**IN THE UNITED STATES DISTRICT COURT**
**FOR THE EASTERN DISTRICT OF TEXAS**
**MARSHALL DIVISION**

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| MYLAN INSTITUTIONAL LLC, | § | |
| APICORE US LLC, | § | |
| | § | Case No. 2:16-CV-00491-RWS-RSP |
| v. | § | |
| | § | |
| AUROBINDO PHARMA LTD, | § | |
| AUROBINDO PHARMA USA INC., | § | |
| AUROMEDICS PHARMA LLC | § | |

**ORDER**

On February 23, 2017, Plaintiffs filed an emergency motion requesting that the Court expedite the entry of a preliminary injunction that the Court had previously stated it would enter upon Plaintiffs' submission of an adequate bond. Docket No. 138. Plaintiffs' emergency motion requested that the preliminary injunction be entered immediately because Defendants are "flooding distributors and wholesalers with their infringing product before formal imposition of the injunction." *Id.* at 1. Plaintiffs also stated that Defendants had manufactured and imported, in a four-day period, more than double the amount of their average monthly sales of isosulfan blue, the product accused of infringement. Docket No. 138 at 3–4.

In response to this motion, the Court issued an Order preliminarily enjoining Defendants from "manufacturing, selling or offering for sale, using, or importing the accused isosulfan blue product within the United States until further order of the Court." Docket No. 139 at 3. The Court gave the Defendants a chance to respond to Plaintiffs' emergency motion and stated that the Court would determine whether a revised preliminary injunction Order is warranted after reviewing both Plaintiffs' and Defendants' submissions.

The parties have now submitted competing proposals for a revised preliminary injunction Order. *See* Docket No. 143. Many of the details concerning the revised Order are no longer disputed. The one remaining dispute is whether the Court should require Defendants to recall the isosulfan blue product that Defendants sold, shipped, or distributed on or after February 7, 2017—the date the Court issued an Order indicating that a preliminary injunction was forthcoming. *See* Docket No. 122. The parties do not dispute that the Court generally has discretionary equity powers to recall products that are already on the market. *See Rohm & Haas Co. v. Cumberland Chem. Corp.*, No. H-82-1241, 1983 WL 52378, at *5 (S.D. Tex. Jan. 21, 1983); *see also Perfect Fit Indus., Inc. v. Acme Quilting Co.*, 646 F.2d 800, 806 (2d Cir. 1981) (collecting cases). The dispute is whether the Court should do so in this case.

Plaintiffs submit evidence supporting the conclusion that Defendants have effectively circumvented the full effect of the preliminary injunction. From February 14 to February 17, 2017 alone, Defendants invoiced and distributed four times as many isosulfan blue units as their average monthly sales between March 2016 and December 2016. Docket No. 145 at 1–2 (citing Ex. C (AUROMED_ISO_0013594) at col. "Ship Qty"; Ex. D (AUROMED_ISO_0013586)). These units have already entered the market and are in the possession of group purchasing organizations (GPOs) and customers. *See* Docket No. 143 at 1–5.

On February 20, 2017, one such GPO that contracts with Defendants issued a "Pharmacy Alert" recommending that customers take "immediate action" "[d]ue to a recent court ruling in a U.S. District Court . . . ." Docket No. 138-7. The Alert explains that an "injunction is pending that will require Auromedics . . . to remove their Isosulfan Blue from the U.S. Market." *Id.* "As of February 20, 2017," however, the Alert states that the "injunction is not yet being enforced, and Auromedics has shipped large quantities to the wholesalers." *Id.*

According to Defendants, this Pharmacy Alert is merely "a document issued by a third-party informing its own clients of a potential product shortage." Docket No. 142 at 4. Yet the document confirms that Auromedics has "shipped large quantities [of isosulfan blue] to the wholesalers." *See* Docket No. 138-7. At a telephone hearing on March 6, 2017, Defendants' counsel represented that the Pharmacy Alert and the increase in Defendants' sales were merely a response by the GPOs and customers to a press release in which the Court's decision concerning the preliminary injunction was announced. Defendants subsequently submitted a declaration from an Auromedics Vice President stating that Defendants have not purposefully flooded the market to avoid the preliminary injunction. *See* Docket No. 150-2.

