20-1373

IN THE
UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

BIOGEN INTERNATIONAL GMBH,

Plaintiff-Appellant,

v.

BANNER LIFE SCIENCES LLC,

Defendant-Appellee.

Appeal from the United States District Court for the District of Delaware, Case No. 1:18-cv-02054-LPS, Chief Judge Leonard P. Stark

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APPELLANT'S PETITION FOR REHEARING EN BANC

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J. Michael Jakes
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May 21, 2020

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

Biogen International GmbH v. Banner Life Sciences LLC

Case No. 20-1373

CERTIFICATE OF INTEREST

Counsel for the:

☐ (petitioner) ☒ (appellant) ☐ (respondent) ☐ (appellee) ☐ (amicus) ☐ (name of party)

Biogen International GmbH

certifies the following (use "None" if applicable):

1. Full Name of Party Represented by me	2. Name of Real Party in interest (Please only include any real party in interest NOT identified in Question 3) represented by me is:	3. Parent corporations and publicly held companies that own 10% or more of stock in the party
Biogen International GmbH	None	Biogen Inc.

4. The names of all law firms and the partners or associates that appeared for the party or amicus now represented by me in the trial court or agency or are expected to appear in this court (**and who have not or will not enter an appearance in this case**) are:

Aaron G. Clay, Andrew E. Renison, Eric J. Fues, Jeanette M. Roorda, John E. Nappi, Li Feng, Megan L. Meyers, FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER, LLP

Steven J. Balick and Andrew C. Mayo, ASHBY & GEDDES, P.A.

5. The title and number of any case known to counsel to be pending in this or any other court or agency that will directly affect or be directly affected by this court's decision in the pending appeal. See Fed. Cir. R. 47.4(a)(5) and 47.5(b).

Biogen International GmbH v. Accord Healthcare Inc., C.A. No. 1:19-cv-00303-MN (D. Del.)

Biogen International GmbH and Biogen MA Inc. v. Amneal Pharmaceuticals LLC, C.A. No. 1:17-cv-00823-MN (D. Del.)

Biogen International GmbH v. Zydus Pharmaceuticals (USA) Inc., C.A. No. 1:19-cv-00333-MN (D. Del.)

Biogen International GmbH and Biogen MA Inc. v. Mylan Pharmaceuticals Inc., C.A. No. 1:17-cv-00116-IMK-JPM (N.D. W. Va.)

Biogen International GmbH v. Cipla Limited and Cipla USA Inc., C.A. No. 1:19-cv-02210-MN (D. Del.)

May 21, 2020
Date

/s/ James B. Monroe
Signature of counsel

Please Note: All questions must be answered

James B. Monroe
Printed name of counsel

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STATEMENT OF COUNSEL

Based on my professional judgment, I believe the panel decision is contrary to at least the following precedents of this Court:

Pfizer Inc. v. Dr. Reddy's Laboratories, Ltd., 359 F.3d 1361 (Fed. Cir. 2004);

Glaxo Operations UK Ltd. v. Quigg, 894 F.2d 392 (Fed. Cir. 1990); and

PhotoCure ASA v. Kappos, 603 F.3d 1372 (Fed. Cir. 2010).

Based on my professional judgment, I believe this appeal requires an answer to one or more precedent-setting questions of exceptional importance:

1. Whether the panel's decision allows an infringer to avoid an innovator's patent term extension by using the claimed and bioequivalent active moiety of the compound in the patentee's approved drug product.

2. Whether patent term extension under 35 U.S.C. § 156(b)(2) for method claims is limited to the "approved product" only, where the only limit that Congress imposed on patent term extension for method claims is "*any use claimed* by the patent *and approved for* the product," and Congress further provided that "[a]s used in this subsection, the term 'product' *includes* an approved product" (i.e., is not "limited" to an approved product). 35 U.S.C. § 156(b) (emphases added).

/s/ James B. Monroe
James B. Monroe

Attorney of Record for Appellant
Biogen International GmbH

INTRODUCTION

This Court has already held—consistent with Congress's express intent under 35 U.S.C. § 156(b)—that patent term extension "does not contain *any* limitation regarding the form of the product subject to the extension. In fact, § 156(f) clearly provides otherwise, in defining the term 'product' as 'including any salt or ester of the active ingredient.'" *Pfizer Inc. v. Dr. Reddy's Laboratories, Ltd.*, 359 F.3d 1361, 1366 (Fed. Cir. 2004) (emphasis added) (quoting 35 U.S.C. § 156(f)). Yet the panel here departed from this Court's precedent, instead holding that Biogen's patent term extension does *not* encompass Banner's proposed monomethyl fumarate ("MMF") product, even though: (1) Biogen's approved dimethyl fumarate ("DMF") product, Tecfidera®, is an *ester* of MMF; (2) Biogen's U.S. Patent No. 7,619,001 ("the '001 patent") claims methods of using MMF or DMF; and (3) both products share the same *active moiety*—i.e., "the compound responsible for the physiological or pharmacological action of the drug substance in the human body," Appx2-3; *see also Pfizer*, 359 F.3d at 1366; 21 C.F.R. § 314.3(b).

The panel's misapplication of *Pfizer* undermines the investment-backed expectation of innovative pharmaceutical companies like Biogen. Under the panel's interpretation of § 156(b), if Biogen had first obtained approval for MMF, then its patent term extension would have covered both MMF and the DMF ester.

