# FEDERAL CIRCUIT DECISIONS FOR WEEK ENDING MARCH 21, 2014

***Alcon Research Ltd., Barr Laboratories, Inc.*, Nos. 2012-1340, -1341 (March 18, 2014) (precedential) (3-0) Patent Nos. 5,631,287, 6,011,062, 5,510,383, and 5,889,052**

**Key points:**

- An infringement analysis based on an ANDA filing requires comparison of the asserted patent claims against the product that is likely to be sold following ANDA approval.
- The written description requirement is about whether the skilled reader of the patent disclosure can recognize that what was claimed corresponds to what was described, while enablement is about whether the patentee has proven to the skilled reader that the invention works, or how to make it work.

**Facts/Background:** Barr filed an ANDA seeking approval for a generic version of Travatan Z® which is manufactured by Alcon. Alcon then filed suit claiming Barr infringed the '287, '062, '383, and '052 patents which are directed to methods for enhancing the stability of prostatglandin compositions in Travatan Z®. Although the '383 and '052 patents were asserted in the complaint, Alcon dropped its claims to these patents soon thereafter. The claims of the '287 and '062 patent recite "a method for enhancing the chemical stability of an aqueous composition comprising…prostaglandin [by] adding a chemically stabilizing amount of ["(PECO)"] to the composition." Following a bench trial, the district court found that Alcon failed to prove that Barr's generic version of Travatan Z® infringed the claims in the '287 or '062 patents. Furthermore, the court found the claims of the '287 and '062 patents invalid for both lack of enablement and lack of an adequate written description. After these rulings, Barr moved for JMOL of noninfringement of the '383 and '052, but the court denied Barr's motion because these patents were not actually litigated.

**Holding:** The Federal Circuit affirmed in part and reversed in part. First, the Federal Circuit affirmed the lower court's finding of noninfringement. The only evidence provided by Alcon of infringement was a development study which showed that for various compositions the amounts of travoprost (a type of prostaglandin) was lost over an eight week period. All of the substances tested, however, were significantly different from the generic product proposed in Barr's ANDA. Because infringement related to an ANDA filing is focused on a comparison of the asserted patent against the product described in the filing, Alcon failed to prove that Barr's generic product infringed the '287 and '062 patents. Regarding lack of enablement, the Federal Circuit explained that Barr must first prove that some experimentation would be required to practice the patented claim (which it did not) before the court must determine whether the amount of experimentation is "undue." Moreover, although there were many different variables to consider when making the composition (*e.g.*, pH, buffer, etc.) these related to optimizing the composition rather than practicing the claims. Regarding written description, the Court held the patents contained the various formulation parameters that may be selected for practicing the invention and reversed the district court finding of invalidity under 35 U.S.C. § 112. Finally, because the '383 and '052 patents were dropped by Alcon, and Barr never filed a counterclaim for declaratory judgment, the Federal Circuit affirmed the district's ruling to deny the JMOL.

## FEDERAL CIRCUIT DECISIONS FOR WEEK ENDING MARCH 21, 2014

***Brain Life, LLC v. Eleckta Inc.*, No. 2013-1239 (March 24, 2014) (Precedential) (3-0) Patent No. 5,398,684**

**Key point:**

- The *Kessler* Doctrine precludes asserting any claim against products deemed noninfringing in a previous suit even if claim and issue preclusion do not.

**Facts/Background:** In a previous suit, the '684 patent, which includes apparatus and method claims, was asserted against Elekta's GammaKnife, GammaPlan, and SurgiPlan products (referred to collectively as "Previous Products"). The litigation focused on the apparatus claim while the method claim was dismissed without prejudice. Based on a narrow claim construction of the apparatus claim, the district court entered a final judgment of noninfringment and denied a motion to revive the method claims. Brain Life then acquired the rights to the '684 patent and filed this suit, asserting that the Previous Products along with Eleckta's new ERGO++ product ("New Product") infringed the method claims. The district court found that the Previous and New Products were substantially the same as the products at issue in the previous suit and dismissed the action under the doctrine of *res judicata*.

**Holding:** The Federal Circuit affirmed in part and vacated in part. The Federal Circuit first determined whether claim preclusion bars Brain Life from asserting the method claims against the Previous and New Products. The Federal Circuit explained that claim preclusion undoubtedly bars Brain Life from asserting the apparatus claims of the '684 patent against the Previous Products. However, claim preclusion does not bar allegations of current infringement that are temporally limited to acts occurring after final judgment was entered. Thus, claim preclusion does not bar asserting the method claim against Previous Products that were created using an infringing method after final judgment was entered, but does bar asserting the method claim against Previous Products created before judgment was entered. Because the New Product was never part of the previous litigation, it too is not be barred by claim preclusion. Turning to issue preclusion, the Federal Circuit reached a similar result. The method claims were never fully litigated to finality, and thus, the method claim can be asserted against the Previous and New Products. However, the Federal Circuit held that the *Kessler* Doctrine bars Brain Life from asserting any claim of the '684 patent against the Previous Products. Under the *Kessler* Doctrine, when an alleged infringer prevails, the specific accused devices acquire the status of noninfringing device vis-à-vis the asserted patent claims. When the accused products in a second suit are essentially the same, they also acquire the status of noninfringing device. Because Brain Life's predecessor asserted all the claims of the '684 patent against the Previous Products, the *Kessler* Doctrine bars asserting the method (and apparatus) claims against the Previous Products. However, Brain Life is not barred under any preclusion doctrine from asserting either the apparatus or the method claims against the New Product.