IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BIOGEN INTERNATIONAL GMBH,	:	
	:	
Plaintiff,	:	
	:	
v.	:	C.A. No. 18-2054-LPS
	:	**FILED UNDER SEAL**
BANNER LIFE SCIENCES LLC,	:	
	:	
Defendant.	:	

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MEMORANDUM OPINION

January 7, 2020
Wilmington, Delaware

STARK, U.S. District Judge:

Plaintiff Biogen International GmbH ("Biogen") alleges that Defendant Banner Life Sciences LLC ("Banner") infringes Biogen's U.S. Patent No. 7,619,001 ("the '001 Patent"), which is subject to a patent term extension. (D.I. 1) Banner has moved under Rule 12(c) for judgment on the pleadings on the basis of non-infringement, reasoning that the '001 Patent's extension does not reach Banner's tentatively-approved generic product. (D.I. 9) Having considered the parties' briefing (D.I. 10, 15, 20) and related materials, and having heard oral argument on August 28, 2019 (D.I. 42) ("Tr."), the Court will grant the motion.

I. BACKGROUND

A. Factual Background

The '001 Patent claims a method of treating multiple sclerosis ("MS") with pharmaceutical preparations of dimethyl fumarate ("DMF") and/or methyl hydrogen fumarate ("MMF"). ('001 Patent, cls. 1-24; D.I. 1 ¶¶ 19-26) Specifically, the relevant claims provide:

> 1. A method of treating multiple sclerosis comprising administering . . . an amount of a pharmaceutical preparation effective for treating multiple sclerosis, the pharmaceutical preparation comprising . . . dimethyl fumarate [DMF], methyl hydrogen fumarate [MMF], or a combination thereof.
>
> 5. The method of claim 1, the pharmaceutical preparation comprising methyl hydrogen fumarate [MMF].

('001 Patent, cls. 1, 5)

Of the compounds listed in the '001 Patent's claims, the "active moiety" – that is, in simple terms, the compound responsible for the physiological or pharmacological action of the

drug substance in the human body[1] – is MMF. DMF metabolizes into the active moiety, MMF, when it is administered in the human body. (*See, e.g.*, D.I. 16-1 Ex. 14 at 8, 11-12, 21; Ex. 15 at 8; Ex. 16 at 5; Exs. 17-19; Tr. at 6, 39, 48-49, 60-61)

DMF is an ester of MMF. (*See* D.I. 10 at 5-6; D.I. 15 at 5) As the Federal Circuit has explained, an "ester" is "a compound derived from an acid by the exchange of a replaceable hydrogen of the latter for an organic radical, usually using an alcohol or other organic compound rich in OH groups." *Glaxo Operations UK Ltd. v. Quigg*, 894 F.2d 392, 393 n.2 (Fed. Cir. 1990).

MMF, however, is not an ester of DMF. (*See* D.I. 8 at ¶¶ 30-31; D.I. 10 at 6; Tr. at 11, 34) Nor is MMF a salt of DMF. (*See id.*) As the Federal Circuit has explained, a salt is "a compound formed when the hydrogen of an acid is replaced by a metal or its equivalent." *Glaxo*, 894 F.2d at 393 n.3.

B. Biogen's Tecfidera Product

In March 2013, Biogen received approval from the U.S. Food and Drug Administration ("FDA") to market Tecfidera (dimethyl fumarate "DMF") delayed-release capsules for the treatment of MS. (D.I. 1 at ¶¶ 25-26) The mechanism by which DMF accomplishes its therapeutic effect in MS is unknown. (D.I. 6 at ¶ 25) As Biogen explains: "Tecfidera contains

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[1] *See also* 21 C.F.R. § 314.3 (FDA defining "active moiety" as "the molecule or ion, excluding those appended portions of the molecule that cause the drug to be an ester, salt . . . , or other noncovalent derivative . . . of the molecule, responsible for the physiological or pharmacological action of the drug substance"); *Actavis Elizabeth LLC v. U.S. Food and Drug Admin.*, 625 F.3d 760, 763 (D.C. Cir. 2010) ("When the drug molecule is not in the form of an ester, salt, or other noncovalent derivative, the FDA treats the entire molecule as that 'responsible for the physiological or pharmacological action of the drug substance,' and therefore a separate 'active moiety.'").

DMF, but DMF rapidly cleaves an ester to become MMF following administration." (D.I. 15 at 5) Thus, just prior to oral administration, Tecfidera DMF capsules do not contain MMF; but, following oral administration, the DMF in Tecfidera capsules converts in the human body into the active moiety, MMF. (*See* D.I. 8 at ¶ 14-15) (Biogen stating that '001 Patent and Tecfidera package insert explain that MMF is a metabolite of DMF)

Biogen, as part of its New Drug Application ("NDA"), submitted to the FDA extensive data on both DMF and MMF. (*See, e.g.*, D.I. 16-1 Ex. 14 at 8, 11-12, 21; Ex. 15 at 8; Ex. 16 at 5; Exs. 17-19; Tr. at 6, 39, 48-49, 60-61)

C. Biogen's Patent Term Extension

The Hatch-Waxman Act, and in particular 35 U.S.C. § 156, "provides the holders of patents on approved patented products with an extended term of protection under the patent to compensate for the delay in obtaining FDA approval." *Merck & Co., Inc. v. Kessler*, 80 F.3d 1543, 1547 (Fed. Cir. 1996); *see also id.* at 1552 ("The statute contemplates a patentee receiving time lost in its patent term by reason of FDA delay, and the statute should be liberally interpreted to achieve this end."). "[T]he restoration period of the patent does not extend to all products protected by the patent but only to the product on which the extension was based." *Id.*

