NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

ROCHE PALO ALTO LLC, GILEAD PALO ALTO, INC. and GILEAD SCIENCES, INC.	:	
Plaintiffs,	:	
v.	:	**CIVIL ACTION NO. 10-3561(ES)**
LUPIN PHARMACEUTICALS, INC. and LUPIN LTD.,	:	**OPINION**
Defendants.	:	

SALAS, District Judge.

This matter is before the Court by way of an application for claims construction by Plaintiffs Roche Palo Alto LLC ("Roche") and Gilead Palo Alto, Inc. and Gilead Sciences, Inc. ("Gilead") (collectively "Plaintiffs") and Defendants Lupin Pharmaceuticals, Inc. and Lupin Ltd. (collectively "Lupin" or "Defendants"). (Docket Entry Nos. 74, 82, 83, & 84). The parties seek the Court's interpretation of the following disputed terms: (1) "pH-dependent binder"; (2) "pH-independent binder"; (3) "binder", (4) "admixture"; (5) "variant and exercised-induced angina"; and (6) "fillers." The Court held a *Markman* hearing on January 19, 2012, and has considered the parties' written and oral arguments. The Court sets forth herein its construction of the disputed claim terms.

I. INTRODUCTION

This is a Hatch-Waxman Act patent action in which each of the following patents-in-suit are directed to sustained release ranolazine medications for the treatment of angina—U.S. Patent Nos. 6,303,607 ("the '607 patent"); 6,479,496 ("the '496 patent"); 6,503,911 ("the '911 patent");

6,525,057 ("the '057 patent"); 6,562,826 ("the '826 patent"); 6,617,328 ("the '328 patent"); 6,620,814 ("the '814 patent"); 6,852,724 ("the '724 patent"); 6,864,258 ("the '258 patent"); 6,369,062 ("the '062 patent") (collectively "the patents-in-suit"). Plaintiffs assert, among other things, that Lupin has infringed the '607 patent (Claim 1), the '496 patent (Claims 1-3 and 5-10), the '911 patent (Claims 1-4), the '057 patent (Claims 1-9), the '826 patent (Claims 1-6, 8, and 10-22), the '328 patent (Claims 1-10 and 16-33), the '814 patent (Claims 1-7, 9, and 11-23), the '724 patent (Claims 1-2, 5-6, and 12-14), and the '258 (Claims 1-4, 6-13, 18-24, and 28-30) patent by filing an Abbreviated New Drug Application ("ANDA") and seeking to commercially market Lupin's ANDA Products prior to the expiration of the patents-in-suit. Lupin argues that the asserted claims of the patents-in-suit are invalid and/or not infringed.

For purposes of most of the terms in dispute, Claim 1 of the '607 Patent is illustrative.

> A method for treating a human patient suffering from **variant or exercise-induced angina** by administering a sustained release pharmaceutical dosage form including at least 50% by weight ranolazine and an **admixture** of at least one **pH-dependent binder** and at least one **pH-independent binder** wherein the pharmaceutical dosage form is administered in no more than two tablets per dose to the human patient to maintain ranolazine plasma levels in the human patient of from about 550 to about 7500 ng base/mL for at least 24 hours wherein the dose is administered at a frequency selected from the group consisting of once, twice or three times over 24 hours and wherein the peak to trough plasma ranolazine level does not exceed 3:1 over a 24 hour period.

See, '607 Patent, Cl. 1 (emphasis added to terms in dispute).

II. LEGAL STANDARD

A court's analysis of a patent infringement claim is two-fold. *Tate Access Floors, Inc. v. Interface Architectural Resources, Inc.*, 279 F.3d 1357, 1365 (Fed. Cir. 2002). The court must first define the meaning and scope of the patent claims as a matter of law. *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 978 (Fed. Cir. 1995) (en banc), *aff'd*, 517 U.S. 370 (1996). The

court then engages in a comparison of the claims as construed to the alleged infringing product (or method). *Tate,* 279 F.3d at 1365. At this stage, the Court must only engage in the first step.

Claim construction is a matter of law to be determined solely by the court. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005), *cert. denied*, 546 U.S. 1170 (2006). "It is a bedrock principle of patent law that the claims of a patent define the invention to which the patentee is entitled the right to exclude." *Id*. (quotations omitted). In construing the terms of a patent, a court should look first to the language of the claim itself. *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996). The terms in the claim "are generally given their ordinary and customary meaning."[1] *Id.* at 1582. "[T]he ordinary and customary meaning of a claim term is the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention, *i.e.*, as of the effective filing date of the patent application." *Phillips*, 415 F.3d at 1313. A court "must look at the ordinary meaning in the context of the written description and the prosecution history." *Medrad, Inc. v. MRI Devices Corp.*, 401 F.3d 1313, 1319 (Fed. Cir. 2005). The court should turn to "those sources available to the public that show what a person of skill in the art would have understood disputed claim language to mean." *Innova/Pure Water, Inc. v. Safari Water Filtration Sys., Inc.*, 381 F.3d 1111, 1116 (Fed. Cir. 2004).

To this end, the court should first examine the intrinsic record—the patent itself, including the claims, the specification, and the prosecution history. *Vitronics*, 90 F.3d at 1582 (citing *Markman*, 52 F.3d at 979). The specification "acts as a dictionary when it expressly

[1] There are two situations in which the court must enter a definition different from the ordinary and customary meaning: (1) where the "patentee has chosen to be his or her own lexicographer by clearly setting forth an explicit definition for a claim term," *Johnson Worldwide Assocs., Inc. v. Zebco Corp.*, 175 F.3d 985, 990 (Fed. Cir. 1999) (citing *In re Paulsen*, 30 F.3d 1475, 1480 (Fed. Cir. 1994)), and (2) where "the term or terms chosen by the patentee so deprive the claim of clarity that there is no means by which the scope of the claim may be ascertained from the language used." *Id.* (citing *Eastman Kodak Co. v. Goodyear Tire & Rubber Co.*, 114 F.3d 1547, 1554 (Fed. Cir. 1997)).

defines terms used in the claims or when it defines terms by implication." *Id.* Indeed, the Federal Circuit explains that the specification is " 'usually . . . dispositive . . . [and] the single best guide the meaning of a disputed term.' " *Phillips,* 415 F.3d at 1315 (quoting *Vitronics,* 90 F.3d at 1582). It is "entirely appropriate for a court, when conducting claim construction, to rely heavily on the written description for guidance as to the meaning of the claims." *Id.* at 1317. The specification is also an important guide in claims construction as it may contain "an intentional disclaimer, or disavowal, of claim scope by the inventor." *Id.* at 1316.

Additionally, the court should consult the patent's prosecution history as it "provides evidence of how the [Patent and Trademark Office, ("PTO")] and the inventor understood the patent." *Id.* The prosecution history is the complete record of the proceedings before the PTO and includes the prior art cited by the patentee during examination of the patent. *Id.* at 1317. Moreover, the prosecution history "can often inform the meaning of the claim language by demonstrating how the inventor understood the invention and whether the inventor limited the invention in the course of prosecution, making the claim scope narrower than it would otherwise be." *Id.* Indeed, the Federal Circuit has repeatedly emphasized the need to consult the prosecution history to "exclude any interpretation that was disclaimed during prosecution." *Chimie v. PPG Indus.,* 402 F.3d 1371, 1384 (Fed. Cir. 2005).

