

**UNITED STATES DISTRICT COURT  
DISTRICT OF NEW JERSEY**

RAYNER SURGICAL INC. and RAYNER  
INTRAOCULAR LENSES LTD.,

Plaintiffs,

v.

SOMERSET THERAPEUTICS, LLC,

Defendant.

C.A. No. 3:24-cv-09017 (GC)(JBD)

(Filed electronically)

**AMENDED JOINT CLAIM CONSTRUCTION AND PRE-HEARING STATEMENT  
PURSUANT TO L. PAT. R. 4.3**

Plaintiffs Rayner Surgical Inc. and Rayner Intraocular Lenses Ltd. (collectively, “Plaintiffs” or “Rayner”) and Defendant Somerset Therapeutics, LLC (“Defendant” or “Somerset”) hereby submit their Amended Joint Claim Construction and Pre-hearing Statement concerning U.S. Patent Nos. 9,066,856 (“the ’856 Patent”), 9,486,406 (“the ’406 Patent”), and 9,855,246 (“the ’246 Patent”), which supersedes their previous Joint Claim Construction and Pre-Hearing Statement (D.I. 76) filed in accordance with the Court’s December 23, 2024 Pretrial Scheduling Order (D.I. 32), February 24, 2025 Amended Scheduling Order (D.I. 54), and Local Patent Rule 4.3.

**I. Background**

This case arises out of Somerset’s filing of an Abbreviated New Drug Application (“ANDA”) with the U.S. Food and Drug Administration (“FDA”) seeking approval to market a generic version of Rayner’s OMIDRIA® Product. Plaintiffs allege, among other things, that Somerset’s submission of its ANDA to FDA constitutes infringement of claims 1, 3–9, and 11–16 of the ’856 Patent, claims 1–6 and 8–13 of the ’406 Patent, and claims 1–3 and 6–7 of the ’246

Patent (collectively, the “Asserted Claims”) under 35 U.S.C. § 273(e)(2). Somerset alleges, among other things, that the Asserted Claims are invalid and/or not infringed.

Pursuant to Local Patent Rules 4.2(a)–(b), on April 14, 2025, the parties exchanged preliminary claim constructions and identified intrinsic and extrinsic evidence in support of their proposed preliminary constructions. Pursuant to Local Patent Rule 4.2(c), on April 28, 2025, the parties identified intrinsic and extrinsic evidence that each party intends to rely on to oppose any other party’s proposed preliminary constructions. Pursuant to Local Patent Rule 4.2(d), the parties met and conferred on May 12, 2025 for purposes of narrowing the issues and preparing the Joint Claim Construction and Pre-hearing Statement.

## **II. Construction of Claim Terms on Which the Parties Agree (L.P.R. 4.3(a))**

Pursuant to Local Patent Rule 4.3(a), the parties’ agreed upon constructions are as follows:

<b>Term for Construction</b>	<b>Claims In Which Term Appears</b>	<b>Parties’ Agreed Construction</b>
stable	’856 Patent (claims 1, 4, 9, 12) ’406 Patent (claims 1, 2, 4, 6, 9) ’246 Patent (claims 1, 3)	“a liquid pharmaceutical formulation that, at the end of a specified storage period of time, contains less than 5% total related substances”

## **III. Proposed Constructions of Dispute Claim Terms (L.P.R. 4.3(b))**

Pursuant to Local Patent Rule 4.3(b), the parties’ proposed constructions for the disputed claim terms are as follows:

<b>Term for Construction</b>	<b>Claims In Which Term Appears</b>	<b>Plaintiffs’ Proposed Construction</b>	<b>Defendant’s Proposed Construction</b>
“ketorolac”	’856 Patent (claims 1, 6–9, 14–16) ’406 Patent (claims 1–2, 6, 12–13) ’246 Patent (claims 1, 6)	ketorolac in a salt form	ketorolac in a salt form, such as ketorolac tromethamine

