

Exhibit B-8

Invalidity of U.S. Patent No. 11,878,076 in view of Hikma/DailyMed

2018 Injectable Product Catalog, HIKMA (2018) (“Hikma”), which was published in 2018, and/or *Label: PHENOBARBITAL SODIUM - phenobarbital sodium injection*, DAILYMED (updated August 2011) (“DailyMed”), which was publicly available by at least October 4, 2015, qualify as prior art under at least 35 U.S.C. §§ 102 and 103 as to the claims 1-20 of U.S. Patent No. 11,878,076 (“the ’076 Patent”), as discussed in greater detail in the chart that follows.¹

To the extent Plaintiff alleges that Hikma/DailyMed does not disclose any particular limitation of claims 1-20 of the ’076 Patent, either expressly or inherently, it would have been obvious to a person of ordinary skill in the art as of the priority date of the ’076 Patent to modify and/or to combine the teachings of Hikma/DailyMed, including but not limited to the prior art references presently found in Sun’s Invalidity Contentions and any supplements thereto and the relevant section of charts for other prior art for the ’076 Patent in a manner that would have rendered the claims 1-20 invalid as obvious. The inclusion of the particular limitation into the pharmaceutical compositions and products described in Hikma/DailyMed would have been obvious for at least the following reasons: It would have been obvious to modify the pharmaceutical compositions and products described in Hikma/DailyMed, alone or in combination with the references identified in Section VII.B.2 of Sun’s Invalidity Contentions, to meet this limitation based on: (a) the teachings of Hikma/DailyMed itself; (b) a person of ordinary skill in the art implementing a predictable variation of the pharmaceutical compositions and products described in Hikma/DailyMed or in the other identified references; (c) the logic, judgment,

¹ Nothing in these claim charts should be construed as an admission regarding infringement, either literally or under the doctrine of equivalents, or as an admission regarding Sun’s understanding of the proper scope of the claims of the ’076 Patent. Given Plaintiff’s vague and ambiguous infringement contentions, the exemplary citations herein necessarily account for a variety of possible infringement arguments and claim constructions. Sun reserves the right to rely on additional citations or sources of evidence that also may be applicable, or that may become applicable in light of claim construction, changes in Plaintiff’s infringement contentions, and/or information obtained during discovery as the case progresses, including, but not limited to, third-party discovery related to any pharmaceutical product available at the time of the alleged invention. Various positions put forth in this document are predicated on Plaintiff’s overly broad interpretation of its claims as evidenced by the infringement allegations received to date. Those positions are not intended to and do not necessarily reflect Sun’s interpretation of the true and proper scope of Plaintiff’s claims, and Sun reserves the right to adopt claim construction positions that differ from or even conflict with various positions put forth in this document.

intelligence, creativity, innovation and common sense a person of ordinary skill in the art would employ; (d) the inferences and creative and routine steps that a person of ordinary skill in the art would employ; (e) market demand for pharmaceutical compositions and products to include this limitation; and/or (f) design needs or market pressures to solve a problem with a finite number of solutions that could have produced the desired outcome.

Sun reserves the right to amend or supplement this claim chart pursuant to the Docket Control Order issued by the Court on September 27, 2024 (Dkt. No. 37).

A. Claim 1

'076 Patent Claim Limitation	Hikma/DailyMed																																														
[1p] A storage stable pharmaceutical product, comprising:	To the extent the preamble is limiting, Hikma/DailyMed discloses and/or renders obvious the preamble based on at least the following citations. <i>See, e.g.:</i> - Hikma at 35 Injectables   PHENOBARBITAL Sodium Injection, USP C-IV <table><tr><td>BRAND EQUIVALENT</td><td>THERAPEUTIC CATEGORY</td><td>PRODUCT DESCRIPTION</td><td>FDA RATING</td><td colspan="3"></td></tr><tr><td>n/a</td><td>Barbiturate</td><td>Clear, Colorless Liquid</td><td>n/a</td><td colspan="3"></td></tr><tr><th>NDC Number</th><th>Concentration</th><th>Total Drug Content</th><th>Fill Volume</th><th>Unit Size</th><th>Case Pack</th><th>Closure</th></tr><tr><td>0641-0476-25</td><td>65 mg / mL</td><td>65 mg / mL</td><td>1 mL</td><td>2 mL</td><td>25 vials</td><td>13 mm</td></tr><tr><td>0641-0477-25</td><td>130 mg / mL</td><td>130 mg / mL</td><td>1 mL</td><td>2 mL</td><td>25 vials</td><td>13 mm</td></tr></table> - Hikma at 62 Wholesaler Numbers  <table><tr><th>Product Family</th><th>NDC Number</th><th>Total Drug Content</th><th>Fill Volume</th><th>Unit Size</th><th>Pack</th><th>ABC</th><th>Cardinal</th><th>HD Smith</th><th>MCK</th><th>M&D</th></tr></table>	BRAND EQUIVALENT	THERAPEUTIC CATEGORY	PRODUCT DESCRIPTION	FDA RATING				n/a	Barbiturate	Clear, Colorless Liquid	n/a				NDC Number	Concentration	Total Drug Content	Fill Volume	Unit Size	Case Pack	Closure	0641-0476-25	65 mg / mL	65 mg / mL	1 mL	2 mL	25 vials	13 mm	0641-0477-25	130 mg / mL	130 mg / mL	1 mL	2 mL	25 vials	13 mm	Product Family	NDC Number	Total Drug Content	Fill Volume	Unit Size	Pack	ABC	Cardinal	HD Smith	MCK	M&D
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'076 Patent Claim Limitation	Hikma/DailyMed										
	Phenobarbital Sodium Injection, USP C-IV	0641-0476-25	65 mg / mL	1 mL	2 mL	25 vials	10034808	1264977	4160156	1140748	967760
	Phenobarbital Sodium Injection, USP C-IV	0641-0477-25	130 mg / mL	1 mL	2 mL	25 vials	10034821	2086585	4160446	1231554	970848
	DailyMed Phenobarbital Sodium Injection, USP is a sterile solution for intramuscular or slow intravenous administration as a long-acting barbiturate. Each mL contains phenobarbital sodium either 65 mg or 130 mg, alcohol 0.1 mL, propylene glycol 0.678 mL and benzyl alcohol 0.015 mL in Water for Injection; hydrochloric acid added, if needed, for pH adjustment. The pH range is 9.2-10.2.										
	HOW SUPPLIED Phenobarbital Sodium Injection, USP is available in the following: 65 mg/mL, 1 mL vials packaged in 25s (NDC 0641-0476-25) 130 mg/mL, 1 mL vials packaged in 25s (NDC 0641-0477-25)										

'076 Patent Claim Limitation	Hikma/DailyMed
	 PRINCIPAL DISPLAY PANEL Phenobarbital Sodium Injection, USP 65 mg/mL 1 mL Vial NDC 0641-0476-21  Phenobarbital Sodium Injection, USP 65 mg/mL 25 x 1 mL Vials NDC 0641-0476-25

'076 Patent Claim Limitation	Hikma/DailyMed
	 CLOSE  PRINCIPAL DISPLAY PANEL Phenobarbital Sodium Injection, USP 130 mg/mL 1 mL Vial NDC 0641-0477-21

'076 Patent Claim Limitation	Hikma/DailyMed
	 NDC 0641-0477-21 Phenobarbital Sodium Injection, USP IV 130 mg/mL Rx only FOR IM OR SLOW IV USE 1 mL Vial Do not use if discolored or precipitated. Manufactured by WEST-WARD 462-351-031 (01)00306410477211 Lot: _____ Exp.: _____

'076 Patent Claim Limitation	Hikma/DailyMed
	Phenobarbital Sodium Injection, USP 130 mg/mL 25 x 1 mL Vials NDC 0641-0477-25  Let: Exp: To open—Cut seal along dotted line. NDC 0641-0477-25 Phenobarbital Sodium Injection, USP 130 mg/mL Rx only FOR IM OR SLOW IV USE 25 x 1 mL Vials DO NOT USE IF DISCOLORED OR CONTAINS A PRECIPITATE Manufactured by:  WEST-WARD Easton, NJ 07724 USA 462-382-00 Each mL contains phenobarbital sodium 130 mg, alcohol 0.1 mL, propylene glycol 0.678 mL, and benzyl alcohol 0.015 mL in Water for Injection, pH 9.2-10.2; hydrochloric acid added, if needed, for pH adjustment. Usual Dosage: See package insert. Store at 20°-25°C (68°-77°F) (See USP Controlled Room Temperature). 0641-0477-25

'076 Patent Claim Limitation

Hikma/DailyMed

INGREDIENTS AND APPEARANCE

PHENOBARBITAL SODIUM

phenobarbital sodium injection

PRODUCT INFORMATION

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:0641-0476
Route of Administration	INTRAMUSCULAR, INTRAVENOUS	DEA Schedule	CIV

ACTIVE INGREDIENT/ACTIVE MOIETY

Ingredient Name	Basis of Strength	Strength
PHENOBARBITAL SODIUM (UNII: SW9M9BB5K3) (PHENOBARBITAL - UNII: YQE403BP4D)	PHENOBARBITAL SODIUM	65 mg in 1 mL

INACTIVE INGREDIENTS

Ingredient Name	Strength
ALCOHOL (UNII: 3K9958V90M)	0.1 mL in 1 mL
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	0.678 mL in 1 mL
BENZYL ALCOHOL (UNII: LKG8494WBH)	0.015 mL in 1 mL
WATER (UNII: 059QF0K00R)	
HYDROCHLORIC ACID (UNII: QTT17582CB)	

PACKAGING

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0641-0476-25	25 in 1 CARTON		
1	NDC:0641-0476-21	1 mL in 1 VIAL		

MARKETING INFORMATION

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
UNAPPROVED DRUG OTHER		01/01/1971	

