IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

TEVA PHARMACEUTICALS USA, INC. and MAYNE PHARMA INTERNATIONAL PTY LTD.,	)	
Plaintiffs,	)	
v.	)	Civil Action No. 13-2002-GMS
FOREST LABORATORIES, INC.,	)	
Defendant.	)	

ORDER CONSTRUING THE TERMS OF U.S. PATENT NO. 6,194,000

The court having considered the submissions of the parties and having heard oral argument on the matter—IT IS HEREBY ORDERED, ADJUDGED, and DECREED that, as used in the asserted claims of U.S. Patent No. 6,194,000 ("the '000 Patent"):

1. The term "wind-up" is construed to mean "an increase in output to a repeated or constant input, resulting in an exaggerated pain response."[1]

[1] The parties' dispute concerns whether wind-up should be defined by a particular physiological mechanism or a more generalized understanding of the condition. The confusion stems essentially from a single passage in the specification:

> [I]t is believed that the NMDA receptor complex plays only a minor role in routine synaptic transmission. However, the receptor complex may be activated following repeated afferent stimuli as occurs during trauma such as surgery. Repeated stimuli cause a temporal summation of C-fibre-mediated responses of dorsal horn nociceptive neurones; this phenomenon, increased output to a constant input, is known as wind-up.

'000 Patent, col. 1 ll. 20–30. Despite failing to provide the court with a clear proposal, the defendant seeks a construction incorporating these specific physiological elements: temporal summation of C-fibre-mediated responses of dorsal horn nociceptive neurons.

The whole of the intrinsic evidence, however, does not support such a narrow interpretation. Indeed, even the above-quoted passage supports the court's ultimate construction. The final clause—"this phenomenon, increased output to a constant input, is known as wind-up"—is an effective definition of wind-up. After going through a complex, lengthy description of the physiology at play, the patentee elected to include a more simplified description in the form of an appositive to describe the "phenomenon" of wind-up: "increased output to a constant input."

2. The term "to diminish or abolish wind-up" is construed to mean "to diminish or abolish wind-up in the human or animal subject of the administration."[2]

See Apposition, MERRIAM-WEBSTER: DICTIONARY & THESAURUS, http://www.merriam-webster.com/dictionary/apposition (last visited July 9, 2015) ("an arrangement of words in which a noun or noun phrase is followed by another noun or noun phrase that *refers to the same thing*" (emphasis added)). Subsequent disclosures explain what the patentee meant by this: "These neural mechanisms may be expressed physically as hyperalgesia (increased pain sensation) and allodynia (pain arising from a stimulus that is not normally painful)." *Id.* col. 1 ll. 34–37. Thus, it is the painful *expression* of the underlying neural mechanisms that constitutes wind-up.

The prosecution history supports this view. In overcoming an indefiniteness rejection, the applicant stated:

> The term "wind up" relates to an increase in output to a repeated constant input or stimulus. The output is manifested as pain and is measured in experiments as the nerve's response. Wind up results in an exaggerated pain response to a stimulus which normally would not be painful . . . .

(D.I. 60 at JA0159.) The Examiner accepted this explanation and in the Notice of Allowance concluded:

> The method of preparing the novel combination and method of treatment provides dissolution profiles which result in serum blood levels of the NMDA receptor antagonist in sufficient amounts to diminish or abolish wind-up. *Wind-up being an increase in output to a repeated constant input or stimulus. The output manifested as pain in the case of wind-up results in an exaggerated pain response* to a stimulus which normally would not be painful.

(*Id.* at JA0207 (emphasis added).) Again, it is the manifestation, or expression, of the nerve response that causes pain. This pain is called wind-up.

Both prosecution statements refer to wind-up as an "exaggerated pain response to a stimulus which normally would not be painful"—allodynia. But the patent specification makes clear that hyperalgesia—a more generalized increased pain sensation—also falls under the umbrella of wind-up. '000 Patent, col. 1 ll. 34–37. Thus, a definition simply requiring an *exaggerated pain response*—regardless of whether the input is normally painful—adequately captures the patent's teaching.

[2] Claim 1 claims:

> A method of preparing an analgesic pharmaceutical composition for the administration of an NMDA receptor antagonist to a human or animal subject for the treatment of pain, comprising:
>
> . . . .
>
> the immediate release form and sustained release form being present in sufficient amounts to diminish or abolish wind-up.

'000 Patent, claim 1. "Claim construction is a matter of resolution of disputed meanings and technical scope, to clarify and when necessary to explain what the patentee covered by the claims, for use in the determination of infringement. It is not an obligatory exercise in redundancy." *U.S. Surgical Corp. v. Ethicon, Inc.*, 103 F.3d 1554, 1568 (Fed. Cir. 1997). The plaintiffs appear to oppose construction not because it would improperly narrow the scope of the claims but, rather, because it is redundant—it restates what is already understood by the plain language. (D.I. 69 at 43–44.) The court, however, agrees with the defendant that the construction does indeed clarify an ambiguity in the claims. Specifically, the construction makes clear that the amounts "sufficient" to diminish or abolish wind-up are not merely *theoretically* sufficient. The immediate and sustained release forms are present in sufficient amounts to diminish wind-up *in the subject actually receiving the treatment.* Thus, the court is comfortable erring on the side of redundancy, as opposed to risking confusion at a later stage of litigation.

