

Keywords: patent infringement, prosecution history estoppel, patent invalidity

General: When a word is changed during prosecution, the change tends to suggest that the new word differs in meaning in some way from the original word.

Ajinomoto Co. v. Int'l Trade Comm'n

United States Court of Appeals for the Federal Circuit

No. 2018-1590, 2018-1629

Decided: August 6, 2019

I. Facts

Ajinomoto Co., Inc. and Ajinomoto Heartland Inc. (collectively, “Ajinomoto”) filed a complaint against CJ CheilJedang Corp., CJ America, Inc., and PT CheilJedang Indonesia (collectively, “CJ”) with the International Trade Commission, alleging that CJ was importing L-tryptophan products produced by strains of *Escherichia coli* bacteria that infringed on Ajinomoto’s U.S. Patent No. 7,666,655. Concerning three groups of *E. coli* strains used by CJ, the Commission found CJ’s first earlier strains did not infringe, but two later strains did infringe, and that the ’655 patent is not invalid for lack of adequate written description.

A. U.S. Patent No. 7,666,655

The ’655 patent claims *E. coli* bacteria that have been genetically engineered to increase production of aromatic L-amino acids, such as L-tryptophan, during fermentation, as well as methods of producing aromatic L-amino acids using such bacteria. Specifically, the patent describes enhancing the *yddG* gene, which encodes for the YddG protein that transports aromatic L-amino acids out of the bacteria cell. When the *yddG* gene is enhanced, the bacteria show an increased production of and increased resistance to aromatic L-amino acids. The ’655 patent describes three ways to enhance the activity of the *yddG* gene: (1) Plasmids containing additional copies of the *yddG* gene can be introduced into the bacterium; (2) Additional copies of the *yddG* gene can be inserted into the bacterial chromosome; (3) A stronger promoter than the one native to the *E. coli yddG* gene can be used. A promoter is a region of DNA that leads to initiation of the first step of DNA based gene expression.

B. CJ’s First Earlier Strains

For this section, the relevant claim in Ajinomoto’s ’655 patent is claim 9 which describes enhancing the *yddG* gene “by replacing the native promoter which precedes the DNA on the chromosome of the bacterium with a more potent promoter.” CJ’s first earlier strains contained both the native *E. coli yddG* gene and the native *E. coli yddG* promoter, except that the first nucleotide of the promoter was changed through chemical mutagenesis, resulting in a stronger promoter.

In August 2017, the administrative law judge (ALJ) issued a final initial determination. The ALJ construed “replacing the native promoter ... with a more potent promoter” to mean “removing the native upstream region of the *yddG* gene and inserting one of a class of promoters that controls expression of a different gene.” Using that construction, the ALJ found that CJ’s earlier strains did not infringe because CJ created the more potent promoter in those strains by mutagenesis of a single nucleotide rather than removal of the entire native promoter and insertion of a new promoter.

In October 2017, the Commission reviewed ALJ’s final initial determination and affirmed its construction of claim 9 and affirmed its finding that Cj’s first earlier strains did not infringe.

C. CJ's Two Later Strains

Regarding CJ's two later strains, the ALJ found that (a) the first later strain did not infringe because Ajinomoto had failed to prove that it met the bacteria had an increased resistance to aromatic L-amino acids, and (b) the second later strain also did not infringe because its non-E. coli YddG protein was not equivalent to the claimed E. coli YddG protein under the doctrine of equivalents. However, the Commission reversed and determined that both of CJ's two later strains were infringing.

D. Patent Invalidity

The ALJ found that claim 20 of the '655 patent is invalid for lack of an adequate written description of the "more potent promoter" limitation incorporated into that claim. However, the Commission found that claim 20 was not proved to lack an adequate written description.

II. Issue

Did the Commission err in finding CJ's first earlier strains did not infringe, but two later strains did infringe, and that the '655 patent is not invalid for lack of adequate written description?

III. Discussion

No, the court affirms the Commission's conclusions on all issues.

