

<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> ( Not for submission under 37 CFR 1.99)	Application Number	14161007
	Filing Date	2014-01-22
	First Named Inventor	Frank Himmelsbach
	Art Unit	1629
	Examiner Name	K. E. Weddington
	Attorney Docket Number	P01-2051/US/3

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/K.W./	1	0342675	EP	A2	1989-11-23	Chugai Pharmaceutical Co Ltd	<input type="checkbox"/>
/K.W./	2	1999038501	WO	A2	1999-08-05	Trustees Of Tufts University,	<input type="checkbox"/>
/K.W./	3	2009022009	WO	A1	2009-02-19	Boehringer Ingelheim International Gmbh,	<input type="checkbox"/>
/K.W./	4	2009111200	WO	A1	2009-09-11	Merck & Co., Inc,	<input type="checkbox"/>
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/K.W./	1	BAETTA, R. et al., "Pharmacology of Dipeptidyl Peptidase-4 Inhibitors." Drugs, 2011, Vol. 71, No. 11, Pgs. 1441-1467.	<input type="checkbox"/>
/K.W./	2	BLECH, et al, Drug Metabolism and Deposition, "The Metabolism and Disposition of the Oral Dipeptidyl Peptidase-4 Inhibitor, Linagliptin, in Humans", 2009, Vol. 38, No. 4, p. 667-678.	<input type="checkbox"/>
/K.W./	3	CHEON, et al., Biochemical Pharmacology, "Inhibition of dipeptidyl IV by novel inhibitors with pyrazolidine scaffold", 2005, Vol. 70, p. 22-29.	<input type="checkbox"/>
/K.W./	4	CROWE, E. et al., "Early identification and management of chronic kidney disease: summary of NICE guidance." British Medical Journal, 2008, Vol. 337, Pgs. 812-815.	<input type="checkbox"/>

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/K.W./	5	GREISCHEL, et al., Drug Metabolism and Deposition, "The Dipeptidyl Peptidase-4 Inhibitor Linagliptin Exhibits Time- and Dose-Dependent Localization in Kidney, Liver, and Intestine after Intravenous Dosing: Results from High Resolution Autoradiography in Rats", 2010, Vol. 38, No.9, p. 1443-1448.	<input type="checkbox"/>
/K.W./	6	GUGLIELMI, C. et al., "Latent autoimmune diabetes in the adults (LADA) in Asia: from pathogenesis and epidemiology to therapy." Diabetes/Metabolism Research and Reviews, 2012, Vol. 28, Supplement 2, Pgs. 40-46.	<input type="checkbox"/>
/K.W./	7	HEISE, et al., Diabetes, Obesity and Metabolism, "Pharmacokinetics, pharmacokinetics and tolerability of multiple oral doses of linagliptin, a dipeptidyl peptidase-4 inhibitor in male type 2 diabetes patients", 2009, Vol. 11, No. 8, p. 786-794.	<input type="checkbox"/>
/K.W./	8	HULL, R. et al., "Nephrotic syndrome in adults." British Medical Journal, 2008, Vol. 336, Pgs. 1185-1190.	<input type="checkbox"/>
/K.W./	9	ISOMAA, B. et al., "Cardiovascular Morbidity and Mortality Associated With the Metabolic Syndrome." Diabetes Care, 2001, Vol. 24, No. 4, Pgs. 683-689.	<input type="checkbox"/>
/K.W./	10	KLEIN, T. et al., "Linagliptin alleviates hepatic steatosis and inflammation in a mouse model of non-alcoholic steatohepatitis." Medical Molecular Morphology, 2014, Vol. 47, Pgs. 137-149.	<input type="checkbox"/>
/K.W./	11	KONSTANTINOOU, D. M. et al., "Pathophysiology-based novel pharmacotherapy for heart failure with preserved ejection fraction." Pharmacology & Therapeutics, 2013, Vol. 140, No. 2, Pgs. 156-166.	<input type="checkbox"/>
/K.W./	12	LAKATOS, P. L. et al., "Elevated serum dipeptidyl peptidase IV (CD26, EC 3.4.14.5) activity in patients with primary biliary cirrhosis." Journal of Hepatol, 1999, Vol. 30, Pg. 740.	<input type="checkbox"/>
/K.W./	13	NAIK, R. et al., "Latent Autoimmune Diabetes in Adults." The Journal of Clinical Endocrinology and Metabolism, 2009, Vol. 94, No. 12, Pgs. 4635-4644.	<input type="checkbox"/>
/K.W./	14	National Program for Care Guidelines, "Type 2 Diabetes mellitus." 2002, First Edition, Pgs. 1-50.	<input checked="" type="checkbox"/>
/K.W./	15	POUDEL, RESHAM R., "Latent autoimmune diabetes of adults: From oral hypoglycemic agents to early insulin." Indian Journal of Endocrinology and Metabolism, 2012, Vol. 16, Supplement 1, Pgs. S41-S46.	<input type="checkbox"/>

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/K.W./	16	STANDL, E. et al., "Diabetes and the Heart." Diabetes Guidelines (DDG), 2002, Pgs. 1-25.	<input checked="" type="checkbox"/>
/K.W./	17	TASKINEN, M.-R. et al., "Safety and efficacy of linagliptin as add-on therapy to metformin in patients with type 2 diabetes: a randomized, double-blind, placebo-controlled study." Diabetes, Obesity and Metabolism, 2011, Vol. 13, Pgs. 65-74.	<input type="checkbox"/>
/K.W./	18	WITTELES, R. M. et al., "Dipeptidyl Peptidase 4 Inhibition Increases Myocardial Glucose Uptake in Nonischemic Cardiomyopathy." Journal of Cardiac Failure, 2012, Vol. 18, No. 10, Pgs. 804-809.	<input type="checkbox"/>
/K.W./	19	YAMAGISHI, S. et al., "Pleiotropic Effects of Glucagon-like Peptide-1 (GLP-1)-Based Therapies on Vascular Complications in Diabetes." Current Pharmaceutical Design, 2012, Vol. 17, Pgs. 4379-4385.	<input type="checkbox"/>
/K.W./	20	ZHIMEI, Xiao et al., "Study progression of oral drugs for treatment of type II diabetes." Drug Evaluation, 2004, Vol. 1, No. 2, Pgs. 138-143.	<input checked="" type="checkbox"/>

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**EXAMINER SIGNATURE**

Examiner Signature	/Kevin Weddington/	Date Considered	07/21/2015
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**CERTIFICATION STATEMENT**

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

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That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

See attached certification statement.

The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

A certification statement is not submitted herewith.

**SIGNATURE**

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/David L. Kershner/	Date (YYYY-MM-DD)	2015-07-10
Name/Print	David L. Kershner	Registration Number	53112

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. **DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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