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**UNITED STATES PATENT AND TRADEMARK OFFICE**

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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ROXANE LABORATORIES, INC.,

Petitioner,

v.

NOVARTIS AG,

Patent Owner.

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Case IPR2016-01461

Patent No. 9,006,224

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**PATENT OWNER'S PRELIMINARY  
RESPONSE UNDER 37 C.F.R. § 42.107**

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## LIST OF EXHIBITS

Exhibit	Description	Abbreviation
2001	Expert Declaration of Matthew H. Kulke, M.D., M.M.Sc.	<b>Kulke Decl.</b>
2002	<i>Curriculum Vitae</i> of Matthew H. Kulke, M.D., M.M.Sc.	<b>Kulke C.V.</b>
2003	Seeley, R. R., Stephens, T.D., & Tate, P., <i>Anatomy &amp; Physiology</i> , 3rd Edition, pages 585 – 586 (1995)	<b>Seeley</b>
2004	Moertel, C.G., <i>et al.</i> , “Streptozocin-Doxorubicin, Streptozocin-Fluorouracil, Or Chlorozotocin In The Treatment Of Advanced Islet-Cell Carcinoma,” <i>New Engl. J. Med.</i> 326(8):519-523 (1992)	<b>Moertel</b>
2005	Laughlin, E.H., <i>Coming To Terms With Cancer: A Glossary Of Cancer-Related Terms</i> , page 4 (2002)	<b>Laughlin Cancer Glossary</b>
2006	Hewitt, M.R. & Yu, K., “Treatment Update For Metastatic Pancreatic Cancer,” <i>Community Oncol.</i> 3(7):428-430 (July 2006)	<b>Hewitt and Yu</b>
2007	Yu, K.H. & Ahman, N.A., Chapter 25, “Diagnosis And Evaluation Of Pancreatic Ductal Adenocarcinoma,” <i>Endoscopic Oncology: Gastrointestinal Endoscopy And Cancer Management</i> (Faigel, D.O. & Kochman, M.L., eds. 2006)	<b>Yu</b>
2008	Motzer, R.J. & Russo, P., “Systemic Therapy For Renal Cell Carcinoma,” <i>J. Urology</i> 163:408-417 (2000)	<b>Motzer</b>
2009	“Wyeth Pharmaceuticals Announces Termination Of Phase 3 Clinical Program With Oral Temsirolimus In Women With Metastatic Breast Cancer,” <i>PR Newswire, AP Alert</i> (March 16, 2006)	<b>Wyeth Press Release</b>

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