IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

PFIZER INC., et al.,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	Civ. No. 15-26-SLR
	)	
MYLAN INC., et al.,	)	
	)	
Defendants.	)	

MEMORANDUM ORDER

At Wilmington this 5th day of May, 2016, 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. 8,372,995 ("the '995 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. **"Form I tigecycline having X-ray powder diffraction peaks at about...:"**[1] "A crystalline tigecycline called Form I having X-ray powder diffraction peaks at ± 0.2° 2θ of the recited peaks . . ." The specification provides guidance that the use of "about" refers to a standard variability of ± 0.2° 2θ as the range of error recognized in XRPD measurements normally tolerated within the field of invention, stating:

[1] Found in claims 1, 2, and 3.

> Due to differences in instruments, samples, and sample preparation, peak values are reported with the modifier "about" in front of the peak values. This is common practice in the solid-state chemical arts because of the variation inherent in peak values. A typical precision of the 2θ x-axis value of a peak in a powder pattern is on the order of plus or minus 0.2° 2θ. Thus, a powder diffraction peak that appears at "about 9.2° 2θ," means that the peak could be between 9.0° 2θ and 9.4° 2θ when measured on most X-ray diffractometers under most conditions.

('995 patent at 3:25-34); *Pall Corp. v. Micron Separations, Inc.*, 66 F.3d 1211, 1217 (Fed. Cir. 1995) ("The use of the word 'about,' avoids a strict numerical boundary to the specified parameter. Its range must be interpreted in its technologic and stylistic context. We thus consider how the term [] was used in the patent specification, the prosecution history, and other claims. It is appropriate to consider the effects of varying that parameter, for the inventor's intended meaning is relevant."). Moreover, the '995 patent applies this teaching when differentiating between the crystalline polymorphs of tigecycline designated as Form I and II when stating that "one could rely upon the 6 listed Form I peaks [in Table I] to characterize Form I because the collection of 6 peaks is not present to +0.2° 2θ in Form II." ('995 patent at 4:64-5:1) Finally, the specification supports the notion that the maximum variation contemplated is 0.4° 2θ as follows:

> [T]he single peak at about 5.2° 2θ in Form I uniquely characterizes Form [I] because the nearest Form II peak to about 5.2° 2θ is found at about 9.2° 2θ, 4 degrees 2θ away. This 4° 2θ difference is significantly greater than the 0.4° 2θ obtained by combining the variability (0.2° 2θ) in any two peaks. In other words, so long as a peak in one sample is more than 0.4° 2θ away from any peak in another sample, then those represent different crystalline solid forms because the chance that any given peak in a crystalline solid form would vary by more than 0.4° 2θ from sample to sample and/or instrument to instrument is extremely small. Therefore, in a system that contains only Form I and Form II, a tigecycline powder pattern containing a peak at about 5.2° 2θ characterizes Form I tigecycline and the presence of that peak may be used to identify Form I. Similarly, when characterizing From II, one could use just the peak at about 9.2° 2θ because there is no Form I peak within 0.4° 2θ of that peak.

('995 patent at 5:2-20) Overall, these teachings of the '995 patent instruct that (1) the term "about" in the claims means ±0.2° 2θ of the recited x-axis peak position and nothing more, and (2) that the plus or minus measurement already takes into account the variability from sample to sample and instrument to instrument.

This construction is also supported by extrinsic evidence, as the U.S. Pharmacopeia, cited during prosecution of the '995 patent, states that "2θ values should typically be reproducible to ±0.10 or ±0.20 degrees." (D.I. 97 at JA-1171) While Pfizer argues the word "typically" recognizes the possibility for variance beyond plus or minus 0.2° 2θ, Pfizer is unable to point to anything, intrinsic or extrinsic, that uses something other than X-ray powder diffraction peaks at ± 0.2° 2θ to define the substance. As the Federal Circuit relied on the data described in the specification in *Ortho-McNeill Pharmaceutical, Inc. v. Caraco Pharmaceutical Laboratories., Ltd.*, 476 F.3d 1321 (Fed. Cir. 2007), the '995 patent provides sufficient technological facts to characterize Form I tigecycline as having X-ray powder diffraction peaks at ± 0.2° 2θ of the recited peaks.

