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Drug delivery methods and systems

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US

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(71) Applicant(s)
Morningside Venture Investments Limited

(72) Inventor(s)
TONG, Ling-Kang;BUCHMAN, Daniela Tamar;HANCOCK, Jackie Joe;TERZULLI, Nicholas

(74) Agent / Attorney
RnB IP Pty Ltd, PO Box 9530, Deakin, ACT, 2600, AU

(56) Related Art
US 2016/0220798 A1
US 2006/0271020 A1



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APPLICATION NO.	ISSUE DATE	PATENT NO.	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/057,318	03/07/2023	11596779	13164-722.US0	1820

66854 7590 02/15/2023
SHAY GLENN LLP
155 BOVET ROAD, SUITE 710
SAN MATEO, CA 94402

ISSUE NOTIFICATION

The projected patent number and issue date are specified above.

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b) (application filed on or after May 29, 2000)

The Patent Term Adjustment is 98 day(s). Any patent to issue from the above-identified application will include an indication of the adjustment on the front page.

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

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Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Application Assistance Unit (AAU) of the Office of Patents Stakeholder Experience (OPSE), Stakeholder Support Division (SSD) at (571)-272-4200.

INVENTOR(s) (Please see PAIR WEB site <http://pair.uspto.gov> for additional inventors):

Ling-Kang TONG, Hayward, CA;
Daniela Tamar BUCHMAN, Mountain View, CA;
Jackie Joe HANCOCK, Berkeley, CA;
Nicholas TERZULLI, Oakland, CA;

APPLICANT(s) (Please see PAIR WEB site <http://pair.uspto.gov> for additional applicants):

MORNINGSIDE VENTURE INVESTMENTS LIMITED, Monaco, MONACO

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PTO/SB/08A (04-07)

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet	1	of	1
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Complete if Known

Application Number	17/057,318
Filing Date	November 20, 2020
First Named Inventor	Ling-Kang Tong
Art Unit	3781
Examiner Name	Arjuna P. Chatrathi
Attorney Docket Number	13164-722.US0

U. S. PATENT DOCUMENTS

[illegible]

FOREIGN PATENT DOCUMENTS

[illegible]

Examiner
Signature

/ARJUNA P CHATRATHI/

Date	
Considered	

11/29/2022

*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. ¹ Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

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ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /A.P.C./



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/057,318	11/20/2020	Ling-Kang TONG	13164-722.US0	1820
66854	7590	12/05/2022		
SHAY GLENN LLP 155 BOVET ROAD, SUITE 710 SAN MATEO, CA 94402			EXAMINER CHATRATHI, ARJUNA P	
			ART UNIT	PAPER NUMBER
			3781	
			NOTIFICATION DATE	DELIVERY MODE
			12/05/2022	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

info@shayglenn.com
shayglenn_pair@firsttofile.com

Supplemental Notice of Allowability	Application No. 17/057,318	Applicant(s) TONG et al.	
	Examiner ARJUNA P CHATRATHI	Art Unit 3781	AIA (FITF) Status Yes

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to the IDS filed 11/22/2022.
☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

2. ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

3. ☒ The allowed claim(s) is/are 1-3 and 5-29. As a result of the allowed claim(s), you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov.

4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

a) ☐ All b) ☐ Some* c) ☐ None of the:

1. ☐ Certified copies of the priority documents have been received.

2. ☐ Certified copies of the priority documents have been received in Application No. _____.

3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892) 2. ☒ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date _____ 3. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material _____ 4. ☐ Interview Summary (PTO-413), Paper No./Mail Date. _____	5. ☐ Examiner's Amendment/Comment 6. ☐ Examiner's Statement of Reasons for Allowance 7. ☐ Other _____
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/ARJUNA P CHATRATHI/ Examiner, Art Unit 3781	/CATHARINE L ANDERSON/ Primary Examiner, Art Unit 3781
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet	1
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of	1
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Application Number

17/057.318

Filing Date

November 20, 2020

First Named Inventor

Ling-Kang Tong

Art Unit

3781	
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Examiner Name

Ariuna P. Chatrathi

Attorney Docket Number

13164-722.US0

U. S. PATENT DOCUMENTS

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FOREIGN PATENT DOCUMENTS

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Examiner
Signature

Date _____

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Ref #	Hits	Search Query	DBs	Default Operator	Plurals	British Equivalents	Time Stamp
L1	0	((("MORNINGSIDE") near3 ("VENTURE") near3 ("INVESTMENTS") near3 ("LIMITED") near3 ("MONACO"))).AS,AAN M.	(USPAT)	OR	ON	ON	2022/06/15 09:45 AM
L2	78	((("TONG") near3 ("Ling-Kang")) OR (("BUCHMAN") near3 ("Daniela")) OR (("HANCOCK") near3 ("Jackie")) OR (("TERZULLI") near3 ("Nicholas"))).INV.	(US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT)	OR	ON	ON	2022/06/15 09:45 AM
L3	1	("20060271020").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2022/06/15 09:48 AM
L4	249	("20090010998" OR "5562607" OR "20150342900" OR "5846559" OR "9555277" OR "20050197625" OR "20100130932" OR "20120078216" OR "20130096495" OR "20140163521" OR "20150057616" OR "20160058939" OR "20160317738" OR "20170232192" OR "4313439" OR "0092481" OR "10004447" OR "10034841" OR "10105487" OR "10143687" OR "10213586" OR "10232156" OR "10258738" OR "10258778" OR "10679516" OR "10716764" OR "20010022978" OR "20010026788" OR "20020002189" OR "20020034535" OR "20020106329" OR "20020127256" OR "20020165170" OR "20020169439" OR	(US-PGPUB; USPAT)	OR	ON	ON	2022/06/15 09:49 AM

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L7	3	("20080220092" "20110137255" "20160339174").pn.	ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS) (US-PGPUB; USPAT)	OR	ON	ON	2022/06/15 10:48 AM
L8	40	L6 AND ((solvent OR fluid OR water) SAME (enviroment OR ambient))	(US-PGPUB; USPAT; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS)	OR	ON	ON	2022/06/15 01:25 PM
L9	6	((US-20160220798-A1 OR US-20060271020- A1 OR US- 20130190683-A1 OR US-20080220092-A1 OR US-20110137255- A1 OR US- 20160339174-A1).did. AND PGPB.dbnm.)	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/06/15 01:28 PM
L10	15671	A61M5/14248	(US-PGPUB; USPAT; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS)	OR	ON	ON	2022/06/15 01:32 PM

L11	15664	(A61M5/14248).cpc.	(US-PGPUB; USPAT; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS)	OR	ON	ON	2022/06/15 01:32 PM
L12	4227	(A61M5/14248).cpc. AND (A61M2005/14268).cpc.	(US-PGPUB; USPAT; FIT (AP, AT, AU, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, MC, MD, MY, NL, NO, NZ, OA, PH, PL, PT, RO, RS, RU, SE, SG, SI, SK, SU, TH, TN, TR, TW, UA, VN, WO); FPRS)	OR	ON	ON	2022/06/15 01:34 PM
L13	639	L12 AND vent	(US-PGPUB; USPAT; FIT (AP, AT, AU, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, MC, MD, MY, NL, NO, NZ, OA, PH, PL, PT, RO, RS, RU, SE, SG, SI, SK, SU, TH, TN, TR, TW, UA, VN, WO); FPRS)	OR	ON	ON	2022/06/15 01:34 PM
L14	692	L12 AND gap	(US-PGPUB; USPAT; FIT (AP, AT, AU, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, MC, MD, MY, NL, NO, NZ, OA, PH, PL, PT, RO, RS, RU, SE, SG, SI, SK, SU, TH, TN, TR, TW, UA, VN, WO); FPRS)	OR	ON	ON	2022/06/15 01:35 PM
L15	18	L12 AND (gap SAME	(US-PGPUB; USPAT;	OR	ON	ON	2022/06/15

		(vent OR evaporat\$3))	FIT (AP, AT, AU, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, MC, MD, MY, NL, NO, NZ, OA, PH, PL, PT, RO, RS, RU, SE, SG, SI, SK, SU, TH, TN, TR, TW, UA, VN, WO); FPRS)				01:40 PM
L16	56	L12 AND (solvent SAME removal)	(US-PGPUB; USPAT; FIT (AP, AT, AU, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, MC, MD, MY, NL, NO, NZ, OA, PH, PL, PT, RO, RS, RU, SE, SG, SI, SK, SU, TH, TN, TR, TW, UA, VN, WO); FPRS)	OR	ON	ON	2022/06/15 02:09 PM
L17	5674	(A61M2005/14268).cpc.	(US-PGPUB; USPAT; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS)	OR	ON	ON	2022/06/15 02:12 PM
L18	90	L17 AND (solvent SAME (remov\$2 OR evaporat\$3 OR vent))	(US-PGPUB; USPAT; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS)	OR	ON	ON	2022/06/15 02:13 PM
L19	1	(11/440169).APP.	(USPAT; USOCR)	OR	ON	ON	2022/06/15 02:29 PM

L20	55	("5097834" "5352456" "5370635" "5820875" "6068853" "6214379" "6436078" "6638528" "6723086" "6861066" "6867342" "6887202" "7780981" "20020169439" "20030065294" "20030065924" "20050034842" "20050182307" "20050238704").pn. OR ("8372040").urpn. AND (PGPB USPT USOC).dbnm.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2022/06/15 02:29 PM
L21	1573	A61M35/10.cpc.	(US-PGPUB; USPAT; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS)	OR	ON	ON	2022/06/15 02:46 PM
L22	1	(10/711389).APP.	(USPAT; USOCR)	OR	ON	ON	2022/06/15 02:47 PM
L23	51	("4379454" "4545990" "4708716" "4917895" "5242941" "5273756" "5352456" "5370635" "5389679" "5405614" "5505958" "5538503" "5616332" "5785688" "5820875" "5879322" "5932240" "5993435" "6068853" "6129702" "6165155" "6211296" "6214379" "6374136" "6539250" "6595956" "6638528" "6723077" "6723086" "6861066" "6867342" "6887202" "20020127256" "20030065294" "20040138074" "20050034842" "20050182307" "20050238704").pn. OR ("8440221").urpn. AND (PGPB USPT USOC).dbnm.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2022/06/15 02:47 PM

L24	245	L21 AND gap	(US-PGPUB; USPAT; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS)	OR	ON	ON	2022/06/15 02:54 PM
L25	71	L21 AND (solvent SAME (remov\$2 OR evaporat\$3 OR vent))	(US-PGPUB; USPAT; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS)	OR	ON	ON	2022/06/15 02:57 PM
L26	18627	(A61M5/14248 OR A61M2005/14268 OR A61M35/10).cpc.	(US-PGPUB; USPAT; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS)	OR	ON	ON	2022/06/15 02:59 PM
L27	1434	L26 AND ((dry\$3) OR (solvent SAME (remov\$2 OR evaporat\$3 OR vent OR recover\$3)))	(US-PGPUB; USPAT; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS)	OR	ON	ON	2022/06/15 03:00 PM
L28	13	L21 AND (vent SAME	(US-PGPUB; USPAT;	OR	ON	ON	2022/06/15

		housing)	FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS)				04:18 PM
L29	1	(10/711389).APP.	(USPAT; USOCR)	OR	ON	ON	2022/06/16 09:08 AM
L30	51	("4379454" "4545990" "4708716" "4917895" "5242941" "5273756" "5352456" "5370635" "5389679" "5405614" "5505958" "5538503" "5616332" "5785688" "5820875" "5879322" "5932240" "5993435" "6068853" "6129702" "6165155" "6211296" "6214379" "6374136" "6539250" "6595956" "6638528" "6723077" "6723086" "6861066" "6867342" "6887202" "20020127256" "20030065294" "20040138074" "20050034842" "20050182307" "20050238704").pn. OR ("8440221").urpn. AND (PGPB USPT USOC).dbnm.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2022/06/16 09:08 AM
L31	1146	((Bente near3 Paul) OR (Hanson near3 Ian)).in.	(US-PGPUB; USPAT; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS)	OR	ON	ON	2022/06/16 09:17 AM
L32	2	("7597682" "7658734").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2022/06/16 09:53 AM

L33	5676	(A61M2005/14268).cpc.	(US-PGPUB; USPAT; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS)	OR	ON	ON	2022/06/16 10:09 AM
L34	2945	L33 AND (gap OR seam OR opening OR vent OR slit OR slot)	(US-PGPUB; USPAT; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS)	OR	ON	ON	2022/06/16 10:09 AM
L35	2135	L33 AND ((gap OR seam OR opening OR vent OR slit OR slot) SAME (between))	(US-PGPUB; USPAT; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS)	OR	ON	ON	2022/06/16 10:10 AM
L36	508	L33 AND ((environment OR ambient) SAME (vapor OR gas\$4))	(US-PGPUB; USPAT; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS)	OR	ON	ON	2022/06/16 11:24 AM
L37	78	("3631847" "3770607"	(US-PGPUB; USPAT; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS)	OR	ON	ON	2022/06/16

		"3771694" "3953566" "4030495" "4194041" "4313439" "4429000" "4498843" "4544369" "4560611" "4657486" "4679562" "4734092" "4846797" "4902278" "5352513" "5390671" "5460603" "5591541" "5607796" "5658356" "5662717" "5688864" "5733676" "5804327" "5904998" "5928194" "5938640" "5957895" "5973055" "5985475" "6143164" "6485461" "6589229" "6638610" "6676993" "6723072" "6740059" "6743516" "6811884" "6854603" "7083849" "7144384" "20030161744" "20050177108" "20060184154" "20070073235" "20070106218" "20070191702" "20070255198" "20080051716" "20080102119" "20080125701" "20080255516" "20080269575" "20080294142" "20100121306" "20100130932" "20100191078" "20100198187" "20100217230" "20100241086" "20100298764").pn. OR ("8491529").urpn. AND (PGPB USPT USOC).dbnm.	USOCR)				11:43 AM
L38	0	(10/774487).APP.	(USPAT; USOCR)	OR	ON	ON	2022/06/16 11:57 AM
L39	9	L33 AND spacer	(USPAT; USOCR)	OR	ON	ON	2022/06/16 01:39 PM
L40	140	L33 AND spacer	(US-PGPUB; USPAT; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO,	OR	ON	ON	2022/06/16 01:40 PM

L41	7962	(A61M5/1413).cpc.	MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS) (US-PGPUB; USPAT; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS)	OR	ON	ON	2022/06/16 01:53 PM
L42	494	L41 AND ((environment OR ambient) SAME (vapor OR gas\$4))	(US-PGPUB; USPAT; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS)	OR	ON	ON	2022/06/16 01:54 PM
L43	12902	(A61M35/10 OR A61M5/15248 OR A61M2005/14268 OR A61M5/1413).cpc.	(US-PGPUB; USPAT; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS)	OR	ON	ON	2022/06/16 02:03 PM
L44	5547	L43 AND (seal\$3)	(US-PGPUB; USPAT; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO,	OR	ON	ON	2022/06/16 02:04 PM

L45	2174	L43 AND ((seal\$3 SAME (disposable OR reservoir) SAME (reusable OR durable OR pump)))	NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS) (US-PGPUB; USPAT; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS)	OR	ON	ON	2022/06/16 02:09 PM
L46	1094	L41 AND gap	(US-PGPUB; USPAT; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS)	OR	ON	ON	2022/06/16 02:33 PM
L47	51	L33 AND (drain\$3 SAME port)	(US-PGPUB; USPAT; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS)	OR	ON	ON	2022/06/16 03:10 PM
L48	109	L43 AND (drain\$3 near3 port)	(US-PGPUB; USPAT; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS)	OR	ON	ON	2022/06/16 03:12 PM

L49	1210	L43 AND (bath\$3 OR shower\$3 OR swim\$4)	RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS) (US-PGPUB; USPAT; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS)	OR	ON	ON	2022/06/16 03:15 PM
L50	36	L43 AND (drain SAME excess)	(US-PGPUB; USPAT; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS)	OR	ON	ON	2022/06/16 05:50 PM
L51	492	L43 AND (drain)	(US-PGPUB; USPAT; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS)	OR	ON	ON	2022/06/16 05:51 PM
L52	37	L6 AND drain	(US-PGPUB; USPAT; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS)	OR	ON	ON	2022/06/16 08:04 PM

L53	138	L6 AND (gap OR spacer)	TH, TN, TR, TW, UA, VN); FPRS) (US-PGPUB; USPAT; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS)	OR	ON	ON	2022/06/16 08:04 PM
L54	13983	L43 OR L6	(US-PGPUB; USPAT; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS)	OR	ON	ON	2022/06/16 08:52 PM
L55	551	L54 AND ((rail OR key OR ridge) SAME (slide))	(US-PGPUB; USPAT; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS)	OR	ON	ON	2022/06/16 08:52 PM
L56	7	(US-5310404-\$.did. OR US-6162214-\$.did. OR US-20060135911-\$.did. OR US-20130041258-\$.did. OR US-20220280763-\$.did. OR WO-2016132368-A1.did.)	(US-PGPUB; USPAT; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS)	OR	ON	ON	2022/10/28 10:12 AM

L57	1908	(A61M35/10).cpc.	VN); FPRS) (US-PGPUB; USPAT; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS)	OR	ON	ON	2022/10/28 10:33 AM
L58	6	L57 AND (gap SAME spacer)	(US-PGPUB; USPAT; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS)	OR	ON	ON	2022/10/28 10:34 AM

PE2E SEARCH - Search History (Interference)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	British Equivalents	Time Stamp
N1	0	(bioactive SAME agent SAME delivery SAME disposable SAME reservoir SAME transdermal SAME permeable SAME membrane SAME reusable SAME power SAME control SAME solvent SAME gap SAME spacer).clm.	(US-PGPUB; USPAT)	OR	ON	ON	2022/10/28 10:23 AM

PTO/SB/08A (04-07)

Approved for use through 09/30/2007. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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Substitute for form 1449/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 1 of 2

Complete if Known

Application Number	17/057,318
Filing Date	November 20, 2020
First Named Inventor	Ling-Kang Tong
Art Unit	3781
Examiner Name	Chatrathi, Arjuna P.
Attorney Docket Number	13164-722.US0

U. S. PATENT DOCUMENTS

[illegible]

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T ⁶
		Country Code ³ Number ⁴ Kind Code ⁵ (if known)				
	887	WO2016/132368A1	8/25/2016	Ozca Eng Solutions Ltd.		

Examiner
Signature

/ARJUNA P CHATRATHI/

Date	Considered
------	------------

10/28/2022

*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. ¹Applicant's unique citation designation number (optional). ²See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁶Applicant is to place a check mark here if English language Translation is attached.

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 2 hours 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, 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.**

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /A.P.C./

PTO/SB/08b (07-09)

Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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

Substitute for form 1449/PTO

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Complete if Known

Application Number	17/057,318
Filing Date	November 20, 2020
First Named Inventor	Ling-Kang Tong
Art Unit	3781
Examiner Name	Chatrathi, Arjuna P.
Attorney Docket Number	13164-722.US0

Sheet 2 of 2

NON PATENT LITERATURE DOCUMENTS

Examiner 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
	896	NETZEL et al.; U.S. Pat. Appl. # 17/815,879 entitled "Drug Delivery methods and systems," filed 7/28/2022	

Examiner Signature	/ARJUNA P CHATRATHI/	Date Considered	10/28/2022
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*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.

¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 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 2 hours 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, 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.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /A.P.C./



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

NOTICE OF ALLOWANCE AND FEE(S) DUE

66854 7590 11/08/2022
SHAY GLENN LLP
155 BOVET ROAD, SUITE 710
SAN MATEO, CA 94402

EXAMINER

CHATRATHI, ARJUNA P

ART UNIT

PAPER NUMBER

3781

DATE MAILED: 11/08/2022

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/057,318	11/20/2020	Ling-Kang TONG	13164-722.US0	1820

TITLE OF INVENTION: DRUG DELIVERY METHODS AND SYSTEMS

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	SMALL	\$600	\$0.00	\$0.00	\$600	02/08/2023

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

HOW TO REPLY TO THIS NOTICE:

I. Review the ENTITY STATUS shown above. If the ENTITY STATUS is shown as SMALL or MICRO, verify whether entitlement to that entity status still applies.

If the ENTITY STATUS is the same as shown above, pay the TOTAL FEE(S) DUE shown above.

If the ENTITY STATUS is changed from that shown above, on PART B - FEE(S) TRANSMITTAL, complete section number 5 titled "Change in Entity Status (from status indicated above)".

For purposes of this notice, small entity fees are 1/2 the amount of undiscounted fees, and micro entity fees are 1/2 the amount of small entity fees.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Maintenance fees are due in utility patents issuing on applications filed on or after Dec. 12, 1980. It is patentee's responsibility to ensure timely payment of maintenance fees when due. More information is available at www.uspto.gov/PatentMaintenanceFees.

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), by mail or fax, or via EFS-Web.

By mail, send to: Mail Stop ISSUE FEE
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

By fax, send to: (571)-273-2885

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

66854 7590 11/08/2022
SHAY GLENN LLP
155 BOVET ROAD, SUITE 710
SAN MATEO, CA 94402

Certificate of Mailing or Transmission

I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being transmitted to the USPTO via EFS-Web or by facsimile to (571) 273-2885, on the date below.

(Typed or printed name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/057,318	11/20/2020	Ling-Kang TONG	13164-722.US0	1820

TITLE OF INVENTION: DRUG DELIVERY METHODS AND SYSTEMS

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	SMALL	\$600	\$0.00	\$0.00	\$600	02/08/2023

EXAMINER	ART UNIT	CLASS-SUBCLASS
CHATRATHI, ARJUNA P	3781	604-290000

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

☐ Change of correspondence address (or Change of Correspondence Address form PTO/AIA/122 or PTO/SB/122) attached.

☐ "Fee Address" indication (or "Fee Address" Indication form PTO/AIA/47 or PTO/SB/47; Rev 03-02 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list

(1) The names of up to 3 registered patent attorneys or agents OR, alternatively,

1 _____

(2) The name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.

2 _____

3 _____

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document must have been previously recorded, or filed for recordation, as set forth in 37 CFR 3.11 and 37 CFR 3.81(a). Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE

(B) RESIDENCE: (CITY and STATE OR COUNTRY)

Please check the appropriate assignee category or categories (will not be printed on the patent) : ☐ Individual ☐ Corporation or other private group entity ☐ Government

4a. Fees submitted: ☐ Issue Fee ☐ Publication Fee (if required) ☐ Advance Order - # of Copies _____

4b. Method of Payment: (Please first reapply any previously paid fee shown above)

☐ Electronic Payment via EFS-Web ☐ Enclosed check ☐ Non-electronic payment by credit card (Attach form PTO-2038)

☐ The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment to Deposit Account No. _____

5. Change in Entity Status (from status indicated above)

☐ Applicant certifying micro entity status. See 37 CFR 1.29

☐ Applicant asserting small entity status. See 37 CFR 1.27

☐ Applicant changing to regular undiscounted fee status.

NOTE: Absent a valid certification of Micro Entity Status (see forms PTO/SB/15A and 15B), issue fee payment in the micro entity amount will not be accepted at the risk of application abandonment.

NOTE: If the application was previously under micro entity status, checking this box will be taken to be a notification of loss of entitlement to micro entity status.

NOTE: Checking this box will be taken to be a notification of loss of entitlement to small or micro entity status, as applicable.

NOTE: This form must be signed in accordance with 37 CFR 1.31 and 1.33. See 37 CFR 1.4 for signature requirements and certifications.

Authorized Signature _____

Date _____

Typed or printed name _____

Registration No. _____



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/057,318	11/20/2020	Ling-Kang TONG	13164-722.US0	1820
66854	7590	11/08/2022	EXAMINER	
SHAY GLENN LLP 155 BOVET ROAD, SUITE 710 SAN MATEO, CA 94402			CHATRATHI, ARJUNA P	
			ART UNIT	PAPER NUMBER
			3781	
DATE MAILED: 11/08/2022				

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b) (Applications filed on or after May 29, 2000)

The Office has discontinued providing a Patent Term Adjustment (PTA) calculation with the Notice of Allowance.

Section 1(h)(2) of the AIA Technical Corrections Act amended 35 U.S.C. 154(b)(3)(B)(i) to eliminate the requirement that the Office provide a patent term adjustment determination with the notice of allowance. See Revisions to Patent Term Adjustment, 78 Fed. Reg. 19416, 19417 (Apr. 1, 2013). Therefore, the Office is no longer providing an initial patent term adjustment determination with the notice of allowance. The Office will continue to provide a patent term adjustment determination with the Issue Notification Letter that is mailed to applicant approximately three weeks prior to the issue date of the patent, and will include the patent term adjustment on the patent. Any request for reconsideration of the patent term adjustment determination (or reinstatement of patent term adjustment) should follow the process outlined in 37 CFR 1.705.

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

<i>Notice Requiring Inventor's Oath or Declaration</i>	Application No. 17/057,318	Applicant(s) Ling-Kang TONG	
	Examiner CHATRATHI, ARJUNA P	Art Unit 3781	

This notice is an attachment to the Notice of Allowability (PTOL-37), or the Notice of Allowability For A Design Application (PTOL-37D).

An inventor's oath or declaration in compliance with 37 CFR 1.63 or 1.64 executed by or with respect to each inventor has not yet been submitted.

An oath or declaration in compliance with 37 CFR 1.63, or a substitute statement in compliance with 37 CFR 1.64, executed by or with respect to each inventor (for any inventor for which a compliant oath, declaration, or substitute statement has not yet been submitted) **MUST** be filed no later than the date on which the issue fee is paid. See 35 U.S.C. 115(f). Failure to timely comply will result in ABANDONMENT of this application.

A properly executed inventor's oath to declaration has not been received for the following inventor(s):

If applicant previously filed one or more oaths, declarations, or substitute statements, applicant may have received an informational notice regarding deficiencies therein.

The following deficiencies are noted:

INFORMAL ACTION PROBLEMS

- Properly executed inventor's oath or declaration for the following inventor(s) has not been submitted: **Ling-Kang TONG, Daniela Tamar BUCHMAN, Jackie Joe HANCOCK, and Nicholas TERZULLI**

Questions relating to this Notice should be directed to the Application Assistance Unit at 571-272-4200.

OMB Clearance and PRA Burden Statement for PTOL-85 Part B

The Paperwork Reduction Act (PRA) of 1995 requires Federal agencies to obtain Office of Management and Budget approval before requesting most types of information from the public. When OMB approves an agency request to collect information from the public, OMB (i) provides a valid OMB Control Number and expiration date for the agency to display on the instrument that will be used to collect the information and (ii) requires the agency to inform the public about the OMB Control Number's legal significance in accordance with 5 CFR 1320.5(b).

The information collected by PTOL-85 Part B is required by 37 CFR 1.311. 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 30 minutes 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, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450. 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.

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether disclosure of these records is required by the Freedom of Information Act.
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 inspection 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.

Notice of Allowability	Application No. 17/057,318	Applicant(s) TONG et al.	
	Examiner ARJUNA P CHATRATHI	Art Unit 3781	AIA (FITF) Status Yes

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to the amendment filed 10/24/2022.
☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

2. ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

3. ☒ The allowed claim(s) is/are 1-3 and 5-29. As a result of the allowed claim(s), you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov.

4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

a) ☐ All b) ☐ Some* c) ☐ None of the:

1. ☐ Certified copies of the priority documents have been received.

2. ☐ Certified copies of the priority documents have been received in Application No. _____.

3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)	5. ☐ Examiner's Amendment/Comment
2. ☒ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date _____.	6. ☒ Examiner's Statement of Reasons for Allowance
3. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material _____.	7. ☐ Other _____.
4. ☐ Interview Summary (PTO-413), Paper No./Mail Date. _____.	

/ARJUNA P CHATRATHI/ Examiner, Art Unit 3781	/CATHARINE L ANDERSON/ Primary Examiner, Art Unit 3781
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DETAILED ACTION

Notice of Pre-AIA or AIA Status

1. The present application, filed on or after March 16, 2013, is being examined under the first inventor to file provisions of the AIA.

Allowable Subject Matter

2. Claims 1-3 and 5-29 are allowed.

3. The following is an examiner's statement of reasons for allowance: Applicant amended independent claims 1 and 23 to include the subject matter of canceled claim 4, which was indicated to include allowable subject matter in the non-final rejection dated 06/23/2022. Accordingly, claims 1-3 and 5-29 are allowed.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ARJUNA P CHATRATHI whose telephone number is (571)272-8063. The examiner can normally be reached M-F 8:30-5:00.

Examiner interviews are available via telephone, in-person, and video conferencing using a USPTO supplied web-based collaboration tool. To schedule an interview, applicant is encouraged to use the USPTO Automated Interview Request (AIR) at <http://www.uspto.gov/interviewpractice>.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of published or unpublished applications may be obtained from Patent Center. Unpublished application information in Patent Center is available to registered users. To file and manage patent submissions in Patent Center, visit: <https://patentcenter.uspto.gov>. Visit <https://www.uspto.gov/patents/apply/patent-center> for more information about Patent Center and <https://www.uspto.gov/patents/docx> for information about filing in DOCX format. For additional questions, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/ARJUNA P CHATRATHI/
Examiner, Art Unit 3781

/CATHARINE L ANDERSON/
Primary Examiner, Art Unit 3781

<i>Search Notes</i> 	Application/Control No. 17/057,318	Applicant(s)/Patent Under Reexamination TONG et al.
	Examiner ARJUNA P CHATRATHI	Art Unit 3781

CPC - Searched*		
Symbol	Date	Examiner
A61M5/14248; A61M2005/14268; A61M35/10;	06/15/2022	APC

CPC Combination Sets - Searched*		
Symbol	Date	Examiner

US Classification - Searched*			
Class	Subclass	Date	Examiner

* See search history printout included with this form or the SEARCH NOTES box below to determine the scope of the search.

Search Notes		
Search Notes	Date	Examiner
Applicant and Inventor Name Search	06/15/2022	APC
IDS references reviewed	06/15/2022	APC
Citation search of relevant references	06/15/2022	APC
Text Search in A61M5/14248; A61M2005/14268; A61M35/10; A61M5/1413	06/16/2022	APC
Consultation with primary Lynne Anderson regarding potential allowable subject matter	06/16/2022	APC
Updated Search	10/28/2022	APC

/ARJUNA P CHATRATHI/ Examiner, Art Unit 3781	
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<i>Search Notes</i> 	Application/Control No. 17/057,318	Applicant(s)/Patent Under Reexamination TONG et al.
	Examiner ARJUNA P CHATRATHI	Art Unit 3781

Interference Search			
US Class/CPC Symbol	US Subclass/CPC Group	Date	Examiner
All	All	10/28/2022	APC

/ARJUNA P CHATRATHI/ Examiner, Art Unit 3781	
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Substitute for form 1449/PTO

(Use as many sheets as necessary)

Sheet 1

of 2

Complete if Known

Application Number	17/057,318
Filing Date	November 20, 2020
First Named Inventor	Ling-Kang Tong
Art Unit	3781
Examiner Name	Chatrathi, Arjuna P.
Attorney Docket Number	13164-722 US0

[illegible]

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T ⁶
		Country Code ³ Number ⁴ Kind Code ⁵ (if known)				
	887	WO2016/132368A1	8/25/2016	Ozca Eng Solutions Ltd.		

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. ¹Applicant's unique citation designation number (optional). ²See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁶Applicant is to place a check mark here if English language Translation is attached.

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 2 hours 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, 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.

If you need assistance in completing the form, call 1-800-PTC-9199 (1-800-786-9199) and select option 2.

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

Substitute for form 1449/PTO

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Complete if Known

Application Number	17/057,318
Filing Date	November 20, 2020
First Named Inventor	Ling-Kang Tong
Art Unit	3781
Examiner Name	Chatrathi, Arjuna P.
Attorney Docket Number	13164-722.US0

Sheet 2 of 2

NON PATENT LITERATURE DOCUMENTS

Examiner 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
	896	NETZEL et al.; U.S. Pat. Appl. # 17/815,879 entitled "Drug Delivery methods and systems," filed 7/28/2022	

Examiner
SignatureDate
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.

¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 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 2 hours 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, 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.**

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

CERTIFICATE OF TRANSMISSION UNDER 37 CFR 1.8

I hereby certify that this correspondence is being transmitted to the USPTO via EFS-Web on October 24, 2022.

/Amy Kasper/

Amy Kasper

October 24, 2022

Date

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appl. No. : 17/057,318 Confirmation No. : 1820
First Named Inventor : Ling-Kang TONG
Filing Date : November 20, 2020
Art Unit : 3781
Examiner : Arjuna P. CHATRATHI
Title : DRUG DELIVERY METHODS AND SYSTEMS
Customer No. : 66854

AMENDMENT AND RESPONSE UNDER 37 C.F.R. § 1.111

This communication is in response to the non-final Office Action dated June 23, 2022, the response to which is due September 23, 2022. A one-month Petition for Extension of Time is filed herewith, extending the due date up to and including October 23, 2022, a Sunday. As a result, a filing on Monday October 24, 2022, is timely.

The Commissioner is hereby authorized to charge any fees to make this filing timely to Deposit Account No. 50-4050 and to credit any overpayments to Deposit Account No. 50-4050.

Prior to reconsidering this application on the merits, please amend the application as follows:

Amendments to the Claims begin on page 2 of this paper.

Remarks begin on page 7 of this paper.

REMARKS

Applicants thank the Examiner for the indication of the allowable subject matter on page 12, paragraph [0041] of the Non-Final Office Action mailed June 23, 2022. This response is a bona fide attempt to advance prosecution by presented claims amended to reflect the indicated allowable subject matter.

Independent claims 1 and 23 are currently amended to reflect the indicated allowable subject matter identified in claim 4, presented in independent form. As a result, claim 4 has been canceled and claim 1 amended to incorporate the limitations of claim 4. The method of claim 23 has been similarly amended to present the allowable subject matter in the form of a method. Support for the amendments to claim 1 and claim 23 is found in at least paragraphs [0011-0012], [0050], and [0057-0059] along with various views in the drawings. As such, no new matter has been introduced by the amendment.

With the cancellation of claim 4, claims 5 and 6 have been amended to depend from amended claim 1. Claims 1-3 and 5-29 are currently pending. Reconsideration of the application in view of the currently pending claims and indicated allowable subject matter is respectfully requested.

INFORMATION DISCLOSURE STATEMENT

Applicants note that the Examiner has considered all references submitted in Information Disclosure Statements dated February 9, 2021, June 23, 2021, August 20, 2021, November 12, 2021, and February 14, 2022. It is respectfully requested that this Supplemental Information Disclosure Statement be considered and the PTO Form 1449 be initialed and returned with the next Action.

CLAIM REJECTIONS UNDER 35 U.S.C. §103

The Examiner bears the initial burden of establishing a *prima facie* case of nonpatentability. *In re Oetiker*, 977 F.2d 1443, 1445 (Fed. Cir. 1992). To establish a *prima facie* case of obviousness requires: (1) determining the scope and content of the prior art; (2) determining differences between the prior art and the claims at issue; and (3) determining the

level of ordinary skill in the pertinent art. *KSR International v. Teleflex, Inc.* 550 U.S. 398 2007, slip op. at 2 decided April 30, 2007, quoting *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1. 17-18 (1966). It is against this background the obviousness or non obviousness of the subject matter is determined. *Id.*

The Supreme Court in *KSR* did not reject the so-called teaching-suggestion-motivation (TSM) test to determine whether the skilled artisan would combine cited references; rather the Court counseled against applying the rule rigidly to limit the obvious inquiry. *KSR*, slip op. at 15. The Federal Circuit, following the grant of certiorari in *KSR* but prior to the Supreme Court's decision, clarified its standard for finding obviousness. *Dystar Textilfarben GMBH & Co v. C.H. Patrick Co.*, 464 F.3d 1356 (Fed. Cir. 2006). In *Dystar* the Federal Circuit clarified that the TSM test is not a rigid rule. "The motivation [to combine] need not be found in the references sought to be combined, but may be found in any number of sources, including common knowledge, the prior art as a whole, or the nature of the problem itself." *Dystar*, 464 F.3d at 1361 (citing *In re Dembiczak*, 175 F.3d 994, 999 (Fed. Cir. 1999)). To find an invention obvious "the prior art, common knowledge, or the nature of the problem, viewed through the eyes of an ordinary artisan, must have suggested [all the elements of the claimed invention]." *Dystar*, 464 F.3d at 1361. The Supreme Court in *KSR* cited *Dystar* with approval. *KSR*, 550 U.S. 398, slip op. at 17-18.

