

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

_____)	
MERCK SHARP & DOHME B.V.,)	
)	
Plaintiff,)	
)	
v.)	Civil Action No. 13-2088-GMS
)	
WARNER CHILCOTT COMPANY, LLC and)	
WARNER CHILCOTT (US), LLC)	
)	
Defendants.)	
_____)	

ORDER

WHEREAS, on December 24, 2013, the plaintiff filed a Complaint (D.I. 1) alleging that the defendants infringe U.S. Patent No. 5,989,581 (“the ’581 patent”);

WHEREAS, the court held a four-day bench trial from January 19 to January 22, 2016;

WHEREAS, over the course of the trial it became apparent that the parties had a dispute regarding the meaning of the term “physiologically required amounts” which the court needed to resolve;¹

WHEREAS, the parties filed opening briefs regarding the proper construction of “physiologically required amounts” on February 2, 2016 (D.I. 131; D.I. 132), and answering briefs

¹ On February 24, 2015, the parties filed a stipulation agreeing on the construction of other disputed terms of the ’581 patent. (D.I. 92). The court accordingly cancelled the scheduled *Markman* hearing (D.I. 93). The plaintiff argues that the defendants raised their claim construction theory for “physiologically required amounts” for the first time at trial. The court has not asked the parties to brief the issue of waiver, but the issue was briefly discussed during trial (*see* D.I. 137 at Ex. 10) and in the parties’ briefs (D.I. 132 at 11–13; D.I. 134 at 17–20). The court does not find clear waiver on the part of the defendants and does not fully address the issue because this ruling renders the issue moot.

on February 9, 2016 (D.I. 134; D.I. 134);

WHEREAS, having considered the parties' positions as set forth during trial, the parties' submissions, and the applicable law;

IT IS HEREBY ORDERED, ADJUDGED, and DECREED that, as used in the asserted claims of the '581 patent, "physiologically required amount" is construed to mean "the amounts of the progestogenic compound and the estrogenic compound required by the body to achieve the full therapeutic effect."²

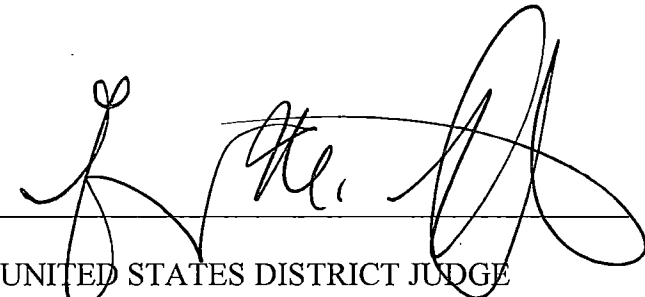
² Claim 1 of the '581 patent is for a drug delivery system comprising "at least one compartment" that releases "physiologically required amounts" of the progestogenic compound and estrogenic compounds. Both the plaintiff and the defendants propose reasonable interpretations of the claim language. Ultimately, the court is convinced that the intrinsic record better supports the plaintiff's proposed construction.

The defendants argue that the claim's recitation of "at least one compartment" changes the meaning of "physiologically required amounts." Based on their reading, the system could comprise *more than one* compartment releasing progestogenic and estrogenic compounds. They contend that physiologically required amounts are "sufficient amounts of each of the drugs to be released into the body, in combination with any other compartments, to cause the desired therapeutic effect." The defendants point to dictionary definitions to support their assertion that "physiologically required amounts" is not a synonym for "desired therapeutic effect." (D.I. 135 at 5-7.) They also note that the patentee did not distinguish this invention from by prior art by focusing on the term "physiologically required amounts." (*Id.* at 12-13.) The defendants point to a disclosed, but not preferred, embodiment that includes a second compartment loaded with progestogenic and estrogenic compounds. 581 patent at 3:49-55. They argue that the plain reading of claim 1 reads on this embodiment. Further, the defendants contend that the single compartment ring is not the focus of the invention, but rather, that as the patentee argued during prosecution, "the present invention is based on the surprising finding that a steroid can be retained in a supersaturated state during prolonged storage." (D.I. 137, Ex. 2 at JTX-2.60.)

The plaintiff disagrees, arguing that the crux of the invention is a single compartment ring. The plaintiff points to the specification's emphasis of a one-compartment device: "Surprisingly, applicant has found that a reliable release ratio over a prolonged period of time can be achieved using a one-compartment, preferably ring shaped, drug delivery system for at least two steroidal compounds." 581 patent at 2:28-31. Further, the patentee distinguished the invention over prior art by noting that the "Groenewegen device discloses a multiple compartment device with different hormones and/or combinations of hormones in each compartment." (D.I. 137, Ex. 2 at JTX-2.59.) The plaintiff contends that the not-preferred embodiment described by the defendants falls outside of claim 1, because "physiologically required amounts" means that the total amount of progestogenic and estrogenic compounds must be found in one compartment. According to the plaintiff, the recitation "at least one compartment" has no effect on the plain meaning of "physiologically required amounts." Rather, the claim contemplates additional compartments may be added which hold a placebo or other drugs, but not estrogenic or progestogenic compounds.

The court finds that although a plain reading of the claim supports the defendants' contentions, the rest of the intrinsic record and the trial testimony aligns with the plaintiff's interpretation of the

Dated: February 25, 2016



UNITED STATES DISTRICT JUDGE

invention. Claims must be read in light of the specification and prosecution history. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1315–17 (Fed. Cir. 2005). The court agrees that the statements in the specification and prosecution history of the '581 patent indicate the one-compartment structure is central to the invention. Additionally, the court has heard credible extrinsic evidence regarding the purpose and development of the invention. Understanding that the court is not required to confine its inquiry to the intrinsic record, this evidence would not have been normally heard during one of this court's typical *Markman* hearings. Candidly, it is somewhat difficult for the court to proceed without being influenced by the trial testimony, which corroborates the plaintiff's representations.

Nevertheless, the court believes it has succeeded in walking the rather fine line in this case between the intrinsic and extrinsic evidence before it, and finds that "physiologically required amounts" has a plain meaning, and that meaning is all of the drug required to have the desired therapeutic effect—in this case, contraception. In this case, the phrase "physiologically required amounts" informs and limits the meaning of "at least one compartment," rather than the other way around. Accordingly, the court adopts the plaintiff's construction.