

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

FOREST LABORATORIES INC., <i>et al.</i>	)	
	)	
Plaintiffs,	)	
	)	
v.	)	C.A. No. 08-21-GMS-LPS
	)	CONSOLIDATED
COBALT LABORATORIES INC., <i>et al.</i> ,	)	
	)	
Defendants.	)	

**MEMORANDUM**

**I. INTRODUCTION**

On January 11, 2008, the plaintiffs filed this consolidated action for infringement of U.S. Patent No. 5,061,703 (“703 patent”) against multiple defendants.<sup>1</sup> (D.I. 1.) On October 17, 2008, the parties filed a Joint Claim Chart identifying the claim terms the parties contend require construction. (D.I. 198.) The parties briefed their positions on claim construction and, on December 15, 2008, Magistrate Judge Leonard P. Stark conducted a *Markman* hearing. *See* Dec. 15, 2008 Hearing Transcript (D.I. 248.) Pursuant to 28 U.S.C. § 636(b)(1)(B), Fed. R. Civ. P. 72(b)(1), and D. Del. LR 72.1, Magistrate Judge Stark issued a report and recommendation regarding claim construction on July 2, 2009.<sup>2</sup> (D.I. 373.) On July 20, 2009, four different subsets of defendants filed objections to the report and recommendation. (D.I. 381-384.) For the reasons that follow, the

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<sup>1</sup> This consolidated ANDA action consists of C.A. Nos. 08-21, 08-22, 08-52, and 08-291 (collectively referred to as the “consolidated action” or the “action”). (D.I. 76.) The plaintiffs in this action are: Merz Pharma GmbH & Co. KGaA, Merz Pharmaceuticals GmbH, Forest Laboratories, Inc., and Forest Laboratories Holdings, Ltd. (collectively, the “plaintiffs”). The defendants in this action include, among others, the following parties: Orchid Chemicals & Pharmaceuticals Ltd. (“Orchid India”), Orchid Pharmaceuticals, Inc. (“Orchid Pharma”), and Orgenus Pharma, Inc. (“Orgenus”). Defendants Orchid India and Orgenus are referred to hereinafter, collectively, in this memorandum as the “defendants.”

court will adopt in part and overrule in part the claim constructions recommended by the Magistrate Judge in the July 2, 2009 Report and Recommendation.

## II. DISCUSSION

The court reviews *de novo* those portions of the report and recommendation to which the parties made a timely objection; the remainder of the report and recommendation are reviewed for clear error. *See* 28 U.S.C. § 636(b)(1). Here, after having considered the record in this case, the Report and Recommendation, the defendants' objections, the plaintiffs' response, and the applicable law, the court will adopt without comment the Magistrate Judge's claim constructions of those terms for which no objections were filed. The remaining claim constructions from the Magistrate Judge's Report and Recommendation are addressed below.<sup>3</sup>

### A. "Cerebral ischemia"

After considering the parties' proposed constructions, the Magistrate Judge recommended that the term "cerebral ischemia" in claims 1 and 14 be construed to mean "an imbalance of neuronal stimulation mechanisms." (D.I. 373 at 32.) The court agrees. The defendants contended in the *Markman* hearing, and contend now in their objections, that "cerebral ischemia" should be construed as "an acute interruption of blood supply to the brain" or "an acute interruption of blood supply to the brain characterized by the destruction of brain cells," citing the ordinary meaning of "ischemia"

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<sup>3</sup> The defendants have also made a number of claim differentiation, 35 U.S.C. § 305, and other invalidity arguments, though they couched these arguments as claim construction objections. (*See* D.I. 381 at 2-6; D.I. 382 at 6-10; D.I. 383 at 8; D.I. 384 at 5-6, 9-10.) Such validity arguments are not properly resolved at the claim construction stage. *See, e.g., Ampex Corp. v. Eastman Kodak Co.*, 460 F. Supp. 2d 541, 543 n.1 (D. Del. 2006) ("The validity of a claim is not an issue of claim construction . . . . I will not convert Defendants' claim construction argument into a motion for summary judgment."). For the same reason, the court will not yet consider the comprehensive claim construction argument rejected by Magistrate Judge Stark in his Report and Recommendation. (*See* D.I. 373 at 29-32; D.I. 381 at 2-6).