'076 Patent Claim Limitation	Hikma/DailyMed																																																																																																									
	<table><tr><th colspan="5">PHENOBARBITAL SODIUM phenobarbital sodium injection</th></tr><tr><th colspan="5">PRODUCT INFORMATION</th></tr><tr><td>Product Type</td><td>HUMAN PRESCRIPTION DRUG</td><td>Item Code (Source)</td><td colspan="2">NDC:0641-0477</td></tr><tr><td>Route of Administration</td><td>INTRAMUSCULAR, INTRAVENOUS</td><td>DEA Schedule</td><td colspan="2">CIV</td></tr><tr><th colspan="5">ACTIVE INGREDIENT/ACTIVE MOIETY</th></tr><tr><td colspan="2">Ingredient Name</td><td>Basis of Strength</td><td colspan="2">Strength</td></tr><tr><td colspan="2">PHENOBARBITAL SODIUM (UNII: SW9M9BB5K3) (PHENOBARBITAL - UNII: YQE403BP4D)</td><td>PHENOBARBITAL SODIUM</td><td colspan="2">130 mg in 1 mL</td></tr><tr><th colspan="5">INACTIVE INGREDIENTS</th></tr><tr><td colspan="2">Ingredient Name</td><td colspan="3">Strength</td></tr><tr><td colspan="2">ALCOHOL (UNII: 3K9958V90M)</td><td colspan="3">0.1 mL in 1 mL</td></tr><tr><td colspan="2">PROPYLENE GLYCOL (UNII: 6DC9Q167V3)</td><td colspan="3">0.678 mL in 1 mL</td></tr><tr><td colspan="2">BENZYL ALCOHOL (UNII: LKG8494WBH)</td><td colspan="3">0.015 mL in 1 mL</td></tr><tr><td colspan="2">WATER (UNII: 059QF0K00R)</td><td colspan="3"></td></tr><tr><td colspan="2">HYDROCHLORIC ACID (UNII: QTT17582CB)</td><td colspan="3"></td></tr><tr><th colspan="5">PACKAGING</th></tr><tr><td>#</td><td>Item Code</td><td>Package Description</td><td>Marketing Start Date</td><td>Marketing End Date</td></tr><tr><td>1</td><td>NDC:0641-0477-25</td><td>25 in 1 CARTON</td><td></td><td></td></tr><tr><td>1</td><td>NDC:0641-0477-21</td><td>1 mL in 1 VIAL</td><td></td><td></td></tr><tr><th colspan="5">MARKETING INFORMATION</th></tr><tr><td>Marketing Category</td><td>Application Number or Monograph Citation</td><td>Marketing Start Date</td><td colspan="2">Marketing End Date</td></tr><tr><td>UNAPPROVED DRUG OTHER</td><td></td><td>01/01/1971</td><td colspan="2"></td></tr></table>	PHENOBARBITAL SODIUM phenobarbital sodium injection					PRODUCT INFORMATION					Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:0641-0477		Route of Administration	INTRAMUSCULAR, INTRAVENOUS	DEA Schedule	CIV		ACTIVE INGREDIENT/ACTIVE MOIETY					Ingredient Name		Basis of Strength	Strength		PHENOBARBITAL SODIUM (UNII: SW9M9BB5K3) (PHENOBARBITAL - UNII: YQE403BP4D)		PHENOBARBITAL SODIUM	130 mg in 1 mL		INACTIVE INGREDIENTS					Ingredient Name		Strength			ALCOHOL (UNII: 3K9958V90M)		0.1 mL in 1 mL			PROPYLENE GLYCOL (UNII: 6DC9Q167V3)		0.678 mL in 1 mL			BENZYL ALCOHOL (UNII: LKG8494WBH)		0.015 mL in 1 mL			WATER (UNII: 059QF0K00R)					HYDROCHLORIC ACID (UNII: QTT17582CB)					PACKAGING					#	Item Code	Package Description	Marketing Start Date	Marketing End Date	1	NDC:0641-0477-25	25 in 1 CARTON			1	NDC:0641-0477-21	1 mL in 1 VIAL			MARKETING INFORMATION					Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		UNAPPROVED DRUG OTHER		01/01/1971		
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	To the extent Hikma/DailyMed does not expressly disclose the preamble, a person of ordinary skill in the art would have determined that the preamble is either inherent and/or obvious to one of ordinary skill in the art in view of the teachings of Hikma/DailyMed. Further, one of ordinary skill in the art would have been motivated to modify Hikma/DailyMed or combine it with any of the present prior art references found in Sun’s Invalidity Contentions and any supplements thereto and the relevant section charts for other prior art for the ’076 Patent in a manner that would result in the subject matter of the preamble given, at the very least, the person’s understanding of the state of the art, the problems addressed and solved in the prior art, and the teachings of Hikma/DailyMed.																												
[1a] a single use dose vial, and	Hikma/DailyMed discloses and/or renders obvious this limitation based on at least the following citations. <i>See, e.g.:</i> - Hikma at 35 Injectables   PHENOBARBITAL Sodium Injection, USP C-IV <table><tr><td>BRAND EQUIVALENT n/a</td><td>THERAPEUTIC CATEGORY Barbiturate</td><td>PRODUCT DESCRIPTION Clear, Colorless Liquid</td><td>FDA RATING n/a</td><td colspan="3"></td></tr><tr><th>NDC Number</th><th>Concentration</th><th>Total Drug Content</th><th>Fill Volume</th><th>Unit Size</th><th>Case Pack</th><th>Closure</th></tr><tr><td>0641-0476-25</td><td>65 mg / mL</td><td>65 mg / mL</td><td>1 mL</td><td>2 mL</td><td>25 vials</td><td>13 mm</td></tr><tr><td>0641-0477-25</td><td>130 mg / mL</td><td>130 mg / mL</td><td>1 mL</td><td>2 mL</td><td>25 vials</td><td>13 mm</td></tr></table> - Hikma at 62	BRAND EQUIVALENT n/a	THERAPEUTIC CATEGORY Barbiturate	PRODUCT DESCRIPTION Clear, Colorless Liquid	FDA RATING n/a	  			NDC Number	Concentration	Total Drug Content	Fill Volume	Unit Size	Case Pack	Closure	0641-0476-25	65 mg / mL	65 mg / mL	1 mL	2 mL	25 vials	13 mm	0641-0477-25	130 mg / mL	130 mg / mL	1 mL	2 mL	25 vials	13 mm
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'076 Patent Claim Limitation	Hikma/DailyMed
	 PRINCIPAL DISPLAY PANEL Phenobarbital Sodium Injection, USP 65 mg/mL 1 mL Vial NDC 0641-0476-21  Phenobarbital Sodium Injection, USP 65 mg/mL 25 x 1 mL Vials NDC 0641-0476-25

'076 Patent Claim Limitation	Hikma/DailyMed
	 NDC 0641-0477-21 Phenobarbital Sodium Injection, USP IV 130 mg/mL Rx only FOR IM OR SLOW IV USE 1 mL Vial Do not use if discolored or precipitated. Manufactured by WEST-WARD (01)00306410477211 Lot: _____ Exp.: _____

'076 Patent Claim Limitation	Hikma/DailyMed
	Phenobarbital Sodium Injection, USP 130 mg/mL 25 x 1 mL Vials NDC 0641-0477-25  The image shows a detailed product label for Phenobarbital Sodium Injection, USP. The label is rectangular with a white background and blue text. At the top, there is a barcode and the text 'To open—Cut seal along dotted line.' Below this, the NDC number 'NDC 0641-0477-25' is printed. The product name 'Phenobarbital Sodium Injection, USP' is prominently displayed in a large, bold font. Below the product name, the concentration '130 mg/mL' is shown in a blue box, followed by 'Rx only'. The label also specifies 'FOR IM OR SLOW IV USE' and '25 x 1 mL Vials'. A warning statement reads 'DO NOT USE IF DISCOLORED OR CONTAINS A PRECIPITATE'. The manufacturer information 'Manufactured by: WEST-WARD, Easton, NJ 07724 USA' is at the bottom left. On the right side, there is a vertical barcode and the text '0641-0477-25'. A small 'IV' symbol is also present.

'076 Patent Claim Limitation

Hikma/DailyMed

INGREDIENTS AND APPEARANCE

PHENOBARBITAL SODIUM

phenobarbital sodium injection

PRODUCT INFORMATION

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:0641-0476
Route of Administration	INTRAMUSCULAR, INTRAVENOUS	DEA Schedule	CIV

ACTIVE INGREDIENT/ACTIVE MOIETY

Ingredient Name	Basis of Strength	Strength
PHENOBARBITAL SODIUM (UNII: SW9M9BB5K3) (PHENOBARBITAL - UNII: YQE403BP4D)	PHENOBARBITAL SODIUM	65 mg in 1 mL

INACTIVE INGREDIENTS

Ingredient Name	Strength
ALCOHOL (UNII: 3K9958V90M)	0.1 mL in 1 mL
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	0.678 mL in 1 mL
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WATER (UNII: 059QF0K00R)	
HYDROCHLORIC ACID (UNII: QTT17582CB)	

PACKAGING

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0641-0476-25	25 in 1 CARTON		
1	NDC:0641-0476-21	1 mL in 1 VIAL		

MARKETING INFORMATION

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
UNAPPROVED DRUG OTHER		01/01/1971	

'076 Patent Claim Limitation	Hikma/DailyMed																																																																																																									
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'076 Patent Claim Limitation	Hikma/DailyMed																												
	To the extent Hikma/DailyMed does not expressly disclose this limitation, a person of ordinary skill in the art would have determined that this limitation is either inherent and/or obvious to one of ordinary skill in the art in view of the teachings of Hikma/DailyMed. Further, one of ordinary skill in the art would have been motivated to modify Hikma/DailyMed or combine it with any of the present prior art references found in Sun’s Invalidity Contentions and any supplements thereto and the relevant section charts for other prior art for the ’076 Patent in a manner that would result in the subject matter of this limitation given, at the very least, the person’s understanding of the state of the art, the problems addressed and solved in the prior art, and the teachings of Hikma/DailyMed.																												
[1b] a composition comprising a 65 mg dose, a 100 mg dose, a 130 mg dose, or a 200 mg dose of phenobarbital sodium, in the single use dose vial,	Hikma/DailyMed discloses and/or renders obvious this limitation based on at least the following citations. <i>See, e.g.:</i> - Hikma at 35 Injectables   PHENOBARBITAL Sodium Injection, USP C-IV <table><tr><td>BRAND EQUIVALENT n/a</td><td>THERAPEUTIC CATEGORY Barbiturate</td><td>PRODUCT DESCRIPTION Clear, Colorless Liquid</td><td>FDA RATING n/a</td><td colspan="3"></td></tr><tr><th>NDC Number</th><th>Concentration</th><th>Total Drug Content</th><th>Fill Volume</th><th>Unit Size</th><th>Case Pack</th><th>Closure</th></tr><tr><td>0641-0476-25</td><td>65 mg / mL</td><td>65 mg / mL</td><td>1 mL</td><td>2 mL</td><td>25 vials</td><td>13 mm</td></tr><tr><td>0641-0477-25</td><td>130 mg / mL</td><td>130 mg / mL</td><td>1 mL</td><td>2 mL</td><td>25 vials</td><td>13 mm</td></tr></table> - Hikma at 62	BRAND EQUIVALENT n/a	THERAPEUTIC CATEGORY Barbiturate	PRODUCT DESCRIPTION Clear, Colorless Liquid	FDA RATING n/a				NDC Number	Concentration	Total Drug Content	Fill Volume	Unit Size	Case Pack	Closure	0641-0476-25	65 mg / mL	65 mg / mL	1 mL	2 mL	25 vials	13 mm	0641-0477-25	130 mg / mL	130 mg / mL	1 mL	2 mL	25 vials	13 mm
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'076 Patent Claim Limitation	Hikma/DailyMed
	 PRINCIPAL DISPLAY PANEL Phenobarbital Sodium Injection, USP 65 mg/mL 1 mL Vial NDC 0641-0476-21  Phenobarbital Sodium Injection, USP 65 mg/mL 25 x 1 mL Vials NDC 0641-0476-25

