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Will the Supreme Court choose to weigh in (again) on prosecution history estoppel?

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It's been almost 20 years since the U.S. Supreme Court, in *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722 (2002), created exceptions to the U.S. Court of Appeals for the Federal Circuit's strict application of prosecution history estoppel to limit the doctrine of equivalents.[1]

Prior to *Festo*, any narrowing claim amendment during prosecution resulted in a presumptive loss of equivalents to the narrowed limitation.

Based on *Festo*, patentees can argue that estoppel should not arise from a particular claim amendment because "the rationale underlying the amendment may bear no more than a tangential relation to the equivalent in question."[2]

While the Federal Circuit has called the tangential exception "very narrow,"[3] in the past year the Supreme Court has permitted several patentees to rely on it to prove infringement under the doctrine of equivalents.[4]

One of those cases, *Eli Lilly & Co. v. Hospira Inc.*, 933 F.3d 1320 (Fed. Cir. 2019), is currently being considered by the Supreme Court.

If the justices take the case, they could provide further guidance on, and potentially cabin, the tangential exception and other aspects of *Festo*.

DOCTRINE OF EQUIVALENTS & PROSECUTION HISTORY ESTOPPEL

The doctrine of equivalents is a court-created rule that enables patent owners to ensnare accused infringers with products that do not literally match a patent's claims, but nonetheless use an "equivalent" of a claimed feature.[5]

Prosecution history estoppel serves to limit infringement claims based on the doctrine of equivalents by preventing a patentee from recapturing subject matter surrendered during prosecution.[6]

The Federal Circuit has stipulated that estoppel can arise "either (1) by making a narrowing amendment to the claim ('amendment-based estoppel') or (2) by surrendering claim scope through argument to the patent examiner ('argument-based estoppel')."[7]

The Supreme Court in in *Festo* said that, where a narrowing amendment is made, the patentee subsequently bears the burden to show that the amendment was not for purposes of patentability, and "[w]hen the patentee is unable to explain the reason for amendment, estoppel not only applies but also 'bar[s] the application of the doctrine of equivalents as to that element.'"[8]

The high court also said it has "consistently applied the doctrine [of prosecution history estoppel] in a flexible way, not a rigid one."[9]

CREATION AND GROWTH OF THE TANGENTIAL EXCEPTION

The tangential exception doctrine is rooted in the *Festo* decision. One of the questions before the Supreme Court was how rigorous of a standard should apply when prosecution history estoppel arises.[10]

In the *Eli Lilly* dispute currently pending high court review, the Federal Circuit held that "when estoppel arises, it bars suit against every equivalent to the amended claim element."[11]

The Supreme Court found that the Federal Circuit's per se rule of a complete bar was inconsistent with the purpose of applying prosecution history estoppel in the first place, "to hold the inventor to the representations made during the application process and to the inferences that may reasonably be drawn from the amendment."[12]

The Supreme Court also held that "the patentee should bear the burden of showing that the amendment does not surrender the particular equivalent in question."[13]

And in elaborating on its guidance, the Supreme Court provided three examples of equivalents that could nonetheless infringe a claim element that had undergone amendment:

> The equivalent may have been unforeseeable at the time of the application; the rationale underlying the amendment bears no more than a tangential relation to the equivalent in question; or there may be some other reason suggesting that the patentee could not reasonably be expected to have described the insubstantial substitute in question.[14]

On remand, the Federal Circuit interpreted the Supreme Court's tangential exception as a determination of "whether the reason for the narrowing amendment was peripheral, or not directly relevant, to the alleged equivalent."[15]

In the years since *Festo*, the Federal Circuit has analyzed the tangential exception doctrine in a handful of cases each year, with the focus of the inquiry turning on the patentee's objectively apparent reason for a narrowing amendment, based on the prosecution history.[16]

However, the past two years have seen an uptick in cases at the Federal Circuit in which patentees have relied on the tangential exception doctrine first outlined in *Festo*.

While the Federal Circuit has called the tangential exception "very narrow," in the past year the Supreme Court has permitted several patentees to rely on it to prove infringement under the doctrine of equivalents.

Notably, the Federal Circuit affirmed a decision finding the tangential exception permitted Eli Lilly to broaden a patent claim that covered a Food and Drug Administration-approved method-of-use for its Alimta (pemetrexel disodium) product,[17] which garnered over $1.2 billion in U.S. sales in 2019.[18]

The two accused infringers — Hospira (a subsidiary of Pfizer) and Dr. Reddy's Labs — filed separate certiorari petitions asking the Supreme Court to review the Federal Circuit's application of the tangential exception doctrine in that case.

