

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number	15809815
	Filing Date	2017-11-10
	First Named Inventor	Eliel Bayever
	Art Unit	1612
	Examiner Name	Celeste A. RONEY
	Attorney Docket Number	01208-0007-01US

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	Examiner Name	Celeste A. RONEY
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Name/Print	Mary R. Henninger	Registration Number	56992

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	1	BOUCHÉ O, et al. "Randomized Multicenter Phase II Trial of a Biweekly Regimen of Fluorouracil and Leucovorin (LV5FU2), LV5FU2 Plus Cisplatin, or LV5FU2 Plus Irinotecan in Patients With Previously Untreated Metastatic Gastric Cancer: A Fédération Francophone De Cancérologie Digestive Group Study—FFCD 9803," J Clin Oncol. 22 (21):4319-28 (2004).	
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18	EP3337478: Generics [UK] Limited Opposition dated May 12, 2021, D12 (KO A, et al., "A Multinational Phase 2 Study of Nanoliposomal Irinotecan Sucrosfate (PEP02, MM-398) for Patients with Gemcitabine-Refractory Metastatic Pancreatic Cancer," Br J Cancer. 109(4):920-5 (2013)).
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27	WAINBERG Z, et al., "First-line Liposomal Irinotecan With Oxaliplatin, 5-Fluorouracil and Leucovorin (NALIRIFOX) in Pancreatic Ductal Adenocarcinoma: A Phase I/II Study," Eur J Cancer. 151:14-24 (2021).

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Name/Print	Mary R. Henninger	Registration Number	56992

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**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
(Not for submission under 37 CFR 1.99)

Application Number	15809815
Filing Date	2017-11-10
First Named Inventor	Eliel Bayever
Art Unit	1612
Examiner Name	Celeste A. RONEY
Attorney Docket Number	01208-0007-01US

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7	DEAN A, et al., "First-Line Liposomal Irinotecan + 5-Fluorouracil/Leucovorin + Oxaliplatin in Patients With Pancreatic Ductal Adenocarcinoma: Results From a Phase 1/2 Study." Presentation presented at the Clinical Oncology Society of Australia (COSA): Virtual meeting, November 11-13, 2020, 10 pages.
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47	HUBNER R, et al., "Effects of nal-IRI (MM-398) ± 5-Fluorouracil on Quality of Life (QoL) in NAPOLI-1: A Phase 3 Study in Patients With Metastatic Pancreatic Ductal Adenocarcinoma (mPDAC) Previously Treated With Gemcitabine," Presentation presented at the European Society for Medical Oncology (ESMO) World Congress on Gastrointestinal Cancer, Barcelona, Spain, June 29-July 2, 2016, 13 pages.
48	HUBNER R, et al., "Prognostic Value of Baseline Neutrophil-to-Lymphocyte Ratio (NLR) for Predicting Clinical Outcome in Metastatic Pancreatic Ductal Adenocarcinoma (mPDAC) Patients Treated With Liposomal Irinotecan (nal-IRI) + 5-Fluorouracil and Leucovorin (5-FU/LV) vs 5-FU/LV Alone." Poster presented at the European Society for Medical Oncology (ESMO) Annual Congress, Madrid, Spain, September 8-12, 2017, 5 pages.
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CERTIFICATION STATEMENT

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Name/Print	Mary R. Henninger	Registration Number	56992

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4	LARSEN A, et al., "Influence of Liposomal Irinotecan (nal-IRI) and Non-Liposomal Irinotecan, Alone and in Combination, on Tumor Growth and Angiogenesis in Colorectal Cancer (CRC) Models." Poster presented at the American Society of Clinical Oncology Gastrointestinal Cancers Symposium (ASCO GI), San Francisco, CA, January 18-20, 2018, 9 pages.
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Signature	/Mary R. Henninger/	Date (YYYY-MM-DD)	2021-03-12
Name/Print	Mary R. Henninger	Registration Number	56992

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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2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number	15809815
	Filing Date	2017-11-10
	First Named Inventor	Eliel Bayever
	Art Unit	1612
	Examiner Name	Celeste A. RONEY
	Attorney Docket Number	01208-0007-01US

