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Exception to Prosecution History Estoppel:

Ajinomoto v. International Trade Commission

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A panel decision of the U.S. Court of Appeals for the Federal Circuit this month affirmed a decision of the International Trade Commission (ITC) to exclude certain products of recombinant bacteria from importation into the U.S. based on patent infringement. *Ajinomoto Co., Inc. v. International Trade Commission*, (2018-1590, 2018-1629) (August 6, 2019).

Although there were multiple issues on appeal, this analysis focuses on the single portion on which the three judge panel (Judges Richard Taranto, Kimberly Moore, and Timothy Dyk) disagreed; that portion of the majority opinion relates to the "tangential relation" exception to the presumption that a narrowing amendment disclaims the territory between the original claim and the amended claim. See *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722 (2002). The majority opinion, penned by Judge Taranto, held that the amendment bore no more than a tangential relation to the equivalent in question, therefore prosecution history estoppel did not apply, and the accused product infringed. Judge Dyk disagreed.

Under 19 U.S.C. § 1337(a)(1)(B)(ii), it is unlawful to import articles made by means of a process covered by the claims of a valid and enforceable U.S. patent. Claim 20 of Ajinomoto's patent, U.S. Patent No. 7,666,655, is directed to a method for producing an aromatic L-amino acid by cultivating certain bacteria defined in other claims (claims 9 and 15). CJ Cheiljedang Corp. (CJ) imported L-tryptophan, an aromatic L-

amino acid, into the United States. Ajinomoto asserted that the CJ L-tryptophan was made by one of three strains, each of which met the limitations of one of its claims to recombinant *E. coli* bacteria. Both of the asserted claims to bacteria, claims 9 and 15, define the bacteria similarly as:

- recombinant *E. coli*
- with enhanced activity of a protein which
    - enhances accumulation of an aromatic L-amino acid,
    - makes the *E. coli* resistant to aromatic L-amino acids, and
    - is caused by
        - transformation with a DNA encoding the protein;
        - replacement of the native promoter of the chromosomal gene encoding the protein with a more potent promoter; or
        - introduction and expression of multiple copies of the DNA encoding the protein.

Claims 9 and 15 differ, however, in how they define the "protein." Claim 9 recites that the protein consists of the amino acid sequence of SEQ ID NO: 2 (the *E. coli* wild type YddG protein, an aromatic L-amino acid transporter protein), and claim 15 defines the protein as encoded by a nucleotide sequence which hybridizes with the complement of SEQ ID NO: 1 under defined stringent conditions. (Copies of claims 20, 9, and 15 are appended below.)

CJ imported product made by three different recombinant bacterial strains. An "early" strain contained the native *E. coli yddG* gene with a mutagenized promoter. The court found this strain did not meet all the limitations of claim 9 because, although it had a more potent promoter, the strain was not made by "replacement" of the less potent promoter by the more potent promoter. The product of this strain may be imported into the United States.

A first "late" strain (strain A) contained the native *yddG* gene and was transformed with a non-*E. coli yddG* gene that contained two promoters. This strain was found to meet all the limitations of claim 15, because the non-*E. coli yddG* gene hybridizes to the *E. coli* gene. The product of this strain may not be imported into the United States.

A second "late" strain (strain B) contained the native *yddG* gene and a codon-randomized version of the same non-*E. coli yddG* gene used in strain A. The YddG protein produced by strains A and B were identical, but the codon randomization caused the DNA of strain B not to hybridize under stringent conditions to the native

E. coli gene (SEQ ID NO: 1). Strain B, therefore, did not literally meet all limitations of claim 15. The strains are summarized in the table below.

Strain	Gene	Promoter	Manner of Making
Early	*E. coli yddG*	*E. coli yddG* more potent	mutagenized
First late (strain A)	native *yddG* gene + non-*E. coli, yddG* gene	Native + non-*E. coli* yddG + a different *E. coli* promoter	transformation
Second late (strain B)	native *yddG* gene + a codon-randomized version of the non-*E. coli, yddG* gene	Native + two *E. coli,* non-yddG promoters	transformation

Finding no literal infringement by the L-tryptophan product produced by strain B, the court looked to infringement under the doctrine of equivalents. The court asked whether the non-*E. coli* YddG protein in strain B encoded by the randomized gene nonetheless is an equivalent of the protein-definitional clause in claim 9, *i.e.,* a protein which consists of the amino acid sequence of SEQ ID NO: 2. Ajinomoto persuasively demonstrated that the non-*E. coli* YddG protein met the function-way-result test to be an equivalent of the *E. coli* YddG protein.

CJ asserted that Ajinomoto should not be entitled to the benefit of equivalents of the protein recited in claim 9 because it had made an amendment during prosecution of claim 9's progenitor claim, application claim 1. Application claim 1 recited two alternative conditions for the recited protein:

> (a) a protein which comprises the amino acid sequence of SEQ ID NO: 2; or
> (b) a protein which comprises an amino acid sequence including deletions, substitutions, insertions, or additions of one or several amino acids in the amino acid sequence of SEQ ID NO: 2.

