

Patent No. 7,332,183  
Attorney Docket No. 2015-GBP-0001

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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GRAYBAR PHARMACEUTICALS, LLC

Petitioner,

v.

POZEN INC.

Patent Owner

U.S. Patent No. 7,332,183

Issue Date: Feb. 19, 2008

Inventors: John R. Plachetka, Venkata Markandeya Kothapalli,  
Donna L. Gilbert

Title: MULTILAYER DOSAGE FORMS CONTAINING NSAIDS AND  
TRIPTANS

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Case Number: Unassigned

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**PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO.  
7,332,183 UNDER TO 35 U.S.C. §§ 311 *ET SEQ.* AND  
37 C.F.R. § 42.100 *ET SEQ.***

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**EXHIBIT LIST**

<b>Exhibit</b>	<b>Description</b>
<b>1001</b>	U.S. Patent No. 7,332,183 (“the ‘183 Patent”)
<b>1002</b>	Declaration of Arthur Kibbe, Ph.D. (“Kibbe Decl.”)
<b>1003</b>	‘183 Patent File History (“FH183”) Office Action 12/20/2006
<b>1004</b>	‘183 Patent File History (“FH183”) Amendment 4/5/2007
<b>1005</b>	U.S. Patent No. 5,872,145 (“Plachetka ‘145”)
<b>1006</b>	U.S. Patent No. 2,951,792 (“Swintosky ‘792”)
<b>1007</b>	U.S. Patent No. 6,060,499 (“the ‘499 Patent”)
<b>1008</b>	Bandelin , F., <i>Compressed Tablets by Wet Granulation</i> , Pharmaceutical Dosage Forms: Tablets, Vol. 1, 2nd Ed., Herbert Lieberman, et al. eds., Marcel Dekker, Inc., New York (1989) (“Bandelin”)
<b>1009</b>	U.S. Patent No. 5,756,125 (“the ‘125 Patent”)
<b>1010</b>	U.S. Patent No. 6,365,184 (“the ‘184 Patent”)
<b>1011</b>	U.S. Patent No. 6,183,779 (“the ‘779 Patent”)
<b>1012</b>	U.S. Patent No. 4,844,907 (“the ‘907 Patent”)
<b>1013</b>	U.S. Patent No. 6,730,325 (“the ‘325 Patent”)
<b>1014</b>	European Patent Application EP 1020182 A2 (“EP182”)

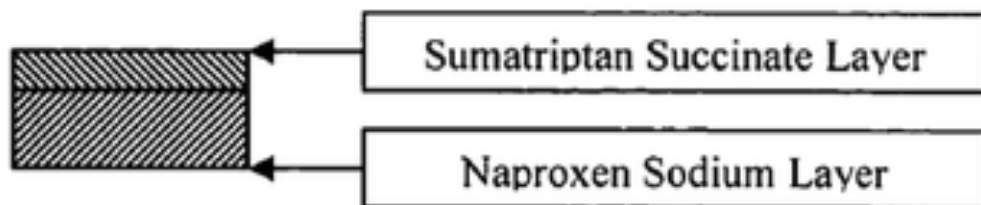
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This is a petition for *Inter Partes* Review pursuant to 35 U.S.C. §§ 311 *et seq.* and 37 C.F.R. §§ 42.100 *et seq.*, of claims 1 and 2 of U.S. Patent No. 7,332,183 (“the ‘183 Patent”) filed Dec. 22, 2003. (Ex. 1001).

## I. Introduction

The ‘183 Patent purports to claim a novel dosage formulation for the treatment of migraine and other pain relief. (Ex. 1001, ‘183 Patent col. 1:12-18). The challenged claims are directed to a combination of two well-known active ingredients, naproxen and a triptan. (*Id.* at col. 18:30-39). Yet, the purported novelty of the patent is not the combination of naproxen and a triptan. Rather, it is formulating naproxen and triptan in a bilayer form, with one layer of naproxen and another layer of a triptan in a “side-by-side arrangement.” (Ex. 1001, ‘183 Patent col. 18:30-39). This is illustrated from FIG. 1 of the patent below.

### Panel A: Multi-Layer Tablet (Bilayer Tablet Shown)



Nothing, however, about this dosage form is novel. The applicants acknowledged that combination therapies of naproxen and triptans were well-known for migraine relief long before the ‘183 Patent’s priority date. (Ex. 1001,

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