<b>Term for Construction</b>	<b>Claims In Which Term Appears</b>	<b>Plaintiffs' Proposed Construction</b>	<b>Defendant's Proposed Construction</b>
"phenylephrine"	'856 Patent (claims 1, 6–9, 14–16) '406 Patent (claims 1–2, 6, 12–13) '246 Patent (claims 1, 6)	phenylephrine in a salt form	phenylephrine in a salt form, such as phenylephrine hydrochloride
"buffer system"	'856 Patent (claims 1, 9) '406 Patent (claims 1–2, 6) '246 Patent (claim 1)	components of a solution that resist changes in pH	A solution including a mixture of a weak acid and its conjugate base, or a weak base and its conjugate acid
"phenylephrine, ketorolac, and a buffer system"	'856 Patent (claims 1, 9) '406 Patent (claims 1–2, 6) '246 Patent (claim 1)	As this term is merely a combination of the terms above, Plaintiffs incorporate their proposed constructions of the constituent terms from above:  phenylephrine in a salt form, ketorolac in a salt form, and components of a solution that resist changes in pH	A formulation with at least three separate components: (1) phenylephrine, (2) ketorolac, and (3) a buffer system.

As required by Local Patent Rule 4.3(b), Exhibit A contains Plaintiffs' proposed constructions for the disputed claim terms and identifies the intrinsic and extrinsic evidence on which Plaintiffs intend to rely on to support their proposed constructions and/or to oppose Defendant's proposed constructions. To the extent Defendant introduces additional intrinsic and extrinsic evidence during the briefing, Plaintiffs reserve the right to rely on additional intrinsic and extrinsic evidence, including expert testimony, to rebut any additional evidence relied upon by Defendant.

As required by Local Patent Rule 4.3(b), Exhibit B contains Defendant's construction for the disputed claim terms and identifies intrinsic and extrinsic evidence on which Defendant intends

to rely on to support its proposed constructions and/or oppose Plaintiffs' proposed constructions.<sup>1</sup>

To the extent Plaintiffs introduce additional intrinsic and extrinsic evidence during the briefing, Defendant reserves the right to rely on additional intrinsic and extrinsic evidence, including expert testimony, to rebut any additional evidence relied upon by Plaintiffs.

#### **IV. Significant or Case Dispositive Claim Terms (L.P.R. 4.3(c))**

Local Patent Rule 4.3(c) requires the parties to identify the terms whose construction will be most significant to the resolution of the case and any disputed terms whose construction will be case or claim dispositive or substantially conducive to promoting settlement.

Plaintiffs do not believe that construction of any disputed claim term will be case or claim dispositive or substantially conducive to promoting settlement.

Defendant believes that construction of the combined term, "phenylephrine, ketorolac, and a buffer system," will be the most significant to the resolution of the case and is likely case dispositive.

#### **V. Anticipated Time Needed for Claim Construction Hearing (L.P.R. 4.3(d))**

The parties estimate that the Claim Construction Hearing will require approximately two and a half hours, divided equally between Plaintiffs and Defendant.

#### **VI. Identification of Witnesses for Claim Construction Hearing (L.P.R. 4.3(e))**

The parties do not anticipate calling witnesses to the Claim Construction Hearing at this time.

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<sup>1</sup> At Defendant's request, Plaintiffs are arranging for the production of emails (and attachments) exchanged between counsel for the parties to the previous Omidria® ANDA litigations concerning the claim construction proposals in those litigations. Defendant reserve the right to amend their disclosure after Plaintiffs produce such material.

Dated: June 11, 2025

/s/ Katherine A. Escanlar

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# EXHIBIT A

***Rayner Surgical Inc. et al. v. Somerset Therapeutics, LLC***  
**Civil Action No. 3:24-cv-9017(GC)(JBD) (D.N.J.)**  
**Exhibit A: Plaintiffs' Proposed Constructions and Evidence**

<b>Term Identified for Construction</b>	<b>Claims In Which Term Appears</b>	<b>Plaintiffs' Proposed Construction</b>	<b>Evidence That May Be Used To Support Plaintiffs' Construction and/or Oppose Defendants' Construction</b>
"ketorolac"	'856 Patent (claims 1, 6–9, 14–16) '406 Patent (claims 1–2, 6, 12–13) '246 Patent (claims 1, 6)	ketorolac in a salt form	<b>Intrinsic Evidence:</b>  The '856 Patent: <ul style="list-style-type: none"> <li>• Abstract</li> <li>• 2:60–3:3</li> <li>• 4:5–12</li> <li>• 4:47–56</li> <li>• 7:60–64</li> <li>• 8:45–50</li> <li>• 8:52–63</li> <li>• 9:4–6</li> <li>• 10:25–35</li> <li>• 10:45–48</li> <li>• 10:49–64</li> <li>• 11:64–12:8</li> <li>• 11:9–11</li> <li>• Table 1</li> <li>• Table 2</li> <li>• 11:54–61</li> <li>• 12:65–13:5</li> <li>• 13:60–64</li> <li>• Claim 6</li> <li>• Claim 7</li> <li>• Claim 8</li> <li>• Claim 14</li> <li>• Claim 15</li> </ul>

