IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BIOGEN INTERNATIONAL GMBH and BIOGEN MA INC.,	)	
Plaintiffs,	)	
v.	)	C.A. No. 17-823 (MN)
AMNEAL PHARMACEUTICALS LLC, et al.,	)	
Defendants.	)	

MEMORANDUM OPINION

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September 16, 2020
Wilmington, Delaware

NOREIKA, U.S. DISTRICT JUDGE:

This is a patent infringement action arising under the Hatch-Waxman Act. Before the Court is the issue of whether the recent judgment in the Northern District of West Virginia that the asserted claims of U.S. Patent No. 8,399,514 ("the '514 Patent") are invalid should apply here under the principles of collateral estoppel. For the reasons set forth below, the Court finds that collateral estoppel applies.

I. BACKGROUND

Plaintiffs Biogen International GmbH and Biogen MA Inc. (collectively, "Plaintiffs" or "Biogen") hold approved New Drug Application ("NDA") No. 204063 for the use of dimethyl fumarate delayed-release capsules for the treatment of relapsing forms of multiple sclerosis ("MS"). (D.I. 335, Ex. 1 ¶ 24). Plaintiffs market their delayed-release dimethyl fumarate ("DMF") capsules under the trade name Tecfidera®, which is an FDA-approved oral medication indicated for relapsing forms of MS. (*Id.* ¶¶ 25-26). Plaintiffs own patents involving fumarates and treatment of MS, two of which (the '514 Patent and another patent) are listed in the Orange Book for NDA No. 204063. (*See id.* ¶ 21). The '514 Patent, titled "Treatment for Multiple Sclerosis," issued on March 19, 2013 and expires on February 7, 2028. (*See* '514 Patent; *see also* D.I. 335, Ex. 1 ¶¶ 18 & 20). The '514 Patent contains twenty claims, all of which are directed to methods of treating MS with about 480 mg of DMF, monomethyl fumarate ("MMF") or a combination thereof.

Plaintiffs sued a number of defendants in this District for patent infringement based on the filings of Abbreviated New Drug Applications ("ANDAs") seeking to market generic versions of

Tecfidera®.[1] This case is a consolidated action that proceeded to trial with following defendants: Hetero USA Inc., Hetero Labs limited Unit-III, Hetero Labs Ltd., Hetero USA Inc. (together, "Hetero"), MSN Laboratories Private Ltd., MSN Pharmaceuticals Inc. (together, "MSN"), Prinston Pharmaceutical Inc. ("Prinston"), Sandoz Inc. ("Sandoz"), Shilpa Medicare Ltd. ("Shilpa") and Zydus Pharmaceuticals (USA) Inc. ("Zydus") (collectively, "Defendants"). The other parties sued by Plaintiffs were either dismissed or stipulated to infringement and the actions were stayed pending resolution of this consolidated action (with the parties agreeing to be bound by the outcome here). In December 2019, the Court presided over a five-day bench trial limited to the issue of the validity of the '514 Patent.[2] (*See* D.I. 393, 394, 395, 396 & 397). At trial, Defendants contended that claims 1-4, 6, 8-13, 15 and 16 ("the Asserted Claims") of the '514 Patent were invalid for lack of written description, lack of enablement, improper inventorship and

[1] (*See* C.A. No. 17-823 (against Amneal Pharmaceuticals LLC), C.A. No. 17-824 (against Aurobindo Pharma U.S.A., Inc. and Aurobindo Pharma USA LLC), C.A. 17-825 (against Hetero USA Inc., Hetero Labs limited Unit-III, Hetero Labs Ltd., Hetero USA Inc., C.A. No. 17-826 (against Impax Laboratories, Inc.), C.A. No. 17-827 (against Slayback Pharma LLC and Slayback Pharma India LLP), C.A. No. 17-829 (against Teva Pharmaceuticals USA, Inc.), C.A. No. 17-845 (against MSN Laboratories Private Ltd. and MSN Pharmaceuticals Inc.), C.A. No. 17-846 (against Graviti Pharmaceuticals Pvt. Ltd. and Graviti Pharmaceuticals Inc.), C.A. No. 17-847 (against Shilpa Medicare Limited), C.A. No. 17-848 (against Sun Pharma Global FZE), C.A. No. 17-849 (against Windlas Healthcare, Pvt. Ltd.), C.A. No. 17-850 (against Alkem Laboratories Ltd. and S&B Pharma, Inc.), C.A. No. 17-851 (against Cipla Limited and Cipla USA Inc.), C.A. No. 17-852 (against Glenmark Pharmaceuticals Limited and Glenmark Pharmaceuticals Inc., USA), C.A. No. 17-853 (against Lupin Atlantis Holdings SA), C.A. No. 17-854 (against Torrent Pharmaceuticals Ltd. and Torrent Pharma Inc.), C.A. No. 17-855 (against Pharmathen S.A.), C.A. No. 17-856 (against TWI Pharmaceuticals, Inc. and TWI Pharmaceuticals USA, Inc.), C.A. No. 17-857 (against Macleods Pharmaceuticals, Ltd. and Macleods Pharma USA, Inc.), C.A. No. 17-872 (against Accord Healthcare Inc.), C.A. No. 17-874 (against Sandoz Inc.), C.A. No. 17-875 (against Sawai USA, Inc. and Sawai Pharmaceutical Co., Ltd.), C.A. No. 17-954 (against Zydus Pharmaceuticals (USA) Inc.), C.A. No. 17-1361 (against Teva Pharmaceuticals USA, Inc.)).

