

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF NEW JERSEY  
CAMDEN VICINAGE

ASTRAZENECA PHARMACEUTICALS,  
LP, et al.,  
  
Plaintiffs/Counterclaim-  
Defendants,

v.

SANDOZ INC.,  
  
Defendant/Counterclaim-  
Plaintiff.

ASTRAZENECA PHARMACEUTICALS,  
LP, et al.,  
  
Plaintiffs/Counterclaim-  
Defendants,

v.

SAGENT PHARMACEUTICALS, INC.,  
  
Defendant/Counterclaim-  
Plaintiff.

ASTRAZENECA PHARMACEUTICALS,  
LP, et al.,  
  
Plaintiffs/Counterclaim-  
Defendants,

v.

GLENMARK GENERICS INC., USA,  
  
Defendant/Counterclaim-  
Plaintiff.

Consolidated Civil Action No.  
1:14-cv-03547 (RMB/KMW)

**ORDER**

The Court having reviewed the parties' submissions and having conducted a Markman hearing,

IT IS ON THIS 29th day of July 2015, **ORDERED** that the Court construes the disputed claims as follows:

1. "[A]dministration to a human in need of such treatment," as it appears in the claims of the '122 and '160 Patents, and "a human in need of such treatment," as it appears in the claims of the '680 and '139 Patents, require no construction.
2. "[F]ulvestrant," as it appears in the claims of the '122, '160, '680, and '139 Patents, means "7 $\alpha$ -[9-(4,4,5,5,5-pentafluoropentylsulphinyl)nonyl]oestra-1,3,5(10)-triene-3,17 $\beta$ -diol, including pharmaceutically acceptable salts thereof, and any possible solvates of either thereof."
3. "[E]thanol," as it appears in the claims of the '122, '160, '680, and '139 Patents, requires no construction.
4. "[S]ufficient amount of a castor oil vehicle," as it appears in the claims of the '122 and '160 Patents, and "sufficient amount of castor oil vehicle," as it appears in the claims of the '680 and '139 Patents, will be reserved for construction until additional expert evidence is available in the record.
5. "[W]hereby a therapeutically significant blood plasma fulvestrant concentration of at least 2.5 ngml<sup>-1</sup> is

attained for at least 2 weeks after injection," as it appears in the claims of the '122 and '160 Patents, means "the blood plasma fulvestrant concentration of at least 2.5 ngml<sup>-1</sup> is achieved and maintained for at least 2 weeks."

6. "[W]herein the blood plasma fulvestrant concentration is attained for at least 4 weeks after injection," as it appears in the claims of the '122 Patent, means "the blood plasma fulvestrant concentration of at least 2.5 ngml<sup>-1</sup> is achieved and maintained for at least 4 weeks."
7. "[W]herein the blood plasma fulvestrant concentration is attained for 2 to 5 weeks after injection," as it appears in the claims of the '122 Patent, means "the blood plasma fulvestrant concentration of at least 2.5 ngml<sup>-1</sup> is achieved and maintained for 2 to 5 weeks."
8. "[F]ormulation," as it appears in the claims of the '680 and '139 Patents, means "pharmaceutical formulation."
9. "[W]herein the method achieves a therapeutically significant blood plasma fulvestrant concentration of at least 2.5 ngml<sup>-1</sup> for at least four weeks," as it appears in the claims of the '680 Patent, means "the blood plasma fulvestrant concentration of at least 2.5 ngml<sup>-1</sup> is achieved and maintained for at least 4 weeks."

10. "[W]herein the therapeutically significant blood plasma fulvestrant concentration is at least  $8.5 \text{ ngml}^{-1}$ ," as it appears in the claims of the '680 Patent, means "the blood plasma fulvestrant concentration of at least  $8.5 \text{ ngml}^{-1}$  is achieved and maintained for at least 4 weeks."
11. "[W]herein the method achieves a blood plasma fulvestrant concentration of at least  $2.5 \text{ ngml}^{-1}$  for at least two weeks," as it appears in the claims of the '139 Patent, means "the blood plasma fulvestrant concentration of at least  $2.5 \text{ ngml}^{-1}$  is achieved and maintained for at least 2 weeks."
12. "[W]herein . . . the blood plasma fuvlestrant concentration is attained for at least 4 weeks," as it appears in the claims of the '139 Patent, means "the blood plasma fulvestrant concentration of at least  $2.5 \text{ ngml}^{-1}$  is achieved and maintained for at least 4 weeks."

The Court will set forth the bases for the foregoing construction if such an explanation becomes necessary as the case progresses.



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RENÉE MARIE BUMB  
UNITED STATES DISTRICT JUDGE