UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF LOUISIANA

IN RE: TAXOTERE (DOCETAXEL) PRODUCTS LIABILITY LITIGATION	)	**MDL No. 16-2740**
	)	**SECTION: "H" (5)**
This document relates to:	)	
Hilda Adams, 16-17583	)	
Gloria Cooper, 18-194	)	
Carol Woodson, 17-12674	)	
Arquice Conley, 18-9799	)	
Tina Hickey, 18-4731	)	

ORDER AND REASONS

Before the Court is a Joint Motion to Certify Order for Interlocutory Appeal filed by Defendants Accord Healthcare, Inc., Sandoz Inc., and Hospira, Inc. and Hospira Worldwide, LLC, f/k/a Hospira Worldwide, Inc. (Doc. 14517). For the following reasons, the Motion is **GRANTED**.

BACKGROUND

Plaintiffs in this multidistrict litigation ("MDL") are suing several pharmaceutical companies that manufactured and/or distributed a chemotherapy drug, Taxotere or docetaxel,[1] that Plaintiffs were administered for the treatment of breast cancer or other forms of cancer. Among these companies are defendants sanofi-aventis U.S. LLC and Sanofi U.S. Services Inc. (collectively, "Sanofi") as well as Accord Healthcare, Inc. ("Accord"); Sandoz Inc. ("Sandoz"); Hospira Worldwide, LLC f/k/a Hospira Worldwide, Inc.; and Hospira, Inc. (collectively, "Hospira"). Plaintiffs allege that the drug caused permanent alopecia—in other words, permanent hair loss—also

[1] Docetaxel is the generic version of Taxotere, although the Court uses the term "generic" loosely.

referred to as "permanent chemotherapy-induced alopecia" ("PCIA"). Plaintiffs bring various claims, including failure to warn, negligent misrepresentation, and fraudulent misrepresentation.

Accord, Sandoz, and Hospira (collectively, "Defendants") are all manufacturers of docetaxel, an unbranded version of Taxotere. Taxotere was developed by Sanofi and approved by the United States Food and Drug Administration ("FDA") in 1996 for the treatment of advanced or metastatic breast cancer. With Sanofi's patent for Taxotere set to expire in 2010, Defendants each submitted "new drug applications," or NDAs, for their docetaxel products pursuant to § 505(b)(2) of the Federal Food, Drug, and Cosmetic Act ("FDCA").

Defendants filed motions for summary judgment, arguing that Plaintiffs' state-law failure-to-warn claims are preempted by federal law.[2] Under federal law, Defendants could have independently changed their docetaxel labels only through the "Changes Being Effected" ("CBE") process, which is available if the change is based on "newly acquired information" that provides evidence of a causal association between the drug and the risk. According to Defendants, Plaintiffs' state-law claims are, therefore, preempted because Plaintiffs cannot and did not identify "newly acquired information" that would have permitted Defendants to independently change their labels via the CBE process before Plaintiffs were treated with docetaxel.

[2] Accord's Motion identified three plaintiffs—Hilda Adams, Carol Woodson, and Gloria Cooper—each of whom received Accord's docetaxel as part of her chemotherapy regimen. *See* Doc. 13425. Plaintiff Adams was treated from January 4, 2013 to April 24, 2013. Plaintiff Woodson was treated from May 1, 2013 to July 3, 2013. And Plaintiff Cooper was treated from November 17, 2014 to March 23, 2015. Sandoz's Motion identifies Plaintiff Arquice Conley. *See* Doc. 13445. Plaintiff Conley was treated with Sandoz's docetaxel as part of her chemotherapy regimen from October 14, 2011 to January 24, 2012. Lastly, Hospira's Motion identifies Plaintiff Tina Hickey. *See* Doc. 13857. Plaintiff Hickey was treated with Hospira's docetaxel as part of her chemotherapy regimen from October 25, 2013 to February 6, 2014.

