

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NOVARTIS PHARMACEUTICALS
CORPORATION and NOVARTIS AG,

Plaintiff;

v.

BRECKENRIDGE PHARMACEUTICAL,
INC.,

Defendant.

Civil Action No. 1:14-cv-1043-RGA

NOVARTIS PHARMACEUTICALS
CORPORATION and NOVARTIS AG,

Plaintiff;

v.

ROXANE LABORATORIES, INC.,

Defendant.

Civil Action No. 1:14-cv-1196-RGA

NOVARTIS PHARMACEUTICALS
CORPORATION and NOVARTIS AG,

Plaintiff;

v.

PAR PHARMACEUTICAL, INC.,

Defendant.

Civil Action No. 1:14-cv-1289-RGA

MEMORANDUM ORDER

The parties dispute whether Plaintiffs are entitled to an injunction under 35 U.S.C. § 271(e)(4)(B) prohibiting Defendants from commercially manufacturing, selling, offering for sale, and/or importing into the United States the product that is the subject of Defendants' ANDAs. There is no dispute that FDA approval of Defendants' ANDAs should be enjoined until after the expiration of Plaintiffs period of pediatric exclusivity. Plaintiffs, however, seek to enjoin Defendants from a broad range of what Defendants contend are non-infringing activities. On the record as it stands and for the reasons given by Judge Stark in *Bayer Pharma* and Judge Robinson in *Alcon*, I do not think Plaintiffs are entitled to such an injunction. *Bayer Pharma AG v. Watson Labs., Inc.*, 2016 WL 7468172, at *2–3 (D. Del. Dec. 28, 2016); *Alcon, Inc. v. Teva Pharm. USA, Inc.*, 2010 WL 3081327, at *2–3 (D. Del. Aug. 5, 2010).

While I am dubious about whether Plaintiffs can establish that they are entitled to the injunction they request, I am also mindful that I do not permit this issue to be addressed at trial. Therefore, if Plaintiffs believe they are entitled to a permanent injunction under § 271(e)(4)(B), they should request a hearing at which they will need to establish (1) they have suffered or will suffer irreparable harm in the absence of an injunction; (2) available legal remedies are inadequate to compensate for this harm; (3) the balance of hardships favors a permanent injunction; and (4) the public interest supports the issuance of a permanent injunction. *eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388, 391 (2006).

Entered this 16 day of May, 2017.


United States District Judge