But because Biogen first obtained approval of DMF, under the panel's new rule, extension for the '001 patent does *not* cover MMF, even though Biogen invented MMF methods too and expressly claimed them in the '001 patent. That loophole cannot be reconciled with *Pfizer*, especially where Banner avoided a full Food and Drug Administration ("FDA") approval process for its MMF-containing product by relying entirely on Biogen's safety and efficacy data, including Biogen's clinical trials measuring *MMF* in patients' blood plasma. *See, e.g.*, Appx4-5; Appx17(n.8); Appx1198-1215; Appx2199.

While acknowledging that *Pfizer* rejected "*precisely* the argument Banner makes here," Appx16 (emphasis added), the district court also candidly recognized that "[a]rguably, . . . there appears to be a conflict between" two of this Court's precedents—*Pfizer* and *Glaxo Operations UK Ltd. v. Quigg*, 894 F.2d 392 (Fed. Cir. 1990). Appx17-18; *see also* Appx11-12. But the panel's decision does not resolve any perceived conflict in this Court's precedent, and its reading of *Pfizer* creates even more confusion.

Not only does the panel opinion depart from this Court's settled precedent, but it also rewrites the plain text of § 156(b) to insert an "approved product" limitation. In allowing Banner to rely on Biogen's MMF safety and efficacy data for regulatory approval while avoiding any complementary patent term restoration awarded to Biogen for delays in approving Tecfidera®, the panel's decision

threatens the value of exclusivity, reducing incentives for research and innovation in the pharmaceutical industry. *See* H.R. Rep. No. 98-857, at 15, 41 (1984). En banc rehearing is necessary to restore patent term extension under § 156(b) to the scope Congress intended.

BACKGROUND

A. Biogen's '001 Patent and Tecfidera® Product

Biogen's '001 patent claims methods of treating patients suffering from multiple sclerosis with pharmaceutical preparations containing DMF, MMF, or a combination thereof. Appx37-38(claims 1-24); Op. at 3-4. There is no dispute that both DMF and MMF methods fall within the scope of at least claim 1. Op. at 3-4; Appx2; Appx6.

Biogen's innovative drug product at issue here is Tecfidera®, which the FDA approved for the treatment of patients with multiple sclerosis. Op. at 2; Appx3-4. Tecfidera® contains DMF, but it is undisputed that following administration DMF rapidly cleaves an ester to become MMF—the metabolite responsible for Tecfidera®'s therapeutic effects. Op. at 2. That is, MMF is the *active moiety* of DMF.

As part of its New Drug Application ("NDA") for Tecfidera®, Biogen submitted extensive testing data on both DMF *and MMF*, including clinical data measuring patients' blood plasma concentrations of MMF. Appx1131. Thus, the

FDA approved Tecfidera® based on the efficacy and safety of both DMF and MMF. Appx4-5; Appx17(n.8).

The twenty-year term of the '001 patent originally ended on April 1, 2018. Pursuant to 35 U.S.C. § 156(a), however, Biogen was granted 811 days of patent term extension based on the period that the use of Tecfidera® to treat multiple sclerosis was under regulatory review by the FDA. Op. at 4. Biogen elected to apply this patent term extension to the '001 patent, which extended its term to June 20, 2020.

B. Banner's MMF-Containing Product

Banner submitted an NDA under § 505(b)(2) of the Federal Food, Drug, and Cosmetic Act, codified at 21 U.S.C. § 355(b)(2), seeking approval to market its MMF-containing product for the treatment of multiple sclerosis. Op. at 4; Appx4-5; Appx1002(¶ 5). A "paper NDA" submitted under § 505(b)(2) is similar to an Abbreviated New Drug Application ("ANDA"). Both may rely on the safety or efficacy data of reference-listed drugs to establish bioequivalence and avoid the expensive and lengthy clinical trials required for innovative drugs like Tecfidera®.

As part of its paper NDA, Banner demonstrated the safety and efficacy of its MMF-containing product by relying on Biogen's MMF data for Tecfidera®. Op. at 4; Appx4-5; Appx17(n.8); Appx1100; Appx1173-1174; Appx1198-1199. In other words, Banner has admitted to the FDA that DMF and MMF are the same for

physiological and biological purposes, so much so that Banner relied on Biogen's efficacy and safety data for Tecfidera®—including testing of MMF in plasma—to avoid a full FDA approval process for its MMF-containing product.

C. The District Court Decision

Biogen filed the present suit against Banner in December 2018, asserting that Banner's proposed MMF-containing product infringes the '001 patent. Op. at 4. Banner moved for judgment on the pleadings under Fed. R. Civ. P. 12(c), arguing that Biogen's patent term extension does not cover Banner's MMF-containing product, even though Banner relied on Biogen's MMF data to avoid a full FDA approval process. Op. at 4; *see also* Appx4-5; Appx17(n.8). While candidly acknowledging that this Court in *Pfizer* rejected "*precisely* the argument Banner makes here," Appx16 (emphasis added), the district court nevertheless granted Banner's motion. Appx1-27.

D. The Panel Decision

A panel of this Court affirmed the district court's judgment, holding that § 156(b)(2) limits Biogen's patent term extension to the ester form of the MMF active moiety in its Tecfidera® product—DMF. Op. at 7-11.

Relying on this Court's settled precedent in *Pfizer*, Biogen urged that § 156(b) "does not contain *any* limitation regarding the form of the product subject to the extension." 359 F.3d at 1366 (emphasis added) (quoting 35 U.S.C. § 156(f));

Op. at 6-7. In that case, Pfizer obtained FDA approval to market amlodipine besylate salt—i.e., Norvasc®—and Dr. Reddy's subsequently filed a 505(b)(2) paper NDA seeking to market amlodipine maleate salt. *Pfizer*, 359 F.3d at 1363-64. This Court determined that under § 156(b), Pfizer's patent term extension encompassed *all* claimed salt and ester forms of the amlodipine active moiety, even though Pfizer's FDA-approved product was the amlodipine besylate *salt*. *Id.* at 1365-67; *see also* 35 U.S.C. § 156(f) (broadly defining the "product" as the "active ingredient . . . including any salt or ester of the active ingredient").