[2] By the time of trial, the only patent asserted was the '514 Patent, and the Defendants that proceeded to trial had stipulated to infringement of the asserted claims. (*See* D.I. 335 §§ I.A.1 & I.A.4).

derivation, obviousness and anticipation. (*See* D.I. 335, Ex. 3 ¶ 110). After trial, the parties submitted proposed findings of fact and post-trial briefs. (*See* D.I. 350, 351, 352, 353, 357, 358, 359, 360; *see also* D.I. 362, 363, 364, 365, 366, 367, 368, 369, 372, 373, 374). Post-trial briefing concluded on March 16, 2020 and this Court has not yet issued its post-trial opinion.

Relevant here, Plaintiffs also sued Mylan Pharmaceuticals, Inc. ("Mylan") in the Northern District of West Virginia for infringement based on Mylan's submission of an ANDA seeking to market a generic version of Tecfidera®. *See* Complaint, *Biogen Int'l GmbH v. Mylan Pharm., Inc.*, No. 1:17-116 (N.D. W. Va. June 30, 2017). In that case, Plaintiffs asserted the '514 Patent against Mylan (the same claims asserted here), as well as a number of other patents that expired prior to or shortly after trial (and were therefore dismissed). The West Virginia court held a bench trial in February 2020 limited to the issue of the validity of the '514 Patent and, on June 18, 2020, issued its post-trial opinion. *See generally Biogen Int'l GmbH v. Mylan Pharm. Inc.*, No. 1:17-116, 2020 WL 3317105 (N.D.W. Va. June 18, 2020) ("the *Mylan* decision"). The court ultimately found that Mylan had proven by clear and convincing evidence that the Asserted Claims of the '514 Patent are invalid for lack of written description. *Id.*

On June 19, 2020, this Court directed the parties to submit limited supplemental briefing on the impact of the *Mylan* decision on the issues pending here. (*See* D.I. 377). The Court received a submission from Plaintiffs (D.I. 387) and a "Supplemental Post-Trial Brief on the Invalidity of the '514 Patent" from Defendants who proceeded to trial in this action (D.I. 388). The defendants who stipulated to stay their respective actions were allowed to participate in Defendants' supplemental briefing. (*See* D.I. 379, 381, 383 & 385). On August 11, 2020, the Court heard oral argument on the effect of the *Mylan* decision on this and the related actions. (D.I. 398). The issue

now before the Court is whether the judgment of invalidity rendered in the *Mylan* case should apply here under the principles of collateral estoppel.

II. LEGAL STANDARD

Collateral estoppel (also known as issue preclusion) is a doctrine that operates to preclude a party from relitigating an issue that has previously been decided. *See Anderson v. Gen. Motors LLC*, No. 18-621-LPS, 2019 WL 4393177, at *4 (D. Del. Sept. 13, 2019). Under Third Circuit law, collateral estoppel applies when: (1) the identical issue was previously adjudicated, (2) that issue was actually litigated, (3) the previous determination was necessary to the decision and (4) the party being precluded from relitigating the issue was fully represented in the prior action. *See Jean Alexander Cosmetics, Inc. v. L'Oreal USA, Inc.*, 458 F.3d 244, 249 (3d Cir. 2006); *see also Allergan, Inc. v. Sandoz, Inc.*, 681 F. App'x 955, 959 (Fed. Cir. 2017) (regional circuit law governs issues of collateral estoppel). The Third Circuit has also described the inquiry as looking to whether the party being precluded had a "full and fair opportunity" to litigate the contested issue in the previous action and whether that issue was decided by a "final and valid judgment." *Jean Alexander*, 458 F.3d at 249 (citations omitted). Similarly, in the patent context, the Federal Circuit has explained that "a judgment of invalidity will have no collateral estoppel effect if the patentee can show that it did not have a full and fair opportunity to litigate." *Pharmacia & Upjohn Co. v. Mylan Pharm., Inc.*, 170 F.3d 1373, 1379 (Fed. Cir. 1999). "The party seeking to effectuate an estoppel has the burden of demonstrating the propriety of its application." *Suppan v. Dadonna*, 203 F.3d 228, 233 (3d Cir. 2000).

III. DISCUSSION

The Court begins with a discussion of the '514 Patent, followed by a discussion of the *Mylan* decision before ultimately turning to the factors in the collateral-estoppel analysis.

A. The ’514 Patent

The ’514 Patent is a continuation of U.S. Patent Application No. 12/529,296 (“the ’296 Application”), which was filed on August 7, 2009 and eventually abandoned. Originally titled “Nrf2 Screening Assays and Related Methods and Compositions,” the ’296 Application contained seventeen claims, all of which were directed to methods of evaluating neuroprotective properties of test compounds or treating mammals with neurological diseases with those test compounds. (’296 Application at Claims 1-17). On June 20, 2011, Plaintiffs amended the ’296 Application by changing the title to “Treatment for Multiple Sclerosis,” deleting all previously presented claims and adding sixteen new claims to methods of treating MS with about 480 mg per day of DMF, MMF or a combination thereof. (’296 Application, June 20, 2011 Preliminary Amendment). On October 28, 2011, Plaintiffs amended the ’296 Application again to add Gilmore O’Neill as a named inventor and to add three new claims directed to elevated gene expression levels. (’296 Application, October 28, 2011 Supplemental Amendment & October 28, 2011 Request to Add Inventor). The ’296 Application was abandoned in favor of U.S. Patent Application No. 13/326,426, which was filed on February 12, 2012 and is a continuation of the ’296 Application. After Plaintiffs successfully overcame obviousness rejections, that continuation application issued as the ’514 Patent on March 29, 2013. The ’514 Patent ultimately claims a priority date of February 8, 2007.[3]

