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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
13/277,789	10/20/2011	Robert A. Ashley	512-53 DIV/CON II	4179
23869 7590 05/14/2012 HOFFMANN & BARON, LLP 6900 JERICHO TURNPIKE SYOSSET, NY 11791			EXAMINER TRAN, SUSAN T	
			ART UNIT 1615	PAPER NUMBER
			MAIL DATE 05/14/2012	DELIVERY MODE PAPER

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.

Office Action Summary	Application No.	Applicant(s)	
	13/277,789	ASHLEY, ROBERT A.	
	Examiner	Art Unit	
	SUSAN TRAN	1615	

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

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ 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.
- 4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 5) ☒ Claim(s) 21-40 is/are pending in the application.
- 5a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 6) ☐ Claim(s) ____ is/are allowed.
- 7) ☒ Claim(s) 21-40 is/are rejected.
- 8) ☐ Claim(s) ____ is/are objected to.
- 9) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 10) ☐ The specification is objected to by the Examiner.
- 11) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 12) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
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)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>02/01/12</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Claim Rejections - 35 USC § 103

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

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 21, 23, 25-28, 30, 32-35 and 38-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Perricone US 6,365,623, in view of Pflugfelder et al. US 6,455,583.

Perricone teaches a method for the treatment of pustule and papule. The method comprises orally administering an antibiotic compound. See column 5, lines 40-45; column 6, lines 20-24; and column 8, lines 24-29.

Perricone does not expressly teach the claimed amount of antibiotic compound, as well as the claimed antibiotic such as doxycycline.

Pflugfelder teaches a method for treating conditions associated with rosacea. The method comprises orally administering a tetracycline compound in a sub-antimicrobial amount that ranges from about 20% to about 80% of the normal antibiotic therapeutic dose of the particular tetracycline compound. See abstract; column 4, lines 1-10; and column 5, lines 1-12. Tetracycline compound includes doxycycline is found in column 6, line 5; and claim 3.

Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to optimize the method of Perricone to administer antibiotic

compound in a sub-antimicrobial amount in view of the teachings of Pflugfelder. This is because: 1) Pflugfelder teaches the use of an antibiotic compound for the treatment of rosacea related conditions is known in the art; 2) Pflugfelder teaches that long term administration of antibiotic compound in a sub-antimicrobial amount will minimized tetracycline advert side-effects such as nausea, vomiting, diarrhea, and epigastric pain (column 1, lines 48-63); and 3) Perricone teaches the desirability for administering antibiotic compound in a lower dosage amount to eliminate advert side-effect such as nausea, GI upset, yeast infection, and interactions with other medication (column 8, lines 30-40).

Claims 24, 25, 31, 32, 37 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Perricone US 6,365,623, in view of Pflugfelder et al. US 6,455,583 and Sheth et al. US 5,300,304.

Perricone is relied upon for the reasons stated above. The reference is silent with respect to the once-a-day sustained release dosage.

Sheth teaches a pulsatile once-a-day dosage form of a non-toxic acid tetracycline compound for the treatment of acne. See abstract; columns 5-6; and claims.

Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to optimize the composition of Perricone to include a once-a-day antibiotic composition because Sheth teaches an antibiotic once-a-day dosage form is known in the art.

Claims 22, 29 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Perricone US 6,365,623, in view of Pflugfelder et al. US 6,455,583 and Heesch US 2002/0165220 A1.

Perricone is relied upon for the reasons stated above. Perricone does not teach the hyclate salt of doxycycline.

Heesch teaches a tetracycline compound useful for the treatment of acne includes doxycycline. Heesch further teaches that doxycycline hyclate exhibits better advantage over the doxycycline compound. See abstract; paragraphs 0093-0094 and claims.

Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to optimize the composition of Perricone to include the hyclate salt of the antibiotic compound in view of the teachings of Heesch. This is because doxycycline monohydrate (hyclate) provides lower dosage requirement, and because Perricone teaches the desirability for lower antibiotic dosage.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SUSAN TRAN whose telephone number is (571)272-0606. The examiner can normally be reached on M-F 8:30 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax can be reached on (571) 272-0623. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/S. TRAN/
Primary Examiner, Art Unit 1615

Notice of References Cited	Application/Control No. 13/277,789		Applicant(s)/Patent Under Reexamination ASHLEY, ROBERT A.	
	Examiner SUSAN TRAN		Art Unit 1615	Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
*	A	US-5,300,304	04-1994	Sheth et al.	424/490
*	B	US-6,365,623	04-2002	Perricone, Nicholas V.	514/448
*	C	US-6,455,583	09-2002	Pflugfelder et al.	514/528
*	D	US-2002/0165220	11-2002	Heesch, Gary V.	514/210.09
	E	US-			
	F	US-			
	G	US-			
	H	US-			
	I	US-			
	J	US-			
	K	US-			
	L	US-			
	M	US-			

FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
	N					
	O					
	P					
	Q					
	R					
	S					
	T					

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
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*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

Doc code: IDS

PTO/SB/08a (01-10)

Doc description: Information Disclosure Statement (IDS) Filed

Approved for use through 07/31/2012. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number		13277789
	Filing Date		2011-10-20
	First Named Inventor	Robert Ashley	
	Art Unit		
	Examiner Name		
	Attorney Docket Number	512-53 DIV/CON II	

U.S.PATENTS						Remove
Examiner Initial*	Cite No	Patent Number	Kind Code ¹	Issue Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear
	1	5998390		1999-12-07	Ramamurthy et al.	
	2	5908838		1999-06-01	Gans	
	3	5827840		2008-10-27	Ramamurthy et al.	
	4	5122519		1992-06-16	Ritter	
	5	5674539		1997-10-07	Tomas et al.	
	6	6673843		2004-01-06	Arbiser	
	7	4704383		1987-11-03	McNamara, et al.	
	8	7014858		2006-03-21	Robert A. Ashley	

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /S.T./

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

Application Number		03277789
Filing Date		2011-10-20
First Named Inventor	Robert Ashley	
Art Unit		
Examiner Name		
Attorney Docket Number	512-53 DIV/CON II	

	9	6455583		2007-09-24	Pflugfelder et al.	
	10	5260292		1993-11-09	Robinson et al.	
	11	5532227		1996-07-02	Golub et al.	
	12	5045538		1991-09-03	Schneider et al.	
	13	6294200		2001-09-25	Conte et al.	

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U.S.PATENT APPLICATION PUBLICATIONS

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Examiner Initial*	Cite No	Publication Number	Kind Code ¹	Publication Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear
	1	20030082120		2003-05-01	Milstein	
	2	20030148945		2003-08-07	McNicol et al.	
	3	20050239723		2005-10-27	Amin et al.	

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

Application Number		1327789
Filing Date		2011-10-20
First Named Inventor	Robert Ashley	
Art Unit		
Examiner Name		
Attorney Docket Number		512-53 DIV/CON II

Examiner Initial*	Cite No	Foreign Document Number ³	Country Code ² j	Kind Code ⁴	Publication Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear	T ⁵
	1	EP 0 410 099	EP	A1	1991-01-30			<input type="checkbox"/>
	2	WO 83/00628	WO		1983-03-03			<input type="checkbox"/>
	3	WO 99/58131	WO		1999-11-18			<input type="checkbox"/>
	4	WO 00/028983	WO		2000-05-25			<input type="checkbox"/>
	5	WO 00/15235	WO		2000-03-23			<input type="checkbox"/>
	6	WO 00/18230	WO		2011-04-06			<input type="checkbox"/>
	7	JP-A-2001-72660	JP		2001-03-21		abstract	<input checked="" type="checkbox"/>
	8	JP-A-5-509288	JP		1993-12-22		abstract	<input checked="" type="checkbox"/>
	9	WO 00/07601	WO		2001-02-17			<input type="checkbox"/>
	10	WO 98/08480	WO		1998-03-05			<input type="checkbox"/>

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

Application Number		13277789
Filing Date		2011-10-20
First Named Inventor	Robert Ashley	
Art Unit		
Examiner Name		
Attorney Docket Number	512-53 DIV/CON II	

11	WO 92/03133	WO		1992-03-05			<input type="checkbox"/>
12	WO 98/05340	WO		1998-02-12			<input type="checkbox"/>
13	JP-A-91-88617	JP		1997-07-22		abstract	<input checked="" type="checkbox"/>

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NON-PATENT LITERATURE DOCUMENTS