The examiner of the application rejected claim 1 over a reference that taught the *E. coli* YfiK protein, *i.e.,* a different protein, that allegedly anticipated the protein defined in the (b) limitation. Ajinomoto amended the (b) limitation to recite: "a protein which is encoded by a nucleotide sequence that hybridizes with the complement of the nucleotide sequence of SEQ ID NO: 1 under stringent conditions." At the same time, Ajinomoto added new claims 9 and 15, which separately recited the (a) and new (b) limitations, respectively.

CJ asserted that the amendment to the definition of the protein of claim 1 precludes Ajinomoto from successfully asserting that the accused product meets the requirements of the protein of claim 9 under the doctrine of equivalents. In reply, Ajinomoto argued that the claim 9 recitation was not amended during prosecution, so prosecution history estoppel should not prevent application of the doctrine of equivalents. Ajinomoto also urged that the presumption that an amendment disclaims all territory between the original and the amended claims should not apply because the rationale underlying the amendment bore no more than a tangential relation to the equivalent in question, *i.e.,* one of the *Festo* exceptions to the presumption that an amendment creates prosecution history estoppel.

The Federal Circuit majority found that Ajinomoto had rebutted the *Festo* presumption because it showed that the amendment was tangential to the equivalent in question. The majority found that the reason for the amendment was to limit the range of *amino acid* alterations in the protein from what was initially recited in claim 1, alternative (b). The majority found that this was wholly unrelated to limiting the range of *encoding DNA* sequences: "The reason for the amendment had nothing to do with choosing among several DNA sequence in the redundant genetic code that correspond to the protein."[1]

Judge Dyk, in his dissent, found the applicant's reason for the narrowing amendment to be "directly related to the equivalent." The cited prior art protein was excluded by the amendment because its encoding gene did not hybridize to the *E. coli yddG* gene. The accused product is similarly excluded by the amendment because its encoding gene does not hybridize to the *yddG* gene. Thus, the amendment and the equivalent are not merely tangentially related, but are directly related.

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[1] Given that "the protein" is the recited element in claim 15 and the applicant clearly added the hybridization recitation to eliminate the prior art YfiK protein from the scope of the claim, it is difficult for this reader to characterize the reason for the amendment as tangential. The amendment's limitation on nucleotide hybridization would in general correspondingly limit amino acid homology. Rather than recognize this general correlation, the majority seemed to be misled by its notice of a particular deviation from the general correlation. The panel noted that strain A, which contained a native, non-*E. coli yddG* gene produced the same YddG protein as strain B which contained the randomized coding sequence. Yet strain A's gene hybridized to the *E. coli* gene while the randomized sequence of strain B did not. Thus, strain A would have literally infringed claim 15 while strain B would not have. This anomaly is not informative of the applicant's objective reason for making the amendment.

The majority let its analysis of tangential relationship rebutting prosecution history estoppel be diverted from the mandated comparison of (a) the objective reason for the amendment to (b) the accused equivalent. Rather, it compared (c) a literally infringing embodiment (strain A with native, non-*E. coli yddG* gene) to the (b) accused equivalent (strain B with randomized codons for non-*E. coli yddG* gene) and from that comparison purported to derive the reason for the amendment. The result of the majority opinion is an expansion of the exceptions to the presumption of prosecution history estoppel. That constitutes a swing away from the fairly strict application of prosecution history estoppel set out in *Festo* almost 20 years ago.

Click here to read the decision in *Ajinomoto Co., Inc. v. International Trade Commission.*

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Appendix

Claims at issue:
20. A method for producing an aromatic L-amino acid, which comprises cultivating the bacterium according to any one of claims 9-12, 13, 14, 15-18, or 19.

9. A recombinant Escherichia coli bacterium, which has the ability to accumulate aromatic L-amino acid in a medium, wherein the aromatic L-amino acid production by said bacterium is enhanced by enhancing activity of a protein in a cell of said bacterium beyond the levels observed in a wild-type of said bacterium, and in which said protein consists of the amino acid sequence of SEQ ID NO: 2 and said protein has the activity to make the bacterium resistant to L-phenylalanine, fluoro-phenylalanine or 5fluoro-DL-tryptophan, wherein the activity of the protein is enhanced by transformation of the bacterium with a DNA encoding the protein to express the protein in the bacterium, by replacing the native promoter which precedes the DNA on the chromosome of the bacterium with a more potent promoter, or by introduction of multiple copies of the DNA encoding said protein into the chromosome of said bacterium to express the protein in said bacterium.

15. A recombinant Escherichia coli bacterium, which has the ability to accumulate aromatic L-amino acid in a medium, wherein the aromatic L-amino acid production by said bacterium is enhanced by enhancing activity of a protein in a cell of said bacterium beyond the levels observed in a wild-type of said bacterium, and in which said protein is encoded by the nucleotide sequence which hybridizes with the complement of the nucleotide sequence of SEQ ID NO: 1 under stringent conditions comprising 60.degree. C., 1.times.SSC, 0.1% SDS and said protein has the activity to make the bacterium resistant to L-phenylalanine, fluoro-phenylalanine or 5fluoro-DL-tryptophan, wherein the activity of the protein is enhanced by transformation of the bacterium with a DNA encoding the protein to express the protein in the bacterium, by replacing the native promoter which precedes the DNA on the chromosome of the bacterium

with a more potent promoter, or by introduction of multiple copies of the DNA encoding said protein into the chromosome of said bacterium to express the protein in said bacterium.