The heart of this analysis requires that the cited references, in the first instance, actually teach or suggest each and every element of the claimed invention. Thus, even assuming an ordinary artisan would have combined the teachings of the cited references, these references must teach or suggest each and every element of the claimed invention. *Dystar*, 464 F.3d at 1363-64. Whether a reference teaches or suggests a particular element of a claimed invention as put forth by an Examiner is determined by viewing the prior art through the eyes and common knowledge of the ordinary artisan. See *Dystar*, 464 F.3d at 1361. Additionally, in determining *Graham* factor number 1, determining the scope and content of the prior art, an Examiner must determine whether an ordinary artisan would have combined the cited references. *Dystar*, 464 F.3d at 1361.

The Examiner has rejected claims 1-3, 8-16, 18, and 23-28 under 35 U.S.C. § 103 as being unpatentable over U.S. Patent Application Publication No. 2016/0220798 to Netzel, et al. (“Netzel”) in view of U.S. Patent Application Publication No. 2005/0238704 to Zumbrunn, et al. (“Zumbrunn”).

Independent claims 1 and 23 have been amended to reflect the indicated allowable subject matter. All claims depend directly or indirectly from the allowable independent claims. Applicant respectfully requests withdrawal of all rejections in view of the present amendments that present allowable subject matter.

The Examiner has rejected claim 7 under 35 U.S.C. § 103 as being unpatentable over Netzel in view of Zumbrunn and further in view of U.S. Patent Application Publication No. 2017/0296317 to Gordon (“Gordon”).

Claim 7 depends from amended allowable independent claim 1. Applicants respectfully requests withdrawal of this rejection in view of the present amendments that present allowable subject matter.

The Examiner has rejected claim 17 under 35 U.S.C. § 103 as being unpatentable over Netzel in view of Zumbrunn and further in view of U.S. Patent Application Publication No. 2011/0160655 to Hanson, et al. (“Hanson ‘655”).

Claim 17 depends indirectly from amended allowable independent claim 1. Applicants respectfully requests withdrawal of this rejection in view of the present amendments that present allowable subject matter.

The Examiner has rejected claims 19-22 and 29 under 35 U.S.C. § 103 as being unpatentable over Netzel in view of Zumbrunn and further in view of U.S. Patent Application Publication No. 2013/0190683 to Hanson, et al. (“Hanson ‘683”).

Claims 19-22 depend indirectly from amended allowable claim 1. Applicants respectfully requests withdrawal of this rejection in view of the present amendments that present allowable subject matter.

Claim 29 depends from amended independent claim 23. Claim 23 has been presented in an amended form believed to present allowable subject matter. Withdrawal of the rejection based on the allowable subject matter of the independent claim is respectfully requested.

ALLOWABLE SUBJECT MATTER

The Applicants thank the Examiner for indicating claims 4-6 as being allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Independent claims 1 and 23 have been amended to include allowable subject matter. Thus, all claims are in condition for allowance.

CONCLUSION

In light of the remarks set forth above, Applicants believe that they are entitled to a letters patent. Applicants respectfully solicit the Examiner to expedite the prosecution of this patent application to issuance. Should the Examiner have any question, the Examiner is encouraged to telephone the undersigned at (650) 287-2187.

Respectfully submitted,

Date: October 24, 2022

By: /W. Benjamin Glenn/
W. Benjamin Glenn
Registration No. 44,713

SHAY GLENN LLP
155 BOVET ROAD, SUITE 710
SAN MATEO, CA 94402
TELEPHONE: 650.287-2187
FACSIMILE: 650.212.7562

AMENDMENTS TO THE CLAIMS

This listing of claims will replace all prior versions, and listings, of claims in the application:

1. (Currently Amended) A two-part bioactive agent delivery system, the system comprising:
a disposable part comprising
 an agent reservoir,
 a transdermal patch communicating with the agent reservoir and adapted to transdermally deliver the bioactive agent to a user, the transdermal patch having a bottom surface adapted to contact skin of the user and a top surface opposite the bottom surface, and
 a gas permeable membrane disposed over the top surface of the transdermal patch;
a reusable part comprising a power source and control electronics, the control electronics being adapted to deliver bioactive agent dissolved in a solvent from the agent reservoir to the transdermal patch; [[and]]
a solvent removal element comprising a gap disposed between the disposable part and the reusable part to create a flow path for gaseous solvent to flow from the gas permeable membrane to ambient air around the bioactive agent delivery system[[.]], and wherein the gap is maintained with a spacer disposed between the disposable part and the reusable part.
2. (Original) The system of claim 1, wherein the gap extends between parallel features on the disposable part and the reusable part.

3. (Original) The system of claim 1, wherein the gap is formed when the disposable part and the reusable part are releasably engaged.
4. (Cancelled)
5. (Currently Amended) The system of claim ~~[[4]]~~ 1, wherein the spacer extends from the disposable part.
6. (Currently Amended) The system of claim ~~[[4]]~~ 1, wherein the spacer extends from the reusable part.
7. (Original) The system of claim 1, further comprising at least one drainage port formed in an exterior surface of the reusable part or the disposable part.
8. (Original) The system of claim 1, wherein the disposable part further comprises an agent outlet communicating with the agent reservoir and the transdermal patch.
9. (Original) The system of claim 8, wherein the agent outlet is configured to provide the bioactive agent dissolved in the solvent to a space between the transdermal patch and the vapor permeable membrane.
10. (Original) The system of claim 1, wherein the agent reservoir comprises a piston movably disposed in a chamber.
11. (Original) The system of claim 10, further comprising a spring extending between the agent reservoir piston and a surface to pressurize the agent reservoir when the spring is compressed and the agent reservoir contains a quantity of bioactive agent solution.

12. (Original) The system of claim 10, further comprising a bolus chamber communicating with the agent reservoir and an agent outlet, the bolus chamber comprising a piston movably disposed in a chamber, the volume of the bolus chamber being less than the volume of the agent reservoir.
13. (Original) The system of claim 12, further comprising a valve having a first position communicating the agent reservoir with the bolus chamber and a second position communicating the bolus chamber with the agent outlet.
14. (Original) The system of claim 13, wherein the reusable part comprises a valve driver, the control electronics being adapted to control the valve driver to actuate the valve to deliver bioactive agent solution from the agent reservoir to the bolus chamber and from the bolus chamber to the agent outlet.
15. (Original) The system of claim 10, further comprising a spring extending between the bolus chamber piston and a surface to pressurize the bolus chamber when the spring is compressed and the bolus chamber contains a quantity of bioactive agent solution.
16. (Original) The system of claim 1, further comprising a latch adapted to removably attach the disposable part to the reusable part.
17. (Original) The system of claim 16, wherein the latch is positioned on one side of the system and a rail is positioned along a second side of the system, the disposable part and the reusable part configured to slide relative to one another along the rail until the latch is activated to attach the disposable part to the reusable part.
18. (Original) The system of claim 1, further comprising a connection detector adapted to detect a connection between the disposable part and the reusable part.

19. (Original) The system of claim 18, wherein the connection detector comprises a magnet.
20. (Original) The system of claim 19, wherein the magnet is disposed in the disposable part.
21. (Original) The system of claim 19, wherein the magnet is disposed in the reusable part.
22. (Original) The system of claim 19, wherein the connection detector further comprises a magnetoresistive switch.
23. (Currently Amended) A method of delivering a bioactive agent, the method comprising:
connecting a reusable part of a delivery system to a disposable part of the delivery system
to form a flow path along a gap between the reusable part and the disposable part
maintained by a spacer disposed between the disposable part and the reusable part;
delivering the bioactive agent dissolved in a solvent from a reservoir of the disposable
part to a transdermal membrane of the disposable part; and
allowing the solvent to evaporate and flow from the transdermal membrane through a gas
permeable membrane and along the flow path to ambient air around the delivery
system.
24. (Original) The method of claim 23, further comprising applying the transdermal
membrane to skin of a user.
25. (Original) The method of claim 24, further comprising delivering the bioactive agent
to the skin.

26. (Original) The method of claim 23, wherein the delivering step comprises controlling with the reusable part movement of the bioactive agent dissolved in the solvent from the reservoir to the transdermal membrane.
27. (Original) The method of claim 26, wherein the controlling step comprises actuating a valve.
28. (Original) The method of claim 23, further comprising detecting a connection between the disposable part and the reusable part.
29. (Original) The method of claim 28, wherein the detecting step comprises sensing a magnetic field.

PE2E SEARCH - Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	British Equivalents	Time Stamp
L1	0	((("MORNINGSIDE") near3 ("VENTURE") near3 ("INVESTMENTS") near3 ("LIMITED") near3 ("MONACO"))).AS,AAN M.	(USPAT)	OR	ON	ON	2022/06/15 09:45 AM
L2	78	((("TONG") near3 ("Ling-Kang")) OR (("BUCHMAN") near3 ("Daniela")) OR (("HANCOCK") near3 ("Jackie")) OR (("TERZULLI") near3 ("Nicholas"))).INV.	(US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT)	OR	ON	ON	2022/06/15 09:45 AM
L3	1	("20060271020").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2022/06/15 09:48 AM
L4	249	("20090010998" OR "5562607" OR "20150342900" OR "5846559" OR "9555277" OR "20050197625" OR "20100130932" OR "20120078216" OR "20130096495" OR "20140163521" OR "20150057616" OR "20160058939" OR "20160317738" OR "20170232192" OR "4313439" OR "0092481" OR "10004447" OR "10034841" OR "10105487" OR "10143687" OR "10213586" OR "10232156" OR "10258738" OR "10258778" OR "10679516" OR "10716764" OR "20010022978" OR "20010026788" OR "20020002189" OR "20020034535" OR "20020106329" OR "20020127256" OR "20020165170" OR "20020169439" OR	(US-PGPUB; USPAT)	OR	ON	ON	2022/06/15 09:49 AM

		"20020182238" OR "20030004187" OR "20030065294" OR "20030065924" OR "20030083645" OR "20030087937" OR "20030119879" OR "20030159702" OR "20040019321" OR "20040034068" OR "20040037879" OR "20040052843" OR "20040062802" OR "20040138074" OR "20040166159" OR "20040191322" OR "20040194793" OR "20040219192" OR "20040229908" OR "20040241218" OR "20040253249" OR "20040259816" OR "20050002806" OR "20050014779" OR "20050021092" OR "20050034842" OR "20050048020" OR "20050053665" OR "20050113452" OR "20050141346" OR "20050151110" OR "20050159419" OR "20050266032" OR "20050276852" OR "20060024358" OR "20060036209" OR "20060057202" OR "20060122577" OR "20060167039" OR "20060184093" OR "20060188859" OR "20060204578" OR "20060206054" OR "20070026054" OR "20070042026" OR "20070065365" OR "20070086275" OR "20070088338" OR "20070104787" OR "20070149952" OR "20070154336" OR "20070168501" OR "20070179172" OR "20070191815" OR "20070250018" OR "20070256684" OR "20070260491" OR "20070279217" OR					
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		"20070299401" OR "20080008747" OR "20080131494" OR "20080138294" OR "20080138398" OR "20080138399" OR "20080138423" OR "20080139907" OR "20080152592" OR "20080195946" OR "20080201174" OR "20080233178" OR "20080274168" OR "20080319272" OR "20090005009" OR "20090024004" OR "20090062754" OR "20090118710" OR "20090169631" OR "20090246265" OR "20090247985" OR "20090259176" OR "20090299156" OR "20100003653" OR "20100068250" OR "20100114008" OR "20100145303" OR "20100179473" OR "20100196463" OR "20100248198" OR "20100273738" OR "20100280432" OR "20110004072" OR "20110053129" OR "20110054285" OR "20110109439" OR "20110137255" OR "20110152635" OR "20110153360" OR "20110160640" OR "20110241446" OR "20110245633" OR "20110245783" OR "20110250576" OR "20110256517" OR "20110264028" OR "20110268809" OR "20110275987" OR "20120046644" OR "20120123387" OR "20120156138" OR "20120171277" OR "20120178065" OR "20120203573" OR "20120209223" OR "20120221251" OR "20120244503" OR "20120302844" OR					
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		"20120316896" OR "20120329017" OR "20130017259" OR "20130123719" OR "20130158430" OR "20130178826" OR "20130190683" OR "20130216989" OR "20130253430" OR "20130302398" OR "20130311917" OR "20130328572" OR "20130345633" OR "201310317384" OR "20140046288" OR "20140073883" OR "20140088554" OR "20140099614" OR "20140100241" OR "20140200525" OR "20140206327" OR "20140207047" OR "20140228736" OR "20140237028" OR "20140240124" OR "20140266584" OR "20140272844" OR "20140272845" OR "20140272846" OR "20140275135" OR "20140275932" OR "20140276127" OR "20140279740" OR "20140302121" OR "20140303574" OR "20140365408" OR "20140378943" OR "20150209783" OR "20150273148" OR "20150310760" OR "20160030412" OR "20160220553" OR "20160227361" OR "20160228383" OR "20160235732" OR "20160235916" OR "20160310664" OR "20160317057" OR "20160339174" OR "20160346462" OR "20170007550" OR "20170079932" OR "20170100573" OR "20170189348" OR "20170189534" OR "20170207825" OR "20170209429" OR "20170249433" OR					
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		"20170296107" OR "20170296317" OR "20170351840" OR "20180014783" OR "20180028069" OR "20180028070" OR "20180028071" OR "20180028072" OR "20180110768" OR "20180110975" OR "20180165566" OR "20180168504" OR "20180197637" OR "20180374381" OR "20190000828" OR "20190054078" OR "20190054235" OR "20190231707" OR "20190275308" OR "20190336738" OR "20190374482" OR "20200030590" OR "20200330369" OR "20200368175" OR "2183482" OR "3279653" OR "3845217" OR "4321387" OR "4327725" OR "4332945" OR "4379454" OR "4545990" OR "4579858" OR "4590278" OR "4708716" OR "4772263" OR "4806356" OR "4853854" OR "4885154" OR "4908213" OR "4917676" OR "4917895").pn. ("4920989" OR "4952928" OR "4953572" OR "4992445" OR "5000956" OR "5001139" OR "5013293" OR "5023252" OR "5049387" OR "5069904" OR "5073380" OR "5097834" OR "5120545" OR "5130139" OR "5149538" OR "5149719" OR				
L5	241	(US-PGPUB; USPAT) OR ON ON 2022/06/15 09:49 AM				

		"5212188" OR "5221254" OR "5227391" OR "5232704" OR "5232933" OR "5236714" OR "5242934" OR "5242935" OR "5242941" OR "5248690" OR "5252604" OR "5262165" OR "5273755" OR "5273756" OR "5304739" OR "5352456" OR "5364630" OR "5370635" OR "5388571" OR "5389679" OR "5393526" OR "5405614" OR "5415629" OR "5445609" OR "5451407" OR "5464387" OR "5472946" OR "5501697" OR "5505958" OR "5512306" OR "5516793" OR "5525351" OR "5545407" OR "5596994" OR "5601839" OR "5616332" OR "5618557" OR "56211194" OR "5653682" OR "5656255" OR "5662920" OR "56689380" OR "5686100" OR "5688232" OR "5697896" OR "5716987" OR "5722418" OR "5733259" OR "5785688" OR "5797867" OR "5820875" OR "5833466" OR "5843979" OR "5865786" OR "5876368" OR "5879292" OR "5879322" OR "5882676" OR					
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		"5908301" OR "5919156" OR "5932240" OR "5945123" OR "5967789" OR "5972389" OR "5993435" OR "5997501" OR "6018679" OR "6019997" OR "6024981" OR "6034079" OR "6059736" OR "6059753" OR "6068853" OR "6081734" OR "6090404" OR "6093419" OR "6120803" OR "6129702" OR "6165155" OR "6211296" OR "6221394" OR "6238689" OR "6274606" OR "6310102" OR "6365182" OR "6368625" OR "6374136" OR "6416471" OR "6417359" OR "6423747" OR "6436078" OR "6437004" OR "6454708" OR "6488959" OR "6492399" OR "6539250" OR "6546281" OR "6567785" OR "6569449" OR "6569866" OR "6576269" OR "6579865" OR "6589229" OR "6595956" OR "6638528" OR "6638543" OR "6660295" OR "6723086" OR "6723340" OR "6746688" OR "6791003" OR "6799576" OR "6849645" OR "6861066" OR "6867342" OR "6887202" OR					
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		"6893655" OR "6900202" OR "6911475" OR "6998176" OR "7011843" OR "7011849" OR "7019622" OR "7064143" OR "7182955" OR "7196619" OR "7229641" OR "7282217" OR "7332182" OR "7376700" OR "7384651" OR "7384653" OR "7579019" OR "7598275" OR "7718677" OR "7780981" OR "7931563" OR "7988660" OR "8003080" OR "8021334" OR "8137314" OR "8140143" OR "8192756" OR "8246581" OR "8252321" OR "8262394" OR "8268475" OR "8285328" OR "8303500" OR "8309568" OR "8372040" OR "8414532" OR "8440220" OR "8440221" OR "8441411" OR "8445010" OR "8449471" OR "8517988" OR "8545445" OR "8574188" OR "8586079" OR "8589174" OR "8614278" OR "8632497" OR "8666781" OR "8673346" OR "8684922" OR "8688189" OR "8690827" OR "8690865" OR "8696637" OR "8703175" OR "8703177" OR "8722233" OR					
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L6	1121	"8727745" OR "8741336" OR "8747348" OR "8753315" OR "8773257" OR "8814822" OR "8862223" OR "8864727" OR "8865207" OR "8872663" OR "8876802" OR "8956644" OR "8962014" OR "8986253" OR "8999356" OR "8999372" OR "9023392" OR "9044582" OR "9050348" OR "9078833" OR "9111085" OR "9114240" OR "9155712" OR "9233203" OR "9238001" OR "9238108" OR "9289397" OR "9308202" OR "9314527" OR "9373269" OR "9380698" OR "9513666" OR "9549903" OR "9555226" OR "9555227" OR "9623017" OR "9636457" OR "9655843" OR "9656441" OR "9669199" OR "9687186" OR "9693689" OR "9700552" OR "9717698" OR "9735893" OR "9782082" OR "9795681" OR "9867539" OR "9895320" OR "9949935" OR "9974492" OR "9993203" OR "RE46217").pn. L3 OR L4 OR L5	(US-PGPUB; USPAT; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP,	OR	ON	ON	2022/06/15 10:36 AM
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L7	3	("20080220092" "20110137255" "20160339174").pn.	ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS) (US-PGPUB; USPAT)	OR	ON	ON	2022/06/15 10:48 AM
L8	40	L6 AND ((solvent OR fluid OR water) SAME (enviroment OR ambient))	(US-PGPUB; USPAT; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS)	OR	ON	ON	2022/06/15 01:25 PM
L9	6	((US-20160220798-A1 OR US-20060271020- A1 OR US- 20130190683-A1 OR US-20080220092-A1 OR US-20110137255- A1 OR US- 20160339174-A1).did. AND PGPB.dbnm.)	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/06/15 01:28 PM
L10	15671	A61M5/14248	(US-PGPUB; USPAT; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS)	OR	ON	ON	2022/06/15 01:32 PM

L11	15664	(A61M5/14248).cpc.	(US-PGPUB; USPAT; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS)	OR	ON	ON	2022/06/15 01:32 PM
L12	4227	(A61M5/14248).cpc. AND (A61M2005/14268).cpc.	(US-PGPUB; USPAT; FIT (AP, AT, AU, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, MC, MD, MY, NL, NO, NZ, OA, PH, PL, PT, RO, RS, RU, SE, SG, SI, SK, SU, TH, TN, TR, TW, UA, VN, WO); FPRS)	OR	ON	ON	2022/06/15 01:34 PM
L13	639	L12 AND vent	(US-PGPUB; USPAT; FIT (AP, AT, AU, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, MC, MD, MY, NL, NO, NZ, OA, PH, PL, PT, RO, RS, RU, SE, SG, SI, SK, SU, TH, TN, TR, TW, UA, VN, WO); FPRS)	OR	ON	ON	2022/06/15 01:34 PM
L14	692	L12 AND gap	(US-PGPUB; USPAT; FIT (AP, AT, AU, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, MC, MD, MY, NL, NO, NZ, OA, PH, PL, PT, RO, RS, RU, SE, SG, SI, SK, SU, TH, TN, TR, TW, UA, VN, WO); FPRS)	OR	ON	ON	2022/06/15 01:35 PM
L15	18	L12 AND (gap SAME	(US-PGPUB; USPAT;	OR	ON	ON	2022/06/15

		(vent OR evaporat\$3))	FIT (AP, AT, AU, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, MC, MD, MY, NL, NO, NZ, OA, PH, PL, PT, RO, RS, RU, SE, SG, SI, SK, SU, TH, TN, TR, TW, UA, VN, WO); FPRS)				01:40 PM
L16	56	L12 AND (solvent SAME removal)	(US-PGPUB; USPAT; FIT (AP, AT, AU, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, MC, MD, MY, NL, NO, NZ, OA, PH, PL, PT, RO, RS, RU, SE, SG, SI, SK, SU, TH, TN, TR, TW, UA, VN, WO); FPRS)	OR	ON	ON	2022/06/15 02:09 PM
L17	5674	(A61M2005/14268).cpc.	(US-PGPUB; USPAT; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS)	OR	ON	ON	2022/06/15 02:12 PM
L18	90	L17 AND (solvent SAME (remov\$2 OR evaporat\$3 OR vent))	(US-PGPUB; USPAT; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS)	OR	ON	ON	2022/06/15 02:13 PM
L19	1	(11/440169).APP.	(USPAT; USOCR)	OR	ON	ON	2022/06/15 02:29 PM

L20	55	("5097834" "5352456" "5370635" "5820875" "6068853" "6214379" "6436078" "6638528" "6723086" "6861066" "6867342" "6887202" "7780981" "20020169439" "20030065294" "20030065924" "20050034842" "20050182307" "20050238704").pn. OR ("8372040").urpn. AND (PGPB USPT USOC).dbnm.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2022/06/15 02:29 PM
L21	1573	A61M35/10.cpc.	(US-PGPUB; USPAT; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS)	OR	ON	ON	2022/06/15 02:46 PM
L22	1	(10/711389).APP.	(USPAT; USOCR)	OR	ON	ON	2022/06/15 02:47 PM
L23	51	("4379454" "4545990" "4708716" "4917895" "5242941" "5273756" "5352456" "5370635" "5389679" "5405614" "5505958" "5538503" "5616332" "5785688" "5820875" "5879322" "5932240" "5993435" "6068853" "6129702" "6165155" "6211296" "6214379" "6374136" "6539250" "6595956" "6638528" "6723077" "6723086" "6861066" "6867342" "6887202" "20020127256" "20030065294" "20040138074" "20050034842" "20050182307" "20050238704").pn. OR ("8440221").urpn. AND (PGPB USPT USOC).dbnm.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2022/06/15 02:47 PM

L24	245	L21 AND gap	(US-PGPUB; USPAT; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS)	OR	ON	ON	2022/06/15 02:54 PM
L25	71	L21 AND (solvent SAME (remov\$2 OR evaporat\$3 OR vent))	(US-PGPUB; USPAT; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS)	OR	ON	ON	2022/06/15 02:57 PM
L26	18627	(A61M5/14248 OR A61M2005/14268 OR A61M35/10).cpc.	(US-PGPUB; USPAT; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS)	OR	ON	ON	2022/06/15 02:59 PM
L27	1434	L26 AND ((dry\$3) OR (solvent SAME (remov\$2 OR evaporat\$3 OR vent OR recover\$3)))	(US-PGPUB; USPAT; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS)	OR	ON	ON	2022/06/15 03:00 PM
L28	13	L21 AND (vent SAME	(US-PGPUB; USPAT;	OR	ON	ON	2022/06/15

		housing)	FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS)				04:18 PM
L29	1	(10/711389).APP.	(USPAT; USOCR)	OR	ON	ON	2022/06/16 09:08 AM
L30	51	("4379454" "4545990" "4708716" "4917895" "5242941" "5273756" "5352456" "5370635" "5389679" "5405614" "5505958" "5538503" "5616332" "5785688" "5820875" "5879322" "5932240" "5993435" "6068853" "6129702" "6165155" "6211296" "6214379" "6374136" "6539250" "6595956" "6638528" "6723077" "6723086" "6861066" "6867342" "6887202" "20020127256" "20030065294" "20040138074" "20050034842" "20050182307" "20050238704").pn. OR ("8440221").urpn. AND (PGPB USPT USOC).dbnm.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2022/06/16 09:08 AM
L31	1146	((Bente near3 Paul) OR (Hanson near3 Ian)).in.	(US-PGPUB; USPAT; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS)	OR	ON	ON	2022/06/16 09:17 AM
L32	2	("7597682" "7658734").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2022/06/16 09:53 AM

L33	5676	(A61M2005/14268).cpc.	(US-PGPUB; USPAT; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS)	OR	ON	ON	2022/06/16 10:09 AM
L34	2945	L33 AND (gap OR seam OR opening OR vent OR slit OR slot)	(US-PGPUB; USPAT; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS)	OR	ON	ON	2022/06/16 10:09 AM
L35	2135	L33 AND ((gap OR seam OR opening OR vent OR slit OR slot) SAME (between))	(US-PGPUB; USPAT; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS)	OR	ON	ON	2022/06/16 10:10 AM
L36	508	L33 AND ((environment OR ambient) SAME (vapor OR gas\$4))	(US-PGPUB; USPAT; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS)	OR	ON	ON	2022/06/16 11:24 AM
L37	78	("3631847" "3770607"	(US-PGPUB; USPAT;	OR	ON	ON	2022/06/16

		"3771694" "3953566" "4030495" "4194041" "4313439" "4429000" "4498843" "4544369" "4560611" "4657486" "4679562" "4734092" "4846797" "4902278" "5352513" "5390671" "5460603" "5591541" "5607796" "5658356" "5662717" "5688864" "5733676" "5804327" "5904998" "5928194" "5938640" "5957895" "5973055" "5985475" "6143164" "6485461" "6589229" "6638610" "6676993" "6723072" "6740059" "6743516" "6811884" "6854603" "7083849" "7144384" "20030161744" "20050177108" "20060184154" "20070073235" "20070106218" "20070191702" "20070255198" "20080051716" "20080102119" "20080125701" "20080255516" "20080269575" "20080294142" "20100121306" "20100130932" "20100191078" "20100198187" "20100217230" "20100241086" "20100298764").pn. OR ("8491529").urpn. AND (PGPB USPT USOC).dbnm.	USOCR)				11:43 AM
L38	0	(10/774487).APP.	(USPAT; USOCR)	OR	ON	ON	2022/06/16 11:57 AM
L39	9	L33 AND spacer	(USPAT; USOCR)	OR	ON	ON	2022/06/16 01:39 PM
L40	140	L33 AND spacer	(US-PGPUB; USPAT; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO,	OR	ON	ON	2022/06/16 01:40 PM

L41	7962	(A61M5/1413).cpc.	MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS) (US-PGPUB; USPAT; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS)	OR	ON	ON	2022/06/16 01:53 PM
L42	494	L41 AND ((environment OR ambient) SAME (vapor OR gas\$4))	(US-PGPUB; USPAT; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS)	OR	ON	ON	2022/06/16 01:54 PM
L43	12902	(A61M35/10 OR A61M5/15248 OR A61M2005/14268 OR A61M5/1413).cpc.	(US-PGPUB; USPAT; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS)	OR	ON	ON	2022/06/16 02:03 PM
L44	5547	L43 AND (seal\$3)	(US-PGPUB; USPAT; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO,	OR	ON	ON	2022/06/16 02:04 PM

L45	2174	L43 AND ((seal\$3 SAME (disposable OR reservoir) SAME (reusable OR durable OR pump)))	NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS) (US-PGPUB; USPAT; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS)	OR	ON	ON	2022/06/16 02:09 PM
L46	1094	L41 AND gap	(US-PGPUB; USPAT; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS)	OR	ON	ON	2022/06/16 02:33 PM
L47	51	L33 AND (drain\$3 SAME port)	(US-PGPUB; USPAT; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS)	OR	ON	ON	2022/06/16 03:10 PM
L48	109	L43 AND (drain\$3 near3 port)	(US-PGPUB; USPAT; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS)	OR	ON	ON	2022/06/16 03:12 PM

L49	1210	L43 AND (bath\$3 OR shower\$3 OR swim\$4)	RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS) (US-PGPUB; USPAT; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS)	OR	ON	ON	2022/06/16 03:15 PM
L50	36	L43 AND (drain SAME excess)	(US-PGPUB; USPAT; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS)	OR	ON	ON	2022/06/16 05:50 PM
L51	492	L43 AND (drain)	(US-PGPUB; USPAT; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS)	OR	ON	ON	2022/06/16 05:51 PM
L52	37	L6 AND drain	(US-PGPUB; USPAT; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS)	OR	ON	ON	2022/06/16 08:04 PM

L53	138	L6 AND (gap OR spacer)	TH, TN, TR, TW, UA, VN); FPRS) (US-PGPUB; USPAT; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS)	OR	ON	ON	2022/06/16 08:04 PM
L54	13983	L43 OR L6	(US-PGPUB; USPAT; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS)	OR	ON	ON	2022/06/16 08:52 PM
L55	551	L54 AND ((rail OR key OR ridge) SAME (slide))	(US-PGPUB; USPAT; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS)	OR	ON	ON	2022/06/16 08:52 PM

PE2E SEARCH - Search History (Interference)

There are no Interference searches to show.

PTO/SB/08A (04-07)

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**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Sheet 1 of 2

Complete if Known

Application Number	17/057,318
Filing Date	November 20, 2020
First Named Inventor	Ling-Kang Tong
Art Unit	3781
Examiner Name	Unassigned
Attorney Docket Number	13164-722.US0

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code ² (if known)			
	880	US- 5,846,559	12/8/1998	Hopp	
	878	US- 2015/0342900	12/3/2015	Putnins	
		US-			
		US-			
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FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁸
		Country Code ³ -Number ⁴ -Kind Code ⁵ (if known)				
	876	JPH09504974A (w/EngEquiv)	5/20/1997	Elan Medical Technologies, L		
	882	JP2000515394A (w/EngEquiv)	11/21/2000	Elan Medical Technologies, L		
	874	JP2001505491A (w/EngEquiv)	4/24/2001	LHD Lab Hygiene Dietetique		
	879	JP2003506477A (w/EngEquiv)	2/18/2003	Microchips Inc.		
	875	JP2005521526A (w/EngEquiv)	7/21/2005	Becton Dickinson & Co.		
	877	JP2010279808A (w/MachTrans)	12/16/2010	Altea Therapeutics Corp.		

Examiner
Signature

/ARJUNA P CHATRATHI/

Date
Considered

06/15/2022

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet	2	of	2
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Application Number	17/057,318
Filing Date	November 20, 2020
First Named Inventor	Ling-Kang Tong
Art Unit	3781
Examiner Name	Unassigned
Attorney Docket Number	13164-722.US0

U. S. PATENT DOCUMENTS

[illegible]

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T ⁶
		Country Code ³ Number ⁴ Kind Code ⁵ (if known)				
	883	JP2011036491A (w/MachTrans)	2/24/2011	Fukae Kasei KK		
	873	JP2013524951A (w/EngEquiv)	6/20/2013	Abbott Biotech Ltd.		
	881	JP2015070868A (w/EngAbs)	4/16/2015	Syndeo LLC		

Examiner Signature	/ARJUNA P CHATRATHI/	Date Considered	06/15/2022
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Sheet 1 of 1

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First Named Inventor	Ling-Kang Tong
Art Unit	3781
Examiner Name	Unassigned
Attorney Docket Number	13164-722.US0

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code ² (if known)			
	866	US- 4,313,439	2/2/1982	Babb et al.	
	870	US- 2005/0197625	9/8/2005	Haueter et al.	
	862	US- 2010/0130932	5/27/2010	Yodfat et al.	
	867	US- 2012/0078216	3/29/2012	Smith et al.	
	869	US- 2013/0096495	4/18/2013	Holmqvist et al.	
	868	US- 2014/0163521	6/12/2014	O'Conner	
	863	US- 2015/0057616	2/26/2015	Shergold et al.	
	861	US- 2016/0058939	3/3/2016	Brewer et al.	
	865	US- 2016/0317738	11/3/2016	Cross et al.	
	864	US- 2017/0232192	8/17/2017	Sasaki	
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FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁸
		Country Code ³ -Number ⁴ -Kind Code ⁵ (if known)				
	850	WO2020/102695A1	5/22/2020	Chrono Therapeutics Inc.		

Examiner
Signature

/ARJUNA P CHATRATHI/

Date
Considered

06/15/2022

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet	1	of	2
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Application Number	17/057,318
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First Named Inventor	Ling-Kang Tong
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Attorney Docket Number	13164-722.US0

U. S. PATENT DOCUMENTS

[illegible]

FOREIGN PATENT DOCUMENTS

[illegible]

Examiner Signature	/ARJUNA P CHATRATHI/	Date Considered	06/15/2022
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PTO/SB/08b (07-09)

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Substitute for form 1449/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>		Complete if Known	
		Application Number	17/057,318
		Filing Date	November 20, 2020
		First Named Inventor	Ling-Kang Tong
		Art Unit	3781
		Examiner Name	Unassigned
Sheet 2	of 2	Attorney Docket Number	13164-722.US0

NON PATENT LITERATURE DOCUMENTS			
Examiner 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
	871	RUANE et al.; U.S. Pat Appl. # 17/293,570 entitled "Thermally regulated transdermal drug delivery system," filed 5/13/2021	

Examiner Signature	/ARJUNA P CHATRATHI/	Date Considered	06/15/2022
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¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 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 2 hours 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, 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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**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

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Sheet 1 of 43

Complete if Known

Application Number	17/057,318
Filing Date	November 20, 2020
First Named Inventor	Ling-Kang Tong
Art Unit	Unassigned
Examiner Name	Unassigned
Attorney Docket Number	13164-722.US0

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code ² (if known)			
	558	US- 2,183,482	12/12/1939	Kurkjian	
	761	US- 3,279,653	10/18/1966	Pfleger	
	342	US- 3,845,217	10/29/1974	Femo et al.	
	529	US- 4,321,387	3/23/1982	Chavdarian et al.	
	530	US- 4,327,725	5/4/1982	Cortese et al.	
	531	US- 4,332,945	6/1/1982	Edwards	
	1	US- 4,379,454	4/12/1983	Campbell et al.	
	2	US- 4,545,990	10/8/1985	Le Foyer de Costil et al.	
	343	US- 4,579,858	4/1/1986	Femo et al.	
	532	US- 4,590,278	5/20/1986	Edwards	
	3	US- 4,708,716	11/24/1987	Sibalis	
	203	US- 4,772,263	9/20/1988	Dorman et al.	
	344	US- 4,806,356	2/21/1989	Shaw	
	204	US- 4,853,854	8/1/1989	Behar et al.	
	4	US- 4,885,154	12/5/1989	Cornier et al.	
	5	US- 4,908,213	3/13/1990	Govil et al.	
	6	US- 4,917,676	4/17/1990	Heiber et al.	
	7	US- 4,917,895	4/17/1990	Lee et al.	
	345	US- 4,920,989	5/1/1990	Rose et al.	

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		Country Code ³ -Number ⁴ -Kind Code ⁵ (if known)				
	403	AU662877B3	9/14/1995	Hakim		
	404	BE899037A (w/EngAbs)	6/18/1984	Trenker Ady		
	103	CA2142871A1 (WOpubln)	3/3/1994	Cygnus Inc.		
	405	CN1704056A (w/EngAbs)	12/7/2005	Chinse Acad Sci Biophysics		
	104	DE10103158A1 (w/EngAbs)	8/1/2002	Von Falkenhausen, C.		
	105	DE10105759C1 (w/EngAbs)	10/25/2001	LTS Lohmann Ther. Sys.		

