IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

FOREST LABORATORIES, LLC, FOREST LABORATORIES HOLDINGS, LTD., CEREXA, INC., TAKEDA PHARMACEUTICAL COMPANY LIMITED and ALLERGAN USA, INC., Plaintiffs, v. APOTEX CORP., APOTEX INC., and SANDOZ INC., Defendants.	Civil Action No. 15-018-GMS CONSOLIDATED

ORDER CONSTRUING THE TERMS OF U.S. PATENT NOS. 6,417,175 AND 8,247,400

After having considered the submissions of the parties, and hearing oral argument on the matter, IT IS HEREBY ORDERED, ADJUDGED, and DECREED that, as used in the asserted claims of U.S. Patent Nos. 6,417,175 ("the '175 patent") and 8,247,400 ("the '400 patent"):

A. The '175 patent

1. The term "**a compound of the formula**" is construed to mean "a compound within the genus defined by the formula."[1]

2. The term "**its salt or its reactive derivative; wherein each symbol has the meaning given in claim 1**" is construed to mean "or salt or reactive derivative thereof; wherein each symbol Q, R^1, and R^2 has the meaning given in claim 1."[2]

[1] After the *Markman* hearing, in accordance with the court's instructions, the parties stipulated to this construction.

[2] Defendants advocate for the construction "salt thereof or activated carbonyl derivative thereof; wherein each symbol Q, R^1, R^2, has the meaning given in claim 1." Defs.' Joint Opening Claim Construction Br. 11. The claim language, specification, and prosecution history do not support

Defendants construction. *See Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 979 (Fed. Cir. 1995), *aff'd*, 517 U.S. 370 (1996) (explaining that to ascertain the meaning of the claims, the court looks to the claims, the specification, and the prosecution history). The claim language never limits the form that reactive derivatives of the second compound in claim 14 ("compound III") can take. Additionally, the specification actually compels the opposite conclusion to the one Defendants proffer. When the specification means to refer to reactive derivatives at the carboxylic acid, it does so explicitly. U.S. Patent No. 6,417,175 col. 21 ll. 51–60 (filed June 6, 2000). It would not make sense for the term "reactive derivative" in claim 14 to be limited to one of the embodiments discussed in the specification, when other examples of reactive derivatives are also discussed in the specification. '175 patent col. 22 l. 65–col. 23 l. 37. If the patentees meant to limit the term "reactive derivative" to reactive derivatives at the carboxylic acid, they would have referred to that form explicitly as they did in the specification. Instead, they described more than one type of reactive derivative in the specification and did not limit the term in the claim 14 to any one embodiment. *See Liebel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 906 (Fed. Cir. 2004) (expounding that even when a single embodiment is described in the specification, the claims of the patent will not be read restrictively absent evidence that the patentee clearly intended that result).

Defendants also point to the prosecution history, which demonstrates that the applicants defined R^1 as a phosphono group to overcome obviousness, ambiguousness, and anticipation rejections. '175 patent prosecution history ("PH"), 5/23/2001 Office Action at 3–6. Defendants contend that the effect of Plaintiffs' definition of R^1 as a phosphono group in claim 1 was to limit the "reactive derivative" of claim 14 to only derivatives including an activated carbonyl group. *Markman* Hr'g 27:17–25. Plaintiffs do not dispute that R^1 must be a phosphono group. *Markman* Hr'g 29:1–3. Plaintiffs also do not dispute that a reactive derivative, capable of producing the compound of claim 1, could have an activated carbonyl group. *Markman* Hr'g 29:11–20. Plaintiffs reason, however, that other sites on the molecule can also be activated—the reactive derivative is not solely an activated carbonyl derivative. *Markman* Hr'g 31:14-22, Oct. 11, 2016. As Defendants point out, there are three possible reaction sites on compound III: one at R^1, one at R^2, and one at the carboxyl group. Defs.' Trial PowerPoint at 15. Defendants claim that only an activated carbonyl derivative will yield the compound of claim 1 when R^1 is a phosphono group. *Id.* While that may be true, Plaintiffs pointed out in oral argument that the reactive derivative of compound III does not necessarily have a phosphono group and multiple reaction sites on compound III can be activated at the same time. *Markman* Hr'g 30:6–8, 31:14–22. So, while the reaction may occur at the carboxyl group, that does not mean another site on the molecule is not also activated.

An analysis of the prosecution history only further supports Plaintiffs' assertion that limiting R^1 to a phosphono group during prosecution was not a clear disavowal of the broad scope of the term "reactive derivative." *See Avid Tech., Inc. v. Harmonic, Inc.*, 812 F.3d 1040, 1045 (Fed. Cir. 2016) (explaining that when the alleged disavowal is open to multiple reasonable interpretations, the court should not find prosecution disclaimer). Nothing in the prosecution history suggests that "reactive derivative" need be limited to an "activated carbonyl derivative." During prosecution, the patentees had to limit R^1 of the *claim 1 compound* to overcome an obviousness rejection by the Examiner. '175 patent PH, 1/22/2002 Response After Final Action at 8. Because claim 14 states that "each symbol has the meaning given in claim 1," R^1 of compound III must be a phosphono group. '175 patent col. 32 l. 23. Plaintiffs do not dispute that. Plaintiffs do dispute, however, the assertion that limiting R^1 in the claim 1 compound has a limiting effect on the reactive derivatives of compound III.

