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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(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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	1	20040037883	A1	2004-02-26	Zhou et al.	
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	1	0342675	EP	A2	1989-11-23	Chugai Pharmaceutical Co Ltd		☐
	2	1999038501	WO	A2	1999-08-05	Trustees Of Tufts University,		☐
	3	2009022009	WO	A1	2009-02-19	Boehringer Ingelheim International Gmbh,		☐
	4	2009111200	WO	A1	2009-09-11	Merck & Co., Inc,		☐
	5	2011163206	WO	A2	2011-12-29	Twi Pharmaceuticals, Inc,		☐

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	1	BAETTA, R. et al., "Pharmacology of Dipeptidyl Peptidase-4 Inhibitors." Drugs, 2011, Vol. 71, No. 11, Pgs. 1441-1467.	☐
	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.	☐
	3	CHEON, et al., Biochemical Pharmacology, "Inhibition of dipeptidyl IV by novel inhibitors with pyrazolidine scaffold", 2005, Vol. 70, p. 22-29.	☐
	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.	☐

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	5	GREISCHEL, et al., Drug Metabolism and Deposition, "The Dipeptidyl Peptidase-4 Inhibitor Linagliptin Exhibits Time- and Dpse-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.	☐
	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.	☐
	7	HEISE, et al., Diabetes, Obesity and Metabolism, "Pharmacokinetics, pharmacokinetics and tolerability of mutilple oral doses of linagliptin, a dipeptidyl peptidase-4 inhibitor in male type 2 diabetes patients", 2009, Vol. 11, No. 8, p. 786-794.	☐
	8	HULL, R. et al., "Nephrotic syndrome in adults." British Medical Journal, 2008, Vol. 336, Pgs. 1185-1190.	☐
	9	ISOMAA, B. et al., "Cardiovascular Morbidity and Mortality Associated With the Metabolic Syndrome." Diabetes Care, 2001, Vol. 24, No. 4, Pgs. 683-689.	☐
	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.	☐
	11	KONSTANTINOU, 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.	☐
	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.	☐
	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.	☐
	14	National Program for Care Guidelines, "Type 2 Diabetes mellitus." 2002, First Edition, Pgs. 1-50.	☒
	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.	☐

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	16	STANDL, E. et al., "Diabetes and the Heart." Diabetes Guidelines (DDG), 2002, Pgs. 1-25.	☒
	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.	☐
	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.	☐
	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.	☐
	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.	☒

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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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☐ 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

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