With its '001 Patent originally set to expire on April 1, 2018, Biogen sought and received a patent term extension ("PTE") of 811 days under 35 U.S.C. § 156 due to delay that had occurred in obtaining FDA approval to market Tecfidera. (*See* D.I. 15 at 5) As a result, the parties agree that the '001 Patent is now set to expire on June 20, 2020. (D.I. 1 at ¶ 22)

D. Banner's Bafiertam Product

On January 18, 2018, prior to the expiration of the '001 Patent's extended term, Banner

submitted NDA No. 210296 under § 505(b)(2), *see* 21 U.S.C. § 355(b)(2), seeking approval to manufacture, use, import, offer to sell, and sell Bafiertam (monomethyl fumarate "MMF") delayed-release capsules for the treatment of MS. (D.I. 1 at ¶ 5; *see also* D.I. 6-1 at 1; D.I. 6-9 at 13) As part of its drug application, Banner demonstrated the safety and efficacy of Bafiertam by relying on Biogen's MMF data. (D.I. 1 at ¶ 28; D.I. 6 at 25 ¶ 32; Tr. at 39) On November 19, 2018, Banner sent a Paragraph IV notice letter to Biogen, *see* 21 U.S.C. § 355(b)(2)(A)(iv), certifying that the '001 Patent was invalid, unenforceable, and/or will not be infringed by Banner's product. (*See e.g.*, D.I. 1 at ¶ 28; D.I. 6 at ¶ 7) Banner received tentative approval from the FDA on November 16, 2018. (*See* D.I. 6 at 2-3; D.I. 6-1)

E. Procedural Background

Biogen sued Banner for infringement of the '001 Patent on December 27, 2018.[2] (D.I. 1) By filing such suit within 45 days of receiving notification of Banner's filing of its NDA, Biogen obtained an automatic 30-month stay of FDA approval of Banner's Bafiertam product. *See* 35 U.S.C. § 355(j)(5)(B)(iii). Thus, at this time, the only impediment to Banner obtaining final FDA approval and having the right to market Bafiertam is the pendency of this litigation. (*See* D.I. 10 at 7)

II. LEGAL STANDARDS

Under Federal Rule of Civil Procedure 12(c), a party may move for judgment on the pleadings "[a]fter the pleadings are closed – but early enough not to delay trial." When

[2] This is the second lawsuit Biogen has filed against Banner for its filing of NDA No. 210296. The first suit – filed after Banner served a Paragraph IV notice letter on Biogen regarding three other patents listed in Orange Book – was voluntarily dismissed by the parties in September 2018. *See Biogen MA Inc. v. Banner Life Sci. LLC*, C.A. No. 18-582-LPS (D. Del.).

evaluating such a motion, the Court must accept all factual allegations in a complaint as true and view the pleadings in the light most favorable to the non-moving party. *See Rosenau v. Unifund Corp.*, 539 F.3d 218, 221 (3d Cir. 2008). A Rule 12(c) motion will not be granted "unless the movant clearly establishes that no material issue of fact remains to be resolved and that he is entitled to judgment as a matter of law." *Id.* (internal citation omitted).

The Court may consider matters of public record as well as authentic documents upon which the complaint is based, if attached to the complaint or as an exhibit to the motion. *See Oshiver v. Levin, Fishbein, Sedran & Berman*, 38 F.3d 1380, 1384 n.2 (3d Cir. 1994); *see also In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1426 (3d Cir. 1997) (explaining that documents integral to pleadings may be considered in connection with Rule 12(c) motion).

III. DISCUSSION

In this litigation, and for purposes of its Rule 12(c) motion for judgment on the pleadings, Banner does not contest that its product, Bafiertam, literally infringes at least claim 1 of Biogen's '001 Patent, as Bafiertam contains MMF and is intended to be used as a method of treatment for MS. (*See, e.g.*, D.I. 10 at 1) Instead, Banner's contention is that the portion of the '001 Patent that Bafiertam practices expired in April 2018. In Banner's view, Biogen's PTE applies only to the claimed embodiment which constitutes Biogen's FDA-approved DMF product, Tecfidera; that is, the '001 Patent was only extended, and can only be enforced, with respect to a DMF-containing product. (*See id.* at 15-17) Because Banner's Bafiertam contains MMF and not DMF, Banner argues it is entitled to judgment on the pleadings of no infringement.

For the reasons described below, the Court agrees with Banner.

A. PTE Statutory Framework

Applications for, and limitations on enforcement of, patent term extensions are governed by 35 U.S.C. § 156.

The first provision relevant here is § 156(a), which provides, in pertinent part:

> (a) ***The term of a patent which claims*** a product, ***a method of using a product***, or a method of manufacturing a product ***shall be extended*** . . . from the original expiration date of the patent . . . ***if*** –
>
> . . .
>
> (4) the product has been subject to a regulatory review period before its commercial marketing or use; [and]
>
> (5)(A) . . . the permission for the commercial marketing or use of the product after such regulatory review period is the first permitted commercial marketing or use of the product under the provision of law under which such regulatory review period occurred . . . .

(Emphasis added)

The next relevant provision is § 156(b), which imposes a limitation on rights obtained by a PTE. In pertinent part, § 156(b) provides:

> (b) . . . [T]he ***rights derived from any patent the term of which is extended under this section shall*** during the period during which the term of the patent is extended –
>
> (1) in the case of a patent which claims a product, be limited to any use approved for the product . . . [and]
>
> (2) in the case of a patent which ***claims a method of using a product, be limited to any use [i] claimed by the patent and [ii] approved for the product*** . . . .

(Emphasis and internal bracketed numbering added)

Finally, § 156(f) defines several terms used throughout § 156, including pertinent terms in §§ 156(a) and (b). In particular, § 156(f) provides:

> (f) For purposes of this section:
>
> (1) The term "product" means:
>
> (A) A drug product. . . .
>
> (2) The term "drug product" means the ***active ingredient*** of –
>
> (A) a ***new drug***, antibiotic drug, or human biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act)[3] . . . ***including any salt or ester of the active ingredient***, as a single entity or in combination with another active ingredient.

