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IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF CALIFORNIA
SAN FRANCISCO DIVISION

SHIRE LLC; SUPERNUS
PHARMACEUTICALS, INC.; AMY F.T.
ARNSTEN, PH.D.; PASKO RAKIC, M.D.;
and ROBERT D. HUNT, M.D.,

No. C 10-5467 RS

**ORDER DENYING MOTION FOR
LEAVE TO FILE FOR
RECONSIDERATION**

Plaintiffs,

v.

IMPAX LABORATORIES, INC.;
WATSON PHARMACEUTICALS, INC.;
WATSON LABORATORIES,
INC.-FLORIDA; WATSON PHARMA,
INC.; and ANDA, INC.,

Defendants.

_____ /

Plaintiffs move for leave to file a motion for reconsideration of the claim construction issued in this patent action on two grounds. First, plaintiffs request that the Court modify language in its constructions of three terms: (1) “non-pH dependent sustained release agent,” (2) “pH dependent agent that increases the rate of release of said at least one pharmaceutically active agent from the tablet at a pH in excess of 5.5,” and (3) “agent that increases the solubility of said at least one pharmaceutically active agent at a pH of greater than 5.5.” The modification plaintiffs request is directed to clarifying, contrary to the result reached in the claim construction order, that the non-pH dependent sustained release agent may also serve as the pH dependent agent. Second, plaintiffs argue that the prior order made an error in fact in finding that the patents-in-suit support two, rather than one, comparator.

1 Civil Local Rule 7-9 permits a party to move for reconsideration of any interlocutory order
2 upon receiving leave from the Court. Under the Rule, to bring such a motion, the moving party
3 must show: (1) “[t]hat at the time of the motion for leave, a material difference in fact or law exists
4 from that which was presented to the Court before entry of the interlocutory order for which
5 reconsideration is sought”; (2) “[t]he emergence of new material facts or a change of law occurring
6 after the time of such order”; or (3) “[a] manifest failure by the Court to consider material facts or
7 dispositive legal arguments which were presented to the Court before such interlocutory order.”
8 Civ. L. R. 7-9(b). A party who repeats written or oral arguments in support or opposition to the
9 interlocutory order subject to reconsideration may be exposed to sanctions. Civ. L. R. 7-9(c). The
10 Court granted plaintiff leave to move for reconsideration, and permitted defendants to file a
11 response to the motion, which they have.

12 The prior order addressed the first issue plaintiffs now raise in the motion seeking leave to
13 file. First, the Court recognized defendant Watson’s position that “the Court’s construction should
14 clarify that the sustained release agent cannot also serve as the third component ... in a given
15 formulation.” Order, at 8. After reviewing Watson’s arguments, the Court turned to Shire’s
16 position:

17 Shire disagrees. It asserts that a given agent may indeed meet both criteria, and serve
18 different functions, depending on the relative amount and location of it within the
19 composition. It again notes that certain agents (including carraegeenan, sodium
20 caboxymethyl cellulose, and alginic acid) are listed in the ’599 patent specification as
21 suitable for both functions. Shire thus reiterates its position that the properties of
22 each agent must be evaluated once the composition is formulated. That somewhat
23 attenuated explanation lacks intrinsic support. While some specified agents may be
24 suitable for both roles in theory, there is no suggestion in the patent itself that a given
25 agent may play both roles within a single iteration of the claimed composition.
26 Furthermore, the plain language of the claim, requiring the second component to be
27 “non-pH dependent” and the third to be “pH dependent,” strongly suggests the patent
28 claims two distinct agents, rather than one agent serving two roles. This conclusion is
further buttressed by the overall structure and syntax of claim 1. Accordingly,
consistent with the Delaware district court’s determination of this issue, defendants’
urged limitation will be adopted.

Order, at 8-9. In other words, Shire seeks to re-litigate an issue already adjudicated, in violation of
Local Rule 7-9. As to that argument, plaintiffs’ motion for leave to file a motion for reconsideration
is denied.

1 Second, plaintiffs maintain the Court misapprehended the data disclosed in Tables 1 and 2 of
2 the specification of U.S. Patent No. 6,287,599. Here, the issue under consideration was whether or
3 not the claim limitations “pH dependent agent that increases the rate of release of said at least one
4 pharmaceutically active agent from the tablet at a pH in excess of 5.5,” and “agent that increases the
5 solubility of said at least one pharmaceutically active agent at a pH of greater than 5.5,” could meet
6 the plaintiffs’ proposed second comparator, that is, “as compared to when the composition is
7 formulated without the pH-dependent agent.” As the Court correctly noted, Table 1 contains no
8 dissolution data. Plaintiffs maintain the Court failed to consider Tables 1 and 2 together, as Table 2
9 does provide dissolution data. Defendants do not appear to disagree that Table 2 provides
10 dissolution data, and the Court so recognized at the time. It remains unclear, however, what
11 conclusion flows from that observation. Defendants insist that if the Court were to accept plaintiffs’
12 suggestion that the interrelation between the data is significant, then *both* comparators, rather than
13 one or the other (as plaintiffs urge), must be met. Plaintiffs failed to address that issue adequately in
14 the initial round of *Markman* briefing, and still have not explained why their position necessarily
15 follows from the data found in the specification. The motion is therefore denied in its entirety.

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17 IT IS SO ORDERED.

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19 Dated: 10/9/12



RICHARD SEEBORG
UNITED STATES DISTRICT JUDGE

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