IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

OMEROS CORPORATION,	:	
	:	
Plaintiff,	:	
	:	
v.	:	Civil Action No. 15-773-RGA
	:	
PAR STERILE PRODUCTS, LLC, and PAR PHARMACEUTICALS, INC.,	:	
	:	
Defendants.	:	

ORDER ON MOTIONS IN LIMINE

The Court now addresses the three motions in limine filed by Plaintiff.

MIL #1. (D.I. 172, Exh. 14). The motion to exclude Mr. Leonard's testimony about EPO practices is **GRANTED IN PART** and **DENIED IN PART**. Plaintiff can fully cross-examine him on Mr. Leonard's expertise, but assuming that Mr. Leonard has some minimal knowledge about how the EPO posts and indexes documents, his testimony about how the EPO works, including when and how filings with it become public, could possibly be helpful. On the other hand, testimony about whether and when EPO filings in general become prior art, and whether the particular EPO filing in this case is prior art, is a legal question that I will decide, and his opinion on that would not be helpful. Thus, he is prohibited from testifying on those topics. The letter from the EPO is simply hearsay. The motion to exclude it will be **GRANTED**. Whether the Omeros letter of September 15, 2011, is shown to be prior art will be decided after trial based on the record created at trial.

MIL #2. (*Id.*, Exh. 15). Plaintiff seeks to exclude a 2009 SEC document, Omeros' Form S-1, which had, somewhere in its thousand pages, a technical discussion that Defendants'

expert(s) have relied upon as prior art for an obviousness argument. Plaintiff says no POSITA would look at an SEC filing to find the state of the art relevant to a medical or pharmaceutical problem. The parties agree that the Federal Circuit has set forth a two part test for when prior art is relevant (or "analogous") prior art. "Two separate tests define the scope of analogous prior art: (1) whether the art is from the same field of endeavor, regardless of the problem addressed and, (2) if the reference is not within the field of the inventor's endeavor, whether the reference still is reasonably pertinent to the particular problem with which the inventor is involved." *In re Bigio*, 381 F.3d 1320, 1325 (Fed. Cir. 2004). For present purposes, there is no argument that the technical discussion is outside of "the field of the inventor's endeavor." The technical discussion is "from the same field of endeavor" and is "reasonably pertinent to the particular problem" at issue in this case. I think *Bigio* does not provide a basis for excluding the SEC document. That being said, neither party's papers cited any cases dealing with an analogous situation, that is, relevant art discussion cleverly concealed in an irrelevant document from a completely unrelated field of endeavor. I think this is more or less what the second prong of *Bigio* is designed to capture as prior art, that is, something which is outside the POSITA's field, but which still counts as prior art because of its pertinence to the matter at hand. Nevertheless, before making a final ruling on this, I will give each side until Monday, June 26, 2017, to file a supplemental letter with any results of a search for cases with closer facts to those presented here.

MIL #3. (D.I. 172, Exh. 16). Claim 6 of the '406 patent claims a "liquid pharmaceutical formulation consisting essentially of phenylephrine, ketorolac and a buffer system in a pH-adjusted aqueous carrier . . . ." Col. 28, ll. 39-42. The parties agree that "consisting essentially of" limits the claim to the specified ingredients and those that "do not materially affect the basic and novel properties of the invention." *AK Steel Corp. v. Sollac*, 344 F.3d 1234, 1239 (Fed. Cir.

2003). One of Defendants' experts is, I think, going to testify that a "solubilizer" is an ingredient that does not materially affect the basic and novel properties of the invention. (Or, the testimony might be that the fact a piece of prior art includes a solubilizer is irrelevant to an obviousness analysis involving that piece of prior art.) As a question of fact, whether a solubilizer is not permitted by the claim would be an issue to be decided based on trial testimony. Plaintiff, however, wants to make it a claim construction issue. Plaintiff cites the specification, which includes a "definition" for "No Other Excipients," which states, "In a further aspect of the invention, in addition to being free of any preservatives or antioxidants, a formulation in accordance with the present invention also does not include any excipients other than the buffering system. For example, . . . the formulation is solubilizing-agent free." Col. 9, ll. 50-55. The "further aspect" of this passage indicates that it is describing an embodiment. Thus, I am doubtful that it is disclaiming the presence of solubilizers in all embodiments. Nevertheless, the described embodiment seems to be consistent with what is claimed by Claim 6. Thus, it may be the case that the specification resolves the question of whether a formula with a solubilizer is excluded from Claim 6's scope. Since I do not have complete claim construction briefing, and since I might also benefit from the trial testimony about the invention, I am hesitant to treat this as a claim construction matter at this point, although I might later decide that is exactly what this is. Thus, the motion to exclude Dr. Laskar's testimony is **DENIED** without prejudice to renewing the argument about the meaning of the claim.

IT IS SO ORDERED this 22 day of June 2017.

United States District Judge