

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. 07-779-SLR
)		
APOTEX INC. and APOTEX CORP.)		
)		
Defendants.)		

MEMORANDUM ORDER

At Wilmington this 14th day of June, 2010, having heard argument on, and having reviewed the papers submitted in connection with, the parties' proposed claim construction;

IT IS ORDERED that the disputed claim language of U.S. Patent No. 6,333,045 ("the '045 patent") shall be construed consistent with the tenets of claim construction set forth by the United States Court of Appeals for the Federal Circuit in *Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005), as follows:

1. **"An aqueous liquid pharmaceutical composition which comprises . . . disodium edetate:"**¹ "Disodium edetate is formulated in an aqueous liquid pharmaceutical composition in an amount of 0.001 to 0.2 w/v%." This construction is consistent with the specification, which directs the formulation of disodium edetate in an amount according to the aforementioned range. (col. 2:49-60; col. 1:58-2:4) Each of the example compositions taught by the '045 patent abides by this range of

¹Claim 1 (and dependent claims).

concentrations. Further, the specification contains a clear disavowal of concentrations of disodium edetate exceeding 0.5%. (col. 2:2-4)

2. “[I]ncorporating disodium edetate into eye drops.”² “Disodium edetate is formulated into eye drops in an amount of 0.001 to 0.2 w/v%.” This construction is consistent with the specification. (col. 4:6-10; col. 8:13-17) All embodiments, including all examples and experiments disclosed in the ‘045 patent, utilize concentrations of disodium edetate in eye drops in an amount of 0.001 to 0.2 w/v%. (col. 4:64-8:23)

3. “[I]ncorporating disodium edetate into an aqueous liquid preparation.”³ “Disodium edetate is formulated into an aqueous liquid preparation in an amount of 0.001 to 0.2 w/v%.” Based on the intrinsic evidence discussed, *supra*, this construction is consistent with the specification. (col. 1:58-2:4; col. 2:49-60)

4. “A method for raising corneal permeability of gatifloxacin.”⁴ “Showing an increased concentration of gatifloxacin in the aqueous humor.” This construction finds support in the specification. (col. 2:23-26; 3:39-4:19) The court is not convinced by defendants’ invocation of *Bristol-Meyers Squibb Co. v. Ben Venue Labs., Inc.*, 246 F.3d 1368, 1375-76 (Fed. Cir. 2001), to show that the preamble to claim 6 does not limit the claim. (D.I. 85 at 13-15) The preamble was used to distinguish the claimed invention from the prior art and the examiner cited the increase in corneal permeability as a reason for allowance. (col. 2:3-4; D.I. 87 at 197) Further, the preamble breathes life

²Claim 6.

³Claims 7 and 8.

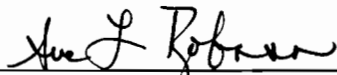
⁴Claim 6.

into the claimed invention - it is the essence of the invention. *Gerber Garment Tech., Inc. v. Lectra Sys., Inc.*, 916 F.2d 683, 688 (Fed. Cir. 1990). Finally, the doctrine of claim differentiation counsels against a finding that the preambles of claims 6 through 8 do not serve as claim limitations, which would essentially result in three identical methods of producing the composition of claim 1. See *Kraft Foods, Inc. v. Int'l Trading Co.*, 203 F.3d 1362, 1365-69 (Fed. Cir. 2000).

5. **“A method of preventing precipitation of gatifloxacin crystals.”**⁵ “A method of improving the resistance to, or hindering the progress, appearance, or fulfillment of, precipitation of gatifloxacin.” Likewise, this preamble limits the claim. This construction finds support both in the specification, (col. 4:20-54), and flows from the plain and ordinary meaning of prevent: “to keep from happening or existing, esp. by precautionary measures: to hinder the progress, appearance, or fulfillment of: to make impossible through advance provisions.” Webster’s Third New International Dictionary (1993).

⁵Claim 7.

6. **“A method of preventing coloration of gatifloxacin crystals:”**⁶ “A method of improving the resistance to, or hindering the progress, appearance, or fulfillment of, coloration of gatifloxacin.” This construction is supported by the specification, experiment 3 of which reports that the presence of disodium edetate does not completely prevent coloration. (col. 4:55-5:35) This comports with the extrinsic evidence of record regarding the plain and ordinary meaning of prevent, discussed *supra*.


United States District Judge

⁶Claim 8.