IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

IN RE COPAXONE 40 MG CONSOLIDATED CASES	)	Civil Action No. 14-1171-GMS
	)	(CONSOLIDATED)

ORDER CONSTRUING THE TERMS OF U.S. PATENT NOS. 8,232,250, 8,399,413, 8,969,302, and 9,155,776

After considering the submissions of the parties and hearing oral argument on the matter, IT IS HEREBY ORDERED, ADJUDGED, and DECREED that, as used in the asserted claims of U.S. Patent Nos. 8,232,250 ("the '250 patent"), 8,399,413 ("the '413 patent"), 8,969,302 ("the '302 patent"), and 9,155,776 ("the '776 patent"):

1. The terms the defendants contend are non-limiting[1] are construed to be non-limiting

[1] The terms the defendants contend are non-limiting are: "alleviating a symptom of relapsing-remitting multiple sclerosis;" "reducing [the] frequency of relapses;" "therapeutically effective;" "regimen being sufficient to alleviate the symptom of the patient;" "wherein alleviating a symptom comprises reducing the frequency of relapses;" "wherein alleviating a symptom comprises reducing the mean cumulative number of Gd-enhancing lesions, reducing the mean number of new T_2 lesions, reducing the total volume of T_2 lesions, or reducing the cumulative number of enhancing lesions on T_1-weighted images in the brain of the patient;" "wherein alleviating a symptom comprises reducing brain atrophy in the patient;" "wherein alleviating a symptom comprises increasing the time to a confirmed relapse in the patient;" "wherein alleviating a symptom comprises reducing the total number of confirmed relapses in the patient;" "wherein alleviating a symptom comprises reducing the progression of MRI-monitored disease activity in the patient;" "wherein alleviating a symptom comprises reducing the number of new hypointense lesions on enhanced T_1 scans in the patient or reducing the total volume of hypointense lesions on enhanced T_1 scans in the patient;" "wherein alleviating a symptom comprises reducing a level of disability as measured by EDSS Score, by the work productivity and activities impairment-General Health (WPAI-GH) questionnaire, or by EuroQoL (EQ5D) questionnaire in the patient;" "wherein alleviating a symptom comprises reducing a change in EDSS Score in the patient or reducing a change in Ambulation Index in the patient;" "wherein the regimen is therapeutically effective;" "the regimen being sufficient to reduce frequency of relapses in the human patient;" "further comprising reducing the mean cumulative number of Gd-enhancing lesions in the brain of the patient;" "further comprising reducing the mean number of new T_2 lesions in the brain of the patient;" "further comprising reducing the cumulative number of enhancing lesions on T_1-weighted images;" "so as to treat the human patient;" "reducing the frequency of relapses by 30% or more as compared to placebo in a human

statements of intended effect.[2]

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population, for reducing brain atrophy, for reducing the cumulative number of enhancing lesions on T1-weighted images, or for reducing the level of disability as measured by EDSS Score;" "so as to thereby reduce the frequency of relapses by 30% or more as compared to placebo in a human population, reduce brain atrophy, reduce the cumulative number of enhancing lesions on T1-weighted images, or reduce the level of disability as measured by EDSS Score of the human patient;" "which reduces brain atrophy and for reducing the frequency of relapses by 30% or more as compared to placebo in a human population;" "which reduces the cumulative number of enhancing lesions on T1-weighted images;" "which reduces the level of disability of the human patient as measured by EDSS Score;" "which is as effective as administration of 20 mg of glatiramer acetate s.c. daily;" "so as to thereby treat the human patient as effectively as by administration of 20 mg glatiramer acetate s.c. daily;" "reducing the frequency of relapses, reducing brain atrophy, reducing the cumulative number of enhancing lesions on T1-weighted images, or reducing the level of disability as measured by EDSS Score;" "so effectively as administration of 20 mg of glatiramer acetate s.c. daily;" "so as to thereby reduce the frequency of relapses, reduce brain atrophy, reduce the cumulative number of enhancing lesions on T1-weighted images, or reduce the level of disability as measured by EDSS Score, of the human patient as effectively as by administration of 20 mg of glatiramer acetate s.c. daily;" "which reduces the frequency of relapses as effectively as administration of 20 mg of glatiramer acetate s.c. daily;" "which reduces brain atrophy as effectively as administration of 20 mg of glatiramer acetate s.c. daily;" which reduces the cumulative number of enhancing lesions on T1-weighted images as effectively as administration of 20 mg of glatiramer acetate s.c. daily;" and "which reduces the level of disability as measured by EDSS Score as effectively as administration of 20 mg of glatiramer acetate s.c. daily."