The claims of the ’514 Patent are all directed to methods of treating MS with “about 480 mg per day” of DMF, MMF or a combination thereof. There is, however, little mention in the

[3] The ’514 Patent’s parent application – the ’296 Application – was a National Stage Entry of PCT/US2008/001602 filed on February 7, 2008, which claims priority to U.S. Provisional Patent Application No. 60/888,921 filed on February 8, 2007.

specification[4] of using these fumarates to treat MS specifically, and the only reference to 480 mg appears in the following paragraph:

> For DMF or MMF, an effective amount can range from 1 mg/kg to 50 mg/kg (e.g., from 2.5 mg/kg to 20 mg/kg or from 2.5 mg/kg to 15 mg/kg). Effective doses will also vary, as recognized by those skilled in the art, dependent on route of administration, excipient usage, and the possibility of co-usage with other therapeutic treatments including use of other therapeutic agents. For example, an effective dose of DMF or MM[F] to be administered to a subject orally can be from about 0.1 g to 1 g per [d]ay, 200 mg to about 800 mg per day (e.g., from about 240 mg to about 720 mg per day; or from about 480 mg to about 720 mg per day; or about 720 mg per day). For example, the 720 mg per day may be administered in separate administrations of 2, 3, 4, or 6 equal doses.

('514 Patent at 18:52-64). This language appears in the specification of the '296 Application, as well as in the National Stage Entry of PCT/US2008/001602. (*See* '296 Application at Paragraph 170; *see also* PCT/US2008/001602 at Paragraph 116). There are no other references in any of the specifications to use of 480 mg per day of DMF, MMF or any combination thereof in treating MS.

B. The *Mylan* Decision

In the case between Plaintiffs and Mylan in the Northern District of West Virginia, Mylan argued that claims 1-4, 6, 8-13 and 15-16 of the '514 Patent were invalid for lack of written description under 35 U.S.C. § 112. In Mylan's view, "the specification described in 2007 bears no resemblance to the invention claimed in 2011." *Mylan*, 2020 WL 3317105, at *7. Mylan argued that the disclosures of the '514 Patent do not sufficiently describe the invention claimed –

[4] The Court understands that, by statute, the "specification" includes the claims. *See* 35 U.S.C. § 112 ¶ 2 ("The specification shall conclude with one or more claims . . . ."). Plaintiffs, however, do not contend that the claims of the '514 Patent or any prior application provide the necessary disclosure in this case. Thus, consistent with the usage by the Federal Circuit and for simplicity, the Court here uses "specification" to mean the portion of the patent containing the written description disclosing the invention but excluding the claims. *See, e.g.*, *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 979 (Fed. Cir. 1995) (en banc) ("To ascertain the meaning of claims, we consider three sources: The claims, the specification, and the prosecution history."), *aff'd*, 517 U.S. 370 (1996).

i.e., a method of treating MS with a therapeutically effective amount of DMF, MMF or a combination thereof where the therapeutically effective amount is 480 mg per day. *Id.* To Mylan, this was unsurprising because Plaintiffs purportedly "grafted the '514 claims onto a specification written to cover an entirely different set of inventions, conceived of by an entirely different inventor, and filed more than four years before Biogen's 2011 Phase III trial results demonstrated the effectiveness of the 480[mg/day] dose." *Id.* In response, Plaintiffs argued that there is sufficient written description for the invention claimed in the '514 Patent by linking Method 4 in the specification[5] with the elements recited in the claims. *Id.* at *8.

The West Virginia court agreed with Mylan that claims 1-4, 6, 8-13 and 15-16 of the '514 Patent were invalid for lack of written description under § 112 because the inventors did not convey with reasonable clarity in the specification that they possessed the invention claimed in the '514 Patent. Turning to the specification, the court found that although the disclosure begins with a discussion of MS, the focus of the specification is more generally on the particular pathway (*i.e.*, Nrf2) at issue in neurodegenerative diseases and the exploration of certain compounds as neuroprotective agents. *Mylan*, 2020 WL 3317105, at *8. The '514 Patent discloses five methods, but the court largely focused on Method 4 in its written-description analysis because Plaintiffs relied on Method 4 as providing adequate written description for the claims.[6] *Id.* at *9.

Method 4 describes administering a therapeutically effective amount of a neuroprotective compound, which may be DMF or MMF, to treat a neurological disease. *Id.* (quoting '514 Patent

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5 Method 4 describes methods of treating "a neurological disease" with "one compound that is at least partially structurally similar to DMF and/or MMF." ('514 Patent at 8:34-38). That neurological disease may be neurodegeneration caused by, *inter alia*, demyelination. (*Id.* at 8:45-47). Elsewhere in the specification, the '514 Patent provides that MS is an example of a demyelinating neurological disease. (*Id.* at 1:12-14).

