

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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COALITION FOR AFFORDABLE DRUGS II LLC  
Petitioner

v.

NPS PHARMACEUTICALS, INC.  
Patent Owner

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IPR2015-01093  
Patent No. 7,056,886

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**PETITIONER'S OBJECTIONS TO PATENT OWNER'S EXHIBITS  
SUBMITTED WITH ITS PATENT OWNER'S RESPONSE**

Pursuant to 37 C.F.R. § 42.64, Petitioner Coalition For Affordable Drugs II

LLC serves the following objections to exhibits submitted with Patent Owner NPS

Pharmaceuticals, Inc.'s Response (Paper 31):

<b>Patent Owner Ex. No.</b>	<b>Description</b>	<b>Objections</b>
2041	Declaration of Gordon Rausser, Ph.D.	Relevancy; Fed. R. Evid. 401, 402 and 403 Hearsay; Fed. R. Evid. 802 Improper expert testimony; Fed. R. Evid. 702, 703 Original Document Requirement; Fed. R. Evid. 1002
2045	Jackson et al., <i>Curr Diab Rep.</i> 2012 December ; 12(6): 705–710.	Relevancy; Fed. R. Evid. 401, 402, and 403 Hearsay; Fed. R. Evid. 802
2046	Onoue et al., <i>Pharmaceutical Research, Vol. 21, No. 7, July 2004</i>	Relevancy; Fed. R. Evid. 401, 402, and 403 Hearsay; Fed. R. Evid. 802
2047	The United States Pharmacopeia Official Monographs (2000)	Hearsay; Fed. R. Evid. 802
2048	Joshi et al., <i>International Journal of Pharmaceutics</i> 203 (2000) 115–125	Hearsay; Fed. R. Evid. 802
2049	Fang et al., <i>Pharm Res</i> (2012) 29:3278–3291	Relevancy; Fed. R. Evid. 401, 402, and 403 Hearsay; Fed. R. Evid. 802
2050	T.L. Blundell, Chapter 3, <i>The Conformation of Glucagon</i> (1983)	Hearsay; Fed. R. Evid. 802
2051	Boesch et al., <i>Eur. J. Biochem.</i> 91, 209-214 (1978)	Hearsay; Fed. R. Evid. 802
2051	Declaration of John F. Carpenter, Ph.D.	Relevancy; Fed. R. Evid. 401, 402 and 403 Hearsay; Fed. R. Evid. 802 Improper expert testimony; Fed. R. Evid.

		702, 703 Original Document Requirement; Fed. R. Evid. 1002
2052	Akers, Journal of Pharmaceutical Sciences, Vol. 91, No. 11, November 2002	Relevancy; Fed. R. Evid. 401, 402, and 403 Hearsay; Fed. R. Evid. 802
2053	<i>Revision Bulletin</i> Official October 1, 2011, <788> Particulate Matter In Injections	Relevancy; Fed. R. Evid. 401, 402, and 403 Hearsay; Fed. R. Evid. 802 Unauthenticated; Fed. R. Evid. 901
2054	Remington's Pharmaceutical Sciences, 18 <sup>th</sup> Edition, pp. 1549-1551	Hearsay; Fed. R. Evid. 802 Incomplete; Fed. R. Evid. 106
2055	United States Patent Application Publication 2013/0310314 published November 21, 2013	Relevancy; Fed. R. Evid. 401, 402, and 403 Hearsay; Fed. R. Evid. 802
2056	Process Validation and/or Evaluation for Gattex	Hearsay; Fed. R. Evid. 802 Unauthenticated; Fed. R. Evid. 901 Original Document Requirement; Fed. R. Evid. 1002
2057	Annex I – Summary of Product Characteristics	Hearsay; Fed. R. Evid. 802 Unauthenticated; Fed. R. Evid. 901 Original Document Requirement; Fed. R. Evid. 1002
2058	Orange Book: Gattex Kit	Unauthenticated; Fed. R. Evid. 901
2059	Information for the Physician, Glucagon for Injection (rDNA Origin)	Hearsay; Fed. R. Evid. 802 Unauthenticated; Fed. R. Evid. 901 Original Document Requirement; Fed. R. Evid. 1002
2060	Al-Hussein et al., Journal of Pharmaceutical Sciences, Vol. 102, No. 3, March 2013	Relevancy; Fed. R. Evid. 401, 402, and 403 Hearsay; Fed. R. Evid. 802
2061	Izutsu et al., <i>Chem. Pharm. Bull.</i> 57(1) 43-48 (2009)	Relevancy; Fed. R. Evid. 401, 402, and 403 Hearsay; Fed. R. Evid. 802
2062	The United States	Hearsay; Fed. R. Evid. 802