A district court may also examine extrinsic evidence—that is "all evidence external to the patent and prosecution history." *Markman,* 52 F.3d at 980; *Phillips,* 415 F.3d at 1317-18 (stating that the Federal Circuit "ha[s] authorized district courts to rely on extrinsic evidence"). Such evidence consists of testimony by the inventor or by experts, dictionaries, and treatises. *Markman,* 52 F.3d at 980. In particular, a court may find reference to technical dictionaries useful "in determining the meaning of particular terminology." *Phillips,* 415 F.3d at 1318.

However, extrinsic evidence is generally thought less reliable than the patent and prosecution history, *id.* at 1318-19; in essence, it is "less significant than the intrinsic record in determining the legally operative meaning of claim language." *C.R. Bard, Inc. v. U.S. Surgical Corp.*, 388 F.3d 858, 862 (Fed. Cir. 2004) (quotation omitted).

III. LEGAL DISCUSSION

First, the Court will address Lupin's contention that the general limitation of "sustained release formulations that possess both a pH-dependent and pH-independent binder in admixture" (hereinafter referred to as "the pHd-pHi binder limitation") must be applied to all claim terms of the patents-in-suit. The Court will then address each of the following specific terms: (1) "pH-dependent binder"; (2) "pH-independent binder"; (3) "binder"; (4) "admixture"; (5) "variant and exercised-induced angina"; and (6) "fillers."

a. "The pHd-pHi Binder Limitation"

Defendant argues that the specifications and prosecution histories of the patents-in-suit restrict all claims to "sustained release formulations that possess both a pH-dependent and pH-independent binder in admixture." (Lupin's Opening Claim Construction Brief ("Lupin Opening Br.") at 6-11). In other words, Lupin argues that the pHd-pHi binder limitation must be read into each and every claim of the patents in suit regardless of whether or not that exact language appears in a particular claim. Plaintiffs argue that while some claims expressly require the pHd-pHi binder limitation,[2] it is improper to use the Applicants' statements during the prosecutions of the '607, '062, and '496 patents regarding these claims to restrict the scope of the claims of the patents that do not expressly impose such a limitation, namely the '826, '328, '814, '724, and '258 patents. (Pl.'s Responsive Claim Construction Br. ("Pl.'s Responding Br.") at 17).

[2] The following patents expressly recite the pHd-pHi binder limitation: '607, '062, '911, and '057.

The Court begins its analysis by looking to the "actual words of the claim." *Becton, Dickinson and Co. v. Tyco Healthcare Group, LP*, 616 F.3d 1249, 1254 (Fed. Cir. 2010). Here, as stated above, although some of the claims of the patents-in-suit expressly recite the pHd-pHi binder limitation, others do not contain such a limitation. Therefore, the actual claim language does not support Lupin's proposed general limitation for each and every claim.[3]

Having not identified the proposed general limitation in the claim language itself, the Court moves to the specification "for guidance as to the meaning of the claims." *Phillips,* 415 F.3d at 1317 (quoting *Vitronics,* 90 F.3d at 1582). The specification is "usually . . . dispositive . . . [and] the single best guide to the meaning of a disputed term" and it may contain "an intentional disclaimer, or disavowal, of claim scope by the inventor." *Id.* at 1315-16. Here, Lupin concedes that all of the patents-in-suit "share a substantially similar specification" and cites only the '607 specification in support of its general limitation argument. (Lupin Opening Br. at 2). Lupin does not, however, direct the Court to any language in any of the specifications where the inventors restrict all claims to "sustained release formulations that possess both a pH-dependent and pH-independent binder in admixture." Moreover, the Court's own review of the '607 specification does not reveal the pHd-pHi binder limitation. In fact, (1) the Summary of the Invention does not refer to a pH-independent binder, (2) the specification teaches that pH-independent binders are not necessary, but rather that they are optional (*see, e.g.* '607 patent at 4:56-57: "pH-independent binders **may be used** in sustained release ranolazine oral dosage forms")(emphasis added), and (3) the preferred embodiments list pH-independent binders as

[3] In fact, the Court finds that Lupin conceded all arguments pertaining the actual claim language when it identified the only issues before the Court with respect to the proposed general limitation as being "[w]hether the specification and prosecution history limits the scope of Asserted Patents to the only types of sustained release formulations that Roche represented to the PTO would work and were inventive, namely: those formulations with both a pH-dependent and pH-independent binder admixed together (where the latter ingredient also is not in the coating)." (Lupin's Opening Br. at 2).

optional excipients. (*see, e.g., id*. at 5:45-49 stating that "[t]he sustained release formulation may also contain pharmaceutical excipients intimately admixed with the ranolazine and the pH-dependent binder. Pharmaceutically acceptable excipients **may include**, for example, pH-independent binders or film-forming agents.")(emphasis added). For these reasons, the Court finds that the specifications of the patents-in-suit do not support Lupin's proposed general limitation.

Finally, the Court turns to the prosecution histories of the patents-in-suit to determine whether they contain statements that narrow the scope of the claims. *Phillips*, 415 F.3d at 1317.[4] Under the doctrine of prosecution disclaimer, a patentee may limit the meaning of a claim term by making a clear and unmistakable disavowal of scope during prosecution. *See Seachange Int'l, Inc. v. C-COR Inc.*, 413 F.3d 1361, 1372-73 (Fed. Cir. 2005); *see also Omega Eng'g, Inc. v. Raytek Corp*., 334 F.3d 1314, 1323-26 (Fed. Cir. 2003). This may occur, for example, when the patentee explicitly characterizes an aspect of his invention in a specific manner to overcome prior art. *See Microsoft Corp. v. Multi-Tech Sys., Inc.*, 357 F.3d 1340, 1349 (Fed. Cir. 2004) (interpreting "sending," "transmitting," and "receiving" limitations as requiring direct transmission over telephone line when patentee stated that invention transmits over a standard telephone line, thus disclaiming transmission over a packet-switched network). That said, a patentee's statements must be "both so clear as to show reasonable clarity and deliberateness, and so unmistakable as to be unambiguous evidence of disclaimer." *Omega Eng'g*, 334 F.3d at 1325 (internal citations omitted).

[4] Here, it bears noting that "[b]ecause the prosecution history represents an ongoing negotiation between the PTO and the applicant, rather than the final product of that negotiation, it often lacks the clarity of the specification and thus is less useful for claim construction purposes." *Phillips*, 415 F.3d at 1317.