Examiner
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/ARJUNA P CHATRATHI/

Date
Considered

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Sheet 2 of 43

Complete if Known

Application Number	17/057,318
Filing Date	November 20, 2020
First Named Inventor	Ling-Kang Tong
Art Unit	Unassigned
Examiner Name	Unassigned
Attorney Docket Number	13164-722.US0

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		Number-Kind Code ² (if known)			
	603	US- 4,952,928	8/28/1990	Carroll et al.	
	346	US- 4,953,572	9/4/1990	Rose et al.	
	796	US- 4,992,445	2/12/1991	Lawter et al.	
	8	US- 5,000,956	3/19/1991	Amkraut et al.	
	797	US- 5,001,139	3/19/1991	Lawter et al.	
	9	US- 5,013,293	5/7/1991	Sibalis	
	798	US- 5,023,252	6/11/1991	Hseih	
	10	US- 5,049,387	9/17/1991	Amkraut	
	347	US- 5,069,904	12/3/1991	Masterson	
	780	US- 5,073,380	12/17/1991	Babu et al.	
	11	US- 5,097,834	3/24/1992	Skrabal	
	12	US- 5,120,545	6/9/1992	Ledger et al.	
	13	US- 5,130,139	7/14/1992	Cormier et al.	
	569	US- 5,149,538	9/22/1992	Granger et al.	
	14	US- 5,149,719	9/22/1992	Ferber et al.	
	348	US- 5,212,188	5/18/1993	Caldwell et al.	
	15	US- 5,221,254	6/22/1993	Phipps	
	349	US- 5,227,391	7/13/1993	Caldwell et al.	
	533	US- 5,232,704	8/3/1993	Franz et al.	

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		Country Code ³ -Number ⁴ -Kind Code ⁵ (if known)				
	106	DE19958554A1 (w/CorresEng)	1/11/2001	LTS Lohmann Ther. Sys.		
	107	EP0314528B1	12/16/1992	Hercon Labs Corp.		
	108	EP0354554B1	1/5/1994	Estee Lauder Inc.		
	109	EP0612525B1	9/19/2001	Bristol Myers Squibb Co		
	273	EP0726005A1 (WOpubin)	8/14/1996	Williams		
	272	EP1662989B1	9/3/2014	Body Media inc.		

Examiner Signature	/ARJUNA P CHATRATHI/	Date Considered	06/15/2022
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Sheet 3 of 43

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Application Number	17/057,318
Filing Date	November 20, 2020
First Named Inventor	Ling-Kang Tong
Art Unit	Unassigned
Examiner Name	Unassigned
Attorney Docket Number	13164-722.US0

U. S. PATENT DOCUMENTS

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		Number-Kind Code ² (if known)			
	350	US- 5,232,933	8/3/1993	Lippiello et al.	
	570	US- 5,236,714	8/17/1993	Lee et al.	
	351	US- 5,242,934	9/7/1993	Lippiello et al.	
	752	US- 5,242,935	9/7/1993	Lippiello et al.	
	16	US- 5,242,941	9/7/1993	Lewy et al.	
	352	US- 5,248,690	9/28/1993	Caldwell et al.	
	17	US- 5,252,604	10/12/1993	Nagy et al.	
	18	US- 5,262,165	11/16/1993	Govil et al.	
	197	US- 5,273,755	12/28/1993	Venkatraman et al.	
	19	US- 5,273,756	12/28/1993	Fallon et al.	
	20	US- 5,304,739	4/19/1994	Klug et al.	
	21	US- 5,352,456	10/4/1994	Fallon et al.	
	313	US- 5,364,630	11/15/1994	Osborne et al.	
	22	US- 5,370,635	12/6/1994	Strausak et al.	
	597	US- 5,388,571	2/14/1995	Roberts et al.	
	23	US- 5,389,679	2/14/1995	Alliger	
	24	US- 5,393,526	2/28/1995	Castro	
	25	US- 5,405,614	4/11/1995	D'Angelo et al.	
	26	US- 5,415,629	5/16/1995	Hentley	

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		Country Code ³ -Number ⁴ -Kind Code ⁵ (if known)				
	721	EP1815784A1	8/8/2007	Amer Mashhour Mustafa		
	319	EP1977746B1	7/30/2014	Parkinson's Institute		
	722	EP3016586A2 (WOPub)	5/11/2016	Mayo Found. Med. Ed.		
	816	EP311313A2	4/12/1989	Yamanouchi Pharma.		
	817	EP857725A1	8/12/1998	Pfizer Inc.		
	818	EP870768A1	10/14/1998	Pfizer Inc.		

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Date
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06/15/2022

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Sheet 4 of 43

Complete if Known

Application Number	17/057,318
Filing Date	November 20, 2020
First Named Inventor	Ling-Kang Tong
Art Unit	Unassigned
Examiner Name	Unassigned
Attorney Docket Number	13164-722.US0

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Examiner Initials*	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code ² (if known)			
	205	US- 5,445,609	8/29/1995	Lattin et al.	
	27	US- 5,451,407	9/19/1995	Cornier et al.	
	206	US- 5,464,387	11/7/1995	Haak et al.	
	28	US- 5,472,946	12/5/1995	Peck et al.	
	207	US- 5,501,697	3/26/1996	Fisher	
	29	US- 5,505,958	4/9/1996	Bello et al.	
	353	US- 5,512,306	4/30/1996	Carlsson et al.	
	30	US- 5,516,793	5/14/1996	Duffy	
	354	US- 5,525,351	6/11/1996	Dam	
	31	US- 5,545,407	8/13/1996	Hall et al.	
	32	US- 5,596,994	1/28/1997	Bro	
	33	US- 5,601,839	2/11/1997	Quan et al.	
	34	US- 5,616,332	4/1/1997	Herstein	
	35	US- 5,618,557	4/8/1997	Wille et al.	
	208	US- 5,653,682	8/5/1997	Sibalis	
	355	US- 5,656,255	8/12/1997	Jones	
	356	US- 5,662,920	9/2/1997	Santus	
	36	US- 5,686,100	11/11/1997	Wille et al.	
	209	US- 5,688,232	11/18/1997	Flower	

FOREIGN PATENT DOCUMENTS						
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	819	EP955301A2	11/10/1999	Pfizer Products Inc		
	406	GB1528391A	10/11/1978	Gildemeister V		
	407	GB2030862A	4/16/1980	Smith		
	408	GB2142822A	1/30/1985	Walter		
	409	GB2230439A	10/24/1990	Walter		
	110	JP02202813A (w/EngTrans)	8/10/1990	Sekisui Chem Co Ltd		

Examiner Signature	/ARJUNA P CHATRATHI/	Date Considered	06/15/2022
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	210	US- 5,697,896	12/16/1997	McNichols et al.	
	37	US- 5,716,987	2/10/1998	Wille	
	211	US- 5,722,418	3/3/1998	Bro	
	38	US- 5,733,259	3/31/1998	Vaicko et al.	
	39	US- 5,785,688	7/28/1998	Joshi et al.	
	212	US- 5,797,867	8/25/1998	Guerre et al.	
	40	US- 5,820,875	10/13/1998	Fallon et al.	
	213	US- 5,833,466	11/10/1998	Borg	
	41	US- 5,843,979	12/1/1998	Wille et al.	
	42	US- 5,865,786	2/2/1999	Sibalis et al.	
	214	US- 5,876,368	3/2/1999	Flower	
	604	US- 5,879,292	3/9/1999	Sternberg et al.	
	43	US- 5,879,322	3/9/1999	Lattin et al.	
	605	US- 5,882,676	3/16/1999	Lee et al.	
	215	US- 5,908,301	6/1/1999	Lutz	
	216	US- 5,919,156	7/6/1999	Stropkay et al.	
	44	US- 5,932,240	8/3/1999	D'Angelo et al.	
	45	US- 5,945,123	8/31/1999	Hermelin	
	217	US- 5,967,789	10/19/1999	Segel et al.	

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	111	JP09512006A (w/EngEquiv)	12/2/1997	Ciba-Geigy AG		
	556	JP2002092180A (w/EngAbs)	3/29/2002	Takahashi Hiroko		
	112	JP2005525147A (w/EngEquiv)	8/25/2005	Encapsulation Sys. Inc.		
	555	JP2009544338A (w/EngEquiv)	12/17/2009	Proteus Biomedical Inc		
	767	JP2010518914A (w/EngEquiv)	6/3/2010	Vyro Games Ltd.		
	766	JP2016202904A (w/EngAbs)	12/8/2016	Canon KK		

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Examiner Name	Unassigned
Attorney Docket Number	13164-722.US0

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code ² (if known)			
	534	US- 5,972,389	10/26/1999	Shell et al.	
	46	US- 5,993,435	11/30/1999	Haak et al.	
	218	US- 5,997,501	12/7/1999	Gross et al.	
	47	US- 6,018,679	1/25/2000	Dinh et al.	
	48	US- 6,019,997	2/1/2000	Scholz et al.	
	535	US- 6,024,981	2/15/2000	Khankari et al.	
	357	US- 6,034,079	3/7/2000	Sanberg et al.	
	49	US- 6,059,736	5/9/2000	Tapper	
	575	US- 6,059,753	5/9/2000	Faust et al.	
	50	US- 6,068,853	5/30/2000	Giannos et al.	
	606	US- 6,081,734	6/27/2000	Batz	
	51	US- 6,090,404	7/18/2000	Meconi et al.	
	607	US- 6,093,419	7/25/2000	Rolf	
	536	US- 6,120,803	9/19/2000	Wong et al.	
	52	US- 6,129,702	10/10/2000	Wojas et al.	
	53	US- 6,165,155	12/26/2000	Jacobsen et al.	
	358	US- 6,211,194	4/3/2001	Westman et al.	
	54	US- 6,211,296	4/3/2001	Frate et al.	
	781	US- 6,221,394	4/24/2001	Gilbert et al.	

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Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
		Country Code ³ -Number ⁴ -Kind Code ⁵ (if known)				
	113	WO86/07269A1	12/18/1986	Drug Delivery Sys. Inc.		
	410	WO88/003803A1 (w/EngEquiv)	6/2/1988	Forsch Ges Rauchen		
	114	WO91/14441A1	10/3/1991	Parnell Pharm. Inc.		
	827	WO92/021339A1	12/10/1992	Abbott Laboratories		
	828	WO94/008992A1	4/28/1994	Abbott Laboratories		
	723	WO94/010987A1	5/26/1994	Pharmetrix Corp.		

Examiner
Signature

/ARJUNA P CHATRATHI/

Date
Considered

06/15/2022

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**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

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Sheet 7

of 43

Complete if Known

Application Number	17/057,318
Filing Date	November 20, 2020
First Named Inventor	Ling-Kang Tong
Art Unit	Unassigned
Examiner Name	Unassigned
Attorney Docket Number	13164-722.US0

U. S. PATENT DOCUMENTS					
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		Number-Kind Code ² (if known)			
	359	US- 6,238,689	5/29/2001	Rhodes et al.	
	360	US- 6,274,606	8/14/2001	Caldwell et al.	
	361	US- 6,310,102	10/30/2001	Dull et al.	
	537	US- 6,365,182	4/2/2002	Khankari et al.	
	538	US- 6,368,625	4/9/2002	Siebert et al.	
	55	US- 6,374,136	4/16/2002	Murdock	
	608	US- 6,416,471	7/9/2002	Kumar et al.	
	362	US- 6,417,359	7/9/2002	Crooks et al.	
	56	US- 6,423,747	7/23/2002	Lanzendörfer et al.	
	57	US- 6,436,078	8/20/2002	Svedman	
	58	US- 6,437,004	8/20/2002	Perricone	
	609	US- 6,454,708	9/24/2002	Ferguson et al.	
	784	US- 6,488,959	12/3/2002	Stanley et al.	
	363	US- 6,492,399	12/10/2002	Dull et al.	
	59	US- 6,539,250	3/25/2003	Bettinger	
	785	US- 6,546,281	4/8/2003	Zhang et al.	
	60	US- 6,567,785	5/20/2003	Clendenon	
	610	US- 6,569,449	5/27/2003	Stinchcomb et al.	
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		Country Code ³ -Number ⁴ -Kind Code ⁵ (if known)				
	115	WO95/06497A1	3/9/1995	Alza Corporation		
	829	WO96/015123A1	5/23/1996	Salk Inst. Biotech.		
	830	WO96/040682A1	12/19/1996	Abbott Laboratories		
	831	WO97/011072A1	3/27/1997	Novo Nordisk		
	832	WO97/011073A1	3/27/1997	Novo Nordisk		
	833	WO97/019059A1	5/29/1997	Sibia Neurosciences		

Examiner Signature	/ARJUNA P CHATRATHI/	Date Considered	06/15/2022
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Sheet 8

of 43

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Application Number	17/057,318
Filing Date	November 20, 2020
First Named Inventor	Ling-Kang Tong
Art Unit	Unassigned
Examiner Name	Unassigned
Attorney Docket Number	13164-722.US0

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		Number-Kind Code ² (if known)			
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	62	US- 6,579,865	6/17/2003	Mak et al.	
	219	US- 6,589,229	7/8/2003	Connelly et al.	
	63	US- 6,595,956	7/22/2003	Gross et al.	
	64	US- 6,638,528	10/28/2003	Kanios	
	65	US- 6,638,543	10/28/2003	Kang et al.	
	612	US- 6,660,295	12/9/2003	Watanabe et al.	
	613	US- 6,689,380	2/10/2004	Marchitto et al.	
	66	US- 6,723,086	4/20/2004	Bassuk et al.	
	539	US- 6,723,340	4/20/2004	Gusler et al.	
	589	US- 6,746,688	6/8/2004	Kushnir et al.	
	614	US- 6,791,003	9/14/2004	Choi et al.	
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	67	US- 6,849,645	2/1/2005	Majeed et al.	
	68	US- 6,861,066	3/1/2005	Van de Casteele	
	69	US- 6,867,342	3/15/2005	Johnston et al.	
	70	US- 6,887,202	5/3/2005	Curie et al.	
	615	US- 6,893,655	5/17/2005	Flanigan et al.	
	365	US- 6,900,202	5/31/2005	Imoto et al.	

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		Country Code ³ -Number ⁴ -Kind Code ⁵ (if known)				
	411	WO97/028801A1	8/14/1997	Mayo Foundation		
	412	WO97/034605A1	9/25/1997	Mayo Foundation		
	413	WO97/042941A2	11/20/1997	Novartis Consumer Health		
	834	WO97/046554A1	12/11/1997	Abbott Laboratories		
	274	WO97/11741A1	4/3/1997	Becton Dickinson & Co.		
	116	WO97/18782A1	5/29/1997	Bristol-Myers Squibb Co		

Examiner Signature	/ARJUNA P CHATRATHI/	Date Considered	06/15/2022
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Sheet 9 of 43

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Filing Date	November 20, 2020
First Named Inventor	Ling-Kang Tong
Art Unit	Unassigned
Examiner Name	Unassigned
Attorney Docket Number	13164-722.US0

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	782	US- 7,011,849	3/14/2006	Storm et al.	
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	617	US- 7,579,019	8/25/2009	Tapolsky et al.	
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	326	US- 7,718,677**	5/18/2010	Quik et al.	
	71	US- 7,780,981**	8/24/2010	DiPiero et al.	
	853	US- 7,931,563	4/26/2011	Shaw et al.	

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	835	WO98/042713A1	10/1/1998	Synthelabo		
	836	WO98/054152A1	12/3/1998	Neurosearch		
	837	WO98/054181A1	12/3/1998	Neurosearch		
	838	WO98/054182A1	12/3/1998	Neurosearch		
	839	WO98/054189A1	12/3/1998	Neurosearch		
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Examiner Signature	/ARJUNA P CHATRATHI/	Date Considered	06/15/2022
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Sheet 10

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Application Number	17/057,318
Filing Date	November 20, 2020
First Named Inventor	Ling-Kang Tong
Art Unit	Unassigned
Examiner Name	Unassigned
Attorney Docket Number	13164-722.US0

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	753	US- 8,003,080	8/23/2011	Rabinowitz et al.	
	222	US- 8,021,334	9/20/2011	Shekalim	
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	223	US- 8,246,581	8/21/2012	Adams et al.	
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	619	US- 8,262,394	9/11/2012	Walker et al.	
	620	US- 8,268,475	9/18/2012	Tucholski	
	582	US- 8,285,328	10/9/2012	Caffey et al.	
	224	US- 8,303,500	11/6/2012	Raheman	
	621	US- 8,309,568	11/13/2012	Stinchcomb et al.	
	73	US- 8,372,040**	2/12/2013	Huang et al.	
	225	US- 8,414,532	4/9/2013	Brandt et al.	
	588	US- 8,440,220	5/14/2013	Gale et al.	
	74	US- 8,440,221**	5/14/2013	Zumbrunn et al.	
	622	US- 8,441,411	5/14/2013	Tucholski et al.	
	623	US- 8,445,010	5/21/2013	Anderson et al.	

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	844	WO98/55107A1	12/10/1998	Depomed Inc.		
	840	WO99/002517A1	1/21/1999	Synthelabo		
	841	WO99/003859A1	1/28/1999	Astra Aktiebolag		
	842	WO99/021834A1	5/6/1999	Neurosearch		
	843	WO99/024422A1	5/20/1999	Neurosearch		
	414	WO99/066916A1	12/29/1999	Pentech Pharmaceuticals Inc		

Examiner Signature	/ARJUNA P CHATRATHI/	Date Considered	06/15/2022
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	226	US- 8,517,988	8/27/2013	Smith	
	227	US- 8,545,445	10/1/2013	Kamen et al.	
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	628	US- 8,684,922	4/1/2014	Tran	
	629	US- 8,688,189	4/1/2014	Shennib	
	298	US- 8,690,827	4/8/2014	Edwards et al.	
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	299	US- 8,696,637	4/15/2014	Ross	
	630	US- 8,703,175	4/22/2014	Kanios et al.	
	631	US- 8,703,177	4/22/2014	Finn et al.	
	632	US- 8,722,233	5/13/2014	Tucholski	
	231	US- 8,727,745	5/20/2014	Rush et al.	

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Foreign Patent Document Country Code ³ -Number ⁴ -Kind Code ⁵ (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T ⁶
	820	WO00/010997A1	3/2/2000	Ortho-McNeil Pharma.		
	821	WO00/032600A1	6/8/2000	Neurosearch		
	822	WO00/034279A1	6/15/2000	Sanofi-Synthelabo		
	823	WO00/034284A1	6/15/2000	Sanofi-Synthelabo		
	415	WO00/035279A1	6/22/2000	Univ. South Florida		
	724	WO00/035456A1	6/22/2000	Samyang Corp.		

Examiner
Signature

/ARJUNA P CHATRATHI/

Date
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06/15/2022

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**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

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Sheet 12

of 43

Complete if Known

Application Number	17/057,318
Filing Date	November 20, 2020
First Named Inventor	Ling-Kang Tong
Art Unit	Unassigned
Examiner Name	Unassigned
Attorney Docket Number	13164-722.US0

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Document Number Number-Kind Code ² (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	76	US- 8,741,336**	6/3/2014	DiPierro et al.	
	232	US- 8,747,348	6/10/2014	Yodfat et al.	
	233	US- 8,753,315	6/17/2014	Alferness et al.	
	234	US- 8,773,257	7/8/2014	Yodfat et al.	
	235	US- 8,814,822	8/26/2014	Yodfat et al.	
	236	US- 8,862,223	10/14/2014	Yanaki	
	300	US- 8,864,727	10/21/2014	Lee	
	301	US- 8,865,207	10/21/2014	Kanios et al.	
	633	US- 8,872,663	10/28/2014	Forster	
	290	US- 8,876,802	11/4/2014	Grigorov	
	634	US- 8,956,644	2/17/2015	Yum et al.	
	635	US- 8,962,014	2/24/2015	Prinz et al.	
	302	US- 8,986,253	3/24/2015	DiPerna	
	303	US- 8,999,356	4/7/2015	Ramirez et al.	
	769	US- 8,999,372	4/7/2015	Davidson et al.	
	304	US- 9,023,392	5/5/2015	Koo et al.	
	305	US- 9,044,582	6/2/2015	Chang et al.	
	636	US- 9,050,348	6/9/2015	Kydonieus et al.	
	637	US- 9,078,833	7/14/2015	Audett	

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	824	WO00/044755A1	8/3/2000	Abbott Laboratories		
	825	WO00/064885A1	11/2/2000	Neurosearch		
	826	WO00/066596A1	11/9/2000	Dow Chem Co.		
	117	WO00/74763A2	12/14/2000	Georgia Tech Research		
	552	WO00/74933A1 (w/MachTrans)	12/14/2000	Lohmann Therapie Syst LTS		
	416	WO01/005459A1	1/25/2001	Aradigm Corp.		

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/ARJUNA P CHATRATHI/

Date
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06/15/2022

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Sheet 13

of 43

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Application Number	17/057,318
Filing Date	November 20, 2020
First Named Inventor	Ling-Kang Tong
Art Unit	Unassigned
Examiner Name	Unassigned
Attorney Docket Number	13164-722.US0

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		Number-Kind Code ² (if known)			
	334	US- 9,111,085	8/18/2015	Darmour et al.	
	306	US- 9,114,240	8/25/2015	Horstmann et al.	
	307	US- 9,155,712	10/13/2015	Kanios et al.	
	763	US- 9,233,203	1/12/2016	Moberg et al.	
	308	US- 9,238,001	1/19/2016	Weyer et al.	
	309	US- 9,238,108	1/19/2016	Edwards et al.	
	638	US- 9,248,104	2/2/2016	Valia et al.	
	639	US- 9,289,397	3/22/2016	Wright	
	640	US- 9,308,202	4/12/2016	Hille et al.	
	641	US- 9,314,527	4/19/2016	Cottrell et al.	
	642	US- 9,373,269	6/21/2016	Bergman et al.	
	643	US- 9,380,698	6/28/2016	Li et al.	
	644	US- 9,513,666	12/6/2016	Li et al.	
	645	US- 9,549,903	1/24/2017	Hille et al.	
	198	US- 9,555,226**	1/31/2017	Zumbrunn et al.	
	199	US- 9,555,227**	1/31/2017	Dipierro	
	646	US- 9,623,017	4/18/2017	Barbier et al.	
	647	US- 9,636,457	5/2/2017	Newberry et al.	
	648	US- 9,655,843	5/23/2017	Finn et al.	

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		Country Code ³ -Number ⁴ -Kind Code ⁵ (if known)	MM-DD-YYYY			
	417	WO01/037814A1	5/31/2001	Robert Gordon Univ.		
	418	WO02/076211A1	10/3/2002	Smithkline Beecham Corp.		
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	419	WO03/026655A1	4/3/2003	Pharmacia AB		
	420	WO03/055486A1	7/10/2003	Pharmacia AB		
	421	WO03/061656A1	7/31/2003	Endo Pharmaceuticals		

Examiner Signature	/ARJUNA P CHATRATHI/	Date Considered	06/15/2022
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STATEMENT BY APPLICANT**

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Sheet 14

of 43

Complete if Known

Application Number	17/057,318
Filing Date	November 20, 2020
First Named Inventor	Ling-Kang Tong
Art Unit	Unassigned
Examiner Name	Unassigned
Attorney Docket Number	13164-722.US0

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code ² (if known)			
	649	US- 9,656,441	5/23/2017	LeDonne et al.	
	102	US- 9,669,199**	6/6/2017	DiPierro et al.	
	772	US- 9,687,186	6/27/2017	Goldstein et al.	
	650	US- 9,693,689	7/4/2017	Gannon et al.	
	651	US- 9,700,552	7/11/2017	Weimann	
	652	US- 9,717,698	8/1/2017	Horstmann et al.	
	653	US- 9,735,893	8/15/2017	Aleksov et al.	
	654	US- 9,782,082	10/10/2017	Gannon et al.	
	655	US- 9,795,681	10/24/2017	Abreu	
	656	US- 9,867,539	1/16/2018	Heikenfeld et al.	
	657	US- 9,895,320	2/20/2018	Ogino et al.	
	658	US- 9,949,935	4/24/2018	Murata	
	659	US- 9,974,492	5/22/2018	Dicks et al.	
	660	US- 9,993,203	6/12/2018	Mei et al.	
	661	US- 10,004,447	6/26/2018	Shen et al.	
	662	US- 10,034,841	7/31/2018	Müller et al.	
	764	US- 10,143,687	12/4/2018	Azhir	
	202	US- 10,213,586***	2/26/2019	Netzel et al.	
	335	US- 10,232,156***	3/19/2019	Netzel et al.	

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		Country Code ³ -Number ⁴ -Kind Code ⁵ (if known)				
	725	WO03/070191A1	8/28/2003	Euro Celtique SA		
	422	WO03/097146A1	11/27/2003	Aradigm Corp.		
	275	WO2004/073429A1	9/2/2004	Martin		
	423	WO2004/024124A1	3/25/2004	Smithkline Beecham Corp.		
	424	WO2005/023227A2	3/17/2005	Pfizer Health AB SE		
	276	WO2005/079161A2	9/1/2005	Newvat-Tech Knowledge		

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Date
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Sheet 15

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Application Number	17/057,318
Filing Date	November 20, 2020
First Named Inventor	Ling-Kang Tong
Art Unit	Unassigned
Examiner Name	Unassigned
Attorney Docket Number	13164-722.US0

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		Number-Kind Code ² (if known)			
	332	US- 10,258,738**	4/16/2019	DiPierro et al.	
	331	US- 10,258,778**	4/16/2019	DiPierro et al.	
	101	US- 10,105,487**	10/23/2018	DiPierro et al.	
	333	US- 10,679,516**	6/9/2020	Darnour et al.	
	316	US- 10,716,764**	7/21/2020	Zumbrunn et al.	
	119	US- RE46217**	11/29/2016	Huang et al.	
	77	US- 2001/0022978	9/20/2001	Lachamere et al.	
	559	US- 2001/0026788	10/4/2001	Piskorz	
	370	US- 2002/0002189	1/3/2002	Smith et al.	
	783	US- 2002/0034535	3/21/2002	Kleiner et al.	
	664	US- 2002/0106329	8/8/2002	Leslie	
	78	US- 2002/0127256	9/12/2002	Murad	
	79	US- 2002/0165170	11/7/2002	Wilson et al.	
	80	US- 2002/0169439	11/14/2002	Flaherty	
	81	US- 2002/0182238	12/5/2002	Cretton	
	590	US- 2003/0004187	1/2/2003	Bedard et al.	
	82	US- 2003/0065294	4/3/2003	Pickup et al.	
	83	US- 2003/0065924	4/3/2003	Wuidart et al.	
	84	US- 2003/0083645	5/1/2003	Angel et al.	

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		Country Code ³ -Number ⁴ -Kind Code ⁵ (if known)				
	425	WO2006/069097A2	6/29/2006	Memory Pharma. Corp.		
	726	WO2007/013975A2	2/1/2007	Pharmorx Inc.		
	746	WO2007/041544A1	4/12/2007	Transcutaneous Tech. Inc.		
	426	WO2007/104574A2	9/20/2007	Niconovum AB SE		
	427	WO2007/104575A2	9/20/2007	Niconovum AB SE		
	428	WO2007/133141A1	11/22/2007	McNeil AB SE		

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Filing Date	November 20, 2020
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Art Unit	Unassigned
Examiner Name	Unassigned
Attorney Docket Number	13164-722.US0

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	371	US- 2003/0087937	5/8/2003	Lindberg	
	372	US- 2003/0119879	6/26/2003	Landh et al.	
	373	US- 2003/0159702	8/28/2003	Lindell et al.	
	237	US- 2004/0019321	1/29/2004	Sage et al.	
	374	US- 2004/0034068	2/19/2004	Warchol et al.	
	375	US- 2004/0037879	2/26/2004	Adusumilli et al.	
	376	US- 2004/0052843	3/18/2004	Lemer et al.	
	85	US- 2004/0062802	4/1/2004	Hermelin	
	86	US- 2004/0138074	7/15/2004	Ahmad et al.	
	377	US- 2004/0166159	8/26/2004	Han et al.	
	378	US- 2004/0191322	9/30/2004	Hansson	
	379	US- 2004/0194793	10/7/2004	Lindell et al.	
	848	US- 2004/0219192	11/4/2004	Horstmann et al.	
	380	US- 2004/0229908	11/18/2004	Nelson	
	592	US- 2004/0241218	12/2/2004	Tavares et al.	
	87	US- 2004/0253249	12/16/2004	Rudnic et al.	
	88	US- 2004/0259816	12/23/2004	Pandol et al.	
	201	US- 2005/0002806	1/6/2005	Fuechstin et al.	
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		Country Code ³ -Number ⁴ -Kind Code ⁵ (if known)				
	574	WO2008/024408A2	2/28/2008	Theraquest BioSci. Inc.		
	599	WO2008/054788A2	5/8/2008	Chrono Therapeutics Inc.		
	429	WO2008/069921A2	6/12/2008	Cima Labs inc.		
	430	WO2008/069970A2	6/12/2008	Aradigm Corp.		
	431	WO2008/069972A2	6/12/2008	Aradigm Corp.		
	795	WO2008/122049A2	10/9/2008	Chrono Therapeutics Inc.		

Examiner Signature	/ARJUNA P CHATRATHI/	Date Considered	06/15/2022
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Sheet 17

of 43

Complete if Known

Application Number	17/057,318
Filing Date	November 20, 2020
First Named Inventor	Ling-Kang Tong
Art Unit	Unassigned
Examiner Name	Unassigned
Attorney Docket Number	13164-722.US0

U. S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code ² (if known)			
	382	US- 2005/0021092	1/27/2005	Yun et al.	
	89	US- 2005/0034842	2/17/2005	Huber et al.	
	90	US- 2005/0048020	3/3/2005	Wille	
	383	US- 2005/0053665	3/10/2005	Ek et al.	
	384	US- 2005/0113452	5/26/2005	Flashner Barak et al.	
	238	US- 2005/0141346	6/30/2005	Rawls et al.	
	91	US- 2005/0151110	7/14/2005	Minor et al.	
	385	US- 2005/0159419	7/21/2005	Stephenson et al.	
	859	US- 2005/0266032	12/1/2005	Srinivasan et al.	
	860	US- 2005/0276852	12/15/2005	Davis et al.	
	92	US- 2006/0024358	2/2/2006	Santini et al.	
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	239	US- 2006/0122577	6/8/2006	Poulsen et al.	
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	240	US- 2006/0184093	8/17/2006	Phipps et al.	
	241	US- 2006/0188859	8/24/2006	Yakobi	
	786	US- 2006/0204578	9/14/2006	Vergez et al.	
	291	US- 2006/0206054	9/14/2006	Shekalim	

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		Country Code ³ -Number ⁴ -Kind Code ⁵ (if known)	MM-DD-YYYY			
	595	WO2008/135283A1 (w/EngAbs)	11/13/2008	Novosis AG		
	277	WO2009/136304A2	11/12/2009	Koninklijke Philips Elect. N.V.		
	727	WO2011/088072A2	7/21/2011	Agile Therapeutics Inc.		
	728	WO2012/012846A1	2/2/2012	Intheshed Australia PTY Ltd		
	754	WO2012/101060A1	8/2/2012	Novartis AG		
	276	WO2013/093666A1	6/27/2013	Koninklijke Philips Elect. N.V.		

Examiner Signature	/ARJUNA P CHATRATHI/	Date Considered	06/15/2022
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Filing Date	November 20, 2020
First Named Inventor	Ling-Kang Tong
Art Unit	Unassigned
Examiner Name	Unassigned
Attorney Docket Number	13164-722.US0

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		Number-Kind Code ² (if known)			
	387	US- 2007/0026054	2/1/2007	Theobald et al.	
	93	US- 2007/0042026**	2/22/2007	Willie	
	665	US- 2007/0065365	3/22/2007	Kugelmann et al.	
	286	US- 2007/0086275	4/19/2007	Robinson et al.	
	598	US- 2007/0088338	4/19/2007	Ehwald et al.	
	787	US- 2007/0104787	5/10/2007	Posey Dowty et al.	
	314	US- 2007/0149952	6/28/2007	Bland et al.	
	760	US- 2007/0154336	7/5/2007	Miyazaki et al.	
	192	US- 2007/0168501	7/19/2007	Cobb et al.	
	388	US- 2007/0179172	8/2/2007	Becker et al.	
	94	US- 2007/0191815**	8/16/2007	DiPierro	
	95	US- 2007/0250018	10/25/2007	Adachi et al.	
	389	US- 2007/0256684	11/8/2007	Kelliher et al.	
	336	US- 2007/0260491	11/8/2007	Palmer et al.	
	666	US- 2007/0279217	12/6/2007	Venkatraman et al.	
	292	US- 2007/0299401	12/27/2007	Alferness et al.	
	337	US- 2008/0008747	1/10/2008	Royds	
	647	US- 2008/0131494	6/5/2008	Reed et al.	
	390	US- 2008/0138294	6/12/2008	Gonda	

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	279	WO2013/168068A1	11/14/2013	Koninklijke Philips N.V.		
	280	WO2014/001877A1	1/3/2014	Elevate Tech. Pty. Ltd.		
	281	WO2014/043502A1	3/20/2014	Wicka		
	729	WO2016/081616A2	5/26/2016	4P Therapeutics		
	601	WO2016/161416A1	10/6/2016	Click Therapeutics Inc.		
	739	WO2017/053938A1	3/30/2017	Pain Thera. Inc.		

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/ARJUNA P CHATRATHI/

Date
Considered

06/15/2022

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Sheet 19

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Application Number	17/057,318
Filing Date	November 20, 2020
First Named Inventor	Ling-Kang Tong
Art Unit	Unassigned
Examiner Name	Unassigned
Attorney Docket Number	13164-722.US0

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		Number-Kind Code ² (if known)			
	391	US- 2008/0138398	6/12/2008	Gonda	
	392	US- 2008/0138399	6/12/2008	Gonda	
	393	US- 2008/0138423	6/12/2008	Gonda	
	854	US- 2008/0139907	6/12/2008	Rao et al.	
	667	US- 2008/0152592	6/26/2008	Rebec	
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	243	US- 2008/0201174	8/21/2008	Ramasubramanian et al.	
	338	US- 2008/0233178	9/25/2008	Reidenberg et al.	
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	245	US- 2009/0118710	5/7/2009	Kortzeborn	
	740	US- 2009/0169631	7/2/2009	Zamlot et al.	
	670	US- 2009/0246265	10/1/2009	Stinchcomb et al.	
	560	US- 2009/0247985	10/1/2009	Meisheimer et al.	
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	855	US- 2009/0299156	12/3/2009	Simpson et al.	

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		Country Code ³ -Number ⁴ -Kind Code ⁵ (if known)				
	730	WO2017/125455A1	7/27/2017	Buzzz Pharma. Ltd.		
	731	WO2018/026759A1	2/8/2018	Noven Pharma. Inc.		
	749	WO2018/129363A1	7/12/2018	Chrono Therapeutics Inc.		
	745	WO2019/090125A2	5/9/2019	Chrono Therapeutics Inc.		
	771	WO2019/232077A1	12/5/2019	Chrono Therapeutics Inc.		
	850	WO2020/102695A1	5/22/2020	Chrono Therapeutics Inc.		

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet	20
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43

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Application Number	17/057,318
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Filing Date	November 20, 2020
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First Named Inventor	Ling-Kang Tong
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Art Unit	Unassigned
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Examiner Name	Unassigned
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Attorney Docket Number	13164-722.US0
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	247	US- 2010/0003653	1/7/2010	Brown	
	593	US- 2010/0068250	3/18/2010	Anderson et al.	
	96	US- 2010/0114008	5/6/2010	Marchitto et al.	
	248	US- 2010/0145303	6/10/2010	Yodfat et al.	
	577	US- 2010/0179473	7/15/2010	Genosar	
	341	US- 2010/0196463**	8/5/2010	Quik et al.	
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	315	US- 2010/0273738	10/28/2010	Valcke et al.	
	97	US- 2010/0280432**	11/4/2010	DiPierro et al.	
	287	US- 2011/0004072	1/6/2011	Fletcher et al.	
	250	US- 2011/0053129	3/3/2011	Basson et al.	
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	671	US- 2011/0109439	5/12/2011	Borlenghi	
	561	US- 2011/0137255	6/9/2011	Nielsen et al.	
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	672	US- 2011/0153360	6/23/2011	Hanina et al.	
	673	US- 2011/0160640	6/30/2011	Yanaki	
	674	US- 2011/0241446	10/6/2011	Tuchofski	
	562	US- 2011/0245633	10/6/2011	Goldberg et al.	

