IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

SENJU PHARMACEUTICAL CO., LTD., KYORIN PHARMACEUTICAL CO., LTD., and ALLERGAN, INC.,	)	
Plaintiffs,	)	
v.	)	Civ. No. 11-271-SLR (Consol.)
LUPIN LIMITED and LUPIN PHARMACEUTICALS, INC.,	)	
Defendants.	)	

SENJU PHARMACEUTICAL CO., LTD., KYORIN PHARMACEUTICAL CO., LTD., and ALLERGAN, INC.,	)	
Plaintiffs,	)	
v.	)	
HI-TECH PHARMACAL CO., INC.,	)	
Defendant.	)	

ORDER

At Wilmington this 26th day of August, 2013, having reviewed the papers submitted in connection with plaintiffs' motion for an injunction pending appeal, and having heard oral argument on the same;

IT IS ORDERED that said motion (D.I. 194) is denied, for the reasons that follow:

1. **Standard of review.** In order to determine whether an injunction pending

appeal should be granted pursuant to Fed. R. Civ. P. 62(c), the court must assess: (1) whether plaintiffs have demonstrated a strong likelihood of success on the merits; (2) whether plaintiffs have demonstrated that they will be irreparably harmed absent an injunction; (3) whether the issuance of an injunction will substantially injure defendants; and (4) where the public interest lies. *See Hilton v. Braunskill*, 481 U.S. 770, 776 (1987); *Eli Lilly & Co. v. Actavis Elizabeth LLC,* Civ. No. 2010-1500, 2010 WL 3374123, at *1 (Fed. Cir. Aug. 26, 2010).

2. **Likelihood of success on the merits.** The court has evaluated the validity of the '045 patent twice, and has found it invalid on both occasions. Although the court cannot predict whether its evaluation will pass muster under the Federal Circuit's review, the court considered plaintiffs' arguments post-trial and rejected them based on the trial record. Plaintiffs identify no issues which resonate to the point of justifying a stay pending appeal.

3. **Balance of harms.** There can be no dispute that plaintiffs will be harmed as a consequence of a generic launch, including loss of market share and lost profits. Clearly defendants will be harmed as well if they are forced to postpone their generic launch (and the revenues attendant to a launch) but ultimately prevail on appeal. The public's interest includes the importance of protecting patent rights (which enable patentees to incur the initial research and development costs), the importance of getting affordable drugs to the public, and of protecting the market itself from disruption by a premature launch.

4. **Conclusion.** When considering the balance of harms in light of the fact that

the likelihood of success on appeal is in the control of the Federal Circuit, not this court, the court concludes that the Federal Circuit, not this court, should resolve any further requests by the plaintiffs for injunctive relief pending appeal. Nevertheless, given the potential harms identified above, it is appropriate to maintain the status quo until plaintiffs have had the opportunity to request such relief from the Federal Circuit.

THEREFORE, IT IS FURTHER ORDERED that the status quo will be maintained until **September 9, 2013** or, if plaintiffs file a timely appeal and a motion for an injunction pending appeal, the stay will remain in effect until such time as the Federal Circuit addresses the issue of whether this stay will be maintained pending its decision on the motion for injunctive relief. Consistent with the August 15, 2013 order, the status quo includes the following conditions: (1) plaintiffs shall not commercially launch an authorized generic version of ZYMAXID or ZYMAR or otherwise permit the marketing of a generic product and/or branded product at a lower tier of pricing; (2) plaintiffs shall not take any steps that would lead to a revocation of FDA approval and/or discontinuation of NDA No. 22-548 to 0.5% ophthalmic gatifloxin solution; and (3) Lupin shall not commercially launch a 0.3% or 0.5% gatifloxin ANDA product.

United States District Judge