THE MEDICINES COMPANY v. MYLAN, INC., Appeal Nos. 15-1113, 15-1151, 15-1181 (Fed. Cir. April 6, 2017). Before Dyk, Wallach, and Hughes. Appealed from N.D. Ill. (Judge Eve).

Background:

The Medicines Company ("Medicines") is the owner of U.S. Patent Nos. 7,582,727 ("the '727 patent") and 7,598,343 ("the '343 patent") directed to pharmaceutical batches of the drug bivalirudin produced through a process that consistently minimizes impurities. Mylan submitted an ANDA to the FDA seeking to market a generic version of the drug. Medicines filed suit in the district court alleging infringement of the patents.

The parties disputed the meaning of two claim terms: "pharmaceutical batches" and "efficiently mixing." The district court construed "pharmaceutical batches" to require batches made by a compounding process, i.e., a particular process. With respect to "efficiently mixing," the district court relied upon the Examples 4 and 5 (describing "inefficient mixing" and "efficient mixing," respectively) in the specification, and construed the limitation to require "not using inefficient mixing conditions such as described in Example 4." The district court held on summary judgment that Mylan's ANDA did not infringe the '343 patent. With respect to the '727 patent, the district court determined that Mylan's ANDA infringed the '727 patent as a matter of law, rejecting Mylan's claim construction argument that the claims require "efficient mixing" as described in Example 5. Mylan appealed, and Medicines cross-appealed.

Issues/Holdings:

Did the district court err in declining to interpret the claims to require "efficient mixing" as part of the batches limitation? Yes, reversed in part and affirmed in part.

Discussion:

Both independent claims of the patents require "the batches have a maximum impurity level of Asp^9-bivalirudin that does not exceed about 0.6% as measured by HPLC." The Federal Circuit concluded that the batches limitation requires the use of a compounding process that achieves batch consistency, and found that the specification and prosecution history of the patents in suit both demonstrate that the invention disclosed by the patents is a compounding process that achieves batch consistency.

The Federal Circuit further construed that the compounding process requires the use of efficient mixing. The Federal Circuit found that the specification and prosecution history demonstrate that efficient mixing is a necessary condition for achieving batch consistency. The Federal Circuit turned to Examples 4 and 5 of the specification for the meaning of efficient mixing, as those Examples clearly demonstrate what efficient mixing is and is not. The Federal Circuit found that Medicines relied on the mixing parameters of Example 5 to overcome prior art cited during prosecution and did not cite any other examples of efficient mixing. Thus, the Federal Circuit concluded that one of ordinary skill in the art would rely on Example 5 to ascertain the metes and bounds of "efficient mixing." Based on the Federal Circuit's claim construction, infringing batches must be compounded using a process that employs the efficient mixing conditions of Example 5. Therefore, Mylan's ANDA does not infringe the claims because Mylan does not use the efficient mixing conditions of Example 5.