Turning to whether Form I is limited to a crystalline solid form, the specification and prosecution history refer to Form I as a "crystalline solid form." First, the title of the patent is "Crystalline Solid Forms of Tigecycline and Methods of Preparing Same," indicating that the invention is limited to the crystalline form. Second, the '995 patent explicitly defines the claimed Form I of tigecycline as crystalline more than thirty times. (e.g., abstract, 1:8-10, 3:56-62, 4:43-36, 5:24-27, 5:31-34, 7:53-55, 9:1-3) Finally, it appears the U.S. Patent and Trademark Office issued the patent because of the inventive crystalline form versus the amorphous form disclosed in the prior art. For instance, in response to an obviousness rejection, the applicants asserted that the cited

prior art "does not disclose or suggest any composition comprising at least one solid form of tigecycline, wherein the crystalline solid form is Form I of tigecycline." (D.I. 97 at JA-1191) In response to an anticipation rejection, the applicants asserted that "[b]ased on a chemical structure (i.e., the compound), one cannot predict with any degree of certainty whether the compound will crystallize, under what conditions it will crystallize, how many crystalline solid forms of the compound might exist, or what structure the molecules of the compound will pack together to form a solid." (D.I. 97 at JA-1243) When the examiner maintained the anticipation rejection, the applicants then submitted a declaration by inventor Subodh Deshmukh which distinguished the claimed invention from the prior art yet again by arguing that the prior art resulted in amorphous tigecycline. (D.I. 97 at JA-1296-1303) Relying on the declaration of the inventor, the examiner allowed the patent, stating:

> The closest prior art is Krishnan et al. (US Patent No. 5675030). Krishnan et al. teach the structure of tigecycline ('030, column 7, legend item f) wherein the compound is concentrated methylene chloride in a vacuum to give a high purity compound ('030, column 8, lines 31-35). Applicants provided data in the form of declaration to prove that the product produced by Krishnan et al. is an amorphous product which is not crystalline. The XRD data also shows different peaks comparing the instantly claimed crystalline polymorph form I of tigecycline with the examples of Krishnan et al. proving that they are not the same crystalline particle. In addition to the comparison data provided in the declaration applicants provided evidence as exhibit F Tsiperman et al. (US 20080090789) that proves that the tigecycline solid products prepared according to Krishnan et al. resulted in amorphous tigecycline. Tsiperman et al. on paragraph 0024 teach that U.S. Pat. No. 5,675,030 mentions isolation of solid Tigecycline by evaporation from a dichloromethane solution. According to FIG. 1, repetition of the evaporation from dichloromethane step results in amorphous tigecycline. The claims are allowed based on the differences in XRD data described in the declaration by Dr. Subodh Deshmukh pursuant to 37 C.F.R. § 1.132.

(D.I. 97 at JA-1440-1441) The court additionally notes that in both the instant case and in prior litigation, Pfizer admitted that Form I tigecycline is crystalline. For example, Pfizer argues in its opening claim construction brief that,

> [a]s relevant to this Markman dispute, tigecycline can exist in either crystalline or non-crystalline (amorphous) form. During development, Pfizer realized that the amorphous form of tigecycline and the process to produce it had a number of disadvantages: it required expensive equipment and time-consuming procedures to produce, transport, and store because of its propensity to degrade quickly on hospital shelves. Pfizer solved this problem by inventing a particularly desirable crystalline form of tigecycline and patented this invention in U.S. Patent No. 8,372,995 ("the '995 patent.").

(*Pfizer v. Apotex*, Civ. No. 13-1613, D.I. 36 at 1) Plaintiffs made similar arguments in *Pfizer v. Fresenius Kabi USA,* Civ. No. 13-1893 (D.I. 73 at 3), *Pfizer v. Aurobindo Pharma Ltd*, Civ. No. 14-872 (D.I. 42 at 4), and *Pfizer v. CFT Pharmaceuticals LLC*, Civ. No. 14-781 (D.I. 39 at 4-5).

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

United States District Judge