Even if the Court credited Defendants' explanation, the quantity of isosulfan blue units that Defendants placed into the market just after the Court informed the parties that a preliminary injunction was forthcoming, relative to Defendants' average monthly sales, warrants recall relief. A prospective injunction against future sales would have little to no impact if the prospective relief had already been effectively circumvented by satisfying the market's need for isosulfan blue. *See Rohm & Haas*, 1983 WL 52378, at *5. To be clear, recall relief is *not* a sanction for any alleged contempt but rather a necessary equitable corollary to the preliminary injunction (at least in this case). *See id.*

Aurobindo contends that a recall is "improper because the injunction was not in effect until February 24, 2017." Docket No. 143 at 5. This argument is not compelling for at least three reasons. First, even if the injunction was not legally operative, equity jurisdiction allows courts to "to mould each decree to the necessities of the particular case." *Hecht Co. v. Bowles*, 321 U.S. 321, 329 (1944). As the precedent cited by Plaintiffs illustrates, a recall remedy is appropriate to address the circumvention of a forthcoming order the Court. *See, e.g., Rohm & Haas*, 1983 WL

52378, at *5. Second, to the extent that the Court's injunction is strictly prospective, equitable relief aimed at past behavior is often viewed as a forward-looking corollary to prospective relief. *See, e.g.*, *Richard v. Hoechst Celanese Chem. Grp., Inc.*, 355 F.3d 345, 354 (5th Cir. 2003) (statutory disgorgement of profits a forward-looking remedy).

Third, and perhaps most important, the record is at odds with Defendants' contention that it believed the injunction was not "legally operative" on February 7, 2017. On February 10, 2017, three days after the Court issued the Order indicating a preliminary injunction was imminent, Defendants filed a notice of appeal, *see* Docket No. 126, which is ordinarily a proper course of action only after a final order. *See, e.g., Kemin Foods, L.C. v. Pigmentos Vegetales Del Centro S.A. De C.V.*, 132 F. App'x 368, 369 (Fed. Cir. 2005) (appeal usually "premature [if] there are still substantive issues for the district court to resolve."). On February 17, 2017, again before the injunction was legally operative according to Defendants, Defendants filed a motion to defer entry of the preliminary injunction, *see* Docket No. 132, pending the Court's decision on Defendants' motion to stay the injunction, a motion that Defendants had also filed on February 10, 2017, *see* Docket No. 124. Defendants also acknowledge that they accepted Plaintiffs' bond offer "only a few hours" after the Court indicated that a preliminary injunction was forthcoming, which at least indicates that Defendants knew that Plaintiffs would be willing and able to offer adequate security. *See* Docket No. 142 at 5.

Assuming, as Defendants maintain, that the February 7 Order had no legally operative effect, the Order at least put Defendants on notice that an injunction was forthcoming. The reasonable and prudent course would have been to prepare for the impending Order, rather than to do the opposite and allow sales and distribution to rise to a level that is over double Defendants' monthly average. Regardless of Defendants' motives, Defendants' atypical market behavior has unquestionably distorted supply and demand for isosulfan blue relative to its state in the months leading up to the preliminary injunction, thus justifying the Court's equitable decision to order recall relief. Such circumstances are precisely why the Court has discretion to fashion equitable remedies peculiar to a particular case. *See Rohm & Haas*, 1983 WL 52378, at *5.

Defendants' remaining arguments are not persuasive. Defendants contend that a recall order would effectively constitute an injunction against non-parties, including GPOs and wholesalers. Docket No. 150 at 4–6. The recall order as set forth below, however, is directed only to the Defendants and does not order relief against non-parties. Finally, as for Defendants' balance of harms arguments, there is no persuasive evidence that the Court's recall order would result in shortages of isosulfan blue. In addition, this Court and the Court of Appeals for the Federal Circuit have both denied Defendants' motion for a stay of the preliminary injunction, which requires the court to consider the balance of harms. *See* Docket Nos. 135, 153.

Accordingly, **IT IS ORDERED**:

(1) Defendants Aurobindo Pharma Ltd., Aurobindo Pharma USA Inc., and AuroMedics Pharma LLC, including but not limited to its officers, agents, servants, employees, parents, subsidiaries, affiliate corporations, other business entities, their successors in interest, and assigns (collectively, "Defendants") and all other persons acting in concert with Defendants, are enjoined from manufacturing, distributing, shipping, selling, or offering for sale, marketing, using, or importing the accused isosulfan blue products in the United States until further order of this Court. The accused products include: Defendants' "isosulfan blue injection 1% ANDA product," which is the drug product described in ANDA No. 206831, and Defendants' "isosulfan blue API," which is the active pharmaceutical ingredient of the pharmaceutical product described in ANDA No. 206831 and the subject of DMF No. 027795.

(2) Defendants shall make a reasonable effort to provide written notice of the injunction to all of Defendants' past and present distributors and wholesalers who have purchased the accused isosulfan blue product within five (5) business days of the issuance of this Order.

(3) Defendants shall take all reasonable steps to promptly recall their isosulfan blue products currently in the channel, including without limitation in the possession of wholesalers and hospitals, that were sold, shipped or distributed by Defendants on or after February 7, 2017, and shall issue within three (3) business days of the date of this order a recall letter to each person or

entity that obtained, delivered, purchased, sold, distributed, or is in possession of Defendants' isosulfan blue product sold, shipped, or distributed on or after February 7, 2017.

This Order is effective immediately and shall remain in effect until further order of this Court dissolving the Preliminary Injunction.

**SIGNED this 24th day of March, 2017.**

Robert W Schroeder III

ROBERT W. SCHROEDER III
UNITED STATES DISTRICT JUDGE