As a general rule, the prosecution of one claim term in a parent application–here, the '607 patent–will not limit different claim language in a continuation application. *Invitrogen Corp. v. Clontech Labs., Inc.*, 429 F.3d 1052, 1078 (Fed. Cir. 2005) ("[T]he prosecution of one claim term in a parent application will generally not limit different claim language in a continuation application."); *ResQNet.com, Inc. v. Lansa, Inc.*, 346 F.3d 1374, 1383 (Fed. Cir. 2003) ("Although a parent patent's prosecution history may inform the claim construction of its descendent . . . prosecution history is irrelevant to the meaning of [a] limitation [if] the two patents do not share the same claim language."); *Advanced Cardiovascular Sys., Inc. v. Medtronic, Inc.*, 265 F.3d 1294, 1305–06 (Fed. Cir. 2001) (finding prosecution history of parent patents to be irrelevant where "there are no common claims in dispute"); *see also Alloc, Inc. v. Int'l Trade Comm'n*, 342 F.3d 1361, 1381 (Fed. Cir. 2003) (Schall, J., dissenting) ("Statements . . . made during the prosecution of a parent application can only apply to continuation applications if the parent and child patents contain the same claim limitations."); *Serrano v. Telular Corp.*, 111 F.3d 1578, 1584 (Fed. Cir. 1997) (stating that "[t]he patentee's statement concerning whether the prior art discloses a 'send' signal means is relevant only to those claims which require the generation of such a signal, and those claims are not asserted here" and reasoning that "[a]lthough statements in a file history may of course be used to explain and potentially limit the meaning of claim limitations, . . . [they] cannot be used to add an entirely new limitation to the claim"); *Ventana Medical Systems, Inc. v. Biogenex Laboratories, Inc.*, 473 F.3d 1173, 1182 (the court examines a patent's prosecution history to "determine whether the inventor disclaimed a particular interpretation of a claim term during the prosecution of the patent in suit or . . . of an ancestor application. But the doctrine of prosecution disclaimer generally does not apply when the claim term in the descendant patent uses different language.").

An exception to this general rule applies where "an amendment to a related limitation in the parent application distinguishes prior art and thereby specifically disclaims a later, though differently worded, limitation in the continuation application." *Invitrogen Corp.*, 429 F.3d at 1078 citing *Elkay Mfg. Co. v. EBCO Mfg. Co.*, 192 F.3d 973, 978-79 (Fed. Cir. 1999).

With this standard in mind, the Court will address the statements made during the prosecutions of the '607, '062, and '496 patents which Lupin argues limit the scope of the claims of the '826, '328, '814, '724, and '258 patents. The Court will address first the '607 patent prosecution history and then turn to the prosecution history of the later filed continuing applications, namely the '062 and '496 patent applications.

i. Prosecution history of the '607

Lupin asks this Court to refer to the prosecution history of the '607 patent when construing claims in later filed patents, namely the '496, '826, '328, '814, '724, and '258 patents. As stated above, the general rule is that that "[a]lthough a parent patent's prosecution history may inform the claim construction of its descendent . . . prosecution history is irrelevant to the meaning of [a] limitation [if] the two patents do not share the same claim language." *ResQNet.com, Inc.*, 346 F.3d at 1383.

Here, certain claims in certain patents in suit contain the pHd-pHi binder limitation language, while others do not. In short, not all of the patents in suit share the same claim language. Thus, the prosecution history of the '607 patent as it pertains to the pHd-pHi binder limitation language is immaterial to the Court's construction of the later filed patents to the extent that the later filed patents do not contain the pHd-pHi binder limitation language. *Id.* The Court declines to apply the prosecution history of the '607 patent to the claim construction of the

descendant patents absent a showing that the '607 patent and the particular descendant at issue share the same claim language.

The Court also rejects Lupin's argument that Plaintiffs restricted the scope of the patents in suit to those that include a pH-independent and pH-dependent binder in admixture when they distinguished the '607 patent over the prior art references of *Dow* and *MacFarlane*. Specifically, Lupin argues that once a Patentee represents to the PTO that an invention is different from the prior art because of a particular novel and essential feature, then every claim of the patent is limited to the scope of that particular novel and essential feature. (*See* Jan. 19, 2012 Hr'ing Trans. ("Hr'ing Tr.") at pp. 111-114). Moreover, the Patentee cannot overcome that limitation in later prosecutions unless the Patentee explicitly recants the limitation. (*See* Hr'ing Tr. at pp. 111-114).

"[The Federal Circuit] recognizes an exception [to the general rule articulated above] where an amendment to a related limitation in the parent application distinguishes prior art and thereby specifically disclaims a later (though differently worded) limitation in the continuation application." *Invitrogen Corp.*, 429 F.3d at 1078 citing *Elkay Mfg. Co.*, 192 F.3d at 978-79. Here, Plaintiffs agree that if they had represented to the PTO during the prosecution of the '607 patent that their invention as a whole required the pHd-pHi binder limitation, then all claims would require said limitation. (*See* Hr'ing Tran. p. 139). However, Plaintiffs argue that the prosecution history reveals that they did not make such a representation. The Court agrees.

In response to the PTO's office action during the prosecution of the '607 patent application, Plaintiffs distinguished the claimed inventions recited in claim 51 and 52 (which later matured into Claims 1 and 2 of the '607 patent) from the pharmaceutical compositions described in *Dow* and *MacFarlane*. Specifically, the Plaintiffs stated:

> Dow does not describe or suggest the methods of claims 51-52 that use a sustained release ranolazine dosage form that includes an admixture of a pH-independent binder and a pH-dependent binder with ranolazine. More precisely, Dow does not disclose a sustained release formulation [sic] having a pH-dependent binder. The Examiner, in rejecting the pending claims acknowledged that Dow does not disclose pH-dependent binders.
>
> The MacFarlane reference does not provide the teaching missing from Dow et al. namely a sustained release formulation including a pH-dependent binder in combination with an admixture with a pH-independent binder. The MacFarlane reference teaches against using pH-independent materials as binders in pharmaceutical dosage forms as claims 51-52 require.

(Shear Decl. in Support of Pl.'s Opening Br. ("Shear Decl.") at Exh. 13: April 6, 2001 Response to October 13, 2000 Office Action at pp. 12-13). The plain language of these statements demonstrates that they were limited to how Claims 51 and 52—and not the invention as a whole—are distinguishable from *Dow* and *MacFarlane*. Even so, to obtain the '607 Patent, Plaintiffs retracted all of the other claims that they sought during the initial application, but reserved the right to pursue those claims in subsequent applications. This squares with Federal Circuit precedent which permits patentees to broaden the claims of parent applications through the filing of a subsequent application. *See, e.g., Symbol Technologies, Inc. v. Lemelson Medical, Education & Research Found.*, 422 F.3d 1378, 1385 (Fed. Cir. 2005) ("Commonly, and justifiably, one might refile an application to add subject matter in order to attempt to support broader claims as the development of an invention progresses.").

Therefore, not only were Plaintiffs representations to the Examiner directed at the particular language of claims 51 and 52 of the application which specifically contain the pHd-pHi binder limitation—and not the invention as a whole—but Plaintiffs abandoned their pursuit of the additional claims—thus clearly indicating to the Examiner that these arguments were not directed at the retracted proposed claims. As such, the Court finds that the doctrine of prosecution disclaimer does not attach by way of the '607 patent prosecution history.

ii. Prosecution history of the later filed continuing applications

The Court now turns to Lupin's prosecution disclaimer arguments as they relate the '062 and '496 patent applications.

