ELI LILLY AND COMPANY v. TEVA PARENTERAL MEDICINES, INC., Appeal No. 2015-2067 (Fed. Cir. January 12, 2017). Before Prost, Newman and Dyk. Appealed from S.D. Ind. (Judge Pratt).

Background:

Eli Lilly holds a patent relating to methods of administering a chemotherapy drug. The independent claims of the patent include a step of administering folic acid in addition to other components. Defendants had filed an ANDA for a generic version of the chemotherapy drug that would be administered in a manner consistent with the method claims of the patent. Both Eli Lilly and the defendants agree that the steps of the claims are not all provided by a single actor. In this case, the step of administering folic acid is done by patients, whereas the other steps are administered by physicians.

The district court held a bench trial applying the law from *Akamai V*, and held that while there was no single actor performing the infringement, the acts of the patients can be attributed to the physicians, and there exists sufficient evidence for induced infringement.

Issue/Holding:

Did the district court err in finding induced infringement of Eli Lilly's method claims? No, affirmed.

Discussion:

The Federal Circuit indicated when no single actor performs all steps of a method claim, direct infringement, upon which induced infringement must be predicated, only occurs if the acts of one are attributable to the other such that a single entity is responsible for the infringement. The Federal Circuit first discussed its *Akamai V* analysis, and indicated that for a case of direct infringement to exist here, the physicians must direct or control their patients' administration of folic acid. This occurs in circumstances in which the actor (1) conditions participation in an activity or receipt of a benefit upon others' performance of one or more steps of the patented method, and (2) establishes the manner or timing of that performance.

The Federal Circuit found that the receipt of the treatment method is necessarily conditioned on folic acid administration, as this will reduce the toxicities of one of the drugs. Further, an expert argued that the drugs would not be safe without also taking folic acid. This was enough to satisfy the first prong of the analysis. The Federal Circuit indicated that the product labeling, which instructs physicians to tell patients to take a particular amount of folic acid for a particular duration, satisfies the second prong. Thus, direct infringement was identified.

Further, the labeling and warnings confirm specific intent and action to induce infringement, and thus, the Federal Circuit held that the District Court did not err, and defendants' distribution of the drug with the product labeling would induce infringement of the asserted claims of the patent.