(Emphasis added)

B. Biogen's PTE May Only Be Enforced Against A DMF-Containing Product

The parties are in agreement that Biogen successfully obtained a PTE on its '001 Patent until June 20, 2020 based on its FDA-approved product, Tecfidera, because Tecfidera was subject to a regulatory review period before its commercial marketing began and Tecfidera is the first commercially-marketed product which is an embodiment of the '001 Patent. (*See* D.I. 1 at ¶ 22; D.I. 6 at ¶ 22; *see also* D.I. 10 at 7-8; D.I. 15 at 5) The parties disagree, however, on the scope of that extension and, particularly, whether it extends to Banner's MMF product.

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[3] *See* 21 U.S.C. § 321(p).

1. The PTE Applies to the Entire '001 Patent

As an initial matter, § 156(a) provides that "the term of a ***patent*** which claims a product [or] a method of using a product . . . ***shall be extended***" (emphasis added). Considering this provision, the Federal Circuit in *Genetics Institute v. Novartis Vaccines and Diagnostics* rejected the argument that a PTE applies on "a claim-by-claim basis." 655 F.3d 1291, 1300 (Fed. Cir. 2011). The term of the entire patent for which a PTE has been obtained is extended.

This does not mean, however, that Biogen, for example, has the right to ***enforce the entirety*** of the '001 Patent. Rather, § 156(b) limits the effect of the extension to the "***rights derived***" under § 156(a). *See Genetics Inst.*, 655 F.3d at 1301; *see also generally* 35 U.S.C. § 156(d)(1)(B) (requiring patent owner to identify each claim "which claims the approved product or a method of using or manufacturing the approved product").

The result here is that, even though the entirety of the '001 Patent term has been extended under § 156(a), the Court must still assess whether Biogen's "rights derived" in the '001 Patent's extended term are enforceable under § 156(b). Specifically, the Court must determine whether the method of using Banner's MMF-product for the treatment of MS comes within the scope of the enforceable "rights derived" by Biogen from the extension of the '001 Patent's term.

2. Biogen's Enforceable Patent Rights are Governed by Subsection 156(b)(2)

The parties agree that claim 1 of the '001 Patent claims a method of use. (*See* D.I. 10 at 15; D.I. 15 at 8) Therefore, Biogen's enforceable patent rights during the '001 Patent's extended term are governed by § 156(b)(2). Subsection 156(b)(2) limits the "rights derived" from a PTE "to any use [i] claimed by the patent and [ii] approved for the product." The parties offer

different interpretations of this statute.

Banner argues that § 156(b)(2) limits the effectiveness of the PTE to "any use claimed by the patent and approved for the [approved] product." (D.I. 10 at 12-15) Under this reasoning, the '001 Patent rights that Biogen may enforce during the extension period are limited to a method of treating MS using DMF (not MMF). (*Id.*) Banner focuses on the fact that treatment of MS with DMF (including with any salts or esters of DMF) is the use claimed in the '001 Patent and is also the use for which the FDA has approved Biogen's DMF-containing Tecfidera. (*Id.*) Banner's interpretation of the statutory scheme recognizes that Biogen's rights extend to salts and esters of DMF because § 156(f) expressly defines "product" to mean "the active ingredient of . . . a new drug . . . including any salt or ester of the active ingredient."

Biogen has a broader understanding of the rights it may enforce during the extension period of the '001 Patent. (*See* D.I. 15 at 9-10) Biogen reads § 156(b)(2) as not just limited to the specific FDA-approved product/use combination (in this case, Tecfidera (DMF) for MS), but as also reaching any claim (or any portion of any claim) in the '001 Patent directed to methods of treating MS. (D.I. 15 at 10) Thus, under Biogen's interpretation, the PTE applies to any drug product disclosed in the claimed methods of the '001 Patent that can be used to treat MS, which in this case, would include the use of DMF, MMF, or any salts or esters thereof.

Having carefully considered the parties' positions, the Court agrees with Banner's view as to the meaning of § 156(b)(2) and how it applies to the undisputed facts of this case. The Court's conclusion is supported by both the statutory language and Federal Circuit caselaw, to which the Court now turns.

a. Analogy to identical language of § 156(b)(1)

In the context of § 156(b)(1), which applies to extensions "of a patent which claims a ***product***" – as opposed to "a patent which claims a ***method of using a product***", which is governed by § 156(b)(2) – the Federal Circuit has held that "the restoration period . . . ***does not extend to all products protected by the patent but only to the product on which the extension was based***." *Merck & Co., Inc. v. Kessler*, 80 F.3d 1543, 1547 (Fed. Cir. 1996) (emphasis added); *see also* MPEP § 2750 (9th ed. Rev. 8.2017) ("[P]ursuant to 35 U.S.C. 156(b), if the patent claims other products in addition to the approved product, the exclusive patent rights to the additional products expire with the original expiration date of the patent."). In other words, the "rights derived" from the PTE do not extend to all embodiments within the scope of the claims that have been extended. Instead, those rights extend ***only*** to the claimed embodiment on which the extension is based, i.e., the FDA-approved drug product (provided that product is also an embodiment of the claims).