'076 Patent Claim Limitation	Hikma/DailyMed
	 Let: Exp: To open—Cut seal along dotted line. NDC 0641-0476-25 Phenobarbital Sodium Injection, USP 65 mg/mL Rx only FOR IM OR SLOW IV USE 25 x 1 mL Vials DO NOT USE IF DISCOLORED OR CONTAINS A PRECIPITATE Manufactured by: WEST-WARD Eatontown, NJ 07724 USA 462-355-01 Each mL contains phenobarbital sodium 65 mg, alcohol 0.1 mL, propylene glycol 0.578 mL, and benzyl alcohol 0.215 mL in Water for Injection, pH 9.2-10.2; hydrochloric acid added, if needed, for pH adjustment. Usual Dosage: See package insert. Store at 20°-25°C (68°-77°F) (See USP Controlled Room Temperature). CLOSE — PRINCIPAL DISPLAY PANEL Phenobarbital Sodium Injection, USP 130 mg/mL 1 mL Vial NDC 0641-0477-21

'076 Patent Claim Limitation	Hikma/DailyMed
	 NDC 0641-0477-21 Phenobarbital Sodium Injection, USP IV 130 mg/mL Rx only FOR IM OR SLOW IV USE 1 mL Vial Do not use if discolored or precipitated. Manufactured by WEST-WARD 462-351-03 (01)00306410477211 Lot: _____ Exp.: _____

'076 Patent Claim Limitation	Hikma/DailyMed
	Phenobarbital Sodium Injection, USP 130 mg/mL 25 x 1 mL Vials NDC 0641-0477-25  The image shows a detailed product label for Phenobarbital Sodium Injection, USP. The label is rectangular with a white background and blue text. At the top, there is a barcode and the text 'To open—Cut seal along dotted line.' Below this, the NDC number 'NDC 0641-0477-25' is printed. The product name 'Phenobarbital Sodium Injection, USP' is prominently displayed in a large, bold font. Below the product name, the concentration '130 mg/mL' is shown in a blue box, followed by 'Rx only'. The label also specifies 'FOR IM OR SLOW IV USE' and '25 x 1 mL Vials'. A warning 'DO NOT USE IF DISCOLORED OR CONTAINS A PRECIPITATE' is included. The manufacturer information 'Manufactured by: WEST-WARD, Easton, NJ 07724 USA' is at the bottom left. On the right side, there is a vertical barcode and the text '0641-0477-25'. The label also contains detailed information about the contents of each mL, storage instructions, and a reference to the USP Controlled Room Temperature.

'076 Patent Claim Limitation

Hikma/DailyMed

INGREDIENTS AND APPEARANCE

PHENOBARBITAL SODIUM

phenobarbital sodium injection

PRODUCT INFORMATION

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:0641-0476
Route of Administration	INTRAMUSCULAR, INTRAVENOUS	DEA Schedule	CIV

ACTIVE INGREDIENT/ACTIVE MOIETY

Ingredient Name	Basis of Strength	Strength
PHENOBARBITAL SODIUM (UNII: SW9M9BB5K3) (PHENOBARBITAL - UNII: YQE403BP4D)	PHENOBARBITAL SODIUM	65 mg in 1 mL

INACTIVE INGREDIENTS

Ingredient Name	Strength
ALCOHOL (UNII: 3K9958V90M)	0.1 mL in 1 mL
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	0.678 mL in 1 mL
BENZYL ALCOHOL (UNII: LKG8494WBH)	0.015 mL in 1 mL
WATER (UNII: 059QF0K00R)	
HYDROCHLORIC ACID (UNII: QTT17582CB)	

PACKAGING

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0641-0476-25	25 in 1 CARTON		
1	NDC:0641-0476-21	1 mL in 1 VIAL		

MARKETING INFORMATION

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
UNAPPROVED DRUG OTHER		01/01/1971	

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[1c] wherein the composition is sterile and lyophilized, and	A person of ordinary skill in the art would have determined that this limitation is either inherent and/or obvious to one of ordinary skill in the art in view of the teachings of Hikma/DailyMed. Further, one of ordinary skill in the art would have been motivated to modify Hikma/DailyMed or combine it with any of the present prior art references found in Sun's Invalidity Contentions and any supplements thereto and the relevant section charts for other prior art for the '076 Patent in a manner that would result in the subject matter of this limitation given, at the very least, the person's understanding of the state of the art, the problems addressed and solved in the prior art, and the teachings of Hikma/DailyMed.
[1d] wherein the composition comprises no less than 98% phenobarbital sodium.	Hikma/DailyMed discloses and/or renders obvious this limitation based on at least the following citations. <i>See, e.g.:</i> • Hikma at 35

'076 Patent Claim Limitation

Hikma/DailyMed

Injectables





PHENOBARBITAL Sodium Injection, USP C-IV

BRAND EQUIVALENT	THERAPEUTIC CATEGORY	PRODUCT DESCRIPTION	FDA RATING	
n/a	Barbiturate	Clear, Colorless Liquid	n/a	  

NDC Number	Concentration	Total Drug Content	Fill Volume	Unit Size	Case Pack	Closure
0641-0476-25	65 mg / mL	65 mg / mL	1 mL	2 mL	25 vials	13 mm
0641-0477-25	130 mg / mL	130 mg / mL	1 mL	2 mL	25 vials	13 mm

- Hikma at 62

Wholesaler Numbers



Product Family	NDC Number	Total Drug Content	Fill Volume	Unit Size	Pack	ABC	Cardinal	HD Smith	MCK	M&D
Phenobarbital Sodium Injection, USP C-IV	0641-0476-25	65 mg / mL	1 mL	2 mL	25 vials	10034808	1264977	4160156	1140748	967760
Phenobarbital Sodium Injection, USP C-IV	0641-0477-25	130 mg / mL	1 mL	2 mL	25 vials	10034821	2086585	4160446	1231554	970848

- DailyMed

'076 Patent Claim Limitation	Hikma/DailyMed
	Phenobarbital Sodium Injection, USP is a sterile solution for intramuscular or slow intravenous administration as a long-acting barbiturate. Each mL contains phenobarbital sodium either 65 mg or 130 mg, alcohol 0.1 mL, propylene glycol 0.678 mL and benzyl alcohol 0.015 mL in Water for Injection; hydrochloric acid added, if needed, for pH adjustment. The pH range is 9.2-10.2.  HOW SUPPLIED Phenobarbital Sodium Injection, USP is available in the following: 65 mg/mL, 1 mL vials packaged in 25s (NDC 0641-0476-25) 130 mg/mL, 1 mL vials packaged in 25s (NDC 0641-0477-25)

'076 Patent Claim Limitation	Hikma/DailyMed
	 PRINCIPAL DISPLAY PANEL Phenobarbital Sodium Injection, USP 65 mg/mL 1 mL Vial NDC 0641-0476-21  Phenobarbital Sodium Injection, USP 65 mg/mL 25 x 1 mL Vials NDC 0641-0476-25

'076 Patent Claim Limitation	Hikma/DailyMed
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'076 Patent Claim Limitation	Hikma/DailyMed
	

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	Phenobarbital Sodium Injection, USP 130 mg/mL 25 x 1 mL Vials NDC 0641-0477-25  The image shows a detailed product label for Phenobarbital Sodium Injection, USP. The label is rectangular with a white background and blue text. At the top, there is a barcode and the text 'To open—Cut seal along dotted line.' Below this, the NDC number 'NDC 0641-0477-25' is printed. The product name 'Phenobarbital Sodium Injection, USP' is prominently displayed in a large, bold font. Below the product name, the concentration '130 mg/mL' is shown in a blue box, followed by 'Rx only'. The label also specifies 'FOR IM OR SLOW IV USE' and '25 x 1 mL Vials'. A warning 'DO NOT USE IF DISCOLORED OR CONTAINS A PRECIPITATE' is included. The manufacturer information 'Manufactured by: WEST-WARD, Easton, NJ 07724 USA' is at the bottom left. On the right side, there is a vertical barcode and the text '0641-0477-25'. The label also contains detailed information about the contents of each mL, including phenobarbital sodium, alcohol, propylene glycol, and benzyl alcohol, and instructions for storage and use.

'076 Patent Claim Limitation

Hikma/DailyMed

INGREDIENTS AND APPEARANCE

PHENOBARBITAL SODIUM

phenobarbital sodium injection

PRODUCT INFORMATION

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:0641-0476
Route of Administration	INTRAMUSCULAR, INTRAVENOUS	DEA Schedule	CIV

ACTIVE INGREDIENT/ACTIVE MOIETY

Ingredient Name	Basis of Strength	Strength
PHENOBARBITAL SODIUM (UNII: SW9M9BB5K3) (PHENOBARBITAL - UNII: YQE403BP4D)	PHENOBARBITAL SODIUM	65 mg in 1 mL

INACTIVE INGREDIENTS

Ingredient Name	Strength
ALCOHOL (UNII: 3K9958V90M)	0.1 mL in 1 mL
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	0.678 mL in 1 mL
BENZYL ALCOHOL (UNII: LKG8494WBH)	0.015 mL in 1 mL
WATER (UNII: 059QF0KO0R)	
HYDROCHLORIC ACID (UNII: QTT17582CB)	

PACKAGING

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0641-0476-25	25 in 1 CARTON		
1	NDC:0641-0476-21	1 mL in 1 VIAL		

MARKETING INFORMATION

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
UNAPPROVED DRUG OTHER		01/01/1971	

'076 Patent Claim Limitation	Hikma/DailyMed																																																																																																									
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'076 Patent Claim Limitation	Hikma/DailyMed
	To the extent Hikma/DailyMed does not expressly disclose this limitation, a person of ordinary skill in the art would have determined that this limitation is either inherent and/or obvious to one of ordinary skill in the art in view of the teachings of Hikma/DailyMed. Further, one of ordinary skill in the art would have been motivated to modify Hikma/DailyMed or combine it with any of the present prior art references found in Sun's Invalidity Contentions and any supplements thereto and the relevant section charts for other prior art for the '076 Patent in a manner that would result in the subject matter of this limitation given, at the very least, the person's understanding of the state of the art, the problems addressed and solved in the prior art, and the teachings of Hikma/DailyMed.