The '062 Prosecution History: From the outset, the Court notes that the '062 patent was prosecuted simultaneously with the '607 patent (*see* Pl.'s Responsive Br. at p. 6 fn.6) and specifically requires the pHd-pHi binder limitation. (*See* '607 Patent, Cl. 1, *supra*¸at p. 2). During the prosecution of the '062 patent application, the Examiner rejected the proposed claims based on *Dow* and *MacFarlane*. In response, Plaintiffs distinguished the claimed inventions from the pharmaceutical compositions described in *Dow* and *MacFarlane* in the following ways. With respect to *Dow,* Plaintiffs explained that

> Dow et al. does not describe or suggest the Applicants invention - - a sustained release ranolazine dosage form that includes an admixture of a pH-independent binder and a pH-dependent binder with ranolazine . . .

(Marx Decl. in Support of Lupin's Opening Br. ("Marx Decl.") at LA 127). And with respect to *MacFarlane,* Plaintiffs stated that

> MacFarlane is fairly understood by one of ordinary skill in the art to disclose sustained release formulations that are prohibited from including pH-independent material that is used as a binder in an admixture with a pH-dependent binder but allows for the use of a pH-independent material as a coating for the dosage form.

(*Id*. at LA 128). Plaintiffs argued to the examiner that the proposed claims of the '062 patent—claims that specifically require the admixed pHd-pHi binder limitation—were patentable over the prior art references—*Dow* and *MacFarlane*—specifically because they required the pHd-pHi binder limitation. (*See, id.,* Oct. 12, 2000 Resp. to July 31, 2000 Office Action (LA119-LA124) at pp. 1-2 (amended claim 31 and new claim 51); *see also,* Mar. 8, 2001 Resp. to Dec. 6, 2000 Office Action (LA125-LA131) at p. 1 (amended claim 31); *see also* Walsh Decl. in Support of Pl.'s Resp. Br. at Exh. 26: Appl. No. 09/538,337 at pp. 42-44 (original claims 31-50)).

Plaintiffs' arguments were tailored specifically to these particular claims. As such, the Court finds that the doctrine of prosecution disclaimer does not attach by way of the '062 patent prosecution history.

The '496 Prosecution History: Despite the fact that none of the claims of the '496 patent expressly require a ranolazine dosage form containing an admixed pHd-pHi binder, Lupin argues that by distinguishing *Dow* during the prosecution of the '496 patent the Plaintiffs restricted the scope of the claimed invention to one which requires a pHd-pHi binder limitation. There are three components to Defendants argument. First, Lupin contends that Plaintiffs distinguished the claimed invention over the Dow prior art by stating that Dow did "not teach any composition that would be capable of achieving the claimed method." (Marx Decl. at LA 173). Second, Lupin contends that Plaintiffs represented to the PTO that the '496 patent teaches only one formulation–"Formulation D"–that is capable of maintaining blood plasma levels necessary for effective treatment in humans. (*See*, '496 pat. at col. 10, l. 20 – col. 16, l. 21; *see also*, Marx Decl. LA 166-6). And, third, "Formulation D" only works because it "includes a pH-independent binder in admixture with a pH-dependent binder." (Marx Decl. at LA 155). In short, Lupin contends that to achieve patentability over *Dow* during the prosecution of the '496 patent, Plaintiffs argued that their invention only worked because it included the pHd-pHi binder limitation. Even assuming that this characterization is accurate, Lupin's argument fails because "a court may not read into a claim a limitation from a preferred embodiment, if that limitation is not present in the claim itself." *BayerAG v. Biovail Corp.*, 279 F.3d 1340, 1348 (Fed. Cir. 2002) ("While a court may look to the specification and prosecution history to interpret what a patentee meant by a word or phrase in a claim, extraneous limitations cannot be read into the claims from the specification or prosecution history.")(internal citations omitted). Here, because Lupin

concedes that the pHd-pHi binder limitation is not present in the claim itself, the Court cannot read that limitation from the preferred embodiment, here "Formulation D," into the claim.

To the extent that Lupin argues that the Applicants' representations to the Examiner during the prosecution of the '496 patent regarding *MacFarlane* qualify as disclaimer, the Court disagrees. The applicants represented to the Examiner that the *MacFarlane* reference is not pertinent to the '496 patent because *MacFarlane* discloses pharmaceutical compositions including calcium channel blockers whereas the '496 claims are neither directed to pharmaceutical compositions nor does ranolazine behave as a calcium channel blocker in the treatment of angina. (Pl.'s Responding Br. 14). Plaintiffs told the PTO office that they were not relying on pHd-pHi binder limitation to distinguish the *MacFarlane* reference as the *MacFarlane* reference was utterly unrelated to the teachings of the '496 patent. (*Id.*). In the context of the entire prosecution history, Plaintiffs statements regarding *MacFarlane* fall far short of the specificity required by the standard. *See, e.g.*, *Omega Eng'g*, at 1325 (a patentee's statements must be "both so clear as to show reasonable clarity and deliberateness, and so unmistakable as to be unambiguous evidence of disclaimer."). As such, the Court finds that the doctrine of prosecution disclaimer does not attach by way of the '496 patent prosecution history.

In sum, the Court will not construe claims that do not specifically recite the pHd-pHi binder limitation to include such a limitation because such a construction is not recited in the claim language, is not supported by the specification, and the doctrine of prosecution disclaimer does not attach.

b. Specific Terms in Dispute

The Court will now address each of the specific terms in dispute in turn, namely (1) "pH-dependent binder"; (2) "pH-independent binder"; (3) "binder", (4) "admixture"; (5) "variant and exercised-induced angina"; and (6) "fillers."

i. pH-dependent binder [5]

The Court now turns the first disputed term: "pH-dependent binder". Plaintiff proposes "a binding material that affects the rate of release of ranolazine from a solid oral dosage form into an aqueous environment based on the pH of that environment," (Joint Claim Construction Statement ("JCC"), Exh. B. at p. 14) whereas Lupin proposes "a 'binder' [i.e., a non-coating pharmaceutical ingredient that serves to prevent rapid dissolution of the drug in a pharmaceutical formulation] that affects the rate of release of ranolazine from a solid oral dosage form into an aqueous environment based on the pH of that environment." (Id.). Here, based on a side-by-side comparison of the competing constructions, the parties agree that a pH-dependent binder "affects the rate of release of ranolazine." Therefore, the Court need only determine whether either or both of Lupin's additional restrictions must be applied, namely (1) "a non-coating pharmaceutical ingredient" and (2) "that serves to prevent rapid dissolution."

The Court begins by looking at the claim language itself. *Vitronics Corp.*, 90 F.3d at 1582. For these purposes, Claim 2 of the '258 patent is illustrative.

