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Bases, and Esters, and Salts, Oh My! Limits on PTE Benefits Provide a Drug Applicant with a Winning Non-Infringement Position

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Biogen International GmbH obtained a patent for methods of treating multiple sclerosis using a fumarate diester (DMF) or fumarate monoester (MMF). Biogen developed and received FDA approval in March 2013 for a DMF-based drug called Tecfidera after submitting extensive data on both DMF and MMF. Tecfidera DMF capsules do not contain MMF, but the DMF in Tecfidera is converted into MMF after it is administered to a patient, and MMF is the active moiety that produces a therapeutic effect. Due to delays in FDA approval of Tecfidera, Biogen obtained 811 days of PTE under 35 U.S.C. § 156, thereby extending the expiration date of the patent from April 1, 2018 to June 20, 2020.

On January 18, 2018, Banner Life Sciences LLC submitted a new drug application (NDA) for an MMF-based drug called Bafiertam. Banner's application relied in part on Biogen's MMF data.

In December 2018, after receiving notice of Banner's application, Biogen sued Banner for infringing its patent. Banner filed an answer and then moved for judgment on the pleadings, arguing that as to MMF, Biogen's patent expired on April 1, 2018, and was therefore not infringed. In other words, the patent term extension to June 20, 2020 was limited to only methods of treatment in which DMF is the administered drug.

The Court began its analysis by setting out § 156's statutory scheme for PTE. In particular, the Court explained that § 156(a) extends the term of the patent, but § 156(b) limited the benefit of the extension to those claims that covered a method of using a particular drug product, which, under § 156(f) meant the active ingredient of a new drug, including any salt or ester of

the active ingredient. Of note here, DMF is an ester of MMF, but MMF is neither an ester nor a salt of DMF.

Next, the Court turned to the parties' competing arguments as to whether the PTE applied to only methods of treating multiple sclerosis using DMF, or whether PTE applied to any method claim in the patent, including the use of MMF. The Court reasoned that both Federal Circuit caselaw and statutory text compelled the more narrow benefit of PTE. The Federal Circuit ruled in the context of product claims that PTE applied only to the claimed embodiments of the FDA-approved drug product. Because the statute's text for method claims is identical in pertinent part to the text for product claims, the Court concluded the same interpretation must apply, and thus, PTE for method claims must be limited to the FDA-approved product.

In light of § 156(f)'s definition of drug product as including the active ingredient, the Court then considered whether the active ingredient for Biogen's FDA-approved product was MMF or DMF. The Court discussed several Federal Circuit opinions that Biogen and Banner raised in support of their competing positions. In an opinion where the Federal Circuit interpreted the § 156(f) definitions for the first time (*Glaxo Operations UK Ltd. v. Quigg*, 894 F.2d 392 (Fed. Cir. 1990)), the panel rejected the Patent Office's position that the active ingredient was the active moiety. Instead, the focus needed to be on the ingredient in the product *before it is administered*.

The Court noted that a later Federal Circuit opinion seemed to cut the other way (*Pfizer v. Dr. Reddy's Labs.*, 359 F.3d 1361 (Fed. Cir. 2004)), ruling that PTE granted for an amlodipine besylate product could be used to cover a competitor's amlodipine maleate product. That decision defined the active ingredient, for PTE purposes, to be amlodipine (i.e., the active moiety), regardless of the form in which it was administered. The Federal Circuit found that because PTE applied, a competitor's product comprising the different amlodipine salt infringed the patent.

The Court then explained that a third Federal Circuit opinion (*PhotoCure ASA v. Kappos*, 603 F.3d 1372 (Fed. Cir. 2010)) had stated that there was no conflict between *Glaxo* and *Pfizer*. According to *PhotoCure*, the *Pfizer* ruling only meant that infringement could not be avoided by just changing the salt.

Finally, the Court reasoned that even if there was a conflict between *Glaxo* and *Pfizer*, it was duty bound to follow *Glaxo* as the earlier precedential opinion. Thus, the Court ruled that the active ingredient in Tecfidera was DMF because it is the material that is administered to a

patient, and that the active ingredient cannot be its metabolite MMF because it is not-yet present. Accordingly, only claims to DMF benefited from PTE, and because MMF is neither a salt nor an ester of DMF, any MMF claims could not be literally infringed because they were expired.

The Court concluded its analysis by ruling that Biogen could not extend the benefit of its patent term extension to MMF-based therapies under a doctrine of equivalence theory. More specifically, the Court held the doctrine of equivalents could not be used to recapture subject matter that § 156 expressly took away through its limitations provision. As such, the Court granted Banner's motion for judgment on the pleadings of no infringement.

Practice Tip: Parties engaged in litigation involving NDAs and the like should be aware of these issues and be cognizant of the possibility that not all data submitted for FDA-approval will yield a patent term extension. This case has been appealed to the Court of Appeals for the Federal Circuit, and the parties have sought an expedited schedule.

Biogen Int'l GmbH v. Banner Life Scis. LLC, 18-cv-02054, (D. Del. Jan. 7, 2020) (Stark, C.J.)

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