WHY THE SUPREME COURT MAY CHOOSE TO REVISIT *FESTO*

The Federal Circuit and district courts need guidance to correctly analyze equivalents under Festo

If either petition is granted, this will likely be because the Supreme Court believes the lower courts need guidance to correctly analyze equivalents under *Festo*.

To wit, Hospira's petition focuses on how the Federal Circuit's decisions since *Festo* have created a flawed process to analyze equivalents, which results in incorrect outcomes.

According to Hospira, the Federal Circuit has "hardened" the *Festo* decision into "a three-part test, in which a patentee may refute the presumption of prosecution history estoppel via either the 'unforeseeable' exception; the 'tangential relation' exception; or the 'some other reason' exception."[19]

This, Hospira contends, is because the Federal Circuit has effectively ignored *Festo*'s holding as a whole, under which "the patentee must show that at the time of the amendment one skilled in the art could not reasonably be expected to have drafted a claim that would have literally encompassed the alleged equivalent."[20]

Hospira aptly notes that Lilly could have drafted a claim that literally encompassed the salt form of pemetrexed used in Hospira's product, but chose instead to more narrowly amend its claim to recite only the specific pemetrexed salt that Lilly uses in Alimta.[21]

According to Hospira, the Federal Circuit's inquiry incorrectly focused on Lilly's intent in amending its claims rather whether Lilly could have drafted a claim at the time that would have encompassed Hospira's equivalent.[22]

Further, Dr. Reddy's petition notes that the Federal Circuit has developed two fundamentally irreconcilable approaches to evaluating whether a narrowing claim amendment is tangential to the alleged equivalent. Under the first approach, "the 'tangential exception' applies when an amendment adds multiple limitations to a claim at the same time, and not all relate to the examiner's rejection."[23]

In such a case, the tangential exception may apply to added limitations unrelated to the examiner's rejection, but not "where the alleged equivalent and the reason for the amendment both concern the same claim element."[24]

Under the Federal Circuit's second approach, the Federal Circuit wrongly bases the tangential exception on "a post hoc assessment of what the patent applicant needed to surrender to avoid an examiner's rejection."[25]

In such cases, "panels begin by phrasing the 'reason' for the disputed narrowing amendment as surrendering only what was necessary to avoid a specific rejection — often to distinguish a particular piece of invalidating prior art."[26]

It follows that these panels do not account for applicant's choice of what to relinquish in response to the examiner's rejection, but instead take the approach that unnecessarily surrendered claim scope is "tangential" to that reason.[27]

The Supreme Court has often criticized the Federal Circuit's willingness to create overly rigid frameworks for analyzing what are, admittedly, complex questions of law.[28]

Some have attributed this to the Federal Circuit's willingness to provide guidance and standards for the district courts to follow.

If the justices choose to revisit *Festo*, this will likely be because they believe the Federal Circuit has created too rigid of a framework, or an incorrect framework, for analyzing equivalents.

Patent applicants and the public need guidance to better define scope of patent rights

A second, related reason that the Supreme Court may revisit *Festo* is to provide guidance for patent applicants and the

public to better define the scope of a patent owner's property right.

A patent claim is a right to exclude others, and patent owners would be well-served by further Supreme Court guidance that more clearly defines the effect of narrowing claim amendments on one's ability to enforce a patent.

Indeed, the Federal Circuit noted over 20 years ago that "a vanishingly small" percentage of patent claims directed to complex inventions are allowed to issue without amendment.[29]

And Hospira notes in its certiorari petition that in the past two years, district court and appellate cases are constantly grappling with the question of whether a narrowing amendment was tangential to the allegedly infringing equivalent.[30]

Patent owners would benefit from having clearer guidance on the metes and bounds of their patent claims and the ability to enforce those claims against others before expending significant money in litigation.

Similarly, the public notice function of a patent's prosecution record is undermined when those who attempt to design around a patent's claims are nonetheless confounded by claims of patent infringement.

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Hospira argues that the current test that the Federal Circuit uses to evaluate equivalents is nothing more than an open invitation for patentees to engage in bait-and-switch tactics in which narrowing amendments are made to obtain allowance of a patent claim, and then that claim scope if recaptured during litigation.[31]

Those attempting to design around patent claims would benefit greatly from further Supreme Court guidance that highlights the presumptive effect of narrowing claim amendments.

Court recognizes the politics of the moment

Finally, the Supreme Court is not insulated from the politics of the moment and branded pharmaceutical companies such as Lilly have been under enormous scrutiny for "patent evergreening" strategies that forestall generic entry until long after the first patents on a new drug have expired.

