated sequences within STR loci varies highly from person to person. These variations are referred to as alleles, or markers, of a particular locus.

No one allele varies enough to differentiate one person from another to a statistically significant degree. However, using STR profiling, a particular set of alleles at multiple loci within an individual’s DNA can be used to create a DNA fingerprint unique to that individual. The STR profiling process includes an “amplification” process where copies of the loci of interest are generated to obtain a detectable amount of DNA for analysis.

It is highly beneficial to amplify multiple STR loci simultaneously, creating a “multiplex” reaction or co-amplification. However, such multiplex reactions are complex, depending on a selection of a set of primer pairs for which each primer pair not only flanks its respective target locus, but does not overlap – and thus interfere – with the primer pairs for other targeted loci.

Identification of STR loci sets and primer pairs that successfully co-amplify is a trial and error process. At the time of invention of the claims at issue, scientists could not predict with any certainty, absent a preexisting publication or teaching, whether a given set of loci would successfully co-amplify. This was true even when adding a new locus to an already successful multiplex, as skilled artisans could not predict loci interactions with one another or how effectively and efficiently the primers would work in a single reaction environment. Further, the greater the number of STR loci sought to be amplified in a single reaction, the more complicated the process of creating a successful multiplex for that loci set.

Promega, Corp. (“Promega”) owns four patents (“the Promega patents”), which are directed towards determining alleles present in a set of STR loci from DNA samples. Each of the claims in the Promega patents includes a limitation that recites the phrase “a set of... loci” followed by a list of particular short tandem repeat (STR) loci multiplexes of varying complexity, ranging from a 3-plex to a 14-plex. Some of the claims recite a closed loci set, using a “consisting of” transitional phrase when reciting the multiplexes, while others recite an open loci set, using a “comprising” transitional phrase.

Life Technologies, Corporation (“LifeTech”) manufactures genetic testing kits that provide components for carrying out a multiplexed amplification of STR loci from DNA samples. These kits are designed to successfully co-amplify STR loci combinations that include the recited loci listed in the Promega patents as well as loci that are not listed in the claims of the Promega patents.

In 2010, Promega sued LifeTech for infringement of the Promega patents. LifeTech filed counterclaims that the asserted claims of the Promega patents were invalid for lack of enablement. The District Court found that the “comprising” language in the Promega patents “makes it clear that they are not limited to the recited loci because they all use the word ‘comprising’ when listing the

loci.” *Promega I*, slip op. at 21. Further, the District Court rejected LifeTech’s enablement challenges, concluding that the recited multiplexes were enabled and that the “asserted claims need not enable ‘unrecited elements.’” Accordingly, the District Court ruled the open-ended claims were enabled, despite non-enablement of unrecited loci covered by the “comprising” language of the claims. LifeTech appealed.

II. Issue

Did the District Court err in holding that the open-ended claims of the Promega patents are not invalid for lack of enablement under 35 U.S.C. § 112, 1st paragraph?

III. Discussion

1) Yes. The Federal Circuit concluded that the District Court erred in holding the open-ended claims of the Promega patents were enabled. Specifically, the Court disagreed that the unrecited STR loci combinations in the “open loci set” limitation of the asserted claims are merely “unrecited elements.” Instead, the Court found that these combinations were part of the claim scope that must be enabled.

Courts have determined that the enablement requirement ensures that “the public knowledge is enriched by the patent specification to a degree at least commensurate with the scope of the claims.” *Nat’l Recovery Techs., Inc. v Magnetic Separation Sys., Inc.*, 166 F.3d 1190, 1195-96 (Fed. Cir. 1999).

Here, the Court found that the scope of the specification was not commensurate with the scope of the claims. The Court noted that under the District Court’s claim construction, the claims having the “comprising” language encompassed not only the recited loci, but also “*any other larger, more complex multiplex reaction*, so long as it includes the three recited loci. *Promega*, page 14. The Court reasoned that “introducing even a single STR locus to an existing loci multiplex significantly alters the chemistry of, and has an unpredictable effect on, whether the resulting multiplex will successfully co-amplify.” *Id.* at 15.