The Court has concluded that the same, governing, Federal Circuit interpretation of § 156(b)(1) applies equally to § 156(b)(2). The pertinent statutory language is identical: subsection 156(b)(1) imposes limits "***limited to any use approved for the product***," while subsection 156(b)(2) imposes limits "***limited to any use*** claimed by the patent and ***approved for the product***" (emphasis added). The identical words are used in the identical manner in both provisions.[4] "The normal rule of statutory construction [is] that identical words used in different

[4]The additional language in 156(b)(2), expressly requiring that the method of use be "claimed by the patent," does not alter this analysis. If anything, this language makes subsection 156(b)(2) ***more restrictive*** than 156(b)(1), which only strengthens the Court's conclusion. In any event, the "claimed by the patent" language does nothing to alter the meaning of the phrase "limited to any use . . . approved for the product" which appears in both 156(b)(1) and 156(b)(2).

parts of the same Act are intended to have the same meaning." *Gustafson v. Alloyd Co., Inc.*, 513 U.S. 561, 562 (1995); *see also* MPEP § 2750 (applying same interpretation to all of § 156(b)). Biogen has pointed to no persuasive reason for why the Federal Circuit's analysis of § 156(b)(1) does not apply equally to § 156(b)(2).

Accordingly, the Court holds that the rights derived by a PTE on a method of use patent "does not extend to all products protected by the patent but only to the product on which the extension was based." *Merck*, 80 F.3d at 1547.

b. Biogen's approved product is DMF, not MMF

Having determined the proper scope of § 156(b)(2), the question then becomes: what is the FDA-approved product in this case? As already noted, § 156(f)(2) defines "product" as "[a] drug product," and further defines "drug product" as "the active ingredient of . . . a new drug . . . including any salt or ester of the active ingredient." Therefore, the pertinent question here is: what is the "active ingredient" of Biogen's approved drug product, Tecfidera?

On this point, the parties again disagree.

Banner argues that the "active ingredient" is the molecule found in the administered drug product before it is administered to the patient. (*See* D.I. 10 at 15-17) Therefore, to Banner, the "active ingredient" of Tecfidera is DMF (as well as the salts and esters of DMF). (*See id.*) Biogen, however, contends that Tecfidera's active ingredient is the active moiety, which here is MMF (as well as salts and esters of MMF). (D.I. 15 at 11-12)

Both parties put forth reasonable interpretations of the statutory framework in light of two precedential Federal Circuit cases. Banner relies on Judge Michel's opinion in *Glaxo Operations UK Ltd. v. Quigg*, 894 F.2d 392 (Fed. Cir. 1990), while Biogen relies on Judge Newman's

opinion in *Pfizer v. Dr. Reddy's Laboratories*, 359 F.3d 1361 (Fed. Cir. 2004). As discussed below, although these cases may appear to be in conflict, the Federal Circuit held in a subsequent opinion, *PhotoCure v. Kappos*, 603 F.3d 1372, 1375 (Fed. Cir. 2010), that no conflicts exists.

i. *Glaxo* - Plain Meaning

Banner's position is supported by *Glaxo*, 894 F.2d at 392, in which the Federal Circuit, interpreting § 156(f)(2) for the first time, focused on the plain meaning of the statutory language and determine that "active ingredient" refers to the molecule in the drug product to be administered, ***not*** the active moiety.

Glaxo owned two patents: (1) the '153 Patent, which claimed cefuroxime and its salts; and (2) the '320 Patent, which claimed cefuroxime axetil, an ester of cefuroxime. *Id.* at 393. The FDA first approved for use two cefuroxime salts, Zinacef and Kefurox, and only later approved a cefuroxime axetil, Ceftin. *See id.* at 393-94. Glaxo applied for a PTE for the '320 Patent, which the United States Patent and Trademark Office ("PTO") denied, since Ceftin – an embodiment of the '320 Patent – was not "the first permitted commercial marketing or use" of the "product," given the previous approved commercial use of Zinacef and Kefurox. *Id.* In denying Glaxo's requested PTE, the PTO interpreted "active ingredient" in § 156(f)(2) to mean "new active moiety," "which would encompass all acid, salt, or ester forms of a single therapeutically active substance." *Id.* at 397. Because the active moiety for cefuroxime, cefuroxime salts, and cefuroxime axetil was the same, *see id.* at 394 ("after being orally administered CEFTIN tablets combine with digestive substances in the human body to produce the same therapuetically active substance contained in both ZINACEF and KEFUROX"), the first relevant approved product was the first product containing any of these, which happened to

be cefuroxime salts, in the form of Zinacef and Kefurox.

Glaxo challenged the PTO's decision in the district court and, on appeal, the Federal Circuit rejected the PTO's "active moiety" interpretation. Instead, the Federal Circuit – which considered § 156(f)(2) to be "unambiguous on its face" and to provide "an explicit and precise definition of 'product' . . . using well-established scientific terms," *id.* at 399 – held that "active ingredient" refers to the active ingredient of the administered drug product, *see id.* at 394-95, 399-400. The approved drug product which was the basis for Glaxo's requested extension of the '320 Patent was Ceftin, which at administration contained cefuroxime axetil. *See id.* At administration (that is, when being placed in the human body), Ceftin did not contain either cefuroxime or cefuroxime salts. *See id.* at 392. Since Zinacef and Kefurox were neither salts nor esters of cefuroxime axetil, and therefore did not constitute the same "drug product" as cefuroxime axetil, those products could not be used to deny Glaxo a PTE for the '320 Patent. *See id.* at 399-400. Therefore, the prior approval of Zinacef and Kefurox – products containing cefuroxime salts – was ***not*** a prior approval of a product containing cefuroxime axetil, and a PTE on the '320 Patent should have been granted.

Notably, in *Glaxo*, the Federal Circuit ***rejected*** the PTO's position that Ceftin, Zinacef, and Kefurox all constituted the same drug product because they all metabolized into the same "therapeutically active substance." *Id.* The Federal Circuit rejected the PTO's interpretation of subsection 156(f)(2)'s "active ingredient" as meaning "new active moiety."

