

Patent Term Extension Under 35 U.S.C. § 156 Covers an Active Pharmaceutical Ingredient—including Any Salt or Ester of the Active Ingredient—but Does Not Encompass a Metabolite of the Active Ingredient or Its De-Esterified Form

APRIL 21, 2020

Biogen International GmbH v. Banner Life Sciences LLC, 956 F.3d 1351 (Fed. Cir. Apr. 21, 2020)

The patentee holds a new drug application (NDA) for the active ingredient dimethyl fumarate (DMF), for treatment of autoimmune diseases. Upon administration, one of DMF's methyl ester groups is readily metabolized, becoming monomethyl fumarate (MMF). DMF is the active ingredient in patentee's approved product, Tecfidera®. The patent at issue covers both DMF and MMF.

The patent's term was extended by 811 days under the provisions of § 156 to compensate the patentee for the period during which the FDA reviewed its Tecfidera® NDA. In 2018, the alleged infringer submitted an application to market a generic version of its MMF pill, and the patentee instituted an infringement action. The lower court granted a judgment of non-infringement, finding that MMF was not covered by the patent's extension because that extension only applied to DMF, not MMF. The patentee appealed.

The Federal Circuit affirmed. Section 156 entitles the NDA holder to extend the term of only one patent for the approved product, and limits the scope of that extension to "any use approved for the product." The statute defines "product" as "the active ingredient of . . . a new drug . . . including any salt or ester of the active ingredient." In other words, the "product" in this case is DMF, not MMF.

The patentee argued that the statute should be interpreted such that the extension also covers MMF. Rejecting this argument, the Federal Circuit held that MMF is not the approved product, nor is it specified as the active ingredient on the Tecfidera® label. Esters are included in the statutory definition of a "product," but MMF is the de-esterified form of DMF, not an ester of DMF. Thus, it is not the same product and does not fall within the scope of the patent's term extension under § 156.

A copy of the opinion can be found [here](#).

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