

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK**

Kowa Company, Ltd., et al.,

Plaintiffs,

v.

Aurobindo Pharma Limited et al.,

Defendants.

Civil Action No. 14-CV-2497 (PAC)

Kowa Company, Ltd., et al.,

Plaintiffs,

v.

Amneal Pharmaceuticals LLC,

Defendant.

Civil Action No. 14-CV-2758 (PAC)

Kowa Company, Ltd., et al.,

Plaintiffs,

v.

Mylan Inc., et al.,

Defendants.

Civil Action No. 14-CV-2647 (PAC)

Kowa Company, Ltd., et al.,

Plaintiffs,

v.

Orient Pharma Co., Ltd.,

Defendant.

Civil Action No. 14-CV-2759 (PAC)

<p>Kowa Company, Ltd., et al.,</p> <p style="text-align: center;">Plaintiffs,</p> <p style="text-align: center;">v.</p> <p>Zydus Pharmaceuticals (USA) Inc., et al.,</p> <p style="text-align: center;">Defendants.</p>	<p>Civil Action No. 14-CV-2760 (PAC)</p>
<p>Kowa Company, Ltd., et al.,</p> <p style="text-align: center;">Plaintiffs,</p> <p style="text-align: center;">v.</p> <p>Sawai USA, Inc., et al.,</p> <p style="text-align: center;">Defendants.</p>	<p>Civil Action No. 14-CV-5575 (PAC)</p>

JOINT DISPUTED CLAIM TERMS CHART

Pursuant to the Civil Case Management Plan and Scheduling Order entered by the Court on October 17, 2014, Plaintiffs Kowa Company, Ltd., Kowa Pharmaceuticals America, Inc. and Nissan Chemical Industries, Ltd. (collectively “Plaintiffs”) and Defendants/Counterclaim-Plaintiffs Amneal Pharmaceuticals LLC (“Amneal”), Apotex Inc. and Apotex Corp. (“Apotex”), Aurobindo Pharma Limited and Aurobindo Pharma USA Inc. (collectively, “Aurobindo”), Mylan Pharmaceuticals Inc. and Mylan Inc. (collectively, “Mylan”), Orient Pharma Co., Ltd. (“Orient”), Sawai USA, Inc. and Sawai Pharmaceutical Co., Ltd. (“Sawai”), Zydus Pharmaceuticals (USA) Inc. and Cadila Healthcare Ltd. (dba Zydus Cadila) (“Zydus”) (collectively, “Defendants”)¹ hereby provide the Court with the below chart, which identifies the

¹ The Apotex case caption is not included in these papers because no Markman issues are in dispute in that case.

parties' proposed constructions of the disputed claim terms of U.S. Patent Nos. 5,856,336 and 6,465,477^{2,3}.

Plaintiffs' Position

Plaintiffs do not believe that Defendants have identified any claim terms as to which claim construction is necessary or appropriate at this time. To the extent the Court believes that claim construction as to those claim terms is necessary and appropriate at this time, Plaintiffs have included herein their view as to the more appropriate construction as to these terms. Plaintiffs reserve the right to supplement and/or amend these proposed constructions.

Defendants' Position

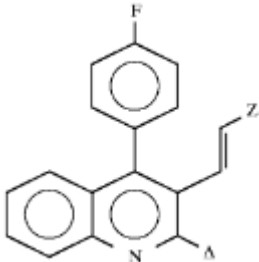
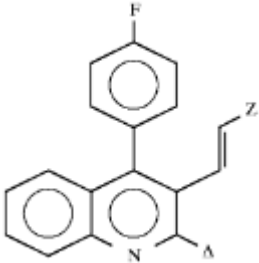
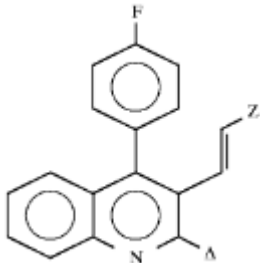
Defendants have identified two claim terms from two of the three asserted patents they believe require construction. The first claim term is from the '336 patent and the second claim term is from the '477 patent. Defendants disagree with Plaintiffs that construction of these terms is unnecessary since Defendants believe construction of these terms will likely bear on their respective invalidity and/or non-infringement positions in the case. Thus, Defendants believe that construing these terms is necessary and appropriate at this time. Defendants reserve the right to supplement and/or amend their proposed constructions of all the potentially disputed claim terms as necessary and appropriate, including in response to any actual construction of the potentially disputed claim terms that Plaintiffs may decide to offer. Defendants further reserve

² U.S. Patent No. 6,465,477 ("the '477 patent") is not at issue in the related cases involving Amneal and Aurobindo. Thus, Amneal and Aurobindo take no position on potentially disputed claim terms with respect to the '477 patent. Furthermore, the Defendants do not believe any terms of U.S. Patent No. 8,557,993 B2 require construction.

³ Pursuant to the Order entered by the Court on October 17, 2014, that the *Markman* hearing will not include indefiniteness, Defendants reserve their rights to raise indefiniteness arguments with respect to the patents-in-suit during the course of this litigation.

the right to object to Plaintiffs' proposed constructions based on, *inter alia*, the timetable for submission of the same.

U.S. Patent No. 5,856,336

Claim Term [applicable claims]	Plaintiffs' Position	Defendants' Proposed Construction
<p>“A compound of the formula,</p>  <p>Z=—CH(OH)—CH₂—CH(OH)— CH₂—COO.^{1/2}Ca.”</p> <p>[claim 1]</p>	<p>No construction necessary, but to the extent the Court finds any construction necessary:</p> <p>“A compound having the following structure:</p>  <p>Z=—CH(OH)—CH₂— CH(OH)—CH₂—COO. ^{1/2}Ca.</p>	<p>“A genus including each optical isomer of the formula</p>  <p>Z=—CH(OH)—CH₂—CH(OH) —CH₂—COO.^{1/2}Ca. and all mixtures thereof.”</p>

U.S. Patent No. 6,465,477

Claim Term [applicable claims]	Plaintiffs' Position	Defendants' Proposed Construction
<p>“an aqueous solution or dispersion of the pharmaceutical composition has pH of from 6.8 to 7.8”</p> <p>[claim 1]</p>	<p>No construction necessary, but to the extent the Court finds any construction necessary, the term “pH” :</p> <p>‘indicates the pH value to be determined in such a manner that a unit dose of a solid preparation comprising NK-104 or its salt or ester is sampled and dissolved or dispersed in from 1 to 10 ml of pure water, and the pH of the resulting aqueous solution or dispersion is measured.’ (See ‘477 patent, Col. 2, ll 56-61)</p>	<p>“A unit dose of a solid preparation of the pharmaceutical composition has pH from 6.8 to 7.8 when dissolved or dispersed in 1 to 10 mL of pure water”</p>

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