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Examiner Initials*	Cite No	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, pages(s), volume-issue number(s), publisher, city and/or country where published.	T ⁵
	1	Akamatsu, et al. "Effect of Keigai-Rengyo-To, a Japanese Kampo Medicine, on Neutrophil Functions: a Possible Mechanism of Action of Keigai-Rengyo-To in Acne," The Journal of International Medical Research, 25: 255-265 (1997).	<input type="checkbox"/>
	2	Baer, et al. "High-Dose Tetracycline Therapy in Severe Acne," Arch Dermatol, 112:479-481 (April 1976).	<input type="checkbox"/>
	3	Cheryl Guttman, "Emerging resistance changes face of antibiotic therapy for acne," Dermatology Times, January 2001, page 22.	<input type="checkbox"/>
	4	Hirohiko Akamatsu, Maki Asada, Jinro Komura, Yasuo Asada, and Yukie Niwa, "Effect of Doxycycline on the Generation of Reactive Oxygen Species: A Possible Mechanism of Action of Acne Therapy with Doxycycline," Acta Derm Venereol (Stockh) 72:178-178 (1992).	<input type="checkbox"/>
	5	Bodokh, Y. Jacomet, J. Ph. Lacour and J.P. Ortonne, "Minocycline Induces an Increase in the Number of Excreting Pilosebaceous Follicles in Acne Vulgaris," Acta Derm Venereol (Stockh), 77:255-259 (1997).	<input type="checkbox"/>
	6	W. J. Cunliffe, M.D., F.R.C.P., "Evolution of a Strategy for the Treatment of Acne," J Am Acad Dermatol, 16:591-9 (1987).	<input type="checkbox"/>

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /S.T./

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

Application Number		13277789
Filing Date		2014-10-29
First Named Inventor	Robert Ashley	
Art Unit		
Examiner Name		
Attorney Docket Number	512-53 DIV/CON II	

7	E. Anne Eady, Eileen Ingham, Christina E. Walters, Jonathan H. Cove, and William J. Cunliffe, "Modulation of Comedonal Levels of Interleukin-1 in Acne Patients Treated with Tetracyclines," J. Invest Dermatol, 101:86-91 (1993).	<input type="checkbox"/>
8	Boni E. Elewski, M.D., Beth A.J. Lamb, W. Mitchell Sams, Jr., M.D., and W. Ray Gammon, M.D., "In Vivo Suppression of Neutrophil Chemotaxis by Systemically and Topically Administered Tetracycline," J Am Acad Dermatol, 8:807-812 (1983).	<input type="checkbox"/>
9	Nancy B. Esterly, M.D., Nancy L. Furey, M.D., and Lillian E. Flanagan, B.S., "The Effect of Antimicrobial Agents on Leukocyte Chemotaxis," The Journal of Investigative Dermatology, 70(1):51-55 (1978).	<input type="checkbox"/>
10	Sainte-Marie, I. Tenaud, O. Jumbou and B. Dréno, "Minocycline Modulation of Alpha-MSH Production by Keratinocytes In vitro," Acta Derm Venereol 79:265-267 (1999).	<input type="checkbox"/>
11	Hoshiki Miyachi, M.D., Akira Yoshioka, M.D., Sadao Imamura, M.D., and Yukie Niwa, M.D., "Effect of Antibiotics on the Generation of Reactive Oxygen Species," J Invest Dermatol, 86(4):449-453 (1986).	<input type="checkbox"/>
12	Gerd Plewig, M.D., and Erwin Schöpf, M.D., "Anti-Inflammatory Effects of Antimicrobial Agents: An In Vivo Study," The Journal of Investigative Dermatology, 65:532-536 (1975).	<input type="checkbox"/>
13	M. Toyoda and M. Morohashi, "An Overview of Topical Antibiotics for Acne Treatment," Dermatology, 196:130-134 (1998).	<input type="checkbox"/>
14	Sheila E. Unkles, and Curtis G. Gemmell, "Effect of Clindamycin, Erythromycin, Lincomycin, and Tetracycline on Growth and Extracellular Lipase Production by Propionibacteria In Vitro," Antimicrobial Agents and Chemotherapy, 21:39-43 (1982).	<input type="checkbox"/>
15	G.F. Webster, K.J. McGinley, and J.J. Leyden, "Inhibition of Lipase Production in Propionibacterium acnes by Sub-Minimal-Inhibitory Concentrations of Tetracycline and Erythromycin," British Journal of Dermatology, 104:453-457 (1981).	<input type="checkbox"/>
16	Guy F. Webster, M.D., Ph.D., Susan M. Toso, M.S., and Lutz Hegemann, M.D., Ph.D., "Inhibition of a Model of In Vitro Granuloma Formation by Tetracyclines and Ciprofloxacin," Arch Dermatol., 130:748-752 (1994).	<input type="checkbox"/>
17	Reynold C. Wong, M.D., Sewon Kang, M.P.H., Jan L. Heezen, L.P.N., John J. Voorhees, M.D., and Charles N. Ellis, M.D., "Oral Ibuprofen and Tetracycline for the Treatment of Acne Vulgaris," J Am Acad Dermatol, 11:1076-1081 (1984).	<input type="checkbox"/>