6 Plaintiffs apparently conceded that the other four methods were not relevant to the analysis.

at 8:34-44). Method 4 further provides that, in some embodiments, the method may be used to slow or prevent neurodegeneration caused by demyelination (among other things). *Mylan*, 2020 WL 3317105, at *9 (quoting '514 Patent at 8:45-53). The court concluded that, contrary to Plaintiffs' argument, "Method 4 broadly describes treating neurological diseases with a therapeutically effective amount of DMF; MS is merely one such disease 'among a slew of competing possibilities.'" *Mylan*, 2020 WL 3317105, at *10 (quoting *Novozymes A/S v. DuPont Nutrition Biosciences APS*, 723 F.3d 1336, 1349 (Fed. Cir. 2013)). Moreover, according to the specification, the neurological disease treatable by all five methods may be ALS, Parkinson's, Alzheimer's or Huntington's, or the neurological disease may be MS or another demyelinating disease, or further still, the neurological disease may be one many others listed in the '514 Patent. *Mylan*, 2020 WL 3317105, at *10 (quoting '514 Patent at 3:10-14 & 16:18-65). Thus, given the broad spectrum of neurological diseases touted as potentially treatable by the methods in the '514 Patent, the court concluded there were no "blaze marks" in Method 4 that would lead a person of ordinary skill in the art ("POSA") to specifically treat MS with DMF. *Mylan*, 2020 WL 3317105, at *10. The court also found that the disclosure of Method 4 – which is silent as to doses – would not lead a POSA to 480 mg per day as a therapeutically effective amount of DMF, MMF or a combination thereof. *Id.*

Addressing the only portion of the '514 Patent specification that mentions 480 mg (*i.e.*, column 18), the court explained that that disclosure – "an effective dose of DMF or MM[F] can be from about 0.1 g to 1 g per [d]ay . . . or from about 480 mg to about 720 mg per day" – does not link the "effective dose" to treating MS, nor does it link the "effective dose" to a dose of 480 mg per day of DMF given the broad range disclosed. *Mylan*, 2020 WL 3317105, at *11 (quoting '514 Patent at 18:53-64). Rejecting Plaintiffs' argument that the "480 mg to about 720 mg per

day" range is the narrowest and therefore the most preferred, the court explained that as of the February 8, 2007 priority date, the results of Plaintiffs' Phase II clinical study would have led a POSA to believe that 720 mg per day was the therapeutically effective dose, disregarding lower doses. *Mylan*, 2020 WL 3317105, at *11. As the court noted, 720 mg per day is singled out in the next sentence. *Id.* In the court's view, "nothing in this passage teaches a POSA that a 480mg/day dose of DMF (BID) is therapeutically effective for treating MS." *Id.*

The court also rejected Plaintiffs' argument that Example 3 provides adequate support for the claimed invention as it was not included in the provisional application (and cannot evidence possession of the claimed invention in 2007) and because the inventors and Plaintiffs' expert could not explain the relevance of Example 3 to treating MS with about 480 mg per day of DMF, MMF or a combination (the claimed invention). *Id.* at *12. Thus, the court disagreed with Plaintiffs that the cited portions of the '514 Patent demonstrate possession of the claimed invention as of the February 2007 priority date and rejected Plaintiffs' attempt to piece together adequate written description from disparate parts of the specification. *Id.* Inventor testimony from Dr. O'Neill could not save the claims because the crux of the written-description inquiry is the specification itself – his testimony of "actual possession" was not enough.[7] *Id.* at *13. The court ultimately concluded that the specification of the '514 Patent "does not demonstrate that, as of February 8, 2007, Dr. Lukashev and Dr. O'Neill 'possessed' the claimed invention – a method of treating MS with a therapeutically effective amount of DMF, *i.e.*, 480mg/day." *Id.*

[7] As the *Mylan* court noted at the outset of its analysis, the specification itself must demonstrate possession of the claimed in the context of § 112 written-description challenges – it is insufficient that actual possession may be shown outside the corners of the specification. *Mylan*, 2020 WL 3317105, at *8 (quoting *Ariad Pharm., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1352 (Fed. Cir. 2010)).

The court also addressed the prosecution history of the '514 Patent. Although the provisional application was filed in February 2007, it was not until shortly after Plaintiffs completed their Phase III clinical study in April 2011 that they filed a patent application on that study's dosage – a patent application that included substantial discussion of the data regarding 480 mg per day as the effective dose for treating MS. *Mylan*, 2020 WL 3317105, at *13. That patent, however, did not claim priority to the '514 Patent's provisional application (and would have been subject to a much later priority date). *Id.* at*14. Plaintiffs therefore amended the '296 Application – which did claim priority to the provisional application filed in 2007 – to change the title and add claims specifically directed to treating MS with "about 480 mg per day" of DMF, MMF or a combination thereof. *Id.* The specification of the '296 Application, however, was not amended to include the additional data from the recent Phase III clinical study regarding the 480 mg per day dose. *Id.* Nor could it have been, according to the court, because it would result in Plaintiffs losing the claim to priority to 2007 from the provisional. *Id.* Plaintiffs were "left with a specification written in 2007 that bore no resemblance to the '514 Patent's title and claimed invention – a method of treating MS with a therapeutically effective amount of DMF, *i.e.*, 480mg/day . . . ." *Id.*

The court ultimately found that the case before it was indistinguishable from *Nuvo Pharmaceuticals (Ireland) Designated Activity Co. v. Dr. Reddy's Laboratories Inc.*, 923 F.3d 1368 (Fed. Cir. 2019), in which the Federal Circuit upheld a finding of invalidity for lack of written description when the specification provided "nothing more than a mere claim that uncoated [proton pump inhibitors] might work, even though [POSAs] would not have thought it would work." *Id.* at 1381. In the *Mylan* court's view, the '514 Patent effectively contained a mere claim that 480 mg per day might work and it was not until later that Plaintiffs discovered the therapeutic effectiveness of the claimed 480 mg per day dosage. *Mylan*, 2020 WL 3317105, at *15.

