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Federal Circuit Affirms Patent Term Extension Only Applies to FDA-Approved Active Ingredients

On April 21, 2020, a Federal Circuit court affirmed a lower court decision holding that patent term extension protection applies only to FDA-approved active ingredients in a drug product. In January 2020, Judge Stark of the Delaware Federal District Court held in *Biogen International GmbH* (Biogen) *v. Banner Life Sciences, LLP* (Banner), No. 1:18-cv-02054-LPS (D. Del. 2020), that Banner's drug Bafiertam™ did not infringe a Biogen patent (U.S. Patent No. 7,619,001) because Banner's product was not covered by the patent term extension applied to the '001 patent. The '001 patent covers Biogen's well-known multiple sclerosis drug, Tecfidera®. Biogen appealed the District Court decision to the Federal Circuit. The Federal Circuit affirmed this decision on April 21, holding "the scope of a patent term extension under 35 U.S.C. § 156 only includes the active ingredient of an approved product, or an ester or salt of that active ingredient, and the product at issue does not fall within one of those categories." See *Biogen International GmbH v. Banner Life Sciences, LLP*, No. 20-1373 (Fed. Cir. April 21, 2020).

Biogen's Tecfidera® currently is the best-selling oral multiple sclerosis drug on the market. The active ingredient in Tecfidera® is dimethyl fumarate (DMF), which was approved for the treatment of multiple sclerosis by the Food and Drug Administration (FDA) in 2013. In contrast, the active ingredient in Banner's drug Bafiertam™ is monomethyl fumarate (MMF). After ingestion of DMF, one of the methyl ester moieties is rapidly hydrolyzed to a carboxylic acid group, forming MMF, before reaching and acting on its molecular target in the body; therefore, DMF is a prodrug of MMF.

Biogen's '001 patent initially was set to expire on April 1, 2018, but the patent term was extended under the patent term restoration provisions of the Hatch-Waxman Act, 35 U.S.C. § 156. This extension of the patent term compensates owners of patents on drug products and

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medical devices for potential marketing time lost during the FDA review process. Patent term extension can only be applied to a single patent covering the first permitted commercial marketing of an FDA-approved product.

Claim 1 of Biogen's '001 patent is directed to a "method of treating multiple sclerosis comprising administering . . . [a] pharmaceutical preparation comprising . . . dimethyl fumarate [DMF], methyl hydrogen fumarate [MMF], or a combination thereof." The issue in both the District Court case and the appeal was whether the patent term extension applies to MMF, as specified in claim 1 of the '001 patent, when Biogen's Tecfidera® contained only DMF.

Banner argued "that § 156(b)(2) limits the scope of the '001 patent's extension to methods of using the [FDA-]approved product as defined in § 156(f) – in this case, DMF, its salts, or its esters – and that MMF is none of those things." An FDA-approved product is defined as the active ingredient of a new drug. Banner argued that Tecfidera®'s active ingredient is "the molecule found in the drug product before it is administered to the patient" – i.e., DMF.

In response, Biogen argued that the scope of the '001 patent is not limited to uses of the FDA-approved product, but to any product in the original claims and that "product" as stated in § 156 encompasses any derivative product with the same pharmacological action. Biogen further argued that "Tecfidera's active ingredient is the active moiety, which here is MMF (as well as salts and esters of MMF)."

The Federal Circuit concluded that the FDA-approved "product here is DMF, not MMF . . . Patent term extension exists to compensate an NDA holder for time consumed during regulatory review of the product. But it would make little sense for an extension — whether for a product patent or a method of treatment patent — to apply to a different product for which the NDA holder was never subjected to a regulatory review period."

The appellate court's conclusion is consistent with how the FDA applies the law when calculating the regulatory review period involved during the investigative new drug (IND) and new drug application (NDA) phases of its regulatory review to advise the U.S. Patent and Trademark Office for purposes of patent term extension for a particular drug. Moreover, the FDA treats prodrugs, like Biogen's Tecfidera® and metabolites such as Banner's Bafiertam™ as having different active ingredients and thus reviews them as different drug products. The FDA therefore reviewed Bafiertam™ under § 505(b)(2) of the Federal Food, Drug and Cosmetic Act (FFDCA) as a new chemical entity and not as a generic drug under § 505(j) of the FFDCA. In doing so, the FDA demonstrated that it does not consider MMF "the same as" DMF. Rather, the two were separate entities with different active ingredients in the FDA's view. It is noteworthy that, whether for prodrugs, metabolites, or other differentiated forms of a drug, the § 505(b)(2) new drug approval pathway is becoming an ever more popular regulatory approval mechanism for generic drug manufacturers to utilize to add to their portfolio of drug products, as profit margins for generic drugs approved under § 505(j) are compressed and the field of generic drug competitors making the same products grows.

The Federal Circuit ruling raises implications for both branded and generic drug makers. Branded drug makers need to be judicious when selecting which patent to extend to block generics from the market. Based on this ruling, a patent drawn to the primary active pharmaceutical ingredient (API) in an FDA-approved drug would be preferable to a patent specifying multiple APIs that are not in the approved product. Composition of matter patents with a broad genus covering multiple potential APIs would be an example. On the other hand, this ruling provides a strategy for generic drug makers to design around an

innovator's patent-term-extended patent that specifies multiple APIs or prodrugs that are not in the innovator's approved product.

Michael Best represents Banner Life Sciences LLC for patent prosecution and performed pre-litigation due diligence for the BAFIERTAM™ product. Michael Best was not involved in the litigations described here.

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