IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	Beckley Psytech Ltd	Confirmation No.: 2356
Serial No.:	18/365,699	Group No.:
Filing or 371(c) Date:	August 4, 2023	Examiner: REBECCA L ANDERSON

Entitled: PHARMACEUTICALLY ACCEPTABLE SALTS AND COMPOSITIONS THEREOF

THIRD-PARTY PRE-ISSUANCE SUBMISSION

Examiner:

The following documents, which are also identified in the Form PTO/SB/429 filed herewith, are submitted for your consideration as being of potential relevance to the examination of the present application.

1. HONG WU SHEN (2011) "Nonlinear Pharmacokinetics of 5-Methoxy-N,N-dimethyltryptamine in Mice" Drug Metabolism and Disposition. 39(7): 1227-1234.
2. ALEXANDER M SHERWOOD (2020) "Synthesis and Characterization of 5-MeO-DMT Succinate for Clinical Use" ACS Omega. 5(49).
3. Int'l Pat. App. Pub. No. WO/2020/169,850 "5-METHOXY-N,N-DIMETHYLTRYPTAMINE (5-MEO-DMT) FOR TREATING DEPRESSION" (Published August 27, 2020)
4. DEEPAK GUPTA (2018) "Salts of Therapeutic Agents: Chemical, Physicochemical, and Biological Considerations" Molecules. 23(7): 1719.

Attached hereto is a claim chart providing a concise description of the relevance of each reference in the document list to the elements of the presently pending claims.

U.S.S.N. 18/365,699 Pending Claims	References
1. A salt of 5-methoxy-N,N dimethyltryptamine (5-MeO-DMT), wherein the salt is 5-MeO-DMT hydrobromide, 5-MeO-DMT phosphate, 5-MeO-DMT fumarate, 5-MeO-DMT oxalate, 5-MeO-DMT tartrate, 5-MeO-DMT benzenesulfonate, 5-MeO-DMT tosylate, 5-MeO-DMT glycolate, 5-MeO-DMT ketoglutarate, 5-MeO-DMT malate, or 5-MeO-DMT saccharinate.	1. HONG WU SHEN (2011) "Nonlinear Pharmacokinetics of 5-Methoxy-N,N-dimethyltryptamine in Mice" Drug Metabolism and Disposition. 39(7): 1227-1234. From **Chemicals and Materials**: **5-MeO-DMT oxalate** and 5-methyl-N,N-dimethyltryptamine (5-Me-DMT) **were purchased from Sigma-Aldrich (St. Louis, MO)**. 2. ALEXANDER M SHERWOOD (2020) "Synthesis and Characterization of 5-MeO-DMT Succinate for Clinical Use" ACS Omega. 5(49). From **5-MeO-DMT Dosage and Salt Form Selection: In parallel to the exploration of viable synthetic routes to 5-MeO-DMT freebase, a range of pharmaceutically acceptable salt forms were considered from acids with sufficient pKa difference to fully protonate 6, including the counterions** chloride**,** sulfate**, fumarate,** succinate**,** maleate**,** lysate, **oxalate,** benzoate**, tartrate,** mesylate, or acetate. 3. Int'l Pat. App. Pub. No. WO/2020/169,850 "5-METHOXY-N,N-DIMETHYLTRYPTAMINE (5-MEO-DMT) FOR TREATING DEPRESSION" (Published August 27, 2020) From **Claim 1**: **5-Methoxy-N,N-dimethyltryptamine (5-MeO-DMT) or a pharmaceutically acceptable salt thereof** for use in treating a patient who is diagnosed with major depressive disorder by a licensed professional in accordance with accepted medical practice. 4. DEEPAK GUPTA (2018) "Salts of Therapeutic Agents: Chemical, Physicochemical, and Biological Considerations" Molecules. 23(7): 1719. From **Abstract**: **This review summarizes several criteria for choosing the appropriate salt forms, along with the effects of salt forms on the pharmaceutical properties of APIs.** From **Solubility and Dissolution Rate: Salt formation approaches have widely been utilized to increase solubility, and therefore, the dissolution rate of a drug.** It is one of the most common methods to increase the solubility of weakly acidic and basic drugs. Hydrochloride, mesylate, **hydrobromide,** acetate, and **fumarate are the most common counterions that are used for basic chemical entities in the past 20 years,** while sodium, calcium, and potassium continue to be the most common counterions for weakly acidic drugs.