Term Identified for Construction	Claims In Which Term Appears	Plaintiffs' Proposed Construction	Evidence That May Be Used To Support Plaintiffs' Construction and/or Oppose Defendants' Construction
			<ul style="list-style-type: none"> <li>• Claim 16</li> </ul> <p>The '406 Patent:</p> <ul style="list-style-type: none"> <li>• Abstract</li> <li>• 2:62–3:7</li> <li>• 4:9–16</li> <li>• 4:17–29</li> <li>• 4:53–62</li> <li>• 5:4–13</li> <li>• 8:4–7</li> <li>• 8:11–30</li> <li>• 8:63–9:8</li> <li>• 10:36–47</li> <li>• 10:56–60</li> <li>• 11:1–7</li> <li>• 12:1–12</li> <li>• Table 1</li> <li>• Table 2</li> <li>• 13:1–10</li> <li>• 13:11–22</li> <li>• 13:33–46</li> <li>• Claim 12</li> <li>• Claim 13</li> </ul> <p>The '246 Patent:</p> <ul style="list-style-type: none"> <li>• Abstract</li> <li>• 2:64–3:9</li> <li>• 4:11–18</li> <li>• 4:19–30</li> <li>• 4:53–62</li> </ul>



Term Identified for Construction	Claims In Which Term Appears	Plaintiffs' Proposed Construction	Evidence That May Be Used To Support Plaintiffs' Construction and/or Oppose Defendants' Construction
			<ul style="list-style-type: none"> <li>• 5:4–13</li> <li>• 8:4–7</li> <li>• 8:11–29</li> <li>• 8:62–9:7</li> <li>• 10:35–46</li> <li>• 10:55–59</li> <li>• 10:67–11:9</li> <li>• 11:15–24</li> <li>• Table 1</li> <li>• Table 2</li> <li>• 12:1–11</li> <li>• 12:12–23</li> <li>• 13:4–10</li> <li>• 13:64–14:1</li> <li>• 16:40–51</li> <li>• 19:8–15</li> <li>• Claim 6</li> <li>• Claim 9</li> </ul> <p>'406 Patent Prosecution History</p> <ul style="list-style-type: none"> <li>• RAY-0006459–6462 (Brandl, et al., <i>Racemization of Ketorolac in Aqueous Solution</i>, 85 J. Pharm. Sci. 1045 (1995))</li> </ul> <p><b>Extrinsic Evidence:</b></p> <ul style="list-style-type: none"> <li>• SOMERSET_OMI_0000129–146</li> <li>• SOMERSET_OMI_0000471–477</li> </ul>

Term Identified for Construction	Claims In Which Term Appears	Plaintiffs' Proposed Construction	Evidence That May Be Used To Support Plaintiffs' Construction and/or Oppose Defendants' Construction
			<p>As further support for their construction, Plaintiffs may also rely on the testimony of Dr. Cory Berkland on one or more of the following subjects: the definition of a person of ordinary skill in the art ("POSA") and how a POSA would understand this term. Dr. Berkland may also respond to opinions rendered by Somerset's expert(s).</p> <p>Although Plaintiffs disagree that the correspondence between the parties and the litigation filings in <i>Omeros Corp. v. Par Sterile Products, LLC</i>, C.A. 15-773 (D. Del) or <i>Omeros Corp. v. Sandoz Inc.</i>, C.A. No. 17-799 (D. Del) are relevant to claim construction in this matter, insofar as Defendant has identified such litigation materials as extrinsic evidence that it may use to support its constructions, Plaintiffs reserve the right to use the same documents—including OMEROS-LUPIN-LITIGATION-000001–418 and Plaintiffs' Statement of Issues of Fact that Remain to Be Litigated, <i>Omeros v. Par</i>, D.I.-181-1—to support Plaintiffs' construction or oppose Defendant's construction.</p> <p>Plaintiffs reserve the right to rely on additional intrinsic and extrinsic evidence, including expert testimony, to rebut any intrinsic or extrinsic evidence relied upon by Somerset in support of its claim construction, pursuant to Local Patent Rule 4.2 (c). Plaintiffs also reserve the right to amend or supplement this preliminary construction and supporting references in connection with the Joint Claim Construction and Prehearing Statement required by Local Patent Rule 4.3. Plaintiffs also reserve the right to amend or supplement this preliminary construction and supporting</p>

