

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

Substitute for form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary) Sheet 1 of 1	<i>Application Number</i>	12/337,144
	<i>Filing Date</i>	12/17/2008
	<i>First Named Inventor</i>	An Vermeulen
	<i>Group Art Unit</i>	1627
	<i>Examiner Name</i>	Claytor, Deirdre
	<i>Attorney Docket Number</i>	PRD2901USNP

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS			
Examiner's Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T ²
		Australian Patent Opposition for AU Patent Appl No. 2008340101 dated 20 May 2015 (J&J File Ref. PRD2901AUPCT)	
		Statement of Grounds and Particulars dated 19 August 2015 re: Australian Patent Opposition for AU Patent Appl No. 2008340101 (J&J File Ref. PRD2901AUPCT)	
		Cleton A, Rossenu S, Crauwels H, et al. A single-dose, open-label, parallel, randomized, dose-proportionality study of paliperidone after intramuscular injections of paliperidone palmitate in the deltoid or gluteal muscle in patients with schizophrenia. <i>J Clin Pharmacol.</i> 2014;54(9):1048-1057	
		Cleton A, Rossenu S, Hough D, Crauwels H, Vandebosch A, Berwaerts J, Eerdeken M, Francetic, I. "Evaluation of the pharmacokinetic profile of gluteal versus deltoid intramuscular Injections of paliperidone palmitate 100 mg equivalent in patients with schizophrenia" <i>Clin.Pharmacol. Therapeutics.</i> Published March 2008	
		Cockshott WP, Thompson GT, Howlett LJ, Seeley ET. Intramuscular or intralipomatous injections? <i>N Engl J Med.</i> 1982;307(6):356-358	
		Haramati N, Lorans R, Lutwin M, Kaleya RN. Injection granulomas. Intramuscle or intrafat? <i>Arch Fam Med.</i> 1994;3(2):146-148	
		Janicak, P. G. and Winans, E. A. "Paliperidone ER: a review of the clinical trial data" <i>Neuropsychiatr. Dis. Treat.</i> 2007, Dec 3(6): 869 - 897	
		Rosen, H, and Aribat, T. "The rise and rise of drug delivery" <i>Nat. Rev. Drug Discov.</i> 2005, May 4(5): 381-5.	
		Rossenu S, Cleton A, Hough D, et al. Pharmacokinetic profile after multiple deltoid or gluteal intramuscular injections of paliperidone palmitate in patients with schizophrenia. <i>Clinical Pharmacology in Drug Development.</i> 2015;4(4):270-278	
		Samtani MN, Vermeulen A, Stuyckens K. Population pharmacokinetics of intramuscular paliperidone palmitate in patients with schizophrenia: a novel once-monthly, long-acting formulation of an atypical antipsychotic. <i>Clin Pharmacokinet.</i> 2009;48(9):585-600	
		Synopsis of the Phase III clinical study described at Example 8 of the opposed application accessed at http://yoda.yale.edu/sites/default/files/nct00590577.pdf on 17 August 2015	
		Yin J, Collier AC, Barr AM, Honer WG, Procyshyn RM. Paliperidone Palmitate Long-Acting Injectable Given Intramuscularly in the Deltoid Versus the Gluteal Muscle: Are They Therapeutically Equivalent? <i>J Clin Psychopharmacol.</i> 2015;35(4):447-449	

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.