Glaxo supports Banner. *Glaxo* instructs that the Court apply § 156(f)(2)'s plain and ordinary meaning and look just to the active ingredient found in the FDA-approved product (on which the PTE is based) when administered; that is, as the product exists ***before it is taken*** by a

human patient. *See also Hoechst-Roussel Pharmaceuticals, Inc. v. Lehman*, 109 F.3d 756, 759 n.3 (Fed. Cir. 1997) ("For purposes of patent term extension, this active ingredient must be present in the drug product when administered.") (citing *Glaxo*, 894 F.2d at 392).[5] *Glaxo* teaches ***not*** to look at the active moiety of the FDA-approved product at the time that moiety is delivering its therapeutic effect in the body.[6]

Therefore, if the Court follows *Glaxo*, Banner would prevail. Biogen's enforceable, extended patent term would extend only to DMF (and its salts and esters), which is the "active ingredient" in the FDA-approved drug (Tecfidera) when administered, and would not extend to DMF's active moiety (which is MMF). Since Banner's Bafiertam product only contains MMF (which is undisputedly not a salt or ester of DMF), Banner could not be found to infringe the extended, enforceable rights Biogen maintains in its '001 Patent.

ii. *Pfizer* - Active Moiety

The above does not end the analysis, however, because Biogen's position also finds

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[5] Notably, Judge Newman, while concurring in the judgment in *Lehman*, disagreed with the majority's analysis on this point, writing: "The approved [accused] product is converted into the claimed product *in vivo*; thus infringement occurs upon use of the approved product. There is no basis in the law for restricting § 156 to exclude this circumstance." 109 F.3d at 763 (Newman, J., dissenting); *see also id.* at 764 ("The distinction drawn by the majority leads to the curious result that the '286 claims would be infringed for all purposes of Title 35 except for § 156. This result is not supported by the law of claiming, of infringement, or of term extension."). The holding of the Federal Circuit in *Lehman* was to the contrary.

[6] While *Glaxo* was expressly considering § 156(a), and whether a patent was ***eligible*** for a PTE, and the instant case instead involves a dispute under § 156(b)(2), and whether the ***rights derived*** by a granted-PTE ***extend*** to the active moiety or are limited to the "active ingredient" in the approved-product when administered, the same defined term in § 156(f)(2) ("active ingredient") was at issue in both *Glaxo* and here. Biogen does not dispute that § 156(f) applies to both § 156(a) and (b). (*See* Tr. at 46) In the Court's view, *Glaxo*'s interpretation of § 156(f)(2) in the context of § 156(a) must also carry through to § 156(b), as § 156(f)(2)'s definitions apply "[f]or purposes of this section," i.e., to the entirety of § 156.

support in Federal Circuit precedent. In *Pfizer v. Dr. Reddy's Laboratories*, 359 F.3d 1361, 1364 (Fed. Cir. 2004), Pfizer, had received a PTE for its FDA-approved drug Norvasc, an amlodipine besylate. During the term extension, Dr. Reddy's sought approval for a product containing amlodipine maleate, which was covered by Pfizer's patent. *See id.* Amlodipine maleate is neither a salt nor ester of amlodipine besylate. *See id.* at 1363-65. Therefore, Dr. Reddy's argued, its product could not be found to infringe during the extension, since amlodipine maleate fell outside the scope of Pfizer's enforceable, extended patent rights. *See id.*

Dr. Reddy's argument is precisely the argument Banner makes here: Biogen received a PTE for its FDA-approved drug Tecfidera, which contains DMF; since Banner's product contains only MMF, which is neither a salt nor ester of DMF, Banner's product falls outside the scope of Biogen's enforceable, extended patent rights. Based on *Glaxo*, then, one might have expected Dr. Reddy's to prevail. Instead, however, the Federal Circuit rejected Dr. Reddy's position and ruled for Pfizer.[7]

Specifically, the Federal Circuit held in *Pfizer* that the "active ingredient" for purposes of the PTE was "amlodipine," i.e., the active moiety, regardless of "whether [it was] administered as a besylate salt [amlodipine besylate] or the maleate salt [amlodipine maleate]." *Id.* at 1366. The Court explained that § 156 "was not intended to be defeated by simply changing the salt." *Id.* Hence, "Dr. Reddy's attempt to limit the extension to the specific approved salt on the basis of the 'rights derived' provision of § 156(b) to the approved product [was] unsound." *Id.; see also id.* (stating that § 156(b)(1) "does not contain any limitation regarding the form of the

[7] *Pfizer* was a 2-1 decision. Judge Meyer advocated for a more narrow view and would have denied the PTE based on Federal Circuit precedent. *See* 359 F.3d at 1367 (Meyer, J., dissenting).

product subject to the extension"). The Federal Circuit further observed that the FDA defines "active ingredient . . . including any salt or ester of the active ingredient" – which is the same language as found in § 156(f)(2) – as "active moiety." *See id.* (citing 59 Fed. Reg. 50338, 50358 (F.D.A. Oct. 3, 1994)).

Applying the reasoning of *Pfizer* would suggest that identifying the "active ingredient" that is the basis for Biogen's enforceable, extended patent rights requires looking to the active moiety of Biogen's approved product, Tecfidera, which is MMF.[8] A holding that Biogen's enforceable PTE rights extend to MMF (as well as any salts and esters of MMF, including DMF), would mean that Banner's Bafiertam, which contains MMF, infringes.

iii. *PhotoCure v. Kappos* – Addressing the Potential Conflict

Arguably, then, there appears to be a conflict between *Glaxo*'s and *Pfizer*'s interpretations of § 156: *Glaxo* views the "active ingredient" of the approved product as limited to only the active ingredient in the product when administered (and salts and esters thereof), while *Pfizer* views the "active ingredient" more broadly as also including the "active moiety" (and salts and esters thereof) doing the therapeutic work in the body of a human patient. *See PhotoCure ASA v.*

