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Federal Circuit's Decision in Eli Lilly v. Hospira May Signal Possible Pro-Patentee Swing

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Two opinions and three judges do not necessarily make a trend, nonetheless, one could suspect that the prosecution history estoppel pendulum is beginning to swing in a more liberal direction for patentees.

Three days after the U.S. Court of Appeals for the Federal Circuit handed down its decision in *Ajinomoto v. ITC,* (2018-1590, 2018-1629) (August 6, 2019), it released an opinion in *Eli Lilly and Co. v. Hospira, Inc.*, (2018-2126, 2018-2127) (August 9, 2019). In both cases, the court held that an amendment made by an applicant during examination bore no more than a tangential relation to the equivalent at issue. Therefore, the amendment in each case — which excluded the equivalent from the literal scope of the claim — did not bar the court from applying the doctrine of equivalents and finding infringement.

Under *Festo,*[1] prosecution history estoppel limits infringement under the doctrine of equivalents when a patent applicant narrows the scope of its claims for a reason substantially related to patentability. A presumption arises that the application has surrendered all equivalents within the territory between the original and the amended claim. A patentee can successfully rebut the presumption if the rationale for its amendment bore no more than a tangential relation to the equivalent in question.[2]

[1] *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 344 F.3d 1359, 1366-67 (Fed. Cir. 2003) (en banc).
[2] *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 740 (2002).

The *Eli Lilly* case arose out of the filings of New Drug Applications (NDA) by parties Hospira and Dr. Reddy's Laboratories. Eli Lilly sued the two NDA filers, alleging that their filings constituted acts of infringement of its U.S. Patent 7,772,209 (the '209 patent) under 35 U.S.C. § 271 (e)(2). Eli Lilly's patent protects use of the drug Alimta® (pemetrexed disodium) when administered after administration of folic acid and a methylmalonic acid-lowering agent. The pre-treatments reduce the severe hematological and immunological side effects of pemetrexed, an antifolate, taken alone.

During examination of the application which resulted in the '209 patent, Eli Lilly amended generic claim term "antifolate" to "pemetrexed disodium," arguing that this amendment overcame a prior art reference that did not disclose "pemetrexed disodium." The two NDA filers sought approval to market a different salt of pemetrexed, a ditromethamine salt.

The Federal Circuit reversed the U.S. District Court of the Southern District of Indiana's finding that administration of pemetrexed ditromethamine literally meets the claim recitation of administration of pemetrexed disodium. The district court had relied on the ionization of the ditromethamine salt in sodium chloride solution to yield the same ionic species as pemetrexed disodium in solution. The appellate court found that despite ionization in solution, administration of a solution of pemetrexed ditromethamine does not meet the claim limitation of administration of pemetrexed disodium. Therefore, the court held that the filing of the NDAs did not constitute literal infringement.

Having found no literal infringement, the Federal Circuit then reviewed the district court's finding of infringement under the doctrine of equivalents. The Federal Circuit affirmed the district court's holding that the reason for Eli Lilly's amendment of "antifolate" to "pemetrexed disodium" was to distinguish pemetrexed from antifolates generally, and the recitation of a salt type was merely tangential to that purpose. The object of the amendment was to avoid the cited prior art disclosure of antifolates, the court stated, and the particular recited salt is only tenuously related to that object.

The Federal Circuit addressed its prior, seemingly harsh, statements about application of the tangential exception, such as, that applicant's remorse at ceding too much territory does not trigger application of the exception. While it acknowledged such tough statements as generally true, the existence of the U.S. Supreme Court-mandated tangential exception requires looking into the purpose of the amendment in the context of the prosecution history. The Federal Circuit found analogies to other cases to be unhelpful. Rather, it directly applied the framework

from the Supreme Court to the specific record in this case. The Federal Circuit also cited Supreme Court statements that the doctrine of prosecution history estoppel is an equitable in nature and must be flexibly applied. The doctrine, according to the Federal Circuit's own precedent, is "resistant to rigid legal formulae" and "there is no hard-and-fast test" for determining a tangential relation.

The *Eli Lilly* panel included Judges Alan Lourie, Kimberly Moore, and Richard Taranto. The *Ajinomoto* panel included Judges Timothy Dyk, Kimberly Moore, and Richard Taranto. In *Ajinomoto,* Judge Dyk dissented from the portion of the majority opinion pertaining to the tangential relation exception to the doctrine of equivalents. Therefore, all told, only three judges out of the full court's 18 judges were involved in this possible pro-patentee swing.

Two opinions by four Federal Circuit judges within three days does not necessarily make a trend. Nonetheless, we should be alert to the possibility that a warm breeze may be melting some of the ice surrounding prosecution history estoppel.

Click here to view the Federal Circuit's decision in *Eli Lilly and Co. v. Hospira, Inc.,* and here for its opinion in *Ajinomoto Co., Inc. v. International Trade Commission.*

To read an August 26 Banner Witcoff alert analyzing the court's decision in *Ajinomoto v. ITC*, click here.