IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BIODELIVERY SCIENCES INTERNATIONAL, INC. and ARIUS TWO, INC., Plaintiffs, v. ALVOGEN PB RESEARCH & DEVELOPMENT LLC, ALVOGEN MALTA OPERATIONS LTD., ALVOGEN PINE BROOK LLC, ALVOGEN, INC., and ALVOGEN GROUP, INC., Defendants.	Civil Action No. 18-1395-CFC

MEMORANDUM ORDER

This case was filed in 2018 by Plaintiffs BioDelivery Sciences International, Inc. and Arius Two, Inc. (collectively, BDSI) against Defendants Alvogen PB Research & Development LLC, Alvogen Malta Operations Ltd., Alvogen Pine Brook LLC, Alvogen, Inc., and Alvogen Group, Inc. (collectively, Alvogen) under the Drug Price Competition and Patent Term Restoration Act—commonly called the Hatch-Waxman Act. BDSI alleged that Alvogen's submission to the Food and Drug Administration (FDA) of Abbreviated New Drug Application (ANDA) No. 211594 for approval to market a generic version of BDSI's Belbuca® drug

product constituted infringement of certain claims of U.S. Patents Nos. 8,147,866 (the #866 patent), 9,655,843 (the #843 patent), and 9,901,539 (the #539 patent) pursuant to 35 U.S.C. § 271(e)(2)(A). Belbuca® is a buprenorphine buccal film—that is, a bioerodable mucoadhesive film for transmucosal delivery of the opioid buprenorphine.

On January 21, 2022, I entered a final judgment and the case was closed. D.I. 308. Pending before me is BDSI's Motion to Enforce the Final Judgment. D.I. 340.

I.

BDSI filed the motion and its opening brief in support of the motion (D.I. 341) on July 22, 2025. Alvogen filed a brief in response to the motion on August 12, 2025. D.I. 354. Five of the lawyers who authored Alvogen's response brief are with the law firm Spencer Fane LLP. *See* D.I. 354 at 22. BDSI filed its reply brief on September 29, 2025. D.I. 400.

Before addressing the merits of the pending motion, I need to say something about another motion BDSI filed the same day it filed its reply brief in support of the pending motion. BDSI titled that motion Plaintiffs' Motion to Strike and Disqualify. D.I. 382. BDSI seeks in that motion an order declaring three things relevant here:

> (1) that the declaration of Mr. Kurt Karst (D.I. 354-3-Ex.D) be struck and removed from the

> docket; . . . [(2)] that the portions of Defendants' Brief in Response to Plaintiffs' Motion to Enforce the Final Judgment (D.I. 354) that rely on Mr. Karst's declaration be struck, as indicated by Exhibit 6 to Plaintiffs' accompanying brief; and [(3)] that the Spencer Fane law firm be disqualified from further work on this case.

D.I. 382 at 1.

I have not yet ruled on the Motion to Strike and Disqualify, but that does not prevent me from deciding the pending motion for two reasons. First, in a previous Memorandum Order (D.I. 422), I granted Alvogen's letter request to withdraw Karst's declaration and strike the portions of Alvogen's response brief to the pending motion (D.I. 354) that cite to or otherwise make reference to Karst's declaration. Thus, in deciding the pending motion I have not considered Karst's declaration or the portions of Alvogen's response brief that depend on that declaration. Second, the only work of Spencer Fane that has come to my attention since BDSI filed the pending motion is by way of Alvogen's Motion for Leave to File a Sur-reply or, in the Alternative, Motion to Strike (D.I. 391), and I denied that motion earlier today by oral order. Thus, I have not considered in deciding the pending motion any work done by Spencer Fane after it filed its response brief on September 29, 2025. Accordingly, I need not rule on the Motion to Strike and Disqualify before ruling on the pending motion.

II.

Turning, then, to the pending motion: BDSI purports to seek by the motion "enforce[ment]" of the judgment I entered on January 21, 2022. D.I. 340 at 1. Four weeks before that date, I had issued an opinion setting forth the findings of fact and conclusions of law I had made after a three-day bench trial. D.I. 300. That same day, I ordered the parties to "submit no later than January 18, 2022 a proposed order by which the Court may enter final judgment consistent with the Opinion[.]" D.I. 301.

The first six paragraphs of the judgment (D.I. 308) were stipulated to by the parties:

> 1. Final Judgment is entered in favor of BDSI and against Alvogen on Counts I, III, IV, and VI, of BDSI's Complaint against Alvogen dated September 7, 2018 that by submitting Abbreviated New Drug Application ("ANDA") No. 211594 to the FDA, Alvogen has infringed, and if manufactured, used, marketed, offered for sale, or sold within the U.S. or imported herein, all dosage strengths of Alvogen's generic buprenorphine film product (75 mcg, 150 mcg, 300 mcg, 450 mcg, 600 mg, 750 mcg and 900 mcg) would infringe claims 4 and 5 of U.S. Patent No. 8,147,866 ("the [#]866 patent"), and claim 9 of U.S. Patent No. 9,901,539 ("the [#]539 patent").
>
> 2. Final Judgment is entered in favor of BDSI and against Alvogen on Counts III and VI of BDSI's Complaint against Alvogen dated September 7, 2018, that by submitting ANDA No. 211594 to the FDA, Alvogen has infringed, and if manufactured, used, marketed, offered for sale, or sold, within the U.S. or imported herein, the 150 mcg dosage strength of Alvogen's generic

buprenorphine film product would infringe claim 20 of the [#]539 patent.

