DAIICHI SANKYO CO, LTD. v. LEE, Appeal No. 2014-1280 (Fed. Cir. July 3, 2015). Before Moore, Reyna, and Taranto. Appealed from D.D.C. (Judge Roberts).

Background:

In 2010, the Federal Circuit issued the *Wyeth* decision that held that the PTO's "greater of A delay or B delay" rubric to calculate PTA was contrary to statute, and that the correct calculation is A delay plus B delay, minus the number of days on which A delay and B delay occurred on the same day. See our January 22, 2010 Special Report for more details.

Shortly thereafter, the PTO implemented an interim procedure for requesting reconsideration of PTA in view of the *Wyeth* decision. Under that procedure, the request could be filed up to 180 days after the issuance date, provided the sole basis for the request was to correct the calculation error addressed in *Wyeth*. The net result of the filing window made the interim procedure available for patents that issued from August 5, 2009 to March 1, 2010.

Daiichi owns two patents to pharmaceuticals that issued before August 5, 2009, and thus did not qualify for the interim procedure. Daiichi claims that the term of each patent was shortened by at least 321 days under the pre-*Wyeth* calculation method. Shortly after the *Wyeth* decision, but before the PTO implemented its interim procedure, Daiichi filed a request for reconsideration of the PTA for both patents, and concurrently filed a petition to waive the two-month window set for requesting reconsideration of PTA. The PTO dismissed the waiver petitions and the requests for reconsideration of PTA. Daiichi then filed suit in the district court.

Daiichi argued that: (1) its challenge to the final PTA determination for its patents is not subject to the 180-day limitation period of §154(b)(4)(A), but is instead subject to the regular six-year statute of limitations of the APA; (2) even if the 180-day period does apply, that period should be equitably tolled; and (3) because statute allows the PTO to correct mistakes in a patent whenever they occur via a Certificate of Correction, the PTO's importation of the 180-day period limitation for its interim procedure after the *Wyeth* decision was overly restrictive, and thus arbitrary, capricious, and not in accordance with the law.

The district court rejected each of Daiichi's arguments. It found that (1) final PTA determinations are subject to the 180-day limitation period of §154(b)(4)(A); (2) Daiichi could have brought a lawsuit making the same arguments that Wyeth did within the 180-day period, yet failed to do so—thus, Daiichi had not shown the existence of extraordinary circumstances, a prerequisite for equitable tolling; and (3) the PTO's refusal to suspend the 180-day filing period of the interim procedure was not contrary to law. The district court granted summary judgment to the government. Daiichi appealed.

Issue/Holding:

Did the district court err in granting summary judgment to the government? No, affirmed.

Discussion:

The Federal Circuit found that the PTO's consistent treatment of all patents issuing prior to the availability of the interim procedure, and its selection and use of the 180-day administrative review period were not arbitrary and capricious actions. The Federal Circuit also held that Daiichi was not entitled to equitable tolling of the judicial review period.