> The method of claim 1 wherein the sustained release dosage form includes at least one pH dependent binder wherein the pH dependent binder inhibits the release of ranolazine from the sustain release dosage from when the sustained release dosage form is subjected to an aqueous environment having a pH of the stomach and wherein the pH dependent binder promotes the release of a therapeutic amount of ranolazine in an aqueous solution having a pH above about 4.5

[5] The following patent claims recite "pH-dependent binder": '607 patent, Cl. 1; '911 patent, Cls. 1, 3; '057 patent, Cls. 1, 8, 9; '826 patent, Cls. 16, 18; '328 patent, Cls. 1, 5, 6, 20; '814 patent, Cls. 17, 19; '724 patent, Cl. 12; '258 patent, Cls. 2, 3, 8, 9, 11, 12.

See '258 Patent, Claim 2. Nothing in the actual claim language suggests that the term pH-dependent binder should be restricted to "a non-coating pharmaceutical ingredient that serves to prevent rapid dissolution of the drug in a pharmaceutical formulation."[6] Therefore, the Court must determine whether the specification and prosecution history support Lupin's proposed construction. Again, the parties' proposed constructions share common language, namely "that affects the rate of release of ranolazine from a solid oral dosage form into an aqueous environment based on the pH of that environment" and, therefore, the Court need only address Lupin's two additional limitations. For ease of analysis, the Court will address these additional limitations separately.

1. "a non-coating pharmaceutical ingredient"

To reiterate, the claim language does not suggest that pH-dependent binders are limited to "non-coating pharmaceutical ingredient[s]." Therefore, the Court turns to the specification for assistance. *Phillips*, 415 F.3d at 1317. The specification provides examples of both pH-dependent binders and pH-independent binders that also function as coating agents. (*See, e.g.*. '607 Patent at 4:25-34)("Accordingly, the pH-dependent binders suitable for use in this invention are those which inhibit rapid release of drug from a tablet during its residence in the stomach (where the pH is-below about 4.5), and which promotes the release of a therapeutic amount of ranolazine from the dosage form in the lower gastrointestinal tract (where the pH is generally greater than about 4.5). Many materials known in the pharmaceutical art as 'enteric' binders and coating agents have the desired pH dissolution properties."). Thus, the specification suggests the opposite of what Lupin's proposed construction commands, namely that an ingredient used as a pH-dependent binder may also be used as a coating agent. For this reason, Lupin's construction

[6] The parties agree that a pH-dependent binder "affects the rate of release of ranolazine."

which would necessarily limit an ingredient used in the coating from functioning as a binder is not supported by the specification.

Accordingly, because neither the claim language, nor the specification support limiting pH-dependent binders to "non-coating pharmaceutical ingredients" the Court will not adopt this element of Lupin's proposed construction.[7]

2. "that serves to prevent rapid dissolution"

Again, because the claim language does not suggest that pH-dependent binders must "serve[] to prevent rapid dissolution," the Court turns to the specification "for guidance as to the meaning of the claims." *Phillips*, 415 F.3d at 1317 (quoting *Vitronics*, 90 F.3d at 1582). Here, the specification provides that although pH-dependent binders inhibit rapid release in the stomach (where there is a low pH) they ***increase release*** rates in the gastrointestinal tract (where there is a high pH). *See* '607 4:19-25 and '826 patent at 4:43-49. In other words, Lupin's proposed construction is in direct conflict with the specification language which teaches that in a specific environment—here, the gastrointestinal tract—pH-dependent binders promote rapid dissolution. Therefore, the Court finds that the specification does not support Lupin's construction as it pertains to "rapid dissolution." Accordingly, because neither the claim language, nor the specification support limiting pH-dependent binders to those that "serve[] to prevent rapid dissolution", the Court will not adopt this element of Lupin's proposed construction.[8]

[7] Because neither party references the prosecution history with respect to this proposed limitation on "pH-dependent binder," the Court will end its inquiry here.

[8] Because neither party references the prosecution history with respect to this proposed limitation on "pH-dependent binder", the Court will end its inquiry here.

Having failed to find support for either element of Lupin's proposed construction, the Court adopts Plaintiffs' proposed construction.

ii. pH-independent binder[9]

The Court now turns the second disputed term: "pH-independent binder." At oral argument, Plaintiff proposed "a binding material that allows drug release at a rate independent of pH"[10] whereas Lupin proposes "a separate 'binder' [i.e., a non-coating pharmaceutical ingredient that serves to prevent rapid dissolution of the drug in a pharmaceutical formulation] ingredient that provides drug release at a rate independent of pH." (JCC, Exh. B at p. 12). For these purposes, Claim 1 of the '607 patent is illustrative.

> A method for treating a human patient suffering from variant or exercise-induced angina by administering a sustained release pharmaceutical dosage form including at least 50% by weight ranolazine and an admixture of at least one pH-dependent binder and at least one **pH-independent binder** wherein the pharmaceutical dosage form is administered in no more than two tablets per dose to the human patient to maintain ranolazine plasma levels in the human patient of from about 550 to about 7500 ng base/mL for at least 24 hours wherein the dose is administered at a frequency selected from the group consisting of once, twice or three times over 24 hours and wherein the peak to trough plasma ranolazine level does not exceed 3:1 over a 24 hour period.

'607 Patent, Claim 1. The actual claim language does not suggest that the term pH-independent binder should be restricted to "a non-coating pharmaceutical ingredient that serves to prevent rapid dissolution of the drug in a pharmaceutical formulation."[11] Therefore, the Court must

[9] The following patent claims recite "pH-independent binder": '607 patent, Cl. 1; '911 patent, Cl. 1; '057 patent, Cl. 1; '826 patent, Cls. 16, 18; '328 patent, Cls. 10, 20; '814 patent, Cls. 17, 19; '724 patent, Cl. 13; '258 patent, Cl. 13.

[10] Plaintiffs originally proposed the following construction: "a binding material that does not affect the rate of release of ranolazine from a solid oral dosage form into an aqueous environment based on the pH of that environment." However, at oral argument, Plaintiffs proposed the above referenced "compromise." The Court, therefore, finds that Plaintiffs have withdrawn their original proposed construction.

[11] A comparison of the competing construction reveals common language, namely "at a rate independent of pH." Therefore, because the parties agree to this piece of the construction, the Court need not examine it any further.

determine whether the specification and prosecution history support Lupin's proposed construction.

The parties' proposed constructions share substantially common language, namely "provides drug release at a rate independent of pH"[12] and, therefore, the Court need only address Lupin's two additional limitations. For ease of analysis, the Court will address each element of Lupin's proposed construction separately.

1. "a non-coating pharmaceutical ingredient"

To repeat, the claim language does not suggest that pH-independent binders are limited to "non-coating pharmaceutical ingredient[s]." The Court now turns the specification which teaches that certain ingredients can potentially serve as binders and as coating materials. The '607 patent specifically teaches that hydroxypropyl methylcellulose ("HPMC") is an example of a pH-independent binder (*see*, '607 patent 5:48-50)[13] that can also be used as an "optional film-forming agent" for coating the resulting ranolazine tablet. (*Id*. at 6:31-40). Thus, the specification suggests the opposite of what Lupin's proposed construction commands, namely that an ingredient used as a pH-independent binder may also be used as a coating agent. For this reason, Lupin's construction which would necessarily limit an ingredient used in the coating from functioning as a binder is not supported by the specification.

