IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

DUCHESNAY INC. and DUCHESNAY USA. INC.,	)	
Plaintiffs,	)	
v.	)	Civ. No. 14-912-SLR
ACTAVIS LABORATORIES FL, INC., ACTAVIS, INC., ACTAVIS PHARMA, INC., and MYLAN PHARMACEUTICALS INC.,	)	
Defendants.	)	

MEMORANDUM ORDER

At Wilmington this 18th day of November, 2015, 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. 6,340,695 ("the '695 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. **"Rapid onset formulation:"**[1] "A formulation that rapidly releases the active ingredients at about pH 6.8 as shown by its in vitro dissolution profile." The specification explains that the invention "seeks to provide a pharmaceutical composition having specific in-vitro dissolution profiles indicative of rapid onset of the active ingredients." (2:13-15) Figures 1 and 2 depict "examples of dissolution profiles in accordance to the rapid onset formulation." (2:30-33) The patentee concludes that "[i]t

[1] Found in claims 1-30.

follows from these results that the novel formulation demonstrates a rapid onset as shown by its dissolution profile." (7:32-34)

2. **"Dissolution profile" and "dissolution characteristics:"**[2] "Average results of a dissolution test in which the amount of pyridoxine HCL and doxylamine succinate released in measured in 1000 ml phosphate buffer at pH 6.8 and 37° C using a USP (United States Pharmacopeia) type 2 dissolution apparatus at 100 rpm." The specification states:

> [A]ny reference to dissolution profile should be construed as referring to the results of a dissolution test in which the amount of pyridoxine HCl and of doxylamine succinate released is measured in 1000 ml phosphate buffer at pH 6.8 and 37° C. using a USP (United States Pharmacopoeia) type 2 dissolution apparatus at 100 rpm; preferably measured by high performance liquid chromatography.

(3:21-28) The specification describes the results of the dissolution testing using the average of six runs (as shown in table 6):

> [T]he novel formulation demonstrates a rapid onset as shown by its dissolution profile. Pyridoxine HCl presents an average dissolution profile of over 90% within 120 minutes of starting the measurements. Similarly, Doxylamine succinate displays an average dissolution profile of over 90% within 120 minutes of starting the measurements.

(7:32-39, table 6)

3. The court has provided a construction in quotes for the claim limitations at issue. The parties are expected to present the claim construction consistently with any explanation or clarification herein provided by the court, even if such language is not included within the quotes.

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[2] Found in claims 1-30.

4. The parties agree[3] that the preamble is limiting.

5. The parties agree that **"enterically-coated . . . formulation"** means "a formulation coated with an enteric coating."

6. The parties agree that **"enteric coating"** means "a coating comprising one or more layers generally resistant to disintegration in human gastric fluids, but which will disintegrate in human intestinal fluids, as well as coatings which disintegrate very slowly in human gastric fluids, but more rapidly in human."

7. The parties agree that **"at least about [X]% of the total amounts of each of pyridoxine HCl and doxylamine succinate are dissolved after [X] minutes of measurement"** means "at least approximately [X]% of each of doxylamine succinate and pyridoxine hydrochloride is dissolved in relation to starting quantities after [X] minutes."

8. The parties agree that **"at least about 40% of the total amounts of each of pyridoxine HCl and doxylamine succinate are dissolved within 5 minutes"** means "at least approximately 40% of each of doxylamine succinate and pyridoxine hydrochloride is dissolved in relation to starting quantities within 5 minutes."

United States District Judge

[3] As requested by the parties, the court includes herein the agreed upon constructions. (*See* D.I. 36)