The Court found no genuine dispute that identifying STR loci multiplexes that will successfully co-amplify is a complex and unpredictable challenge requiring undue experimentation to identify a successfully co-amplifying multiplex that adds even a single new locus to an existing loci combination. Indeed, Promega itself, when defending against obviousness of the Promega patents, had previously argued that multiplex amplification of specific STR loci combinations disclosed in the prior art cannot be extended to predict the success of multiplexing unrelated combinations of loci. *Id.* at 15. More specifically, Promega represented to the Patent Office that the addition of even a single locus to an existing loci combination rendered that new loci combination patentable. *Id.* at 16. For example, Promega argued that a claim reciting a 3-plex loci combination was patentable over prior art that disclosed only two of the three loci. *Id.* Thus, Promega explained that without a preexisting publication or teaching, a skilled artisan “could not predict with any certainty... whether a given set of loci would co-amplify successfully together. *Id.* at 16-17.

The Court analogized Promega’s claims with those in *MagSil Corp. v. Hitachi Global Storage Techs., Inc.* (“*MagSil*”) and *Wyeth v. Abbott* (“*Wyeth*”). In *MagSil*, a patentee sought to extend its scope in order to cover later-invented devices that achieved greater than 600% changes in resistance, while the *MagSil* invention only enabled a change in resistance of 11.8%. Thus, the Court held that the specification did not support the infinite range of resistive changes encompassed by *MagSil*’s claim limitation.

In *Wyeth*, claims covering a broad class of drug compounds with certain structures and properties were asserted by the patentee. The specification only disclosed one species of the compound having these particular characteristics, despite the patentee’s contention that the claims covered “tens of thousands

of other species within the genus that were not disclosed by the patent.” The Court found that because the specification disclosed only a starting point for further iterative research in an unpredictable and poorly understood field, practicing the *full scope* of the claims required more than routine experimentation. Thus, the Court held that the claims were invalid for lack of enablement.

The Court reasoned that similar to *MagSil*, the claims of the Promega patents cover complex subject matter not enabled in the specification. Further, the Court found a similarity with *Wyeth*, stating that “the claims at issue here similarly cover potentially thousands of undisclosed embodiments in an unpredictable field... The specification of the Promega patents provides only a starting point – specific STR loci combinations that successfully co-amplify – with no disclosure that would have allowed a skilled artisan, absent laborious testing, to add new loci to these recited STR loci combinations that would still successfully co-amplify.” *Id.* at 19.

The Court then found that in contrast to open claims that “embrace technology that may add features to devices *otherwise within the claim definition*,” the current claims are open-ended “within the specific claim limitation that lists combinations of successfully co-amplifying STR loci, combinations whose identification and discovery Promega itself asserts is a complex and unpredictable endeavor.” *Id.* at 20. “Promega’s claims differ from customary “open-ended” claims in that Promega’s usage of “comprising” in its “open loci set” limitation, as construed, expands the claims at a key limitation in order to cover what are indisputably advances in this unpredictable art.” *Id.* at 20-21. Accordingly, the Court held that since the Promega patents do not enable a skilled artisan to practice the full breadth of this claim scope without undue experimentation, the challenged claims of the Promega patents are invalid for lack of enablement.

IV. Conclusion

When using “comprising” language outside the pre-amble of a claim, ensure that the expansion encompassed by the open-ended nature of the “comprising” language does not cover indisputable advances that are complex and an unpredictable endeavor. If these complex and unpredictable endeavors are not disclosed in the specification, thus necessitating undue experimentation to practice the full scope of the claims, the claims may be found invalid for lack of enablement. If there is any doubt, it may be beneficial to draft a separate claim using “consisting of” language.