B. Claim 2

'076 Patent Claim Limitation	Hikma/DailyMed
[2p] The pharmaceutical product of claim 1,	<i>See supra</i> Claim 1.
[2a] wherein the composition has the property that when the composition is stored at 40° C. for 6 months and then reconstituted for injection with 10 mL of an aqueous solution to form a reconstituted composition, the reconstituted composition contains no more than 0.1% PEAU.	A person of ordinary skill in the art would have determined that this limitation is either inherent and/or obvious to one of ordinary skill in the art in view of the teachings of Hikma/DailyMed. Further, one of ordinary skill in the art would have been motivated to modify Hikma/DailyMed or combine it with any of the present prior art references found in Sun's Invalidity Contentions and any supplements thereto and the relevant section charts for other prior art for the '076 Patent in a manner that would result in the subject matter of this limitation given, at the very least, the person's understanding of the state of the art, the problems addressed and solved in the prior art, and the teachings of Hikma/DailyMed.

C. Claim 3

'076 Patent Claim Limitation	Hikma/DailyMed
[3p] The pharmaceutical product of claim 1,	<i>See supra</i> Claim 1.
[3a] wherein the composition has the property that when the composition is stored at room temperature for 6 months and then reconstituted for injection with 10 mL of an aqueous solution to form a reconstituted composition, the reconstituted composition contains no more than 0.05% PEAU.	A person of ordinary skill in the art would have determined that this limitation is either inherent and/or obvious to one of ordinary skill in the art in view of the teachings of Hikma/DailyMed. Further, one of ordinary skill in the art would have been motivated to modify Hikma/DailyMed or combine it with any of the present prior art references found in Sun's Invalidity Contentions and any supplements thereto and the relevant section charts for other prior art for the '076 Patent in a manner that would result in the subject matter of this limitation given, at the very least, the person's understanding of the state of the art, the problems addressed and solved in the prior art, and the teachings of Hikma/DailyMed.

D. Claim 4

'076 Patent Claim Limitation	Hikma/DailyMed
[4p] The pharmaceutical product of claim 1,	<i>See supra</i> Claim 1.
[4a] wherein the composition has the property that when the composition is stored at 40° C. for 6 months and then reconstituted for injection	A person of ordinary skill in the art would have determined that this limitation is either inherent and/or obvious to one of ordinary skill in the art in view of the teachings of Hikma/DailyMed. Further, one of ordinary skill in the art would have been motivated to modify Hikma/DailyMed or combine it with any of the present prior art references found in Sun's Invalidity Contentions and any supplements thereto and the relevant section charts for other prior art for the '076 Patent in a manner that would result in the subject matter of this limitation given, at the very least, the person's understanding of the state of the

'076 Patent Claim Limitation	Hikma/DailyMed
with 10 mL of an aqueous solution to form a reconstituted composition, the reconstituted composition contains no more than 0.05% of 2-ethyl-2-phenylmalonamide (2EPMM) or alpha-phenylbutyrylguanidine (PBG).	art, the problems addressed and solved in the prior art, and the teachings of Hikma/DailyMed.

E. Claim 5

'076 Patent Claim Limitation	Hikma/DailyMed
[5p] The pharmaceutical product of claim 1,	<i>See supra</i> Claim 1.
[5a] wherein the composition is amorphous.	A person of ordinary skill in the art would have determined that this limitation is either inherent and/or obvious to one of ordinary skill in the art in view of the teachings of Hikma/DailyMed. Further, one of ordinary skill in the art would have been motivated to modify Hikma/DailyMed or combine it with any of the present prior art references found in Sun's Invalidity Contentions and any supplements thereto and the relevant section charts for other prior art for the '076 Patent in a manner that would result in the subject matter of this limitation given, at the very least, the person's understanding of the state of the art, the problems addressed and solved in the prior art, and the teachings of Hikma/DailyMed.

F. Claim 6

'076 Patent Claim Limitation	Hikma/DailyMed
[6p] The pharmaceutical	<i>See supra</i> Claim 1.

'076 Patent Claim Limitation	Hikma/DailyMed
product of claim 1,	
[6a] wherein the composition has the property that when the composition is stored at room temperature for 24 months and then reconstituted for injection with 10 mL of an aqueous solution to form a reconstituted composition, the reconstituted composition contains at most 0.1% phenylethylacetylurea (PEAU).	A person of ordinary skill in the art would have determined that this limitation is either inherent and/or obvious to one of ordinary skill in the art in view of the teachings of Hikma/DailyMed. Further, one of ordinary skill in the art would have been motivated to modify Hikma/DailyMed or combine it with any of the present prior art references found in Sun's Invalidity Contentions and any supplements thereto and the relevant section charts for other prior art for the '076 Patent in a manner that would result in the subject matter of this limitation given, at the very least, the person's understanding of the state of the art, the problems addressed and solved in the prior art, and the teachings of Hikma/DailyMed.

G. Claim 7

'076 Patent Claim Limitation	Hikma/DailyMed
[7p] A pharmaceutical product, comprising:	To the extent the preamble is limiting, Hikma/DailyMed discloses and/or renders obvious the preamble based on at least the following citations. <i>See, e.g.:</i> Hikma at 35

'076 Patent Claim
Limitation

Hikma/DailyMed

Injectables





PHENOBARBITAL Sodium Injection, USP C-IV

BRAND EQUIVALENT	THERAPEUTIC CATEGORY	PRODUCT DESCRIPTION	FDA RATING	  
n/a	Barbiturate	Clear, Colorless Liquid	n/a	

NDC Number	Concentration	Total Drug Content	Fill Volume	Unit Size	Case Pack	Closure
0641-0476-25	65 mg / mL	65 mg / mL	1 mL	2 mL	25 vials	13 mm
0641-0477-25	130 mg / mL	130 mg / mL	1 mL	2 mL	25 vials	13 mm

- Hikma at 62

Wholesaler Numbers



Product Family	NDC Number	Total Drug Content	Fill Volume	Unit Size	Pack	ABC	Cardinal	HD Smith	MCK	M&D
Phenobarbital Sodium Injection, USP C-IV	0641-0476-25	65 mg / mL	1 mL	2 mL	25 vials	10034808	1264977	4160156	1140748	967760
Phenobarbital Sodium Injection, USP C-IV	0641-0477-25	130 mg / mL	1 mL	2 mL	25 vials	10034821	2086585	4160446	1231554	970848

- DailyMed

'076 Patent Claim Limitation	Hikma/DailyMed
	Phenobarbital Sodium Injection, USP is a sterile solution for intramuscular or slow intravenous administration as a long-acting barbiturate. Each mL contains phenobarbital sodium either 65 mg or 130 mg, alcohol 0.1 mL, propylene glycol 0.678 mL and benzyl alcohol 0.015 mL in Water for Injection; hydrochloric acid added, if needed, for pH adjustment. The pH range is 9.2-10.2.  HOW SUPPLIED Phenobarbital Sodium Injection, USP is available in the following: 65 mg/mL, 1 mL vials packaged in 25s (NDC 0641-0476-25) 130 mg/mL, 1 mL vials packaged in 25s (NDC 0641-0477-25)

'076 Patent Claim Limitation	Hikma/DailyMed
	 PRINCIPAL DISPLAY PANEL Phenobarbital Sodium Injection, USP 65 mg/mL 1 mL Vial NDC 0641-0476-21  Phenobarbital Sodium Injection, USP 65 mg/mL 25 x 1 mL Vials NDC 0641-0476-25

'076 Patent Claim Limitation	Hikma/DailyMed
	 NDC 0641-0477-21 Phenobarbital Sodium Injection, USP IV 130 mg/mL Rx only FOR IM OR SLOW IV USE 1 mL Vial Do not use if discolored or precipitated. Manufactured by WEST-WARD 462-351-03 (01)00306410477211 Lot: _____ Exp.: _____

'076 Patent Claim Limitation	Hikma/DailyMed
	Phenobarbital Sodium Injection, USP 130 mg/mL 25 x 1 mL Vials NDC 0641-0477-25  Let: Exp: To open—Cut seal along dotted line. NDC 0641-0477-25 Phenobarbital Sodium Injection, USP 130 mg/mL Rx only FOR IM OR SLOW IV USE 25 x 1 mL Vials DO NOT USE IF DISCOLORED OR CONTAINS A PRECIPITATE Manufactured by:  WEST-WARD Easton, NJ 07724 USA 462-382-00 Each mL contains phenobarbital sodium 130 mg, alcohol 0.1 mL, propylene glycol 0.678 mL, and benzyl alcohol 0.015 mL in Water for Injection, pH 9.2-10.2; hydrochloric acid added, if needed, for pH adjustment. Usual Dosage: See package insert. Store at 20°-25°C (68°-77°F) [See USP Controlled Room Temperature]. 0641-0477-25

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[7a] a single use dose vial, and	Hikma/DailyMed discloses and/or renders obvious this limitation based on at least the following citations. <i>See, e.g.:</i> - Hikma at 35 Injectables   PHENOBARBITAL Sodium Injection, USP C-IV <table><tr><td>BRAND EQUIVALENT n/a</td><td>THERAPEUTIC CATEGORY Barbiturate</td><td>PRODUCT DESCRIPTION Clear, Colorless Liquid</td><td>FDA RATING n/a</td><td colspan="3"></td></tr><tr><th>NDC Number</th><th>Concentration</th><th>Total Drug Content</th><th>Fill Volume</th><th>Unit Size</th><th>Case Pack</th><th>Closure</th></tr><tr><td>0641-0476-25</td><td>65 mg / mL</td><td>65 mg / mL</td><td>1 mL</td><td>2 mL</td><td>25 vials</td><td>13 mm</td></tr><tr><td>0641-0477-25</td><td>130 mg / mL</td><td>130 mg / mL</td><td>1 mL</td><td>2 mL</td><td>25 vials</td><td>13 mm</td></tr></table> - Hikma at 62	BRAND EQUIVALENT n/a	THERAPEUTIC CATEGORY Barbiturate	PRODUCT DESCRIPTION Clear, Colorless Liquid	FDA RATING n/a	  			NDC Number	Concentration	Total Drug Content	Fill Volume	Unit Size	Case Pack	Closure	0641-0476-25	65 mg / mL	65 mg / mL	1 mL	2 mL	25 vials	13 mm	0641-0477-25	130 mg / mL	130 mg / mL	1 mL	2 mL	25 vials	13 mm
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	 PRINCIPAL DISPLAY PANEL Phenobarbital Sodium Injection, USP 65 mg/mL 1 mL Vial NDC 0641-0476-21  Phenobarbital Sodium Injection, USP 65 mg/mL 25 x 1 mL Vials NDC 0641-0476-25

'076 Patent Claim Limitation	Hikma/DailyMed
	

'076 Patent Claim Limitation	Hikma/DailyMed
	Phenobarbital Sodium Injection, USP 130 mg/mL 25 x 1 mL Vials NDC 0641-0477-25  The image shows a detailed product label for Phenobarbital Sodium Injection, USP. The label is rectangular with a white background and blue text. At the top, there is a barcode and the text 'To open—Cut seal along dotted line.' Below this, the NDC number 'NDC 0641-0477-25' is printed. The product name 'Phenobarbital Sodium Injection, USP' is prominently displayed in a large, bold font. Below the product name, the concentration '130 mg/mL' is shown in a blue box, followed by 'Rx only'. The label also specifies 'FOR IM OR SLOW IV USE' and '25 x 1 mL Vials'. A warning statement reads 'DO NOT USE IF DISCOLORED OR CONTAINS A PRECIPITATE'. The manufacturer information 'Manufactured by: WEST-WARD, Easton, NJ 07724 USA' is at the bottom left. On the right side, there is a vertical barcode and the text '0641-0477-25'. A small 'IV' symbol is also present.