In response, Plaintiffs emphasized that preemption is an affirmative defense that Defendants must plead and prove and, therefore, Defendants' argument should be rejected because it improperly shifts the burden to Plaintiffs to disprove preemption. They argued that to prove preemption, Defendants must present "clear evidence" that the FDA would not have approved the change to their docetaxel labels, which requires that each Defendant show (1) that it "fully informed the FDA of the justifications for the warning required by state law" and (2) "that the FDA, in turn, informed the drug manufacturer, that the FDA would not approve changing the drug's label to include that warning."[3] According to Plaintiffs, because Defendants could not make this showing, they were not entitled to summary judgment.

In its Order denying Defendants' motions for summary judgment, the Court first addressed the applicable burden of proof and who bears it. The Court held that "when the issue for determination is whether a manufacturer could have unilaterally updated its label pursuant to the CBE regulation, plaintiffs bear the initial burden of identifying the specific information that they contend the manufacturer could have used to modify the drug's label."[4] "Once plaintiffs point to this specific information, the manufacturer bears the burden of proving that it does not meet the requirements of the CBE regulation."[5]

Next, the Court addressed whether that burden of proof had been satisfied. In doing so, the Court analyzed what constitutes "newly acquired information" for purposes of initiating a label change via the CBE regulation. Defendants relied on the definition of newly acquired information provided in the Code of Federal Regulations, wherein it states

[3] Merck Sharp & Dohme Corp. v. Albrecht, 139 S. Ct. 1668, 1672 (2019).
[4] Doc. 14477 at 16–17.
[5] *Id.* at 17.

> [n]ewly acquired information is data, analyses, or other information not previously submitted to the Agency, which may include (but is not limited to) data derived from new clinical studies, reports of adverse events, or new analyses of previously submitted data (e.g., meta-analyses) if the studies, events, or analyses reveal risks of a different type or greater severity or frequency than previously included in submissions to FDA.[6]

Defendants, therefore, contended that the information identified by Plaintiffs was not newly acquired information because: (1) it was previously submitted to the FDA, or (2) it did not reveal risks of a different type or greater severity or frequency than previously included in submissions to the FDA.

This Court rejected Defendants' interpretation of "newly acquired information," finding it would produce a nonsensical result in the context of NDAs that were approved under § 505(b)(2). Specifically, the "FDA's longstanding interpretation of section 505(b)(2) is intended to permit the pharmaceutical industry to rely to the greatest extent possible under the law on what is already known about a drug."[7] Because of the similarities between each Defendant's docetaxel and Taxotere, the FDA did not require Defendants to conduct their own toxicological or clinical studies. Rather, the FDA permitted Defendants to rely on the Agency's findings of safety and efficacy for Sanofi's Taxotere, including Taxotere's approved labeling, for the approval of their docetaxel NDAs. The language of the Warnings and Adverse Reactions sections of Defendants' docetaxel labels was therefore based on what *Sanofi* had previously submitted to the FDA, not Accord, Hospira, or Sandoz.

Against this background, the Court found Defendants' interpretation of "newly acquired information" to be unworkable because without knowing the full extent of what was previously submitted to the FDA, Defendants could never determine whether information revealed risks of a different type or

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[6] 21 C.F.R. § 314.3(b).

[7] *See* Doc. 13595-3 at 3 (Woodcock Letter); Doc. 13596-3 at 3 (same); Doc. 13978-3 at 3 (same).

greater severity or frequency than included in previous submissions to the FDA, and consequently, never have "newly acquired information" sufficient to utilize the CBE process. The Court further found this result to be nonsensical considering that the FDA made the CBE regulation available to 505(b)(2) NDA holders, like Accord, Hospira, and Sandoz.[8]

The Court instead adopted the FDA's interpretation that "if later data or analyses demonstrate that prior warnings were insufficient, such data would clearly qualify as newly acquired information under the rule."[9] Although Defendants proposed a narrower interpretation of "newly acquired information" sufficient to justify a CBE change, this Court did not find the FDA's interpretation "plainly erroneous or inconsistent with the regulation."[10] Rather, the Court found that the FDA's interpretation cures the nonsensical result Defendants' position would have produced. Accordingly, this Court held that any post-approval data or analysis that would have demonstrated that the warnings in Defendants' labels were insufficient would have qualified as newly acquired information under the CBE regulation.