3. Final Judgment is entered in favor of BDSI and against Alvogen that claims 4 and 5 of the [#]866 patent and claims 9 and 20 of the [#]539 patent are not invalid for the reasons set forth in the Court's Findings of Facts and Conclusions of Law on December 20, 2021 (D.I. 300).

4. Final Judgment is entered in favor of Alvogen and against BDSI on Counts II and V of BDSI's Complaint, dated September 7, 2018, that claims 8, 9, and 20 of U.S. Patent No. 9,655,843 ("the [#]843 patent") are invalid, and Final Judgment is entered in favor of Alvogen against BDSI that claims 3 and 10 of the '866 patent are invalid, for the reasons set forth in the Court's Findings of Facts and Conclusions of Law on December 20, 2021 (D.I. 300), and that Alvogen is thus not liable for infringement of these claims.

5. Pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any final approval by the United States Food and Drug Administration of Alvogen's ANDA No. 211594 shall be a date no earlier than the December 21, 2032 expiration date of the [#]539 patent, which is the later to expire patent between the [#]866 and [#]539 patents, or later due to any extensions and/or additional periods of exclusivity to that date, except to the extent subsequently agreed between BDSI and Alvogen.

6. Alvogen shall notify the FDA in writing within five (5) days after entry of this final judgment (with a copy of such notice given simultaneously to BDSI) of this Court's decision that claims 4 and 5 of the [#]866 patent and 9 and 20 of the [#]539 patent are valid and that Alvogen's filing of ANDA No. 211594 infringes claims 4 and 5 of the [#]866 patent and claims 9 and 20 of the [#]539 patents as set forth above in paragraphs 1 and 2.

D.I. 308 ¶¶ 1–6.

Paragraph 7 of the judgment was drafted by Alvogen and agreed to by BDSI. *See* D.I. 307 at 2, 6. But on the eve of filing the proposed judgment, Alvogen changed its mind and took the position that paragraph 7 should not be included in the judgment. The reasons for Alvogen's change of heart are not relevant here. To be honest, I paid scant attention at the time I entered the judgment to the reasons Alvogen gave for changing its position. This case in general, including the post-trial briefing (and consistent with the pending motion), was marred by obstreperous behavior by both sides to a degree I have rarely experienced as a judge. Frustrated (and exhausted) by the case, I decided to include paragraph 7 in the judgment for the simple reason that both sides had at least at one point in time agreed to it.

Paragraph 7 of the judgment reads:

> Pursuant to 35 U.S.C. § 271(e)(4)(B), Defendants and its officers, agents, servants, employees, successors, and attorneys, and those persons in active concert or participation with them, are enjoined, until the expiration of each of the [#]866 patent, and the [#]539 patent, from commercially manufacturing, using, selling or offering for sale in the United States, or importing into the United States Defendants' ANDA Products.

D.I. 308 ¶ 7. The term "ANDA Products" is not defined in paragraph 7 and is not used anywhere else in the judgment. But I think it is beyond debate that ANDA Products refers to products covered by Alvogen's ANDA No. 211594.

Alvogen appealed the judgment. It argued on appeal that I clearly erred in making certain findings underlying my conclusion that claims 9 and 20 of the #539 patent and claims 4 and 5 of the #866 patent are not invalid. BDSI filed a cross-appeal in which it argued that I applied the incorrect legal standard when I weighed secondary considerations of nonobviousness in deciding that claims 8, 9, and 20 of the #843 patent and claims 3 and 10 of the #866 are invalid.

In an opinion issued on December 21, 2022, the Federal Circuit affirmed the judgment insofar as it declared that claims 9 and 20 of the #539 patent and claims 4 and 5 of the #866 patent are not invalid. The court vacated the judgment insofar as it declared that claims 8, 9, and 20 of the #843 patent and claims 3 and 10 of the #866 patent are invalid. The court said in the opinion that it would remand the case to me "for the sole purpose of reconsidering the evidence already presented at trial regarding long-felt need and unexpected results under the correct evidentiary standard." D.I. 337-1 at 11–12; *Arius Two, Inc. v. Alvogen Pb Research & Development LLC*, 2022 WL 17828352, at *5 (Fed. Cir. 2022).

The Federal Circuit issued its mandate of the appeals on February 10, 2023. D.I. 337. Cognizant that the injunction in paragraph 7 of the judgment bars Alvogen from commercially manufacturing, using, selling, or offering for sale in the United States its products covered by ANDA No. 211594 before the expiration of the #539 patent and aware that, as set forth in Paragraph 5 of the judgment, the

expiration date of the #539 patent is December 21, 2032, I decided to take no action in the case unless and until I heard from the parties.