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	INGREDIENTS AND APPEARANCE PHENOBARBITAL SODIUM phenobarbital sodium injection PRODUCT INFORMATION <table><tr><td>Product Type</td><td>HUMAN PRESCRIPTION DRUG</td><td>Item Code (Source)</td><td>NDC:0641-0476</td></tr><tr><td>Route of Administration</td><td>INTRAMUSCULAR, INTRAVENOUS</td><td>DEA Schedule</td><td>CIV</td></tr></table> ACTIVE INGREDIENT/ACTIVE MOIETY <table><tr><td>Ingredient Name</td><td>Basis of Strength</td><td>Strength</td></tr><tr><td>PHENOBARBITAL SODIUM (UNII: SW9M9BB5K3) (PHENOBARBITAL - UNII: YQE403BP4D)</td><td>PHENOBARBITAL SODIUM</td><td>65 mg in 1 mL</td></tr></table> INACTIVE INGREDIENTS <table><tr><td>Ingredient Name</td><td>Strength</td></tr><tr><td>ALCOHOL (UNII: 3K9958V90M)</td><td>0.1 mL in 1 mL</td></tr><tr><td>PROPYLENE GLYCOL (UNII: 6DC9Q167V3)</td><td>0.678 mL in 1 mL</td></tr><tr><td>BENZYL ALCOHOL (UNII: LKG8494WBH)</td><td>0.015 mL in 1 mL</td></tr><tr><td>WATER (UNII: 059QF0KO0R)</td><td></td></tr><tr><td>HYDROCHLORIC ACID (UNII: QTT17582CB)</td><td></td></tr></table> PACKAGING <table><tr><td>#</td><td>Item Code</td><td>Package Description</td><td>Marketing Start Date</td><td>Marketing End Date</td></tr><tr><td>1</td><td>NDC:0641-0476-25</td><td>25 in 1 CARTON</td><td></td><td></td></tr><tr><td>1</td><td>NDC:0641-0476-21</td><td>1 mL in 1 VIAL</td><td></td><td></td></tr></table> MARKETING INFORMATION <table><tr><td>Marketing Category</td><td>Application Number or Monograph Citation</td><td>Marketing Start Date</td><td>Marketing End Date</td></tr><tr><td>UNAPPROVED DRUG OTHER</td><td></td><td>01/01/1971</td><td></td></tr></table>	Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:0641-0476	Route of Administration	INTRAMUSCULAR, INTRAVENOUS	DEA Schedule	CIV	Ingredient Name	Basis of Strength	Strength	PHENOBARBITAL SODIUM (UNII: SW9M9BB5K3) (PHENOBARBITAL - UNII: YQE403BP4D)	PHENOBARBITAL SODIUM	65 mg in 1 mL	Ingredient Name	Strength	ALCOHOL (UNII: 3K9958V90M)	0.1 mL in 1 mL	PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	0.678 mL in 1 mL	BENZYL ALCOHOL (UNII: LKG8494WBH)	0.015 mL in 1 mL	WATER (UNII: 059QF0KO0R)		HYDROCHLORIC ACID (UNII: QTT17582CB)		#	Item Code	Package Description	Marketing Start Date	Marketing End Date	1	NDC:0641-0476-25	25 in 1 CARTON			1	NDC:0641-0476-21	1 mL in 1 VIAL			Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	UNAPPROVED DRUG OTHER		01/01/1971	
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	Let: Exp.: To open - Cut seal along dotted line. NDC 0641-0476-25 Phenobarbital Sodium Injection, USP 65 mg/mL Rx only FOR IM OR SLOW IV USE 25 x 1 mL Vials DO NOT USE IF DISCOLORED OR CONTAINS A PRECIPITATE Manufactured by: WEST-WARD Eatontown, NJ 07724 USA 462-355-01 Each mL contains phenobarbital sodium 65 mg, alcohol 0.1 mL, propylene glycol 0.578 mL, and benzyl alcohol 0.215 mL in Water for Injection, pH 9.2-10.2; hydrochloric acid added, if needed, for pH adjustment. Usual Dosage: See package insert. Store at 20°-25°C (68°-77°F) (See USP Controlled Room Temperature). CLOSE PRINCIPAL DISPLAY PANEL Phenobarbital Sodium Injection, USP 130 mg/mL 1 mL Vial NDC 0641-0477-21

'076 Patent Claim Limitation	Hikma/DailyMed
	

'076 Patent Claim Limitation	Hikma/DailyMed
	Phenobarbital Sodium Injection, USP 130 mg/mL 25 x 1 mL Vials NDC 0641-0477-25  Let: Exp: To open—Cut seal along dotted line. NDC 0641-0477-25 Phenobarbital Sodium Injection, USP 130 mg/mL Rx only FOR IM OR SLOW IV USE 25 x 1 mL Vials DO NOT USE IF DISCOLORED OR CONTAINS A PRECIPITATE Manufactured by:  WEST-WARD Easton town, NJ 07724 USA 462-382-02 Each mL contains phenobarbital sodium 130 mg, alcohol 0.1 mL, propylene glycol 0.678 mL, and benzyl alcohol 0.015 mL in Water for Injection, pH 9.2-10.2; hydrochloric acid added, if needed, for pH adjustment. Usual Dosage: See package insert. Store at 20°-25°C (68°-77°F) [See USP Controlled Room Temperature]. 0641-0477-25

**'076 Patent Claim
Limitation**

Hikma/DailyMed

INGREDIENTS AND APPEARANCE

PHENOBARBITAL SODIUM
phenobarbital sodium injection

PRODUCT INFORMATION

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:0641-0476
Route of Administration	INTRAMUSCULAR, INTRAVENOUS	DEA Schedule	CIV

ACTIVE INGREDIENT/ACTIVE MOIETY

Ingredient Name	Basis of Strength	Strength
PHENOBARBITAL SODIUM (UNII: SW9M9BB5K3) (PHENOBARBITAL - UNII: YQE403BP4D)	PHENOBARBITAL SODIUM	65 mg in 1 mL

INACTIVE INGREDIENTS

Ingredient Name	Strength
ALCOHOL (UNII: 3K9958V90M)	0.1 mL in 1 mL
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	0.678 mL in 1 mL
BENZYL ALCOHOL (UNII: LKG8494WBH)	0.015 mL in 1 mL
WATER (UNII: 059QF0K00R)	
HYDROCHLORIC ACID (UNII: QTT17582CB)	

PACKAGING

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0641-0476-25	25 in 1 CARTON		
1	NDC:0641-0476-21	1 mL in 1 VIAL		

MARKETING INFORMATION

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
UNAPPROVED DRUG OTHER		01/01/1971	

'076 Patent Claim Limitation	Hikma/DailyMed																																																																																																									
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'076 Patent Claim Limitation	Hikma/DailyMed
	To the extent Hikma/DailyMed does not expressly disclose this limitation, a person of ordinary skill in the art would have determined that this limitation is either inherent and/or obvious to one of ordinary skill in the art in view of the teachings of Hikma/DailyMed. Further, one of ordinary skill in the art would have been motivated to modify Hikma/DailyMed or combine it with any of the present prior art references found in Sun's Invalidity Contentions and any supplements thereto and the relevant section charts for other prior art for the '076 Patent in a manner that would result in the subject matter of this limitation given, at the very least, the person's understanding of the state of the art, the problems addressed and solved in the prior art, and the teachings of Hikma/DailyMed.
[7c] wherein the composition is sterile and lyophilized,	A person of ordinary skill in the art would have determined that this limitation is either inherent and/or obvious to one of ordinary skill in the art in view of the teachings of Hikma/DailyMed. Further, one of ordinary skill in the art would have been motivated to modify Hikma/DailyMed or combine it with any of the present prior art references found in Sun's Invalidity Contentions and any supplements thereto and the relevant section charts for other prior art for the '076 Patent in a manner that would result in the subject matter of this limitation given, at the very least, the person's understanding of the state of the art, the problems addressed and solved in the prior art, and the teachings of Hikma/DailyMed.
[7d] wherein the composition comprises no less than 98% phenobarbital sodium, and	Hikma/DailyMed discloses and/or renders obvious this limitation based on at least the following citations. <i>See, e.g.:</i> • Hikma at 35

'076 Patent Claim Limitation

Hikma/DailyMed

Injectables





PHENOBARBITAL Sodium Injection, USP C-IV

BRAND EQUIVALENT	THERAPEUTIC CATEGORY	PRODUCT DESCRIPTION	FDA RATING	
n/a	Barbiturate	Clear, Colorless Liquid	n/a	  

NDC Number	Concentration	Total Drug Content	Fill Volume	Unit Size	Case Pack	Closure
0641-0476-25	65 mg / mL	65 mg / mL	1 mL	2 mL	25 vials	13 mm
0641-0477-25	130 mg / mL	130 mg / mL	1 mL	2 mL	25 vials	13 mm

- Hikma at 62

Wholesaler Numbers



Product Family	NDC Number	Total Drug Content	Fill Volume	Unit Size	Pack	ABC	Cardinal	HD Smith	MCK	M&D
Phenobarbital Sodium Injection, USP C-IV	0641-0476-25	65 mg / mL	1 mL	2 mL	25 vials	10034808	1264977	4160156	1140748	967760
Phenobarbital Sodium Injection, USP C-IV	0641-0477-25	130 mg / mL	1 mL	2 mL	25 vials	10034821	2086585	4160446	1231554	970848

- DailyMed

'076 Patent Claim Limitation	Hikma/DailyMed
	Phenobarbital Sodium Injection, USP is a sterile solution for intramuscular or slow intravenous administration as a long-acting barbiturate. Each mL contains phenobarbital sodium either 65 mg or 130 mg, alcohol 0.1 mL, propylene glycol 0.678 mL and benzyl alcohol 0.015 mL in Water for Injection; hydrochloric acid added, if needed, for pH adjustment. The pH range is 9.2-10.2.  HOW SUPPLIED Phenobarbital Sodium Injection, USP is available in the following: 65 mg/mL, 1 mL vials packaged in 25s (NDC 0641-0476-25) 130 mg/mL, 1 mL vials packaged in 25s (NDC 0641-0477-25)