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[8] *See* 21 C.F.R. § 314.70(c)(6)(iii) (explaining that "*the holder of an approved NDA*" may distribute its drug product after making certain changes to the label without first receiving FDA approval) (emphasis added).

[9] When the FDA amended the CBE regulation in 2008 to include the language that a CBE change is permissible if the change is made "to reflect newly acquired information," its notice of the final rule explained

> *if later data or analyses demonstrate that prior warnings were insufficient, such data would clearly qualify as newly acquired information under the rule.* Indeed, the rule expressly provides that new analyses of previously submitted information are considered new information that could be submitted by a CBE supplement (provided that other requirements for a CBE supplement are met). Therefore, if a sponsor determined that existing warnings were insufficient based on newly acquired information such as a new analysis of previously submitted data, the sponsor could still submit a CBE based on its new analysis of the previous data, provided the other requirements of the rule are met.

Supplemental Applications Proposing Labeling Changes for Approved Drugs, Biologics, and Medical Devices, 73 Fed. Reg. 49603, 49606 (August 22, 2008) (emphasis added).

[10] Auer v. Robbins, 519 U.S. 452, 461 (1997).

Finally, after reviewing the relevant, publicly available scientific literature, the Court concluded that Defendants also could have analyzed such literature, and it would have shown that there was some basis to believe there was a causal relationship between docetaxel and the occurrence of permanent hair loss. Further, because Defendants' labels contained no reference to permanent alopecia, the Court held that an analysis of this scientific literature would have demonstrated that their labels were insufficient and, therefore, would have qualified as newly acquired information.[11] As a result, Defendants could have updated their labels via the CBE regulation, and it was not impossible for them to comply with both federal and state requirements.[12] Defendants' motions for summary judgment were therefore denied.

Subsequently, Accord, Sandoz, and Hospira jointly filed the instant Motion requesting this Court to certify its August 2, 2022 Order and Reasons (Doc. 14477) ("Order") for immediate appeal pursuant to 28 U.S.C. § 1292(b).[13]

LAW AND ANALYSIS

Pursuant to 28 U.S.C. § 1292, a court can allow for interlocutory appeal of orders without directing entry of a final judgment on the order. For an interlocutory order to be appealable pursuant to § 1292(b), three conditions must be satisfied. The trial judge must certify in writing that: (1) the order involves a controlling question of law, (2) there exists a substantial ground for difference of opinion on that question of law, and (3) an immediate appeal from

[11] *See* Supplemental Applications Proposing Labeling Changes for Approved Drugs, Biologics, and Medical Devices, 73 Fed. Reg. 49603, 49606 (August 22, 2008) ("[I]f later data or analyses demonstrate that prior warnings were insufficient, such data would clearly qualify as newly acquired information under the rule.").
[12] *See* 21 C.F.R. § 314.70(c)(6)(iii)(A).
[13] Doc. 14517.

the order may "materially advance the ultimate termination of [the] litigation."[14] The moving party carries the burden of showing the necessity of interlocutory appeal.[15] Interlocutory appeals are "exceptional" and should not be granted "simply to determine the correctness of a judgment."[16]

The Court finds that Defendants have carried their burden with respect to each of the three conditions required for an interlocutory order to be appealable pursuant to § 1292(b).