as referring to an interruption in blood supply. But it is clear from the language of the specification that the term “cerebral ischemia” as used in the patent refers to a neuronal imbalance. *See, e.g.*, D.I. 243 at JA002, col. 2 lines 46-48 (“[C]erebral ischemia is characterized by an imbalance of neuronal stimulation mechanisms.”); *id.* at col. 2 line 67 to col. 3 line 3 (“The present invention is aimed at preparing and employing compounds which can be chemically generated by simple methods, exhibiting an NMDA receptor channel-antagonistic and anticonvulsive action, for use in the prevention and treatment of cerebral ischemia.”).<sup>4</sup>

The patentee defined “cerebral ischemia” with sufficient and “reasonable clarity, deliberateness, and precision,” thereby meeting their burden of establishing that the term as used in the patent carries a meaning different than the plain and ordinary meaning of the term. *See Abbot Labs. v. Syntron Bioresearch, Inc.*, 334 F.3d 1343, 1354 (Fed. Cir. 2003). Furthermore, during the reexamination proceedings for the ‘703 patent, the patentee again expressly defined “cerebral ischemia” as “an imbalance of neuronal stimulation,” thus confirming the meaning of the term in the context of this patent. (*See* D.I. 243 at JA00760.) Different uses of the terms “ischemia” or “cerebral ischemia” in studies and other sources cited in the patent do not override the specification’s clear use of the term to refer to a neuronal situation. Thus, for the reasons set forth in the Report and Recommendation, the court will adopt the Magistrate Judge’s construction.<sup>5</sup>

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<sup>4</sup> As the Magistrate Judge noted, the descriptions in the specification focus on a neuronal situation, and nowhere in the specification is the term “cerebral ischemia” used to refer to an interruption in blood supply to the brain. (*See* D.I. 373 at 12-16.) Thus, at the very least, it is clear that the court cannot adopt the defendant’s suggested construction of “cerebral ischemia” as referring to an interruption in the blood supply.

<sup>5</sup> Some of the defendants assert that the Report “expressed the view that, since ‘ischemia’ alone means an interruption of blood supply, ‘cerebral ischemia’ must mean something completely different,” citing page 13 of the Report and Recommendation for this proposition.

**B. “Prevention of cerebral ischemia” and “treatment of cerebral ischemia”**

The Magistrate Judge recommends that the term “prevention of cerebral ischemia” in claim 1 be construed to mean “prevention of an imbalance of neuronal stimulation mechanisms.” (D.I. 373 at 32.) This construction follows from the construction of “cerebral ischemia.” The Magistrate Judge recommends that the term “treatment of cerebral ischemia” in claims 1 and 14 be construed to mean “an antagonistic intervention with regard to the N-methyl-D-aspartate [NMDA] receptor channels.” (*Id.* at 32.)

The defendants’ objections to both of these constructions stems from their insistence that “cerebral ischemia” should be construed as an interruption of blood supply to the brain. As described above such a construction is contrary to the specification, which defines cerebral ischemia with reference to an imbalance in neuronal stimulation mechanisms and states that “in order to treat this pathological situation, an antagonistic intervention is required with regard to the NMDA receptor channels.” (D.I. 243 at JA2, col. 2 lines 53-55.) Thus, for the reasons set forth in the Report and Recommendation, the court will adopt the Magistrate Judge’s construction for these terms.

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(*See* D.I. 384 at 3.) Even a cursory review of the Report and Recommendation reveals this to be a gross mischaracterization of Magistrate Judge Stark’s reasoning. Magistrate Judge Stark makes clear in his reasoning that the use of “ischemia” alone to mean “an interruption in blood supply” does not *automatically* mean that the term “cerebral ischemia” has a distinct meaning in the context of its use in the patent. (D.I. 373 at 11, 13.) At no point does the Magistrate Judge state or imply that the addition of the word “cerebral” means that “ischemia” and “cerebral ischemia” *must* have distinct meanings, as the defendants baldly assert in their objection. Distortions such as this of a clearly stated analysis by one of this court’s judicial officers are not welcome and come very close to crossing the line that separates zealous advocacy from a failure of an attorney to properly attend the ethical responsibilities that accompany the grant of the privilege to practice law.

