UNITED STATES DISTRICT COURT

DISTRICT OF SOUTH DAKOTA

WESTERN DIVISION

UNITED STATES OF AMERICA,

Plaintiff,

vs.

2035, INC., a corporation, and ROBERT L. LYTLE, an individual, d/b/a 2035 PMA and QLASERS PMA,

Defendants.

CIV. 14-5075-JLV

SECOND ORDER DENYING STAY AND DENYING CONTINUANCE

On January 14, 2015, the court entered a preliminary junction against defendants 2035, Inc., a corporation, and Robert L. Lytle, an individual, d/b/a 2035 PMA and QLASERS PMA. (Docket 48). On January 20 and 21, 2015, defendant Robert L. Lytle filed an emergency motion to stay enforcement of the preliminary injunction and other motions. (Dockets 49, 50 & 51). On January 23, 2015, the court denied Mr. Lytle's motion for stay of the preliminary injunction and other motions. (Docket 52). On the same day, the court entered an order requiring the parties to file a report and indicate the earliest date by which they can proceed to trial on plaintiff's motion for a permanent injunction. (Docket 53). On January 26, 2015, Mr. Lytle filed an emergency notice of interlocutory appeal. (Docket 54). On January 28, 2015, Mr. Lytle filed a second emergency motion to stay the preliminary injunction and continue the trial date during the pendency of his appeals to the United States Court of Appeals for the Eighth Circuit. (Docket 56). On February 6, 2015, the government filed its brief in opposition to Mr. Lytle's second request for an emergency stay of the preliminary injunction.(Docket 65). In the meantime, Mr. Lytle filed a verified emergency motion for clarification. (Docket 59).

Mr. Lytle has appeals in two cases pending before the Eighth Circuit. Those are <u>United States v. 2035 Inc., *et al.*</u>, CIV. 14-5075 (Docket 54) and <u>Dr.</u> <u>Larry Lytle v. United States Department of Health and Human Services, *et al.*, CIV. 13-5083. (Docket 32).</u>

Unless this court rules otherwise, there is no automatic stay following an appeal from an interlocutory order which grants a preliminary injunction. Fed. R. Civ. P. 62(a). The Federal Rules of Appellate Procedure require that a party seeking a stay pending appeal must first make the motion in the district court. Fed. R. App. P. 8(a)(1)(c). In determining whether to grant a stay pending an appeal, the court considers the following factors: "(1) whether the stay applicant has made a strong showing that he is likely to succeed on the merits; (2) whether the applicant will be irreparably injured absent a stay; (3) whether issuance of the stay will substantially injure the other parties interested in the proceeding; and (4) where the public interest lies." <u>Hilton v. Braunskill</u>, 481 U.S. 770, 776 (1987). <u>See also Reserve Mining Co. v. United States</u>, 498 F.2d 1073, 1076-77 (8th Cir. 1974) (applying the same four factors to analyze a motion for stay of a preliminary injunction under Fed. R. Civ. P. 62 and Fed. R. App. P. 8).

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"A stay is not a matter of right, even if irreparable injury might otherwise result. . . . It is instead an exercise of judicial discretion, and the propriety of its issue is dependent upon the circumstances of the particular case. . . . The party requesting a stay bears the burden of showing that the circumstances justify an exercise of that discretion." <u>Nken v. Holder</u>, 556 U.S. 418, 433-34 (2009) (internal citations, quotation marks and brackets omitted). For the reasons stated in the order granting preliminary injunction (Docket 47), the court makes the following findings.

First, Mr. Lytle is not likely to succeed on the merits of his appeals. Based on the plaintiff's "well developed record," the court found Mr. Lytle is "violating 21 U.S.C. § 331(a). . . .[and he has] shown no intent to discontinue [his] activities and voluntarily comply with the FDCA." (Docket 47 at p. 14). "[A[stay should not ordinarily be granted if the court determines that the injunction will ultimately take effect in any event." <u>Reserve Mining Co.</u>, 498 F.2d at 1077.

