IP Alert | Federal Circuit: More than a Tangential Relation Permits Prosecution History Estoppel to Block Finding of Infringement

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Last month, the U.S. Court of Appeals for the Federal Circuit declined to apply the tangential relation exception to prosecution history estoppel in Pharma Tech Solutions' infringement suit regarding LifeScan's blood glucose meter for home use.[1]

Following the Eli Lilly and Ajinomoto cases earlier in 2019,[2] in which the Federal Circuit applied the tangential relation exception, the court has now declined to apply the exception, preventing it from overtaking the rule. However, the court in Pharma Tech did not provide a clear test for determining when the exception applies.

Background

Pharma Tech asserted that LifeScan's blood glucose meter infringed two of its patents (U.S. 6,153,069 and 6,413,411) under the doctrine of equivalents. During prosecution, Pharma Tech amended its claims to include recitations of means for (1) measuring a Cottrell current (a diffusion limiting electric current) at a first and a second time, (2) converting the two current measurements to analyte concentrations, and (3) linearly comparing the two analyte concentrations. Pharma Tech not only added these recitations to the claims by amendment but also used them in arguments to distinguish over the prior art.

LifeScan's accused infringing blood glucose meter does not measure Cottrell currents and does not compare analyte concentrations. Therefore, the LifeScan blood glucose meter is outside the literal scope of the amended claims. LifeScan argued that doctrine of equivalents was not available to

Pharma Tech to reach equivalents of the amended elements, because prosecution history estoppel bars the application of the doctrine of equivalents in this case.

Pharma Tech identified a relevant equivalent as a system that (a) measures current at two different times, (b) compares the currents to ensure they are within a prescribed percentage of each other, and (c) converts the current readings to a glucose concentration. This equivalent would encompass LifeScan's blood glucose meter, it asserted.

Court's Opinion

Circuit Judges Kimberly Moore, Jimmie Reyna, and Kara Stoll decided the case, with Judge Stoll writing the opinion. The Federal Circuit panel began its analysis by pointing out that the purpose of prosecution history estoppel is to prevent a patentee from using the doctrine of equivalents to recapture subject matter surrendered from the literal scope of the claims during examination.

Prosecution history estoppel, the court explained, can be generated either by a patent applicant's narrowing claim amendment or by its arguments to the patent examiner. Territory between an original and narrowed claim is presumed to be disclaimed by the patentee. The presumption can be overcome, however, by showing that (1) the equivalent was unforeseeable, (2) the rationale for the amendment is only tangentially related to the equivalent, or (3) some other reason that the patentee would not have reasonable been expected to describe the equivalent.[3]

Consideration of argument-based estoppel and exceptions to the presumption of surrender should be made from the objective point of view of a competitor, the court explained. These should be clear from the record of the prosecution of the patent application. Both argument-based and amendment-based estoppel can occur even if the particular amendment or argument was not required to gain allowance, the court explained, citing its own precedent over the past 10-15 years. For example, a patentee may have disclaimed more than is necessary, but will nonetheless be estopped from asserting equivalents. A patentee's simple regret at its prosecution choices does not create an exception to prosecution history estoppel.

To assess argument-based estoppel, the Pharma Tech panel evaluated whether the prosecution history evinces a clear and unmistakable surrender of blood glucose meters that do not convert and compare analyte concentration measurements. The panel found the inventors' remarks accompanying the amendment clearly indicated that the amendment was made to distinguish over prior art — specifically, that the prior art did not compare analyte concentration measurements converted from current readings. The panel opinion quotes repeated instances in the prosecution history where Pharma Tech used the language of the recitations added by amendment to distinguish over the cited prior art. The panel found these instances created argument-based estoppel.

To assess whether the tangential relation exception applied, the panel compared the objectively apparent rationale underlying the amendment and the accused infringing product of LifeScan. The same arguments that created argument-based estoppel also provided the panel with an objectively apparent rationale for the amendment that negated Pharma Tech's assertion that the various amendments were merely tangential to the equivalents in question.

Distinguishing Previous Decisions

Distinguishing the facts in the case at hand from the Federal Circuit's 2004 Insituform decision, which applied the tangential relation exception, the panel noted that the prosecution history of the patent in Insituform did not provide any relationship between the narrowing amendment (one-cup vacuum process) and the accused equivalent (multiple-cup process).[4] The Insituform court found a rationale for the amendment in the prosecution history that did not require a single cup.

The panel also distinguished its 2019 Eli Lilly case in which the tangential relation exception was applied. The patentee narrowed its claim from reciting an antifolate generally to reciting a particular salt of a particular anti-folate, i.e., permetrexed disodium. The accused equivalent was a different salt of the same anti-folate, i.e., permetrexed ditromethamine. The court found only a tangential relation between the rationale for the amendment and the accused equivalent. The panel explained that the cited prior art was a different anti-folate, methotrexate, but not a different salt of permetrexed. (Click here to read a previous Banner Witcoff alert on this decision).

Finally, the panel distinguished its 2019 Ajinomoto case. In Ajinomoto, the applicant narrowed the scope of a recited E. coli YddG protein to avoid prior art E. coli YfiK protein. It amended from a recitation of an amino acid sequence with unspecified possible modifications to a recitation of a YddG protein encoded by a nucleotide sequence that hybridzes with the E. coli yddG gene sequence. Focusing on the amendment to recite nucleic acid sequences, the Ajinomoto panel deemed the amendment not more than tangentially related to the accused equivalent non-E. coli YddG protein encoded by a codon-randomized sequence for the non-E. coli YddG protein.[5] (Click here to read a previous Banner Witcoff alert on this decision).

In contrast to the Insitutform, Eli Lilly, and Ajinomoto cases, the Pharma Tech panel held that the rationale for the Pharma Tech amendment directly related to the accused equivalent. In this case, Pharma Tech's arguments distinguishing over the prior art may have made the rationale for its amendment easy to discern. However, in general, the tangential relation test seems difficult to apply because it involves categorizing and boundary-defining.[6] Will a court define the issue necessitating an amendment narrowly or broadly? Although the exercise of finding not more than a tangential relationship requires comparing the rationale for the narrowing amendment to the asserted equivalent, the prior art also seems to play a key but tacit role in how broadly a court defines the issue necessitating the amendment. The determination of tangentiality seems to turn

on the distance between the accused equivalent and the prior art. The closer the accused equivalent is to the prior art, the harder it becomes to define the issue necessitating the amendment as excluding the accused equivalent. The closer the accused equivalent is to the prior art, the more likely it is that a court will find more than a tangential relationship to the reason for the amendment.

The court's opinion in Pharma Tech Solutions, Inc. v. LifeScan, Inc., can be viewed here.

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[1] Pharma Tech Solutions, Inc. v. LifeScan, Inc., (2019-1163) (Fed. Cir.) (Nov. 22, 2019)

[2] Eli Lilly and Co. v. Hospira, Inc., 933 F. 3d 1320 (Fed. Cir. 2019); Ajinomoto Co. v. Int'l. Trade Comm'n, 932F.3d 1320 (Fed. Cir. 2019)

[3] Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co. Ltd., 525 U.S. 722 (2002)

[4] Insituform Technologies, Inc. v. CAT Contracting, Inc., 385 F.3d 1360 (Fed. Cir. 2004)

[5] The parties in Ajinomoto filed petitions for rehearing and rehearing en banc on the proper application of the tangential relation exception. The panel and the regular active service circuit judges denied the rehearing petitions on November 25, 2019.

[6] See J. Dyk's dissent in Ajinomoto, supra.

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