**C. “Treatment of imbalance of neuronal stimulation after Alzheimer’s disease”**

The Magistrate Judge recommends that the term “treatment of imbalance of neuronal stimulation after Alzheimer’s disease” in claim 17 be construed to mean “an antagonistic intervention with regard to the excessive inflow of calcium through [NMDA] receptor channels.” (D.I. 373 at 33.) All parties appear to agree that this definition reads out the words “after Alzheimer’s disease.” (*See* D.I. 382 at 5-6; D.I. 383 at 7-8; D.I. 405 at 14-15.) The court agrees with the plaintiffs that this omission appears to be a clerical error or other inadvertent oversight on the part of the Magistrate Judge. Thus, for the reasons set forth in the Report and Recommendation (*see* D.I. 373 at 20-22, 25-26), the court adopts the Magistrate Judge’s construction with the following italicized addition: “Treatment of imbalance of neuronal stimulation after Alzheimer’s disease” as that term is used in claim 17 means “an antagonistic intervention with regard to the excessive inflow of calcium through [NMDA] receptor channels *after Alzheimer’s disease.*”

**D. “Treatment of Alzheimer’s Disease”**

The Magistrate Judge recommends that the term “treatment of Alzheimer’s disease” in claim 10 be construed to mean “treatment of cerebral ischemia after Alzheimer’s disease (as those terms are defined therein).” (D.I. 373 at 33.) Several of the defendants filed a brief objecting to this construction as circular and internally inconsistent, since “those terms” could conceivably refer either to “cerebral ischemia” and “Alzheimer’s disease” or “treatment of cerebral ischemia” and “Alzheimer’s disease.” (D.I. 382 at 3.) The court agrees with the plaintiffs that this supposed ambiguity is resolved by the text of the report, which specifies that it is the term “cerebral ischemia” rather than “treatment of cerebral ischemia” that should be used. (*See* D.I. 373 at 26.) The defendants assert, however, that this construction would give the phrase “treatment of cerebral

ischemia” a different meaning in claim 10 than in claims 1 and 14. (D.I. 382 at 3-4, n.2.)

The court agrees that the construction recommended by the Magistrate Judge should be amended. Given that after reexamination, claim 1 was amended so that it applied only to “patient[s] diagnosed with Alzheimer’s disease,” the court sees no reason to construe the term “treatment of Alzheimer’s disease” in claim 10 beyond incorporating the construction of “Alzheimer’s disease” provided above. It seems clear from the post-reexamination claims that the distinction between claim 1 and claim 10 lies not in the persons receiving the treatment, but rather in the characteristics of the adamantane derivative described. Consequently, the court will give “treatment of Alzheimer’s disease” its plain and ordinary meaning, giving the term “Alzheimer’s disease” the construction provided in the Order of this same date.<sup>6</sup>

**E. “Patient in need thereof” and “patient in need of such treatment”**

The Magistrate Judge recommends that the term “patient . . . in need thereof” as that term is used in claims 1 and 14 and the term “patient . . . in need of such treatment” as that term is used in claim 17 be given their plain and ordinary meaning. (D.I. 373 at 28-29.) The court agrees that these terms are clear and unambiguous as they are and sees no need to expand further on the Magistrate Judge’s reasoning. Thus, for the reasons set forth in the Report and Recommendation, the court will adopt the Magistrate Judge’s construction for these terms.

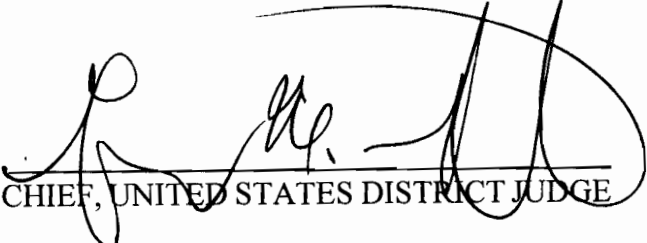
**III. CONCLUSION**

For the reasons discussed above, the court will adopt in part and overrule in part the Magistrate Judge’s Report and Recommendation regarding claim construction (D.I. 373).

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<sup>6</sup> None of the defendants objected to the Magistrate Judge’s construction of the term “Alzheimer’s disease.”