	Pharmacopeia, USP 23, pp. 1650-1651 (1995)	Incomplete; Fed. R. Evid. 106
2063	Center for Drug Evaluation and Research, Application Number: 203441Orig1s000, Chemistry Review(s)	Hearsay; Fed. R. Evid. 802 Unauthenticated; Fed. R. Evid. 901 Original Document Requirement; Fed. R. Evid. 1002 Incomplete; Fed. R. Evid. 106
2064	Label and Approval History, Zorbtive	Relevancy; Fed. R. Evid. 401, 402, and 403 Hearsay; Fed. R. Evid. 802 Unauthenticated; Fed. R. Evid. 901
2065	Shire Completes Acquisition of NPS Pharma, February 21, 2015 <a href="https://www.shire.com/newroom/2015/february/shire-completes-acquisition-of-nps-pharma">https://www.shire.com/newroom/2015/february/shire-completes-acquisition-of-nps-pharma</a>	Hearsay; Fed. R. Evid. 802 Unauthenticated; Fed. R. Evid. 901
2066	Tom Engellenner, Bass Goes Fishing: Trouble Ahead For Pharma, Or For Hedge-Fund Trolls? <a href="http://www.forbes.com/sites/danielfisher/2015/07/15/bass-goes-fishing-trouble-ahead-for-pharma-or-for-hedge-fundtrolls/#2715e4857a0b47e56d7f225e">http://www.forbes.com/sites/danielfisher/2015/07/15/bass-goes-fishing-trouble-ahead-for-pharma-or-for-hedge-fundtrolls/#2715e4857a0b47e56d7f225e</a>	Hearsay; Fed. R. Evid. 802
2067	New Hedge Fund Strategy: Dispute the Patent, Short the Stock – WSJ	Hearsay; Fed. R. Evid. 802
2068	Jen Wieczner, Why drug price controversy is great news for this hedge fund Manager, <a href="http://fortune.com/2015/09/30/drug-prices-stocks-kyle-bass/">http://fortune.com/2015/09/30/drug-prices-stocks-kyle-bass/</a>	Hearsay; Fed. R. Evid. 802
2069	Alan L. Buchman,	Relevancy; Fed. R. Evid. 401, 402, and 403

	GASTROENTEROLOGY 2006;130:S5–S15	Hearsay; Fed. R. Evid. 802
2070	Pironi et al., Clinical Nutrition 34 (2015) 171- 180	Relevancy; Fed. R. Evid. 401, 402, and 403 Hearsay; Fed. R. Evid. 802
2071	O’Keefe et al., CLINICAL GASTROENTEROLOGY AND HEPATOLOGY 2006;4:6–10	Relevancy; Fed. R. Evid. 401, 402, and 403 Hearsay; Fed. R. Evid. 802
2072	Alan L. Buchman, Nutrition Vol. 13, No. 10, 1997	Hearsay; Fed. R. Evid. 802
2073	NPS Pharmaceuticals, Developing Orphan Products for Patients with Rare Gastrointestinal and Endocrine Disorders, August 2012	Relevancy; Fed. R. Evid. 401, 402, and 403 Hearsay; Fed. R. Evid. 802 Unauthenticated; Fed. R. Evid. 901 Original Document Requirement; Fed. R. Evid. 1002
2074	Hofstetter et al., Current Medical Research and Opinion Vol. 29, No. 5, 2013, 495–504	Relevancy; Fed. R. Evid. 401, 402, and 403 Hearsay; Fed. R. Evid. 802
2075	Gattex Physician Report	Relevancy; Fed. R. Evid. 401, 402, and 403 Lack of Foundation; Fed. R. Evid 602, 701, 702 Hearsay; Fed. R. Evid. 802 Unauthenticated; Fed. R. Evid 901 Original Document Requirement; Fed. R. Evid. 1002
2076	Meier RF, Reddy BR, Soeters PB (eds): The Importance of Nutrition as an Integral Part of Disease Management. Nestlé Nutr Inst Workshop Ser, vol 82, pp 75–90, 2015, Nutritional Issues in the Short Bowel Syndrome – Total Parenteral Nutrition, Enteral Nutrition and the	Relevancy; Fed. R. Evid. 401, 402, and 403 Hearsay; Fed. R. Evid. 802

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