

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

MYLAN INSTITUTIONAL LLC,	§	
APICORE US LLC,	§	
	§	Case No. 2:16-CV-00491-RWS-RSP
<i>Plaintiffs,</i>	§	
	§	
v.	§	
	§	
AUROBINDO PHARMA LTD, et al.,	§	
	§	
<i>Defendants.</i>	§	

ORDER ADOPTING REPORT AND RECOMMENDATION

Before the Court is the Report and Recommendation (Docket No. 101) filed by Magistrate Judge Payne on November 21, 2016 recommending that Plaintiffs' motion for a preliminary injunction (Docket No. 20) be granted. Aurobindo objects to the Report and Recommendation, contending that it includes four incorrect conclusions of law. The Court disagrees for the following reasons.

First, Aurobindo argues that the Report incorrectly determines that Aurobindo failed to raise a substantial question regarding noninfringement of the '992 and '616 patents. Docket No. 106 at 2-6. The Report explains, however, that "it is undisputed that Aurobindo's process performs every step and includes every element recited in claim 1 of the '992 and '616 patents except silver oxide." Docket No. 101 at 21. Aurobindo's process uses manganese oxide, which is likely to be found equivalent to silver oxide by a fact-finder. *Id.* at 21-24. The Court finds Aurobindo's arguments to the contrary unpersuasive for the extensive reasons explained in the Report. *Id.* at 11-14, 20-24.

Second, Aurobindo contends that the Report incorrectly finds that Aurobindo failed to raise a substantial question concerning validity of the '050 patent. Docket No. 10-6 at 6-8. However, the numerous prior art references presented by Aurobindo suggest that those skilled in the art were unable to achieve isosulfan blue purity levels of greater than 95 percent. On the basis of a thorough review of the prior art and live testimony from the expert witnesses, the Court concludes that the Report correctly finds that there is not a substantial question regarding validity of the '050 patent. *See* Docket No. 101 at 26-47.

Aurobindo's third objection is that the Report incorrectly concludes that Plaintiffs established a causal nexus between Aurobindo's alleged infringement and Plaintiffs' alleged harm. Docket No. 106 at 8-10. As the Report explains, however, Aurobindo's causal nexus arguments are largely irrelevant to a product such as the accused isosulfan blue product, which would not be on the market if Aurobindo had not obtained Food and Drug Administration approval for a product that will likely be found to be covered by the patents-in-suit. *See* Docket No. 101 at 49-50. The Report's conclusion is consistent with other courts who have evaluated the causal nexus requirement in the context of pharmaceutical products. *See, e.g., Janssen Prod., L.P. v. Lupin Ltd.*, 109 F. Supp. 3d 650, 697-701 (D.N.J. 2014).

Fourth, Aurobindo argues that the Report incorrectly finds irreparable harm. However, the Report identifies hallmark examples of irreparable harm that are demonstrated by the preliminary record, including lost sales, lost research and development opportunities, price erosion, and the fact that Apicore must now directly compete with an infringer. Docket No. 101 at 47-49. These findings were more than adequately supported by the record evidence.¹

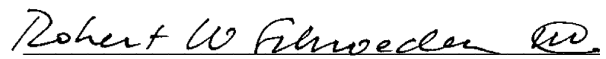
¹ *See, e.g.*, Docket No. 20-29 ¶¶ 5, 7, 9-22; Docket No. 79-11 ¶¶ 5-6, 9, 12-25, 32-23; Hr'g Tr. At 156:11-158:4, 159:22-163:9, 176:19-25; Docket No. 20-2 ¶¶ 39-46, 53-55, 60; Hr'g Tr. at 40:18-

Finally, Aurobindo does not object to the Report's findings with respect to Aurobindo's infringement of the '050 patent or the validity of the '992 and '616 patents. Accordingly, the Court affirms those findings. *See United States v. Wilson*, 864 F.2d 1219, 1221 (5th Cir. 1989) (findings to which no specific objections are made do not require de novo review).

Plaintiffs' Motion for Preliminary Injunction (Docket No. 20) will be **GRANTED** following Plaintiffs' submission of an adequate injunction bond. *See* Fed. R. Civ. P. 65. Defendants will be enjoined 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.

Defendants are **ORDERED** to submit a brief of no more than five pages providing a supported and reasoned amount of an appropriate injunction bond **within 14 days** of this Order. Plaintiffs are **ORDERED** to file any response **within seven days** after service of Defendants brief. The matter remains referred to Magistrate Judge Payne for further proceedings.

SIGNED this 7th day of February, 2017.


ROBERT W. SCHROEDER III
UNITED STATES DISTRICT JUDGE