2. The salt of claim 1, wherein the salt is in a crystalline form.	1. HONG WU SHEN (2011) "Nonlinear Pharmacokinetics of 5-Methoxy-N,N-dimethyltryptamine in Mice" Drug Metabolism and Disposition. 39(7): 1227-1234. From **Chemicals and Materials**: **5-MeO-DMT oxalate** and 5-methyl-N,N-dimethyltryptamine (5-Me-DMT) **were purchased from Sigma-Aldrich (St. Louis, MO)**. 2. ALEXANDER M SHERWOOD (2020) "Synthesis and Characterization of 5-MeO-DMT Succinate for Clinical Use" ACS Omega. 5(49). From **5-MeO-DMT Dosage and Salt Form Selection: In parallel to the exploration of viable synthetic routes to 5-MeO-DMT freebase, a range of pharmaceutically acceptable salt forms were considered from acids with sufficient pKa difference to fully protonate 6, including the counterions** chloride**,** sulfate**, fumarate,** succinate**,** maleate**,** lysate, **oxalate,** benzoate**, tartrate,** mesylate, or acetate. 3. Int'l Pat. App. Pub. No. WO/2020/169,850 "5-METHOXY-N,N-DIMETHYLTRYPTAMINE (5-MEO-DMT) FOR TREATING DEPRESSION" (Published August 27, 2020) From **Claim 1**: **5-Methoxy-N,N-dimethyltryptamine (5-MeO-DMT) or a pharmaceutically acceptable salt thereof** for use in treating a patient who is diagnosed with major depressive disorder by a licensed professional in accordance with accepted medical practice. From **Description**: **Relevant variables in this context include** a) the dose of the compound, b) **the morphological state in which that compound is made available for aerosolization (e.g. in crystal form,** or in form as a thin layer), c) the amount of thermal energy to which the compound is exposed (defined by temperature and duration of exposure), and d) the volume of air introduced to create the aerosol (defined by flow rate and duration of air flow). 4. DEEPAK GUPTA (2018) "Salts of Therapeutic Agents: Chemical, Physicochemical, and Biological Considerations" Molecules. 23(7): 1719. From **Abstract**: **This review summarizes several criteria for choosing the appropriate salt forms, along with the effects of salt forms on the pharmaceutical properties of APIs.** From **Solubility and Dissolution Rate: Salt formation approaches have widely been utilized to increase solubility, and therefore, the dissolution rate of a drug.** It is one of the most common methods to increase the solubility of weakly acidic and basic drugs. Hydrochloride, mesylate, **hydrobromide,** acetate, and **fumarate are the most common counterions that are used for basic chemical entities in the past 20 years,** while sodium, calcium, and potassium continue to be the most common counterions for weakly acidic drugs.

	From **Flowability**: APIs with poor flow properties may result in final products with unacceptable uniformity content, weight variation, and physical inconsistency. **The crystalline nature of an API is mostly preferred**, as it is amenable to techniques that improve flow properties

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ELECTRONIC ACKNOWLEDGEMENT RECEIPT

APPLICATION #	RECEIPT DATE / TIME	ATTORNEY DOCKET #
18/365,699	**09/25/2024 02:49:48 PM Z ET**	

Title of Invention

Application Information

APPLICATION TYPE		PATENT #	
CONFIRMATION #		FILED BY	Jeremy Rolquin
PATENT CENTER #	67318482	FILING DATE	08/04/2023
CUSTOMER #	–	FIRST NAMED INVENTOR	
CORRESPONDENCE ADDRESS	-	AUTHORIZED BY	-

Documents

TOTAL DOCUMENTS: 11

DOCUMENT		PAGES	DESCRIPTION	SIZE (KB)
third-party-preissuance-submission.pdf		2	Third-Party Submission Under 37 CFR 1.290	52 KB
Concise-description-generated.pdf		2	Concise Description of Relevance	28 KB
Third-party-notification-request.pdf		1	Request for Notification of Non-compliant Third-Party Submission	13 KB
2_Sherwood Embedded.pdf		9	-	503 KB
2_Sherwood Embedded-NPL.pdf	(1-9)	9	Non Patent Literature	513 KB
Beckley US20240101514 3PS-5 Embedded.pdf		4	-	154 KB
Beckley US20240101514 3PS-5 Embedded-	(1-4)	4	Concise Description of Relevance	152 KB