[2] These terms are strikingly similar to those in the patents in *Bristol-Myers Squibb Co. v. Ben Venue Laboratories, Inc.*, 246 F.3d 1368 (Fed. Cir. 2001). Those patents also covered a method of administering a drug. The Federal Circuit upheld the district court's interpretation of the preambles, "for reducing hematologic toxicity" and "[a] method for treating a cancer patient to effect regression of a taxol-sensitive tumor, said method being associated with reduced hematologic toxicity," as non-limiting statements of intended outcome. *Id.* at 1375–76. These statements had no bearing on the claimed methods. *Id.* at 1375 ("The steps of the three-hour infusion method are performed the same way regardless whether or not the patient experiences a reduction in hematologic toxicology."). The court also concluded that the statement "an antineoplastically effective amount" was a statement of intended result because it duplicated the dosage amounts recited in the claims. *Id.* ("The express dosage amounts are material claim limitations; the statement of the intended result of administering those amounts does not change those amounts or otherwise limit the claim.").

The prosecution history in *Bristol-Myers Squibb* also did not support construing the contested terms as limitations. It was "not a case in which a new use of a process should be considered to be a limitation because the new use distinguishes the process over the prior art." *Id.* at 1376. Further, "unsolicited assertions of patentability made during prosecution" such as voluntarily adding the phrase "antineoplastically effective amount" did not "create a material claim limitation where . . . the language does not create one." *Id.* The plaintiff in *Bristol-Myers Squibb* argued that claim differentiation required the terms to be limitations, because holding otherwise would cause several of the independent claims to have identical scope. The Federal Circuit disagreed, "declin[ing] to blindly apply the doctrine in this case to supplant other canons of claim construction" that compelled the conclusion that those terms were not limitations.

The same principles apply here. Just as in *Bristol-Myers Squibb*, these claim terms do not "result in a manipulative difference in the steps of the claim[s]." *See id.* at 1376. Rather, terms such as "alleviating a symptom of relapsing-remitting multiple sclerosis" and "further comprising reducing the . . . lesions in the brain of the patient" list the intended outcome from following the claimed steps. Other terms, such as

2. The regimen terms[3] are construed to mean "a continuous treatment requiring three and only three subcutaneous injections each and every week [with at least one day between every injection]."[4]

3. The term "brain atrophy" is construed to mean a reduction in gray matter and white matter volume over time.[5]

"therapeutically effective," duplicate the dosage requirements and do not provide any additional required structure or condition for the claims. Here, there is also no evidence that these terms are central to patentability or were used to meaningfully distinguish the claims from the prior art. It is true that the court's ruling eviscerates many of the dependent claims, which only contain these non-limiting terms to distinguish them from their independent claims. But just as in *Bristol-Myers Squibb*, the doctrine of claim differentiation alone cannot save claims that do not contain any true limitations. The court agrees with the defendants that these numerous claim terms are not limitations.

[3] The regimen terms are: "comprising administering . . . regimen of three subcutaneous injections . . . over a period of seven days with at least one day between every subcutaneous injection;" "comprising administration of three subcutaneous injections . . . per week;" and "comprising subcutaneous injection . . . three times per week [with at least one day between every subcutaneous injection]."

[4] The parties' dispute centers on whether the terms contemplate a fourth injection every other week—in other words, whether the patent allows an alternate-day dosing regimen. The defendants argue that the use of the open ended term "comprising" means that additional doses may be added, as long as there is a day between every injection. Ordinarily, the court would agree because comprising is an open ended transition. The language of the claims does not preclude an alternate-day dosing regimen. But in this case, the prosecution history limits the scope of these claims. The court finds the patentee clearly disclaimed an alternate-day dosing regimen to distinguish the inventions from the prior art. (D.I. 104 at JA218, JA223, JA1766, JA1761).

[5] The court recognizes that based on its construction that the preamble terms are nonlimiting, "brain atrophy" does not need to be construed. Nevertheless, the court construes the term out of an abundance of caution. Here, the task is simple because the specification clearly defines the term. The patent repeatedly defines brain atrophy as the percent change in brain volume over time—more specifically, the change "in normalized gray matter volume and in normalized white matter volume." 250 patent at 12:19–20, 12:46–49, 13:66–14:5, 14:62–15:4.

4. The reduced severity terms[6] are construed to have their plain and ordinary meaning.[7]

Dated: March 7, 2016

UNITED STATES DISTRICT JUDGE

[6] The reduced severity terms are: "reduced severity of injection site reactions" and "reduced frequency and severity of immediate post injection site reactions and injection site reactions."

[7] Paradoxically, the court adopts the plaintiffs' proposed construction, but the defendants' interpretation for these terms. The defendants' proposed construction is "a reduction in the intensity of a patient's injection site reactions." The plaintiffs correctly note that this is redundant, because the claims explicitly state they are methods for treating a human patient. But this clear indication that the claims are directed to "a human patient" informs the plain meaning of this term. Contrary to the plaintiffs' assertions, the court finds that in context of the claims, the plain meaning of these terms requires reduced severity of *a patient's* injection site reactions.