MOMENTA PHARMACEUTICALS, INC. v. TEVA PHARMACEUTICALS USA INC., Appeal Nos. 2014-1274, -1276, -1277, -1278 (Fed. Cir. November 10, 2015). Before Dyk, Moore, and Wallach. Appealed from D. Mass. (Judge Gorton).

Background:

In a pair of companion cases, Momenta sued Teva and Amphastar (a collection of pharmaceutical companies) under 35 USC §§271(a) (Amphastar) and 271(g) (Teva and Amphastar) for allegedly infringing its patented process for testing batches of the anticoagulant drug enoxaparin for compliance with U.S. quality requirements. The companies compete to supply generic forms of enoxaparin to the U.S. market. Teva *imports* enoxaparin and uses the testing method to *sort* for batches of sufficient quality to enter the U.S. market. Amphastar *manufactures* enoxaparin *within* the U.S., and uses the test as *intermediate* and *final* steps to sort its batches.

The district court granted summary judgment in favor of Teva and Amphastar, holding that their activities fell within safe harbor provisions of 35 USC §271(e)(1) by being performed "solely for uses reasonably related to the development and submission of required information under Federal law," and further holding that neither defendant infringed under 35 USC §271(g) because neither imported a product that was "made by" a process patented in the U.S.

Issues/Holdings:

Did the district court err in granting summary judgment that: (i) there was no infringement under 35 USC § 271(a) because Amphastar's activities for testing drug batches fell within the safe harbor provisions of 35 USC §271(e)(1); and (ii) neither party infringed under 35 USC §271(g)? Yes. Affirmed in part; remanded in part.

Discussion:

The Federal Circuit first affirmed the district court's summary judgment granting of non-infringement under §271(g) because neither Teva nor Amphastar *made* enoxaparin by the patented process. The Court stated "[T]he ordinary meaning of 'made' as used in § 271(g) means 'manufacture,' and extends to the creation or transformation of a product, such as by synthesizing, combining components, or giving raw materials new properties. However, 'ma[king]' does not extend to testing to determine whether an already synthesized drug substance possesses existing qualities or properties." Because alleged infringement under §271(g) was the only issue regarding Teva, and summary judgment of non-infringement had been affirmed, the district court's holding regarding safe harbor provisions was moot with respect to Teva.

The Federal Circuit then considered the scope of the safe harbor provisions under §271(e)(1) with respect to Amphastar's activities under §271(a). The Court held that the safe-harbor provision was inapplicable in this case, because use of the testing process was not for developing and submitting required information under Federal law. The Court held that "[t]he routine quality control testing of each batch of generic enoxaparin as part of the post-approval, commercial production process is therefore not 'reasonably related to the development and submission of information' to the FDA, and it was clearly erroneous to conclude otherwise." The court then remanded Amphastar's summary judgment to determine whether its *routine* use of the process for quality control purposes infringed under §271(a).