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	193	US- 2011/0250576	10/13/2011	Hester	
	253	US- 2011/0256517	10/20/2011	Swanson	
	254	US- 2011/0264028	10/27/2011	Ramdas et al.	
	544	US- 2011/0268809	11/3/2011	Brinkley et al.	
	583	US- 2011/0275987	11/10/2011	Caffey et al.	
	255	US- 2012/0046644	2/23/2012	Ziaie et al.	
	578	US- 2012/0123387	5/17/2012	Gonzalez et al.	
	545	US- 2012/0156138	6/21/2012	Smith	
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	677	US- 2012/0209223	8/16/2012	Saiman et al.	
	98	US- 2012/0221251	8/30/2012	Rosenberg et al.	
	257	US- 2012/0244503	9/27/2012	Nevelidine	
	258	US- 2012/0302844	11/29/2012	Schnidrig et al.	
	259	US- 2012/0316896	12/13/2012	Rahman et al.	
	260	US- 2012/0329017	12/27/2012	Pham	
	327	US- 2013/0017259**	1/17/2013	Azhir	

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	563	US- 2013/0190683	7/25/2013	Hanson et al.	
	261	US- 2013/0216989	8/22/2013	Cuthbert	
	293	US- 2013/0253430	9/26/2013	Kouyoumjian et al.	
	294	US- 2013/0302398	11/14/2013	Ambati et al.	
	262	US- 2013/0311917	11/21/2013	Bar-or et al.	
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	296	US- 2014/0046288	2/13/2014	Geipel et al.	
	663	US- 2014/0073883	3/13/2014	Rao et al.	
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	339	US- 2014/0100241	4/10/2014	Slater et al.	
	99	US- 2014/0200525**	7/17/2014	DiPierro	
	265	US- 2014/0206327	7/24/2014	Ziernianska et al.	
	100	US- 2014/0207047**	7/24/2014	DiPierro et al.	

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Examiner Signature	/ARJUNA P CHATRATHI/	Date Considered	06/15/2022
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet	23
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of	43
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Application Number

17/057,318

Filing Date

November 20, 2020

First Named Inventor	
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Ling-Kang Tong

Art Unit

Unassigned	
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Examiner Name

Unassigned

Attorney Docket Number

13164-722.US0

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code ² (if known)			
	553	US- 2014/0228736	8/14/2014	Eppstein et al.	
	744	US- 2014/0237028	8/21/2014	Messenger et al.	
	288	US- 2014/0240124	8/28/2014	Bychkov	
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/ARJUNA P CHATRATHI/

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06/15/2022

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet	24
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Application Number	17/057,318
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Filing Date	November 20, 2020
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First Named Inventor	Ling-Kang Tong
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Art Unit	Unassigned
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Examiner Name	Unassigned
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Attorney Docket Number	13164-722.US0
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U. S. PATENT DOCUMENTS					
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		Number-Kind Code ² (if known)			
	329	US- 2016/0220553**	8/4/2016	Azhir	
	683	US- 2016/0227361	8/4/2016	Booth et al.	
	684	US- 2016/0228383	8/11/2016	Zhang et al.	
	330	US- 2016/0235732**	8/18/2016	Quik et al.	
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	687	US- 2017/0079932	3/23/2017	Emgenbroich et al.	
	317	US- 2017/0100573**	4/13/2017	DiPierro	
	688	US- 2017/0189348	7/6/2017	Lee et al.	
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	692	US- 2017/0249433	8/31/2017	Hagen et al.	
	693	US- 2017/0296107	10/19/2017	Reid et al.	
	694	US- 2017/0296317	10/19/2017	Gordon	

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Examiner Signature	/ARJUNA P CHATRATHI/	Date Considered	06/15/2022
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Sheet	25
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of	43
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Application Number

17/057,318

Filing Date

November 20, 2020

First Named Inventor

Ling-Kang Tong

Art Unit

Unassigned

Examiner Name

Unassigned

Attorney Docket Number

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U. S. PATENT DOCUMENTS

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		Number-Kind Code ² (if known)			
	695	US- 2017/0351840	12/7/2017	Goguen	
	696	US- 2018/0014783	1/18/2018	Shi et al.	
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	699	US- 2018/0028071	2/1/2018	Shi	
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	340	US- 2018/0110768**	4/26/2018	Quik et al.	
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	770	US- 2019/0231707**	8/1/2019	Stiles et al.	
	773	US- 2019/0275308**	9/12/2019	Netzel et al.	
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Date
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet	26
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of	43
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Application Number

17/057,318

Filing Date

November 20, 2020

First Named Inventor

Ling-Kang Tong

Art Unit

Unassigned

Examiner Name

Unassigned

Attorney Docket Number

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U. S. PATENT DOCUMENTS

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Substitute for form 1449/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>		Complete if Known	
		Application Number	17/057,318
		Filing Date	November 20, 2020
		First Named Inventor	Ling-Kang Tong
		Art Unit	Unassigned
		Examiner Name	Unassigned
Sheet 27	of 43	Attorney Docket Number	13164-722.US0

NON PATENT LITERATURE DOCUMENTS			
Examiner 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
	549	ABOOD et al.; Structure-activity studies of carbamate and other esters: agonists and antagonists to nicotine; Pharmacology Biochemistry and Behavior; 30(2); pp. 403-408; June 1988	
	436	AHLSKOG et al.; Frequency of levodopa-related dyskinesias and motor fluctuations as estimated from the cumulative literature; Movement Disorders; 16(3); pp. 448-458; May 1, 2001	
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	318	AZHIR, Arasieh; U.S. Provisional Patent App. No. 62/320,871 entitled "Compositions and methods for treatment related to fall and fall frequency in neurodegenerative diseases", filed 4/11/2016	
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	759	BENOWITZ et al.; Stable isotope studies of nicotine kinetics and bioavailability; Clin Pharm and Ther; 49(3); pp. 270-277; March 1991	
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Examiner Signature	/ARJUNA P CHATRATHI/	Date Considered	06/15/2022
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		Application Number	17/057,318
		Filing Date	November 20, 2020
		First Named Inventor	Ling-Kang Tong
		Art Unit	Unassigned
		Examiner Name	Unassigned
Sheet 28	of 43	Attorney Docket Number	13164-722.US0

NON PATENT LITERATURE DOCUMENTS			
Examiner 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
	441	BOVE et al.; Toxin-induced models of Parkinson's disease; NeuroRx; 2(3); pp. 484-494; July 31, 2005	
	284	BRICKER et al.; Randomized controlled pilot trial of a smartphone app for smoking cessation using acceptance and commitment therapy; Drug and Alcohol Dependence; 143; pp. 87-94; Oct. 1, 2014 (Author Manuscript)	
	442	BROTCHIE et al.; Levodopa-induced dyskinesia in Parkinson's disease; Journal of Neural Transmission; 112(3); pp. 359-391; March 1, 2005	
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	568	CALABRESI et al.; Levodopa-induced dyskinesias inpatients with parkinson's disease: filling the bench-to-bedside gap; The Lancet Neurology; 9(11); pp. 1106-1117; November 1, 2010	
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	550	DAMAJ et al.; Antinociceptive responses to nicotinic acetylcholine receptor ligands after systemic and intrathecal administration in mice; Journal of Pharmacology and Experimental Therapeutics; 284(3); pp. 1058-1065; March 1, 1998	
	444	DAVIE; A review of Parkinson's disease. British Medical Bulletin 2008 86(1): 109-127; April 8, 2008.	
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Examiner Signature	/ARJUNA P CHATRATHI/	Date Considered	06/15/2022
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		Art Unit	Unassigned
		Examiner Name	Unassigned
Sheet 29	of 43	Attorney Docket Number	13164-722.US0

NON PATENT LITERATURE DOCUMENTS			
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Examiner Signature	/ARJUNA P CHATRATHI/	Date Considered	06/15/2022
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Substitute for form 1449/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>		Complete if Known	
		Application Number	17/057,318
		Filing Date	November 20, 2020
		First Named Inventor	Ling-Kang Tong
		Art Unit	Unassigned
		Examiner Name	Unassigned
Sheet 30	of 43	Attorney Docket Number	13164-722.US0

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Sheet 31 of 43

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Sheet 33

of

43

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	750	KUMAR et al.; Levodopa-dyskinesia incidence by age of Parkinson's disease onset; Movement disorders; 20(3); pp. 342-344; March 2005	
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>		Complete if Known			
		Application Number	17/057,318		
		Filing Date	November 20, 2020		
		First Named Inventor	Ling-Kang Tong		
		Art Unit	Unassigned		
		Examiner Name	Unassigned		
Sheet	36	of	43	Attorney Docket Number	13164-722.US0

NON PATENT LITERATURE DOCUMENTS			
Examiner 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
	483	MESHUL et al.; Nicotine Affects Striatal Glutamatergic Function in 6-OHDA Lesioned Rats; Advanced in Behavioural Biology. Basal Ganglia VI.; Springer, Boston, MA.; vol. 54; pp. 589-598; (year of pub. sufficiently earlier than effective US filing date and any foreign priority date) 2002	
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	157	OHDO; Changes in toxicity and effectiveness with timing of drug administration: implications for drug safety; Drug Safety; 26(14); pp. 999-1010; December 2003	
	486	OLANOW; The scientific basis for the current treatment of Parkinson's disease; Annu. Rev. Med.; 55; pp. 41-60; February 18, 2004	
	158	OLSSON et al.; A valve-less planar pump in silicon; IEEE; The 8th International Conference on Solid-State Sensors and Actuators; vol.2; pp. 291-294, June 1995	
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	160	PRIANO et al.; Nocturnal anomalous movement reduction and sleep microstructure analysis in parkinsonian patients during 1-night transdermal apomorphine treatment; Neurol Sci.; 24(3); pp. 207-208; October 2003	
	132	PROSISE et al.; Effect of abstinence from smoking on sleep and daytime sleepiness; Chest; 105(4); pp. 1136-1141; April 1994	
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	491	QUIK et al.; Chronic oral nicotine treatment protects against striatal degeneration in MPTP-treated primates; Journal of Neurochemistry; 98(6); pp. 1866-1875; September 1, 2006	
	492	QUIK et al.; Differential alterations in nicotinic receptor $\alpha 6$ and $\beta 3$ subunit messenger RNAs in monkey substantia nigra after nigrostriatal degeneration; Neuroscience; 100(1); pp. 63-72; September 7, 2000	
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	323	QUIK et al.; L-DOPA treatment modulates nicotinic receptors in monkey striatum; Mol Pharmacol; 64(3); pp. 619-628; September 2003	
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	322	QUIK et al.; Nicotine and nicotinic receptors; relevance to Parkinson's disease; Neurotoxicology; 23(4-5); pp. 581-594; October 2002	
	500	QUIK et al.; Nicotine and Parkinson's disease: implications for therapy; Movement Disorders; 23(12); pp. 1641-1652; (Author Manuscript); September 1, 2008	
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	505	QUIK et al.; Subunit composition of nicotinic receptors in monkey striatum: Effect of treatments with l-methyl-4-phenyl-1,2,3,6-tetrahydropyridine or L-DOPA; Molecular Pharmacology; 67(1); pp. 32-41; January 2005	
	506	QUIK et al.; Vulnerability of 125I-α-conotoxin MII binding sites to nigrostriatal damage in monkey; The Journal of Neuroscience; 21(15); pp. 5494-5500; August 1, 2001	
	324	QUIK; Smoking, nicotine and Parkinson's disease; Trends in Neurosciences; 27 (9); pp. 561-568; September 2004	

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	161	REDFERN et al.; Circadian rhythms, jet lag, and chronobiotics: An overview; Chronobiology International; 11(4); pp. 253-265; August 1994	
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	513	SCHOBER et al.; Classic toxin-induced animal models of Parkinson's disease: 6-OHDA and MPTP; Cell and Tissue Research; 318(1); pp. 215-224; October 1, 2004	
	133	SHIN et al.; Enhanced bioavailability of triprolidine from the transdermal TPX matrix system in rabbits; Int. J. Pharm.; 234(1-2); pp. 67-73; March 2002	

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	515	STOCCHI et al.; Motor fluctuations in levodopa treatment: clinical pharmacology; European Neurology; 36(Suppl 1); pp. 38-42; January 1996	
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	517	TOGASAKI et al.; Dyskinesias in normal squirrel monkeys induced by nomifensine and levodopa; Neuropharmacology; 48(3); pp. 398-405; March 31, 2005	
	518	TOGASAKI et al.; Levodopa induces dyskinesias in normal squirrel monkeys; Annals of Neurology; 50(2); pp. 254-257; August 1, 2001	
	519	TOGASAKI et al.; The Webcam system: A simple, automated, computer-based video system for quantitative measurement of movement of nonhuman primates; Journal of Neuroscience Methods; 145(1); pp. 159-166; June 30, 2005	
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		Examiner Name	Unassigned
Sheet 42	of 43	Attorney Docket Number	13164-722.US0

NON PATENT LITERATURE DOCUMENTS			
Examiner 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
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Examiner Signature	/ARJUNA P CHATRATHI/	Date Considered	06/15/2022
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1 Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached.

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PTO/SB/08b (07-09)

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Substitute for form 1449/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>		Complete if Known	
		Application Number	17/057,318
		Filing Date	November 20, 2020
		First Named Inventor	Ling-Kang Tong
		Art Unit	Unassigned
		Examiner Name	Unassigned
Sheet 43	of 43	Attorney Docket Number	13164-722.US0

NON PATENT LITERATURE DOCUMENTS			
Examiner 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
	166	WILLE et al.; Inhibition of Irritation and Contact Hypersensitivity by Phenoxyacetic Acid Methyl Ester in Mice; Skin Pharm Appl Skin Physiol; 13(2); pp. 65-74; March 2000	
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Examiner Signature	/ARJUNA P CHATRATHI/	Date Considered	06/15/2022
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Sheet	1	of	1
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Complete if Known

Application Number	17/057,318
Filing Date	November 20, 2020
First Named Inventor	Ling-Kang Tong
Art Unit	3781
Examiner Name	Unassigned
Attorney Docket Number	13164-722.US0

U. S. PATENT DOCUMENTS

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<i>Notice of References Cited</i>	Application/Control No. 17/057,318		Applicant(s)/Patent Under Reexamination TONG et al.	
	Examiner ARJUNA P CHATRATHI		Art Unit 3781	Page 1 of 1

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*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	CPC Classification	US Classification
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*	B	US-20100010443-A1	01-2010	MORGAN; Roy	A61M5/14244	604/151
*	C	US-20100198187-A1	08-2010	Yodfat; Ofer	A61M5/14248	604/131
*	D	US-20110160655-A1	06-2011	Hanson; Ian B.	A61M5/14248	604/533
*	E	US-20130190683-A1	07-2013	Hanson; Ian B.	A61M5/1413	604/67
*	F	US-20160220798-A1	08-2016	NETZEL; Zita S.	A61M5/145	1/1
*	G	US-20170296317-A1	10-2017	Gordon; Tal	A01K13/003	1/1
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/057,318	11/20/2020	Ling-Kang TONG	13164-722.US0	1820
66854	7590	06/23/2022	EXAMINER	
SHAY GLENN LLP			CHATRATHI, ARJUNA P	
2929 CAMPUS DRIVE			ART UNIT	PAPER NUMBER
SUITE 225			3781	
SAN MATEO, CA 94403			NOTIFICATION DATE	DELIVERY MODE
			06/23/2022	ELECTRONIC

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The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

info@shayglenn.com
shayglenn_pair@firsttofile.com

DETAILED ACTION

Notice of Pre-AIA or AIA Status

1. The present application, filed on or after March 16, 2013, is being examined under the first inventor to file provisions of the AIA.

Claim Rejections - 35 USC § 103

2. In the event the determination of the status of the application as subject to AIA 35 U.S.C. 102 and 103 (or as subject to pre-AIA 35 U.S.C. 102 and 103) is incorrect, any correction of the statutory basis for the rejection will not be considered a new ground of rejection if the prior art relied upon, and the rationale supporting the rejection, would be the same under either status.

3. The following is a quotation of 35 U.S.C. 103 which forms the basis for all obviousness rejections set forth in this Office action:

A patent for a claimed invention may not be obtained, notwithstanding that the claimed invention is not identically disclosed as set forth in section 102, if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1-3, 8-16, 18, and 23-28 are rejected under 35 U.S.C. 103 as being unpatentable over Netzel et al. (US 2016/0220798 A1) in view of Zumbrunn et al. (US 2005/0238704).

5. **Regarding claim 1**, Netzel discloses *a two-part bioactive agent delivery system (Figs. 26-28, feat. 1700; ¶0218-0228), the system comprising: a disposable part (1708) comprising an agent reservoir (1801), a transdermal patch (1811) communicating with the agent reservoir and adapted to transdermally deliver the bioactive agent to a user (¶0224-0225), the transdermal patch having a bottom surface adapted to contact skin of*

the user (¶0222-0223) and a top surface opposite the bottom surface, and a gas permeable membrane disposed over the top surface of the transdermal patch (Fig. 28E, feat. 1812; ¶0222-0223 – gas permeable membrane 1812 sits on the opposite side of the transdermal membrane 1811 from the skin adhesive membrane 1739); a reusable part (1706) comprising a power source (1950) and control electronics (1942), the control electronics being adapted to deliver bioactive agent dissolved in a solvent from the agent reservoir to the transdermal patch (¶0219 and 0224-0226); and a solvent removal element (1808; ¶0169-170, 0222, and 0225 – absorbent material 1808 removes solvent vapors that pass through the gas permeable membrane).

6. The system disclosed by Netzel differs from the claimed system by the substitution of a solvent removal element comprising *a gap disposed between the disposable part and the reusable part to create a flow path for gaseous solvent to flow from the gas permeable membrane to ambient air around the bioactive agent delivery system* for a solvent removal element comprising an absorbent material that absorbs solvent vapors that pass through the gas permeable membrane.

7. Zumbrunn teaches transdermal drug delivery systems (Figs. 1-2, feat. 1; ¶00057-0064 and 0066-0067) which each comprise an administration reservoir for contacting the skin (9; ¶0059) and a solvent recovery means (13; ¶0059-0064 and 0066-0067). The solvent recovery means of the first embodiment (Fig. 1; ¶0057-0064) comprises desiccants and/or adsorbents for acquiring solvent vapors (¶0062) in a similar manner to the solvent removal element disclosed by Netzel (Netzel: ¶0169-170, 0222, and 0225). The solvent recovery means of the second embodiment (Fig. 2; ¶0066-0067) comprises discharging solvent vapors (17) through the housing (20) to the environment

surrounding the drug delivery system (¶0066-0067). Therefore, Zumbrunn teaches a solvent removal element comprising a flow path from the transdermal patch to the ambient air around the drug delivery system. One of ordinary skill in the art could have substituted a solvent removal element comprising a flow path to the ambient air for the absorbent based solvent removal element disclosed by Netzel and found that such a system would predictably remove the solvent because Zumbrunn teaches system comprising each solvent recovery elements as alternate embodiments. Furthermore, modifying the system disclosed by Netzel so that the solvent removal element discharges solvent vapor through a gap between the disposable part and the reusable part would be obvious to one of ordinary skill in the art because it would obviate the need to introduce any additional vents through the chassis of the disposable part or the reusable part. Therefore, it would have been *prima facie* obvious to modify the system disclosed by Netzel so that the solvent removal element comprises *a gap disposed between the disposable part and the reusable part to create a flow path for gaseous solvent to flow from the gas permeable membrane to ambient air around the bioactive agent delivery system*. Please see MPEP §2143.I(B).

8. **Regarding claim 2**, Netzel in view of Zumbrunn discloses the system of claim 1. As discussed above, the system disclosed by Netzel (Figs. 26-28) comprises a disposable part (1708) and a reusable part (1706). The housing of the disposable part (1737) and the housing of the reusable part (1902) comprise substantially parallel features which interface with each other when the disposable part is releasably attached to the reusable part (Fig. 26). Introducing a gap between the disposable part and the reusable part such that gaseous solvent can flow to the ambient air would involve

introducing a gap between the parallel features of the housings because that is where the housings of the parts of the system interface with each other. Therefore, it would have been *prima facie* obvious to one of ordinary skill in the art prior to the effective filing date of the claimed invention to modify the system disclosed by Netzel in view of Zumbrunn so that *the gap extends between parallel features on the disposable part and the reusable part* because the parallel features of the disposable part and the reusable part are where the housings of the parts of the system interface with each other.

9. **Regarding claim 3**, Netzel in view of Zumbrunn discloses the system of claim 1. Netzel further discloses that the disposable part can be releasably engaged with the reusable part (¶0218) in order to activate the drug delivery system (¶0224). Drug delivery, and thereafter solvent removal, only occurs when the reusable part and disposable part are connected (¶0225). It would be *prima facie* obvious to one of ordinary skill in the art prior to the effective filing date of the claimed invention to modify the system disclosed by Netzel in view of Zumbrunn so that *the gap is formed when the disposable part and the reusable part are releasably engaged* so that the gaseous solvent will be removed from the system when the system is active.

10. **Regarding claim 8**, Netzel in view of Zumbrunn discloses the system of claim 1. Netzel further discloses that *the disposable part further comprises an agent outlet* (1807; ¶0222 and 0224-0225) *communicating with the agent reservoir (1801) and the transdermal patch (1811)*.

11. **Regarding claim 9**, Netzel in view of Zumbrunn discloses the system of claim 1. Netzel further discloses that *the agent outlet is configured to provide the bioactive agent*

dissolved in the solvent to a space between the transdermal patch and the vapor permeable membrane (¶0222).

12. **Regarding claim 10**, Netzel in view of Zumbrunn discloses the system of claim

1. Netzel further discloses that *the agent reservoir comprises a piston movably disposed in a chamber (1802; ¶0221).*

13. **Regarding claim 11**, Netzel in view of Zumbrunn discloses the system of claim

10. Netzel further discloses *a spring extending between the agent reservoir piston and a surface to pressurize the agent reservoir when the spring is compressed and the agent reservoir contains a quantity of bioactive agent solution (1954; ¶0221).*

14. **Regarding claim 12**, Netzel in view of Zumbrunn discloses the system of claim

10. Netzel further discloses *a bolus chamber communicating with the agent reservoir and an agent outlet (1803; ¶0021), the bolus chamber comprising a piston movably disposed in a chamber (1804), the volume of the bolus chamber being less than the volume of the agent reservoir (Fig. 28D – bolus chamber 1803 is smaller than reservoir 1801).*

15. **Regarding claim 13**, Netzel in view of Zumbrunn discloses the system of claim

12. Netzel further discloses *a valve (1745; ¶0221) having a first position communicating the agent reservoir with the bolus chamber and a second position communicating the bolus chamber with the agent outlet (¶0217, lines 18-23).*

16. **Regarding claim 14**, Netzel in view of Zumbrunn discloses the system of claim

13. Netzel further discloses that *the reusable part comprises a valve driver (1956; ¶0220), the control electronics being adapted to control the valve driver to deliver*

bioactive agent solution from the agent reservoir to the bolus chamber and from the bolus chamber to the agent outlet (¶0217, lines 18-23; ¶0225).

17. **Regarding claim 15**, Netzel in view of Zumbrunn discloses the system of claim

10. Netzel further discloses *a spring extending between the bolus chamber piston and a surface to pressurize the bolus chamber when the spring is compressed and the bolus chamber contains a quantity of bioactive agent solution* (1952; ¶0220).

18. **Regarding claim 16**, Netzel in view of Zumbrunn discloses the system of claim

1. Netzel further discloses *a latch adapted to removably attach the disposable part to the reusable part* (¶0218 – snap connections).

19. **Regarding claim 18**, Netzel in view of Zumbrunn discloses the system of claim

1. Netzel further discloses *a connection detector adapted to detect a connection between the disposable part and the reusable part* (1962; ¶0219-0220).

20. **Regarding claim 23**, Netzel discloses *a method of delivering a bioactive agent*

(¶0019 and 0224-0225), *the method comprising: connecting a reusable part of a delivery system (1706) to a disposable part of the delivery system (1708) to form a flow path between the reusable part and the disposable part (¶0224-0225); delivering the bioactive agent dissolved in a solvent from a reservoir (1801) of the disposable part to a transdermal membrane (1811) of the disposable part (¶0224-0225); and allowing the solvent to evaporate and flow from the transdermal membrane through a gas permeable membrane (1812).*

21. Netzel does not disclose that the solvent flows *along the flow path to ambient air around the delivery system.*

22. As discussed above, Zumbrunn teaches a transdermal drug delivery system in which solvent vapors are discharged to the environment surrounding the drug delivery system (§0066-0067). Zumbrunn further teaches that discharging vapors to the environment provides the advantage of ensuring that depleted solvent does not need to be separately collected (§0067). Therefore, it would have been *prima facie* obvious to one of ordinary skill in the art prior to the effective filing date of the claimed invention to modify the method disclosed by Netzel so that the solvent flows *along the flow path to ambient air around the delivery system* in order to discharge gaseous solvent to the environment and ensuring that the gaseous solvent does not need to be separately collected as motivated by Zumbrunn.

23. **Regarding claim 24**, Netzel in view of Zumbrunn discloses the method of claim 23. Netzel further discloses *applying the transdermal membrane to the skin of a user* (§0225).

24. **Regarding claim 25**, Netzel in view of Zumbrunn discloses the method of claim 24. Netzel further discloses *delivering the bioactive agent to the skin* (§0225).

25. **Regarding claim 26**, Netzel in view of Zumbrunn discloses the method of claim 23. Netzel further discloses *controlling with the reusable part movement of the bioactive agent dissolved in the solvent from the reservoir to the transdermal membrane* (§0217 and 0225).

26. **Regarding claim 27**, Netzel in view of Zumbrunn discloses the method of claim 26. Netzel further discloses that *the controlling step comprises actuating a valve* (§0225).

27. **Regarding claim 28**, Netzel in view of Zumbrunn discloses the method of claim

23. Netzel further discloses *detecting a connection between the disposable part and the reusable part* (§0224).

28. Claim 7 is rejected under 35 U.S.C. 103 as being unpatentable over Netzel et al. (US 2016/0220798 A1) in view of Zumbrunn et al. (US 2005/0238704) and in further view of Gordon (US 2017/0296317 A1).

29. **Regarding claim 7**, Netzel in view of Zumbrunn and in further view of Gordon discloses the system of claim 1. Netzel in view of Zumbrunn does not disclose *a drainage port formed in an exterior surface of the reusable part or the disposable part*.

30. Gordon teaches a drug delivery pump (10; §0067) for delivering a drug (32; §0071). Gordon teaches that the pump comprises a vent passage (27; §0076) which may be used to drain off the drug if it leaks through the pump (§0076). Therefore, it would have been *prima facie* obvious to one of ordinary skill in the art prior to the effective filing date of the claimed invention to modify the system disclosed by Netzel in view of Zumbrunn so that it comprises *a drainage port formed in an exterior surface of the reusable part or the disposable part* in order to drain off any fluids that leak out of the system.

31. Claim 17 is rejected under 35 U.S.C. 103 as being unpatentable over Netzel et al. (US 2016/0220798 A1) in view of Zumbrunn et al. (US 2005/0238704) and in further view of Hanson et al. (US 2011/0160655 A1) (hereinafter Hanson '655).

32. **Regarding claim 17**, Netzel in view of Zumbrunn discloses the system of claim 16. Netzel further discloses that *the disposable part and the reusable part configured to slide relative to one another until the latch is activated to attach the disposable part to*

the reusable part (Fig. 26; ¶0218). Netzel in view of Zumbrunn does not disclose that *the latch is positioned on one side of the system and a rail is positioned along a second side of the system* such that the disposable part and the reusable part are configured to slide relative to one another *along the rail until the latch is activated*.

33. Hanson '655 teaches a drug delivery device comprising a first portion that slides relative to a second portion from a first, unlocked position, to a second, locked position (¶0016). Hanson '655 teaches that the first portion may slide along a dovetail, groove, or ridge such that the dovetail, groove, or ridge acts to guide the movement of the first portion (¶0017, 0018, 0019, 0025). Therefore, it would have been *prima facie* obvious to one of ordinary skill in the art prior to the effective filing date of the claimed invention to modify the system disclosed by Netzel in view of Zumbrunn so that *the latch is positioned on one side of the system and a rail is positioned along a second side of the system* such that the disposable part and the reusable part are configured to slide relative to one another *along the rail until the latch is activated* in order to guide the movement of the disposable and reusable parts as they slide relative to each other as taught by Hanson '655.

34. Claims 19-22 and 29 are rejected under 35 U.S.C. 103 as being unpatentable over Netzel et al. (US 2016/0220798 A1) in view of Zumbrunn et al. (US 2005/0238704) and in further view of Hanson et al. (US 2013/0190683 A1) (hereinafter Hanson '683).

35. **Regarding claim 19**, Netzel in view of Zumbrunn discloses the system of claim 18. Netzel in view of Zumbrunn does not disclose that *the connection detector comprises a magnet*.

36. Hanson '683 teaches a drug delivery device comprising a first housing portion that is connectable to a second housing portion, wherein a magnet and a magnet-responsive device are used to detect the connection between the first housing portion and the second housing portion (§0014-0018). Hanson '683 teaches that magnet-based connection detection may also provide information about whether or not the first and second housing portions are properly aligned as well as connected (§0195). Therefore, it would have been *prima facie* obvious to one of ordinary skill in the art prior to the effective filing date of the claimed invention to modify the system disclosed by Netzel in view of Zumbrunn so that *the connection detector comprises a magnet* in order to determine both connection status and alignment status as taught by Hanson '683.

37. **Regarding claims 20 and 21**, Netzel in view of Zumbrunn and in further view of Hanson '683 discloses the system of claim 19. Hanson '683 further teaches that magnets may be provided on one or both parts of the system (§0144). Therefore, Netzel in view of Zumbrunn and in further view of Hanson '683 discloses that *the magnet is disposed in the disposable part* and that *the magnet is disposed in the reusable part*.

38. **Regarding claim 22**, Netzel in view of Zumbrunn and in further view of Hanson '683 discloses the system of claim 19. Hanson '683 further teaches that the sensor may be a switch that activates upon sensing a strong enough magnetic field (§0193-0196). Therefore, Netzel in view of Zumbrunn and in further view of Hanson '683 discloses that *the connection detector further comprises a magnetoresistive switch*.

39. **Regarding claim 29**, Netzel in view of Zumbrunn discloses the method of claim 28. Netzel in view of Zumbrunn does not disclose that *the detecting step comprises sensing a magnetic field*.

40. As discussed above, Hanson '683 teaches a drug delivery device comprising a first housing portion that is connectable to a second housing portion, wherein a magnet and a magnet-responsive device are used to detect the connection between the first housing portion and the second housing portion (§0014-0018). Hanson '683 teaches that magnet-based connection detection may also provide information about whether or not the first and second housing portions are properly aligned as well as connected (§0195). Therefore, it would have been *prima facie* obvious to one of ordinary skill in the art prior to the effective filing date of the claimed invention to modify the method disclosed by Netzel in view of Zumbrunn so that *the detecting step comprises sensing a magnetic field* in order to determine both connection status and alignment status as taught by Hanson '683.

Allowable Subject Matter

41. Claims 4-6 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

42. The following is a statement of reasons for the indication of allowable subject matter: Claim 4 recites that the gap is maintained with a spacer disposed between the disposable part and the reusable part. Netzel in view of Zumbrunn renders obvious a gap between the disposable part and the reusable part in order to vent evaporated solvent through the gap, but are silent with respect to how the gap is maintained. Accordingly, claim 4 is objected to as being dependent upon a rejected base claim, but would be allowable over the prior art on record if rewritten in independent form. Claims 5 and 6 are similarly objected to by virtue of their dependence on claim 4.

Conclusion

43. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

- a. Morgan et al. (US 2010/0010443 A1) discloses an infusion pump employing a magnetic switch for reservoir detection.
- b. Yodfat et al. (US 2010/0198187 A1) discloses a two part drug dispensing device.

44. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ARJUNA P CHATRATHI whose telephone number is (571)272-8063. The examiner can normally be reached M-F 8:30-5:00.

Examiner interviews are available via telephone, in-person, and video conferencing using a USPTO supplied web-based collaboration tool. To schedule an interview, applicant is encouraged to use the USPTO Automated Interview Request (AIR) at <http://www.uspto.gov/interviewpractice>.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of published or unpublished applications may be obtained from Patent Center. Unpublished application information in Patent Center is available to registered users. To file and manage patent submissions in Patent Center, visit: <https://patentcenter.uspto.gov>. Visit <https://www.uspto.gov/patents/apply/patent-center> for more information about Patent Center and

<https://www.uspto.gov/patents/docx> for information about filing in DOCX format. For additional questions, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

45. /ARJUNA P CHATRATHI/
Examiner, Art Unit 3781

46. /CATHARINE L ANDERSON/
Primary Examiner, Art Unit 3781

<i>Search Notes</i> 	Application/Control No. 17/057,318	Applicant(s)/Patent Under Reexamination TONG et al.
	Examiner ARJUNA P CHATRATHI	Art Unit 3781

CPC - Searched*		
Symbol	Date	Examiner
A61M5/14248; A61M2005/14268; A61M35/10;	06/15/2022	APC

CPC Combination Sets - Searched*		
Symbol	Date	Examiner

US Classification - Searched*			
Class	Subclass	Date	Examiner

* See search history printout included with this form or the SEARCH NOTES box below to determine the scope of the search.

Search Notes		
Search Notes	Date	Examiner
Applicant and Inventor Name Search	06/15/2022	APC
IDS references reviewed	06/15/2022	APC
Citation search of relevant references	06/15/2022	APC
Text Search in A61M5/14248; A61M2005/14268; A61M35/10; A61M5/1413	06/16/2022	APC
Consultation with primary Lynne Anderson regarding potential allowable subject matter	06/16/2022	APC

Interference Search			
US Class/CPC Symbol	US Subclass/CPC Group	Date	Examiner

/ARJUNA P CHATRATHI/ Examiner, Art Unit 3781	
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/ARJUNA P CHATRATHI/ Examiner, Art Unit 3781	
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet	1
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of	1
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Application Number

17/057.318

Filing Date

November 20, 2020

First Named Inventor

Ling-Kang Tong

Art Unit

3781

Examiner Name

Unassigned

Attorney Docket Number

13164-722.US0

U. S. PATENT DOCUMENTS

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FOREIGN PATENT DOCUMENTS

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Sheet	1
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of	2
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Art Unit

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Examiner Name

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Attorney Docket Number

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FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T ⁶
		Country Code ³ -Number ⁴ -Kind Code ⁵ (if known)	MM-DD-YYYY			
	876	JPH09504974A (w/EngEquiv)	5/20/1997	Elan Medical Technologies, L		
	882	JP2000515394A (w/EngEquiv)	11/21/2000	Elan Medical Technologies, L		
	874	JP2001505491A (w/EngEquiv)	4/24/2001	LHD Lab Hygiene Dietetique		
	879	JP2003506477A (w/EngEquiv)	2/18/2003	Microchips Inc.		
	875	JP2005521526A (w/EngEquiv)	7/21/2005	Becton Dickinson & Co.		
	877	JP2010279808A (w/MachTrans)	12/16/2010	Altea Therapeutics Corp.		