Term Identified for Construction	Claims In Which Term Appears	Plaintiffs' Proposed Construction	Evidence That May Be Used To Support Plaintiffs' Construction and/or Oppose Defendants' Construction
			references based on conferral with Somerset or as otherwise appropriate under the Local Patent Rules.
"phenylephrine"	'856 Patent (claims 1, 6–9, 14–16) '406 Patent (claims 1–2, 6, 12–13) '246 Patent (claims 1, 6)	phenylephrine in a salt form	<b>Intrinsic Evidence:</b>  The '856 Patent: <ul style="list-style-type: none"> <li>• Abstract</li> <li>• 2:11–23</li> <li>• 4:5–12</li> <li>• 4:47–56</li> <li>• 7:65–67</li> <li>• 8:45–50</li> <li>• 8:65–9:2</li> <li>• 9:4–6</li> <li>• 10:25–35</li> <li>• 10:45–48</li> <li>• 10:49–64</li> <li>• 11:54–61</li> <li>• 11:64–12:8</li> <li>• 11:9–11</li> <li>• Table 1</li> <li>• Table 2</li> <li>• 12:65–13:5</li> <li>• 13:60–64</li> <li>• Claim 6</li> <li>• Claim 7</li> <li>• Claim 8</li> <li>• Claim 14</li> <li>• Claim 15</li> <li>• Claim 16</li> </ul>

Term Identified for Construction	Claims In Which Term Appears	Plaintiffs' Proposed Construction	Evidence That May Be Used To Support Plaintiffs' Construction and/or Oppose Defendants' Construction
			<p>The '406 Patent:</p> <ul style="list-style-type: none"> <li>• Abstract</li> <li>• 2:13–25</li> <li>• 4:9–16</li> <li>• 4:17–29</li> <li>• 4:53–62</li> <li>• 5:4–13</li> <li>• 8:8–10</li> <li>• 8:57–62</li> <li>• 9:10–14</li> <li>• 10:36–47</li> <li>• 10:56–60</li> <li>• 11:1–7</li> <li>• 12:1–12</li> <li>• Table 1</li> <li>• Table 2</li> <li>• 13:1–10</li> <li>• 13:11–22</li> <li>• 13:33–46</li> <li>• Claim 12</li> <li>• Claim 13</li> </ul> <p>The '246 Patent:</p> <ul style="list-style-type: none"> <li>• Abstract</li> <li>• 2:15–27</li> <li>• 4:11–18</li> <li>• 4:19–30</li> <li>• 4:53–62</li> <li>• 5:4–13</li> <li>• 8:8–10</li> </ul>

Term Identified for Construction	Claims In Which Term Appears	Plaintiffs' Proposed Construction	Evidence That May Be Used To Support Plaintiffs' Construction and/or Oppose Defendants' Construction
			<ul style="list-style-type: none"> <li>• 8:56–61</li> <li>• 9:8–13</li> <li>• 10:35–46</li> <li>• 10:55–59</li> <li>• 10:67–11:9</li> <li>• 11:15–24</li> <li>• Table 1</li> <li>• Table 2</li> <li>• 12:1–11</li> <li>• 12:12–23</li> <li>• 13:4–10</li> <li>• 13:64–14:1</li> <li>• 16:40–51</li> <li>• 19:8–15</li> <li>• Claim 6</li> <li>• Claim 9</li> </ul> <p><b>Extrinsic Evidence:</b></p> <ul style="list-style-type: none"> <li>• SOMERSET_OMI_0000129–146</li> <li>• SOMERSET_OMI_0000471–477</li> </ul> <p>As further support for their construction, Plaintiffs may also rely on the testimony of Dr. Cory Berkland on one or more of the following subjects: the definition of a person of ordinary skill in the art (“POSA”) and how a POSA would understand this term. Dr. Berkland may also respond to opinions rendered by Somerset’s expert(s).</p>