Thus, the *Mylan* court found that the specification of the '514 Patent did not convey that the inventors were – as of the February 8, 2007 priority date – in possession of a method of treating MS with a therapeutically effective amount of DMF, MMF or a combination where the therapeutically effective amount is 480 mg per day. That conclusion was bolstered by the story of how the '514 Patent claims came to be – *i.e.*, by Plaintiffs receiving clinical trial data in 2011 and adding claims to cover that specific clinical dosage to an already pending application focused on drug discovery but leaving the specification otherwise untouched to preserve a priority claim back to 2007. The disconnect between the invention claimed in 2011 and the 2007 specification rendered claims 1-4, 6, 8-13 and 15-16 of the '514 Patent invalid for lack of written description under § 112.

C. Collateral Estoppel

Here, Plaintiffs have asserted the same claims of the '514 Patent that were found invalid for lack of written description in the *Mylan* case. Moreover, Defendants contend here that the Asserted Claims are invalid for the same reason that Mylan asserted – and prevailed upon – in its own litigation with Plaintiffs. The Court now turns to the individual factors in the collateral-estoppel analysis to determine whether the *Mylan* judgment precludes Plaintiffs from continuing to defend the validity of the '514 Patent in this case.

1. Identity of the Issue Asserted Here and Decided in the *Mylan* Case

The first step in the collateral-estoppel analysis is to determine whether the issue to be precluded is identical to the issue previously decided. *See Jean Alexander*, 458 F.3d at 249. "Identity of the issue is established by showing that the same general legal rules govern both cases and that the facts of both cases are indistinguishable as measured by those rules." *Suppan v. Dadonna*, 203 F.3d 228, 233 (3d Cir. 2000) (quotation marks and citation omitted). In the context

of patent infringement, Federal Circuit law applies in determining whether the "identity of the issue" requirement of collateral estoppel is met.[8] *Cf. Aspex Eyewear, Inc. v. Marchon Eyewear, Inc.*, 672 F.3d 1335, 1341 n.1 (Fed. Cir. 2012) (for res judicata, noting that Federal Circuit law applies to "the question of whether a particular claim in a patent case is the same as or separate from another claim [because that question] has special application to patent cases"). "[O]nce the claims of a patent are held invalid in a suit involving one alleged infringer, an unrelated party who is sued for infringement of those claims may reap the benefit of the invalidity decision under the principles of collateral estoppel." *Pharmacia*, 170 F.3d at 1379. In applying collateral estoppel to invalidity rulings, there is some question as to whether invalidity is a single issue or is divided into distinct issues based on the invalidity grounds – *i.e.*, invalidity for obviousness is a different issue than invalidity for anticipation. *See Orexo AB v. Actavis Elizabeth LLC*, 371 F. Supp. 3d 175, 183 (D. Del. 2019) (noting the outstanding question, compiling cases addressing the issue and concluding that validity should not be treated as a single issue for collateral estoppel).

As to the present dispute, the Court finds that under either approach, the "identity of the issues" requirement for collateral estoppel is met here. Indeed, not only was the general issue of invalidity decided by the *Mylan* judgment, but that judgment also concerns the same invalidity defense asserted by Defendants in this case against the same patent claims – *i.e.*, that claims 1-4, 6, 8-13 and 15-16 of the '514 Patent are invalid under § 112 for lack of adequate written description. Moreover, the particular § 112 arguments made by Mylan in West Virginia bear

[8] *Ohio Willow Wood Co. v. Alps S., LLC*, 735 F.3d 1333, 1342 (Fed. Cir. 2013) ("Our review of a collateral estoppel determination is generally guided by regional circuit precedent, but we apply our own precedent to those aspects of such a determination that involve substantive issues of patent law."); *see also Soverain Software*, 778 F.3d at 1314 ("We apply this court's precedent to questions involving substantive issues of patent law, issues of issue preclusion that implicate substantive patent law issues, or issues of issue preclusion that implicate the scope of our own previous decisions.").

striking similarity to the § 112 arguments advanced by Defendants here. (*See, e.g.*, D.I. 366 at 4-8 (Defendants arguing that the specification is concerned with drug screening, not tethered to any particular disease or therapeutically useful doses, leading to a glaring disconnect from the later-added claimed method of treating MS with 480 mg per day of DMF, MMF or a combination)). And although Plaintiffs maintain that the *Mylan* court reached the wrong conclusion on validity, Plaintiffs do not actually dispute that the same issue was previously decided. (*See* D.I. 398 at 11:23-25 ("For purposes of the argument today and the issues before [the Court, Plaintiffs] are not contesting that those four factors [of the collateral-estoppel analysis] are met in this circumstance.")). Therefore, the "identity of the issues" requirement of collateral estoppel is satisfied here.

2. Whether the Invalidity Issue Was Actually Litigated

The next factor in the collateral-estoppel analysis is whether the issue of invalidity was actually litigated in the *Mylan* action. *See Jean Alexander*, 458 F.3d at 249. It is undisputed here that the issue of invalidity of the Asserted Claims of the '514 Patent was actually litigated (and decided) in the *Mylan* case. (*See* D.I. 398 at 11:23-25). In February 2020, the court in *Mylan* held a bench trial limited to the issue of whether the Asserted Claims of the '514 Patent were invalid for lack of written description under § 112. *See Mylan Pharm.*, 2020 WL 3317105, at *1 n.2. After receiving post-trial briefing, the *Mylan* court issued its post-trial opinion on June 18, 2020 and the judgment of invalidity was entered on June 22, 2020. *See* Order Granting Motion for Final Judgment, *Biogen Int'l GmbH v. Mylan Pharm., Inc.*, No. 1:17-116 (N.D. W. Va. June 22, 2020); *see also* Clerk's Judgment, *Biogen Int'l GmbH v. Mylan Pharm., Inc.*, No. 1:17-116 (N.D. W. Va. June 22, 2020). Again, Plaintiffs dispute the correctness of the outcome in the *Mylan* case, but

Plaintiffs do not – and cannot – dispute that the same invalidity issue at issue here was previously decided in the *Mylan* case. Thus, this factor also supports application of collateral estoppel here.