'076 Patent Claim Limitation	Hikma/DailyMed
	PRINCIPAL DISPLAY PANEL Phenobarbital Sodium Injection, USP 65 mg/mL 1 mL Vial NDC 0641-0476-21 Phenobarbital Sodium Injection, USP 65 mg/mL 25 x 1 mL Vials NDC 0641-0476-25

'076 Patent Claim Limitation	Hikma/DailyMed
	 CLOSE  PRINCIPAL DISPLAY PANEL Phenobarbital Sodium Injection, USP 130 mg/mL 1 mL Vial NDC 0641-0477-21

'076 Patent Claim Limitation	Hikma/DailyMed
	

'076 Patent Claim Limitation	Hikma/DailyMed
	Phenobarbital Sodium Injection, USP 130 mg/mL 25 x 1 mL Vials NDC 0641-0477-25  The image shows a detailed product label for Phenobarbital Sodium Injection, USP. The label is rectangular with a white background and blue text. At the top, there is a barcode and the text 'To open—Cut seal along dotted line.' Below this, the NDC number 'NDC 0641-0477-25' is printed. The product name 'Phenobarbital Sodium Injection, USP' is prominently displayed in a large, bold font. Below the product name, the concentration '130 mg/mL' is shown in a blue box, followed by 'Rx only'. The label also specifies 'FOR IM OR SLOW IV USE' and '25 x 1 mL Vials'. A warning 'DO NOT USE IF DISCOLORED OR CONTAINS A PRECIPITATE' is included. The manufacturer information 'Manufactured by: WEST-WARD, Easton, NJ 07724 USA' is at the bottom left. On the right side, there is a vertical barcode and the text '0641-0477-25'. The label also contains detailed information about the contents of each mL, storage conditions, and a reference to the USP Controlled Room Temperature.

**'076 Patent Claim
Limitation**

Hikma/DailyMed

INGREDIENTS AND APPEARANCE

PHENOBARBITAL SODIUM
phenobarbital sodium injection

PRODUCT INFORMATION

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:0641- 0476
Route of Administration	INTRAMUSCULAR, INTRAVENOUS	DEA Schedule	CIV

ACTIVE INGREDIENT/ACTIVE MOIETY

Ingredient Name	Basis of Strength	Strength
PHENOBARBITAL SODIUM (UNII: SW9M9BB5K3) (PHENOBARBITAL - UNII: YQE403BP4D)	PHENOBARBITAL SODIUM	65 mg in 1 mL

INACTIVE INGREDIENTS

Ingredient Name	Strength
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PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	0.678 mL in 1 mL
BENZYL ALCOHOL (UNII: LKG8494WBH)	0.015 mL in 1 mL
WATER (UNII: 059QF0K00R)	
HYDROCHLORIC ACID (UNII: QTT17582CB)	

PACKAGING

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0641-0476- 25	25 in 1 CARTON		
1	NDC:0641-0476- 21	1 mL in 1 VIAL		

MARKETING INFORMATION

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
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'076 Patent Claim Limitation	Hikma/DailyMed
	To the extent Hikma/DailyMed does not expressly disclose this limitation, a person of ordinary skill in the art would have determined that this limitation is either inherent and/or obvious to one of ordinary skill in the art in view of the teachings of Hikma/DailyMed. Further, one of ordinary skill in the art would have been motivated to modify Hikma/DailyMed or combine it with any of the present prior art references found in Sun's Invalidity Contentions and any supplements thereto and the relevant section charts for other prior art for the '076 Patent in a manner that would result in the subject matter of this limitation given, at the very least, the person's understanding of the state of the art, the problems addressed and solved in the prior art, and the teachings of Hikma/DailyMed.
[7e] wherein the composition has the property that when the composition is stored at room temperature for 6 months and then reconstituted for injection with 10 mL of an aqueous solution to form a reconstituted composition, the reconstituted composition contains no more than 0.1% phenylethylacetylurea (PEAU).	A person of ordinary skill in the art would have determined that this limitation is either inherent and/or obvious to one of ordinary skill in the art in view of the teachings of Hikma/DailyMed. Further, one of ordinary skill in the art would have been motivated to modify Hikma/DailyMed or combine it with any of the present prior art references found in Sun's Invalidity Contentions and any supplements thereto and the relevant section charts for other prior art for the '076 Patent in a manner that would result in the subject matter of this limitation given, at the very least, the person's understanding of the state of the art, the problems addressed and solved in the prior art, and the teachings of Hikma/DailyMed.

H. Claim 8

'076 Patent Claim Limitation	Hikma/DailyMed
[8p] The pharmaceutical product of claim 7,	<i>See supra</i> Claim 7.

'076 Patent Claim Limitation	Hikma/DailyMed
[8a] wherein the composition has the property that when the composition is stored at room temperature for 6 months and then reconstituted for injection with 10 mL of an aqueous solution to form a reconstituted composition, the reconstituted composition contains no more than 0.05% PEAU.	A person of ordinary skill in the art would have determined that this limitation is either inherent and/or obvious to one of ordinary skill in the art in view of the teachings of Hikma/DailyMed. Further, one of ordinary skill in the art would have been motivated to modify Hikma/DailyMed or combine it with any of the present prior art references found in Sun's Invalidity Contentions and any supplements thereto and the relevant section charts for other prior art for the '076 Patent in a manner that would result in the subject matter of this limitation given, at the very least, the person's understanding of the state of the art, the problems addressed and solved in the prior art, and the teachings of Hikma/DailyMed.

I. Claim 9

'076 Patent Claim Limitation	Hikma/DailyMed
[9p] The pharmaceutical product of claim 7,	<i>See supra</i> Claim 7.
[9a] wherein the composition has the property that when the composition is stored at room temperature for 6 months and then reconstituted for injection with 10 mL of an aqueous solution to form a reconstituted composition, the reconstituted	A person of ordinary skill in the art would have determined that this limitation is either inherent and/or obvious to one of ordinary skill in the art in view of the teachings of Hikma/DailyMed. Further, one of ordinary skill in the art would have been motivated to modify Hikma/DailyMed or combine it with any of the present prior art references found in Sun's Invalidity Contentions and any supplements thereto and the relevant section charts for other prior art for the '076 Patent in a manner that would result in the subject matter of this limitation given, at the very least, the person's understanding of the state of the art, the problems addressed and solved in the prior art, and the teachings of Hikma/DailyMed.

'076 Patent Claim Limitation	Hikma/DailyMed
composition contains no more than 0.05% of 2-ethyl-2-phenylmalonamide (2EPMM).	

J. Claim 10

'076 Patent Claim Limitation	Hikma/DailyMed
[10p] The pharmaceutical product of claim 7,	<i>See supra</i> Claim 7.
[10a] wherein the composition has the property that when the composition is stored at room temperature for 6 months and then reconstituted for injection with 10 mL of an aqueous solution to form a reconstituted composition, the reconstituted composition contains no more than 0.05% of alpha-phenylbutyrylguanidine (PBG).	A person of ordinary skill in the art would have determined that this limitation is either inherent and/or obvious to one of ordinary skill in the art in view of the teachings of Hikma/DailyMed. Further, one of ordinary skill in the art would have been motivated to modify Hikma/DailyMed or combine it with any of the present prior art references found in Sun's Invalidity Contentions and any supplements thereto and the relevant section charts for other prior art for the '076 Patent in a manner that would result in the subject matter of this limitation given, at the very least, the person's understanding of the state of the art, the problems addressed and solved in the prior art, and the teachings of Hikma/DailyMed.

K. Claim 11

'076 Patent Claim Limitation	Hikma/DailyMed
[11p] The pharmaceutical product of claim 10,	<i>See supra</i> Claim 10.
[11a] wherein the composition has the property that when the composition is stored at room temperature for 6 months and then reconstituted for injection with 10 mL of an aqueous solution to form a reconstituted composition, the reconstituted composition contains no more than 0.05% of 2-ethyl-2-phenylmalonamide (2EPMM).	A person of ordinary skill in the art would have determined that this limitation is either inherent and/or obvious to one of ordinary skill in the art in view of the teachings of Hikma/DailyMed. Further, one of ordinary skill in the art would have been motivated to modify Hikma/DailyMed or combine it with any of the present prior art references found in Sun's Invalidity Contentions and any supplements thereto and the relevant section charts for other prior art for the '076 Patent in a manner that would result in the subject matter of this limitation given, at the very least, the person's understanding of the state of the art, the problems addressed and solved in the prior art, and the teachings of Hikma/DailyMed.

L. Claim 12

'076 Patent Claim Limitation	Hikma/DailyMed
[12p] The pharmaceutical product of claim 7,	<i>See supra</i> Claim 7.
[12a] wherein the composition is amorphous.	A person of ordinary skill in the art would have determined that this limitation is either inherent and/or obvious to one of ordinary skill in the art in view of the teachings of Hikma/DailyMed. Further, one of ordinary skill in the art would have been motivated to modify Hikma/DailyMed or combine it with any of the present prior art references found in Sun's Invalidity Contentions and any supplements thereto

'076 Patent Claim Limitation	Hikma/DailyMed
	and the relevant section charts for other prior art for the '076 Patent in a manner that would result in the subject matter of this limitation given, at the very least, the person's understanding of the state of the art, the problems addressed and solved in the prior art, and the teachings of Hikma/DailyMed.

M. Claim 13

'076 Patent Claim Limitation	Hikma/DailyMed
[13p] The pharmaceutical product of claim 12,	<i>See supra</i> Claim 12.
[13a] wherein the composition has the property that when the composition is stored at room temperature for 6 months and then reconstituted for injection with 10 mL of an aqueous solution to form a reconstituted composition, the reconstituted composition contains no more than 0.05% of alpha-phenylbutyrylguanidine (PBG).	A person of ordinary skill in the art would have determined that this limitation is either inherent and/or obvious to one of ordinary skill in the art in view of the teachings of Hikma/DailyMed. Further, one of ordinary skill in the art would have been motivated to modify Hikma/DailyMed or combine it with any of the present prior art references found in Sun's Invalidity Contentions and any supplements thereto and the relevant section charts for other prior art for the '076 Patent in a manner that would result in the subject matter of this limitation given, at the very least, the person's understanding of the state of the art, the problems addressed and solved in the prior art, and the teachings of Hikma/DailyMed.

