

## The “Tangential Relation” Exception to Prosecution History Estoppel Can Apply Where the Purpose of an Amendment Is to Eliminate a Certain Set of Proteins From the Claims, but the Equivalence Argument Focuses on the Choice of DNA Sequences That Encode

AUGUST 7, 2019

*Ajinomoto Co. et al. v. International Trade Commission et al.*, No. 2018-1590, 2018-1629 (Fed. Cir. Aug. 6, 2019)

The patent owner brought suit before the ITC alleging that the importation of animal feed products made by its “strains” of genetically modified E. Coli bacteria infringed its patent. The patent-at-issue claims E. Coli bacteria genetically engineered to increase production of a certain amino acid. This is accomplished by a specific E. Coli protein’s amino acid sequence being present in the bacterium (the “protein limitation”), and by “replacing the native promoter . . . with a more potent promoter” in the DNA of the bacterium.

The patentee accused different sets of strains. The accused “earlier” strains contained the claimed protein, the native gene, and the native promoter, although a single nucleotide within that promoter had been changed. The ITC found no infringement because changing a single nucleotide in the promoter did not amount to “replacing the native promoter.” “Later” accused strains did contain alternate promoters, but did **not** contain the specific claimed E. Coli amino acid sequence. The ITC still found infringement of this later strain under the doctrine of equivalents. The ITC also found that the patent had not been proven to lack adequate written description regarding what constitutes a “more potent promoter.”

Both parties appealed, and the Federal Circuit affirmed. The ITC’s claim construction of the “replacement” phrase was correct and does **not** encompass mere changes to individual nucleotides in the promoter. Specification examples and the “ordinary and customary meaning” of “replacing” supported the ITC’s claim construction. Further, the patentee’s narrowing amendment during prosecution acted to “surrender more through amendment than may have been absolutely necessary,” but “there is no principle of patent law that the scope of a surrender of subject matter during prosecution is limited to what is absolutely necessary” to avoid prior art or a 112 rejection. Therefore, the earlier strains that did not “replace” the promoter do not infringe.

On the later strains, the “protein” limitation was met under the doctrine of equivalents’ “function-way-result” test, and prosecution history estoppel did not apply because of the “tangential relation” exception. Although a narrowing amendment is presumed to be a disclaimer of the “territory between the original claim and the amended claim,” the “objectively evident rationale for the amendment” at issue was to limit the set of proteins within the claim’s scope, which had nothing to do with the patentee’s equivalence argument—the choice of DNA sequences that **encode** a particular protein. Further, the Federal Circuit held that there was substantial evidence, including expert testimony, to find the claim limitation met by a non-E. Coli protein through function-way-result equivalence.

Regarding the term “more potent promoter,” the patent was not invalid for lack of written description. The patent disclosed four examples of promoters, and cited to an article providing 14 more. Further, a POSA would have been able to identify others based on the known “correlation” between the strength of the promoter and its distance from the “consensus sequence.” Therefore, the written description for this genus was adequate.

Judge Dyk dissented in part, and would have found that the “very narrow” “tangential relation” exception does not apply, such that there could be no infringement under the DOE of the later strains. In his view, the reason for the amendment at issue was directly related to the alleged equivalent. The claims before the amendment would have encompassed the accused protein, and after the amendment they did not, so as to avoid prior art anticipation.

[A copy of the opinion can be found here.](#)

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