Second, while Mr. Lytle may be financially compromised absent a stay of the preliminary injunction, these consequences result only because the defendants chose to engage in a course of conduct with the intent to avoid compliance with the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 332 *et seq.* ("FDCA").

Third, the interests of the United States and the public will continue to suffer harm through the actions of the defendants if a stay of the preliminary

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injunction is granted. For purposes of granting the preliminary injunction the court adopted the opinions of Dr. Ilev, one of plaintiff's witnesses. Dr. Ilev testified "the 808 and Q1000 lines of QLaser devices could be dangerous to health when used in the dosage or manner, or with the frequency or duration prescribed, recommended, or suggested in their labeling. . . . [and] [a]pplying any of these devices directly over the open eye [as Mr. Lytle's manual instructs] could lead to temporary or permanent damage to the eye." (Docket 47 at p. 12 [citing Docket 12 at ¶ 20]). "[F]oremost consideration must be given to any demonstrable danger to the public health." <u>Reserve</u> <u>Mining Co.</u>, 498 F.2d at 1077.

Fourth, the public interest lies in having every commercial enterprise and individual subject to the FDCA comply with the federal law. "[P]rotecting consumer health and safety is a primary purpose of the FDCA." <u>United</u> <u>States v. Lane Labs-USA Inc.</u>, 427 F.3d 219, 226 (3d Cir. 2005).

After balancing all four factors, the court finds Mr. Lytle has not carried his burden to warrant a stay of the preliminary injunction. No good cause has been shown to stay enforcement of the preliminary injunction. The court denies Mr. Lytle's motion to stay enforcement of the preliminary injunction during the pendency of his appeals to the Eighth Circuit.

The court retains jurisdiction to resolve plaintiff's application for a permanent injunction against the defendants. "[T]he pendency of an interlocutory appeal from an order granting . . . a preliminary injunction does

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not wholly divest the District Court of jurisdiction over the entire case." <u>West</u> Publishing Co. v. Mead Data Central, Inc., 799 F.2d 1219, 1229 (8th Cir.

1986). "When it is tried, and when judgment is entered, another appeal can be filed." <u>Id.</u> <u>See also Thomas v. Board of Education</u>, 607 F.2d 1043, 1055 n.7 (2d Cir. 1979) ("an appeal from an interlocutory order granting . . . preliminary injunctive relief does not strip the district court of jurisdiction to proceed with the action on the merits.") (internal citations omitted); <u>Shevlin v.</u> <u>Schewe</u>, 809 F.2d 447, 451 (7th Cir. 1987) ("an appeal from an order granting . . . a preliminary injunction does not divest the district court of jurisdiction to proceed with the action on the merits.") (citing 9 <u>Moore's Federal Practice</u> ¶ 203.11 (2d ed. 1986) (footnote omitted)).

The court entered an order setting the trial on plaintiff's application for a permanent injunction. (Docket 64). Consistent with the order, the court provides the following clarifications to Mr. Lytle:

- The court is prohibited from acting as Mr. Lytle's attorney. <u>See</u> Docket 47 at p. 2 n.3.;
- Defendants are required to comply with the preliminary injunction.
 <u>See</u> Docket 48.; and
- Hearing on plaintiff's application for a permanent injunction is set.
 <u>See</u> Docket 64.

Accordingly, it is hereby

ORDERED that defendant Robert L. Lytle's emergency motion to stay the preliminary injunction and continue the trial date during appeal (Docket 56) is denied.

IT IS FURTHER ORDERED that defendant Robert L. Lytle's emergency motion for clarification (Docket 59) is granted in part and denied in part consistent with this order.

Dated February 23, 2015.

BY THE COURT:

/s/ Jeffrey L. Viken

JEFFREY L. VIKEN CHIEF JUDGE