IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

TAKEDA PHARMACEUTICALS U.S.A., INC., Plaintiff, v. PAR PHARMACEUTICAL COMPANIES, INC., and PAR PHARMACEUTICAL, INC. Defendants.	)	Civ. No. 13-1524-SLR
TAKEDA PHARMACEUTICALS U.S.A., INC., Plaintiff, v. AMENEAL PHARMACEUTICALS, LLC, Defendant.	)	Civ. No. 13-1729-SLR
TAKEDA PHARMACEUTICALS U.S.A., INC. Plaintiff, v. WATSON LABORATIRES, INC., Defendant.	)	Civ. No. 14-268-SLR

MEMORANDUM ORDER

At Wilmington this 1st day of June, 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 Nos. 7,619,004 ("the '004 patent"), 7,964,647 ("the '647 patent"), 7,981,938 ("the '938 patent"), 8,415,395 ("the '395 patent"), and 8,415,396 ("the '396 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. **"[A]fter waiting 12 hours:"**[1, 2] No construction required. Claim 1 of the '938 patent calls for administering 1.2 mgA oral colchicine at the onset of an acute gout flare, followed by 0.6 mgA colchicine about one hour later and, "after waiting 12 hours, continuing prophylactic treatment." Defendants propose the alternative construction of "after waiting at least 12 hours," fearing that the ordinary meaning of the claim language would require resuming prophylactic treatment at exactly 12 hours. (D.I. 189 at 20) Plaintiff, however, does not appear to advocate such an exacting interpretation. Plaintiff cites the applicant's statement during prosecution that the 12-hour waiting period is based on pharmacokinetic studies examining "the time interval for safely resuming the prophylactic dosing regimen after treating an acute flare." (D.I. 154, ex. 22 at A00411) The applicant referenced the inventor's declaration that "the prophylactic treatment can be safely resumed 12 hours after treating the acute flare without fear of toxicity." (*Id.*) The applicant's characterization of the 12-hour waiting period highlights the biological,

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[1] Claim 1 of the '938 patent.

[2] Unless otherwise specified, the court relies solely on intrinsic evidence in reaching its claim construction. *See generally Teva Pharm. USA, Inc. v. Sandoz, Inc.*, 135 S. Ct. 831, 834 (2015).

evidence-based nature of the time limit, and does not support an interpretation in which the treatment is resumed at precisely 12 hours.

2. By the same token, 12 hours is not so inexact as to merely represent a lower limit for a potentially uncapped time interval. Even though the applicant stated during prosecution that "the claimed method provides unexpectedly beneficial results to physicians and their patients by providing the minimal time interval required after treating an acute flare for safe resumption of prophylactic treatment by the patient" (D.I. 174, ex. R at A001343), the applicant also stated that the present invention "provided the . . . data to determine when prophylaxis can be safely restarted after treatment of an acute flare (only 12 hours rather than 3 days)" (D.I. 154, ex. 23 at A00434). The applicant could not have intended 12 hours to be an uncapped lower time interval while simultaneously disclaiming prior art with a longer time interval of 3 days. The court agrees with plaintiff that the ordinary meaning of the claim language is "readily apparent," and would be widely understood to mean resuming treatment after 12 hours, but not necessarily at exactly 12 hours or "at least" 12 hours. *See Phillips*, 415 F.3d at 1314.

3. **"[C]oncurrently:"**[3] "Concomitant but not sequential – i.e., the patient has not ceased clarithromycin treatment prior to administration of colchicine." Dependent claim 8 of the '004 patent states, "wherein the clarithromycin is administered concurrently with the second colchicine daily dosage amount." The parties dispute whether the specification draws a distinction between "concurrently" and "sequentially," or if concurrent administration encompasses sequential administration. In describing a

[3] Claim 8 of the '004 patent.

preferred embodiment, the specification states that "the concomitant[4] macrolide antibiotic is administered concurrently, **or** the patient has recently completed a dosing regimen of a macrolide antibiotic to treat an infection, and the patient is . . . administered a single dose of no more than about 0.6mg of colchicine." ('008 patent, col. 7:32-37) (emphasis added) In so stating, the specification sub-divides concomitant administration into concurrent administration and sequential administration in which colchicine is administered following completion of a dosing regimen of antibiotic. The applicant's statement during prosecution that claim 8 "require[s] that the colchicine and macrolide antibiotic . . . by administered concurrently (i.e., at about the same time)" (D.I. 154, ex. 24 at A000451) is consistent with the specification, and does not purport to expand concurrent administration to also include sequential administration.

4. **"[O]nset of the acute gouty arthritis attack / onset of gout flare:"**[5] "The time at which a patient experiences an acute gout flare, e.g., one or more joints are affected with swelling, erythema, marked tenderness, and pain." The parties dispute whether all four symptoms must be present in order to qualify as an acute gout flare within the meaning of the claims. As support for the position that all four symptoms are required, defendants point to example 3 in the specification, which provides a description of a clinical trial in which treatment was "administered at the onset of an acute gout attack." ('647 patent, col. 33:58-60) Example 3 describes using "a

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[4] The parties agreed that the construction of "concomitant" is "the administration of colchicine and [another drug] to patient either simultaneously or within a time period during which the effects of one drug are still operative in the patient when the other drug is administered." (D.I. 125, ex. A at 2)

[5] Claim 1 of the '647 patent, claim 1 of the '938 patent, claims 1 and 13 of the '395 patent, and claim 11 of the '396 patent.

standardized questionnaire . . . to document that the patient has all of the following signs/symptoms of the affected joint(s): swelling, erythema, marked tenderness, and pain." ('647 patent, col. 32:4-9) Defendants argue that example 3 provides the only criteria for determining "onset" of an acute gout flare, while the remaining disclosures throughout the specification merely teach what a person experiences during a gout flare. Defendants argue that the scope of the claims at issue is properly limited to the disclosure in example 3 because the applicant stated during prosecution that one of the two dosing regimens disclosed in example 3 is "the colchicine dosing regimen recited in claim 1 for treating an acute flare." (D.I. 154, ex. 26 at A00469)

5. The Federal Circuit has repeatedly cautioned against "reading a limitation from the written description into the claims" absent a "clear" disclaimer of claim scope. *SciMed Life Sys., Inc. v. Advanced Cardiovascular Sys., Inc.*, 242 F.3d 1337, 1341 (Fed. Cir. 2001). It is unclear from the applicant's statement whether "dosing regimen" refers to dosing quantity and timing (1.2 mg initially, followed by 0.6 mg one hour later), symptomatic criteria for "onset," or both. Given the lack of a clear intent to limit claim scope and the disclosure elsewhere in the intrinsic evidence of an "acute gout" attack with less than all four symptoms (*see* '647 patent, col. 1:50-63 (symptoms include "warmth, redness and tenderness" but not swelling); D.I. 154, ex. 26 at A00472 (symptoms include "pain, tenderness and swelling" but not redness)), the court is unwilling to limit "onset of the acute gouty arthritis attack" to only those symptoms disclosed in example 3.

6. Defendants also argue that the disclosure of "a method of treating patients with some but not all of the symptoms of acute gout" ('647 patent, col. 24:13-18)

elsewhere in the specification implies that the claimed treatment regimen applies to only patients experiencing "all" of the symptoms. Although this disclosure does suggest that some clinical symptomatic threshold must be met in order to qualify as an "acute gout" attack, it does not compel the conclusion that the four symptoms identified in example 3 are necessary to reach that threshold.

United States District Judge