But the panel here determined that this is "not a *Pfizer* case." Op. at 8. To get there, the panel recast the issue in *Pfizer* as follows: "whether an extension *for amlodipine* encompassed a § 505(b)(2) applicant's amlodipine maleate product under § 156(b)(2)." *Id.* (emphasis added). According to the panel, *Pfizer* was inapposite "because amlodipine maleate is a salt of the active ingredient, amlodipine," while DMF is an ester of MMF, and not the other way around. *Id.* at 7-8. Indeed, the panel's ability to distinguish *Pfizer* hinged on the approved product in that case being the active moiety amlodipine, not the amlodipine besylate salt. But the facts of *Pfizer* are different than how the panel describes them—the extension there was based on the FDA's approval of *amlodipine besylate salt*, not amlodipine. *Pfizer*, 359 F.3d at 1364-66. In fact, in its notice to the U.S. Patent and Trademark Office reporting the length of regulatory review, the

FDA identified Pfizer's approved formulation only as Norvasc®—i.e., amlodipine besylate salt—not amlodipine. Appx2499-2500; *see also* Appx2502-2503 (notice of patent term extension identifying Pfizer's product as "Norvasc").

Biogen additionally urged that § 156(b)(2) does not limit patent term extension for method-of-use patents to the "approved product" only, but instead only limits the extension "to *any use claimed* by the patent *and approved for* the product." 35 U.S.C. § 156(b)(2) (emphases added); *see* Op. at 9-10. In other words, Congress limited the patent term extension to the *use* that is *claimed* and *approved* by the FDA, not to the underlying approved product. The panel disagreed, instead concluding that "*the* product" in § 156(b)(2) can only mean an "approved product" limitation. Op. at 10. And according to the panel, because Biogen's approved product here is DMF, patent term extension does not apply to its claimed methods of treating multiple sclerosis with MMF. *Id.* The panel, however, never addressed the 1988 amendment to § 156(b), where Congress confirmed that "[a]s used in this subsection, the term 'product' *includes* an approved product," and is not limited to the "approved product" only. *See* Generic Animal Drug and Patent Term Restoration Act, Pub. L. No. 100-670, 102 Stat. 3971, 3985 (1988) (emphasis added).

ARGUMENT

I. The Panel Opinion Contradicts *Pfizer* and Sows Confusion

"*Stare decisis*—in English, the idea that today's Court should stand by yesterday's decisions—is a 'foundation stone of the rule of law.'" *Kimble v. Marvel Entm't, LLC*, 135 S. Ct. 2401, 2409 (2015) (citation omitted). Yet the panel here sidestepped controlling precedent, which will only lead to greater uncertainty and reduced incentives for pioneering drug research.

This Court held in *Pfizer* that patent term extension encompassed *any* salt and ester forms of the same *active moiety* as provided in § 156(f) and covered by Pfizer's patent, not just Pfizer's FDA-approved salt form. *Pfizer*, 359 F.3d at 1366-67. The facts in that case matter. Pfizer obtained FDA approval to market a product containing amlodipine besylate salt, and Dr. Reddy's subsequently filed a 505(b)(2) paper NDA seeking to market amlodipine maleate salt. *Id.* at 1363-64. Like Banner here, Dr. Reddy's relied on the safety and efficacy data submitted to the FDA by Pfizer, which included testing of both the amlodipine besylate salt and amlodipine maleate salt. *Id.* at 1365. Both forms of amlodipine were covered by the same Pfizer patent. *Id.* at 1363-64.

In holding that Pfizer's patent term extension under § 156(b) for amlodipine besylate salt encompassed Dr. Reddy's 505(b)(2) paper NDA for amlodipine maleate salt, this Court explained:

> 35 U.S.C. § 156(f) defines the drug product as including "any salt or ester of the active ingredient." The FDA ruled that "the term 'active ingredient' as used in the phrase 'active ingredient including any salt or ester of the active ingredient' means *active moiety*." The FDA has defined "active moiety" as "the molecule or ion, excluding those appended portions of the molecule that cause the drug to be an ester [or] salt . . . *responsible for the physiological or pharmacological action of the drug substance*."

Id. at 1366 (emphases added) (citation omitted) (quoting 21 C.F.R. § 314.108(a) (2004), now 21 C.F.R. § 314.3(b)). Thus, when applying § 156(f)(2) to § 156(b) in the context of enforcing patent term extension against a proposed product that was neither pharmacologically distinct nor separately patentable, this Court equated "active ingredient" with "active moiety." *Id.* at 1363-67.

Under the reasoning of *Pfizer*, it makes no difference that DMF is an ester of MMF, and not the other way around. After all, in *Pfizer*, amlodipine maleate was not a salt of amlodipine besylate. Yet this Court held in *Pfizer* that amlodipine—the molecule responsible for the pharmacological action—was the "active ingredient," not the FDA-approved amlodipine besylate salt. *Id.* at 1366. The point of *Pfizer* is that "[t]he statute *foresaw variation in the salt or ester* of an *active ingredient*, and guarded against the very loophole now urged." *Id.* (emphases added). And here, MMF—expressly claimed in the '001 patent and the molecule undisputedly responsible for the pharmacological action in Biogen's Tecfidera®—is the "active ingredient" for purposes of enforcing patent term extension under § 156(b).

