

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ASTELLAS PHARMA INC., *et al.*

Plaintiffs,

v.

LUPIN LTD., *et al.*

Defendants.

CIVIL ACTION NO. 23-819-JFB-CJB

ORDER

This matter is before the Court on the Magistrate Judge’s Report and Recommendation, [D.I. 200](#), recommending denial of Plaintiffs’ motion for preliminary injunction, [D.I. 98](#), and Plaintiffs’ emergency motion for temporary restraining order, [D.I. 203](#).

Plaintiffs filed a motion for preliminary injunction, [D.I. 98](#), seeking to enjoin Defendants from making, using, offering to sell, or selling in the United States or importing into the United States, Defendants’ mirabegron ANDA products, arguing those products infringed the claims of its patent, United States Patent No. 11,707,451. In a thoughtful and thorough Report and Recommendation, Magistrate Judge Burke concluded the Defendants had put forward a substantial question of invalidity as to the ’451 patent and Plaintiffs were therefore not entitled to the “extraordinary” remedy of a preliminary injunction. [D.I. 200 at 35](#).

Following the issuance of Judge Burke’s R&R, Plaintiffs filed an emergency motion for temporary restraining order, [D.I. 203](#), seeking to enjoin Defendants from selling their product while the Court decided whether to adopt or reject Judge Burke’s R&R and while

Plaintiffs seek an interlocutory appeal should the Court adopt the recommendation to deny their preliminary injunction. [D.I. 203](#).

Injunctive relief is warranted when a party can show a “reasonable likelihood of success on the merits, irreparable harm in the absence of a preliminary injunction, a balance of hardships tipping in its favor, and the injunction’s favorable impact on the public interest.” *Nat’l Steel Car, Ltd. v. Canadian Pac. Ry., Ltd.*, 357 F.3d 1319, 1324–25 (Fed. Cir. 2004).

The Court has reviewed the parties’ arguments and the R&R de novo and concludes no further objections, briefing, or motions would aid in its decision. Plaintiffs have not shown a likelihood of success on the merits as the pleadings and evidence lead the Court to conclude Plaintiffs are unlikely to overcome the argument that the ’451 patent is invalid. As Judge Burke explained, the ’451 patent is not likely to withstand an invalidity challenge on the ground that the claims are indefinite because the “reduced food effect” limitation likely fails to provide objective boundaries in light of the specification and prosecution history. See [D.I. 200 at 11–34](#). Furthermore, Plaintiffs have not convincingly shown that the monetary harm they argue they will suffer is “irreparable.” The balance of hardships and public interest do not alter the Court’s calculus based on the first two factors weighing strongly against the issuance of injunctive relief.

The Court notes that the United States Court of Appeals for the Federal Circuit has recently entered an order temporarily enjoining Lupin and Zydus Pharmaceuticals (USA) Inc. from selling generic copies of Astellas’s Myrbetriq in a related case currently on appeal, *Astellas Pharma Inc. v. Sandoz et al.*, 23-2032, [D.I. 72](#). As a practical matter, the Federal Circuit’s order may effectively result in the same relief Astellas seeks by

means of the present motions. However, the Circuit Court's order does not alter the Court's analysis and conclusions on the merits of the injunctive relief sought in the present case, and the Court thus declines to grant a temporary restraining order simply on the basis that the Federal Circuit has done so.

Accordingly, the Court adopts Magistrate Judge Burke's Report and Recommendation in full and denies Plaintiffs' motions for a preliminary injunction and for a temporary restraining order.

IT IS ORDERED:

1. The Court adopts the Magistrate Judge's Report and Recommendation in full, [D.I. 200](#), and accordingly denies Plaintiffs' Motion for Preliminary Injunction, [D.I. 98](#).
2. The Court denies Plaintiffs' Emergency Motion for Temporary Restraining Order, [D.I. 203](#).

Dated this 24th day of April, 2024.

BY THE COURT:

s/ Joseph F. Bataillon
Senior United States District Judge