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Sheet	2
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2

of

2

Complete if Known

Application Number	17/057,318
Filing Date	November 20, 2020
First Named Inventor	Ling-Kang Tong
Art Unit	3781
Examiner Name	Unassigned
Attorney Docket Number	13164-722.US0

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Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T ⁶
		Country Code ³ -Number ⁴ -Kind Code ⁵ (if known)				
	883	JP2011036491A (w/MachTrans)	2/24/2011	Fukae Kasei KK		
	873	JP2013524951A (w/EngEquiv)	6/20/2013	Abbott Biotech Ltd.		
	881	JP2015070868A (w/EngAbs)	4/16/2015	Syndeo LLC		

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Sheet	1
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of 2

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17/057.318

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First Named Inventor

Ling-Kang Tong

Art Unit

3781	
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Application Number	17/057,318
Filing Date	November 20, 2020
First Named Inventor	Ling-Kang Tong
Art Unit	3781
Examiner Name	Unassigned
Attorney Docket Number	13164-722.US0

Sheet

2

of

2

NON PATENT LITERATURE DOCUMENTS

Examiner 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
	871	RUANE et al.; U.S. Pat Appl. # 17/293,570 entitled "Thermally regulated transdermal drug delivery system," filed 5/13/2021	

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Sheet 1 of 1

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Application Number	17/057,318
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Attorney Docket Number	13164-722.US0

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code ² (if known)			
	866	US- 4,313,439	2/2/1982	Babb et al.	
	870	US- 2005/0197625	9/8/2005	Haueter et al.	
	862	US- 2010/0130932	5/27/2010	Yodfat et al.	
	867	US- 2012/0078216	3/29/2012	Smith et al.	
	869	US- 2013/0096495	4/18/2013	Holmqvist et al.	
	868	US- 2014/0163521	6/12/2014	O'Conner	
	863	US- 2015/0057616	2/26/2015	Shergold et al.	
	861	US- 2016/0058939	3/3/2016	Brewer et al.	
	865	US- 2016/0317738	11/3/2016	Cross et al.	
	864	US- 2017/0232192	8/17/2017	Sasaki	
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		Country Code ³ -Number ⁴ -Kind Code ⁵ (if known)				
	850	WO2020/102695A1	5/22/2020	Chrono Therapeutics Inc.		

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Sheet 1 of 43

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Application Number	17/057,318
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Examiner Name	Unassigned
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		Number-Kind Code ² (if known)			
	558	US- 2,183,482	12/12/1939	Kurkjian	
	761	US- 3,279,653	10/18/1966	Pfleger	
	342	US- 3,845,217	10/29/1974	Femo et al.	
	529	US- 4,321,387	3/23/1982	Chavdarian et al.	
	530	US- 4,327,725	5/4/1982	Cortese et al.	
	531	US- 4,332,945	6/1/1982	Edwards	
	1	US- 4,379,454	4/12/1983	Campbell et al.	
	2	US- 4,545,990	10/8/1985	Le Foyer de Costil et al.	
	343	US- 4,579,858	4/1/1986	Femo et al.	
	532	US- 4,590,278	5/20/1986	Edwards	
	3	US- 4,708,716	11/24/1987	Sibalis	
	203	US- 4,772,263	9/20/1988	Dorman et al.	
	344	US- 4,806,356	2/21/1989	Shaw	
	204	US- 4,853,854	8/1/1989	Behar et al.	
	4	US- 4,885,154	12/5/1989	Cornier et al.	
	5	US- 4,908,213	3/13/1990	Govil et al.	
	6	US- 4,917,676	4/17/1990	Heiber et al.	
	7	US- 4,917,895	4/17/1990	Lee et al.	
	345	US- 4,920,989	5/1/1990	Rose et al.	

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		Country Code ³ -Number ⁴ -Kind Code ⁵ (if known)				
	403	AU662877B3	9/14/1995	Hakim		
	404	BE899037A (w/EngAbs)	6/18/1984	Trenker Ady		
	103	CA2142871A1 (WOpubln)	3/3/1994	Cygnus Inc.		
	405	CN1704056A (w/EngAbs)	12/7/2005	Chinse Acad Sci Biophysics		
	104	DE10103158A1 (w/EngAbs)	8/1/2002	Von Falkenhausen, C.		
	105	DE10105759C1 (w/EngAbs)	10/25/2001	LTS Lohmann Ther. Sys.		

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Sheet **2** of **43****Complete if Known**

Application Number	17/057,318
Filing Date	November 20, 2020
First Named Inventor	Ling-Kang Tong
Art Unit	Unassigned
Examiner Name	Unassigned
Attorney Docket Number	13164-722.US0

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	603	US- 4,952,928	8/28/1990	Carroll et al.	
	346	US- 4,953,572	9/4/1990	Rose et al.	
	796	US- 4,992,445	2/12/1991	Lawter et al.	
	8	US- 5,000,956	3/19/1991	Amkraut et al.	
	797	US- 5,001,139	3/19/1991	Lawter et al.	
	9	US- 5,013,293	5/7/1991	Sibalis	
	798	US- 5,023,252	6/11/1991	Hsieh	
	10	US- 5,049,387	9/17/1991	Amkraut	
	347	US- 5,069,904	12/3/1991	Masterson	
	780	US- 5,073,380	12/17/1991	Babu et al.	
	11	US- 5,097,834	3/24/1992	Skrabal	
	12	US- 5,120,545	6/9/1992	Ledger et al.	
	13	US- 5,130,139	7/14/1992	Cormier et al.	
	569	US- 5,149,538	9/22/1992	Granger et al.	
	14	US- 5,149,719	9/22/1992	Ferber et al.	
	348	US- 5,212,188	5/18/1993	Caldwell et al.	
	15	US- 5,221,254	6/22/1993	Phipps	
	349	US- 5,227,391	7/13/1993	Caldwell et al.	
	533	US- 5,232,704	8/3/1993	Franz et al.	

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Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	† ⁸
		Country Code ³ -Number ⁴ -Kind Code ⁵ (if known)				
	106	DE19958554A1 (w/CorresEng)	1/11/2001	LTS Lohmann Ther. Sys.		
	107	EP0314528B1	12/16/1992	Hercon Labs Corp.		
	108	EP0354554B1	1/5/1994	Estee Lauder Inc.		
	109	EP0612525B1	9/19/2001	Bristol Myers Squibb Co		
	273	EP0726005A1 (WOpubin)	8/14/1996	Williams		
	272	EP1662989B1	9/3/2014	Body Media Inc.		

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**INFORMATION DISCLOSURE
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Sheet **3** of **43****Complete if Known**

Application Number	17/057,318
Filing Date	November 20, 2020
First Named Inventor	Ling-Kang Tong
Art Unit	Unassigned
Examiner Name	Unassigned
Attorney Docket Number	13164-722.US0

U. S. PATENT DOCUMENTS					
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		Number-Kind Code ² (if known)			
	350	US- 5,232,933	8/3/1993	Lippiello et al.	
	570	US- 5,236,714	8/17/1993	Lee et al.	
	351	US- 5,242,934	9/7/1993	Lippiello et al.	
	752	US- 5,242,935	9/7/1993	Lippiello et al.	
	16	US- 5,242,941	9/7/1993	Lewy et al.	
	352	US- 5,248,690	9/28/1993	Caldwell et al.	
	17	US- 5,252,604	10/12/1993	Nagy et al.	
	18	US- 5,262,165	11/16/1993	Govil et al.	
	197	US- 5,273,755	12/28/1993	Venkatraman et al.	
	19	US- 5,273,756	12/28/1993	Fallon et al.	
	20	US- 5,304,739	4/19/1994	Klug et al.	
	21	US- 5,352,456	10/4/1994	Fallon et al.	
	313	US- 5,364,630	11/15/1994	Osborne et al.	
	22	US- 5,370,635	12/6/1994	Strausak et al.	
	597	US- 5,388,571	2/14/1995	Roberts et al.	
	23	US- 5,389,679	2/14/1995	Alliger	
	24	US- 5,393,526	2/28/1995	Castro	
	25	US- 5,405,614	4/11/1995	D'Angelo et al.	
	26	US- 5,415,629	5/16/1995	Hentley	

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Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T ⁶
		Country Code ³ -Number ⁴ -Kind Code ⁵ (if known)				
	721	EP1815784A1	8/8/2007	Amer Mashhour Mustafa		
	319	EP1977746B1	7/30/2014	Parkinson's Institute		
	722	EP3016586A2 (WOPub)	5/11/2016	Mayo Found. Med. Ed.		
	816	EP311313A2	4/12/1989	Yamanouchi Pharma.		
	817	EP857725A1	8/12/1998	Pfizer Inc.		
	818	EP870768A1	10/14/1998	Pfizer Inc.		

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Sheet 4 of 43

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Application Number	17/057,318
Filing Date	November 20, 2020
First Named Inventor	Ling-Kang Tong
Art Unit	Unassigned
Examiner Name	Unassigned
Attorney Docket Number	13164-722.US0

U. S. PATENT DOCUMENTS					
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		Number-Kind Code ² (if known)			
	205	US- 5,445,609	8/29/1995	Lattin et al.	
	27	US- 5,451,407	9/19/1995	Cornier et al.	
	206	US- 5,464,387	11/7/1995	Haak et al.	
	28	US- 5,472,946	12/5/1995	Peck et al.	
	207	US- 5,501,697	3/26/1996	Fisher	
	29	US- 5,505,958	4/9/1996	Bello et al.	
	353	US- 5,512,306	4/30/1996	Carlsson et al.	
	30	US- 5,516,793	5/14/1996	Duffy	
	354	US- 5,525,351	6/11/1996	Dam	
	31	US- 5,545,407	8/13/1996	Hall et al.	
	32	US- 5,596,994	1/28/1997	Bro	
	33	US- 5,601,839	2/11/1997	Quan et al.	
	34	US- 5,616,332	4/1/1997	Herstein	
	35	US- 5,618,557	4/8/1997	Wille et al.	
	208	US- 5,653,682	8/5/1997	Sibalis	
	355	US- 5,656,255	8/12/1997	Jones	
	356	US- 5,662,920	9/2/1997	Santus	
	36	US- 5,686,100	11/11/1997	Wille et al.	
	209	US- 5,688,232	11/18/1997	Flower	

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		Country Code ³ -Number ⁴ -Kind Code ⁵ (if known)				
	819	EP955301A2	11/10/1999	Pfizer Products Inc		
	406	GB1528391A	10/11/1978	Gildemeister V		
	407	GB2030862A	4/16/1980	Smith		
	408	GB2142822A	1/30/1985	Walter		
	409	GB2230439A	10/24/1990	Walter		
	110	JP02202813A (w/EngTrans)	8/10/1990	Sekisui Chem Co Ltd		

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Sheet 5

of 43

Complete if Known

Application Number	17/057,318
Filing Date	November 20, 2020
First Named Inventor	Ling-Kang Tong
Art Unit	Unassigned
Examiner Name	Unassigned
Attorney Docket Number	13164-722.US0

U. S. PATENT DOCUMENTS					
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		Number-Kind Code ² (if known)			
	210	US- 5,697,896	12/16/1997	McNichols et al.	
	37	US- 5,716,987	2/10/1998	Wille	
	211	US- 5,722,418	3/3/1998	Bro	
	38	US- 5,733,259	3/31/1998	Vaicke et al.	
	39	US- 5,785,688	7/28/1998	Joshi et al.	
	212	US- 5,797,867	8/25/1998	Guertera et al.	
	40	US- 5,820,875	10/13/1998	Fallon et al.	
	213	US- 5,833,466	11/10/1998	Borg	
	41	US- 5,843,979	12/1/1998	Wille et al.	
	42	US- 5,865,786	2/2/1999	Sibalis et al.	
	214	US- 5,876,368	3/2/1999	Flower	
	604	US- 5,879,292	3/9/1999	Sternberg et al.	
	43	US- 5,879,322	3/9/1999	Lattin et al.	
	605	US- 5,882,676	3/16/1999	Lee et al.	
	215	US- 5,908,301	6/1/1999	Lutz	
	216	US- 5,919,156	7/6/1999	Stropkay et al.	
	44	US- 5,932,240	8/3/1999	D'Angelo et al.	
	45	US- 5,945,123	8/31/1999	Hermelin	
	217	US- 5,967,789	10/19/1999	Segel et al.	

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		Country Code ³ -Number ⁴ -Kind Code ⁵ (if known)				
	111	JP09512006A (w/EngEquiv)	12/2/1997	Ciba-Geigy AG		
	556	JP2002092180A (w/EngAbs)	3/29/2002	Takahashi Hiroko		
	112	JP2005525147A (w/EngEquiv)	8/25/2005	Encapsulation Sys. Inc.		
	555	JP2009544338A (w/EngEquiv)	12/17/2009	Proteus Biomedical Inc.		
	767	JP2010518914A (w/EngEquiv)	6/3/2010	Vyro Games Ltd.		
	766	JP2016202904A (w/EngAbs)	12/8/2016	Canon KK		

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Sheet 6

of 43

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Application Number	17/057,318
Filing Date	November 20, 2020
First Named Inventor	Ling-Kang Tong
Art Unit	Unassigned
Examiner Name	Unassigned
Attorney Docket Number	13164-722.US0

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	534	US- 5,972,389	10/26/1999	Shell et al.	
	46	US- 5,993,435	11/30/1999	Haak et al.	
	218	US- 5,997,501	12/7/1999	Gross et al.	
	47	US- 6,018,679	1/25/2000	Dinh et al.	
	48	US- 6,019,997	2/1/2000	Scholz et al.	
	535	US- 6,024,981	2/15/2000	Khankari et al.	
	357	US- 6,034,079	3/7/2000	Sanberg et al.	
	49	US- 6,059,736	5/9/2000	Tapper	
	575	US- 6,059,753	5/9/2000	Faust et al.	
	50	US- 6,068,853	5/30/2000	Giannos et al.	
	606	US- 6,081,734	6/27/2000	Batz	
	51	US- 6,090,404	7/18/2000	Meconi et al.	
	607	US- 6,093,419	7/25/2000	Rolf	
	536	US- 6,120,803	9/19/2000	Wong et al.	
	52	US- 6,129,702	10/10/2000	Wojas et al.	
	53	US- 6,165,155	12/26/2000	Jacobsen et al.	
	358	US- 6,211,194	4/3/2001	Westman et al.	
	54	US- 6,211,296	4/3/2001	Frate et al.	
	781	US- 6,221,394	4/24/2001	Gilbert et al.	

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	113	WO86/07269A1	12/18/1986	Drug Delivery Sys. Inc.		
	410	WO88/003803A1 (w/EngEquiv)	6/2/1988	Forsch Ges Rauchen		
	114	WO91/14441A1	10/3/1991	Parnell Pharm. Inc.		
	827	WO92/021339A1	12/10/1992	Abbott Laboratories		
	828	WO94/008992A1	4/28/1994	Abbott Laboratories		
	723	WO94/010987A1	5/26/1994	Pharmetrix Corp.		

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Sheet 7 of 43

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Art Unit	Unassigned
Examiner Name	Unassigned
Attorney Docket Number	13164-722.US0

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	361	US- 6,310,102	10/30/2001	Dull et al.	
	537	US- 6,365,182	4/2/2002	Khankari et al.	
	538	US- 6,368,625	4/9/2002	Siebert et al.	
	55	US- 6,374,136	4/16/2002	Murdock	
	608	US- 6,416,471	7/9/2002	Kumar et al.	
	362	US- 6,417,359	7/9/2002	Crooks et al.	
	56	US- 6,423,747	7/23/2002	Lanzendörfer et al.	
	57	US- 6,436,078	8/20/2002	Svedman	
	58	US- 6,437,004	8/20/2002	Perricone	
	609	US- 6,454,708	9/24/2002	Ferguson et al.	
	784	US- 6,488,959	12/3/2002	Stanley et al.	
	363	US- 6,492,399	12/10/2002	Dull et al.	
	59	US- 6,539,250	3/25/2003	Bettinger	
	785	US- 6,546,281	4/8/2003	Zhang et al.	
	60	US- 6,567,785	5/20/2003	Clendenon	
	610	US- 6,569,449	5/27/2003	Stinchcomb et al.	
	611	US- 6,569,866	5/27/2003	Simon	

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	115	WO95/06497A1	3/9/1995	Alza Corporation	
	829	WO96/015123A1	5/23/1996	Salk Inst. Biotech.	
	830	WO96/040682A1	12/19/1996	Abbott Laboratories	
	831	WO97/011072A1	3/27/1997	Novo Nordisk	
	832	WO97/011073A1	3/27/1997	Novo Nordisk	
	833	WO97/019059A1	5/29/1997	Sibia Neurosciences	

Examiner Signature	Date Considered
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**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

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Sheet 8 of 43

Complete if Known

Application Number	17/057,318
Filing Date	November 20, 2020
First Named Inventor	Ling-Kang Tong
Art Unit	Unassigned
Examiner Name	Unassigned
Attorney Docket Number	13164-722.US0

U. S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code ² (if known)			
	61	US- 6,576,269	6/10/2003	Komeyev	
	62	US- 6,579,865	6/17/2003	Mak et al.	
	219	US- 6,589,229	7/8/2003	Connelly et al.	
	63	US- 6,595,956	7/22/2003	Gross et al.	
	64	US- 6,638,528	10/28/2003	Kanios	
	65	US- 6,638,543	10/28/2003	Kang et al.	
	612	US- 6,660,295	12/9/2003	Watanabe et al.	
	613	US- 6,689,380	2/10/2004	Marchitto et al.	
	66	US- 6,723,086	4/20/2004	Bassuk et al.	
	539	US- 6,723,340	4/20/2004	Gusler et al.	
	589	US- 6,746,688	6/8/2004	Kushnir et al.	
	614	US- 6,791,003	9/14/2004	Choi et al.	
	364	US- 6,799,576	10/5/2004	Farr	
	67	US- 6,849,645	2/1/2005	Majeed et al.	
	68	US- 6,861,066	3/1/2005	Van de Casteele	
	69	US- 6,867,342	3/15/2005	Johnston et al.	
	70	US- 6,887,202	5/3/2005	Curie et al.	
	615	US- 6,893,655	5/17/2005	Flanigan et al.	
	365	US- 6,900,202	5/31/2005	Imoto et al.	

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Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T ⁶
		Country Code ³ -Number ⁴ -Kind Code ⁵ (if known)				
	411	WO97/028801A1	8/14/1997	Mayo Foundation		
	412	WO97/034605A1	9/25/1997	Mayo Foundation		
	413	WO97/042941A2	11/20/1997	Novartis Consumer Health		
	834	WO97/046554A1	12/11/1997	Abbott Laboratories		
	274	WO97/11741A1	4/3/1997	Becton Dickinson & Co.		
	116	WO97/18782A1	5/29/1997	Bristol-Myers Squibb Co		

Examiner Signature		Date Considered	
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STATEMENT BY APPLICANT**

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Sheet 9 of 43

Complete if Known

Application Number	17/057,318
Filing Date	November 20, 2020
First Named Inventor	Ling-Kang Tong
Art Unit	Unassigned
Examiner Name	Unassigned
Attorney Docket Number	13164-722.US0

U. S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code ² (if known)			
	325	US- 6,911,475	6/28/2005	Villafane et al.	
	367	US- 6,998,176	2/14/2006	Morita et al.	
	571	US- 7,011,843	3/14/2006	Becher et al.	
	782	US- 7,011,849	3/14/2006	Storm et al.	
	285	US- 7,019,622	3/28/2006	Orr et al.	
	368	US- 7,064,143	6/20/2006	Gurley et al.	
	572	US- 7,182,955	2/27/2007	Hart et al.	
	220	US- 7,196,619	3/27/2007	Pertman et al.	
	540	US- 7,229,641	6/12/2007	Cherukuri	
	541	US- 7,282,217	10/16/2007	Grimshaw et al.	
	591	US- 7,332,182	2/19/2008	Sackler	
	221	US- 7,376,700	5/20/2008	Clark et al.	
	616	US- 7,384,651	6/10/2008	Hille et al.	
	542	US- 7,384,653	6/10/2008	Wright et al.	
	617	US- 7,579,019	8/25/2009	Tapolsky et al.	
	369	US- 7,598,275	10/6/2009	Cooke et al.	
	326	US- 7,718,677**	5/18/2010	Quik et al.	
	71	US- 7,780,981**	8/24/2010	DiPiero et al.	
	853	US- 7,931,563	4/26/2011	Shaw et al.	

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		Country Code ³ -Number ⁴ -Kind Code ⁵ (if known)			
	835	WO98/042713A1	10/1/1998	Synthelabo	
	836	WO98/054152A1	12/3/1998	Neurosearch	
	837	WO98/054181A1	12/3/1998	Neurosearch	
	838	WO98/054182A1	12/3/1998	Neurosearch	
	839	WO98/054189A1	12/3/1998	Neurosearch	
	289	WO98/46093A1	10/22/1998	Lindburg	

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Sheet 10

of 43

Complete if Known

Application Number	17/057,318
Filing Date	November 20, 2020
First Named Inventor	Ling-Kang Tong
Art Unit	Unassigned
Examiner Name	Unassigned
Attorney Docket Number	13164-722.US0

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		Number-Kind Code ² (if known)			
	581	US- 7,988,660	8/2/2011	Byland et al.	
	753	US- 8,003,080	8/23/2011	Rabinowitz et al.	
	222	US- 8,021,334	9/20/2011	Shekalim	
	762	US- 8,137,314	3/20/2012	Mounce et al.	
	618	US- 8,140,143	3/20/2012	Picard et al.	
	543	US- 8,192,756	6/5/2012	Berner et al.	
	223	US- 8,246,581	8/21/2012	Adams et al.	
	72	US- 8,252,321**	8/28/2012	DiPierro et al.	
	619	US- 8,262,394	9/11/2012	Walker et al.	
	620	US- 8,268,475	9/18/2012	Tucholski	
	582	US- 8,285,328	10/9/2012	Caffey et al.	
	224	US- 8,303,500	11/6/2012	Raheman	
	621	US- 8,309,568	11/13/2012	Stinchcomb et al.	
	73	US- 8,372,040**	2/12/2013	Huang et al.	
	225	US- 8,414,532	4/9/2013	Brandt et al.	
	588	US- 8,440,220	5/14/2013	Gale et al.	
	74	US- 8,440,221**	5/14/2013	Zumbrunn et al.	
	622	US- 8,441,411	5/14/2013	Tucholski et al.	
	623	US- 8,445,010	5/21/2013	Anderson et al.	

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Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T ⁶
		Country Code ³ -Number ⁴ -Kind Code ⁵ (if known)	MM-DD-YYYY			
	844	WO98/55107A1	12/10/1998	Depomed Inc.		
	840	WO99/002517A1	1/21/1999	Synthelabo		
	841	WO99/003859A1	1/28/1999	Astra Aktiebolag		
	842	WO99/021834A1	5/6/1999	Neurosearch		
	843	WO99/024422A1	5/20/1999	Neurosearch		
	414	WO99/066916A1	12/29/1999	Pentech Pharmaceuticals Inc		

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Sheet 11

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Application Number	17/057,318
Filing Date	November 20, 2020
First Named Inventor	Ling-Kang Tong
Art Unit	Unassigned
Examiner Name	Unassigned
Attorney Docket Number	13164-722.US0

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		Number-Kind Code ² (if known)			
	624	US- 8,449,471	5/28/2013	Tran	
	226	US- 8,517,988	8/27/2013	Smith	
	227	US- 8,545,445	10/1/2013	Kamen et al.	
	228	US- 8,574,188	11/5/2013	Potter et al.	
	625	US- 8,586,079	11/19/2013	Hansted et al.	
	229	US- 8,589,174	11/19/2013	Nelson et al.	
	626	US- 8,614,278	12/24/2013	Loubert et al.	
	230	US- 8,632,497	1/21/2014	Yodfat et al.	
	627	US- 8,666,781	3/4/2014	Hanina et al.	
	75	US- 8,673,346**	3/18/2014	Zumbrunn et al.	
	628	US- 8,684,922	4/1/2014	Tran	
	629	US- 8,688,189	4/1/2014	Shennib	
	298	US- 8,690,827	4/8/2014	Edwards et al.	
	779	US- 8,690,865	4/8/2014	Prausnitz et al.	
	299	US- 8,696,637	4/15/2014	Ross	
	630	US- 8,703,175	4/22/2014	Kanios et al.	
	631	US- 8,703,177	4/22/2014	Finn et al.	
	632	US- 8,722,233	5/13/2014	Tucholski	
	231	US- 8,727,745	5/20/2014	Rush et al.	

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Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T ⁶
		Country Code ³ -Number ⁴ -Kind Code ⁵ (if known)				
	820	WO00/010997A1	3/2/2000	Ortho-McNeil Pharma.		
	821	WO00/032600A1	6/8/2000	Neurosearch		
	822	WO00/034279A1	6/15/2000	Sanofi-Synthelabo		
	823	WO00/034284A1	6/15/2000	Sanofi-Synthelabo		
	415	WO00/035279A1	6/22/2000	Univ. South Florida		
	724	WO00/035456A1	6/22/2000	Samyang Corp.		

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Sheet 12

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Application Number	17/057,318
Filing Date	November 20, 2020
First Named Inventor	Ling-Kang Tong
Art Unit	Unassigned
Examiner Name	Unassigned
Attorney Docket Number	13164-722.US0

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	76	US- 8,741,336**	6/3/2014	DiPierro et al.	
	232	US- 8,747,348	6/10/2014	Yodfat et al.	
	233	US- 8,753,315	6/17/2014	Alferness et al.	
	234	US- 8,773,257	7/8/2014	Yodfat et al.	
	235	US- 8,814,822	8/26/2014	Yodfat et al.	
	236	US- 8,862,223	10/14/2014	Yanaki	
	300	US- 8,864,727	10/21/2014	Lee	
	301	US- 8,865,207	10/21/2014	Kanios et al.	
	633	US- 8,872,663	10/28/2014	Forster	
	290	US- 8,876,802	11/4/2014	Grigorov	
	634	US- 8,956,644	2/17/2015	Yum et al.	
	635	US- 8,962,014	2/24/2015	Prinz et al.	
	302	US- 8,986,253	3/24/2015	DiPerna	
	303	US- 8,999,356	4/7/2015	Ramirez et al.	
	769	US- 8,999,372	4/7/2015	Davidson et al.	
	304	US- 9,023,392	5/5/2015	Koo et al.	
	305	US- 9,044,582	6/2/2015	Chang et al.	
	636	US- 9,050,348	6/9/2015	Kydonieus et al.	
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		Country Code ³ -Number ⁴ -Kind Code ⁵ (if known)				
	824	WO00/044755A1	8/3/2000	Abbott Laboratories		
	825	WO00/064885A1	11/2/2000	Neurosearch		
	826	WO00/066596A1	11/9/2000	Dow Chem Co.		
	117	WO00/74763A2	12/14/2000	Georgia Tech Research		
	552	WO00/74933A1 (w/MachTrans)	12/14/2000	Lohmann Therapie Syst LTS		
	416	WO01/005459A1	1/25/2001	Aradigm Corp.		

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Sheet 13

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Attorney Docket Number	13164-722.US0

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	334	US- 9,111,085	8/18/2015	Darmour et al.	
	306	US- 9,114,240	8/25/2015	Horstmann et al.	
	307	US- 9,155,712	10/13/2015	Kanios et al.	
	763	US- 9,233,203	1/12/2016	Moberg et al.	
	308	US- 9,238,001	1/19/2016	Weyer et al.	
	309	US- 9,238,108	1/19/2016	Edwards et al.	
	638	US- 9,248,104	2/2/2016	Valia et al.	
	639	US- 9,289,397	3/22/2016	Wright	
	640	US- 9,308,202	4/12/2016	Hille et al.	
	641	US- 9,314,527	4/19/2016	Cottrell et al.	
	642	US- 9,373,269	6/21/2016	Bergman et al.	
	643	US- 9,380,698	6/28/2016	Li et al.	
	644	US- 9,513,666	12/6/2016	Li et al.	
	645	US- 9,549,903	1/24/2017	Hille et al.	
	198	US- 9,555,226**	1/31/2017	Zumbrunn et al.	
	199	US- 9,555,227**	1/31/2017	Dipierro	
	646	US- 9,623,017	4/18/2017	Barbier et al.	
	647	US- 9,636,457	5/2/2017	Newberry et al.	
	648	US- 9,655,843	5/23/2017	Finn et al.	

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Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T ⁶
		Country Code ³ -Number ⁴ -Kind Code ⁵ (if known)				
	417	WO01/037814A1	5/31/2001	Robert Gordon Univ.		
	418	WO02/076211A1	10/3/2002	Smithkline Beecham Corp.		
	118	WO03/022349A2	3/20/2003	Walmough, David John		
	419	WO03/026655A1	4/3/2003	Pharmacia AB		
	420	WO03/055486A1	7/10/2003	Pharmacia AB		
	421	WO03/061656A1	7/31/2003	Endo Pharmaceuticals		

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**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

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Sheet 14

of 43

Complete if Known

Application Number	17/057,318
Filing Date	November 20, 2020
First Named Inventor	Ling-Kang Tong
Art Unit	Unassigned
Examiner Name	Unassigned
Attorney Docket Number	13164-722.US0

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		Number-Kind Code ² (if known)			
	649	US- 9,656,441	5/23/2017	LeDonne et al.	
	102	US- 9,669,199**	6/6/2017	DiPierro et al.	
	772	US- 9,687,186	6/27/2017	Goldstein et al.	
	650	US- 9,693,689	7/4/2017	Gannon et al.	
	651	US- 9,700,552	7/11/2017	Weimann	
	652	US- 9,717,698	8/1/2017	Horstmann et al.	
	653	US- 9,735,893	8/15/2017	Aleksov et al.	
	654	US- 9,782,082	10/10/2017	Gannon et al.	
	655	US- 9,795,681	10/24/2017	Abreu	
	656	US- 9,867,539	1/16/2018	Heikenfeld et al.	
	657	US- 9,895,320	2/20/2018	Ogino et al.	
	658	US- 9,949,935	4/24/2018	Murata	
	659	US- 9,974,492	5/22/2018	Dicks et al.	
	660	US- 9,993,203	6/12/2018	Mei et al.	
	661	US- 10,004,447	6/26/2018	Shen et al.	
	662	US- 10,034,841	7/31/2018	Müller et al.	
	764	US- 10,143,687	12/4/2018	Azhir	
	202	US- 10,213,586***	2/26/2019	Netzel et al.	
	335	US- 10,232,156***	3/19/2019	Netzel et al.	

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		Country Code ³ -Number ⁴ -Kind Code ⁵ (if known)				
	725	WO03/070191A1	8/28/2003	Euro Celtique SA		
	422	WO03/097146A1	11/27/2003	Aradigm Corp.		
	275	WO2004/073429A1	9/2/2004	Martin		
	423	WO2004/024124A1	3/25/2004	Smithkline Beecham Corp.		
	424	WO2005/023227A2	3/17/2005	Pfizer Health AB SE		
	276	WO2005/079161A2	9/1/2005	Newvat-Tech Knowledge		

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Sheet 15

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Application Number	17/057,318
Filing Date	November 20, 2020
First Named Inventor	Ling-Kang Tong
Art Unit	Unassigned
Examiner Name	Unassigned
Attorney Docket Number	13164-722.US0

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		Number-Kind Code ² (if known)			
	332	US- 10,258,738**	4/16/2019	DiPierro et al.	
	331	US- 10,258,778**	4/16/2019	DiPierro et al.	
	101	US- 10,105,487**	10/23/2018	DiPierro et al.	
	333	US- 10,679,516**	6/9/2020	Darmour et al.	
	316	US- 10,716,764**	7/21/2020	Zumbrunn et al.	
	119	US- RE46217**	11/29/2016	Huang et al.	
	77	US- 2001/0022978	9/20/2001	Lachmiere et al.	
	559	US- 2001/0026788	10/4/2001	Piskorz	
	370	US- 2002/0002189	1/3/2002	Smith et al.	
	783	US- 2002/0034535	3/21/2002	Kleiner et al.	
	664	US- 2002/0106329	8/8/2002	Leslie	
	78	US- 2002/0127256	9/12/2002	Murad	
	79	US- 2002/0165170	11/7/2002	Wilson et al.	
	80	US- 2002/0169439	11/14/2002	Flaherty	
	81	US- 2002/0182238	12/5/2002	Cretton	
	590	US- 2003/0004187	1/2/2003	Bedard et al.	
	82	US- 2003/0065294	4/3/2003	Pickup et al.	
	83	US- 2003/0065924	4/3/2003	Wuidart et al.	
	84	US- 2003/0083645	5/1/2003	Angel et al.	

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		Country Code ³ -Number ⁴ -Kind Code ⁵ (if known)				
	425	WO2006/069097A2	6/29/2006	Memory Pharma. Corp.		
	726	WO2007/013975A2	2/1/2007	Pharmorx Inc.		
	746	WO2007/041544A1	4/12/2007	Transcutaneous Tech. Inc.		
	426	WO2007/104574A2	9/20/2007	Niconovum AB SE		
	427	WO2007/104575A2	9/20/2007	Niconovum AB SE		
	428	WO2007/133141A1	11/22/2007	McNeil AB SE		

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Sheet 16

of 43

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Application Number	17/057,318
Filing Date	November 20, 2020
First Named Inventor	Ling-Kang Tong
Art Unit	Unassigned
Examiner Name	Unassigned
Attorney Docket Number	13164-722.US0

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		Number-Kind Code ² (if known)			
	371	US- 2003/0087937	5/8/2003	Lindberg	
	372	US- 2003/0119879	6/26/2003	Landh et al.	
	373	US- 2003/0159702	8/28/2003	Lindell et al.	
	237	US- 2004/0019321	1/29/2004	Sage et al.	
	374	US- 2004/0034068	2/19/2004	Warchol et al.	
	375	US- 2004/0037879	2/26/2004	Adusumilli et al.	
	376	US- 2004/0052843	3/18/2004	Lemer et al.	
	85	US- 2004/0062802	4/1/2004	Hermelin	
	86	US- 2004/0138074	7/15/2004	Ahmad et al.	
	377	US- 2004/0166159	8/26/2004	Han et al.	
	378	US- 2004/0191322	9/30/2004	Hansson	
	379	US- 2004/0194793	10/7/2004	Lindell et al.	
	848	US- 2004/0219192	11/4/2004	Horstmann et al.	
	380	US- 2004/0229908	11/18/2004	Nelson	
	592	US- 2004/0241218	12/2/2004	Tavares et al.	
	87	US- 2004/0253249	12/16/2004	Rudnic et al.	
	88	US- 2004/0259816	12/23/2004	Pandol et al.	
	201	US- 2005/0002806	1/6/2005	Fuechstin et al.	
	381	US- 2005/0014779	1/20/2005	Papke	

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Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T ⁶
		Country Code ³ -Number ⁴ -Kind Code ⁵ (if known)				
	574	WO2008/024408A2	2/28/2008	Theraquest BioSci. Inc.		
	599	WO2008/054788A2	5/8/2008	Chrono Therapeutics Inc.		
	429	WO2008/069921A2	6/12/2008	Cima Labs Inc.		
	430	WO2008/069970A2	6/12/2008	Aradigm Corp.		
	431	WO2008/069972A2	6/12/2008	Aradigm Corp.		
	795	WO2008/122049A2	10/9/2008	Chrono Therapeutics Inc.		

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**INFORMATION DISCLOSURE
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Sheet 17

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Application Number	17/057,318
Filing Date	November 20, 2020
First Named Inventor	Ling-Kang Tong
Art Unit	Unassigned
Examiner Name	Unassigned
Attorney Docket Number	13164-722.US0

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		Number-Kind Code ² (if known)			
	382	US- 2005/0021092	1/27/2005	Yun et al.	
	89	US- 2005/0034842	2/17/2005	Huber et al.	
	90	US- 2005/0048020	3/3/2005	Wille	
	383	US- 2005/0053665	3/10/2005	Ek et al.	
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	238	US- 2005/0141346	6/30/2005	Rawls et al.	
	91	US- 2005/0151110	7/14/2005	Minor et al.	
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	92	US- 2006/0024358	2/2/2006	Santini et al.	
	576	US- 2006/0036209	2/16/2006	Subramony et al.	
	849	US- 2006/0057202	3/16/2006	Antarkar et al.	
	239	US- 2006/0122577	6/8/2006	Poulsen et al.	
	386	US- 2006/0167039	7/27/2006	Nguyen et al.	
	240	US- 2006/0184093	8/17/2006	Phipps et al.	
	241	US- 2006/0188859	8/24/2006	Yakobi	
	786	US- 2006/0204578	9/14/2006	Vergez et al.	
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		Country Code ³ -Number ⁴ -Kind Code ⁵ (if known)				
	595	WO2008/135283A1 (w/EngAbs)	11/13/2008	Novosis AG		
	277	WO2009/136304A2	11/12/2009	Koninklijke Philips Elect. N.V.		
	727	WO2011/088072A2	7/21/2011	Agile Therapeutics Inc.		
	728	WO2012/012846A1	2/2/2012	Intheshed Australia PTY Ltd		
	754	WO2012/101060A1	8/2/2012	Novartis AG		
	276	WO2013/093666A1	6/27/2013	Koninklijke Philips Elect. N.V.		

