

BEFORE THE UNITED STATES
JUDICIAL PANEL ON MULTIDISTRICT LITIGATION

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	)	
	)	
In re Ozempic® (Semaglutide) Patent	)	MDL No. 3038
Litigation	)	
	)	
	)	

**REPLY MEMORANDUM IN SUPPORT OF PLAINTIFFS' MOTION FOR TRANSFER
OF ACTION TO THE DISTRICT OF DELAWARE PURSUANT TO 28 U.S.C. § 1407
FOR COORDINATED AND CONSOLIDATED PRETRIAL PROCEEDINGS**

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I. INTRODUCTION

Since its last attempt to avoid consolidation of a Hatch-Waxman litigation in 2019, Mylan did not oppose centralization in five separate actions, each of which was transferred from West Virginia to Delaware for consolidated pretrial proceedings. The circumstances of those cases and this one are far more similar than Mylan suggests. Mylan seizes on additional patents asserted against it to grossly exaggerate the uniqueness of its case. However, Mylan omits that if consolidated in Delaware, Judge Connolly will likely require Novo Nordisk to narrow its case to ten asserted patents, mooted this argument. Even absent narrowing, the patents Mylan calls “unique” are closely related to patents already asserted in Delaware or otherwise litigated before Judge Connolly. Mylan’s other primary distinction—its device and the asserted device patents—falls flat because Mylan’s device is already at-issue in the Delaware Actions. This fact strongly favors consolidation to avoid two courts simultaneously considering infringement of the same device. Novo Nordisk respectfully requests that the Panel see through Mylan’s vague assertions of the uniqueness of its case and reject its unsupported claims that consolidation of these overwhelmingly similar actions will not promote convenience and efficiency.

II. ARGUMENT

A. Common Issues Among the Actions Far Outnumber the Differences

Mylan argues that consolidation would not be efficient because “each case concerns a different accused ANDA product.” MDL No. 3038, Dkt. No. 20 (J.P.M.L. May 31, 2022) (“Opp’n”) at 10. While that statement is technically correct, the accused products are not different in a meaningful way here. On the contrary, Mylan and the Delaware generics each seek FDA approval for a generic version of Ozempic®. Consequently, by statute, their generic products must be bioequivalent to Ozempic® and must share an active ingredient, dosage form, dosage route, and conditions of use and labeling with Ozempic®. 21 U.S.C. § 355(j)(2)(A). These strict statutory

requirements mean that the generics' products will all be highly similar to Ozempic[®]—and to each other. This high degree of similarity between products accused of infringement makes this case dissimilar from Mylan's authority. Opp'n at 6-7, citing *In re Alexsam, Inc. ('608 & '787) Pat. & Cont. Litig.*, 437 F. Supp. 3d 1374 (J.P.M.L. 2020) (involving prepaid card systems, including gift and medical cards, which are, in fact, different products, as opposed to bioequivalent copies of the same drug). Indeed, each case will require highly similar discovery concerning the defendant's proposed generic product, Ozempic[®], and the asserted patents, entailing near identical document productions by Novo Nordisk, many overlapping Novo Nordisk fact and expert witnesses, and anticipated overlapping expert witnesses for the generics, who often share experts. Mylan's assertion that its case "differs vastly from the Delaware cases" (Opp'n at 1) is simply not true.

Semaglutide, the novel chemical compound and active ingredient in Ozempic[®], will be at the center of the Ozempic[®] Patent Litigations. Semaglutide is protected by the '343 patent, which is commonly asserted in West Virginia and Delaware, and will be critical in both jurisdictions. Saying little about the '343 patent, Mylan instead focuses on the device component of the case, arguing that there are "myriad injection devices available" to generics and therefore Mylan's "proposed device may be entirely different" from the devices at issue in Delaware. Opp'n at 1, 7, 8. Mylan is incorrect. Subsequent to Novo Nordisk filing this motion, Mylan and the Delaware defendants produced documents which describe the device used with each product. In fact, Mylan's device is the same as that of some Delaware defendants.¹ This fact weighs in favor of consolidation, not against it as Mylan suggests.