[12] The Court notes that the only difference between these portions of the parties' proposed constructions is that Plaintiffs' proposal replaces "provides" with "allows." At oral argument, Lupin did not specifically object to this portion of the proposed construction. Moreover, Lupin did not seek to submit supplement argument regarding this proposed construction. Because the parties have not identified an appreciable difference between "provides" and "allows" the Court interprets these portions of the parties' proposed constructions to be identical.

[13] Although the cited language identifies HPMC as a pH-independent binder, certain portions of the intrinsic record refer to HPMC as a pH-dependent binder. *See, e.g.,* '607 patent, 5:57-63 ("It is to be noted that **pH-dependent binders** and viscosity enhancing agents **such as hydroxypropyl methylcellulose** . . .."). However, despite this apparent inconsistency, for the purposes of this opinion, the Court will accept the parties' representations that HPMC is a pH-independent binder. *See, e.g.*, Pl.'s Resp. Br. at pp. 17, 20, 21, and 23; *see also*, Lupin's Opening Br. at pp. 17, 18, and 27; *see* also, Hr'ing Tr. at p. 9, lns. 9-14).

Moreover, if the Court were to apply Lupin's construction, then HPMC—which the specifications explicitly identify as an optional pH-independent binder suitable for use in the sustained release ranolazine dosage forms[14]—would not meet the "pH-independent binder" limitation simply because it may also be used as a coating agent. In other words, accepting Lupin's construction would improperly exclude a preferred embodiment. *In re Katz Interactive Call Processing Patent Litig.*, 639 F.3d 1303, 1324 (Fed. Cir. 2011) (A claim construction that excludes a preferred embodiment is rarely correct.); *Chimie v. PPG Indus., Inc.*, 402 F.3d 1371, 1377 (Fed. Cir. 2005).

Having not found support for Lupin's construction in either the claim language or the specification, the Court now turns to the prosecution history. Here, Lupin relies on the doctrine of prosecution disclaimer (*See, infra.*, Section III. a.) and directs the Court to the following statement as "a clear and unmistakable disavowal" of claim scope: "The pH-independent material used in the Applicant's invention is used as a binder and not as a coating." (Shear Decl. at Exh. 13: April 6, 2001 Response to October 13, 2000 Office Action at p. 14). When considered in isolation, this statement seems to support Lupin's argument. However, when considering the full statement in concert with the specification's teaching that a single ingredient can serve as both a binder and as a coating material, this statement does not rise to level of a "a clear and unmistakable disavowal" of claim scope limiting pH-independent binders to "non-coating pharmaceutical materials." The full passage states:

> MacFarlane is fairly understood by one of ordinary skill in the art to disclose sustained release formulations that are prohibited from including pH-independent material that is used as a binder in an admixture with a pH-dependent binder but allows for the use of a pH-independent material as a coating for the dosage form. New claims 51 and 52 are all drawn to a method for treating angina that includes the use of pharmaceutical dosage forms that include an admixture of a pH-

[14] *See*, '607 patent at 4:59.

> independent binder and a pH-dependent binder. The pH-independent material used in the claimed compounds is used as a binder and not as a coating. Contrary to the teachings of MacFarlane et al., the Applicants have found that sustained release formulations that include an admixture of a pH-independent binder and pH-dependent binder in the bulk formulation provides good ranolazine dissolution control.

(Marx Decl.'607 Patent Response to Oct. 13, 2000 Office Action)(emphasis added). In other words, the prosecution history reveals that the Applicants argued to the Examiner that the *MacFarlane* reference teaches that pH-independent material may be used as a coating, but does not teach that it can be used as binding material. When read in conjunction with the specification, which, as stated above, teaches that the same pharmaceutical material may be used as both a binder and a coating, the Applicant's statement to the Examiner can reasonably be interpreted to argue that the invention at bar is patentable over the MacFarlane reference because is teaches that pH-independent material can be in both a binder and a coating whereas MacFarlane teaches that pH-independent material is only effective as a coating. *See Elkay Mfg. Co. v. Ebco Mfg. Co.*,192 F.3d 973 (Fed. Cir. 1999) ("it is the totality of the prosecution history that must be assessed, not the individual segments of the presentation made to the Patent and Trademark Office by the applicant"). As such, the Court finds that this statement does not rise to a level of a "a clear and unmistakable disavowal" of claim scope.

Accordingly, because the claim language, the specification, and the prosecution history do not support limiting pH-independent binders to "non-coating pharmaceutical ingredients" the Court will not adopt this element of Lupin's proposed construction.[15]

[15] To the extent that Lupin argues that the material cited by Plaintiffs is not in fact used as a binder but rather is used as a coating said argument is more appropriate for the merits phase rather than the claim construction phase.

2. "that serves to prevent rapid dissolution"

The Court finds that the specification does not support Lupin's proposed construction that pH-independent binders "serve[] to prevent rapid dissolution." This limitation does not appear in the actual claim language and, in fact, the specification teaches that pH-independent binders do not prevent dissolution. (*See* '607 patent at 4:47-63; '826 patent at 5:17-23) (pH-independent binders "do not themselves provide the required dissolution control provided by the identified pH-dependent binders."). Accordingly, because the claim language and the specification do not support limiting pH-independent binders to binders "that serve[] to prevent rapid dissolution" the Court will not adopt this element of Lupin's proposed construction.[16]

Having failed to find support for either element of Lupin's proposed construction, the Court adopts Plaintiffs' proposed construction.

iii. Binder

Lupin contends that the term "binder" must be construed in isolation and defined by its function within the formulation, namely a "non-coating pharmaceutical ingredient that is not merely a filler or a dilutent, but prevents rapid dissolution of the drug from the formulation." (JCC, Exh. B, p. 4). In other words, Lupin's proposed construction requires that all binders in the formulation (1) prevent rapid dissolution of the drug; and (2) exclude any ingredient that may also be used as a coating material. (Pl.s Resp. Br. 18). For the reasons stated above (*See, infra*, Sections III.b.i & ii), the Court finds that a Lupin's proposed construction of "binder" does not find support in the claim language, the specification, or the prosecution history.[17]

[16] Because neither party references the prosecution history with respect to this proposed limitation on "pH-independent binder," the Court will end its inquiry here.

[17] Lupin also argues that Plaintiffs' inclusion of "binding material" in its proposed constructions "could lead to the counterintuitive conclusion that an ingredient qualifies as a binder when that ingredient, in the context of the formulation, is not really binding anything together at all (e.g., when an ingredient is acting as a coating or a mere

iv. Admixture[18]

The Court now turns to the fourth disputed term: "admixture." Plaintiffs propose that the Court apply the plain and ordinary meaning of "admixture" whereas Lupin proposes an "[i]ntimate mixture of at least one pH-dependent binder and at least one pH-independent binder, which are coprocessed by granulation and compression in the bulk formulation during the tablet manufacturing process. Materials in the tablet coating are not in 'admixture' with materials in the tablet core." (JCC, Exh. B, pp. 14-15).