3. Whether the Invalidity Issue Was Necessary for the *Mylan* Judgment

The next factor in the collateral-estoppel analysis is whether the previous determination of invalidity was necessary to the judgment in the *Mylan* case. *See Jean Alexander*, 458 F.3d at 249; *see also id.* at 250 ("Because litigants are likely to view an issue that is necessary to the resolution of a case as important and to litigate it vigorously, it is fair to give such a determination preclusive effect."). Here, there is again no dispute that this factor is met. (*See* D.I. 398 at 11:23-25). Indeed, the only issue tried in *Mylan* was whether the Asserted Claims of the '514 Patent were invalid under § 112 for lack of written description. And the only issue addressed in the final judgment was that the Asserted Claims were invalid on this basis. Thus, the invalidity issue advanced by Defendants here and previously decided by the *Mylan* court was clearly necessary to the judgment in that case.

4. Whether Plaintiffs Were Fully Represented in the *Mylan* Case

The last factor evaluates whether Plaintiffs were fully represented in previously litigating the invalidity issue sought to be precluded here. *See Jean Alexander*, 458 F.3d at 249; *see also Pharmacia*, 170 F.3d at 1379 ("[A] judgment of invalidity will have no collateral estoppel effect if the patentee can show that it did not have a full and fair opportunity to litigate." (citing *Blonder-Tongue Labs., Inc. v. Univ. of Illinois Found.*, 402 U.S. 313, 332 (1971))). The Supreme Court has articulated the relevant inquiry as one giving the patentee the ability to demonstrate that it "did not have a fair opportunity procedurally, substantively and evidentially to pursue [its] claim the first time."[9] *Blonder-Tongue*, 402 U.S. at 333 (internal quotation marks and citation omitted). But

[9] The Supreme Court provided some "relatively rare" scenarios where this may apply, such as when trial courts "wholly failed to grasp the technical subject matter and issues in suit"

as the Federal Circuit has cautioned, this factor is not focused on whether the prior invalidity determination was correct but rather on whether the patentee had a fair opportunity to litigate the issue. *See Stevenson v. Sears, Roebuck & Co.*, 713 F.2d 705, 709 (Fed. Cir. 1983) ("[I]t is clear from the case law that has developed since *Blonder-Tongue* that an inappropriate inquiry is whether the prior finding of invalidity was correct; instead, the court is only to decide whether the patentee had a full and fair opportunity to litigate the validity of [the] patent in the prior unsuccessful suit.").

Here, Plaintiffs have not demonstrated that they were deprived of a full and fair opportunity to defend against the § 112 validity challenge asserted by Mylan. In fact, Plaintiffs have not even attempted to so argue. (*See* D.I. 398 at 11:23-25). Indeed, it would be a hard sell as Plaintiffs were represented by the same competent counsel in the *Mylan* case as here, and Plaintiffs spent a number of days trying the § 112 issues to the *Mylan* court (relying on numerous fact and expert witnesses) and submitted post-trial briefs with more-than ample cites to record evidence. *See, e.g.*, Biogen's Responsive Post-Trial Brief, *Biogen Int'l GmbH v. Mylan Pharm., Inc.*, No. 1:17-116 (N.D. W. Va. Apr. 3, 2020). Thus, this last factor also supports application of collateral estoppel here.

5. Other Considerations

As set forth above, the four requirements in the collateral-estoppel analysis are all met in this case. Plaintiffs argue that, notwithstanding the requirements being met, collateral estoppel is "an equitable doctrine" and that this Court can and should exercise discretion and decline to apply collateral estoppel, instead reaching a decision on the merits. (D.I. 387 at 1). Plaintiffs maintain

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or when, through no fault of its own, the "patentee was deprived of crucial evidence or witnesses in the first litigation." *Blonder-Tongue*, 402 U.S. at 333.

that collateral estoppel should not apply because of "the advanced stage of these proceedings and the unusual circumstances that required Biogen to litigate in parallel in both West Virginia and Delaware." (*Id.*). In Plaintiffs' view, the fairer course here is for the Court to decide the written description issue anew, as well as the other invalidity issues raised by Defendants (anticipation, obviousness, enablement, improper inventorship and derivation), so that Plaintiffs could have this Court's decision "reviewed on appeal alongside the West Virginia decision."[10] (*Id.*). The thrust of Plaintiffs' argument is that applying collateral estoppel here is not in the interest of "judicial efficiency and fairness" because "[d]uplicative litigation has already occurred," given that this case and the *Mylan* case proceeded on largely parallel tracks with trial being completed in both cases (around the same time). (*Id.* at 2). Before turning to the efficiency and fairness arguments that Plaintiffs advance, the Court first addresses a threshold issue raised by Plaintiffs – *i.e.*, whether the decision to apply collateral estoppel under these facts is indeed an equitable consideration committed to the Court's discretion.