Mylan additionally relies on the device patents to distinguish four of the five cases in which it previously consented to consolidation. Opp'n at 8, 15. But Mylan fails to articulate how device

¹ Novo Nordisk cannot disclose the specific devices being used due to confidentiality restrictions.

patents make consolidation inappropriate here. If Mylan's position is based on the potential for differing non-infringement theories, infringement disputes are common in Hatch-Waxman cases and would not make this one unique. Moreover, cases with "different legal theories" are appropriate for consolidation under § 1407. *In re Ameriquest Mortg. Co. Mortg. Lending Practices Litig.*, 408 F. Supp. 2d 1354, 1355 (J.P.M.L. 2005) ("Transfer under Section 1407 does not require a complete identity, or even majority, of common factual issues as a prerequisite to transfer [...]").

Mylan argues repeatedly that its case is "unique," citing to alleged unique "questions of law and fact" (Opp'n at 6), "claim construction issues" (*id.* at 7), "patent claims" (*id.* at 7), "non-infringement grounds" (*id.* at 9), and "witness lineup" (*id.* at 10). Any cases consolidated under § 1407 will have some distinctions due to different parties and underlying acts. The relevant inquiry is not whether there are *any differences*, but whether the similarities are strong enough such that conveniences and efficiencies will be realized through consolidation. *See In re: Nebivolol ('040 Pat. Litig.*, 867 F. Supp. 2d 1354, 1355 (J. P.M.L. 2012) (centralizing despite "different proposed generic formulations at issue"). The answer to that question here is a resounding yes.

Mylan's claim that its case is unique hinges largely on the West Virginia Action presently involving eight patents and 125 claims not asserted in Delaware.² However, Judge Connolly's new scheduling order requires Hatch-Waxman plaintiffs to narrow to only 32 asserted claims by the start of fact discovery. Furthermore, at a recent scheduling conference in the Saxenda® Litigation, Judge Connolly ordered Novo Nordisk to reduce the asserted patents from 17 to 10. *Novo Nordisk v. Teva Pharm., Inc.*, Case No. 21-cv-1782-CFC, Dkt. No. 22, at 3 ¶5 (D. Del. May

² Mylan chose to challenge 18 patents covering Ozempic®, Dr. Reddy's and Alvogen chose to challenge 10, Rio chose to challenge five, and Zydus and Sun chose to challenge two. The number of patents asserted against each reflects how soon, prior to expiration of Novo Nordisk's patents, the defendant seeks to market its generic of Ozempic®, which is a strategic choice *by the defendant*.

20, 2022). Novo Nordisk expects that Judge Connolly will impose similar restrictions here, which would lead to the reduction of patents asserted against Mylan from 18 to 10, thus eliminating this source of alleged “uniqueness” and further distinguishing this case from those that Mylan cites. *See* Opp’n at 15-16. For example, Mylan cites *In re Porcine Circovirus (PCV) Vaccine Prods. Pat. Litig.*, 655 F. Supp. 2d 1348 (J.P.M.L. 2009), but there two of the five cases-at-issue had *no overlap* in asserted patents, while the three actions with an overlapping patent were likely to soon be in one jurisdiction due to a pending motion for transfer under § 1404. *Id.* at 1349.

Mylan cites the ’833 patent, the “only one with claims covering manufacturing methods,” as a reason not to consolidate. Opp’n at 6-7. But Judge Connolly has already presided over two cases involving the ’833 patent and has construed its claims twice. Those cases have settled, but Judge Connolly is expected to preside over another *five* cases involving the ’833 patent. Specifically, Novo Nordisk recently received notice of three more ANDAs: two concerning Saxenda[®] (certifying against 17 and 18 patents, 15 of which overlap with the West Virginia Action) and one concerning Victoza[®]; this will yield three additional cases before Judge Connolly concerning the ’833 patent. If anything, the ’833 patent weighs in favor of consolidation.