The panel opinion undermines this Court's controlling precedent and creates confusion as to how patent term extension under § 156(b) will apply moving forward. According to the panel, the issue in *Pfizer* was "whether an extension *for amlodipine* encompassed a § 505(b)(2) applicant's amlodipine maleate product under § 156(b)(2)." Op. at 8 (emphasis added). But lost in the panel's retelling is the fact that Pfizer's FDA-approved product was not amlodipine, but *amlodipine besylate salt*—Norvasc®. *Pfizer*, 359 F.3d at 1364-66; Appx2499-2500; Appx2502-2503. And that is a distinction with a difference. While Pfizer's FDA-approved product was a salt form of amlodipine, this Court nevertheless recognized that the "active ingredient" was amlodipine itself. *Pfizer*, 359 F.3d at 1364-66. It did not matter that amlodipine mesylate was a switched-salt form of Pfizer's approved amlodipine besylate. Nor should it matter here that MMF is the "de-esterified form" of Biogen's approved Tecfidera®. Op. at 6-8. The statute foresaw these variations in salts and esters. *Pfizer*, 359 F.3d at 1366.

The panel opinion dismisses this Court's holding in *Pfizer* equating "active ingredient" with "active moiety" as simply "illuminat[ing] the purpose of the statute" and providing "context" to the fact "that amlodipine maleate is a salt of amlodipine." Op. at 8. But the panel never confronts that the approved product in *Pfizer*—amlodipine besylate—was itself a salt of amlodipine. Nor does the panel address *Abbott Laboratories v. Young*, 920 F.2d 984 (D.C. Cir. 1990)—expressly

relied on in *Pfizer*, 359 F.3d at 1366—where this Court's sister circuit held that an interpretation of "active ingredient" like the one adopted by the panel here "fails to serve any conceivable statutory purpose." *Abbott*, 920 F.2d at 986-89 (rejecting Abbott's argument that "active ingredient" referred only to the originally approved salt and not the active moiety). As Banner candidly admitted to the district court, "[i]t appears that the holding in *Pfizer relied* on a finding that the definition of 'product' in § 156(f) means 'active moiety' . . . ." Appx2340-2341 (emphasis added).

Hoechst-Roussel Pharmaceuticals, Inc. v. Lehman, 109 F.3d 756 (Fed. Cir. 1997), does not justify the panel's disregard of *Pfizer* either. Op. at 7. In that case, this Court determined that Hoechst was not entitled to patent term extension under 35 U.S.C. § 156(a) where its approved product—tacrine hydrochloride—was not claimed in its patent. *Hoechst-Roussel*, 109 F.3d at 760-61. This Court's decision turned on the plain meaning of the term "claims," not on "product" or "active ingredient" under § 156(b) and (f). *Id.* Here, both MMF and DMF methods are expressly claimed in Biogen's '001 patent. Op. at 3-4.

Nevertheless, relying on *Hoechst-Roussel*, the panel held that an "active ingredient" under § 156(f) "must be present in the drug product as administered." Op. at 7 (quoting *Hoechst-Roussel*, 109 F.3d at 759 n.3). The facts of *Pfizer*, however, show that *Hoechst-Roussel* cannot mean what the panel here says it does.

In *Pfizer*, the approved product as administered was the amlodipine besylate salt, not amlodipine alone. 359 F.3d at 1364-66. But this Court held that Pfizer's "active ingredient" was the active moiety amlodipine. *Id.* at 1365-66. In defining the term "product" as "including any salt or ester of the active ingredient," Congress intended for patent term extension to apply to these minor—and claimed—variations that do not require a new lengthy regulatory approval process. *Id.* at 1366 (quoting 35 U.S.C. § 156(f)). *PhotoCure*—which the panel sidestepped as "dictum," Op. at 9—confirms as much. *PhotoCure ASA v. Kappos*, 603 F.3d 1372, 1376 (Fed. Cir. 2010) (holding that "the incentive purpose of term extension 'was not intended to be defeated by simply changing the salt,'" where "the changed salt *had no effect* on the activity of the product, for *the 'active moiety' of the product was unchanged*" (emphases added) (quoting *Pfizer*, 359 F.3d at 1366)).

The panel's assertions notwithstanding, Biogen does not advance "a different meaning" for "product" under § 156(b) compared to § 156(a). Op. at 6-7. In *Glaxo*, this Court held that a separately patentable and biologically distinct salt that went through a "lengthy FDA review process" was eligible for patent term extension under § 156(a). *Glaxo*, 894 F.2d at 393-94. But that is entirely distinguishable from the situation here, where Banner has admitted to the FDA that DMF and MMF are the same for physiological and biological purposes, so much so that Banner relied

on Biogen's efficacy and safety data for Tecfidera®—including testing of MMF in plasma—to avoid a full FDA approval process for its MMF-containing product. Appx4-5; Appx17(n.8).

Even with these important differences, the district court recognized that "[a]rguably, . . . there appears to be a conflict between" two of this Court's precedents—*Pfizer* and *Glaxo*. Appx17-18. The panel's application of *Pfizer* to justify its decision here creates more confusion for patentees. While Biogen's '001 patent will expire on June 20, 2020, "[i]t is well-established that [this Court's] decision . . . would have a consequence on any infringement that occurred during the life of the ['001] patent." *Sony Corp. v. Iancu*, 924 F.3d 1235, 1238 n.1 (Fed. Cir. 2019) (finding that expiration of patent did not moot the appeal). That is especially true here, where Banner has now received FDA approval to launch its MMF-containing product. The scope of patent term extension is a recurring issue warranting this Court's en banc review.