Term Identified for Construction	Claims In Which Term Appears	Plaintiffs' Proposed Construction	Evidence That May Be Used To Support Plaintiffs' Construction and/or Oppose Defendants' Construction
			<p>Although Plaintiffs disagree that the correspondence between the parties and the litigation filings in <i>Omeros Corp. v. Par Sterile Products, LLC</i>, C.A. 15-773 (D. Del) or <i>Omeros Corp. v. Sandoz Inc.</i>, C.A. No. 17-799 (D. Del) are relevant to claim construction in this matter, insofar as Defendant has identified such litigation materials as extrinsic evidence that it may use to support its constructions, Plaintiffs reserve the right to use the same documents—including OMEROS-LUPIN-LITIGATION-000001–418 and Plaintiffs' Statement of Issues of Fact that Remain to Be Litigated, <i>Omeros v. Par</i>, D.I.-181-1—to support Plaintiffs' construction or oppose Defendant's construction.</p> <p>Plaintiffs reserve the right to rely on additional intrinsic and extrinsic evidence, including expert testimony, to rebut any intrinsic or extrinsic evidence relied upon by Somerset in support of its claim construction, pursuant to Local Patent Rule 4.2 (c).</p> <p>Plaintiffs also reserve the right to amend or supplement this preliminary construction and supporting references in connection with the Joint Claim Construction and Prehearing Statement required by Local Patent Rule 4.3. Plaintiffs also reserve the right to amend or supplement this preliminary construction and supporting references based on conferral with Somerset or as otherwise appropriate under the Local Patent Rules.</p>
"buffer system"	'856 Patent (claims 1, 9)	components of a solution that resist changes in pH	<p><b>Intrinsic Evidence:</b></p> <p>The '856 Patent:</p>

Term Identified for Construction	Claims In Which Term Appears	Plaintiffs' Proposed Construction	Evidence That May Be Used To Support Plaintiffs' Construction and/or Oppose Defendants' Construction
	'406 Patent (claims 1–2, 6) '246 Patent (claim 1)		<ul style="list-style-type: none"> <li>• Abstract</li> <li>• 3:54–61</li> <li>• 4:25–32</li> <li>• 9:15–36</li> </ul> <p>The '406 Patent:</p> <ul style="list-style-type: none"> <li>• Abstract</li> <li>• 3:58–65</li> <li>• 4:18–29</li> <li>• 9:26–48</li> </ul> <p>The '246 Patent:</p> <ul style="list-style-type: none"> <li>• Abstract</li> <li>• 3:60–67</li> <li>• 4:19–30</li> <li>• 9:25–47</li> </ul> <p><b>Extrinsic Evidence:</b></p> <ul style="list-style-type: none"> <li>• De Villiers, Melgardt, Chapter 18, “Buffers and pH Adjusting Agents,” in A PRACTICAL GUIDE TO CONTEMPORARY PHARMACY PRACTICE (pp. 224-230) (3rd Ed. 2009)</li> <li>• <i>McGraw-Hill's Dictionary of Chemistry</i> 56 (1997) (“Buffer”)</li> <li>• <i>Merriam-Webster's Collegiate Dictionary</i> 161 (11th Ed. 2012) (“Buffer”)</li> <li>• <i>New Oxford American Dictionary</i> 227 (3rd ed. 2010) (“Buffer”)</li> </ul>

Term Identified for Construction	Claims In Which Term Appears	Plaintiffs' Proposed Construction	Evidence That May Be Used To Support Plaintiffs' Construction and/or Oppose Defendants' Construction
			<ul style="list-style-type: none"> <li>• USP35-NF30 at 1067–69 (2012) (“Buffer Solutions”)</li> <li>• U.S. Patent No. 11,523,987</li> <li>• U.S. Patent No. 11,478,491</li> <li>• U.S. Patent No. 12,064,440</li> <li>• Patent Pub. No. 2021/0299121</li> <li>• Patent Pub. No. 2022/0133844</li> </ul> <p>As further support for their construction, Plaintiffs may also rely on the testimony of Dr. Cory Berkland on one or more of the following subjects: the definition of a person of ordinary skill in the art (“POSA”) and how a POSA would understand this term. Dr. Berkland may also respond to opinions rendered by Somerset’s expert(s).</p> <p>Although Plaintiffs disagree that the correspondence between the parties and the litigation filings in <i>Omeros Corp. v. Par Sterile Products, LLC</i>, C.A. 15-773 (D. Del) or <i>Omeros Corp. v. Sandoz Inc.</i>, C.A. No. 17-799 (D. Del) are relevant to claim construction in this matter, insofar as Defendant has identified such litigation materials as extrinsic evidence that it may use to support its constructions, Plaintiffs reserve the right to use the same documents—including OMEROS-LUPIN-LITIGATION-000001–418 and Plaintiffs’ Statement of Issues of Fact that Remain to Be Litigated, <i>Omeros v. Par</i>, D.I.-181-1—to support Plaintiffs’ construction or oppose Defendant’s construction.</p> <p>Plaintiffs reserve the right to rely on additional intrinsic and extrinsic evidence, including expert testimony, to rebut</p>