Mylan otherwise does little to explain what makes the eight patents so “unique.” In fact, they are highly similar to patents already asserted in Delaware due to the almost complete overlap in “patent families” between the Delaware and West Virginia Actions. *See* Memorandum in Support of Plaintiffs’ Motion for Transfer, Dkt. No. 1-1 (“Mem.”) at 11-13. For example, two of the “unique-to-West Virginia” patents (the ’757 and ’616 patents) are a child and grandchild, respectively, of the ’154 patent, which is commonly asserted in West Virginia and Delaware. These three patents have the same title, inventors, and figures, and describe the invention using the same words, including in their claims. All three patents claim priority to the same U.S.

provisional and foreign applications, meaning that the universe of prior art for each—relevant to hypothetical anticipation, obviousness, enablement, written description, and potentially claim construction issues—is excepted to be the same. The same is true with, for example, the '611 patent (asserted in both West Virginia and Delaware), and the '969 patent (asserted only in West Virginia). These two patents share a title, inventors, priority date, specification, and figures, and use many of the same claim terms. The notion that it would be *more* efficient for two courts to construe claims terms and assess infringement and validity of such similar patents defies logic.

B. Transfer and Consolidation Is the Most Convenient and Efficient Approach

1. Proceeding in Parallel Would Be Highly Inefficient

Mylan argues that “centralization will not serve the convenience of the parties or witnesses” because discovery “will be materially different in West Virginia and Delaware.” Opp’n at 10. This claim is not true, and Mylan provides no concrete examples to support it. To the contrary, maintaining separate cases would result in numerous inefficiencies, potentially including: duplicate fact depositions (including numerous inventors in Europe);³ the application of different local rules, different protective orders, different protocols for e-discovery, different case schedules, and different discovery burdens; multiple *Markman* hearings concerning the same patents, possibly leading to different and even conflicting claim constructions; multiple expert reports on the same issues, including by the same experts⁴ and served at different times; and a

³ Mylan argues that “four inventors [...] are not inventors on any patent asserted in Delaware,” (Opp’n at 10), but fails to reference the other ten inventors common to all actions.

⁴ Mylan did not rule out sharing experts with other defendants, as often occurs in multi-filer Hatch-Waxman litigations. If Mylan does share experts, it is another reason transfer and consolidation will convenience the parties and witnesses and further the efficient conduct of the actions.

possible split on the question of Orange Book-listability of the asserted device patents, which defendants in both courts have raised.

Mylan takes the untenable position that two courts considering complex questions of pharmaceutical patent infringement and validity, in parallel cases involving the same drug product and numerous overlapping patents, would be the “key to efficiency.” Opp’n at 11. In so arguing, Mylan focuses entirely on itself and ignores convenience and efficiency for the courts, other defendants, and Novo Nordisk. If the status quo were so efficient, and consolidation so *inefficient*, any one of the Delaware defendants might have objected. But none did—nor have they opposed consolidation of the Delaware Actions.⁵ In fact, Judge Connolly has scheduled a joint scheduling conference for the Delaware Actions on June 29, 2022. Case No. 22-cv-294-CFC, Dkt. No. 19 (D. Del. June 6, 2022). All but Mylan appear to recognize the inefficiency of multiple courts overseeing litigation concerning the same product instead of oversight by a single judge who is already familiar with certain issues and patents from prior and concurrent cases.

2. Consolidating in Delaware, Which Is the Most Appropriate Jurisdiction, Will Promote the Just Conduct of All Actions

Mylan argues that consolidation “conflicts” with its rights, labelling this an “attempted end run around MPI’s right to litigate this case in a proper forum.” Opp’n at 2, 14. Mylan cites no authority because consolidation does no such thing. Mylan ignores that 28 U.S.C. § 1407 provides for only “coordinated and consolidated *pretrial* proceedings” (emphasis added). If transfer and consolidation is granted, the West Virginia Action will return to West Virginia for trial there. Suggestion that consolidation would trample on Mylan’s rights is nonsense.

⁵ See, e.g., Case No. 22-cv-294-CFC, Dkt. No. 18 (D. Del. June 3, 2022) (letter to Judge Connolly indicating that no defendant opposes consolidation).