II. The Panel Opinion Makes a Nullity of the Very Statutory Language It Purports to Explain

The panel's decision also incorrectly imports an "approved product" requirement into § 156(b)(2) governing patent term extension for method claims. Op. at 10. For "a patent which claims a method of using a product," § 156(b)(2) provides that the "rights derived from any patent" during patent term extension are "limited to *any use claimed* by the patent *and approved for* the product." 35 U.S.C.

§ 156(b) (emphases added). Banner does not dispute that the '001 patent recites methods for treating multiple sclerosis with MMF, and that the FDA approved Biogen's Tecfidera® product for this same use. Op. at 2-4. Nor does Banner dispute that it seeks to market its MMF-containing product to treat multiple sclerosis. Appx4-5. Thus, under the plain language of § 156(b)(2), Biogen's patent term extension covers the use of Banner's MMF-containing product to treat multiple sclerosis.

Nevertheless, the panel concluded that "*the* product" in § 156(b)(2) can only mean that patent term extension is limited to the "approved product." Op. at 10. Yet the panel never addressed what § 156(b) says about the term "product": "As used in this subsection, the term 'product' *includes* an approved product." 35 U.S.C. § 156(b) (emphasis added). That is, while including the "approved product," § 156(b)(2) is not limited to the "approved product" only. The panel did not discuss this provision, and ignoring it violates the "surplusage canon—the presumption that each word Congress uses is there for a reason." *See Advocate Health Care Network v. Stapleton*, 137 S. Ct. 1652, 1659 (2017) (citing Antonin Scalia & Bryan A. Garner, *Reading Law: The Interpretation of Legal Texts* 174-79 (2012)); *see also* 2A Norman J. Singer & J.D. Shambie Singer, *Sutherland on Statutes and Statutory Construction* § 47.23, at 417 (7th ed. 2007) ("When

'include' is utilized, it is generally improper to conclude that entities not specifically enumerated are excluded.").

That the FDA approves products and indications together does not insert an "approved product" limitation into § 156(b)(2). Op. at 10. In fact, Congress *removed* the word "approved" before "product" in 1988. Pub. L. No. 100-670, 102 Stat. at 3985. And while the panel is correct that the statute includes the word "limited," *id.*, the imposed limitation is on the "use," not on the form of the product. As this Court held in *Pfizer*,

> [t]he "rights derived" provision of § 156(b) specifically limits the extension to "any use approved for the product," *which means* that other, *e.g.*, non-pharmaceutical uses, are not subject to the extension. That provision does not contain *any limitation regarding the form of the product* subject to the extension.

359 F.3d at 1366 (emphases added).

Merck & Co. v. Kessler, 80 F.3d 1543 (Fed. Cir. 1996), does not rewrite § 156(b). *See* Op. at 10. Rather, *Merck* considered in the context of the Uruguay Round Agreements Act, 80 F.3d at 1546 (citing 35 U.S.C. § 154), "whether a patent whose term at the time of grant was 17-years-from-grant, and whose term had duly been extended under § 156, could obtain a second extension after the 20-years-from-filing term became available to that patent." *Pfizer*, 359 F.3d at 1366-67. The scope of § 156(b)—and § 156(b)(2) in particular—was simply not at issue in *Merck*.

According to the panel, "it would make little sense for an extension . . . to apply to a different product for which the NDA holder was never subjected to a regulatory review period." Op. at 10. But here, the FDA approved Tecfidera® based on the efficacy and safety of *MMF* in patients. Appx1131; Appx4-5; Appx17(n.8). What's more, "'[j]ust as Congress' choice of words is presumed to be deliberate' and deserving of judicial respect, 'so too are its structural choices.'" *SAS Inst. Inc. v. Iancu*, 138 S. Ct. 1348, 1355 (2018) (alteration in original) (citation omitted). The panel wholly ignores that the '001 patent provides Biogen not only the right to exclude others from marketing its approved DMF product, but also the right to exclude others from marketing its claimed MMF product. *See Presidio Components, Inc. v. Am. Tech. Ceramics Corp.*, 702 F.3d 1351, 1363 (Fed. Cir. 2012). And if Biogen is truly to recoup the same market exclusivity that it would have enjoyed during its original patent term, both DMF *and MMF* must be excluded from the market during the extended term.

CONCLUSION

This Court should grant rehearing en banc.

Date: May 21, 2020

Respectfully submitted,

/s/ James B. Monroe

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ADDENDUM

United States Court of Appeals for the Federal Circuit

BIOGEN INTERNATIONAL GMBH,
Plaintiff-Appellant

v.

BANNER LIFE SCIENCES LLC,
Defendant-Appellee

2020-1373

Appeal from the United States District Court for the District of Delaware in No. 1:18-cv-02054-LPS, Chief Judge Leonard P. Stark.

Decided: April 21, 2020

JAMES B. MONROE, Finnegan, Henderson, Farabow, Garrett & Dunner, LLP, Washington, DC, for plaintiff-appellant. Also represented by PAUL WILLIAM BROWNING, J. MICHAEL JAKES, LAURA POLLARD MASUROVSKY, JASON LEE ROMRELL.

KYLE MUSGROVE, Parker Poe Adams & Bernstein LLP, Charlotte, NC, for defendant-appellee. Also represented by JOHN WORTHINGTON BATEMAN, ELIZABETH CROMPTON, SCOTT A. CUNNING, II, Washington, DC.

Before LOURIE, MOORE, and CHEN, *Circuit Judges*.

LOURIE, *Circuit Judge*.