As Hospira notes in its certiorari petition, the applicability of the tangential exception was at issue in several pharmaceutical patent cases in the past year.[32]

Cabining the "tangential exception" to instances in which a patentee could not have drafted a claim during prosecution that would have encompassed an accused generic equivalent would result in fewer legitimate lawsuits being filed, or generic companies winning dismissals on the pleadings.

Conversely, if the "post hoc approach" (as Dr. Reddy's framed it), becomes the standard for applying the tangential exception, patent owners can reevaluate their patent portfolio for creative ways to assert infringement claims under the doctrine of equivalents.

And companies looking to develop a generic product will need to adjust their approach early on with the understanding that a particular salt form, or formulation, that was once considered a rock-solid permissible alternative may now be deemed by a court to be an infringing equivalent.

Regardless, without Supreme Court intervention, we are likely to see courts continue to apply the tangential exception in a varied and unpredictable way.

Notes

1 *See* 535 U.S. 740-41 (2002).

2 *Id.*

3 *See, e.g., Cross Med. Prods. v. Medtronic Sofamor Danek Inc.*, 480 F.3d 1335 (Fed. Cir. 2007).

4 *See Eli Lilly & Co. v. Hospira Inc.*, 933 F.3d 1320 (Fed. Cir. 2019); *Ajinomoto Co. v. U.S. Int'l Trade Comm'n*, 932 F.3d 1342 (Fed. Cir. 2019); *Pharma Tech Sols. Inc. v. LifeScan Inc.*, 942 F.3d 1372 (Fed. Cir. 2019); *Amgen Inc. v. Amneal Pharms. LLC*, 945 F.3d 1368 (Fed. Cir. 2020).

5 *Winans v. Denmead*, 56 U.S. 33 (1853).

6 *Trading Techs. Int'l Inc. v. Open E Cry LLC*, 728 F.3d 1309 (Fed. Cir. 2013).

7 *Pharma Tech Sols. Inc.*, 942 F.3d at 1380, citing *Conoco Inc. v. Energy & Envtl. Int'l L.C.*, 460 F.3d 1349, 1363 (Fed. Cir. 2006).

8 *Festo*, 535 U.S. at 740 (quoting *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17 (1997)).

9 *Id.*

10 *Id.* at 728.

11 *Id.*

12 *Id.* at 738.

13 *Id.* at 740.

14 *Id.* at 740-41.

15 *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 344 F.3d 1359 (Fed. Cir. 2003).

16 *Integrated Tech. Corp. v. Rudolph Techs. Inc.*, 734 F.3d 1352 (Fed. Cir. 2013), citing *Festo*, 344 F.3d at 1369.

17 *Eli Lilly & Co.*, 933 F.3d at 1336.

18 *See, e.g., Lilly Reports Strong Fourth-Quarter and Full-Year 2019 Financial Results*, UPDATES 2020 GUIDANCE FOR PENDING DERMIRA ACQUISITION, ELI LILLY & CO. (Jan. 30, 2020), https://investor.lilly.com/news-releases/news-release-details/lilly-reports-strong-fourth-quarter-and-full-year-2019-financial.

[19] *Hospira Inc. v. Eli Lilly & Co.*, No. 19-1058, *petition for cert. filed* (U.S. Feb. 24, 2020).

[20] *Id.* (quoting *Festo*, 535 U.S. at 741).

[21] *Id.* at 6.

[22] *Id.* at 19-20.

[23] *Dr. Reddy's Labs Ltd. v. Eli Lilly & Co.*, No. 19-1061, *petition for cert. filed* (U.S. Feb. 24, 2020).

[24] *Id.*

[25] *Id.*

[26] *Id.*

[27] *Id.*

[28] *See*, e.g., *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398 (2007) ("The Federal Circuit addressed the obviousness question in a narrow, rigid manner that is inconsistent with Section 103 and this court's precedents"); see also *Festo*, 535 U.S. at 738 ("While this court has not weighed the merits of the complete bar against the flexible bar in its prior cases, we have consistently applied the doctrine in a flexible way, not a rigid one.").

[29] *See Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 234 F.3d 558 (Fed. Cir. 2000) (Newman, J., concurring in part and dissenting in part).

[30] *See supra* note 19

[31] *Id.*

[32] *See*, e.g., *Amgen Inc. v. Amneal Pharms. LLC*, 945 F.3d 1368 (Fed. Cir. 2020); *Pharma Tech Sols. Inc.*, 942 F.3d at 1380; *Ajinomoto Co.*, 932 F.3d at 1355; *Water Tech. v. Kokido Dev.*, 2020 WL 418549 (E.D. Mo. Jan. 27, 2020); *iCeutica Pty Ltd. v. Lupin Ltd.*, 2018 WL 656447 (D. Md. Feb. 1, 2018).

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