Mylan further argues, without support, that the unavailability of summary judgment in Delaware is inefficient and a reason to deny consolidation. Opp’n at 12. Not so. First, Delaware judges, who Mylan agrees see a very high volume of Hatch-Waxman cases, disallow summary judgment in such cases because it is an *inefficient* alternative to hearing technical witness testimony at trial, which is often necessary to resolve complex cases. Second, other avenues exist for a streamlined resolution of the de-listing counterclaims. Mylan is well aware because it cross-moved for judgment on the pleadings under Rule 12(c) (*not* Rule 56) on this issue in Delaware just last year. *See Novo Nordisk Inc. v. Mylan Institutional LLC*, 19-cv-1551-CFC, Dkt. No. 129 (D. Del. Jan. 15, 2021). Third, given Judge Connolly’s early case narrowing procedures, transfer to Delaware will result in a more immediate narrowing of issues than remaining in West Virginia.

Mylan does not contest, nor could it, that Judge Connolly has prior experience with certain asserted patents and will grow in familiarity with all asserted patents through numerous pending cases. Mylan instead argues that Delaware and Judge Connolly are overburdened, which according to Mylan counsels against consolidation in Delaware and in favor of West Virginia. *Id.* at 12-14, 16. Without denying Judge Connolly’s busy docket, Novo Nordisk respectfully submits that the marginal burden of one more patent case is outweighed by the overall efficiency gains of having the same judge address the same and similar issues, pursuant to a single schedule.

In raising arguments concerning Delaware’s docket, Mylan cites motions for transfer under 28 U.S.C. § 1404, which involve analysis of different factors, including “administrative difficulties flowing from court congestion.” Opp’n at 12-14, citing *Scramoge Tech. Ltd. v. Samsung Elecs. Co.*, 21-cv-454 (W.D. Tex. May 23, 2022), ECF No. 92 and *Allen Med. Sys., Inc. v. Mizuho Orthopedic Sys., Inc.*, 21-1739, 2022 WL 1046258 (D. Del. Apr. 7, 2022). But a transfer under §

1404 is not an option here given Mylan will not consent to venue in Delaware, and the busyness of the transferee district is not a consideration in a transfer under § 1407 in the same way.⁶

C. The Number of Cases or Jurisdictions Involved Does Not Change the Analysis

Mylan cites dissimilar authority to argue that involvement of only two jurisdictions weighs against consolidation under § 1407. Opp’n at 5-6. But Mylan’s authority does not contradict the many cases favoring consolidation under our circumstances. Mem. at 4-6, 10-11. Novo Nordisk never suggested that centralization is “automatic,” or that Hatch-Waxman litigations should “always be centralized,” as Mylan incorrectly asserts. Opp’n at 9. Rather, Novo Nordisk demonstrated that consolidation is appropriate here, in view of common questions of fact and law, convenience, and the just and efficient conduct of the actions. Mem. at 4-11. It happens that these factors almost always favor consolidating Hatch-Waxman cases, as evidenced by the Panel’s record. Mem. at 4-6, 10-11.

In re Sumatriptan Succinate Pat. Litig., 381 F. Supp. 2d 1378 (J.P.M.L. 2005) is the only denied request for consolidation of Hatch-Waxman cases Mylan cites. The actions in *Sumatriptan* were at very different stages, filed nearly *two years* apart. *Id.* at 1378-79. That fact alone suggests that consolidation would not lead to convenience or efficiencies. Here the cases for consolidation are at the same stage, filed only two weeks apart, making *Sumatriptan* inapposite.

