

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

HERON THERAPEUTICS, INC., <p style="text-align: center;">Plaintiff,</p> <p style="text-align: center;">v.</p> AZURITY PHARMACEUTICALS, INC., AZURITY PHARMACEUTICALS INDIA LLP f/k/a SLAYBACK PHARMA INDIA LLP, and SLAYBACK PHARMA LLC, <p style="text-align: center;">Defendants.</p>
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C.A. No. 24-1363-WCB

DEFENDANTS’ STIPULATION OF INVALIDITY CONTENTIONS

Defendants Azurity Pharmaceuticals, Inc., Azurity Pharmaceuticals India LLP f/k/a Slayback Pharma India LLP, and Slayback Pharma LLC (collectively, “Azurity”) submit this stipulation of invalidity contentions.

On February 28, 2025, Azurity filed petition numbers PGR2025-00035 and PGR2025-00036 with the Patent Trial and Appeal Board (“PTAB”) requesting Post Grant Review of U.S. Patent Nos. 12,115,254 (“the ’254 patent”) and. 12,115,255 (“the ’255 patent”), respectively. The petitions assert the following grounds of invalidity:

PGR Pet. No.	Patent No.	PGR Ground	Claims	Grounds of Invalidity
PGR2025-00035	’254 patent	1	1-30	Obvious under 35 U.S.C. §103 over Chinese Patent No. CN102379845 to Zhou (“Zhou”) in view of Washington, “Stability of lipid emulsions for drug delivery,” <i>Advanced Drug Delivery Reviews</i> , 20, (1996), 131-145 (“Washington”), Bagwe et al., “Improved Drug Delivery Using Microemulsions: Rationale, Recent Progress, and New Horizons,” <i>Critical Reviews TM in Therapeutic Drug Carrier Systems</i> , 18(1):77-140 (2001) (“Bagwe”), and Weng et al., “Formulation, preparation, and stability of intravenous bufadienolides-loaded lipid microspheres,” <i>Eur. J. Lipid Sci. Technol.</i> 2012, 114, 1154-1164 (“Weng”)

PGR Pet. No.	Patent No.	PGR Ground	Claims	Grounds of Invalidity
		2	1-30	Lack of written description under 35 U.S.C. §112
		3	1-30	Lack of enablement under 35 U.S.C. §112
PGR2025-00036	'255 patent	1	1-30	Obvious under 35 U.S.C. §103 over Chinese Patent No. CN102379845 to Zhou (“Zhou”) in view of Washington, “Stability of lipid emulsions for drug delivery,” <i>Advanced Drug Delivery Reviews</i> , 20, (1996), 131-145 (“Washington”), Bagwe et al., “Improved Drug Delivery Using Microemulsions: Rationale, Recent Progress, and New Horizons,” <i>Critical Reviews™ in Therapeutic Drug Carrier Systems</i> , 18(1):77-140 (2001) (“Bagwe”), Weng et al., “Formulation, preparation, and stability of intravenous bufadienolides-loaded lipid microspheres,” <i>Eur. J. Lipid Sci. Technol.</i> 2012, 114, 1154-1164 (“Weng”), and U.S. Application Publication No. 2011/0038925 to Wan (“Wan”)
		2	1-30	Lack of written description under 35 U.S.C. §112
		3	1-30	Lack of enablement under 35 U.S.C. §112

Azurity hereby stipulates that if the PTAB institutes PGR2025-00035 and/or PGR2025-00036, Defendants will not pursue in this case the specific grounds identified above in connection with the referenced patent(s) and claim(s) as originally issued on the instituted Post Grant Review petition, or any other ground for a given patent for which the Board institutes, that could have been reasonably raised in a Post Grant Review.

Dated: July 11, 2025

MORRIS JAMES LLP

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Other Documents

[1:24-cv-01363-WCB Heron Therapeutics, Inc. v. Azurity Pharmaceuticals, Inc., et al.](#)

ANDA,PATENT

U.S. District Court

District of Delaware

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Azurity Pharmaceuticals, Inc.
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Docket Text:

STIPULATION of Invalidity Contentions by Azurity Pharmaceuticals India LLP, Azurity Pharmaceuticals, Inc., Slayback Pharma LLC. (Hitch, Cortlan)

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