N. Claim 14

'076 Patent Claim Limitation	Hikma/DailyMed
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'076 Patent Claim Limitation	Hikma/DailyMed
[14p] The pharmaceutical product of claim 1,	<i>See supra</i> Claim 1.
[14a] wherein the composition has the property that when the composition is stored at room temperature for 6 months and then reconstituted for injection with 10 mL of an aqueous solution to form a reconstituted composition, the reconstituted composition contains no more than 0.05% PEAU, and wherein the reconstituted composition contains no more than 0.05% of 2-ethyl-2-phenylmalonamide (2EPMM) or alpha-phenylbutyrylguanidine (PBG).	A person of ordinary skill in the art would have determined that this limitation is either inherent and/or obvious to one of ordinary skill in the art in view of the teachings of Hikma/DailyMed. Further, one of ordinary skill in the art would have been motivated to modify Hikma/DailyMed or combine it with any of the present prior art references found in Sun's Invalidity Contentions and any supplements thereto and the relevant section charts for other prior art for the '076 Patent in a manner that would result in the subject matter of this limitation given, at the very least, the person's understanding of the state of the art, the problems addressed and solved in the prior art, and the teachings of Hikma/DailyMed.

O. Claim 15

'076 Patent Claim Limitation	Hikma/DailyMed
[15p] The pharmaceutical product of claim 14,	<i>See supra</i> Claim 14.
[15a] wherein the	A person of ordinary skill in the art would have determined that this limitation is either inherent and/or

'076 Patent Claim Limitation	Hikma/DailyMed
composition is amorphous.	obvious to one of ordinary skill in the art in view of the teachings of Hikma/DailyMed. Further, one of ordinary skill in the art would have been motivated to modify Hikma/DailyMed or combine it with any of the present prior art references found in Sun's Invalidity Contentions and any supplements thereto and the relevant section charts for other prior art for the '076 Patent in a manner that would result in the subject matter of this limitation given, at the very least, the person's understanding of the state of the art, the problems addressed and solved in the prior art, and the teachings of Hikma/DailyMed.

P. Claim 16

'076 Patent Claim Limitation	Hikma/DailyMed
[16p] The pharmaceutical product of claim 1,	<i>See supra</i> Claim 1.
[16a] wherein the product comprises the 100 mg dose in the single use dose vial.	Hikma/DailyMed discloses and/or renders obvious this limitation based on at least the following citations. <i>See, e.g.:</i> • Hikma at 35

'076 Patent Claim Limitation

Hikma/DailyMed

Injectables





PHENOBARBITAL Sodium Injection, USP C-IV

BRAND EQUIVALENT	THERAPEUTIC CATEGORY	PRODUCT DESCRIPTION	FDA RATING
n/a	Barbiturate	Clear, Colorless Liquid	n/a



NDC Number	Concentration	Total Drug Content	Fill Volume	Unit Size	Case Pack	Closure
0641-0476-25	65 mg / mL	65 mg / mL	1 mL	2 mL	25 vials	13 mm
0641-0477-25	130 mg / mL	130 mg / mL	1 mL	2 mL	25 vials	13 mm

- Hikma at 62

Wholesaler Numbers



Product Family	NDC Number	Total Drug Content	Fill Volume	Unit Size	Pack	ABC	Cardinal	HD Smith	MCK	M&D
Phenobarbital Sodium Injection, USP C-IV	0641-0476-25	65 mg / mL	1 mL	2 mL	25 vials	10034808	1264977	4160156	1140748	967760
Phenobarbital Sodium Injection, USP C-IV	0641-0477-25	130 mg / mL	1 mL	2 mL	25 vials	10034821	2086585	4160446	1231554	970848

- DailyMed

'076 Patent Claim Limitation	Hikma/DailyMed
	Phenobarbital Sodium Injection, USP is a sterile solution for intramuscular or slow intravenous administration as a long-acting barbiturate. Each mL contains phenobarbital sodium either 65 mg or 130 mg, alcohol 0.1 mL, propylene glycol 0.678 mL and benzyl alcohol 0.015 mL in Water for Injection; hydrochloric acid added, if needed, for pH adjustment. The pH range is 9.2-10.2.  HOW SUPPLIED Phenobarbital Sodium Injection, USP is available in the following: 65 mg/mL, 1 mL vials packaged in 25s (NDC 0641-0476-25) 130 mg/mL, 1 mL vials packaged in 25s (NDC 0641-0477-25)

'076 Patent Claim Limitation	Hikma/DailyMed
	 PRINCIPAL DISPLAY PANEL Phenobarbital Sodium Injection, USP 65 mg/mL 1 mL Vial NDC 0641-0476-21  Phenobarbital Sodium Injection, USP 65 mg/mL 25 x 1 mL Vials NDC 0641-0476-25

'076 Patent Claim Limitation	Hikma/DailyMed
	

'076 Patent Claim Limitation	Hikma/DailyMed
	Phenobarbital Sodium Injection, USP 130 mg/mL 25 x 1 mL Vials NDC 0641-0477-25  The image shows a detailed product label for Phenobarbital Sodium Injection, USP. The label is rectangular with a white background and blue text. At the top, there is a barcode and the text 'To open—Cut seal along dotted line.' Below this, the NDC number 'NDC 0641-0477-25' is printed. The product name 'Phenobarbital Sodium Injection, USP' is prominently displayed in a large, bold font. Below the product name, the concentration '130 mg/mL' is shown in a blue box, followed by 'Rx only'. The label also specifies 'FOR IM OR SLOW IV USE' and '25 x 1 mL Vials'. A warning statement reads 'DO NOT USE IF DISCOLORED OR CONTAINS A PRECIPITATE'. The manufacturer information 'Manufactured by: WEST-WARD, Easton, NJ 07724 USA' is at the bottom left. On the right side, there is a vertical barcode and the text '0641-0477-25'. A small 'IV' symbol is also present.

'076 Patent Claim Limitation

Hikma/DailyMed

INGREDIENTS AND APPEARANCE

PHENOBARBITAL SODIUM

phenobarbital sodium injection

PRODUCT INFORMATION

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:0641-0476
Route of Administration	INTRAMUSCULAR, INTRAVENOUS	DEA Schedule	CIV

ACTIVE INGREDIENT/ACTIVE MOIETY

Ingredient Name	Basis of Strength	Strength
PHENOBARBITAL SODIUM (UNII: SW9M9BB5K3) (PHENOBARBITAL - UNII: YQE403BP4D)	PHENOBARBITAL SODIUM	65 mg in 1 mL

INACTIVE INGREDIENTS

Ingredient Name	Strength
ALCOHOL (UNII: 3K9958V90M)	0.1 mL in 1 mL
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	0.678 mL in 1 mL
BENZYL ALCOHOL (UNII: LKG8494WBH)	0.015 mL in 1 mL
WATER (UNII: 059QF0K00R)	
HYDROCHLORIC ACID (UNII: QTT17582CB)	

PACKAGING

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0641-0476-25	25 in 1 CARTON		
1	NDC:0641-0476-21	1 mL in 1 VIAL		

MARKETING INFORMATION

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
UNAPPROVED DRUG OTHER		01/01/1971	

'076 Patent Claim Limitation	Hikma/DailyMed																																																																																																									
	<table><tr><th colspan="5">PHENOBARBITAL SODIUM phenobarbital sodium injection</th></tr><tr><th colspan="5">PRODUCT INFORMATION</th></tr><tr><td>Product Type</td><td>HUMAN PRESCRIPTION DRUG</td><td>Item Code (Source)</td><td colspan="2">NDC:0641-0477</td></tr><tr><td>Route of Administration</td><td>INTRAMUSCULAR, INTRAVENOUS</td><td>DEA Schedule</td><td colspan="2">CIV</td></tr><tr><th colspan="5">ACTIVE INGREDIENT/ACTIVE MOIETY</th></tr><tr><td colspan="2">Ingredient Name</td><td>Basis of Strength</td><td colspan="2">Strength</td></tr><tr><td colspan="2">PHENOBARBITAL SODIUM (UNII: SW9M9BB5K3) (PHENOBARBITAL - UNII: YQE403BP4D)</td><td>PHENOBARBITAL SODIUM</td><td colspan="2">130 mg in 1 mL</td></tr><tr><th colspan="5">INACTIVE INGREDIENTS</th></tr><tr><td colspan="2">Ingredient Name</td><td colspan="3">Strength</td></tr><tr><td colspan="2">ALCOHOL (UNII: 3K9958V90M)</td><td colspan="3">0.1 mL in 1 mL</td></tr><tr><td colspan="2">PROPYLENE GLYCOL (UNII: 6DC9Q167V3)</td><td colspan="3">0.678 mL in 1 mL</td></tr><tr><td colspan="2">BENZYL ALCOHOL (UNII: LKG8494WBH)</td><td colspan="3">0.015 mL in 1 mL</td></tr><tr><td colspan="2">WATER (UNII: 059QF0KO0R)</td><td colspan="3"></td></tr><tr><td colspan="2">HYDROCHLORIC ACID (UNII: QTT17582CB)</td><td colspan="3"></td></tr><tr><th colspan="5">PACKAGING</th></tr><tr><td>#</td><td>Item Code</td><td>Package Description</td><td>Marketing Start Date</td><td>Marketing End Date</td></tr><tr><td>1</td><td>NDC:0641-0477-25</td><td>25 in 1 CARTON</td><td></td><td></td></tr><tr><td>1</td><td>NDC:0641-0477-21</td><td>1 mL in 1 VIAL</td><td></td><td></td></tr><tr><th colspan="5">MARKETING INFORMATION</th></tr><tr><td>Marketing Category</td><td>Application Number or Monograph Citation</td><td>Marketing Start Date</td><td colspan="2">Marketing End Date</td></tr><tr><td>UNAPPROVED DRUG OTHER</td><td></td><td>01/01/1971</td><td colspan="2"></td></tr></table>	PHENOBARBITAL SODIUM phenobarbital sodium injection					PRODUCT INFORMATION					Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:0641-0477		Route of Administration	INTRAMUSCULAR, INTRAVENOUS	DEA Schedule	CIV		ACTIVE INGREDIENT/ACTIVE MOIETY					Ingredient Name		Basis of Strength	Strength		PHENOBARBITAL SODIUM (UNII: SW9M9BB5K3) (PHENOBARBITAL - UNII: YQE403BP4D)		PHENOBARBITAL SODIUM	130 mg in 1 mL		INACTIVE INGREDIENTS					Ingredient Name		Strength			ALCOHOL (UNII: 3K9958V90M)		0.1 mL in 1 mL			PROPYLENE GLYCOL (UNII: 6DC9Q167V3)		0.678 mL in 1 mL			BENZYL ALCOHOL (UNII: LKG8494WBH)		0.015 mL in 1 mL			WATER (UNII: 059QF0KO0R)					HYDROCHLORIC ACID (UNII: QTT17582CB)					PACKAGING					#	Item Code	Package Description	Marketing Start Date	Marketing End Date	1	NDC:0641-0477-25	25 in 1 CARTON			1	NDC:0641-0477-21	1 mL in 1 VIAL			MARKETING INFORMATION					Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		UNAPPROVED DRUG OTHER		01/01/1971		
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'076 Patent Claim Limitation	Hikma/DailyMed
	To the extent Hikma/DailyMed does not expressly disclose this limitation, a person of ordinary skill in the art would have determined that this limitation is either inherent and/or obvious to one of ordinary skill in the art in view of the teachings of Hikma/DailyMed. Further, one of ordinary skill in the art would have been motivated to modify Hikma/DailyMed or combine it with any of the present prior art references found in Sun's Invalidity Contentions and any supplements thereto and the relevant section charts for other prior art for the '076 Patent in a manner that would result in the subject matter of this limitation given, at the very least, the person's understanding of the state of the art, the problems addressed and solved in the prior art, and the teachings of Hikma/DailyMed.

