

ALCON RESEARCH LTD. v. BARR LABS., INC., Appeal No. 2012-1340, 1341 (Fed. Cir. March 18, 2014). Before Newman, Lourie, and Bryson. Appealed from D. Del. (Judge Davis).

Background:

Barr filed an ANDA seeking approval of a generic version of one of Alcon's FDA approved pharmaceutical compositions. Alcon initiated suit, asserting that Barr's ANDA filing infringed a number of its patents, including two patents with claims directed to methods for enhancing the stability of a prostaglandin composition by adding a chemically-stabilizing amount of a polyethoxylated castor oil ("PECO"). The district court held that the asserted method claims were invalid under 35 U.S.C. §112, ¶1, for lack of enablement and lack of an adequate written description. Alcon appealed.

Issue/Holding:

Did the district court err in finding Alcon's claims invalid under 35 U.S.C. §112, ¶1? Yes, reversed and remanded.

Discussion:

As to the enablement issue, the Federal Circuit explained that to prove that a claim is invalid for lack of enablement, a challenger must show by clear and convincing evidence that one of ordinary skill in the art would not be able to practice the claimed invention without "undue experimentation." However, before such experimentation can be deemed to be undue or not by applying the *Wands* factors, the challenger must first put forward evidence that some experimentation is needed to practice the patented claim. The district court erred in its enablement analysis because Barr failed to make the threshold showing that any experimentation is necessary to practice the claimed methods. Instead, the district court's holding rested on its finding that the full scope of the claims was not enabled after applying the *Wands* factors as if they were a generalized test for deciding whether a patent disclosure is sufficiently detailed to enable a broad claim.

With regard to the written description issue, Barr argued that the method claims encompass enhancing the chemical stability of innumerable prostaglandins by adding to them PECO in an infinite number of combinations and concentrations. Barr contended that because the specification discloses physical data from only one compound, the claims overreach the scope of the disclosure. The Federal Circuit disagreed, emphasizing that there is no requirement that the disclosure contains examples or an actual reduction to practice; rather, the critical inquiry is whether the description identifies the claimed invention in sufficient detail that one of ordinary skill in the art would understand that the inventor was in possession of it at the time of filing. The Federal Circuit pointed to a number of different disclosures made in the specification that indicated that the inventors possessed the claimed invention, including the idea that adding PECO would enhance the chemical stability of prostaglandins across a range of various formulation parameters. Moreover, Barr adduced no evidence, let alone clear and convincing evidence, indicating that an ordinarily skilled artisan would not have understood from the patent disclosures that the inventors were in possession of the claimed method at the time of filing. Without that evidence, there was no basis on which to find a lack of an adequate written description.