Dated: September 21, 2009



CHIEF, UNITED STATES DISTRICT JUDGE

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

FOREST LABORATORIES INC., *et al.* )

Plaintiffs, )

e. )

COBALT LABORATORIES INC., *et al.*, )

Defendants. )

Civil Action No. 08-21-GMS-LPS

**ORDER**

For the reasons stated in the court's Memorandum of this same date, IT IS HEREBY ORDERED that the Magistrate Judge's Report and Recommendation (D.I. 373) is ADOPTED IN PART and OVERRULED IN PART and IT IS HEREBY ORDERED, ADJUDGED, and DECREED that, as used in the asserted claims of U.S. Patent No. 5,061,703:

1. The term "cerebral ischemia" in claims 1 and 14 is construed to mean "an imbalance of neuronal stimulation mechanisms."

2. The term "prevention of cerebral ischemia" in claim 1 be construed to mean "prevention of an imbalance of neuronal stimulation mechanisms."

3. The term "treatment of cerebral ischemia" in claims 1 and 14 is construed to mean "an antagonistic intervention with regard to the N-methyl-D-aspartate [NMDA] receptor channels."

4. The term "Alzheimer's disease" in claims 1, 10, 14, and 17 means "dementia of the Alzheimer's type, as characterized by accepted diagnostic criteria, such as those set forth in the Diagnostic and Statistical Manual of Mental Disorders, version III-R, and further characterized by the presence of neuritic plaques and neurofibrillary tangles in the brain."

5. The term "patient diagnosed with Alzheimer's disease" in claims 1, 14, and 17 means



“a live person diagnosed with dementia of the Alzheimer’s type, as characterized by accepted diagnostic criteria, such as those set forth in the Diagnostic and Statistical Manual of Mental Disorders, version III-R.”

6. The term “treatment of Alzheimer’s disease” in claim 10 is construed to have its plain and ordinary meaning.<sup>1</sup>

7. The term “imbalance of neuronal stimulation after Alzheimer’s disease” in claim 17 means “a pathophysiological situation characterized by an excessive inflow of calcium through the NMDA receptor channels after Alzheimer’s disease.”<sup>2</sup>

8. The term “treatment of imbalance of neuronal stimulation after Alzheimer’s disease” in claim 17 means “an antagonistic intervention with regard to the excessive inflow of calcium through NMDA receptor channels after Alzheimer’s disease.”<sup>3</sup>

9. The term “effective amount” in claims 1, 14, and 17 means “an amount shown to cause improvement, in comparison to placebo.”

10. The term “effective cerebral ischemia-alleviating or preventive amount” in claim 11 means “an amount shown to treat or eliminate an imbalance of neuronal stimulation, in comparison to placebo treatment.”

11. The term “amount effective to prevent degeneration and loss of nerve cells after ischemia” in claim 13 means “an amount shown to eliminate degeneration and loss of nerve cells

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<sup>1</sup> This construction incorporates by inference the court’s construction of “Alzheimer’s disease” provided in Paragraph 4 of this Order. The court finds that no additional construction is required for this term.

<sup>2</sup> This construction incorporates by inference the court’s construction of “Alzheimer’s disease” provided in Paragraph 4 of this Order.

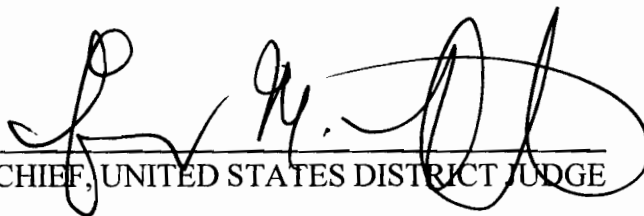
<sup>3</sup> See footnote 2.

after an acute interruption of blood supply.”

12. The term “patient . . . in need thereof” in claims 1 and 14 is construed to have its plain and ordinary meaning.<sup>4</sup>

13. The term “patient . . . in need of such treatment” in claim 17 is construed to have its plain and ordinary meaning.<sup>5</sup>

Dated: September 24, 2009

  
CHIEF, UNITED STATES DISTRICT JUDGE

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<sup>4</sup> The court finds that no construction is required for this term.

<sup>5</sup> See footnote 4.