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	93	US- 2007/0042026**	2/22/2007	Wille	
	665	US- 2007/0065365	3/22/2007	Kugelmann et al.	
	286	US- 2007/0086275	4/19/2007	Robinson et al.	
	598	US- 2007/0088338	4/19/2007	Ehwald et al.	
	787	US- 2007/0104787	5/10/2007	Posey Dowty et al.	
	314	US- 2007/0149952	6/28/2007	Bland et al.	
	760	US- 2007/0154336	7/5/2007	Miyazaki et al.	
	192	US- 2007/0168501	7/19/2007	Cobb et al.	
	388	US- 2007/0179172	8/2/2007	Becker et al.	
	94	US- 2007/0191815**	8/16/2007	DiPierro	
	95	US- 2007/0250018	10/25/2007	Adachi et al.	
	389	US- 2007/0256684	11/8/2007	Kelliher et al.	
	336	US- 2007/0260491	11/8/2007	Palmer et al.	
	666	US- 2007/0279217	12/6/2007	Venkatraman et al.	
	292	US- 2007/0299401	12/27/2007	Alferness et al.	
	337	US- 2008/0008747	1/10/2008	Royds	
	647	US- 2008/0131494	6/5/2008	Reed et al.	
	390	US- 2008/0138294	6/12/2008	Gonda	

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	279	WO2013/168068A1	11/14/2013	Koninklijke Philips N.V.		
	280	WO2014/001877A1	1/3/2014	Elevate Tech. Pty. Ltd.		
	281	WO2014/043502A1	3/20/2014	Wicka		
	729	WO2016/081616A2	5/26/2016	4P Therapeutics		
	601	WO2016/161416A1	10/6/2016	Click Therapeutics Inc.		
	739	WO2017/053938A1	3/30/2017	Pain Thera. Inc.		

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	392	US- 2008/0138399	6/12/2008	Gonda	
	393	US- 2008/0138423	6/12/2008	Gonda	
	854	US- 2008/0139907	6/12/2008	Rao et al.	
	667	US- 2008/0152592	6/26/2008	Rebec	
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	338	US- 2008/0233178	9/25/2008	Reidenberg et al.	
	668	US- 2008/0274168	11/6/2008	Baker et al.	
	200	US- 2008/0319272	12/25/2008	Patangay et al.	
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	669	US- 2009/0024004	1/22/2009	Yang	
	196	US- 2009/0062754	3/5/2009	Tang	
	245	US- 2009/0118710	5/7/2009	Kortzeborn	
	740	US- 2009/0169631	7/2/2009	Zamlot et al.	
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		Country Code ³ -Number ⁴ -Kind Code ⁵ (if known)				
	730	WO2017/125455A1	7/27/2017	Buzzz Pharma. Ltd.		
	731	WO2018/026759A1	2/8/2018	Noven Pharma. Inc.		
	749	WO2018/129363A1	7/12/2018	Chrono Therapeutics Inc.		
	745	WO2019/090125A2	5/9/2019	Chrono Therapeutics Inc.		
	771	WO2019/232077A1	12/5/2019	Chrono Therapeutics Inc.		
	850	WO2020/102695A1	5/22/2020	Chrono Therapeutics Inc.		

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet	20
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of	43
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Complete if Known

Application Number

17/057,318

Filing Date

November 20, 2020

First Named Inventor	
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Ling-Kang Tong

Art Unit

Unassigned	
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Examiner Name

Unassigned

Attorney Docket Number

13164-722.US0

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Examiner Initials*	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
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	593	US- 2010/0068250	3/18/2010	Anderson et al.	
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	248	US- 2010/0145303	6/10/2010	Yodfat et al.	
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**INFORMATION DISCLOSURE
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Sheet 21

of 43

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Application Number	17/057,318
Filing Date	November 20, 2020
First Named Inventor	Ling-Kang Tong
Art Unit	Unassigned
Examiner Name	Unassigned
Attorney Docket Number	13164-722.US0

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Sheet	22
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of 43

Complete if Known

Application Number	17/057,318
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Filing Date	November 20, 2020
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First Named Inventor	Ling-Kang Tong
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Art Unit	Unassigned
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Examiner Name	Unassigned
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Attorney Docket Number	13164-722.US0
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet	23
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of 43

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First Named Inventor	Ling-Kang Tong
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Art Unit	Unassigned
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet	24
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of	43
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Application Number

17/057.318

Filing Date

November 20, 2020

First Named Inventor	
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Ling-Kang Tong

Art Unit

Unassigned

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	330	US- 2016/0235732**	8/18/2016	Quik et al.	
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STATEMENT BY APPLICANT**

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Sheet 25

of 43

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First Named Inventor	Ling-Kang Tong
Art Unit	Unassigned
Examiner Name	Unassigned
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Sheet	26
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of	43
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Application Number	17/057,318
Filing Date	November 20, 2017
First Named Inventor	Ling-Kang Tong
Art Unit	Unassigned
Examiner Name	Unassigned
Attorney Docket Number	13164-722.US0

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Sheet 28

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43

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	446	DI MONTE et al.; Relationship among nigrostriatal denervation, parkinsonism, and dyskinesias in the MPTP primate model; Movement Disorders; 15(3); pp. 459-466; May 1, 2000	
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Application Number	17/057,318
Filing Date	November 20, 2020
First Named Inventor	Ling-Kang Tong
Art Unit	Unassigned
Examiner Name	Unassigned
Attorney Docket Number	13164-722.US0

Sheet 34

of

43

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	147	LEMMER; Clinical Chronopharmacology: The Importance of Time in Drug Treatment, in Ciba Foundation Symposium 183 - Circadian Clocks and their Adjustment (eds. Chadwick and Ackrill); John Wiley & Sons, Inc.; pp. 235-253; April 1995	
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Sheet 41

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43

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Sheet 42

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CLAIMS

What is claimed is:

1. A two-part bioactive agent delivery system, the system comprising:
5 a disposable part comprising
an agent reservoir,
a transdermal patch communicating with the agent reservoir and adapted to
transdermally deliver the bioactive agent to a user, the transdermal patch
having a bottom surface adapted to contact skin of the user and a top surface
10 opposite the bottom surface, and
a gas permeable membrane disposed over the top surface of the transdermal
patch;
a reusable part comprising a power source and control electronics, the control electronics
being adapted to deliver bioactive agent dissolved in a solvent from the agent
15 reservoir to the transdermal patch; and
a solvent removal element comprising a gap disposed between the disposable part and the
reusable part to create a flow path for gaseous solvent to flow from the gas permeable
membrane to ambient air around the bioactive agent delivery system.
- 20 2. The system of claim 1, wherein the gap extends between parallel features on the
disposable part and the reusable part.
3. The system of claim 1, wherein the gap is formed when the disposable part and the
reusable part are releasably engaged.
25
4. The system of claim 1, wherein the gap is maintained with a spacer disposed between the
disposable part and the reusable part.
5. The system of claim 4, wherein the spacer extends from the disposable part.
30
6. The system of claim 4, wherein the spacer extends from the reusable part.
7. The system of claim 1, further comprising at least one drainage port formed in an exterior
surface of the reusable part or the disposable part.
35

8. The system of claim 1, wherein the disposable part further comprises an agent outlet communicating with the agent reservoir and the transdermal patch.

9. The system of claim 8, wherein the agent outlet is configured to provide the bioactive agent dissolved in the solvent to a space between the transdermal patch and the vapor permeable membrane.

10. The system of claim 1, wherein the agent reservoir comprises a piston movably disposed in a chamber.

11. The system of claim 10, further comprising a spring extending between the agent reservoir piston and a surface to pressurize the agent reservoir when the spring is compressed and the agent reservoir contains a quantity of bioactive agent solution.

12. The system of claim 10, further comprising a bolus chamber communicating with the agent reservoir and an agent outlet, the bolus chamber comprising a piston movably disposed in a chamber, the volume of the bolus chamber being less than the volume of the agent reservoir.

13. The system of claim 12, further comprising a valve having a first position communicating the agent reservoir with the bolus chamber and a second position communicating the bolus chamber with the agent outlet.

14. The system of claim 13, wherein the reusable part comprises a valve driver, the control electronics being adapted to control the valve driver to actuate the valve to deliver bioactive agent solution from the agent reservoir to the bolus chamber and from the bolus chamber to the agent outlet.

15. The system of claim 10, further comprising a spring extending between the bolus chamber piston and a surface to pressurize the bolus chamber when the spring is compressed and the bolus chamber contains a quantity of bioactive agent solution.

16. The system of claim 1, further comprising a latch adapted to removably attach the disposable part to the reusable part.

17. The system of claim 16, wherein the latch is positioned on one side of the system and a rail is positioned along a second side of the system, the disposable part and the reusable part configured to slide relative to one another along the rail until the latch is activated to attach the disposable part to the reusable part.

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18. The system of claim 1, further comprising a connection detector adapted to detect a connection between the disposable part and the reusable part.

19. The system of claim 18, wherein the connection detector comprises a magnet.

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20. The system of claim 19, wherein the magnet is disposed in the disposable part.

21. The system of claim 19, wherein the magnet is disposed in the reusable part.

15 22. The system of claim 19, wherein the connection detector further comprises a magnetoresistive switch.

23. A method of delivering a bioactive agent, the method comprising:
connecting a reusable part of a delivery system to a disposable part of the delivery system
20 to form a flow path between the reusable part and the disposable part;
delivering the bioactive agent dissolved in a solvent from a reservoir of the disposable
part to a transdermal membrane of the disposable part; and
allowing the solvent to evaporate and flow from the transdermal membrane through a gas
permeable membrane and along the flow path to ambient air around the delivery
25 system.

24. The method of claim 23, further comprising applying the transdermal membrane to skin of a user.

30 25. The method of claim 24, further comprising delivering the bioactive agent to the skin.

26. The method of claim 23, wherein the delivering step comprises controlling with the reusable part movement of the bioactive agent dissolved in the solvent from the reservoir to the transdermal membrane.

35

27. The method of claim 26, wherein the controlling step comprises actuating a valve.

28. The method of claim 23, further comprising detecting a connection between the disposable part and the reusable part.

5

29. The method of claim 28, wherein the detecting step comprises sensing a magnetic field.

DRUG DELIVERY METHODS AND SYSTEMS**CROSS-REFERENCE TO RELATED APPLICATIONS**

[0001] This application claims priority to U.S. Provisional Patent Application No.

5 62/677,494, filed on May 29, 2018, the entirety of which is incorporated by reference herein.

[0002] This application may also be related to U.S. Patent Application No 15/699,382, filed on September 8, 2017, the entirety of which is incorporated by reference herein.

STATEMENT AS TO FEDERALLY SPONSORED RESEARCH

10 **[0003]** This invention was made with Government support under Contract No. 2R22CA171786-04 awarded by the National Institute of Health. The Government has certain rights in the invention.

INCORPORATION BY REFERENCE

15 **[0004]** All publications and patent applications mentioned in this specification are herein incorporated by reference in their entirety to the same extent as if each individual publication or patent application was specifically and individually indicated to be incorporated by reference.

BACKGROUND

20 **[0005]** Medicinal drugs are given to people to manage or improve their health for a variety of reasons, such as to prevent or treat a medical condition or disease such as diabetes, Parkinson's disease, ulcerative colitis, or to manage nicotine or another addiction or dependency, or to manage pain.

[0006] Some medicinal drugs are rapidly metabolized by the body. As a result, multiple
25 doses of the drug over a period of time are often needed to provide a desired effect. In addition to having desired preventative or therapeutic effects, medicinal drugs can also have negative side-effects on the body that can range from irritating to life-threatening. Further, a person's body can develop tolerance to a drug, experience a diminished response to the drug after taking it for a period of time, and require higher doses to have an effect, resulting in increased drug use
30 and additional side-effects. It is therefore beneficial to a person taking a drug to minimize the amount of drug he or she takes to prevent or minimize tolerance and other unwanted side-effects while still receiving the desired therapeutic effect from the drug.

[0007] Tobacco use (such as smoking) causes serious health problems and can lead to premature death. According to the United States Center for Disease Control (CDC), tobacco use
35 causes more than 5 million deaths per year and contributes to the development of serious

illnesses such as cancer, diabetes, heart disease, lung disease (bronchitis, chronic airway destruction, emphysema), and stroke. Despite anti-smoking advertising campaigns, legislation, taxation, and development of smoking cessation products to stop or prevent people from using tobacco, tobacco sales remains a multibillion dollar industry, generating an estimated \$35 billion dollars per year in profits. Tobacco initially causes physical and mood-altering effects that are temporarily pleasing. Further, it is difficult for a person to stop using a tobacco product because tobacco contains nicotine. Nicotine is highly addictive, and not having the nicotine causes harsh withdrawal symptoms. It is very difficult for a person to overcome a nicotine addiction and stop smoking.

[0008] Medicinal drugs can be taken by tobacco users to help them overcome their nicotine addiction. Some products to help a person stop smoking contain small amounts of nicotine as a medicinal drug to minimize withdrawal symptoms and gradually wean a person from their nicotine addiction. Medicinal smoking cessation drugs such as nicotine have to be taken over an extended period of time (often over the course of many months) to give the body time to adjust to having less nicotine. Medicinal drugs, medical devices, and other products, including smoking cessation products, are regulated in the United States by the U.S. Food and Drug Administration (FDA). FDA approved products on the market to help a person quit smoking include various medicinal drugs that require a doctor's prescription as well as over-the-counter products. These products include capsules or tablets, gums, inhalers, lozenges, nasal sprays, and skin patches. These products have thus far been inadequate to get people to stop smoking: 68.9 % of adult cigarette smokers say they want to stop smoking, and every year some 42.7% make an attempt to stop smoking, but are unsuccessful.

[0009] Existing smoking cessation products and other therapeutic and prophylactic treatments for health issues suffer from a variety of problems. They may be inconvenient or socially awkward to use. They may require careful and troublesome tracking of when they were used and how much was used to prevent overdosing. They may act too slowly after being administered and not produce a desired effect when it's needed. They may not be readily available when needed (such as while a person is sleeping). None have been wholly effective to for preventing or treating various medical or other conditions, and smoking remains a significant health and social problem.

[0010] Thus, new and improved drug delivery systems for bioactive agents, such as smoking cessation agents, are needed.

SUMMARY OF THE DISCLOSURE

[0011] In general, in one embodiment, a two-part bioactive agent delivery system includes a disposable part, a reusable part, and a solvent removal element. The disposable part includes an agent reservoir, a transdermal patch communicating with the agent reservoir and adapted to transdermally deliver the bioactive agent to a user. The transdermal patch has a bottom surface adapted to contact skin of the user, a top surface opposite the bottom surface, and a gas permeable membrane disposed over the top surface of the transdermal patch. The reusable part includes a power source and control electronics that are adapted to deliver bioactive agent dissolved in a solvent from the agent reservoir to the transdermal patch. The solvent removal element includes a gap disposed between the disposable part and the reusable part to create a flow path for gaseous solvent to flow from the gas permeable membrane to ambient air around the bioactive agent delivery system.

[0012] This and any other embodiments can include one or more of the following elements. The gap can extend between parallel features on the disposable part and the reusable part. The gap can be formed when the disposable part and the reusable part are releasably engaged. The gap can be maintained with a spacer disposed between the disposable part and the reusable part. The spacer can extend from the disposable part. The spacer can extend from the reusable part. The system can further include at least one drainage port formed in an exterior surface of the reusable part or the disposable part. The disposable part can further include an agent outlet communicating with the agent reservoir and the transdermal patch. The agent outlet can be configured to provide the bioactive agent dissolved in the solvent to a space between the transdermal patch and the vapor permeable membrane. The agent reservoir can include a piston movably disposed in a chamber. The system can further include a spring extending between the agent reservoir piston and a surface to pressurize the agent reservoir when the spring is compressed and the agent reservoir contains a quantity of bioactive agent solution. The system can further include a bolus chamber communicating with the agent reservoir and an agent outlet, and the bolus chamber can include a piston movably disposed in a chamber. The volume of the bolus chamber can be less than the volume of the agent reservoir. The system can further include a valve having a first position communicating the agent reservoir with the bolus chamber and a second position communicating the bolus chamber with the agent outlet. The reusable part can include a valve driver, and the control electronics can be adapted to control the valve driver to actuate the valve to deliver bioactive agent solution from the agent reservoir to the bolus chamber and from the bolus chamber to the agent outlet. The system can further include a spring extending between the bolus chamber piston and a surface to pressurize the bolus chamber when the spring is compressed and the bolus chamber contains a quantity of bioactive agent solution.

The system can further include a latch adapted to removably attach the disposable part to the reusable part. The latch can be positioned on one side of the system and a rail can be positioned along a second side of the system. The disposable part and the reusable part can be configured to slide relative to one another along the rail until the latch is activated to attach the disposable part to the reusable part. The system can further include a connection detector adapted to detect a connection between the disposable part and the reusable part. The connection detector can include a magnet. The magnet can be disposed in the disposable part. The magnet can be disposed in the reusable part. The connection detector further can include a magnetoresistive switch.

[0013] In general, in one embodiment, a method of delivering bioactive agent includes: connecting a reusable part of a delivery system to a disposable part of the delivery system to form a flow path between the reusable part and the disposable part, delivering the bioactive agent dissolved in a solvent from a reservoir of the disposable part to a transdermal membrane of the disposable part, and allowing the solvent to evaporate and flow from the transdermal membrane through a gas permeable membrane and along the flow path to ambient air around the delivery system.

[0014] This and any other embodiments can include one or more of the following elements. The method can further include applying the transdermal membrane to skin of a user. The method can further include delivering the bioactive agent to the skin. The delivering step can include controlling with the reusable part movement of the bioactive agent dissolved in the solvent from the reservoir to the transdermal membrane. The controlling step can include actuating a valve. The method can further include detecting a connection between the disposable part and the reusable part. The detecting step can include sensing a magnetic field.

BRIEF DESCRIPTION OF THE DRAWINGS

[0015] The novel features of the invention are set forth with particularity in the claims that follow. A better understanding of the features and advantages of the present invention will be obtained by reference to the following detailed description that sets forth illustrative embodiments, in which the principles of the invention are utilized, and the accompanying drawings of which:

[0016] Figure 1 is a perspective view of a two-part bioactive agent delivery system according to an embodiment.

[0017] Figure 2 is a perspective view of a partially connected two-part bioactive agent delivery system according to an embodiment.

[0018] Figure 3 is a perspective view of a portion of the disposable part of the two-part bioactive agent delivery system of Figure 1 or Figure 2.

[0019] Figure 4 is an exploded view of the disposable part of the two-part bioactive agent delivery system of Figure 1 or Figure 2.

5 **[0020]** Figure 5 is a side view of a chassis of the disposable part of the two-part bioactive agent delivery system of Figure 1 or Figure 2.

[0021] Figure 6 is a side view of the two-part bioactive agent delivery system of Figure 1 or Figure 2.

[0022] Figure 7 is an exploded view of the reusable part of the two-part bioactive agent
10 delivery system of Figure 1 or Figure 2.

[0023] Figure 8 shows a connection sensor for a two-part bioactive agent delivery system according to an embodiment.

[0024] Figure 9 is a perspective view of a partially connected two-part bioactive agent delivery system according to an embodiment.

15 **[0025]** Figure 10 is a perspective view of the two-part bioactive agent delivery system of Figure 9.

[0026] Figure 11 is a top view of the disposable part of the two-part bioactive agent delivery system of Figure 9.

[0027] Figure 12 is a top view of the reusable part of the two-part bioactive agent delivery
20 system of Figure 9.

[0028] Figure 13 is a top view of the two-part bioactive agent delivery system of Figure 9.

[0029] Figures 14-16 are additional perspective views of the partially connected two-part bioactive agent delivery system of Figure 9.

[0030] Figure 17 is another perspective view of the two-part bioactive agent delivery system
25 of Figure 9.

[0031] Figure 18 is a top view of the chassis of the two-part bioactive agent delivery system of Figure 9.

[0032] Figures 19A-19C are side view of the two-part bioactive agent delivery system of Figure 9.

30 **[0033]** Figures 20A-20C are perspective views of the disposable part of the two-part bioactive agent delivery system of Figure 9.

[0034] Figure 21A is another perspective view of the disposable part of the two-part bioactive delivery system of Figure 9.

[0035] Figure 21B is an exploded view of the disposable part of Figure 21A.

35 **[0036]** Figure 21C is an exploded view of the fluidics assembly of Figures 21A and 21B.

[0037] Figure 22 is an exploded view of the reusable part of the two-part bioactive agent delivery system of Figure 9.

DETAILED DESCRIPTION

- 5 [0038] Described herein are systems and methods for delivering bioactive agents. The systems can include two parts: a disposable part and a reusable part. The disposable part may include bioactive agent and system parts that come into contact with bioactive agent, and the reusable part may not contain bioactive agent and system parts that come into contact with bioactive agent.
- 10 [0039] In some embodiments, the disposable part can include an agent reservoir, a bolus chamber, a valve alternately communicating the reservoir with the bolus chamber and the bolus chamber with an outlet, a solvent removal element, and a transdermal membrane receiving the agent from the outlet. The reusable part can include a valve driver and control electronics.
- [0040] These bioactive agent delivery systems described herein can deliver a solution of the
15 bioactive agent to a transdermal patch. Solvent from the bioactive agent solution can evaporate from the transdermal patch through the solvent removal element (e.g., a gap between the reusable part and the disposable part) to control the manner in which the bioactive agent passes from the patch into the user's skin.
- [0041] A bioactive agent delivery system as described herein may be useful for delivering a
20 bioactive agent to any part on or in a user's body. In some particular variations, a bioactive agent delivery system as described herein may be especially useful for delivering a bioactive agent topically or transdermally to or through a user's skin to a skin layer or bloodstream. Effective topical or transdermally delivery may be aided by use of a skin delivery membrane such as described herein for transferring active agent across the skin that is fully or sufficiently
25 wetted to effectively transfer a dose of bioactive agent to a user's skin. In some variations, a bioactive agent delivery system may be electronically controlled, programmable, portable, and/or wearable.
- [0042] The bioactive agent delivery systems described herein may reproducibly deliver a fixed amount of a bioactive agent to a user, such as to a user's skin, to have a therapeutic or
30 prophylactic effect on the user. In some variations, the bioactive agent delivery systems may be configured to be wearable and to deliver a fixed amount of a bioactive agent to a user's skin in a relatively thin, quiet, easy to use, convenient, electronically controlled system. The bioactive agent delivery systems may be configured to be attached to a user's body (such as for a day or shorter or longer), connect with a user's skin, and deliver a bioactive agent across the user's skin.

[0043] The bioactive agent delivery systems as described herein may be useful for delivering a bioactive agent to a user for addiction or dependency management or prevention such as for a drug addiction, for diabetes or other disease management or prevention, for pain management or prevention, or for another therapeutic or prophylactic purpose. The systems, devices, and methods may be especially useful for delivering multiple doses of a drug or other bioactive agent to a user over time with a safe, inexpensive, convenient, and easy-to-use system that minimizes risk of a drug or other bioactive agent overdose.

[0044] A bioactive agent delivery system as described herein may be configured to deliver multiple doses or boluses during the course of a day and/or for multiple days. Delivering multiple boluses may be especially useful to help a user control cravings or other withdrawal symptoms by delivering a bioactive agent dose (e.g., a dose of nicotine) especially during (or before) a time of day when cravings or withdrawal symptoms are normally most troublesome (such as delivering a dose during the night to prevent cravings upon waking).

[0001] Further, having a bioactive agent delivery system with a disposable part may allow the system to be relatively small or flat and easy to wear. For example, a system may be relatively small or flat because the disposable part needs only contain a limited amount of bioactive agent and/or the reusable part needs only be imparted with sufficient force or power for a limited number of dose deliveries before being recharged. In some examples, a bioactive delivery system as described herein may be less than about 20 mm, less than about 16 mm, less than about 15 mm, less than about 14 mm, less than about 13 mm, less than about 12 mm, less than about 11 mm or less than about 10mm in thickness and may be less than 40 mm, less than 35 mm in length or width, or less than 30 mm in length or width. In some examples, a system may have less than 1500 mm² or less than 1000 mm² top (or bottom) surface area. "Bottom" in this context generally refers the part(s) of the system closest to a user. If a system includes a transdermal patch, bottom may refer to the transdermal patch and to the skin delivery member of a transdermal patch. A surface area of one side of a skin delivery member may be at least 100 mm², at least 500 mm², at least 1500 mm², at least 2000 mm², at least 2500 mm² at least 3000 mm² or less than or between any of these numbers (such as at least 500 mm² and less than 2000 mm²).

[0045] Figures 1 and 2 show a two-part bioactive agent delivery system according to an embodiment of this invention. The system 10 has a reusable part 12 connectable to a disposable part 14. An adhesive element 16 (such as, e.g., adhesive foam) extends around the periphery of the disposable part 14, and a removable release liner 18 covers the adhesive surface of the adhesive element 16. The disposable part 14 also has a reservoir 20 containing a solution of the bioactive agent (e.g., nicotine) to be delivered transdermally to user. The reusable part 12 has

control electronics, a user interface button 72, and an LED mode status indicator 24. One or more latches 22 may be used to connect and disconnect the disposable part 14 from the reusable part 12. An outer surface of the bioactive agent delivery system 10 when the reusable part 12 and the disposable part 14 are connected together may have any shape, such as circular, ovoid, rectangular, square, and may be contoured (or able to be contoured) to better fit a user's skin

5 [0046] Further details of the disposable part 14 are shown in Figures 3-5. Mounted on a chassis 26 are the reservoir 20, a bolus chamber 28, and a valve chamber 30. A manifold communicates the reservoir 20 with the valve chamber 30 and the valve chamber 30 with the bolus chamber 28. Movable pistons 32 and 34 are disposed in the reservoir 20 and bolus chamber 28, respectively. A rotatable valve element 36 is disposed in valve chamber 30.

10 [0047] Attached to the underside of chassis 26 (e.g., by heat bonding) are a gas permeable membrane 38 (formed, e.g., from Poreflon® polytetrafluoroethylene) and a transdermal drug delivery patch 40 (e.g., a Celgard® membrane). An upper housing 42 supports latch(es) 22 and partially covers reservoir 20, valve chamber 30, bolus chamber 28, and chassis 26. An opening 15 44 in housing 42 leads to a fill port 46 that can be used to add a solution of the bioactive agent to reservoir 20 and bolus chamber 28. A fill port plug 48 seals fill port 46 after filling the reservoir and bolus chamber with a solution of the bioactive agent.

[0048] Chassis 26 has supports 53, 54, and 59 engaging the reservoir 20, valve chamber 30, and bolus chamber 28, respectively, to hold the reservoir 20, valve chamber 30, and bolus chamber 28 in place. One or more raised spacers 60 extend upwardly from the top side of chassis 26. Open vents 62 in chassis 26 are disposed over the gas permeable membrane 38. Spacers 60 engage the underside of the reusable part 12 to establish a gap 64 forming a flow path for evaporated solvent passing from transdermal patch 40 through gas permeable membrane 38 and chassis vents 62, as described below. In an alternative embodiment, the one or more spacers 25 60 may extend from the reusable part instead of, or in addition to, the spacer(s) extending from the disposable part. Ramped ledges 99 can transition the chassis from a thinner section 56 to a thicker section 58.

[0049] Figure 7 shows components of the reusable part 12. A latch element 86 adapted to engage with the latch 22 of the disposable part is formed in an upper housing 70. Disposed 30 between an upper housing 70 and a lower housing 74 are a spring assembly 76 for the reservoir 20 and a spring assembly 78 for the bolus chamber 28. When the disposable part 14 is engaged and latched with the reusable part 12, the spring assemblies 76 and 78 engage with the pistons 32 and 34, respectively, and the springs of the spring assemblies 76, 78 compress to pressurize the bioactive agent solution in reservoir 20 and bolus chamber 28, respectively. A motor assembly 35 80 engages valve element 36 and operates under the control of a microprocessor on the printed

circuit board 82 using power from battery 84 to turn valve element 36 between a position in which reservoir 20 communicates with bolus chamber 28 and a position in which bolus chamber 28 communicates with patch 40. A control button 72 in the upper housing 70 communicates with the microprocessor. The control button 72 can further serve as a user input mechanism. It may be depressed, e.g., to power on the electronics; to pair the device with a smartphone application; to provide information about the user, such as the experience of a craving for a cigarette; or to request a device status update or other information. Status indicator 24 can indicate the status of the system, e.g., whether the system is delivering fluid, in stand-by mode, or empty of bioactive agent.

[0050] The system 10 may be used to deliver a bioactive agent transdermally to a user. Disposable part 14 may be prefilled with a solution of the bioactive agent. The disposable part 14 may be connected to the reusable part 12 and latched with latch components 22 and 86. This connection compresses spring assemblies 76 and 78 against pistons 32 and 34 of reservoir 20 and bolus chamber 28, respectively, to pressurize the bioactive agent solution in the reservoir 20 and bolus chamber 28. Release liner 18 may be removed so that the adhesive on the underside of adhesive element 16 can be attached to the user's skin. In response to a signal from the device's microprocessor, motor assembly 80 turns rotatable valve element 36 to a position in which the contents of bolus chamber 28 are delivered through an agent outlet in chassis 26 to a space between gas permeable membrane 38 and transdermal patch 40. As the bioactive agent moves from the patch 40 into the user's skin, solvent from the bioactive agent solution evaporates and passes through gas permeable membrane 38 and the vents 62 in chassis 26 to reach the flow path defined by gap 64. Removal of solvent from the transdermal patch 40 enables the percentage of bioactive agent in liquid solution in the patch to remain high enough to maintain a desired transdermal delivery rate of the bioactive agent until essentially all of the bioactive agent in the bolus of bioactive agent solution has been delivered. Subsequent boluses of bioactive agent may be delivered by actuating the valve element 36 to enable refilling of the bolus chamber 28 with solution from the reservoir 20 followed by movement of the valve element 36 to permit delivery of the next bolus from bolus chamber 28 to the transdermal patch 40. The timing of the bolus deliveries are under the control of the programmed microprocessor.

[0051] Further details of the operation of the reusable and disposable parts and components, including reservoir 20, bolus chamber 28, and valve 36 and/or the control button 72 and indicator 24, to deliver the bioactive agent solution to the transdermal patch at controlled times may be found in US Publication No. 2016/0220798, the entirety of which is incorporated by reference.

[0052] In some embodiments, the systems described herein can include a sensor to detect connection of a disposable part with the reusable part. In one embodiment shown in Figure 8, a

system 210 includes a magnetoresistive switch 290 disposed in the reusable part 212 that detects a magnet 292 disposed in the spring assembly 278. In an alternative embodiment, the magnet can be disposed in the disposable part 214 (see, for example, magnet 392 in Figure 21B). Use of the magnetoresistive switch 290 enables the electronics to be encapsulated and waterproof. In some embodiments, a reed switch or a Hall sensor may be used as an alternative to the magnetoresistive switch. Information about the connection times and durations of the reusable part with the disposable part may be used, e.g., to monitor compliance with a drug delivery regimen.

[0053] Another exemplary two-part bioactive agent delivery system 310 that is similar to system 10 is shown in Figures 9-22. Referring to Figures 9-10, system 310 includes a reusable part 312 connectable to a disposable part 314, an adhesive element 316, and release liner 318. The reusable part 312 has control electronics, a user interface button 372, and an LED mode status indicator 324. When the reusable part 312 and the disposable part 314 are connected together, the upper housing 342 of the disposable part 314 and the housing 370 of the reusable part abut one another to create a substantially smooth outer contour.

[0054] As shown in Figures 11-16, the system 310 further includes a single latch 322 and rail 333 to connect and disconnect the disposable part 314 from the reusable part 312. The latch 322 can be on a first side of the disposable part 314 while the rail 333 can be positioned on a second opposite side of the disposable part 314. The rail 333 can extend substantially parallel with the longitudinal axis of the system 310. Further, the rail 333 can be configured to mate with a sliding element 335 (e.g., a c-shaped element) on the housing 730 of the reusable part 312. In use, the sliding element 335 can slide along the rail 333 as the disposable part 314 and reusable part 312 are engaged. The rail 333 can thus advantageously ensure that the disposable part 314 and reusable part 312 remain aligned as they are connected or disconnected. The latch 322 can have a cantilevered first end 361 and a sloped or ramped second end 366 (see Figure 11). The ramped second end 366 can be connected to the upper housing 342 of the disposable part 314 while the cantilevered first end 361 can be configured to mate with a latch element 386 (e.g., an opening) on the housing 370 of the reusable part 312. The latch 322 and latch element 386 can function to hold the disposable part 314 and reusable part 312 together until the latch 322 is depressed by the user.

[0055] Referring to Figures 17-19C, the system 310 can include open vents 362 through the chassis 326 so as to expose the membrane 338 thereunder. The vents 362 can be positioned in a central portion of the chassis 326 and can be cut so as to maximize the exposure of the surface of the membrane 338. For example, the vents 362 can expose 5-30% of the surface of the membrane 338, such as 10-20% of the surface. Diagonal struts 375 can extend between the

vents 362 to maintain the strength of the chassis 362. The vents 326 can connect to gap 364 between the reusable part 312 and the disposable part 314. The gap 364 can be formed between the parallel bottom surface 381 of the reusable part 312 and top surface 383 of the disposable part 314. The gap 364 can be formed by the framework of the system, including the mating between the rail 333 and sliding element 335 and the mating between the latch 322 and latch element 382. Additionally, one or more spacers 360 can be configured to help maintain the gap 364. The spacers 360 can be, for example, cylindrical or semi-spherical elements that protrude upwards (i.e., from the top surface 383 of) the chassis 326. Further, the spacers 360 can be positioned on a side of the chassis 360 that is opposite to the reservoir 320, bolus chamber 320, and valve chamber 330 (e.g., on the thinner section 356). There can be a plurality of spacers 360, such as 3-5 spacers 360, that are substantially equally spaced around the vents 362. Each of the spacers 360 can have a small diameter (e.g., a diameter that is less than 10% of the width of the chassis 26). Additionally, ramped ledges 399 can transition between the thinner section 356 of the chassis 326 and the thicker section 358 of the chassis 326. In some embodiments, there can be two ledges 399 that are axially aligned with one another at approximately the center of the chassis 326.

[0056] The spacers 360 can engage the bottom surface 381 of the reusable part 312 to maintain the gap 364 and therefore to form a flow path for evaporated solvent passing through the vents 362. In an alternative embodiment, the one or more spacers may extend from the reusable part instead of, or in addition to, the spacers extending from the disposable part. Additionally, the thick section 358 of the chassis 326 can engage the bottom surface 381 of the reusable part 312 (i.e., can be coincident with the bottom of the reusable part 312), which can further maintain the gap 364 above the thin section 356.

[0057] Referring to Figures 20A-20C, the system 310 can further include one or more drainage ports 371 therein that are aligned with or connected with the gap 364 and can provide drainage for any excess fluid left in the side of the system 310. The drainage ports 371 can be formed in the upper housing 377 of the disposable part 312 proximate to the thicker section 358 of the chassis 326 and can facilitate water drainage (e.g., from the user bathing and/or otherwise getting fluid in or on the system 310). In some embodiments, the drainage ports 371 can be positioned such that, when the system is worn on the body (e.g., on the arm) and the device 310 is turned vertically, water will exit the device by gravity via ports 371. The ports 371 can be sized so as to avoid capillary pooling of water therein.