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1	WANG-GILLAM A, et al., Abstract 459. "Nomogram for Predicting Overall Survival (OS) in Patients (pts) Treated With Liposomal Irinotecan (nal-IRI) ± 5-Fluorouracil/Leucovorin (5-FU/LV) in Metastatic Pancreatic Ductal Adenocarcinoma (mPDAC) Previously Treated With Gemcitabine-Based Therapy in NAPOLI-1," J Clin Oncol. 36(4_Suppl):459 DOI: 10.1200/JCO.2018.36.4_suppl.459 (2018), 2 printed pages.
2	WANG-GILLAM A, et al., Abstract e15795. "The Prognostic Value of Baseline Neutrophil-to-Lymphocyte Ratio (NLR) and Platelet-to-Lymphocyte ratio (PLR) for Predicting Clinical Outcome in Patients with Metastatic Pancreatic Ductal Adenocarcinoma (mPDAC) Treated With Liposomal Irinotecan (nalIRI; MM398) + 5-Fluorouracil and Leucovorin (5-FU/LV) vs 5-FU/LV," J Clin Oncol. 35(15_Suppl):e15795 DOI: 10.1200/JCO.2017.35.15_suppl.e15795 (2017), 3 printed pages.
3	WANG-GILLAM A, et al., Abstract e16204. "A Survival Prediction Nomogram for Liposomal Irinotecan (nal-IRI)+5-Fluorouracil/Leucovorin (5-FU/LV) in Patients (pts) With Metastatic Pancreatic Ductal Adenocarcinoma (mPDAC) Previously Treated With Gemcitabine-Based Therapy," J Clin Oncol. 36(15_Suppl):e16204 DOI: 10.1200/JCO.2018.36.15_suppl.e16204 (2018), 2 printed pages.
4	WANG-GILLAM A, et. al., letter to editor, "Nanoliposomal Irinotecan in the Clinical Practice Guideline for Metastatic Pancreatic Cancer: Applicability to Clinical Situations," J Clin Oncol. 35(6):689-90 (2017). Epub 2016.
5	XIONG H, et. al., "Phase 2 Trial of Oxaliplatin Plus Capecitabine (XELOX) as Second-line Therapy for Patients With Advanced Pancreatic Cancer," Cancer. 113(8):2046-52 (2008).
6	YU K, et al., "Hospitalizations and Real-World Clinical Outcomes of Liposomal Irinotecan in a NAPOLI1-Based Regimen Among Patients With Metastatic Pancreatic Ductal Adenocarcinoma (mPDAC): A Multi-Center Chart Review," Poster presented at the Academy of Managed Care Pharmacy, Nexus (AMCP, Nexus): virtual meeting, week of October 19, 2020, 9 pages.
7	YU K, et al., Abstract C3. "Hospitalizations and Real-World Clinical Outcomes of Liposomal Irinotecan in a NAPOLI1-Based Regimen Among Patients With Metastatic Pancreatic Ductal Adenocarcinoma (mPDAC): A Multi-Center Chart Review," J Manag Care Spec Pharm. 26(10-a):S19 (2020).
8	YU K, et al., "A US Multicenter Chart Review Study of Patients With Metastatic Pancreatic Ductal Adenocarcinoma Receiving Liposomal Irinotecan after Gemcitabine-Based Therapy." Poster presented at the International Conference on Pharmacoepidemiology & Therapeutic Risk Management (ICPE) All Access, September 16-17, 2020, 8 pages.
9	YU K, et al., "Real-World Treatment Patterns and Effectiveness of Liposomal Irinotecan in a NAPOLI1-Based Regimen Among Patients With Metastatic Pancreatic Ductal Adenocarcinoma (mPDAC): A Multi-Academic Center Chart Review." Poster presented at the European Society for Medical Oncology (ESMO) Virtual Congress 2020, September 19-21, 2020, 9 pages.
10	YU K, et al., Abstract 1555P. "Real-World Treatment Patterns and Effectiveness of Liposomal Irinotecan in a NAPOLI1-Based Regimen Among Patients With Metastatic Pancreatic Ductal Adenocarcinoma (mPDAC): A Multi-Academic Center Chart Review," Ann Oncol. 31(Suppl_4):S950-S951 doi.org/10.1016/j.annonc.2020.08.2038 (2020), 2 printed pages.
11	YU K, et al., Abstract e16733. "A Multicenter Chart Review Study of Patients with Metastatic Pancreatic Ductal Adenocarcinoma Receiving Liposomal Irinotecan after Gemcitabine-Based Therapy," J Clin Oncol. 38(15_Suppl):e16733 DOI: 10.1200/JCO.2020.38.15_suppl.e16733 (2020), 4 printed pages.

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12	YU K, et al., Abstract PO-3727. "A US Multicenter Chart Review Study of Patients With Metastatic Pancreatic Ductal Adenocarcinoma Receiving Liposomal Irinotecan after Gemcitabine-Based Therapy," International Conference on Pharmacoepidemiology & Therapeutic Risk Management (ICPE), September 14, 2020, available at eventscribe.com/2020/ICPEAllAccess/PosterTitles.asp?pf=PosterTitles, 1 page.
13	YU X, et. al., "Targeted Drug Delivery in Pancreatic Cancer," Biochim Biophys Acta. 21805(1):97-104 (2010). Epub 2009, author manuscript version, 16 pages.

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EXAMINER SIGNATURE

Examiner Signature	/GOLLAMUDI S KISHORE/	Date Considered	07/07/2021
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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).

OR

☐ 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	/Mary R. Henninger/	Date (YYYY-MM-DD)	2021-02-25
Name/Print	Mary R. Henninger	Registration Number	56992

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