

# INSIGHT: Patent Disputes— Navigating the Tangential Relation Exception

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*Akin Gump attorneys examine two recent Federal Circuit decisions involving patent disputes. They explain the importance for patent holders to be specific in identifying amendments to any patent claim and offer advice for those challenging the holder.*

In its Aug. 9 decision in *Eli Lilly & Co. v. Hospira Inc.*, the Federal Circuit conveyed that while few “propositions of patent law have been so consistently sustained by the Supreme Court as the doctrine of equivalents,” it remains the exception, and not the rule for every infringement charge.

Nevertheless, the doctrine of equivalents has been a popular topic recently in biotech/pharma cases at the Federal Circuit. The doctrine, which imposes liability for equivalents to patented technology that don’t literally infringe a patent’s claims, has even played a dominant role in at least four recent decisions.

Inventors who apply for a patent are allowed to change claims to address an examiner’s concerns. However, the inventor can’t say at a later date that his or her claims broadly include similar products. This concept, known as prosecution history estoppel, can provide accused infringers with a potent defense against claims asserted under the doctrine of equivalents.

In *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, the U.S. Supreme Court held that a “patentee’s decision to narrow his claims through amendment may be presumed to be a general disclaimer of the territory between the original claim and the amended claim.”

## Presumption Not Absolute

However, the presumption is not absolute—it can be rebutted under certain circumstances.

First, prosecution history estoppel will not apply if the equivalent was unforeseeable at the time of the application.

Similarly, if the rationale underlying the amendment bears no more than a tangential relation to the equivalent in question, a patentee will not be estopped from arguing infringement under the doctrine of equivalents.

And lastly, prosecution history estoppel will not apply if there is some other reason indicating the patentee could not have reasonably expected to describe the equivalent in question.

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## Tangential Relation Test

The Federal Circuit recently issued two decisions applying the tangential relation exception to prosecution history estoppel.

On its face, the tangential relation test appears straightforward. Recognizing that patentees sometimes over-narrow claims during prosecution, it **examines** whether “the reason for the narrowing amendment was peripheral, or not directly relevant, to the alleged equivalent.”

However, its practical application is not so clear.

As a first step, the analysis looks to the prosecution history to identify an objectively apparent reason for the amendment. Once the rationale for the amendment is defined, the analysis turns to whether the alleged equivalent bears a tangential relation to the rationale. Therefore, whether a patentee can make use of the tangential relation exception may ultimately turn on the clarity and conciseness of its statements during prosecution.

## Must Identify What Amendment Is Intended to Disclaim

The Federal Circuit’s recent decision in *Ajinomoto Co. v. Int’l Trade Comm’n* highlights the importance of identifying what the amendment was intended to disclaim, and by extension, what was not within the scope disclaimed.

In *Ajinomoto*, the majority held the patentee successfully rebutted the presumption of prosecution history estoppel under the tangential relation exception over Judge Timothy B. Dyk’s dissent. The difference between the majority and dissenting positions centered on how each defined the rationale for the amendment.

According to the majority, the “objectively evident rationale” for the amendment was to exclude *a protein* disclosed in the prior art by redefining the claimed characteristics. Dyk defined the reason underlying the amendment more broadly. In his view, the patentee amended the claims to exclude *all proteins*, including the accused equivalent, that do not meet the amended limitation.

The Federal Circuit reached a similar conclusion days later in its *Hospira* decision. The original claims in that case broadly covered methods of administering antifolates, a class of antineoplastic molecules. The patentee amended the claims to cover only a particular antifolate, pemetrexed disodium, in order to exclude methotrexate, another antifolate found in the prior art. Lilly sued Hospira and others for infringement under the doctrine of equivalents for their proposed use of pemetrexed ditromethamine.

There again, the court held that prosecution history estoppel did not bar Lilly’s infringement claim under the doctrine of equivalents because the reason for the amendment, to exclude methotrexate, bore only a tangential relation to the accused product. In other words, Lilly did not amend its claims to cede other, functionally identical, pemetrexed salts.

## Consistent Theme

If there is one consistent theme in the Federal Circuit’s recent decisions, it is the importance of having an objectively identifiable reason for claim amendments that does not encompass the claimed equivalent.

The Federal Circuit has **previously held** that nonsubstantive reasons, such as to “facilitate prosecution,” do not help the analysis.

Likewise, the Federal Circuit has **rejected** the argument that amendments only cede those embodiments disclosed in the prior art where the prosecution history indicated more subject matter was disclaimed.

Thus, when amending claims in prosecution, it may be useful to provide a specific, but narrowly-tailored, basis for the amendment that tracks the rejection at issue. And when invoking the tangential relation exception in litigation, it is important to provide context for the amendment by direct reference to the prosecution history.

On the other hand, litigants tasked with countering the tangential relation exception must focus their arguments on drawing a connection between the alleged equivalent and the specific subject matter of the rejection that triggered the amendment. As in the *Ajinomoto* case, such an analysis is likely to turn on how a court defines the patentee’s intent when the amendment was entered.

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