A. CJ's First Earlier Strains

Ajinomoto argues that, properly construed, the relevant phrase within claim 9 is not limited to removing the entire native promoter and inserting a new promoter, as the Commission concluded, but encompasses mutagenesis of individual nucleotides within the native promoter. However, the court concludes that the ordinary and customary meaning of the claim language provides support for the Commission's claim construction because "[i]n many contexts, one would not refer to swapping out one small component of a larger unit as 'replacing' the unit or as providing a 'substitute' for the unit, even though the net result is a differently constituted larger unit." *Ajinomoto Co. v. Int'l Trade Comm'n*, No. 2018-1590, 2019 WL 3558560, at *3 (Fed. Cir. Aug. 6, 2019). Additionally, the specification supports this conclusion by referring to the promoter as a unit.

The court finds prosecution history reinforces what is already suggested by the claim language and specification. In the original application, claim 2 referred to enhancing "by alteration of expression regulation sequence of said DNA on the chromosome of the bacterium" which was rejected for lack of an adequate written description and lack of enablement. The applicants amended the claim to recite "replacing the native promoter...with a more potent promoter" and explained the amendment as follows: "Applicants have amended Claim 2...wherein the native promoter for the DNA encoding SEQ ID NO: 2 has been changed by substitution with a more potent promoter."

The court concluded that this is a case where the applicants surrendered more than may have been necessary. The court suggests that to overcome the written-description and enablement rejections, the applicants only needed to narrow their claims from alterations to the overall expression-regulation sequence to alterations to the promoter, instead of "replacing the native promoter." However, the court held that 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 a prior art reference that was the basis for an examiner's rejection; indeed the question is what a person of ordinary skill would understand the patentee to have disclaimed during prosecution, not what a person of ordinary skill would think the patentee needed to disclaim during prosecution.

B. CJ's Two Later Strains

CJ asserts that prosecution history estoppel bars Ajinomoto from relying on the doctrine of equivalents for the second of the two later strains. In *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 740, 122 S.Ct. 1831, 152 L.Ed.2d 944 (2002), the Supreme Court specified three ways the patentee can rebut the presumption that an amendment is a general disclaimer of the territory between the original claim and the amended claim: (1) “[T]he equivalent may have been unforeseeable at the time of the application;” (2) “[T]he rationale underlying the amendment may bear no more than a tangential relation to the equivalent in question;” and (3) “[T]here may be some other reason suggesting that the patentee could not reasonably be expected to have described the insubstantial substitute in question.” *Id.*

In this case, the court found the tangential exception applies. In applying the “tangential relation” exception, the standard is to “ask[] whether the reason for the narrowing amendment was peripheral, or not directly relevant, to the alleged equivalent.” *Id.* Claim 1 originally stated “a protein which comprises an amino acid sequence including deletion, substitution, insertion or addition of one or several amino acids in the amino acid sequence shown in SEQ ID NO:2.” After rejection for a reference for an amino acid sequence different from the SEQ ID NO: 2 but still satisfying the original claim limitations, the applicants amended the claim stating “a protein which comprises an amino acid sequence that is encoded by a nucleotide sequence that hybridizes with the nucleotide sequence of SEQ ID NO:1 under stringent conditions.”

The court concluded that the reason for the narrowing amendment—limiting *the amino-acid makeup of the proteins* included in one of the alternatives covered by the claim—is unrelated to differences among *the several DNA sequences that encode a given protein*. Therefore the court rejected CJ’s contention that prosecution history estoppel precludes the Commission’s finding of infringement under the doctrine of equivalents for the second later strain.

CJ also argues that substantial evidence does not exist to support the finding that both of CJ’s later strains meet the resistance limitation that the bacteria had increased resistance to aromatic L-amino acids. However, the court relies on data and expert testimony and does not find CJ’s argument persuasive.

C. Patent Invalidity

The court rejected CJ’s argument that substantial evidence does not support the Commission’s finding that CJ did not prove lack of an adequate written description.

IV. Conclusion

The court ruled that the Commission was not erroneous in finding CJ’s first earlier strains did not infringe, but two later strains did infringe, and that the ’655 patent is not invalid for lack of adequate written description.

V. Concurrence in Part

Circuit Judge Dyk dissents from the majority’s conclusion that Ajinomoto successfully rebutted the presumption of prosecution history estoppel under the tangential exception as to CJ’s second later strain. The Judge construes the tangential exception more narrowly, arguing that the rationale for the narrowing amendment (avoiding a prior art protein based on its encoding nucleotide sequence that does not meet the newly claimed hybridization requirement) directly relates to the accused equivalent (a protein made by an encoding nucleotide sequence that does not meet the newly claimed hybridization requirement).