Biogen International GmbH ("Biogen") appeals from a judgment of the United States District Court for the District of Delaware that Banner Life Sciences LLC ("Banner") does not infringe the extended portion of U.S. Patent 7,619,001 (the "'001 patent"), extended under the patent term restoration provisions of the Hatch-Waxman Act, Pub. L. No. 98-417, § 201, 98 Stat. 1585, 1598 (as codified at 35 U.S.C. § 156 (2018)). *Biogen Int'l GmbH v. Banner Life Scis. LLC*, No. 18-2054-LPS, 2020 WL 109499 (D. Del. Jan. 7, 2020) ("*Decision*").

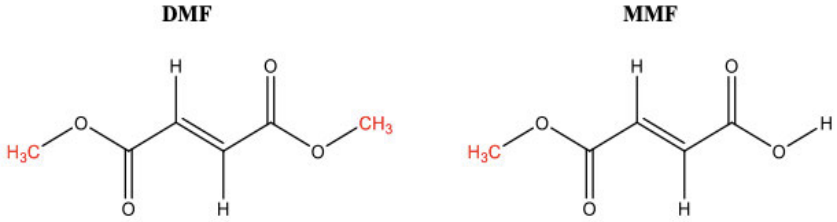
Because the scope of a patent term extension under 35 U.S.C. § 156 only includes the active ingredient of an approved product, or an ester or salt of that active ingredient, and the product at issue does not fall within one of those categories, we affirm the judgment of the district court.

BACKGROUND

Biogen holds the New Drug Application ("NDA") for the active ingredient dimethyl fumarate ("DMF"), which was approved by the Food and Drug Administration ("FDA") in 2013 as Tecfidera®, a twice-daily pill indicated "for the treatment of patients with relapsing forms of multiple sclerosis" at a daily dose of 480 mg. J.A. 1123. DMF is the dimethyl ester of fumaric acid. An ester is a compound derived from the combination of a carboxylic acid and an alcohol, minus a molecule of water.

DMF, a double ester, is the approved product in this appeal. Upon administration to a patient, one of DMF's methyl ester groups is readily metabolized to a carboxylic acid group, becoming monomethyl fumarate ("MMF") before the compound reaches its pharmacological site of action. J.A. 1131.

DMF and MMF are represented below. DMF contains two methyl groups (in red), which are part of the ester functional groups. MMF is virtually identical, except that it has only one methyl ester group; the other group is simply a carboxylic acid.



Banner Opening Br. at 6, *Biogen Int'l GmbH v. Banner Life Scis. LLC*, No. 18-2054-LPS (D. Del. Feb. 1, 2019), ECF No. 10.

The '001 patent, entitled "Utilization of Dialkylfumarates," ultimately claims priority from a German application filed in 1998. It discloses that dialkylfumarates may have therapeutic uses "in transplantation medicine and for the therapy of autoimmune diseases," '001 patent col. 3 ll. 44–45, including multiple sclerosis, *id.* col. 4 l. 57. Claim 1 is representative:

> 1. A method of treating multiple sclerosis comprising administering, to a patient in need of treatment for multiple sclerosis, an amount of a pharmaceutical preparation effective for treating multiple sclerosis, the pharmaceutical preparation comprising
>
> at least one excipient or at least one carrier or at least one combination thereof; and
>
> dimethyl fumarate, methyl hydrogen fumarate, or a combination thereof.

Both the dimethyl ester and monomethyl ester forms are covered by this claim, monomethyl ester being an

alternative way to describe the claimed methyl hydrogen fumarate. The '001 patent was originally set to expire on April 1, 2018, but its term was extended by 811 days under the provisions of § 156 to compensate Biogen for the period during which the FDA reviewed its Tecfidera® NDA. The '001 patent is now set to expire on June 20, 2020. The question in this appeal is whether the monomethyl ester, covered by the claim, is covered by the extension. We conclude, consistent with the district court, that it is not.

In 2018, after the five-year data exclusivity period for Tecfidera® had expired, Banner submitted an application under 21 U.S.C. § 355(b)(2) (a § 505(b)(2) application or a "paper NDA") to market a twice-daily MMF pill at a daily dose of 380 mg. A paper NDA is a form of generic application used before the enactment of the Hatch-Waxman Act. Banner performed clinical studies to assess whether its proposed product was bioequivalent to Tecfidera®, *see* 21 C.F.R. § 314.3(b), but it relied on the clinical data Biogen submitted to the FDA in its Tecfidera® NDA to satisfy the safety and efficacy requirements.

In December 2018, Biogen asserted the '001 patent in an infringement action against Banner in the District of Delaware. Banner immediately moved for a judgment of noninfringement, arguing that § 156(b)(2) limits the scope of the '001 patent's extension to methods of using the approved product as defined in § 156(f)—in this case, DMF, its salts, or its esters—and that MMF is none of those things. Biogen responded that § 156(b)(2) does not limit extension of a method of treatment patent to uses of the approved product, but instead only to uses of any product within the original scope of the claims. Biogen further argued that, in any event, "product" in § 156 has a broader meaning encompassing any compound that shares with the approved product an "active moiety." *See* 21 C.F.R. § 314.3(b) (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"). Since DMF and MMF share an active moiety (MMF), Biogen contended that Banner's proposed MMF product infringes the '001 patent even as extended.

The district court agreed with Banner's interpretation of § 156 in both respects and rendered a judgment of non-infringement. It rejected Biogen's argument that extension of a method of treatment patent under § 156(b)(2) is not limited to uses of the approved product. *Decision*, 2020 WL 109499, at *4–5. The district court also reasoned that this court's interpretation of "product" in § 156 forecloses Biogen's argument that MMF is the same product as Tecfidera®. *Id.* at *9–10 (citing *Glaxo Ops. UK Ltd. v. Quigg*, 894 F.2d 392, 395 (Fed. Cir. 1990)).