Term Identified for Construction	Claims In Which Term Appears	Plaintiffs' Proposed Construction	Evidence That May Be Used To Support Plaintiffs' Construction and/or Oppose Defendants' Construction
			<p>any intrinsic or extrinsic evidence relied upon by Somerset in support of its claim construction, pursuant to Local Patent Rule 4.2 (c). Plaintiffs also reserve the right to amend or supplement this preliminary construction and supporting references in connection with the Joint Claim Construction and Prehearing Statement required by Local Patent Rule 4.3.</p> <p>Plaintiffs also reserve the right to amend or supplement this preliminary construction and supporting references based on conferral with Somerset or as otherwise appropriate under the Local Patent Rules.</p>
<p>“phenylephrine, ketorolac, and a buffer system”</p>	<p>'856 Patent (claims 1, 9) '406 Patent (claims 1–2, 6) '246 Patent (claim 1)</p>	<p>As this term is merely a combination of the terms above, Plaintiffs incorporate their proposed constructions of the constituent terms from above:</p> <p>phenylephrine in a salt form, ketorolac in a salt form, and components of a solution that resist changes in pH</p>	<p>As this term is merely a combination of the three terms above, Plaintiffs may rely on the intrinsic and extrinsic evidence above for each of its constituent terms (“phenylephrine,” “ketorolac,” and “buffer system,”) including testimony of Dr. Cory Berkland on how a POSA would understand these terms, and incorporates that intrinsic and extrinsic evidence herein.</p>

# EXHIBIT B

***Rayner Surgical Inc. et al. v. Somerset Therapeutics, LLC***  
**Civil Action No. 3:24-cv-9017(GC)(JBD) (D.N.J.)**  
**Exhibit B: Defendant's Proposed Constructions and Evidence**

Term Identified for Construction	Claims In Which Term Appears	Defendant's Proposed Construction	Evidence That May Be Used To Support Defendant's Construction and/or Oppose Plaintiffs' Construction
phenylephrine	'856 Patent (claims 1, 6–9, 14–16) '406 Patent (claims 1–2, 12–13) '246 Patent (claims 1, 6)	Phenylephrine in a salt form, such as phenylephrine hydrochloride.	<p><b><u>Intrinsic Evidence:</u></b></p> <p>'856 patent<sup>1</sup>, 7:65–67, 8:65–67, 9:38–46, 13:60–64, 15:59–67, 16:10–14, 16:35–49, all claims.</p> <p>'406 patent, all claims.</p> <p>'246 patent, all claims.</p> <p>Amendment and Response in U.S. Patent Application No. 14/061,039 (Mar. 19, 2015) (RAY-0005161 - RAY-0005171).</p> <p>Amendment and Response in U.S. Patent Application No. 14/721,151 (Aug. 5, 2016) (RAY-0006815 – RAY-0006820).</p> <p><b><u>Extrinsic Evidence:</u></b></p> <p>RAY-0015191–2  RAY-0015244–74  RAY-0015681–2  OMEROS-LUPIN-LITIGATION-000001–418</p> <p>Rayner's Citizen Petition submitted November 27, 2024 (RAY-0552222–33)</p>

<sup>1</sup> As the '856, '406, and '246 patents all have a substantially identical written description, and for ease of reading, reference to the written description of the '406 and 246 patents are made to the common portions of the '856 patent specification. Somerset reserves the right to make reference to the identical portions of the '406 or '246 specifications, where appropriate.