3P.RELEVANCE.pdf				
Beckley US20240101514 3PS-5 Embedded-3P.RELEVANCE.pdf	(1-4)	4	Concise Description of Relevance	152 KB
Beckley US20240101514 3PS-5 Embedded-3P.RELEVANCE.pdf	(1-4)	4	Concise Description of Relevance	152 KB
Beckley US20240101514 3PS-5 Embedded-3P.RELEVANCE.pdf	(1-4)	4	Concise Description of Relevance	152 KB
1_Hong Wu Shen Embedded.pdf		8	-	269 KB
1_Hong Wu Shen Embedded-NPL.pdf	(1-8)	8	Non Patent Literature	278 KB
3_WO2020169850A1 Embedded.pdf		10	-	6632 KB
3_WO2020169850A1 Embedded-FOR.pdf	(1-10)	10	Foreign Reference	6628 KB
4_Gupta Embedded.pdf		15	-	463 KB
4_Gupta Embedded-NPL.pdf	(1-15)	15	Non Patent Literature	464 KB

Digest

DOCUMENT	MESSAGE DIGEST(SHA-512)
third-party-preissuance-submission.pdf	194825B87CA50BA7D8DE6B25F6D5BA33BB361A9C38C4396E0EF9C1FEA516FE87AC89E3A53F937A6A1DEEDD70B515CB506C6270D619C7369B5BFD9B49D0D97469
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Beckley US20240101514 3PS-5 Embedded-3P.RELEVANCE.pdf	E69531370B5B0FFE40C3924D1B68EB819F4DBEE6764635E9FB8A5F707DBF5E47E5D1F10F2E7D6F45862DD08005BA58CE590535EBF795E22F8C743BB3FC19A6EF
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1_Hong Wu Shen Embedded-NPL.pdf	D9A381B651D2C911B90DC992426F4057F9DD79EF25A337FBB33BF299E086B2E2F180D82CAD3559C81E4D4F64C4519BED1793B3577A54DECDA0D6115562AE7934
3_WO2020169850A1 Embedded.pdf	9DF4C8233CCDFB5884D7666B1374E4868EBB6238F287434CF40ABE2F739FAC6F6E68D143D99A2ED824FB737590F36F6699E95D9F474D9CEFBD3D39723A1EFF45
3_WO2020169850A1 Embedded-FOR.pdf	C24F7A32FC148380ED911C9EE08EAED2C11590A79DE895F1AF18AB822806A19839F07F0213CAF7662D6F6B13980936A874EB5559C5BB302659D1CE89F4F87EB7
4_Gupta Embedded.pdf	8354EC767C43BE0622C7F7C396D704BC7ED7E5A8FD31C37D976E74767269E9E2A4DAFBFFC6447F110FDE77E6819A204A1C597623FC17FC9AA37C30521E939FF8
4_Gupta Embedded-NPL.pdf	4878FC7B18B732D1B29FED6A3F52A7276DED60FD4D93D998E9CE6CC23F7D882826F6C0816F5565E4B87CB9F8F42DFB172CD8754D16C4980C4D75269A5F2B9F69

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New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement

Receipt will establish the filing date of the application

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

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ELECTRONIC PAYMENT RECEIPT

APPLICATION #	RECEIPT DATE / TIME	ATTORNEY DOCKET #
18/365,699	**09/25/2024 02:49:48 PM Z ET**	

Title of Invention

Application Information

APPLICATION TYPE		PATENT #	
CONFIRMATION #		FILED BY	Jeremy Rolquin
PATENT CENTER #	67318482	AUTHORIZED BY	-
CUSTOMER #	–	FILING DATE	08/04/2023
CORRESPONDENCE ADDRESS	-	FIRST NAMED INVENTOR	

Payment Information

PAYMENT METHOD	PAYMENT TRANSACTION ID	PAYMENT AUTHORIZED BY
CARD / 7409	**E20249OE50599002**	**Jeremy Rolquin**

FEE CODE	DESCRIPTION	ITEM PRICE($)	QUANTITY	ITEM TOTAL($)
2818	DOCUMENT FEE FOR THIRD-PARTY SUBMISSIONS (SEE 37 CFR 1.290(F))	72.00	1	72.00
			TOTAL AMOUNT:	**$72.00**

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New Applications Under 35 U.S.C. 111

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