[8] The facts in *Pfizer* and the facts here share some similarities. As was true of the drugs involved in *Pfizer*, here Biogen's DMF and Banner's MMF are minimally different, such that MMF would not constitute a "new drug" in the view of the FDA. (*See, e.g.*, Tr. at 6, 39, 48-49, 60-61) Also, like the alleged infringer in *Pfizer*, here Banner relied in its NDA on Biogen's MMF data. (*See id.*) However, other facts make this case distinguishable from *Pfizer*. Unlike the drugs involved in *Pfizer*, *see* 359 F.3d at 1366, DMF and MMF are not analogous salts with a common active moiety; rather, Banner's drug product is the active moiety of Biogen's product (*see, e.g.*, Tr. at 6, 39, 48-49, 60-61). Also, Biogen does not contend that the FDA, in approving Tecfidera, approved the active moiety (MMF) as a "drug product," while by contrast in *Pfizer* "the FDA's approval describes the approved product as [the moiety] 'amlodipine.'" 359 F.3d at 1365. Finally, here, Biogen does not allege that producing an administrable version of MMF (i.e., Banner's accused product) involved a simple modification of "changing the salt," which is all that the accused infringer had done in *Pfizer*.

Dudas, 622 F. Supp. 2d 338, 347 (E.D. Va. 2009) (discussing apparent conflict), *aff'd sub nom. PhotoCure ASA v. Kappos*, 603 F.3d 1372, 1375 (Fed. Cir. 2010).

However, the Federal Circuit has itself expressly held that there is no conflict. In *PhotoCure ASA v. Kappos*, 603 F.3d at 1375, the Federal Circuit stated that its *Glaxo* and *Pfizer* decisions "are not in conflict," as "*Pfizer* did not concern the *Glaxo* ruling that the active ingredient is the ingredient in the drug product as administered." The Federal Circuit quoted *Glaxo* and reaffirmed that "a compound can only qualify as the 'active ingredient' of a drug if that compound itself is present in the drug." *Id.* at 1375-76. Further, *PhotoCure* emphatically states: "*Pfizer* did not change the law of § 156." *Id.* at 1376. Rather, the Federal Circuit explained that "[t]he issue in *Pfizer* was whether infringement of an extended patent . . . was avoided by changing the salt," and *Pfizer*'s holding was that one cannot avoid infringement of an extended patent term simply by changing the salt of the active moiety. *Id.* at 1376. Moreover, "*Pfizer* did not hold that extension is not available when an existing product is substantively changed in a way that produces a new and separately patentable product having improved properties and requiring full FDA approval." *Id.*

In *PhotoCure*, then, the Federal Circuit allowed a PTE for a patent covering MAL hydrochloride notwithstanding that a previously-approved product contained ALA hydrochloride, even though MAL hydrochloride and ALA hydrochloride shared the same active moiety. *See* 603 F.3d at 1375. The Federal Circuit based its decision in *PhotoCure*, at least in part, on the fact that MAL hydrochloride was, by FDA standards, a "new drug" requiring a full (not abbreviated) approval process. *See id.* By contrast, according to *PhotoCure*, "*Pfizer* did not concern a different, separately patented product requiring full regulatory approval." *Id.* at 1376.

iv. Biogen's Active Ingredient Is DMF

Given the Federal Circuit's instruction that there is no direct conflict between *Glaxo* and *Pfizer*, the Court must, consistent with *Glaxo* and the unambiguous meaning of § 156(f)(2), look for the "active ingredient" of Biogen's FDA-approved product in that product at the time of administration, before the product is taken by a human patient. *See Glaxo*, 894 F.3d at 1392-95. Here, the FDA-approved product that is the basis for the '001 Patent's PTE is Biogen's Tecfidera. It is undisputed that the "active ingredient" in Tecfidera when administered (i.e., before it is ingested by a human patient) is DMF. Therefore, Biogen's enforceable, extended patent rights extend only to DMF.

This holding does not conflict with *Pfizer* because, as *PhotoCure* holds, *see* 603 F.3d at 1376, *Pfizer* does not affect *Glaxo*'s ruling that one looks for the active ingredient in the product when administered – which is what the Court is doing here.[9] Also, *Pfizer* emphasizes that § 156(f)(2) does not allow one to avoid infringement of an extended patent simply by changing the salt of the active moiety. *See* 359 F.3d. at 1361. The Court's holding today complies with that directive: Banner's MMF is ***not*** a salt (or ester) of DMF, so Banner is not avoiding infringement via the Hatch-Waxman "loophole" the Federal Circuit feared might arise in *Pfizer*. *Id.* at 1366 ("The Hatch-Waxman Act foresaw and averted the potential loophole of a change in the salt of the active ingredient.").

In any event, even if there were a direct conflict between *Glaxo* and *Pfizer*, the Court

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[9] The Court recognizes that *Pfizer*, like the instant case, explicitly concerns the enforcement of a patent term extension. By contrast, *Glaxo* and *PhotoCure* concerned the predicate issue of PTE eligibility. Nevertheless, for the reasons explained in this Opinion, the Court believes *Glaxo* is the binding precedent on the disputes this Court must resolve in connection with the pending motion.

would be bound to follow *Glaxo*, as it is the earlier of what would then be two conflicting precedential opinions of different panels of the Federal Circuit. *See Newell Cos., Inc. v. Kenney Mfg. Co.*, 864 F.2d 757, 765 (Fed. Cir. 1988) ("[P]rior decisions of a panel of the court are binding precedent on subsequent panels unless and until overturned *in banc*. . . . Where there is direct conflict, the precedential decision is the first."). Thus, even if the Court is incorrect and there actually is a conflict, the outcome here would still be the same: the Court would follow *Glaxo* and would grant Banner's motion.

c. Banner Cannot Be Found Liable for Literal Infringement By Its MMF Product

Reading §§ 156(b)(2) and 156(f)(2) together, then, the Court concludes that the "active ingredient" of Biogen's approved drug product, Tecfidera, is DMF, so the enforceable "rights derived" from the PTE on the '001 Patent are limited to any use claimed in the '001 Patent and approved for the approved DMF product. Biogen's enforceable rights in the '001 Patent are limited to DMF and salts and esters of DMF. While DMF is an ester of MMF, MMF is neither a salt nor ester of DMF. (*See* D.I. 6 at ¶¶ 30-31; D.I. 8 at ¶ 28 (admitting MMF differs from DMF by ester linkage); Tr. at 11, 34)) Therefore, by operation of §§ 156(b)(2) and 156(f)(2), Biogen has no enforceable rights during the patent extension period with respect to MMF. Any rights to MMF conveyed by the '001 Patent expired in April 2018.