3. The preamble phrase "for the administration . . . to a human or animal subject for the treatment of pain" is construed not to be limiting.[3]

4. The terms "immediate release form" and "immediate release" are construed to mean "pharmaceutical form in which the release of the active ingredient is not delayed and/or extended" and "release that is not delayed and/or extended," respectively.[4]

5. The terms "sustained release form" and "sustained release" are construed to mean "pharmaceutical form in which the release of the active ingredient is delayed and/or extended" and "release that is delayed and/or extended," respectively.[5]

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[3] "In general, a preamble limits the invention if it recites essential structure or steps, or if it is necessary to give life, meaning, and vitality to the claim. Conversely, a preamble is not limiting where a patentee defines a structurally complete invention in the claim body and uses the preamble only to state a purpose or intended use for the invention." *Catalina Mktg. Int'l, Inc. v. Coolsavings.com, Inc.*, 289 F.3d 801, 808 (Fed. Cir. 2002) (internal citation and quotation marks omitted). The preamble phrase does not recite essential structure or steps and does not serve as an antecedent basis for subsequent elements in the claim body. *See id.* The court is satisfied that the disputed portion of the preamble is not limiting because it merely states an intended purpose of the invention.

[4] The court's construction is consistent with a plain and ordinary understanding of the word "immediate." The plaintiffs point to a statement in the specification perhaps suggesting that immediate release is achieved "promptly." '000 Patent, col. 3 ll. 55–60 ("[D]elayed release dosage forms . . . release the drug at a time other than promptly after administration."). But the specification did not unambiguously redefine "immediate" to mean "prompt," and the court is reluctant to inject ambiguity into the claims with a word like "prompt," which has no ascertainable boundaries.

The specification is consistent with the view that immediate release forms of the NMDA receptor antagonist are not altered to extend or delay release. "A suitable immediate release (IR) form of the NMDA receptor antagonist may simply be particles of the antagonist or particles of the antagonist admixed with [various different components]." *Id.* col. 3 ll. 30–45. The patent does not teach that the combination of the active ingredient with these different components—even insoluble components—affects the release profile. But it does describe other functions: "A core used herein the description contains the active ingredient and other carriers and excipients, fillers, stablising agents, binders, core seeds or colorants." *Id.* col. 3 ll. 61–63. Moreover, the patent teaches that coatings can be used on immediate release cores but only "for aesthetic, handling, or stability purposes." *Id.* col. 6 ll. 11–13. Thus, there is nothing in the intrinsic record to suggest a different understanding of "immediate" should be applied—it means without delay and/or extension.

The plaintiffs' contention that constructions in the form of negative limitations—such as that proposed by the defendant—are disfavored or face a more exacting standard is a misunderstanding of Federal Circuit case law. *See Omega Eng'g, Inc, v. Raytek Corp.*, 334 F.3d 1314, 1322 (Fed. Cir. 2003).

[5] Whereas immediate release is not delayed and/or extended, *supra* note 4, sustained release is just the opposite. The specification supports this view. *See* '000 Patent, col. 3 ll. 53–54 ("The controlled release may be a *sustained release or delayed/modified release.*" (emphasis added)); col. 4 ll. 6–7 ("Preferably, the controlled release component is a *sustained (or extended) release form.*" (emphasis added)).

The plaintiffs argue that the sustained release form releases the active ingredient over a longer period than that of the immediate release form. This relative construction—dependent entirely on immediate release—is simply not how the specification treats the claim term.

6. The term "immediate release form and sustained release form being present in sufficient amounts" is construed to mean "immediate release form and sustained release form together being present in sufficient amounts."[6]

Dated: July 9, 2015

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[6] The defendant seeks to construe the claim term as requiring independently sufficient amounts of both the immediate release form and the sustained release form to diminish or abolish wind-up. In other words, either form, standing alone, would serve to treat wind-up. But such a construction is neither required by the language of the claims nor supported by the teachings of the specification.

In particular, the defendant emphasizes the claims' use of the plural "amounts" rather than a single "amount" capable of diminishing or abolishing wind-up. *See, e.g.*, '000 Patent, claim 1. The claim drafters perhaps could have framed the claims to require a single unified amount capable of treating wind-up. But the usage of "amounts" does not automatically require a different understanding. The combination of the immediate release form and the sustained release form will indeed result in two "amounts" of active ingredient, even if only the combined total is relevant. Thus, the plaintiffs' understanding is not an improper revision of the claims.

Moreover, "[c]laim language must be viewed in light of the specification, which is 'the single best guide to the meaning of a disputed term.'" *Interval Licensing LLC v. AOL, Inc.*, 766 F.3d 1364 (Fed. Cir. 2014) (quoting *Phillips v. AWH Corp.*, 415 F.3d 1303, 1315 (Fed. Cir. 2005)). The specification always refers to the combined amount(s) as having the therapeutic effect, rather than the individual amount of each. "We have found that a particularly effective composition for the administration of an NMDA receptor antagonist to diminish or abolish wind up is *one providing both immediate release* of an NMDA receptor antagonist *and controlled or sustained release* of an NMDA receptor antagonist." *Id.* col. 1 ll. 52–56 (emphasis added); *see also id.* col. 5 ll. 6–10 ("The IR [intermediate release] and SR [sustained release] forms of the NMDA receptor antagonist are then *combined into a single dosage* such that *the amount of NMDA receptor antagonist in the composition* of the invention is in the range of about 1–5000 mg typically."). Never does the patent teach that each form is present in a sufficient amount to treat wind-up on its own. The court adjusts the construction to mirror the original claim language as closely as possible but largely adopts the plaintiffs' reasoning.