The Court looks first to the actual claim language. Here, the asserted claims reciting "admixture" do not require that the ingredients in the admixture be "coprocessed by granulation and compression in the bulk formulation during the tablet manufacturing process." Moreover, not all claims reciting "admixture" require that the admixture include "at least one pH-dependent binder and at least one pH-independent binder." (*See, e.g.*, '328 patent, Cls. 25, 27, 29, 31, 32). Nor do all claims reciting "admixture" require that the admixture be part of a tablet. (*See, e.g.*, '911 patent, Cl. 1; '057 patent, Cl. 1; '826 patent, Cls. 16, 18; '328 patent, Cls. 25, 27, 29, 31, 32; '814 patent, Cls. 17, 19).

Having failed to find support for each element of Lupin's proposed construction in the actual claim language, the Court turns to the specification and prosecution history. Lupin argues that in order to overcome the prior art *MacFarlane* reference, Plaintiffs made several statements to the Examiner that, under the doctrine of prosecution disclaimer, serve to limit the "claim scope notwithstanding the ordinary meaning of the claim language." (Lupin's Responsive Br.

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filler)." (Def. Opening Br. 21). Although Lupin's argument is well taken, this argument is not suited for claim construction, but rather for a decision on the merits.

[18] The following patent claims recite "admixture": '607 patent, Cl. 1; 911 patent, Cl. 1; '507 patent, Cl. 1; '826 patent, Cls. 16 and 18; '328 patent, Cls. 25-27, 29-32; and '814 patent, Cls. 17 and 19.

19). Specifically, Lupin argues that "during the prosecution of the '607 patent, Roche explained that while MacFarlane contained two ingredients from Roche's list of a pH-dependent binder and a pH-independent binder, the former was in the tablet core whereas the latter was in the coating." *Id*. In support of this argument, Lupin points to the following statement made by the Applicants to the Examiner.

> Contrary to the teachings of MacFarlane et al., the Applicants have found that sustained release formulations that include an admixture of a pH-independent binder and a pH-dependent binder in the bulk formulation provides a good ranolazine dissolution control.

(Shear Decl. at Exh. 13: April 6, 2000 Response to Oct. 13, 2000 Official Action at p. 14; *see also*, Mar. 8, 2001 Resp. to Dec. 6, 2000 Office Action (LA125-LA131) at 4). Lupin argues that this statement is "so clear as to show reasonable clarity and deliberateness, and so unmistakable as to be unambiguous evidence of disclaimer." *Omega Eng'g*, 334 F.3d at 1325 (internal citations omitted). Specifically, Lupin argues that Plaintiffs differentiated the claimed invention from the *MacFarlane* prior art reference by explaining that although *MacFarlane* contained two ingredients from Plaintiffs' list of pH-dependent binders and pH-independent binders–the pH-dependent binder was in the tablet core whereas the pH-independent binder was in the coating. (Lupin Opening Br. at 26).

Plaintiffs, however, argue that these statements distinguishing the claimed invention as patentable over *MacFarlane* cannot be read to redefine or disavow the plain and ordinary meaning of "admixture," but rather identify the elements of the patents in suit that are not present in the *MacFarlane* reference. In support of this contention, Plaintiffs direct the Court to the following statement made in response to the Examiner's obviousness objection in light of the *MacFarlane* and *Dow* prior art references.

> The MacFarlane reference does not provide the teaching missing from Dow et al. namely a sustained release formulation including a pH-dependent binder in

> combination with an admixture with a pH-independent binder. The MacFarlane reference teaches against using pH-independent materials as binders in pharmaceutical dosage forms as *claims 51-52* require. Because the claimed invention encompasses pharmaceutical dosage forms that MacFarlane says will not work, (the combination of a pH-dependent binder and a pH-independent binder) and because the Dow reference does not disclose the use of pH-independent materials in a pharmaceutical dosage form, the combination of MacFarlane with Dow do not render *claims 51-52* obvious.

(Shear Decl. at Exh. 13: April 6, 2001 Response to October 13, 2000 Office Action at p. 13). As previously stated in this opinion, the doctrine of prosecution disclaimer "attaches only where an application by amendment or by argument has 'unequivocally disavowed a certain meaning to obtain his patent.' " *Schindler Elevator Corp.*, 593 F.3d at 1285. At bottom, Plaintiffs argued that the proposed claimed invention encompassed teachings that *MacFarlane* said could not work and include teachings not contained in *Dow*. Although Plaintiff's argued that their claimed invention was different from the prior art, their statements—when considered in totality—do not necessarily—and certainly not unmistakably and unambiguously—disclaim the proposed invention's incorporation of the prior arts' teachings.

1. "Formulation D" & Admixture

In further support of its proposed construction, Lupin directs the Court to "Formulation D," which describes the "intimate mixing" of pH-dependent binder and pH-independent binder using a "granulation" and "compression" process, as an example of "a pH-independent binder in an admixture with a pH-independent binder." (Lupin's Opening Br. 27). Lupin contends that "Formulation D" is an exemplary process for making the claimed dosage forms and Plaintiffs concede as much. (Pl.'s Opening Br. 17).

To the extent that Lupin argues that the exemplary process articulated in "Formulation D" for making the claimed dosage form should limit the claims at issue to that specific embodiment, the Court finds such an argument contrary to law. *Phillips*, 415 F.3d at 1323

("[W]e have repeatedly warned against confining the claims to those [specific] embodiments."); *see also CollegeNet, Inc. v. ApplyYourself*, Inc., 418 F.3d 1225, 1231 (Fed. Cir. 2005) ("In examining the specification for proper context, however, this court will not at any time import limitations from the specification into the claims."); *see also SRI Int'l v. Matsushita Elec. Corp.*, 775 F.2d 1107, 1121 n.14 (Fed. Cir. 1985) ("That a specification describes only one embodiment does not require that each claim be limited to that one embodiment."). Accordingly, the Court rejects this argument.

v. "variant AND exercised-induced angina"[19]

The Court now turns the fifth disputed term: "variant and exercised-induced angina." Plaintiff proposes "a cardiovascular disease selected from variant angina and exercise induced angina" whereas Lupin proposes "both (1) variant angina; and (2) exercise-induced angina." (JCC, Exh. B, pp. 18-19). Here, Claim 1 of the '496 patent is illustrative:

> A method for treating a human patient suffering from variant and exercise-induced angina by administering a sustained release pharmaceutical dosage form including at least 50% by weight ranolazine in no more than two tablets per dose to the human patient to maintain ranolazine plasma levels in the human patient at a minimum of 850 ng base/mL for at least 24 hours wherein the dose is administered at a frequency selected from once, twice and three times over 24 hours.

('496 patent, Cl. 1.).