Therefore, the Court Banner's motion for judgment on the pleadings of no literal infringement.

C. Doctrine of Equivalents

As an alternative theory for proving infringement, Biogen argues that at least some claim

scope lost during the extended period of its PTE may be reclaimed through the doctrine of equivalents ("DOE"). (D.I. 15 at 18-19; Tr. at 52-53) Biogen's theory is essentially as follows:

> Banner does not dispute that PTE applies to the DMF element of the '001 patent claims, e.g., claim 1. Banner also admits that DMF differs from MMF only by an ester linkage to a methyl group, and that MMF is the known "active moiety" of the DMF in Tecfidera®. . . . Banner's admissions regarding the relationship of DMF and MMF and reliance on Biogen's data demonstrate that using MMF to treat MS is an insubstantial change to using DMF for that same purpose. Thus, the use of Banner's MMF-containing product to treat MS infringes the '001 patent at least under the doctrine of equivalents. At a minimum, this is a factual dispute precluding judgment on the pleadings.

(D.I. 15 at 19) (internal citations omitted)

The Court agrees with Banner that Biogen's assertion of DOE infringement does not raise factual issues and should be resolved, as a matter of law, against Biogen. As Banner persuasively argues:

> Biogen is not free to use the DOE to recapture subject matter – such as the use of MMF – that § 156(b) takes away. . . . [Section] 156(b) says that the "rights derived from any patent" – i.e., the right to assert infringement, either literally or under the DOE – are limited during the extended term. Thus, the statutory language itself forecloses use of the DOE to recapture active ingredients other than the active ingredient in the approved drug product.

(D.I. 20 at 10)[10]

Thus, because the Court has held that Biogen's enforceable PTE rights do not extend to MMF (and its MMF rights expired with the expiration of the original patent term), there is no meritorious basis to hold that Biogen can recapture that expired subject matter through the

[10] The parties' limited briefing on DOE cites essentially no caselaw addressing the issue now before the Court. (*See* D.I. 10 at 20; D.I. 15 at 18-20; D.I. 20 at 9-10)

doctrine of equivalents. (*See* D.I. 20 at 9-10) The Court is persuaded by Banner's analogy to prosecution history estoppel, which prevents a patentee from using DOE to recapture claim scope it disclaimed during prosecution of its patent. *See generally Pharma Tech Sols., Inc. v. LifeScan, Inc.*, 942 F.3d 1372, 1380 (Fed. Cir. 2019) ("Prosecution history estoppel applies as part of an infringement analysis to prevent a patentee from using the doctrine of equivalents to recapture subject matter surrendered from the literal scope of a claim during prosecution.").[11]

Therefore, the Court will grant Banner's motion for judgment on the pleadings of no infringement under the DOE.

IV. CONCLUSION

For the reasons stated above, the Court will grant Banner's motion for judgment on the pleadings. An appropriate order follows.

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[11] Hence, Biogen's reliance on a statement in *Genetics Institute*, which quoted a 1984 House Report accompanying the Hatch-Waxman Act, as providing that "'***all provisions of the patent law apply to the patent during the period of extension***," does not help Biogen. 655 F.3d at 1301 (quoting H.R. Rep. No. 98-857, pt. 1, at 39, 1984 U.S.C.C.A.N. 2647, 2672) (emphasis added by Federal Circuit). While a patentee may assert DOE infringement during a PTE, that patentee may also confront a prosecution history estoppel ("PHE") defense as well as the PHE-type of defense described by Banner. Consistent with PHE, the patentee cannot use DOE to reclaim claim scope it has otherwise already disclaimed or lost.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BIOGEN INTERNATIONAL GMBH, Plaintiff, v. BANNER LIFE SCIENCES LLC, Defendant.	C.A. No. 18-2054-LPS

~~[PROPOSED]~~ FINAL JUDGMENT AND LIMITED TEMPORARY RESTRAINING ORDER

Pursuant to the Court's Memorandum Opinion and Order (D.I. 52, 53) of January 7, 2020, granting Banner's Motion for Judgment on the Pleadings, and the Court having considered the parties' positions in the Joint Status Report dated January 13, 2020 (D.I. 55) and in a joint teleconference on January 17, 2020, and for the reasons stated on the record during that teleconference and in the Court's January 21, 2020 Order, it is hereby ORDERED and ADJUDGED that:

1. Final Judgment of non-infringement is entered on behalf of Defendant Banner Life Sciences ("Banner") with regard to its counterclaim and against Plaintiff Biogen International GmbH's ("Biogen") claim of infringement regarding all claims of U.S. Patent No. 7,619,001 for the reasons stated in the Court's Memorandum Opinion of January 7, 2020.

2. Defendant is the prevailing party as to Plaintiff's claims of infringement of U.S. Patent No. 7,619,001 and as to Defendant's counterclaims for declaratory judgment of noninfringement of U.S. Patent No. 7,619,001.

3. Any motion for an award of costs or attorneys' fees shall be deferred until all appeals relating to this litigation have been exhausted and the Mandate has issued from the Court of Appeals. If Plaintiff does not file an appeal in this litigation, Defendant's deadline for filing such motions and their bills of costs shall be extended to 45 days after the deadline for Plaintiff to file an appeal has lapsed.