Q. Claim 17

'076 Patent Claim Limitation	Hikma/DailyMed
[17p] The pharmaceutical product of claim 7,	<i>See supra</i> Claim 7.
[17a] wherein the product comprises the 100 mg dose in the single use dose vial.	Hikma/DailyMed discloses and/or renders obvious this limitation based on at least the following citations. <i>See, e.g.:</i> • Hikma at 35

'076 Patent Claim Limitation

Hikma/DailyMed

Injectables





PHENOBARBITAL Sodium Injection, USP C-IV

BRAND EQUIVALENT	THERAPEUTIC CATEGORY	PRODUCT DESCRIPTION	FDA RATING	
n/a	Barbiturate	Clear, Colorless Liquid	n/a	  

NDC Number	Concentration	Total Drug Content	Fill Volume	Unit Size	Case Pack	Closure
0641-0476-25	65 mg / mL	65 mg / mL	1 mL	2 mL	25 vials	13 mm
0641-0477-25	130 mg / mL	130 mg / mL	1 mL	2 mL	25 vials	13 mm

- Hikma at 62

Wholesaler Numbers



Product Family	NDC Number	Total Drug Content	Fill Volume	Unit Size	Pack	ABC	Cardinal	HD Smith	MCK	M&D
Phenobarbital Sodium Injection, USP C-IV	0641-0476-25	65 mg / mL	1 mL	2 mL	25 vials	10034808	1264977	4160156	1140748	967760
Phenobarbital Sodium Injection, USP C-IV	0641-0477-25	130 mg / mL	1 mL	2 mL	25 vials	10034821	2086585	4160446	1231554	970848

- DailyMed

'076 Patent Claim Limitation	Hikma/DailyMed
	Phenobarbital Sodium Injection, USP is a sterile solution for intramuscular or slow intravenous administration as a long-acting barbiturate. Each mL contains phenobarbital sodium either 65 mg or 130 mg, alcohol 0.1 mL, propylene glycol 0.678 mL and benzyl alcohol 0.015 mL in Water for Injection; hydrochloric acid added, if needed, for pH adjustment. The pH range is 9.2-10.2.  HOW SUPPLIED Phenobarbital Sodium Injection, USP is available in the following: 65 mg/mL, 1 mL vials packaged in 25s (NDC 0641-0476-25) 130 mg/mL, 1 mL vials packaged in 25s (NDC 0641-0477-25)

'076 Patent Claim Limitation	Hikma/DailyMed
	 PRINCIPAL DISPLAY PANEL Phenobarbital Sodium Injection, USP 65 mg/mL 1 mL Vial NDC 0641-0476-21  Phenobarbital Sodium Injection, USP 65 mg/mL 25 x 1 mL Vials NDC 0641-0476-25

'076 Patent Claim Limitation	Hikma/DailyMed
	 Let: Exp: To open—Cut seal along dotted line. NDC 0641-0476-25 Phenobarbital Sodium Injection, USP 65 mg/mL Rx only FOR IM OR SLOW IV USE 25 x 1 mL Vials DO NOT USE IF DISCOLORED OR CONTAINS A PRECIPITATE Manufactured by: WEST-WARD Eatontown, NJ 07724 USA 462-950-01 Each mL contains phenobarbital sodium 65 mg, alcohol 0.1 mL, propylene glycol 0.578 mL, and benzyl alcohol 0.215 mL in Water for Injection, pH 9.2-10.2; hydrochloric acid added, if needed, for pH adjustment. Usual Dosage: See package insert. Store at 20°-25°C (68°-77°F) (See USP Controlled Room Temperature). CLOSE — PRINCIPAL DISPLAY PANEL Phenobarbital Sodium Injection, USP 130 mg/mL 1 mL Vial NDC 0641-0477-21

'076 Patent Claim Limitation	Hikma/DailyMed
	

'076 Patent Claim Limitation	Hikma/DailyMed
	Phenobarbital Sodium Injection, USP 130 mg/mL 25 x 1 mL Vials NDC 0641-0477-25  Let: Exp: To open—Cut seal along dotted line. NDC 0641-0477-25 Phenobarbital Sodium Injection, USP 130 mg/mL Rx only FOR IM OR SLOW IV USE 25 x 1 mL Vials DO NOT USE IF DISCOLORED OR CONTAINS A PRECIPITATE Manufactured by:  WEST-WARD Easton town, NJ 07724 USA 462-382-02 Each mL contains phenobarbital sodium 130 mg, alcohol 0.1 mL, propylene glycol 0.678 mL, and benzyl alcohol 0.015 mL in Water for Injection, pH 9.2-10.2; hydrochloric acid added, if needed, for pH adjustment. Usual Dosage: See package insert. Store at 20°-25°C (68°-77°F) [See USP Controlled Room Temperature]. 0641-0477-25

'076 Patent Claim Limitation

Hikma/DailyMed

INGREDIENTS AND APPEARANCE

PHENOBARBITAL SODIUM

phenobarbital sodium injection

PRODUCT INFORMATION

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:0641-0476
Route of Administration	INTRAMUSCULAR, INTRAVENOUS	DEA Schedule	CIV

ACTIVE INGREDIENT/ACTIVE MOIETY

Ingredient Name	Basis of Strength	Strength
PHENOBARBITAL SODIUM (UNII: SW9M9BB5K3) (PHENOBARBITAL - UNII: YQE403BP4D)	PHENOBARBITAL SODIUM	65 mg in 1 mL

INACTIVE INGREDIENTS

Ingredient Name	Strength
ALCOHOL (UNII: 3K9958V90M)	0.1 mL in 1 mL
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	0.678 mL in 1 mL
BENZYL ALCOHOL (UNII: LKG8494WBH)	0.015 mL in 1 mL
WATER (UNII: 059QF0K00R)	
HYDROCHLORIC ACID (UNII: QTT17582CB)	

PACKAGING

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0641-0476-25	25 in 1 CARTON		
1	NDC:0641-0476-21	1 mL in 1 VIAL		

MARKETING INFORMATION

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
UNAPPROVED DRUG OTHER		01/01/1971	

'076 Patent Claim Limitation	Hikma/DailyMed																																																																																																									
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Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date																																																																																																							
UNAPPROVED DRUG OTHER		01/01/1971																																																																																																								

'076 Patent Claim Limitation	Hikma/DailyMed
	To the extent Hikma/DailyMed does not expressly disclose this limitation, a person of ordinary skill in the art would have determined that this limitation is either inherent and/or obvious to one of ordinary skill in the art in view of the teachings of Hikma/DailyMed. Further, one of ordinary skill in the art would have been motivated to modify Hikma/DailyMed or combine it with any of the present prior art references found in Sun's Invalidity Contentions and any supplements thereto and the relevant section charts for other prior art for the '076 Patent in a manner that would result in the subject matter of this limitation given, at the very least, the person's understanding of the state of the art, the problems addressed and solved in the prior art, and the teachings of Hikma/DailyMed.

R. Claim 18

'076 Patent Claim Limitation	Hikma/DailyMed
[18p] The pharmaceutical product of claim 8,	<i>See supra</i> Claim 8.
[18a] wherein the composition has the property that when the composition is stored at room temperature for 6 months and then reconstituted for injection with 10 mL of an aqueous solution to form a reconstituted composition, the reconstituted composition contains no more than 0.05% of 2-ethyl-2-phenylmalonamide (2EPMM).	A person of ordinary skill in the art would have determined that this limitation is either inherent and/or obvious to one of ordinary skill in the art in view of the teachings of Hikma/DailyMed. Further, one of ordinary skill in the art would have been motivated to modify Hikma/DailyMed or combine it with any of the present prior art references found in Sun's Invalidity Contentions and any supplements thereto and the relevant section charts for other prior art for the '076 Patent in a manner that would result in the subject matter of this limitation given, at the very least, the person's understanding of the state of the art, the problems addressed and solved in the prior art, and the teachings of Hikma/DailyMed.

S. Claim 19

'076 Patent Claim Limitation	Hikma/DailyMed
[19p] The pharmaceutical product of claim 8,	<i>See supra</i> Claim 8.
[19a] wherein the composition has the property that when the composition is stored at room temperature for 6 months and then reconstituted for injection with 10 mL of an aqueous solution to form a reconstituted composition, the reconstituted composition contains no more than 0.05% of alpha-phenylbutyrylguanidine (PBG).	A person of ordinary skill in the art would have determined that this limitation is either inherent and/or obvious to one of ordinary skill in the art in view of the teachings of Hikma/DailyMed. Further, one of ordinary skill in the art would have been motivated to modify Hikma/DailyMed or combine it with any of the present prior art references found in Sun's Invalidity Contentions and any supplements thereto and the relevant section charts for other prior art for the '076 Patent in a manner that would result in the subject matter of this limitation given, at the very least, the person's understanding of the state of the art, the problems addressed and solved in the prior art, and the teachings of Hikma/DailyMed.

T. Claim 20

'076 Patent Claim Limitation	Hikma/DailyMed
[20p] The pharmaceutical product of claim 8,	<i>See supra</i> Claim 8.
[20a] wherein the composition is amorphous.	A person of ordinary skill in the art would have determined that this limitation is either inherent and/or obvious to one of ordinary skill in the art in view of the teachings of Hikma/DailyMed. Further, one of ordinary skill in the art would have been motivated to modify Hikma/DailyMed or combine it with any

'076 Patent Claim Limitation	Hikma/DailyMed
	of the present prior art references found in Sun's Invalidity Contentions and any supplements thereto and the relevant section charts for other prior art for the '076 Patent in a manner that would result in the subject matter of this limitation given, at the very least, the person's understanding of the state of the art, the problems addressed and solved in the prior art, and the teachings of Hikma/DailyMed.