Term Identified for Construction	Claims In Which Term Appears	Defendant's Proposed Construction	Evidence That May Be Used To Support Defendant's Construction and/or Oppose Plaintiffs' Construction
			<p>USP34-NF29 monograph for “phenylephrine hydrochloride” (SOMERSET_OMI_0037246–50)</p> <p>Dr. Maureen Donovan may present a declaration in support of Somerset’s construction and in rebuttal to any of Dr. Berkland’s opinions regarding the level of ordinary skill in the art or the meaning of “ketorolac” to a person of ordinary skill in the art.</p> <p>All evidence Plaintiffs identify with respect to this Term on Exhibit A of this Joint Claim Construction and Prehearing Statement.</p> <p>Somerset further reserves the right to amend or supplement these disclosures, including as a result of the discovery or investigation of further information. Specifically, Somerset has requested and is awaiting production of documents and correspondence relating to previous constructions on this term from Plaintiffs and reserves the right to incorporate such evidence once received.</p>
ketorolac	<p>’856 Patent (claims 1, 6–9, 14–16)</p> <p>’406 Patent (claims 1–2, 6, 12–13)</p> <p>’246 Patent (claims 1, 6)</p>	Ketorolac in a salt form, such as ketorolac tromethamine.	<p><b><u>Intrinsic Evidence:</u></b></p> <p>’856 patent at 2:59–3:3, 7:61–64, 8:52–55, 9:38–46, 11:4–6, 13:60–64, 15:59–67, 16:10–14, 16:35–49, all claims.</p> <p>Amendment and Response in U.S. Patent Application No. 14/061,039 (Mar. 19, 2015) (RAY-0005161 - RAY-0005171).</p> <p>Amendment and Response in U.S. Patent Application No. 14/721,151 (Aug. 5, 2016) (RAY-0006815 – RAY-0006820).</p> <p><b><u>Extrinsic Evidence:</u></b></p> <p>RAY-0014662–8</p> <p>RAY-0014669–75</p>

Term Identified for Construction	Claims In Which Term Appears	Defendant's Proposed Construction	Evidence That May Be Used To Support Defendant's Construction and/or Oppose Plaintiffs' Construction
			<p>RAY-0015244-74 RAY-0015191-2 RAY-0015681-2 OMEROS-LUPIN-LITIGATION-000001-418</p> <p>Rayner's Citizen Petition submitted November 27, 2024 (RAY-0552222-33)</p> <p>USP34-NF29 monograph for "ketorolac tromethamine" (SOMERSET_OMI_0037241-45)</p> <p>Dr. Maureen Donovan may present a declaration in support of Somerset's construction and in rebuttal to any of Dr. Berkland's opinions regarding the level of ordinary skill in the art or the meaning of "ketorolac" to a person of ordinary skill in the art.</p> <p>All evidence Plaintiffs identify with respect to this Term on Exhibit A of this Joint Claim Construction and Prehearing Statement.</p> <p>Somerset further reserves the right to amend or supplement these disclosures, including as a result of the discovery or investigation of further information. Specifically, Somerset has requested and is awaiting production of documents and correspondence relating to previous constructions on this term from Plaintiffs and reserves the right to incorporate such evidence once received.</p>
buffer system	'856 Patent (claims 1, 9)	A solution including a mixture of a weak acid and its conjugate base, or	<p><b><u>Intrinsic Evidence</u></b> '856 patent at 2:59-3:3, 3:54-67, 4:5-38, 4:43-46, 7:55-60, 8:45-50, 9:15-48, 11:4-19, Table 1, Table 2, all claims.</p>

