

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NOVARTIS PHARMACEUTICALS :
CORP., et al., :
Plaintiffs, :
 :
v. : Civil Action No. 11-1077-RGA
 :
WATSON LABORATORIES, INC., :
et al., :
Defendants. :

ORDER

The Court having considered the Parties' Joint Claim Construction Brief (D.I. 224) and appendix (D.I. 225), Plaintiffs' additional submission (D.I. 240), and oral argument on June 13, 2013 (D.I. 244), **IT IS HEREBY ORDERED** that the terms below, as used in U.S. Patent Nos. 6,335,031 and 6,316,023¹ are construed as follows:

A. "*antioxidant*"

The term "antioxidant" is construed to mean "agent that reduces oxidative degradation." Over the course of briefing and oral argument, the parties' substantive disputes over the construction of this term narrowed to whether the antioxidant must reduce oxidative degradation "of Compound A," as Defendants propose. Defendants point to disclosure in the specifications and prosecution histories that Compound A is problematically susceptible to degradation, and to the disclosed solution of pairing it with an antioxidant. *E.g.*, '031 Patent, col.1 ll.22-24, 29-33; D.I. 225-1 at 20.

Plaintiffs characterize these disclosures as providing three classes of embodiments: a)

¹ The patents share the same specification, and claim terms are construed consistently between them.

compositions containing Compound A and an antioxidant, b) transdermal devices containing Compound A and an antioxidant, and c) a method of using an antioxidant to stabilize Compound A. Plaintiffs note that the disclosures for the compositions and the transdermal devices disclose the presence of the antioxidant, without specifically referring to any reduction in the degradation of Compound A. *See* '031 Patent, Abst.; col.1 ll.34-36; col.3 l.61 - col.4 l.4; col.4 ll.5-7; col.7 l.55 - col.8 l.10. The claims for a method for stabilizing Compound A require the antioxidant be present in an amount effective to stabilize Compound A, whereas the claims for the composition and some of the claims for the transdermal device do not explicitly limit the antioxidant's amount or effect. *Compare* '031 Patent, col.9 ll.10-15 (claim 15) *and* col.8 ll.59-67 (claim 11) *with* col.8 ll.14-21 (claim 1) and col.8 ll.49-51 (claim 7).

The patents repeatedly disclose the combination of Compound A and the antioxidant without specifically requiring that the antioxidant affect Compound A. '031 Patent, Abst.; col.1 ll.34-36; col.3 l.61 - col.4 l.4; col.4 ll.5-7; col.7 l.55 - col.8 l.10. It would be improper to preclude those embodiments by limiting "antioxidant" to require that interaction. It is also improper to impute the antioxidant's stabilizing effect on Compound A, explicitly claimed in some claims, into claims that do not contain that explicit limitation. *See Phillips v. AWH Corp.*, 415 F.3d 1303, 1314-15 (Fed. Cir. 2005)(en banc). The flip side of that coin is that it is also improper to construe "antioxidant" to require that it reduce degradation of Compound A, and therefore render superfluous or redundant the explicit limitation in some claims that the antioxidant stabilize Compound A.

B. "*an amount of antioxidant effective to stabilize Compound A from degradation*"

The term "an amount of antioxidant effective to stabilize Compound A from degradation"

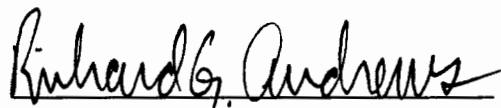
is construed to mean “an amount of antioxidant that will significantly reduce degradation of Compound A over a prolonged period of time.” Claim language of an “effective amount” has a customary usage: the amount that will achieve the claimed effect. *Abbott Labs v. Baxter Pharm. Prods., Inc.*, 334 F.3d 1274, 1277-78 (Fed. Cir. 2003). The patentee here did not deviate from that customary usage.

Of the remaining term language, only “stabilize” requires construction. The specification provides that “stable pharmaceutical compositions comprising compound A *can* now be obtained, which show insignificant degradation of compound A over a prolonged time period, e.g. 2 years, as indicated by standard tests, e.g. stress tests.” ‘031 Patent, col.1 ll.29-33 (emphasis added). While the “can” language is permissive, such that the pharmaceutical compositions comprising compound A need not always be stable, the language “show insignificant degradation of compound A over a prolonged time period, e.g. 2 years, as indicated by standard tests, e.g. stress tests” indicates what the patentee meant by “stable.” The patentee went on to describe “an effective stabilizing effect” in terms of a reduction of degradation products in two and three month stress tests. *Id.* col.4 ll.11-30. Examples 1-3 describe “insignificant degradation” after storage for certain periods. *Id.* col.7 ll.16-51. This disclosure indicates that “stabilizing” means “significantly reducing degradation over a prolonged period of time.”

C. “*stabilizing*”

The term “stabilizing” means “significantly reducing degradation over a prolonged period of time.”

Entered this 21st day of June, 2013.


United States District Judge