Biogen appealed to this court. We have jurisdiction under 28 U.S.C. § 1295(a)(1).

DISCUSSION

We review a district court's judgment on the pleadings under Federal Rule of Civil Procedure Rule 12(c) according to the law of the regional circuit. *Koninklijke KPN N.V. v. Gemalto M2M GmbH*, 942 F.3d 1143, 1149 (Fed. Cir. 2019) (citing *Allergan, Inc. v. Athena Cosmetics, Inc.*, 640 F.3d 1377, 1380 (Fed. Cir. 2011)). In the Third Circuit, judgment under Rule 12(c) is reviewed *de novo* and is appropriate when "no material issue of fact remains to be resolved," and the movant "is entitled to judgment as a matter of law." *Jablonski v. Pan Am. World Airways, Inc.*, 863 F.2d 289, 290–91 (3d Cir. 1988) (quoting *Society Hill Civic Ass'n v. Harris*, 632 F.2d 1045, 1054 (3d Cir. 1980)).

Infringement is a question of fact. *Amgen Inc. v. Sandoz Inc.*, 923 F.3d 1023, 1027 (Fed. Cir. 2019), *reh'g granted, opinion modified*, 776 F. App'x 707 (Fed. Cir. 2019) (citing *Lucent Techs., Inc. v. Gateway, Inc.*, 580 F.3d 1301, 1309 (Fed. Cir. 2009)). Statutory interpretation is a

question of law that we review *de novo*. *Power Integrations, Inc. v. Semiconductor Components Indus., LLC*, 926 F.3d 1306, 1313–14 (Fed. Cir. 2019) (citing *Unwired Planet, LLC v. Google Inc.*, 841 F.3d 1376, 1379 (Fed. Cir. 2016)).

Section 156 was enacted as part of the Hatch-Waxman Act, otherwise intended to provide for approval of generic products, to restore part of a patent's term consumed during clinical testing and FDA review of an NDA relating to a compound covered by the patent. As the Supreme Court has noted, the ordinary term of a pharmaceutical patent is diminished by the time spent in the FDA approval process. *See Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 669–71 (1990). While the patent's term is running, the NDA applicant may not commercialize its product until it receives FDA approval. The Hatch-Waxman Act provided for patent term extensions in § 156 to partially compensate NDA applicants for this loss of patent life. *Id.*

Under § 156, an NDA holder is entitled to extend the term of only one patent for the corresponding approved product. *Id.* § 156(c)(4). Subsection (a) places several conditions on term extension for an NDA holder, including that the applicant's approved NDA must be "the first permitted commercial marketing or use of the product." § 156(a)(5)(A). Subsection (b) limits the scope of the patent extension to "any use approved for the product," and further, for method of treatment patents, to uses also "claimed by the patent." § 156(b)(2). Critically, for the purposes of this appeal, subsection (f) defines "product" as "the active ingredient of . . . a new drug . . . including any salt or ester of the active ingredient." § 156(f)(2)(A).

Biogen primarily argues that the district court misinterpreted "product" in § 156(f) as not encompassing a deesterified form of an approved product. Biogen maintains that this court decided in *Pfizer Inc. v. Dr. Reddy's Labs., Ltd.*, 359 F.3d 1361 (Fed. Cir. 2004), that "product" has a different meaning under § 156(b), encompassing the de-

esterified form, particularly where "a later applicant's patentably indistinct drug product . . . relies on the patentee's clinical data." Appellant Br. 17. In that circumstance, Biogen contends, "active ingredient" means "active moiety," and our holdings in *Glaxo* and *PhotoCure ASA v. Kappos*, 603 F.3d 1372 (Fed. Cir. 2004), are thus inapposite because they ultimately concerned the availability of separate extension under § 156(a).

Banner responds that § 156(f) provides a consistent definition of "product" for the entire statute, a definition that this court expressly held in *Glaxo* excludes a de-esterified form of the active ingredient. It further argues that Biogen has misinterpreted the holding of *Pfizer*.

We agree with Banner that the extended portion of Biogen's patent does not encompass its MMF product.

The parties here argue that either *Glaxo or Pfizer* helps their case. But this case is neither a *Glaxo* case nor a *Pfizer* case. It is governed by the statute. *Glaxo* involved the question whether a separate ester compound, not the same active ingredient as its previously approved carboxylic acid, was entitled to its own extension under § 156(a). We held that it was so entitled because the ester compound was not the same product as the previously approved carboxylic acid within the meaning of § 156(f). "Active ingredient" is a term of art, defined by the FDA as "any component that is intended to furnish pharmacological activity or other direct effect," 21 C.F.R. § 210.3(b)(7), and it "must be present in the drug product when administered." *Hoechst-Roussel Pharm., Inc. v. Lehman*, 109 F.3d 756, 759 n.3 (Fed. Cir. 1997) (citation omitted). The active ingredient of a given drug product is defined by what is approved and is specified on the drug's label. *See* 21 U.S.C. § 352(e)(1)(A)(ii); 21 C.F.R. § 201.100(b)(4). 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 what can be extended, but MMF is the

de-esterified form of DMF, not an ester of DMF. Thus, it is not the same product under § 156(f) and does not fall within the scope of the '001 patent's term extension under § 156(b)(2).