The Supreme Court explained that the decision to apply collateral estoppel "will necessarily rest on the trial courts' sense of justice and equity." *Blonder-Tongue*, 402 U.S. at 334. Although this language suggests that this Court should engage in some level of equitable rumination when reaching a decision on collateral estoppel, the context in which this language appears is important to highlight. The Supreme Court's guidance on "justice and equity" is the closing language in a paragraph that begins with the following: "Determining whether a patentee has had a full and fair chance to litigate the validity of his patent in an earlier case is of necessity not a simple matter." *Id.* And all that appears in the paragraph between the opening and closing

[10] At this point, it is unclear whether such a consolidated review would be possible given the pace at which the *Mylan* appeal is proceeding.

language relates to the inquiry into whether there was that crucial "full and fair" opportunity to litigate. *Id.* To the Court, this suggests that "justice and equity" are not standalone considerations in the collateral-estoppel analysis, but instead guides for the fourth factor.

The Third Circuit has analyzed this language similarly and cast doubt on the notion that "generalized concepts of justice and equity constitute an independent ground for denying an estoppel defense," as well as on the notion that deciding "whether such independent ground exists should rest in the discretion of the trial court." *Kaiser Indus. Corp. v. Jones & Laughlin Steel Corp.*, 515 F.2d 964, 978 (3d Cir.), *amended*, 524 F.2d 1154 (3d Cir. 1975). Other circuits – including the Federal Circuit – have stated more explicitly that equitable considerations are not standalone grounds to avoid collateral estoppel in cases like this one. *See, e.g., Mississippi Chem. Corp. v. Swift Agr. Chemicals Corp.*, 717 F.2d 1374, 1379 (Fed. Cir. 1983) ("The short of the matter is that under *Blonder-Tongue*, the only inquiry open to the district judge is whether the patentee had a full and fair opportunity to litigate the validity of the patent in the prior case in which it was held invalid. . . . The judge cannot permit relitigation because of equitable considerations."); *Blumcraft of Pittsburgh v. Kawneer Co.*, 482 F.2d 542, 547 (5th Cir. 1973) ("[T]he only discretion left to the district court's 'sense of equity and justice' by *Blonder-Tongue* is in the determination of whether the plaintiff had a full and fair opportunity to litigate in the prior suit finding invalidity."). Thus, in a case like this where defensive collateral estoppel is at issue,[11]

[11] This is in contrast to offensive collateral estoppel, where the Court does have some discretion and can decline to apply the doctrine based on equitable considerations. *See Dana v. E.S. Originals, Inc.*, 342 F.3d 1320, 1325-26 (Fed. Cir. 2003); *see also Jean Alexander*, 458 F.3d at 248-49 (noting that "the predominant question in preclusion cases involving defensive or mutual collateral estoppel is whether the basic requirements for issue preclusion are satisfied" but that trial courts have discretion in cases involving non-mutual offensive collateral estoppel because that "presents a unique potential for unfairness").

this Court believes that considerations of justice and equity are not standalone considerations committed to the Court's discretion that can be used to avoid estoppel when the four requirements are otherwise satisfied.

Although this should be the end of the inquiry, the Court will nevertheless address the individual issues raised by Plaintiffs for the sake of completeness.[12] The main premise underlying Plaintiffs' opposition is that this case has already been tried and only the Court's post-trial opinion is outstanding, thereby making application of collateral estoppel less prudent here. That a judgment can have preclusive effect in a subsequent case already on appeal clearly means that collateral estoppel may apply in situations where, as here, the case in which preclusion is sought has already been tried. *See Soverain Software*, 778 F.3d at 1315 ("[I]ssue preclusion applies even though the precluding judgment (*Newegg*) comes into existence while the case as to which preclusion is sought (this case) is on appeal."); *see also U.S. Ethernet Innovations, LLC v. Texas Instruments Inc.*, No. 6:11-491, 2015 WL 1001637 (E.D. Tex. Feb. 19, 2015) (finding that judgment of patent invalidity rendered in Northern District of California action applied under principles of collateral estoppel in Eastern District of Texas action where jury had already rendered

[12] The Court is aware of *In re Freeman*, 30 F.3d 1459 (Fed. Cir. 1994), in which the Federal Circuit suggested that some equitable exceptions to collateral estoppel may exist notwithstanding the four requirements being met. Although the Federal Circuit ultimately found that collateral estoppel applied in that case, as Plaintiffs point out, the language of this opinion supports an argument that courts have some discretion in determining whether to apply collateral estoppel under the facts of each case. This position, however, is at odds with the Federal Circuit's earlier decision in *Mississippi Chemical*, 717 F.2d at 1379. In such situations of conflict, the earlier panel decision controls. *See Ateliers de la Haute-Garonne v. Broetje Automation USA Inc.*, 717 F.3d 1351, 1357 n.3 (Fed. Cir. 2013). Moreover, *Freeman* dealt with collateral estoppel based on construction of a term necessary to a prior noninfringement ruling, whereas *Mississippi Chemical* addressed preclusion from a prior invalidity ruling – *i.e.*, the situation here.

verdict and only certain post-trial issues were still outstanding), *aff'd*, 645 F. App'x 1026 (Fed. Cir. 2016).