1. Controlling Question of Law

First, the Court finds that the Order involves a controlling question of law. "A controlling question of law is one 'that would require reversal on appeal from a final judgment or would materially affect the outcome of the case.'"[17] Resolution of a controlling question of law need not terminate the litigation entirely so long as it "would have some significant impact on the advancement of the litigation."[18] "Additionally, controlling questions of law generally must be purely legal in nature."[19] The Fifth Circuit has held that federal preemption "certainly falls within the ambit of 28 U.S.C. § 1292(b)."[20]

Here, the Order involves a purely legal question: whether Plaintiffs' state law failure-to-warn claims are preempted by federal law.[21] And, as

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[14] 28 U.S.C. § 1292; *see also* Rico v. Flores, 491 F.3d 234, 238 (5th Cir. 2007).
[15] Chauvin v. State Farm Mut. Auto. Ins. Co., No. 06-7145, 2007 WL 4365387, at *2 (E.D. La. Dec. 11, 2007).
[16] *Id.* (quoting Clark-Dietz & Assocs.-Eng'rs, Inc. v. Basic Constr. Co., 702 F.2d 67, 68–69 (5th Cir. 1983)).
[17] D.H. Griffin Wrecking Co. v. 1031 Canal Dev., LLC, No. 20-1051, 2020 WL 7626817, at *3 (E.D. La. July 14, 2020) (quoting Jesclard v. Babcock & Wilcox, Civ. A. No. 82-1570, 1990 WL 182315, at *1 (E.D. La. Nov. 21, 1990)).
[18] *Id.* (citing Ryan v. Flowserve Corp., 444 F. Supp. 2d 718, 723 (N.D. Tex. 2006)); S.E.C. v. Credit Bancorp, Ltd., 103 F. Supp. 2d 223, 227 (S.D.N.Y. 2000).
[19] *Id.* (citing Williams v. Taylor, No. CIV.A. 15-321, 2015 WL 4755162, at *2 (E.D. La. Aug. 11, 2015)).
[20] Spong v. Fid. Nat'l Prop. & Cas. Ins. Co., 787 F.3d 296, 304 (5th Cir. 2015).
[21] *See* Merck Sharp & Dohme Corp. v. Albrecht, 139 S. Ct. 1668, 1672 (2019) (stating that "this question of pre-emption is one for a judge to decide, not a jury."). *See also* Lyons v. Boehringer Ingelheim Pharms., Inc., 491 F. Supp. 3d 1350, 1363 (N.D. Ga. 2020) ("Like all

Defendants note, this purely legal question is controlling because it is dispositive. If the five Plaintiffs involved in the Order were to proceed to final judgments on their failure-to-warn claims, and Defendants were to successfully appeal on preemption grounds, the Fifth Circuit would have to reverse the judgments. Moreover, resolution of this question may not end the entire MDL, but it will have a substantial impact, as it will provide this Court with guidance as to the preemption analysis applicable to the other cases against § 505(b)(2) defendants in this MDL.

2. Substantial Ground for Difference of Opinion

Next, there exists substantial ground for difference of opinion as to this Court's interpretation of "newly acquired information" as applied to § 505(b)(2) NDA holders. Courts often find that substantial ground for difference of opinion exists if "novel and difficult questions of first impression are presented."[22] As the Order explained, this Court is the only federal court to have addressed how the "newly acquired information" requirement of the CBE

other court's that have addressed this question post-*Albrecht*, this Court finds that both the 'newly acquired information' and 'FDA action' questions are for a Judge to decide, not a jury."); Knight v. Boehringer Ingelheim Pharms. Inc., 984 F.3d 329, 337 n.8 (4th Cir. 2021) (concluding that whether there exists "newly acquired information," for purposes of preemption, is a legal question); *In re* Incretin-Based Therapies Prods. Liab. Litig., 524 F. Supp. 3d 1007, 1016 (S.D. Cal. 2021) (same); Spong v. Fid. Nat'l Prop. & Cas. Ins. Co., 787 F.3d 296, 304 (5th Cir. 2015) ("Whether federal law preempts the [plaintiffs'] claims certainly falls within the ambit of 28 U.S.C. § 1292(b).").