Term Identified for Construction	Claims In Which Term Appears	Defendant's Proposed Construction	Evidence That May Be Used To Support Defendant's Construction and/or Oppose Plaintiffs' Construction
	'406 Patent (claims 1–2, 6,) '246 Patent (claim 1)	a weak base and its conjugate acid.	<p>'406 patent, all claims. '246 patent, all claims.</p> <p>Amendment and Response in U.S. Patent Application No. 14/061,039 (Mar. 19, 2015) (RAY-0005161 - RAY-0005171).</p> <p>Amendment and Response in U.S. Patent Application No. 14/721,151 (Aug. 5, 2016) (RAY-0006815 – RAY-0006820).</p> <p><b><u>Extrinsic Evidence:</u></b> Stipulated Order Regarding Claim Construction in <i>Omeros Corp. v. Sandoz Inc.</i>, C.A. No. 17-799 (RGA) (consolidated) (D.I. 70, July 3, 2018) (SOMERSET_OMI_0008988–92)</p> <p>Plaintiffs' Statement of Issues of Fact that Remain to Be Litigated, <i>Omeros v. Par</i>, D.I. 181-1 (June 30, 2017) (SOMERSET_OMI_0012148, 0012159–12246)</p> <p>Rayner's Citizen Petition submitted November 27, 2024 (RAY-0552222–33)</p> <p>Handbook of Pharmaceutical Excipients, Sixth Edition (2009), Preface, pg. 5–6 (Acetic acid), 503–504, (Phosphoric acid), 620–621 (sodium acetate) (SOMERSET_OMI_0037224–40)</p> <p>Harry G. Brittain. "Buffers, Buffering Agents, and Ionic Equilibria." Encyclopedia of Pharmaceutical Science and Technology, Fourth Edition, 348–355 (2013) (SOMERSET_OMI_0037224–40)</p>

Term Identified for Construction	Claims In Which Term Appears	Defendant's Proposed Construction	Evidence That May Be Used To Support Defendant's Construction and/or Oppose Plaintiffs' Construction
			<p>McGraw-Hill Dictionary of Scientific and Technical Terms, Sixth Ed., 294–295 and 756 (2003) (SOMERSET_OMI_0037219–23)</p> <p>RAY0014662–8 RAY0014669–75 RAY0015681–2 OMEROS-LUPIN-LITIGATION-000001–418</p> <p>Dr. Maureen Donovan may present a declaration in support of Somerset's construction and in rebuttal to any of Dr. Berkland's opinions regarding the level of ordinary skill in the art or the meaning of "buffer system" to a person of ordinary skill in the art.</p> <p>All evidence Plaintiffs identify with respect to this Term on Exhibit A of this Joint Claim Construction and Prehearing Statement.</p> <p>Somerset further reserves the right to amend or supplement these disclosures, including as a result of the discovery or investigation of further information. Specifically, Somerset has requested and is awaiting production of documents and correspondence relating to previous constructions on this term from Plaintiffs and reserves the right to incorporate such evidence once received.</p>
phenylephrine, ketorolac and a buffer system.	'856 Patent (claims 1, 9) '406 Patent (claims 1–2, 6)	A formulation with at least three separate components: (1) phenylephrine, (2) ketorolac, and (3) a buffer system.	<p><b><u>Intrinsic Evidence:</u></b></p> <p>'856 patent, 2:59–3:3, 3:54–67, 4:5–38, 4:43–46, 7:55–60, 7:65–67, 8:1–21, 8:45–50, 9:15–48, 11:4–19, Table 1, Table 2, 11:54–12:8, 12:10–13:5, 13:55–16:49, FIGS. 1–19, all claims.</p> <p>'406 patent, all claims.</p>

Term Identified for Construction	Claims In Which Term Appears	Defendant's Proposed Construction	Evidence That May Be Used To Support Defendant's Construction and/or Oppose Plaintiffs' Construction
	'246 Patent (claim 1)		<p>'246 patent, all claims.</p> <p>Amendment and Response in U.S. Patent Application No. 14/061,039 (Mar. 19, 2015) (RAY-0005161 - RAY-0005171).</p> <p>Amendment and Response in U.S. Patent Application No. 14/721,151 (Aug. 5, 2016) (RAY-0006815 – RAY-0006820).</p> <p><b><u>Extrinsic Evidence:</u></b>  Plaintiffs' Statement of Issues of Fact that Remain to Be Litigated, <i>Omeros v. Par</i>, D.I. 181-1 (June 30, 2017) (SOMERSET_OMI_0012148, 0012159–12246)</p> <p>Rayner's Citizen Petition submitted November 27, 2024 (RAY-0552222–33)</p> <p>RAY-0014662–8  RAY-0014669–75  RAY-0015244–74  RAY-0015191–2  RAY-0015681–2  OMEROS-LUPIN-LITIGATION-000001–418</p> <p>Somerset further reserves the right to amend or supplement these disclosures, including as a result of the discovery or investigation of further information. Specifically, Somerset has requested and is awaiting production of documents and correspondence relating to previous constructions on this term from Plaintiffs and reserves the right to incorporate such evidence once received.</p>