Nevertheless, Plaintiffs attempt to distinguish *Soverain* and similar cases on the basis that the preclusive judgment to be applied in those cases came from the Federal Circuit. (D.I. 387 at 3). This distinction cannot be reconciled with cases that apply collateral estoppel based on another district court's decision when that preclusive decision is on appeal or an appeal is imminent. *See DietGoal Innovations LLC v. Chipotle Mexican Grill, Inc.*, 70 F. Supp. 3d 808 (E.D. Tex. 2014) (Bryson, J. sitting by designation) (judgment of invalidity under § 101 from litigation in Southern District of New York applied in litigation in Eastern District of Texas despite likely appeal of the prior invalidity decision); *see also Pharmacia*, 170 F.3d at 1381 ("[T]he law is well settled that the pendency of an appeal has no effect on the finality or binding effect of a trial court's holding. (citations omitted)). Indeed, in *Pharmacia*, the Federal Circuit upheld application of collateral estoppel where there was only a possibility that the preclusive judgment would be appealed. *See Pharmacia*, 170 F.3d at 1382 ("We accordingly conclude that the district court did not err in applying collateral estoppel based on the judgment of invalidity and unenforceability in *Mova*, despite the fact that the motion for JMOL/new trial had not yet been resolved by the *Mova* court, and despite the possibility of a subsequent appeal of the *Mova* judgment.").[13] Thus, in the Court's view, the *Mylan* judgment is no less preclusive because it was rendered by a district court rather than the Federal Circuit and the judgment's preclusive effect is in no way diminished because it is presently on appeal or because this case – where preclusion is sought – has already proceeded through trial.

[13] That is, even the pendency of post-trial motions "does not affect the finality of a judgment and thus does not prevent its preclusive effect." *Pharmacia*, 170 F.3d at 1381.

Plaintiffs raise general issues of "fairness" and "judicial efficiency" in arguing against the application of collateral estoppel here. First, Plaintiffs emphasize that there are more invalidity theories at issue in this case than in the *Mylan* action. In Plaintiffs' view, applying collateral estoppel "could slow the ultimate resolution" of this case because the *Mylan* court only addressed written description but there are numerous other invalidity defenses at issue here – *i.e.*, anticipation, obviousness, derivation, improper inventorship and enablement. (D.I. 387 at 3). Plaintiffs' argument is, at its core, as follows: that there is the possibility of something other than affirmance means that collateral estoppel is not in the interest of judicial efficiency.[14] It is undeniable, however, that short-term judicial efficiency is served by the Court not issuing a post-trial opinion addressing the additional invalidity defenses. But, contrary to Plaintiffs' suggestion, there is similarly long-term conservation of resources achieved by applying collateral estoppel here. If the Federal Circuit affirms the *Mylan* judgment of invalidity, there is no need (and would have been no need) for this Court to address anticipation, obviousness, derivation, improper inventorship and enablement. If the Federal Circuit does not, however, affirm the *Mylan* judgment, this Court would benefit from the Federal Circuit's review of the '514 Patent and the written-description issue. Although there are more and different invalidity grounds asserted here, the Federal Circuit's guidance on written description is likely to impact this Court's decision on other invalidity theories asserted by Defendants in this case.[15]

Plaintiffs also argue that judicial efficiency would not be served by the Court applying collateral estoppel because Plaintiffs would be forced to seek an injunction against Defendants

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[14] Of course, this argument is contradicted by the fact that judgments retain their preclusive effect during a pending appeal (which obviously carries a possibility of reversal or vacatur).

[15] Enablement, for example. *See Univ. of Rochester v. G.D. Searle & Co.*, 358 F.3d 916, 921 (Fed. Cir. 2004) (noting that "there is often significant overlap" in the written description and enablement requirements set forth in § 112).

from launching their generic products pending appeal of this Court's decision. (D.I. 387 at 3-4). This argument assumes that Plaintiffs will prevail on the merits of all issues litigated here. Indeed, if the Court were to find that the Asserted Claims are invalid under any of the theories advanced by Defendants, Plaintiffs would be in the same situation as they would be were the Court to apply collateral estoppel. That is, Plaintiffs would still be in a situation where an injunction pending appeal is necessary from their point of view. Although the Court is not holding that the ultimate outcome here would be definitively the same as in *Mylan*, the Court must reject the notion that an imminent injunction pending appeal weighs against the application of collateral estoppel when the same outcome could very well result from this Court's decision of the issues anew.

In sum, although the Court has doubts that it has discretion to decline to apply collateral estoppel for equitable reasons in a case like this when all the requirements are otherwise met, the Court disagrees with Plaintiffs that fairness and judicial efficiency are served by doing so here. The *Mylan* court conducted a careful analysis of the '514 Patent and its written description deficiencies, and the now-preclusive judgment of invalidity presents the very real prospect that this Court would never need to address any of the invalidity grounds raised by Defendants here. For the Court to undertake the effort to decide all the issues anew seems like an exercise in judicial inefficiency and disregard for a judgment that should be afforded preclusive effect.

Having found that collateral estoppel applies here, the Court also notes that Plaintiffs and the stayed defendants agree that the Court's decision on collateral estoppel has the same effect in the related cases where the parties stipulated to stay and agreed be bound by the outcome of this consolidated action. (*See, e.g.*, D.I. 398 at 42:2-43:7). Therefore, the Court's collateral-estoppel conclusion applies to all pending actions related to this consolidated action – *i.e.*, to all cases involving infringement of the '514 Patent still before the Court.

Finding it unnecessary to do so, the Court declines to reach the other invalidity defenses raised by Defendants at trial.[16]

IV. CONCLUSION

For the foregoing reasons, the Court finds that the judgment of invalidity rendered in the Northern District of West Virginia applies here under the principles of collateral estoppel. An appropriate order will follow.

[16] The Court recognizes that the Federal Circuit could reverse or vacate and remand the judgment from the Northern District of West Virginia, thereby leaving undecided the other invalidity defenses raised by Defendants in this action. In that situation, this Court would consult with the parties and likely revisit the post-trial briefing already filed and issue its post-trial opinion on any remaining issues (and consistent with any guidance from the Federal Circuit on written description).