More than two years passed. On July 22, 2025, BDSI filed the pending motion. BDSI filed the motion in response to Alvogen's filing with the FDA earlier that year ANDA No. 220582. As it had sought with ANDA No. 211594, Alvogen seeks by ANDA No. 220582 approval to market a buprenorphine buccal film, i.e., a generic version of Belbuca®. D.I. 341-1 at 74. BDSI says the drug product covered by ANDA No. 220582 is "substantially identical" to the product covered by ANDA No. 211594 and that ANDA No. 220582 "appears to be an attempt by Alvogen to circumvent the Final Judgment" I entered in this case. D.I. 341 at 11. BDSI requests in its motion that I

> issue an order (1) confirming that the generic products Alvogen seeks to sell under its ANDA (No. 220582) are within the scope of the Final Judgment, including, but not limited to, [sic] (2) finding that the sale of Alvogen's proposed generic products will infringe claims 9 and 20 of the [#]539 patent, and (3) granting all relief necessary to prevent Alvogen from marketing any generic buprenorphine film product until the expiration of the [#]539 patent in 2032.

D.I. 340 at 1. BDSI says that it is "not seeking to modify the Final Judgment," but "[r]ather[] i[s] ask[ing] the Court to enforce the existing judgment in light of Alvogen's current conduct." D.I. 381 at 9.

Alvogen counters that the ANDA No. 220582 product is a "reformulation" of the ANDA No. 211594 product that has a more basic backing layer pH than the ANDA No. 211594 product. D.I. 354 at 1. According to Alvogen, this change of the pH constitutes a legitimate design-around that removes the ANDA No. 220582 product from the scope of the #539 patent's claims and thus the scope of the injunction in paragraph 7 of the judgment. D.I. 354 at 1, 6. Alvogen also says that BDSI's motion is procedurally barred because "permanent injunctions are only 'enforced' via a contempt motion under the standard in *TiVo* [*Inc. v. EchoStar Corp.*, 646 F.3d 869 (Fed. Cir. 2011).]" D.I. 354 at 3.

I need not decide whether the products covered by ANDA No. 220582 are an "ANDA Product" covered by paragraph 7's injunction because I agree that the motion is procedurally improper, and I will deny it for that reason. But to be clear, that result is not dictated by *TiVo*. The Federal Circuit held in *TiVo* that "[t]he criteria for adjudicating a violation of a prohibition against continued infringement by a party whose products have already been adjudged to be infringing is a matter of Federal Circuit law." 646 F.3d at 881. And the court affirmed in *TiVo* a district court's finding of contempt based on a defendant's failure to comply with an injunction that required the defendant to disable parts of products that a jury had held infringed the plaintiff's patents. 646 F.3d at 890. The court, however, did not hold in *TiVo* that injunctions are only enforced through contempt motions.

Nonetheless, I agree that to the extent BDSI seeks to enforce the injunction in paragraph 7, it must do so by way of a contempt motion. An injunction is "an equitable decree compelling obedience under the threat of contempt[.]" *Int'l Longshoremen's Ass'n, Loc. 1291 v. Philadelphia Marine Trade Ass'n*, 389 U.S. 64, 75 (1967). And thus "injunctions are enforced through the district court's civil contempt power." *Thomas v. Blue Cross & Blue Shield Ass'n*, 594 F.3d 823, 829 (11th Cir. 2010) (internal quotation marks and citations omitted). Accordingly, "[i]f a party contends that another party is violating an injunction, the aggrieved party should move the court for an order to show cause why the other party should not be held in civil contempt." *Id.* (citation omitted).

BDSI insists that "a motion to enforce judgment is appropriate for addressing post-judgment developments." D.I. 381 at 9. But not surprisingly, none of the cases it cites in its briefing support this unworkable proposition. The adoption of such a rule would subject courts to never-ending motion practice to address the infinite "developments" that might arise following entry of a judgment.

BDSI also complains that Alvogen's submission of ANDA No. 220582 has "left [it] in the untenable position of being forced to file a new lawsuit . . . , which represents a manifest waste of judicial and party resources, and attempts to transform the Court's prior opinion into an impermissible advisory opinion." D.I. 341 at 15. But it is BDSI's motion that constitutes a manifest waste of judicial

resources. BDSI could have filed a motion asking me to hold Alvogen in contempt for violating the injunction in paragraph 7. Had it done so, it would have had to prove by clear and convincing evidence "both that the [ANDA No. 220582] product is not more than colorably different from the [ANDA No. 211594] product found to infringe and that the [ANDA No. 220582] product actually infringes" the #539 patent. *TiVo*, 646 F.3d at 882–83. Instead of taking on that burden, BDSI filed in this Court *both* the pending motion *and* a new lawsuit accusing Alvogen of infringement under the Hatch-Waxman Act (*BioDelivery Scis. Int'l, Inc. v. Alvogen PB Rsch. & Dev. LLC*, No. 25-926-CFC). A waste of judicial resources indeed.

* * * *

NOW THEREFORE, at Wilmington on this Twelfth Day of January in 2026, it is HEREBY ORDERED that BDSI's Motion to Enforce the Final Judgment (D.I. 340) is DENIED.

CHIEF JUDGE