IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

SALIX PHARMACEUTICALS, LTD.; SALIX PHARMACEUTICALS, INC.; BAUSCH HEALTH IRELAND LTD.; ALFASIGMA S.P.A., Plaintiffs, v. NORWICH PHARMACEUTICALS, INC., Defendant.	Civil Action No. 20-430-RGA

MEMORANDUM

The parties have a dispute concerning the final judgment. (D.I. 190). I am entering a final judgment in accordance with the following rationale.

Plaintiffs sued Defendant under § 271(e)(2)(A) of the Patent Act for submitting an abbreviated new drug application ("ANDA") to the Food and Drug Administration ("FDA"). At trial, Plaintiffs asserted three patent families against Defendants: one on the product, one on the hepatic encephalopathy indication (the "HE indication"), and one on the irritable bowel syndrome with diarrhea indication (the "IBS-D indication"). After a bench trial, I determined that only the patents on the HE indication were both not invalid and infringed by Norwich's proposed ANDA.

The parties dispute whether the final judgment ought to order the FDA approval date for "Norwich's ANDA No. 214369" or "Norwich's ANDA with proposed labeling containing [the HE indication]" as the expiry date of the HE patents. (D.I. 190).

35 U.S.C. § 271(e)(2)(A) makes it an "act of infringement to submit" an ANDA "for a drug claimed in a patent or the use of which is claimed in a patent." Because the ANDA's HE indication would infringe Plaintiffs' patents, the ANDA submission is an act of infringement. In such cases, the Patent Act states, "the court shall order the effective date of any approval of the drug . . . involved in the infringement to be a date which is not earlier than the date of the expiration of the patent which has been infringed." 35 U.S.C. § 271(e)(4). Thus, the effective date of the approval of this infringing ANDA must not be earlier than the expiration of the latest asserted HE claim.

The scope of my ruling is that the HE patents are not invalid, and that the HE indication would infringe the HE patents. Norwich's proposed ANDA has the HE indication. I cannot rule on facts that are not before me. That Norwich may seek to carve out the HE indication as permitted by 21 U.S.C. § 355(j)(2)(A)(viii) is immaterial to this analysis. That label is not before me.

The parties dispute whether I ought to enter injunctive relief. (D.I. 190 at 2, 4). I have never had a hearing on whether injunctive relief should issue after a finding of ANDA infringement, or so far as I can recall, even an argument in a pleading that it should not issue.[1] An injunction seems unlikely to make a practical difference when only method patents are not invalid and infringed. The only reason I would enter an injunction directed at Defendant would be to enjoin infringing activity that could be undertaken in the absence of FDA approval. But, the absence of FDA approval blocks direct infringement of the HE method claims. Without that direct infringement, Defendant cannot induce infringement. An injunction would therefore be redundant of the order barring FDA approval, because the FDA cannot approve the ANDA

[1] There have been disputes about the details of the injunctive language.

before the patents expire. For that reason, I suspect it will be difficult for Salix to show irreparable harm. *See Alcon, Inc. v. Teva Pharms. USA, Inc.*, 2010 WL 3081327, at *2 (D. Del. Aug. 5, 2010). Should Salix have a good faith belief that it is entitled to an injunction, it can file a motion to reconsider the matter, and I will reconsider the matter.

So entered this 10th day of August 2022.

Richard G. Andrews
United States District Judge