Mylan cites *In re: JumpSport, Inc., ('845 & '207) Pat. Litig.*, 338 F. Supp. 3d 1356 (J.P.M.L. 2018), an infringement action concerning trampolines, to argue that consolidation is inappropriate where “multiple actions in one district had already been consolidated and a lone case

⁶ To the extent Mylan presents the District of Delaware being “down a judge” (Opp’n at 2) as a reason to deny transfer and consolidation, in April 2022 President Biden nominated Greg Williams, whom the ABA has rated as “well qualified,” to fill the vacancy. This suggests the seat should be filled relatively soon, and, in any event, early in the life of the Ozempic® Patent Litigations. See [https://ballotpedia.org/Gregory_Williams_\(Delaware\)](https://ballotpedia.org/Gregory_Williams_(Delaware)).

was pending in a different district.” Opp’n at 6. But Mylan omits that in *JumpSport*, the Texas actions had “progressed significantly,” while the Georgia actions had been “recently filed.” *Id.* As with *Sumatriptan*, this significant staggering of case timelines is not present here. Moreover, defendants in both jurisdictions shared counsel, making informal coordination “practical and preferable.” *Id.* at 1357. Additionally, parties to two actions had already noticed settlements, and the Panel feared “hinder[ing] the[ir] orderly and efficient resolution.” *Id.* *JumpSport* presents several convincing reasons a Panel might deny consolidation, none of which are present here.

In re: Select Retrieval, LLC, (’617) Pat. Litig., 883 F. Supp. 2d 1353 (J.P.M.L. 2012) involved a patented method of retrieving and displaying information, asserted against 18 retailers. Consolidation was inappropriate because the parties had not determined “to what extent infringement allegations will be common to the defendants across these actions.” *Id.* at 1354. By contrast, defendants here committed an identical infringing activity by submitting competing ANDAs, seeking approval to market an alleged “equivalent” copy of Ozempic® prior to patent expiration. This is in stark contrast to *Select Retrieval*, where the accused websites were unrelated.

Finally, *In re: Zeroclick, LLC, (’691 & ’443) Pat. Litig.*, 437 F. Supp. 3d 1362 (J.P.M.L. 2020) is readily distinguishable. Zeroclick filed four suits in Texas against Dell, LG, Microsoft, and Samsung. Six days later, HP, who shared counsel with Microsoft and Dell, filed a declaratory judgment action against Zeroclick in California, after which Texas Defendants Microsoft and Dell filed an MDL petition seeking transfer of the original four cases to California. The request was not denied due to involvement of only two jurisdictions, as Mylan suggests, but rather due to the gamesmanship on display. *Id.* at 1362. (“the multidistrict character of this litigation exists only because HP brought its declaratory judgment action against Zeroclick in the Northern District of California rather than the Western District of Texas.”). No such gamesmanship concerns apply

here, and none of the defendants here have common counsel, a factor the *Zeroclick* Panel considered in finding that “alternatives to centralization are practicable.” *Id.* at 1362.

D. Informal Coordination Alone Is Insufficient and Impracticable

As it argued in *In re Kerydin (Tavaborole) Topical Sol. 5% Pat. Litig.*, 366 F. Supp. 3d 1370 (J.P.M.L. 2019), Mylan proposes that *coordination* can achieve the benefits of consolidation. To the contrary, a single decisionmaker, following a common schedule, and overseeing all parties, will necessarily be more efficient than burdening two courts with ongoing coordination. The Panel should reject Mylan’s proposal here as it did in *Kerydin*, a case involving three actions in two courts, because “[g]iven the complexity of the allegations [...] placing all actions before a single judge should foster the efficient resolution of all of the actions.” *Id.* at 1371. *In re: Genetic Techs.*, 883 F. Supp. 2d 1337 (J.P.M.L. 2012), which Mylan cites in support of informal coordination, is inapposite. There “the patent’s litigation history suggests that most actions [...] have not required significant judicial intervention;” the plaintiff had an “extensive licensing history [...] to over 60 entities;” and the only common inventor was deceased, making opportunities for common discovery “more limited.” *Id.* at 1337-38. None of those reasons apply here.

III. CONCLUSION

For the foregoing reasons and those stated in Novo Nordisk’s motion and opening memorandum, Novo Nordisk respectfully requests that the Panel transfer the West Virginia Action to Delaware and consolidate it for coordinated pretrial proceedings with the Delaware Actions.

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