The first Office Action rejected claims 1–11 and 14–28 as being indefinite because the meaning of a "group convertible to a phosphono group" was unclear to the Examiner. '175 patent PH, 5/23/2001 Office Action at 3–4. The Examiner also rejected claims 1, 5–11, and 13–28 as being anticipated because a prior art reference disclosed the same compound as the '175 patent except the prior art compound had R^1 as a protected amino. *Id.* at 5–6. The '175 patent disclosed that R^1 was a phosphono group or one convertible to a phosphono group. *Id.* The Examiner explained that ordinary protecting groups can be removed and then replaced with a phosphono, rendering the claims anticipated. *Id.* Lastly, the Examiner

3. The term "**the compound shown in claim 1**" is construed to mean "a compound within the genus defined by the formula shown in claim 1."[3]

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rejected all the claims as obvious because a prior art reference disclosed the same phosphono groups that are recited in claim 3 of the '175 patent. *Id.* at 6.

To overcome the Examiner's indefiniteness rejection, the applicants modified the definition of R^1 by removing "a group convertible to a phosphono group" and adding "phosphono, dialkoxy-phophoryl, O-alkyl-phosphono, diaminiophosphoryl (amino)(hydroxyl)phosphoryl, (alkoxy)(morpholineo)phoryl or dihalophosphoryl." '175 patent PH, 10/09/2001 Response After First Office Action at 17. To overcome the Examiner's anticipation rejection, the applicants argued that the phosphono derivatives set forth in the amended form of claim 1 were not among the protecting groups disclosed in the citing reference. *Id.* at 18. Lastly, applicants submitted a declaration proving the superiority of a compound of the present invention over a compound where R^1 is NH_2, as taught by the prior art reference. *Id.* at 19.

In the final Office Action, the Examiner maintained that claims 1, 4, 9-11, 14, 17, 21, and 25-28 were obvious because, while the declaration "established unexpected results arising from the use of the phospho group, it did not establish unexpected results for the parts of the claims that covered "esters, the amide, an esterimide and the acide dihalide." '175 patent PH, 11/28/2001 Final Office Action at 2. The applicants defeated the obviousness rejection by limiting R^1 to a phosphono group in claim 1 and removing esters from claims 1, 12, 13 and 14. '175 patent PH, 01/22/2002 Response After Final Office Action at 8. It is worth noting that esters were removed from claim 14, but that impacted the first compound in claim 14, not the second compound (compound III). *Id.* at 7. The phrase "followed by converting R^1 to a phosphono group was also removed from claim 14," but that still did not have an effect on the term "reactive derivative." *Id.*

As is clear from the prosecution history, the form the reactive derivative could take was never limited or impacted by changing the definition of R^1 in compound 1. While compound III—depicted in claim 14—must have a phosphono group attached to NH due to the language of the claim, reactive derivatives of compound III are not so constrained. The reactive derivative in claim 14 can take any number of the forms disclosed in the specification, including forms where the group attached to the NH group is not a phosphono group. The specification discloses an R^0 attached to the NH group, where R^0 is an esterfied phosphono group. The specification also discloses an $R^{0\alpha}$ attached to the NH group that is defined as a dihalophosphoryl group. All that matters is that the resulting compound from the reactions of the two compounds in claim 14 has a phosphono group attached to the NH. Therefore, Defendants are incorrect in their assertion that scientifically, and legally, the only form the reactive derivative can take is one where only the carbonyl group is activated. The court will not unnecessarily limit the reactive derivatives of compound III to activated carbonyl derivatives when such a construction is not supported by the claims, the specification, or the prosecution history.

[3] After the *Markman* hearing, in accordance with the court's instructions, the parties stipulated to this construction.

4. The term "**the compound of claim 4**" is construed to mean "a compound within the genus defined by the formula shown in claim 4."[4]

5. The preamble "**a method for treating a bacterial infection**" is construed to be limiting.[5]

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[4] After the *Markman* hearing, in accordance with the court's instructions, the parties stipulated to this construction.