4. After this Court rendered its January 7, 2020, Memorandum Opinion finding that Banner did not infringe, Biogen orally requested on January 17 either a Temporary Restraining Order or an Injunction pending appeal. Having considered the premises and the arguments of the parties, and for the reasons stated on the record at the teleconference of January 17, 2020, this Court denies Biogen's motion for an injunction pending appeal but grants a limited Temporary Restraining Order.

5. To allow Biogen time to pursue an injunction pending appeal from the Court of Appeals for the Federal Circuit, Banner is enjoined from launching the product that is the subject of its NDA No. 210296 prior to the expiration of this Temporary Restraining Order.

6. For the avoidance of doubt, this Temporary Restraining Order will not prohibit the FDA from finally approving Banner's NDA No. 210296 should the FDA determine that the NDA has otherwise satisfied the conditions of final approval.

7. Nor does this Temporary Restraining Order prohibit Banner from engaging in pre-launch activities such as manufacturing or stocking product in warehouses. This Temporary Restraining Order does prohibit Banner from selling or offering for sale the product that is the subject of its NDA No. 210296.

8. This Temporary Restraining Order will expire on the earlier of (a) February 4, 2020 at 10:00 a.m. Eastern Standard Time or (b) a decision from the Federal Circuit denying any motion for an injunction during the pendency of any appeal.

9. Additionally, this limited Temporary Restraining Order is expressly conditioned on Biogen's compliance with the following terms, all of which the Court deems reasonable and appropriate to preserve the status quo for (at most) until February 4, 2020 at 10:00 a.m. Eastern Standard Time:

(i) Biogen will move to expedite its appeal in the Federal Circuit. Biogen agrees that it will file its motion for relief before the Federal Circuit with all deliberate speed and that Banner can expedite its opposition as it deems appropriate;

(ii) Biogen shall not take any steps or actions to delay or inhibit final approval of Banner's NDA product;

(iii) Biogen agrees to provide security in the form of a corporate undertaking during the pendency of this Temporary Restraining Order in the amount of $ **SEE BELOW**, pursuant to Fed. R. Civ. P. 65(c) to cover proven damages, if any, to the extent that Banner proves damages in a later proceeding.

$30,000,000.00 LPD

Biogen's Proposal

The standard should not be what Biogen currently is earning on its longstanding, well-established, market-leading product, but rather, is the *profit* that Banner realistically could earn in the next 13 days on a product which is not substitutable for Tecfidera, for which it still needs to secure final FDA approval, will be trying to enter a crowded field of competing products, does not yet have any established market relationships or distribution channels, and does not yet have any ongoing marketing, name recognition, or foothold in the medical community. Even assuming a very reasonable profit margin of 14%, a new entrant, without published favorable clinical trial results, just starting the ramping-up process, cannot be expected to make $30 million in just the next 13 days, nor capture much more than a small percent of the market in 13 days and certainly not the significant percent of Tecfidera revenue which is the amount Banner's proposal represents. Biogen respectfully submits that $300,000 is more than reasonable security under these circumstances.

Regarding Banner's protestations about timing, Biogen also apologizes to the Court for the late filing. However, we did not receive Banner's revised proposal (from $50 million to $30 million) until 7:43 p.m., and until that point we assumed that they were working on a very brief explanation of their position just as we were. We hope the Court will find the short explanations helpful for the Court's evaluation.

Banner's Proposal

Banner's proposal is $30,000,000. First, Banner apologizes for this submission getting in after the Court ordered deadline of 8 p.m. ET. Biogen stated that it would send a proposed form of order for Banner's review. It did not do so. Banner then sent a proposed order inserting the amounts (which is all it understood the Court to be requesting) to Biogen. At 7:59 p.m., Biogen finally responded and for the first time inserted its "Proposal" language. Banner did not understand the Court to be requesting further briefing, and thus, thinks the Court can determine reasonableness. But, given Banner's receipt of new information from Biogen at 7:59 p.m., obviously Banner was put in the position of being unable to meet the Court's deadline, and Banner apologizes to the Court.

Nevertheless, by way of brief explanation, as the Court noted, in roughly 2 weeks, Biogen will make approximately $125 million in U.S. sales for Tecfidera® (with worldwide sales being closer to $170 million). Banner believes its product can compete effectively with Tecfidera and believes that $30 million over two weeks is an appropriate amount for security. Of course, Banner can only ultimately recover what it can actually show it suffers in damages should the TRO have been wrongly entered. This is not the time to decide that issue. Rather, the issue is, assuming Banner can later show losses, what should be the cap on those losses? Clearly, Biogen's proposed $300,000 is insufficient security to offset Banner's potential losses during the TRO.

January 21, 2020

Chief Judge

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BIOGEN INTERNATIONAL GMBH,	:	
	:	
Plaintiff,	:	
	:	
v.	:	C.A. No. 18-2054-LPS
	:	
BANNER LIFE SCIENCES LLC,	:	
	:	
Defendant.	:	

ORDER

At Wilmington this **7th** day of **January, 2020**:

For the reasons set forth in the Memorandum Opinion issued this date,

IT IS HEREBY ORDERED that:

1 Defendant's motion for judgment on the pleadings (D.I. 9) is **GRANTED**.

2. The parties shall meet and confer and, no later than **January 8, 2020**, submit a joint proposed redacted version of the Memorandum Opinion, should either party feel it can demonstrate a meritorious basis to redact any portion of the Memorandum Opinion. Thereafter, the Court will docket a public version.

3. The parties shall meet and confer and, no later than **January 13, 2020**, provide the Court with a joint status report, indicating their position(s) as to how this case should now proceed and with forms of any additional order(s) any party wishes the Court to enter.

HONORABLE LEONARD P. STARK
UNITED STATES DISTRICT JUDGE