Plaintiffs urge this court to correct what they characterize as a clerical error. (Pl.'s Opening Br. 19). Plaintiffs cite to *CBT Flint Partners, LLC v. Return Path, Inc.*, --- F.3d ---, 2011 WL 3487023 (Fed. Cir. Aug. 10, 2011) for the proposition that "in a patent infringement suit, a district court may correct an obvious error in a patent claim." *Id.* at *4 (Fed. Cir. Aug. 10, 2011). In *Novo Indus., L.P. v. Micro Molds Corp.*, 350 F.3d 1348 (Fed. Cir. 2003), the Federal

[19] The following patent claims recite "variant and exercised-induced angina": '496 patent, Cl. 1; '826 patent, Cls. 1, 4, 6, 8, 10, 13, 15-18; '814 patent, Cls. 5, 7, 9, 11, 14, 16-19; and '724 patent, Cl. 14.

Circuit held that a District Court may correct an obvious error when "(1) the correction is not subject to reasonable debate based on consideration of the claim language and the specification and (2) the prosecution history does not suggest a different interpretation of the claims." *Id.* at 1354.

However, the Court lacks authority to correct the alleged clerical error where, as here, the error is not facially apparent, there are multiple correct interpretations, and the intrinsic evidence does not provide clear direction. In *Novo Industries L.P. v. Mocro Molds Corp*., 350 F.3d 1348 the Federal Circuit reversed the district court's attempt to "correct" claim language by construing the word "a" to mean "and." The Federal Circuit noted that when the "nature of the error is not apparent from the face of the patent," and there may be multiple correct ways of interpreting the claim language, the intrinsic evidence lacked the "necessary clarity to overcome the ambiguity of the claim." *Id*. at 1357. Since under these circumstances "the district court was required to guess as to what was intended" by the scope of the claims, correction via claim construction was "beyond its authority." *Id*. at 1358.

Here, if the term "and" in the claim language "variant and exercise-induced angina" were construed to mean that a patient must have <u>both</u> conditions, as opposed to just one or the other, the scope of covered conditions—and therefore infringing activity—will necessarily differ. Thus, here, as in *Novo*, this Court lacks the authority to modify the claim language as a "correction" of a clerical error because the intrinsic evidence does not provide the requisite clarity to apply a correction that necessarily alters the scope of the claim. As such, the Court adopts Lupin's construction.

vi. *Fillers*

Dependent Claim 14 of the '724 patent recites: "The method of claim 12 wherein said optional excipients comprise one or more of the following: **fillers**, coloring agents, flavoring agents, plasticizers, or film-forming agents." (emphasis added). Plaintiff proposes that the Court apply the plain and ordinary meaning whereas Lupin proposes "a pharmaceutical excipient that is not used as a binder." (JCC, Exh. B, p. 21). Logically, therefore, Lupin's proposed construction means, that if a particular pharmaceutical excipient is used as a binder, then it cannot be used as a filler (and vice-a-versa, an excipient used as a filler, cannot be used as a binder).

Plaintiffs' expert and Lupin's expert agree that the plain and ordinary meaning of "filler" is "an excipient that adds bulk to a tablet." (Pl.'s Resp. Br. 25, citing Chambliss Decl. at ¶ 50; Davis Decl. at ¶ 39). And, Plaintiffs argue that the plain and ordinary meaning of "fillers" is supported by the specification and argue that a person of ordinary skill in the art ("POSA") "would not exclude an agent as a 'binder' simply because it may also be used as a filler. Nor would [a POSA] exclude an agent as a 'filler' simply because it may also be used as a binder." (Pl.'s Opening Br. 25).

Lupin, on the other hand, argues that plain and ordinary meaning must be modified based on (1) the specification itself (Lupin Opening Br. at 23), (2) Plaintiffs' own statements to the FDA and the PTO (*Id*. at 23-24), and (3) Plaintiffs' failure to show that the same excipient actually performs two functions in the formulation (Lupin Resp. Br. 29). The Court will address these three arguments in turn.

1. The Specification

Lupin argues that the specification indicates that Plaintiffs consider the term "filler" to involve a different and distinct ingredient classification from "binders." (Lupin Opening Br. at 24). Plaintiffs concede that "fillers" and "binders" are distinct categories of excipients by function, but the particular ingredients can overlap by serving multiple functions within a given formulation. (Lupin Resp. Br. at 29). Lupin's argument that, in the context of the patents in suit, "fillers" are distinct from "binders" based on the ingredients lists, is overcome by Plaintiffs' identification of specific ingredients that can allegedly serve dual purposes within the same formulation.

For instance, Plaintiffs cite to Claim 14 of the '724 patent which requires that fillers–if present–be in addition to the "at least one pH-dependent binder" recited in Claim 12 of the '724 patent (but does not exclude other materials that may be used as binders from being used as fillers). Additionally, the specification lists excipients that can be used as **both** fillers (*See* '724 patent 5:50-52) and "pH-independent binders or film-forming agents." (*See* '724 patent 5:42-49).

> The sustained release formulation may also contain pharmaceutical excipients intimately admixed with the ranolazine and the pH-dependent binder. Pharmaceutically acceptable excipients may include, for example, pH-independent **binders** or film-forming agents such as hydroxypropyl methylcellulose, hydroxypropyl cellulose, methylcellulose, polyvinylpyrrolidone, neutral poly(meth)acrylate esters (e.g. the methyl methacrylate/ethyl acrylate copolymers sold under the trademark Eudragit NE by Rahm Pharmai, **starch**, gelatin, **sugars**, carboxymethylcellulose, and the like. Other useful pharmaceutical excipients include **diluents** such as **lactose**, **mannitol**, dry starch, microcrystalline cellulose and the like.

('724 patent 5:42-52)(emphasis added). Plaintiffs have offered evidence that "diluents" are synonymous with "fillers."[20] In the context of the asserted patents, the specification teaches that same ingredients—here, starches and sugars such as lactose and mannitol—can be both binders

[20] *See, Shear Decl.*, Exh. 23: REMINGTON'S (17th ed 1985) at 1605-1606; *see also, id.*, Exh. 24: PHARMACEUTICAL DOSAGE FORMS, Vol. 1 – Tablets (1980) at 72-86.

and fillers (or diluents). Therefore, because the specification teaches that sugars and starches can be both fillers and diluents, Lupin's proposed construction is directly at odds with the specification. As such, the Court finds Lupin's argument unpersuasive.

2. Statements to FDA

Because neither party cites to authority standing for the proposition that the Court may consider statements made to regulatory authorities–here, the FDA–for purposes of claim construction, the Court will not consider these statements.

3. Actual Performance of a Dual Function

Lupin does not cite to any case law supporting its contention that Plaintiff's must–at this stage–present evidence of actual performance. The Court finds that this argument is not appropriate for claim construction and in more squarely before the Court at the merits stage.

In sum, the Court finds that claim language, specification, and prosecution history do not support departing from what the parties' experts agree to be the plain and ordinary meaning of the term "filler." As such, the Court adopts Plaintiffs' proposed construction.

IV. CONCLUSION

For the aforementioned reasons, the Court construes the disputed terms of the patents-in-suit as detailed above. An appropriate Order accompanies this Opinion.

/s/ Esther Salas
United States District Judge

March 21, 2012