[0058] Further details of the disposable part 314 are shown in Figures 21A-21C, and further details of the reusable part 312 are shown in Figure 22. The disposable part 314 can further include a transdermal delivery patch 340, a permeable membrane 338 and a foam adhesive 365

with deadening strips 364. The deadening strips 364 can provide the user with an edge or small flap to grab onto to help remove the system 310 from the skin. An opening 344 in housing 342 leads to a fill port 346 that can be used to add a solution of the bioactive agent to reservoir 320 and bolus chamber 328. Movable pistons 332 and 334 are disposed within the reservoir 320 and bolus chamber 328, respectively. The reusable part 312 can include a printed circuit board 382 positioned over the lower housing 374, bolus spring assembly 378 (to control piston 334), reservoir spring assembly 376 (to control piston 332). A motor 329 can control activation of the valve 336 and spring assemblies 376, 378. A power supply 384 (e.g., batteries) can provide power to the motor 329. A detect magnet 392 can be positioned in the disposable part 314 while a magnetoresistive switch 390 can be positioned on the printed circuit board 382 of the reusable part 312 to detect attachment of the disposable part 314 to the reusable part 312 (i.e., when the magnet 392 and switch 390 are adjacent to one another upon attachment of the reusable part 312 and the disposable part 314).

[0059] The system 310 can operate similar to system 10. The disposable part 314 may be connected to the reusable part 312 by sliding the rail 333 and sliding element 382 relative to one another until the components are latched with latch components 322 and 386. This connection compresses spring assemblies 376 and 378 against pistons 332 and 334 of reservoir 320 and bolus chamber 328, respectively, to pressurize the bioactive agent solution in the reservoir 320 and bolus chamber 328. In response to a signal from the device's microprocessor, motor assembly 380 turns rotatable valve element 336 to a position in which the contents of bolus chamber 328 are delivered to the patient's skin through the transdermal delivery patch 340. As the bioactive agent moves onto the user's skin, solvent from the bioactive agent solution evaporates through the gas permeable membrane 338 and the vents 362 in chassis 326 to reach the flow path defined by gap 364. Further details of the operation of the reusable and disposable parts and components to deliver the bioactive agent solution to the transdermal patch at controlled times may be found in US Publication No. 2016/0220798, the disclosure of which is incorporated by reference.

[0060] It should be understood that any element described herein with respect to one embodiment can be added to or substituted for any element described with respect to another embodiment.

[0061] When a feature or element is herein referred to as being "on" another feature or element, it can be directly on the other feature or element or intervening features and/or elements may also be present. In contrast, when a feature or element is referred to as being "directly on" another feature or element, there are no intervening features or elements present. It will also be understood that, when a feature or element is referred to as being "connected", "attached" or

“coupled” to another feature or element, it can be directly connected, attached or coupled to the other feature or element or intervening features or elements may be present. In contrast, when a feature or element is referred to as being “directly connected”, “directly attached” or “directly coupled” to another feature or element, there are no intervening features or elements present.

5 Although described or shown with respect to one embodiment, the features and elements so described or shown can apply to other embodiments. It will also be appreciated by those of skill in the art that references to a structure or feature that is disposed “adjacent” another feature may have portions that overlap or underlie the adjacent feature.

[0062] Terminology used herein is for the purpose of describing particular embodiments
10 only and is not intended to be limiting of the invention. For example, as used herein, the singular forms “a”, “an” and “the” are intended to include the plural forms as well, unless the context clearly indicates otherwise. It will be further understood that the terms “comprises” and/or “comprising,” when used in this specification, specify the presence of stated features, steps, operations, elements, and/or components, but do not preclude the presence or addition of one or
15 more other features, steps, operations, elements, components, and/or groups thereof. As used herein, the term “and/or” includes any and all combinations of one or more of the associated listed items and may be abbreviated as “/”.

[0063] Spatially relative terms, such as “under”, “below”, “lower”, “over”, “upper” and the like, may be used herein for ease of description to describe one element or feature’s relationship
20 to another element(s) or feature(s) as illustrated in the figures. It will be understood that the spatially relative terms are intended to encompass different orientations of the device in use or operation in addition to the orientation depicted in the figures. For example, if a device in the figures is inverted, elements described as “under” or “beneath” other elements or features would then be oriented “over” the other elements or features. Thus, the exemplary term “under” can
25 encompass both an orientation of over and under. The device may be otherwise oriented (rotated 90 degrees or at other orientations) and the spatially relative descriptors used herein interpreted accordingly. Similarly, the terms “upwardly”, “downwardly”, “vertical”, “horizontal” and the like are used herein for the purpose of explanation only unless specifically indicated otherwise.

[0064] Although the terms “first” and “second” may be used herein to describe various
30 features/elements (including steps), these features/elements should not be limited by these terms, unless the context indicates otherwise. These terms may be used to distinguish one feature/element from another feature/element. Thus, a first feature/element discussed below could be termed a second feature/element, and similarly, a second feature/element discussed below could be termed a first feature/element without departing from the teachings of the present
35 invention.

[0065] Throughout this specification and the claims which follow, unless the context requires otherwise, the word “comprise”, and variations such as “comprises” and “comprising” means various components can be co-jointly employed in the methods and articles (e.g., compositions and apparatuses including device and methods). For example, the term “comprising” will be understood to imply the inclusion of any stated elements or steps but not the exclusion of any other elements or steps.

[0066] As used herein in the specification and claims, including as used in the examples and unless otherwise expressly specified, all numbers may be read as if prefaced by the word “about” or “approximately,” even if the term does not expressly appear. The phrase “about” or “approximately” may be used when describing magnitude and/or position to indicate that the value and/or position described is within a reasonable expected range of values and/or positions. For example, a numeric value may have a value that is +/- 0.1% of the stated value (or range of values), +/- 1% of the stated value (or range of values), +/- 2% of the stated value (or range of values), +/- 5% of the stated value (or range of values), +/- 10% of the stated value (or range of values), etc. Any numerical values given herein should also be understood to include about or approximately that value, unless the context indicates otherwise. For example, if the value “10” is disclosed, then “about 10” is also disclosed. Any numerical range recited herein is intended to include all sub-ranges subsumed therein. It is also understood that when a value is disclosed that “less than or equal to” the value, “greater than or equal to the value” and possible ranges between values are also disclosed, as appropriately understood by the skilled artisan. For example, if the value “X” is disclosed the “less than or equal to X” as well as “greater than or equal to X” (e.g., where X is a numerical value) is also disclosed. It is also understood that the throughout the application, data is provided in a number of different formats, and that this data, represents endpoints and starting points, and ranges for any combination of the data points. For example, if a particular data point “10” and a particular data point “15” are disclosed, it is understood that greater than, greater than or equal to, less than, less than or equal to, and equal to 10 and 15 are considered disclosed as well as between 10 and 15. It is also understood that each unit between two particular units are also disclosed. For example, if 10 and 15 are disclosed, then 11, 12, 13, and 14 are also disclosed.

[0067] Although various illustrative embodiments are described above, any of a number of changes may be made to various embodiments without departing from the scope of the invention as described by the claims. For example, the order in which various described method steps are performed may often be changed in alternative embodiments, and in other alternative embodiments one or more method steps may be skipped altogether. Optional features of various device and system embodiments may be included in some embodiments and not in others.

Therefore, the foregoing description is provided primarily for exemplary purposes and should not be interpreted to limit the scope of the invention as it is set forth in the claims.

[0068] The examples and illustrations included herein show, by way of illustration and not of limitation, specific embodiments in which the subject matter may be practiced. As mentioned, other embodiments may be utilized and derived there from, such that structural and logical substitutions and changes may be made without departing from the scope of this disclosure. Such embodiments of the inventive subject matter may be referred to herein individually or collectively by the term “invention” merely for convenience and without intending to voluntarily limit the scope of this application to any single invention or inventive concept, if more than one is, in fact, disclosed. Thus, although specific embodiments have been illustrated and described herein, any arrangement calculated to achieve the same purpose may be substituted for the specific embodiments shown. This disclosure is intended to cover any and all adaptations or variations of various embodiments. Combinations of the above embodiments, and other embodiments not specifically described herein, will be apparent to those of skill in the art upon reviewing the above description.

08 Jan 2025

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CLAIMS

What is claimed is:

1. A two-part bioactive agent delivery system, the system comprising:
a disposable part comprising
an agent reservoir,
a transdermal patch communicating with the agent reservoir and adapted to
transdermally deliver the bioactive agent to a user, the transdermal patch
having a bottom surface adapted to contact skin of the user and a top surface
opposite the bottom surface, and
a gas permeable membrane disposed over the top surface of the transdermal
patch;
a reusable part comprising a power source and control electronics, the control electronics
being adapted to deliver bioactive agent dissolved in a solvent from the agent
reservoir to the transdermal patch; and
a solvent removal element comprising a gap disposed between the disposable part and the
reusable part to create a flow path for gaseous solvent to flow from the gas permeable
membrane to ambient air around the bioactive agent delivery system,
wherein the gap is maintained with a spacer disposed between the disposable part and the
reusable part.
2. The system of claim 1, wherein the gap extends between parallel features on the
disposable part and the reusable part.
3. The system of claim 1, wherein the gap is formed when the disposable part and the
reusable part are releasably engaged.
4. The system of claim 1, wherein the gap is maintained with a spacer disposed between the
disposable part and the reusable part.
5. The system of claim 4, wherein the spacer extends from the disposable part.
6. The system of claim 4, wherein the spacer extends from the reusable part.

7. The system of claim 1, further comprising at least one drainage port formed in an exterior surface of the reusable part or the disposable part.

8. The system of claim 1, wherein the disposable part further comprises an agent outlet communicating with the agent reservoir and the transdermal patch.

9. The system of claim 8, wherein the agent outlet is configured to provide the bioactive agent dissolved in the solvent to a space between the transdermal patch and the vapor permeable membrane.

10. The system of claim 1, wherein the agent reservoir comprises a piston movably disposed in a chamber.

11. The system of claim 10, further comprising a spring extending between the agent reservoir piston and a surface to pressurize the agent reservoir when the spring is compressed and the agent reservoir contains a quantity of bioactive agent solution.

12. The system of claim 10, further comprising a bolus chamber communicating with the agent reservoir and an agent outlet, the bolus chamber comprising a piston movably disposed in a chamber, the volume of the bolus chamber being less than the volume of the agent reservoir.

13. The system of claim 12, further comprising a valve having a first position communicating the agent reservoir with the bolus chamber and a second position communicating the bolus chamber with the agent outlet.

14. The system of claim 13, wherein the reusable part comprises a valve driver, the control electronics being adapted to control the valve driver to actuate the valve to deliver bioactive agent solution from the agent reservoir to the bolus chamber and from the bolus chamber to the agent outlet.

15. The system of claim 10, further comprising a spring extending between the bolus chamber piston and a surface to pressurize the bolus chamber when the spring is compressed and the bolus chamber contains a quantity of bioactive agent solution.

16. The system of claim 1, further comprising a latch adapted to removably attach the disposable part to the reusable part.
17. The system of claim 16, wherein the latch is positioned on one side of the system and a rail is positioned along a second side of the system, the disposable part and the reusable part configured to slide relative to one another along the rail until the latch is activated to attach the disposable part to the reusable part.
18. The system of claim 1, further comprising a connection detector adapted to detect a connection between the disposable part and the reusable part.
19. The system of claim 18, wherein the connection detector comprises a magnet.
20. The system of claim 19, wherein the magnet is disposed in the disposable part.
21. The system of claim 19, wherein the magnet is disposed in the reusable part.
22. The system of claim 19, wherein the connection detector further comprises a magnetoresistive switch.

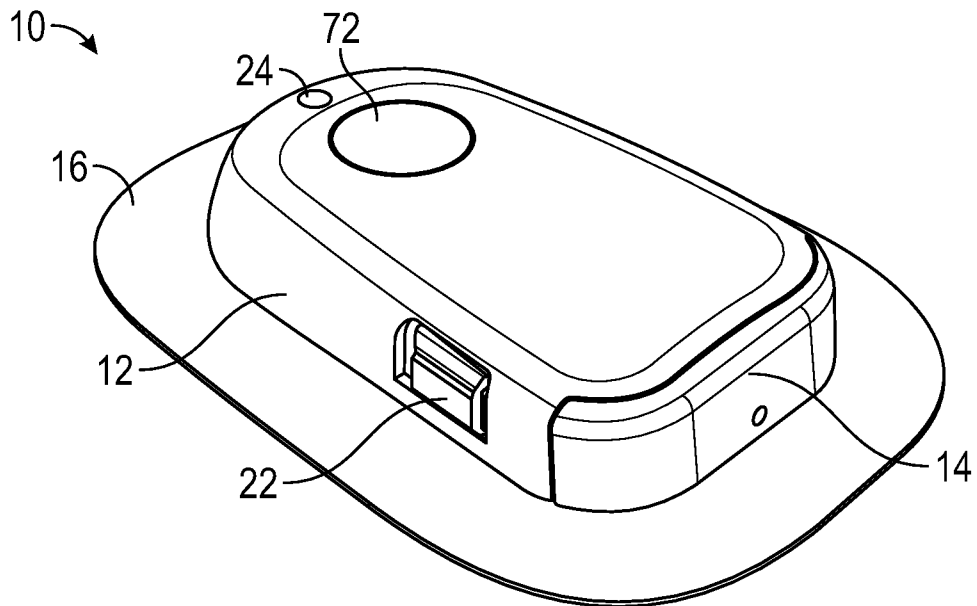


FIG. 1

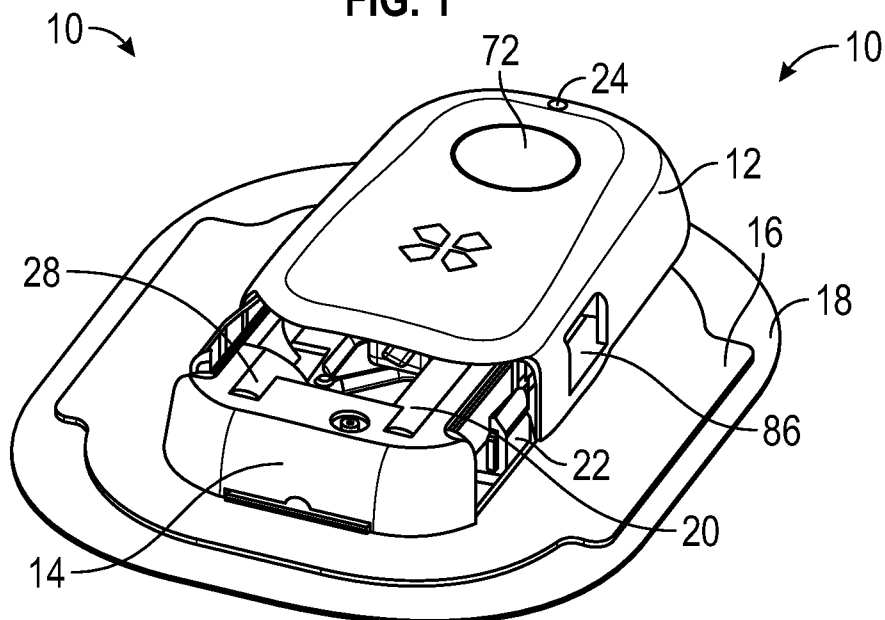


FIG. 2

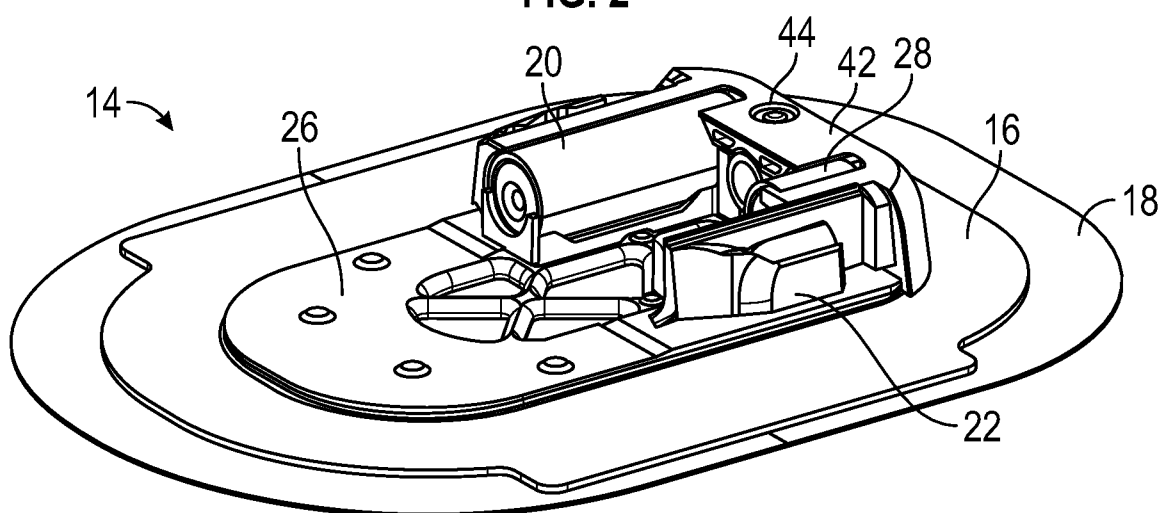


FIG. 3

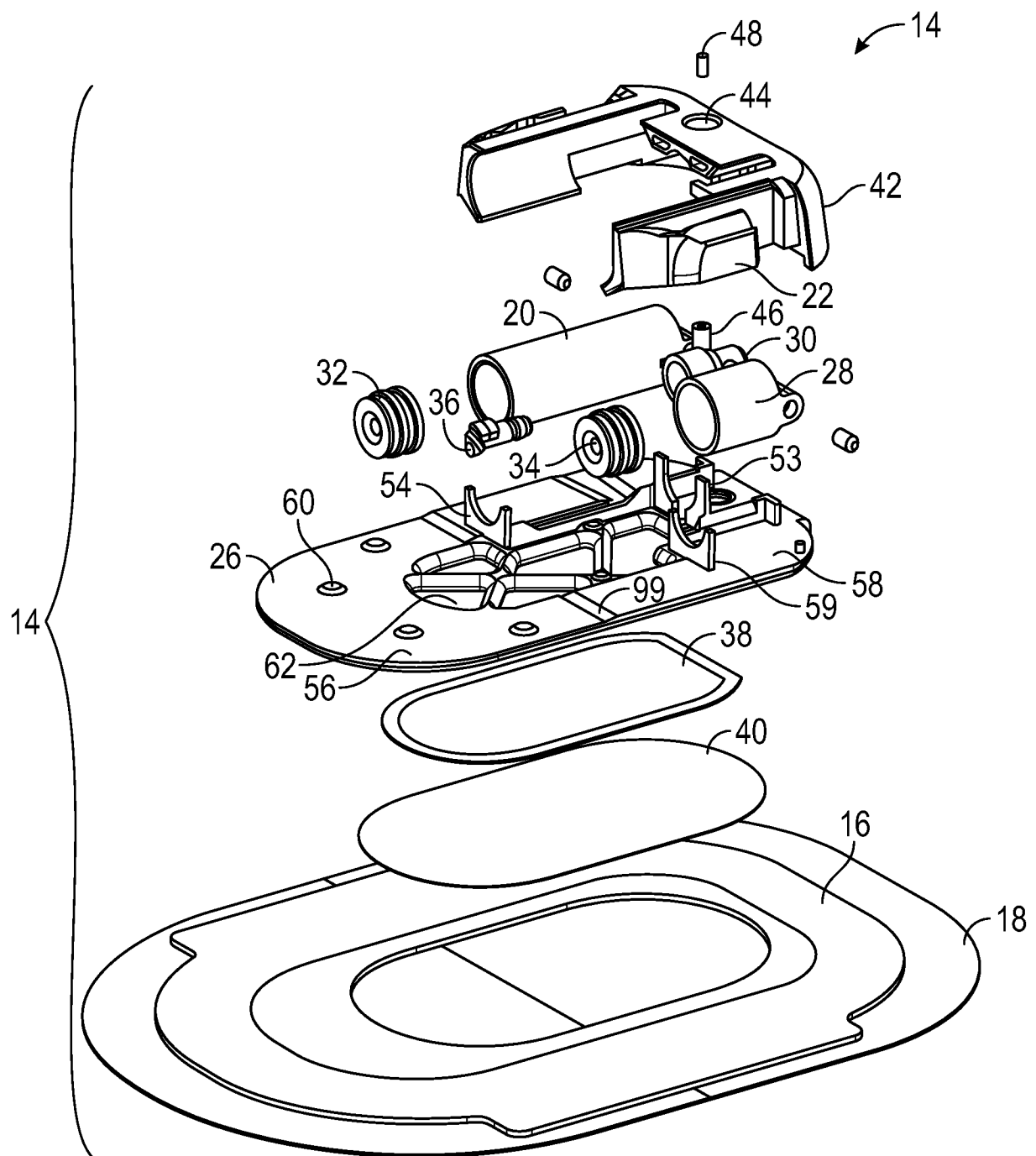


FIG. 4

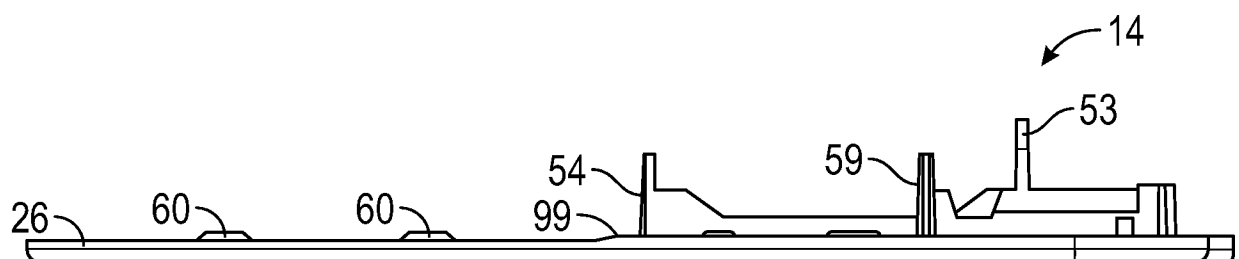


FIG. 5

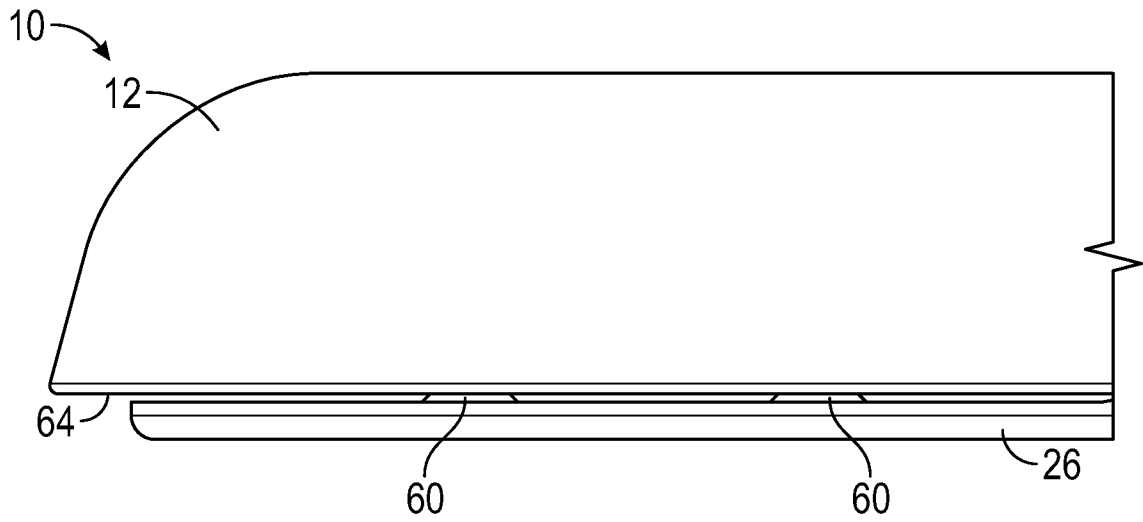


FIG. 6

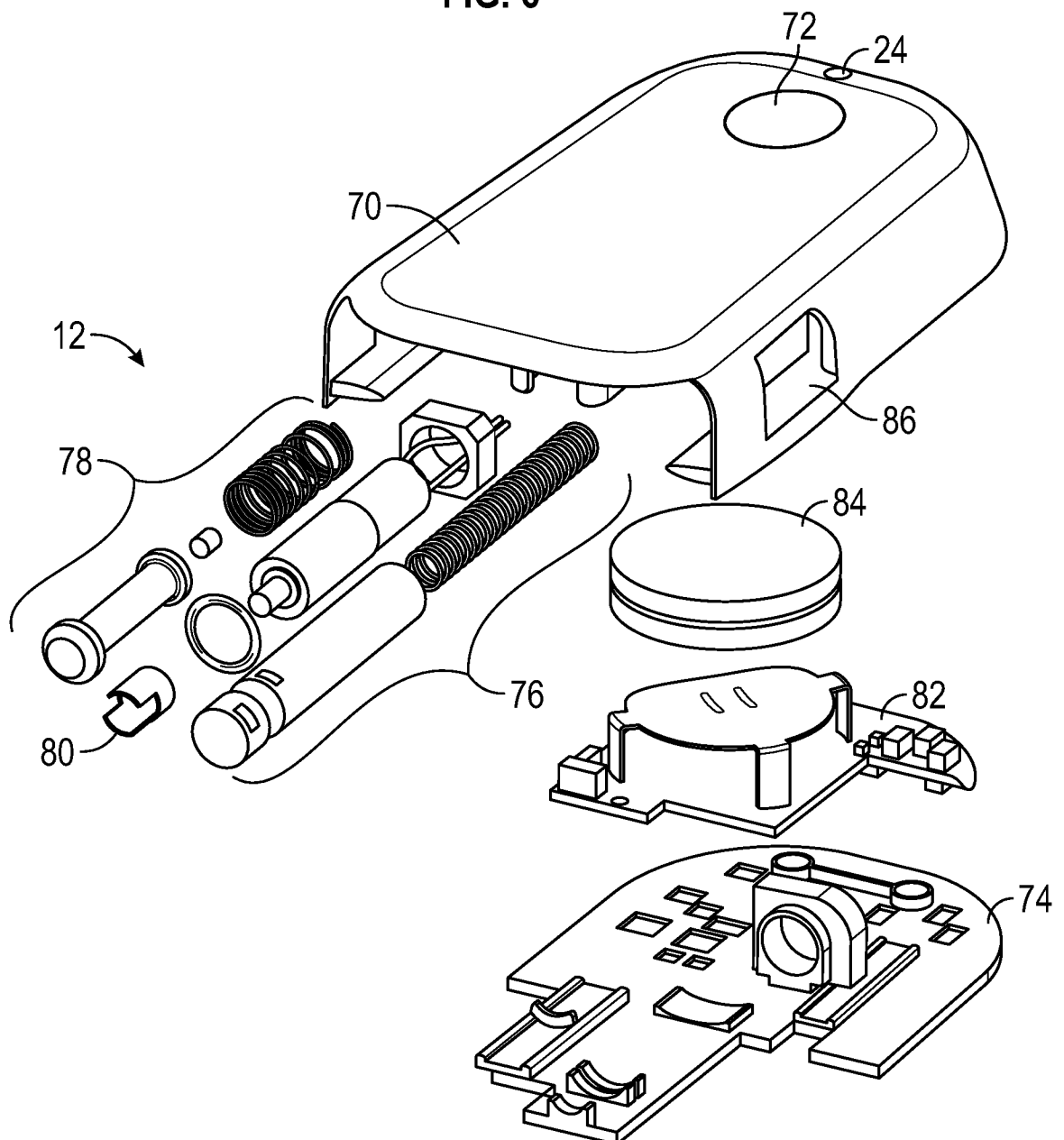


FIG. 7

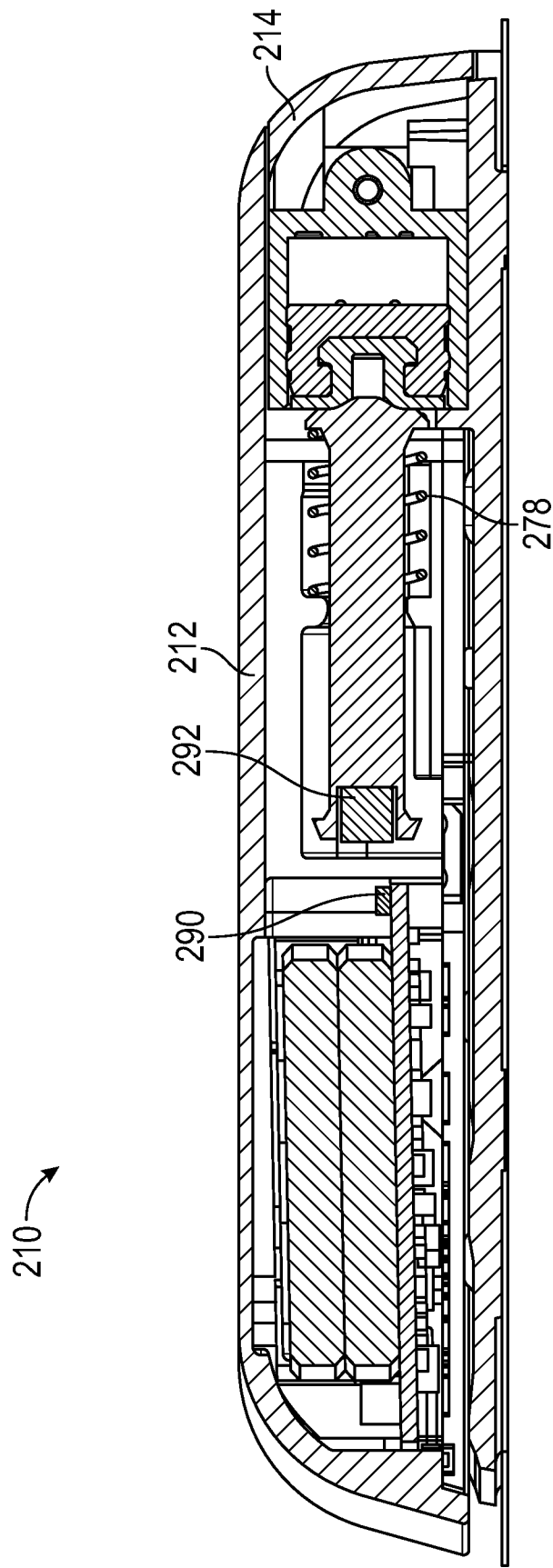


FIG. 8

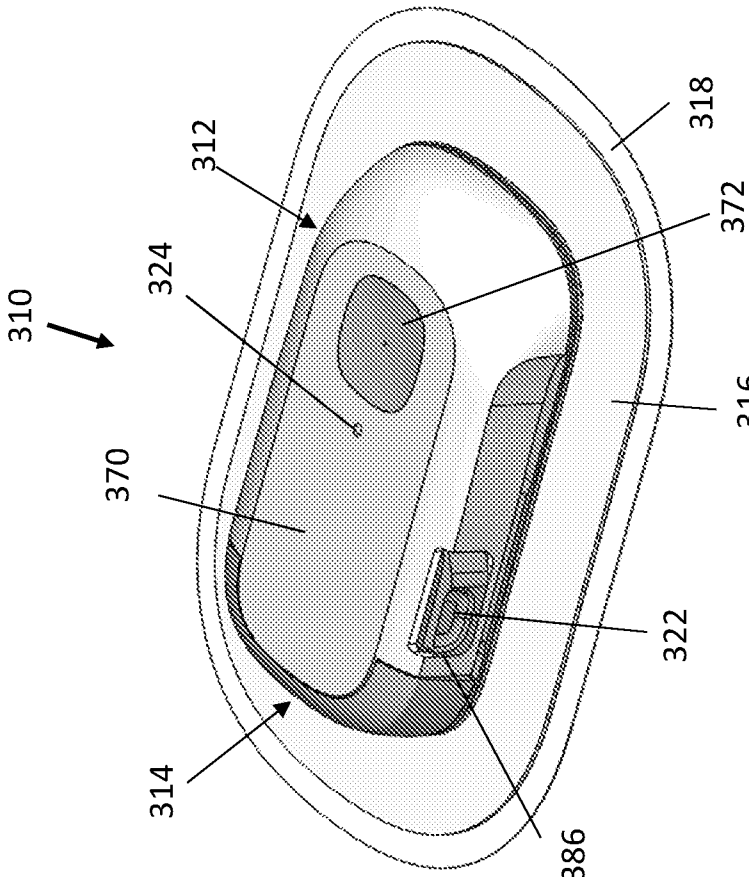


FIG. 10

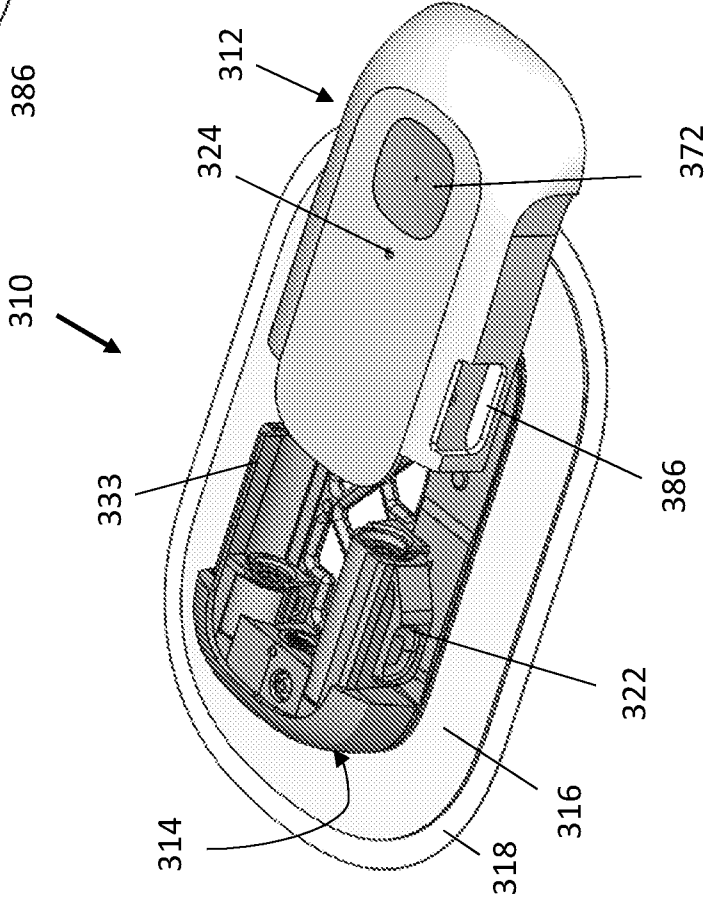
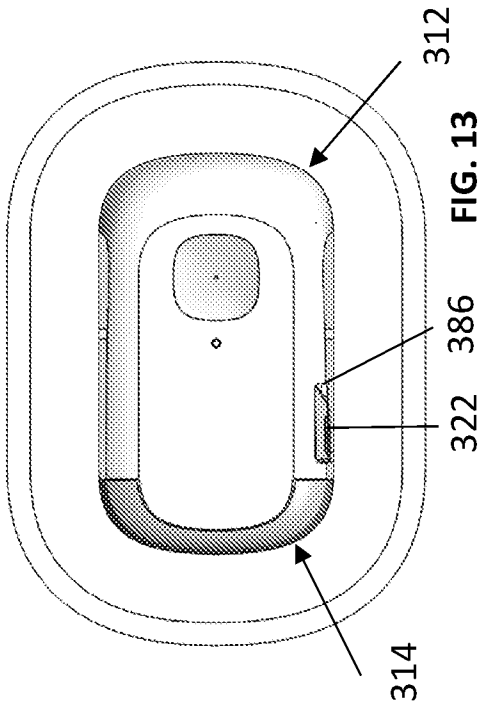
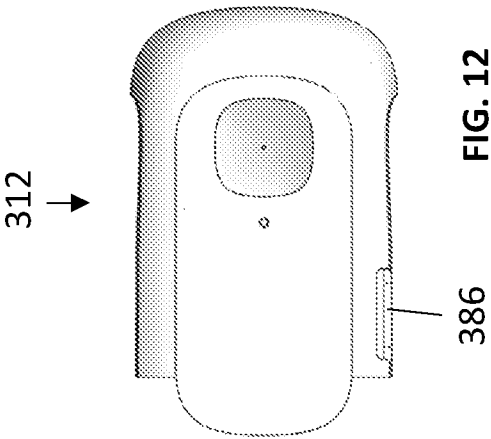
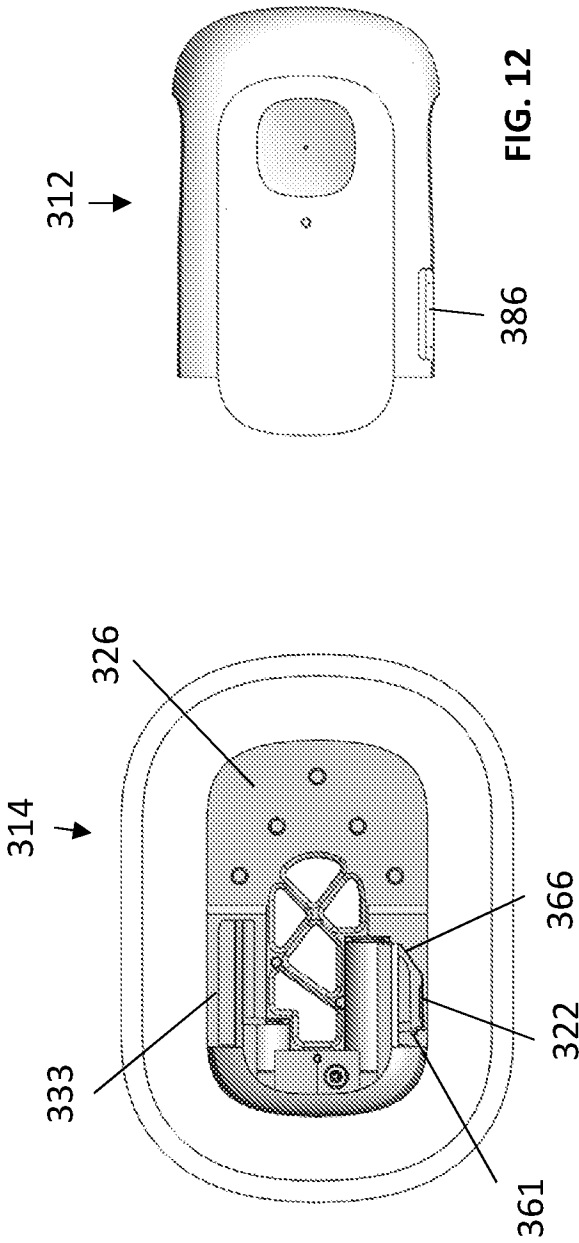