[22] Mitchell v. Hood, No. 13-5875, 2014 WL 1764779, at *5 (E.D. La. May 2, 2014) (quoting Couch v. Telescope, Inc., 611 F.3d 629, 633 (9th Cir. 2010)); *see also In re* Miedzianowski, 735 F.3d 383, 384 (6th Cir. 2013) (stating that a substantial ground for difference of opinion exists when "(1) the question is difficult, novel and either a question on which there is little precedent or one whose correct resolution is not substantially guided by previous decisions; (2) the question is difficult and of first impression; (3) a difference of opinion exists within the controlling circuit; or (4) the circuits are split on the question.").

process applies to holders of NDAs that were approved under the § 505(b)(2) pathway. Thus, this issue is novel.

This question is also difficult. Defendants interpretation of "newly acquired information" is that a manufacturer only has newly acquired information if it "reveals risks of a different type or greater severity or frequency than what was previously submitted to the FDA."[23] Considering the Defendants did not have access to everything that was previously submitted to the FDA at the time in question, the Court rejected this narrow interpretation in favor of the FDA's interpretation that "if later data or analyses demonstrate that prior warnings were insufficient, such data would clearly qualify as newly acquired information under the rule."[24]

Thus, there is substantial ground for disagreement as to whether "newly acquired information" is as narrow as Defendants assert, or whether it is as the Court held and as the FDA stated in its position statement.

3. Immediate Appeal May Advance the Ultimate Termination of Litigation

Finally, an immediate appeal from the Order may materially advance the termination of this litigation. This inquiry is inherently related to the first condition, namely, the controlling question of law.[25] Plaintiffs argue that immediate appeal will "not materially advance the litigation as a whole because, at best, reversal would only address the particular records considered, and not some overarching purely legal question that could control in this MDL."[26] This Court disagrees. "The fact that the Court's ruling likely impacts

[23] 21 C.F.R. § 314.3(b).
[24] Supplemental Applications Proposing Labeling Changes for Approved Drugs, Biologics, and Medical Devices, 73 Fed. Reg. 49603, 49606 (August 22, 2008) (emphasis added).
[25] D.H. Griffin Wrecking Co. v. 1031 Canal Dev., LLC, No. 20-1051, 2020 WL 7626817, at *3 (E.D. La. July 14, 2020) ("To this extent, the 'controlling question' inquiry is inherently related to the requirement that resolution of the issue materially advance the outcome of the litigation.")
[26] Doc. 14737 at 2.

a large number of claims further counsels in favor of appeal."[27] As explained above, an immediate appeal of the Order will provide this Court with guidance as to the preemption analysis applicable to other cases against § 505(b)(2) defendants pending in this MDL.

Accordingly, the Court finds that its August 2, 2022 Order and Reasons (Doc. 14477) is appealable pursuant to 28 U.S.C. § 1292(b) because it involves a controlling question of law as to which there is substantial ground for difference of opinion and an immediate appeal from the Order may materially advance the ultimate termination of the litigation.

CONCLUSION

For the foregoing reasons, **IT IS ORDERED** that Defendants' Joint Motion to Certify Order for Interlocutory Appeal (Doc. 14517) is **GRANTED**.

IT IS FURTHER ORDERED that, should application for appeal be made timely after this Order, these cases will be **STAYED** pending the outcome of the appeal. If such application is not timely made, the case will proceed without a stay.

New Orleans, Louisiana, this 14th day of November, 2022.

HON. JANE TRICHE MILAZZO
UNITED STATES DISTRICT JUDGE

[27] *In re* General Motors Ignition Switch Litig., 427 F. Supp. 3d 374, 393 (S.D.N.Y. 2019). *See also* Klinghoffer v. S.N.C. Achille Lauro Ed Altri-Gestione Motonave Achille Lauro in Amministrazione Straordinaria, 921 F.2d 21, 24 (2d Cir. 1990) ("[T]he impact that an appeal will have on other cases is a factor that we may take into account in deciding whether to accept an appeal that has been properly certified by the district court.").