[5] It is well established that the preamble generally does not limit the claims. *Allen Eng'g Corp. v. Bartell Indus., Inc.*, 299 F.3d 1336, 1346 (Fed. Cir. 2002). A preamble simply stating "the intended use or purpose of the invention will usually not limit the scope of the claim." *Boehringer Ingelheim Vetmedica, Inc. v. Schering-Plough Corp.*, 320 F.3d 1339, 1345 (Fed. Cir. 2003). A preamble will limit a claim, however, if it recites the essence of the invention—the aspect of the invention that makes it more than just an academic exercise. *Id.* Another exception to the general rule against construing preambles as limiting occurs when the preamble provides antecedent basis for the ensuring claim terms. *Id.* When a term in a preamble provides antecedent basis that is indicative of the patentee's intention to rely on both the preamble and the body of the claim to define the scope of the invention. *Catalina Mktg. Int'l, Inc. v. Coolsavings.com, Inc.*, 289 F.3d 801, 808 (Fed. Cir. 2002). Antecedent basis occurs when a term in the preamble is essential to understanding the limitation or term in the body of the claim. *Id.*

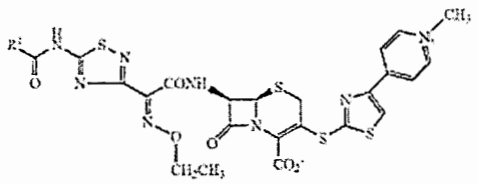
Defendants maintain that "a method for treating a bacterial infection" is merely a statement of intended outcome. Defs.' Claim Construction Answering Br. 3. Defendants analogize the preamble language at issue here to the preamble at issue in *Bristol-Myers Squibb Co. v. Ben Venue Labs., Inc.*, 246 F.3d 1368 (Fed. Cir. 2001). *Id.* In *Bristol-Myers*, the Federal Circuit found no error in the district court's interpretation of the phrase "for reducing hematologic toxicity" as non-limiting. *Id.* at 1375. The Federal Circuit found that the steps of the claimed infusion method are performed the same way regardless of whether there is a reduction in hematologic toxicity. *Id.* The preamble did not alter or explain the meaning of the term "effective amount," found in the body of the claim.

The court finds Defendants' assertion unpersuasive. Similar to Judge Andrews' analysis in *Sanofi v. Lupin Atlantis Holdings S.A.*, 2016 WL 5842327, at *2 (D. Del. Oct. 3, 2016), the court finds *Bristol-Myers* inapposite. In *Bristol-Myers*, the preamble did not provide antecedent basis for any terms in the body of the claims. *Bristol-Myers*, 246 F.3d at 1375. The body of the claim provided the definition for "an antineoplastically effective amount" because the dosage requirements outlined in the claims were described as antineoplastically effective in the specification. *Id.* The claims at issue here do not provide a definition for "effective amount" in the body of the claim. Instead, "effective amount" derives its meaning from the preamble, just as the same term derived its meaning from the preamble in *Sanofi*. *See Sanofi*, 2016 WL 5842327, at *2 (holding that the preamble provides antecedent basis for effective amount because the meaning of the term could not be discerned when reading the claim without the preamble).

To determine if the preamble provides antecedent basis for a term in the body of the claim, it is helpful, as Judge Andrews pointed out, to read the body of the claim without it. *Id.* at *3. When the court reads the body of the claims at issue without the preamble, it is left with the same question Judge Andrews was left with in *Sanofi*: effective for what? *See id.* While Claim 5 in the '175 patent does state that the "effective amount" of the compound is given to a "patient suffering from the bacterial infection," that does not necessarily mean that the amount of the compound must be effective in treating that bacterial infection. *See* '175 patent, col. 31 ll. 13–15. Instead the amount of the compound administered to a patient could be effective in preventing the infection or in remedying side-effects of the infection. Because the meaning of effective amount is unclear without the preamble, the preamble is construed as limiting.

B. The '400 patent

1. The term "**(6R, 7R)-7-[[(2Z)-2-(ethoxyimino)-2-[5-(acetamido)-1,2,4-thiadiazole-3-yl]acetyl]amino]-3-[[4-(1-methylpyridium-4-yl)-1,3-thiazole-2-yl]sulfanyl]-8-oxo-5-thia-1-azabicyclo[4.4.0]oct-2-ene-2-carboxylate**" is construed to mean "Compound A" or[6]



$R^1 = CH_3$

2. The term "**up to about**" is construed to mean "contains an amount of (6R, 7R)-7-[[(2Z)-2-(ethoxyimino)-2-[5-(acetamido)-1,2,4-thiadiazol-3-yl]amino]-3-[[4-(1-methylpyridinium-4-yl)-1,3-thiazole-2-yl]sulfanyl]-8-oxo-5-thialazabicyclo[4.2.0]oct-2-ene-2-carboxylate not over [for Claim 6] 10 mg (plus/minus 20%) [for Claim 7] 5mg (plus/minus 20%) [for Claim 8] 2.5mg (plus/minus 20%) [for Claim 9] 1 mg (plus/minus 20%)."[7]

Dated: November 8, 2016

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[6] After the *Markman* hearing, in accordance with the court's instructions, the parties stipulated to this construction.

[7] After the *Markman* hearing, in accordance with the court's instructions, the parties stipulated to this construction. The court adopts the agreed upon construction without prejudice to any indefiniteness challenge that Defendants decide to make with regard to this term.