As this court held in *Glaxo*, "product" is plainly defined in § 156(f)—not as the active moiety—but as the active ingredient or an ester or salt of the active ingredient. We concluded in that case that a product whose active ingredient, cerufoxime axetil, was an ester of a previously approved active ingredient, cerufoxime, was eligible for its own separate extension under § 156(a) because neither cerufoxime axetil, nor salts or esters of that compound, had previously been approved. 894 F.2d at 395–96. This case is not directly governed by *Glaxo*, as it does not involve an issue of a separate extension.

This case is also not a *Pfizer* case. In *Pfizer*, we considered whether an extension for amlodipine encompassed a § 505(b)(2) applicant's amlodipine maleate product under § 156(b)(2). We held that it did because amlodipine maleate is a salt of the active ingredient, amlodipine, and was therefore the same product under § 156(f). *Pfizer*, 359 F.3d at 1366 ("We conclude that the active ingredient is amlodipine . . . ."). *Pfizer* does not govern this case because MMF is not a salt of DMF. Biogen's assertion that *Pfizer* endorsed an "active moiety" interpretation of § 156(f) finds little support in our opinion. Instead, *Pfizer* noted the follow-on applicant's reliance on the patentee's clinical data in its own application and the FDA's construction of similar phrases in the Hatch-Waxman Act. But these statements simply illuminated the purpose of the statute and gave context to our holding that amlodipine maleate is a salt of amlodipine and therefore the same product under § 156(f), as expressly provided by the language of the statute. *Id.* ("including any salt or ester of the active ingredient"); *see PhotoCure ASA v. Kappos*, 603 F.3d 1372, 1376 (Fed. Cir. 2010).

While Biogen highlights a dictum of *PhotoCure,* our observation that the new ester in that case was separately patentable, 603 F.3d at 1376, *PhotoCure* presented a situation virtually identical to that in *Glaxo*—a new ester's eligibility for term extension under § 156(a)—and was thus decided according to the holding of *Glaxo*, *id.* at 1375–76 (rejecting argument for an "active moiety" interpretation of § 156(f) as contrary to the holding of *Glaxo*).

All these precedents, and now this case, rest on the same holding: the term "product," defined in § 156(f) as the "active ingredient . . . including any salt or ester of the active ingredient," has a plain and ordinary meaning that is not coextensive with "active moiety." It encompasses the active ingredient that exists in the product as administered and as approved—as specified by the FDA and designated on the product's label—or changes to that active ingredient which serve only to make it a salt or an ester. It does not encompass a metabolite of the active ingredient or its de-esterified form. This case is unlike *Glaxo* or *Pfizer* in that it concerns a de-esterified compound, not an ester or salt.

Biogen makes two other arguments, neither of which has merit. Biogen first contends that, unlike the provision for product patents under § 156(b)(1), § 156(b)(2) does not limit extension for method of treatment patents to approved uses of the *approved* product, but only to approved uses of *any* approved product. Otherwise, Biogen maintains, the additional clause in subsection (b)(2), further limiting extension to "any use claimed by the patent," would be superfluous.[1] Banner responds that the relevant

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[1] As Biogen points out, this clause in § 156(b)(2) is somewhat redundant because a method of treatment claim is already limited by its own terms to the uses it claims. Nevertheless, this slight redundancy certainly does not reverse the limitation imposed by the "any use . . . approved for the product" clause.

language of § 156(b) is identical for product patents and method of treatment patents, limiting extension for each to "any use approved for the product." *Id.*

Like Banner, we see no basis for Biogen's interpretation of § 156(b)(2). As an initial matter, subsection (b)(2) is limited to "use[s] approved for *the* product," *id.* (emphasis added), which is defined in § 156(f), and an indication of use is obviously inseparable from a specific product. *See, e.g.*, 21 C.F.R. § 201.57(a)(6) (requiring "[a] concise statement of each of *the product's* indications" (emphasis added)). The approved product here is DMF, not MMF. And the statute uses the word "limited," which runs contra to Biogen's argument for extension. 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. *See Merck & Co., Inc. v. Kessler*, 80 F.3d 1543, 1547 (Fed. Cir. 1996) (concluding for product patents that "the 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").

Finally, Biogen argues that the district court erred in rejecting its claim for infringement under the doctrine of equivalents because "*all provisions of the patent law apply* to the patent during the period of extension." Appellant Br. 28 (quoting *Genetics Inst., LLC v. Novartis Vaccines & Diagnostics, Inc.*, 655 F.3d 1291 (Fed. Cir. 2011) (emphasis in Biogen's brief)).

We disagree. To infringe a patent claim extended under § 156, an accused product or process must meet, either literally or through equivalence, each individual element of the claim. *See Johnson & Johnston Assocs. Inc. v. R.E. Serv. Co.*, 285 F.3d 1046, 1052 (Fed. Cir. 2002) (en banc). But such a product or process cannot logically infringe an

extended patent claim under equivalence if it is statutorily not included in the extension under § 156. That would make judge-made law prevail over statute.

CONCLUSION

We have considered Biogen's further arguments but find them unpersuasive. For the foregoing reasons, the judgment of the district court is

AFFIRMED

CERTIFICATE OF COMPLIANCE

1. This petition complies with the type-volume limitation of Federal Rule of Appellate Procedure 35(b)(2):

> This petition contains 3,860 words, excluding the parts of the petition exempted by Federal Circuit Rule 35(c)(2).

2. This petition complies with the typeface requirements of Federal Rule of Appellate Procedure 32(a)(5) or Federal Circuit Rule 28.1 and the type style requirements of Federal Rule of Appellate Procedure 32(a)(6):

> This petition has been prepared in a proportionally spaced typeface using Microsoft Word 2016 in 14-point Times New Roman.

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