FIG. 9



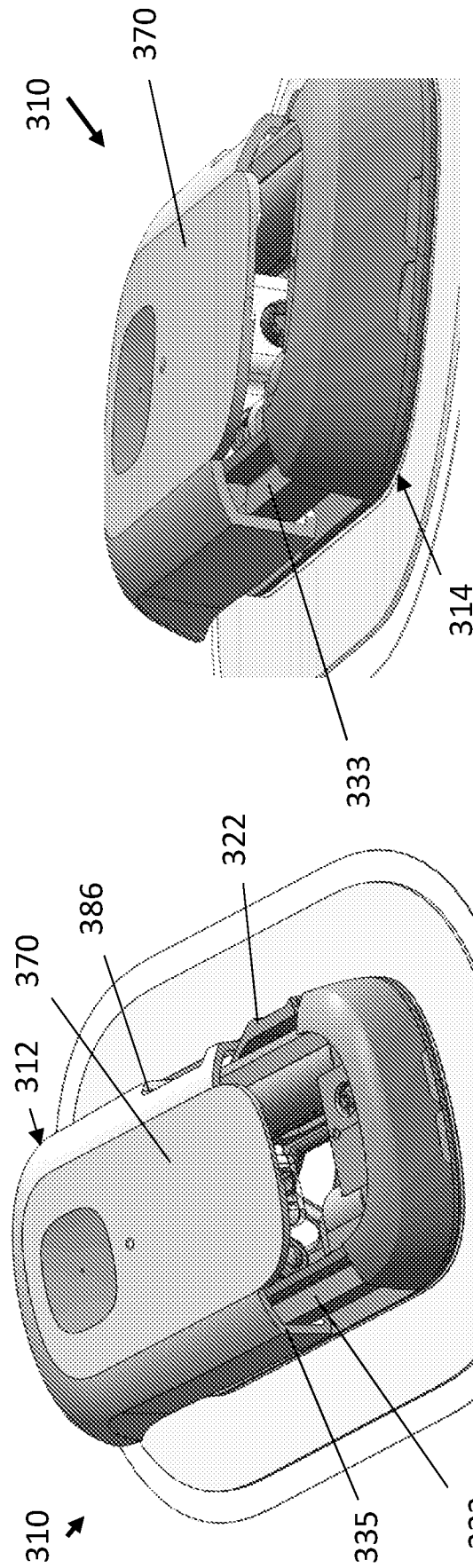


FIG. 15

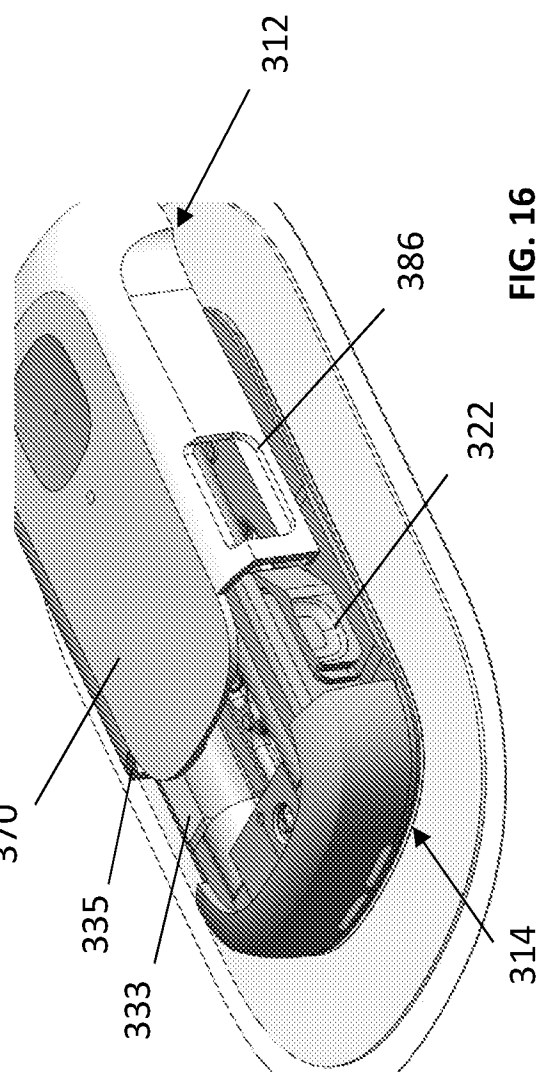


FIG. 16

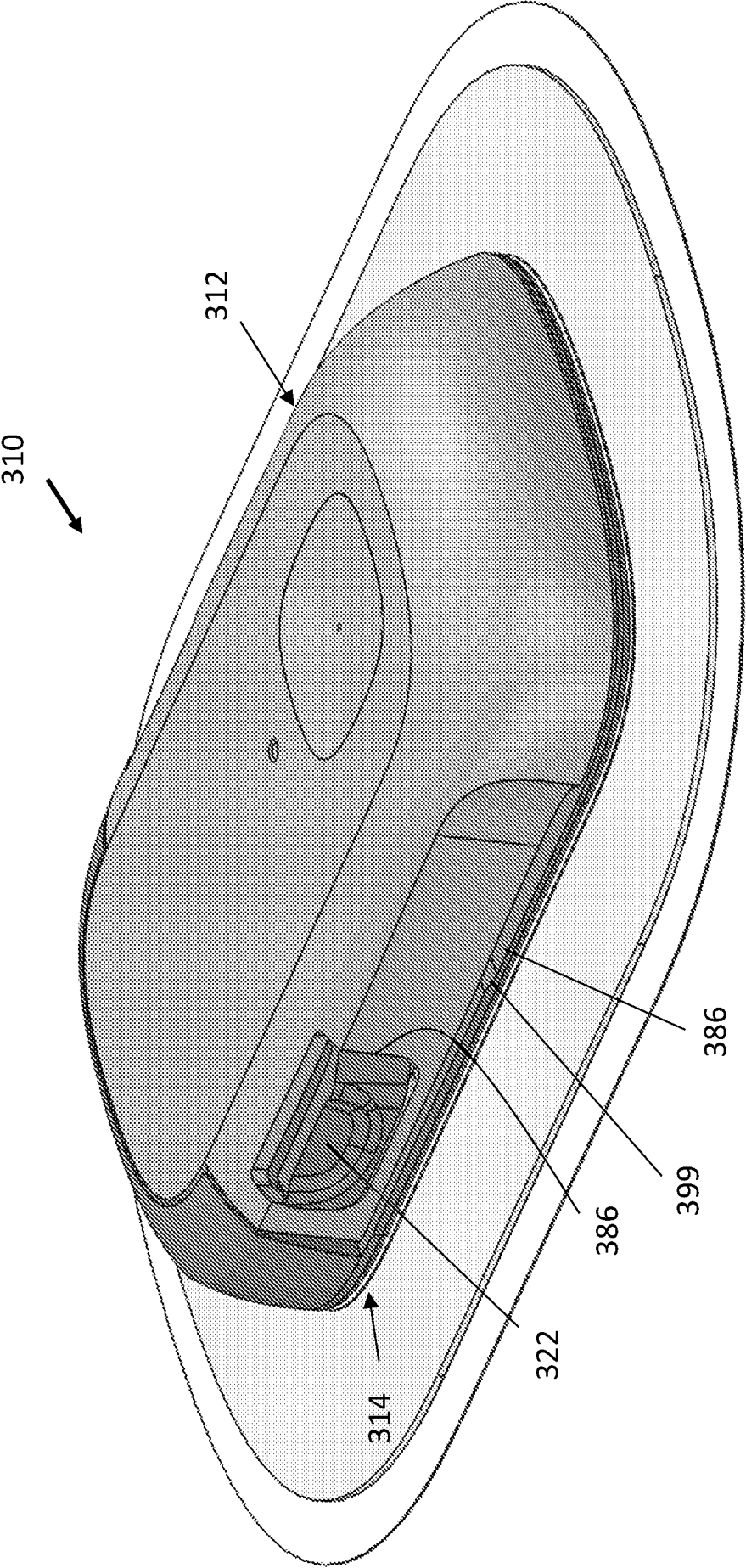


FIG. 17

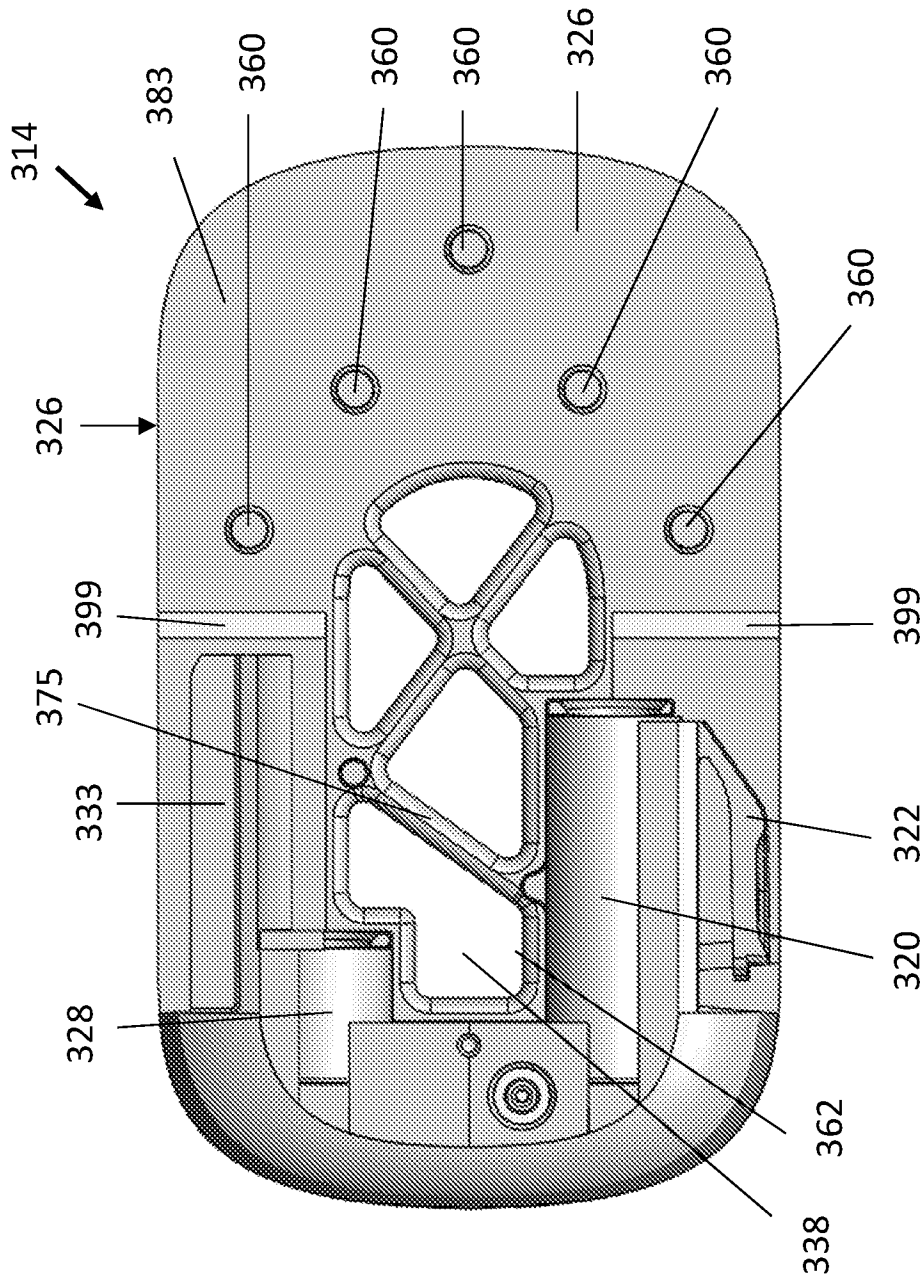


FIG. 18

FIG. 19A

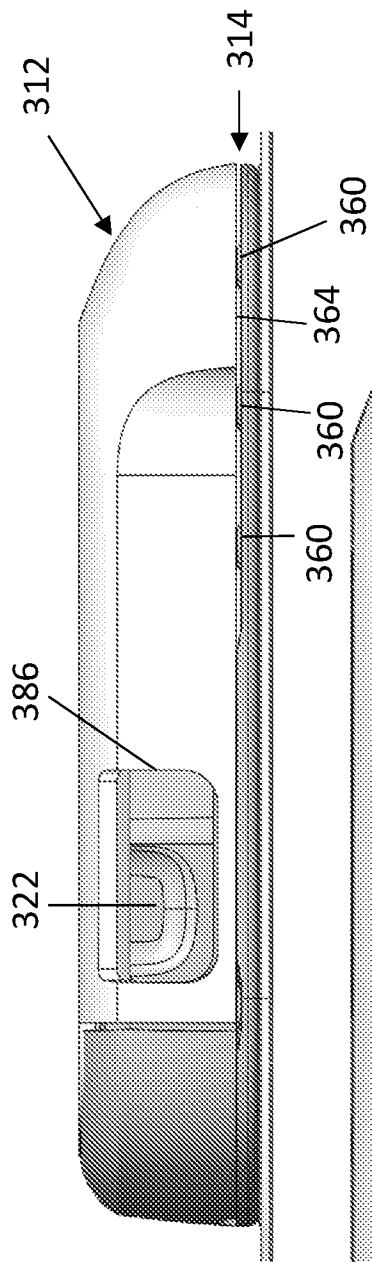


FIG. 19B

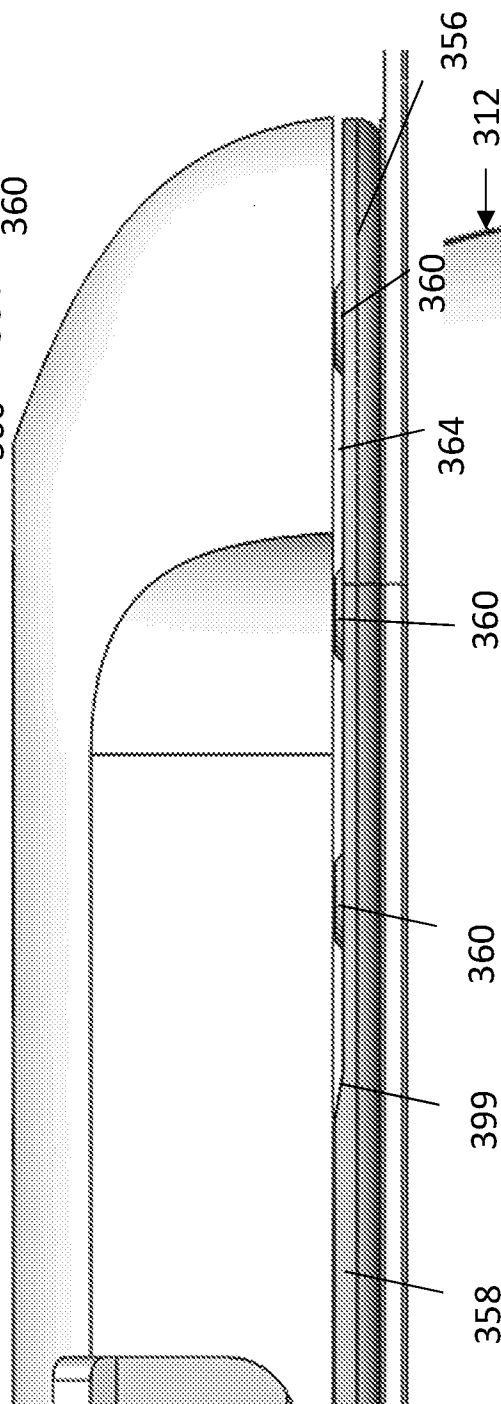
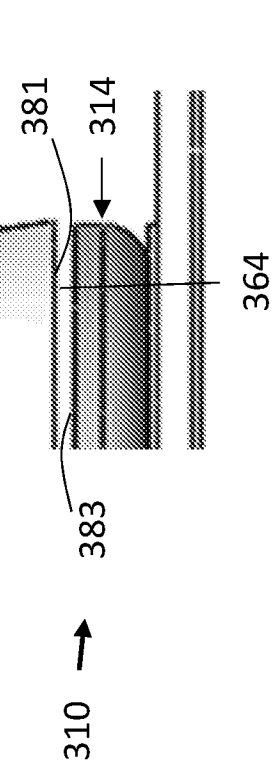


FIG. 19C



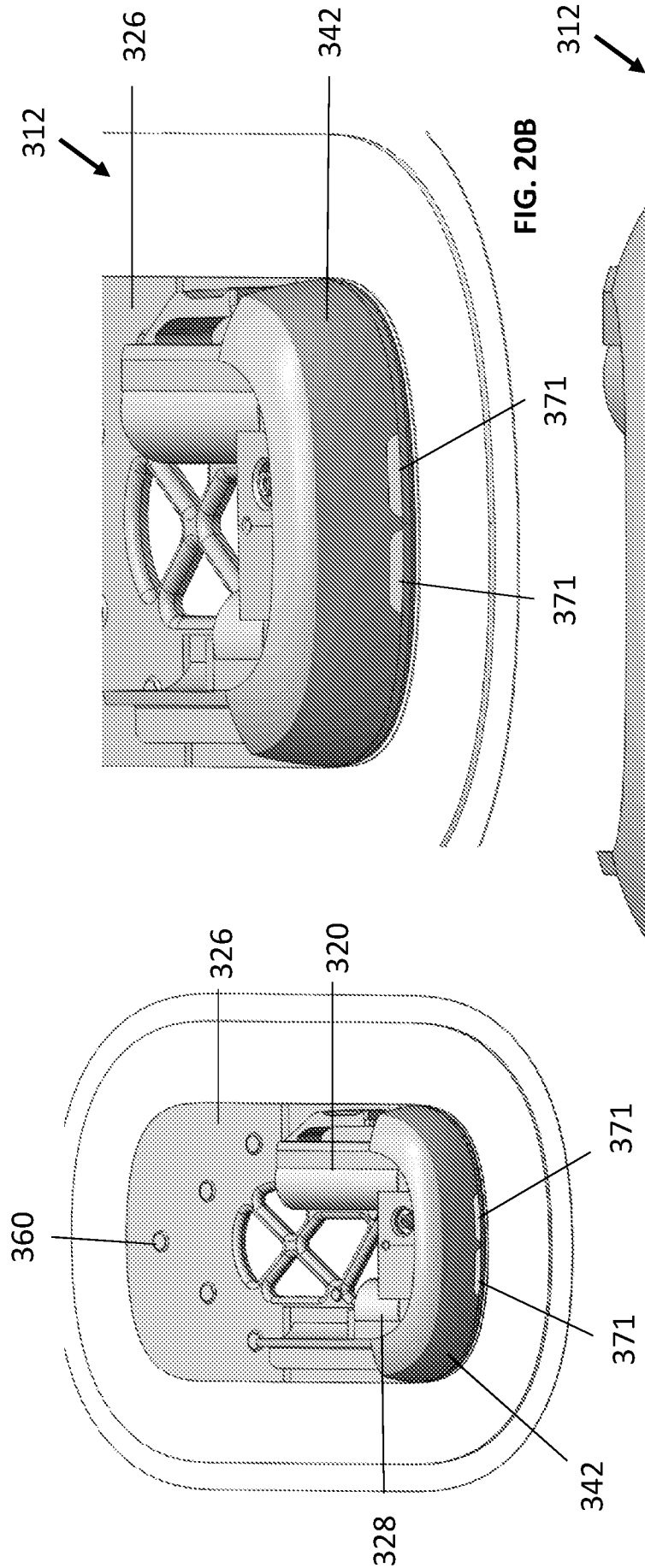


FIG. 20B

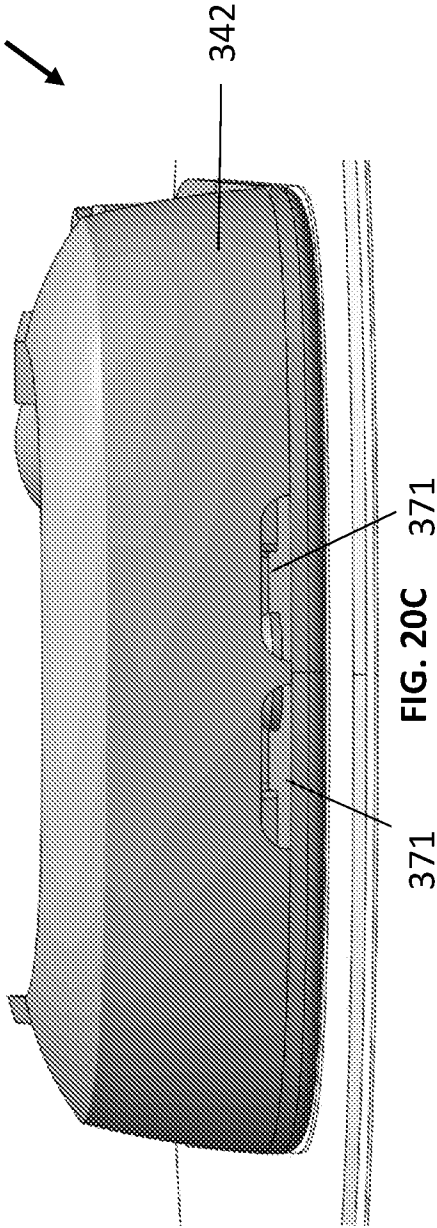


FIG. 20C

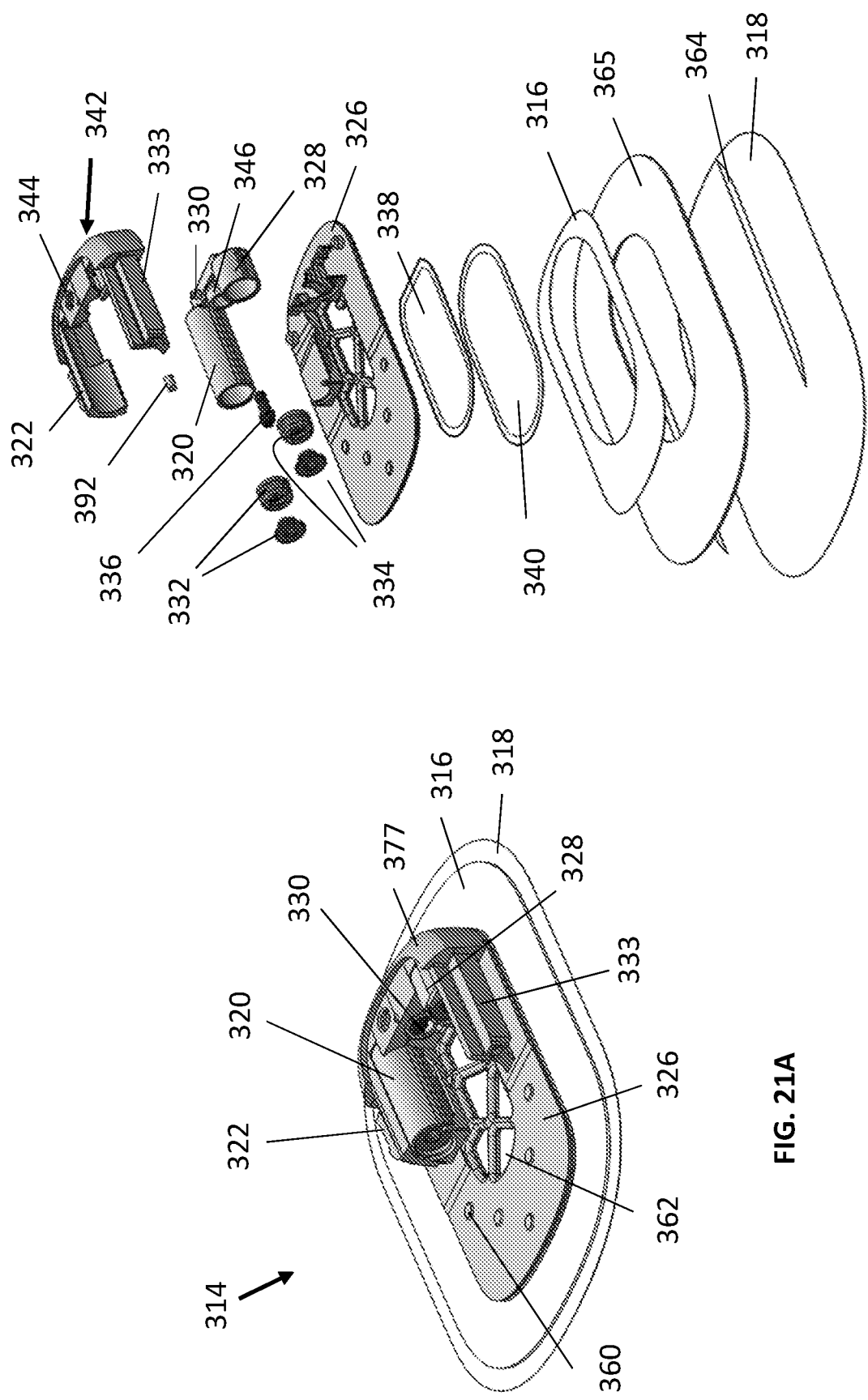


FIG. 21B

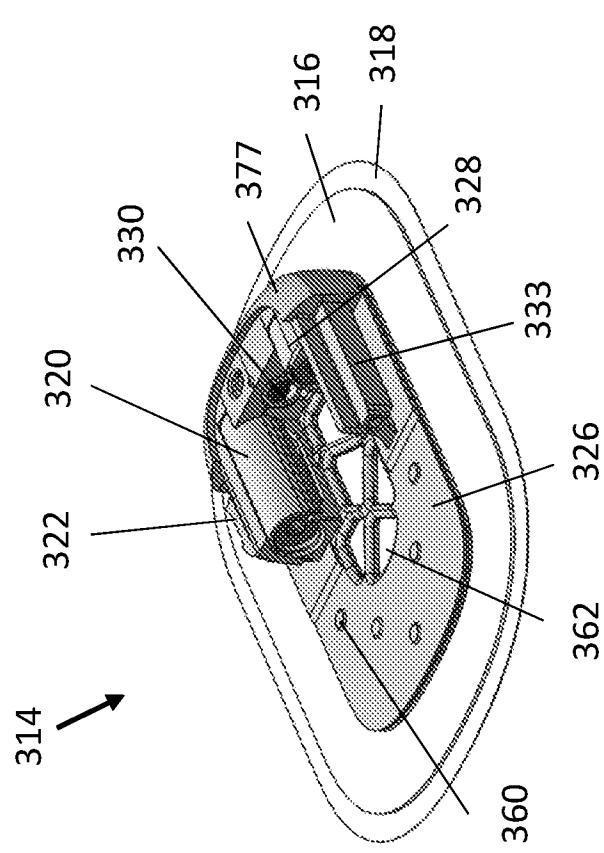


FIG. 21A

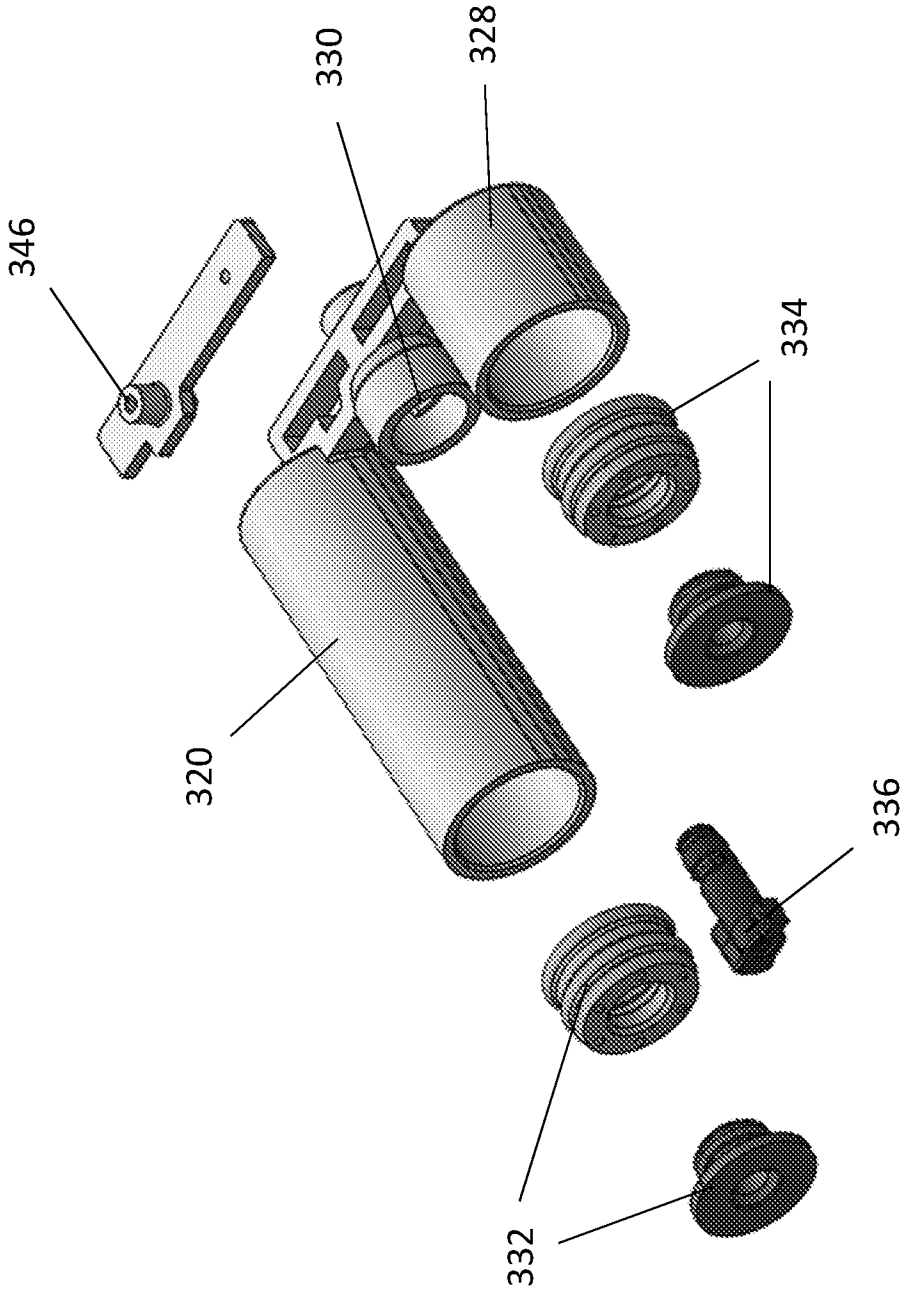


FIG. 21C

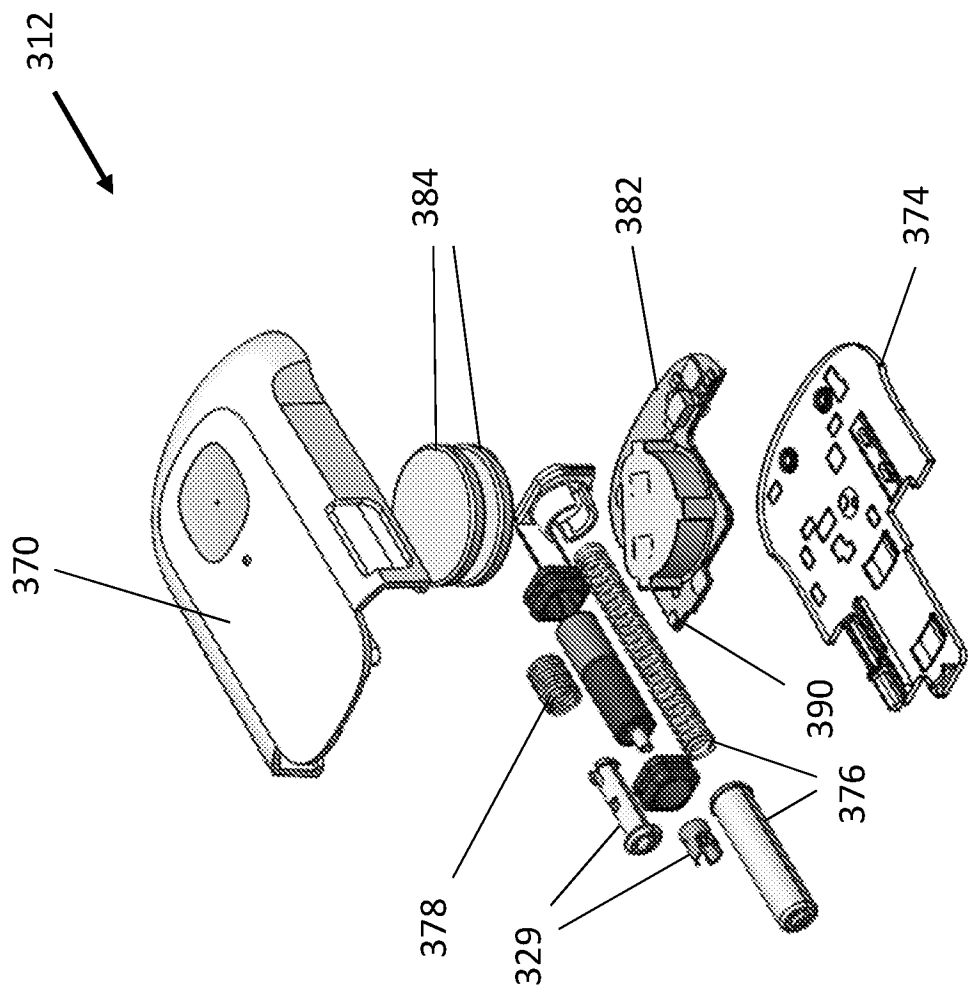


FIG. 22