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18	Kenneth S. Kornman and Edward H. Karl, "The Effect of Long-Term Low-Dose Tetracycline Therapy on the Subgingival Microflora in Refractory Adult Periodontitis," J. Periodontol., 53(10):604-610 (October 1982).	<input type="checkbox"/>
19	Bikowski, J.B., "Treatment of rosacea with doxycycline monohydrate," Curtis. 2000 Aug., 66(2):149-152.	<input type="checkbox"/>
20	Jimenez-Acosta, "Response to tetracycline of telangiectasias in male hemophiliac with human immunodeficiency virus infection," J. Am. Acad. Dermatol. 1988 Aug., 19(2 Pt. 1):369-379.	<input type="checkbox"/>
21	Torresani, C., "Clarithromycin versus doxycycline in the treatment of rosacea," Int. J. Clin. Dermatol. 1997 Dec., 36 (12):942-946.	<input type="checkbox"/>
22	McClellan, K.J., "Topical Metronidazole. A review of its use in rosacea," Am. J. Clin. Dermatol. 2000 May-June, 1 (3):191-199.	<input type="checkbox"/>
23	Quarterman, M.J., "Ocular Rosacea. Signs, symptoms and tear studies before and after treatment with doxycycline," Arch. Dermatol. 1997 Jan., 133(1):49-54.	<input type="checkbox"/>
24	Skidmore et al., "Effects of Subantimicrobial-Dose Doxycycline in the Treatment of Moderate Acne," Archives of Dermatology 139:459-464 (April 2003), XP009047590.	<input type="checkbox"/>
25	Akamatsu, et al. "Effects of subminimal inhibitory concentrations of minocycline on neutrophil chemotactic factor production in comedonal bacteria, neutrophil phagocytosis and oxygen metabolism." Arch Dermatol Res 283:524-528 (1991).	<input type="checkbox"/>
26	Bikowski, et al. "Treatment of rosacea with doxycycline monohydrate" Cutis, 66:149-152 (Aug 2000).	<input type="checkbox"/>
27	Golub, et al. "Tetracyclines inhibit connective tissue breakdown: New therapeutic implications for an old family of drugs" Critical Reviews in Oral Biology and Medicine, 2(2):297-322 (1991)	<input type="checkbox"/>
28	Illig "Positive side effects of antibiotic and antimicrobial substances in therapy" Infection 7 (Suppl. 6): S 584-588 (1979) (English translation. Original document in German.)	<input type="checkbox"/>

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	29	Knight, et al. "A follow-up of tetracycline-treated rosacea" British Journal of Dermatology 93:577-580 (1975).	<input type="checkbox"/>
	30	Marks, et al. "Comparative effectiveness of tetracycline and ampicillin in rosacea" The Lancet, 1049-1052 (November 13, 1971).	<input type="checkbox"/>
	31	Millar, et al. "A general practice study investigating the effect of minocycline (Minocin) 50 mg bd for 12 weeks in the treatment of acne vulgaris" The British Journal of Clinical Practice 41(8):882-886 (August 1987)	<input type="checkbox"/>
	32	Plewig, et al. Acne: Morphogenesis and Treatment, Springer-Verlag 297-301 (1975)	<input type="checkbox"/>
	33	Webster, et al. "Suppression of Polymorphonuclear Leukocyte Chemotactic Factor Production in Propionibacterium acnes by Subminimal Inhibitory Concentrations of Tetracycline, Ampicillin, Minocycline, and Erythromycin" Antimicrobial Agents and Chemotherapy 21(5):770-772 (1982)	<input type="checkbox"/>

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EXAMINER SIGNATURE

Examiner Signature	/Susan Tran/	Date Considered	05/07/2012
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*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /S.T./

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

Application Number	13277789
Filing Date	2011-10-20
First Named Inventor	Robert Ashley
Art Unit	
Examiner Name	
Attorney Docket Number	512-53 DIV/CON II

CERTIFICATION STATEMENT

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

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

OR

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

- ☐ See attached certification statement.
- ☐ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.
- ☒ A certification statement is not submitted herewith.

SIGNATURE

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

Signature	/susan a. sipos/	Date (YYYY-MM-DD)	2012-02-01
Name/Print	Susan A. Sipos	Registration Number	43,128

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BIB DATA SHEET

CONFIRMATION NO. 4179

SERIAL NUMBER 13/277,789	FILING or 371(c) DATE 10/20/2011 RULE	CLASS 424	GROUP ART UNIT 1615	ATTORNEY DOCKET NO. 512-53 DIV/CON II		
APPLICANTS Robert A. Ashley, Newtown, PA; ** CONTINUING DATA ***** This application is a CON of 11/876,478 10/22/2007 PAT 8,052,983 which is a CON of 10/757,656 01/14/2004 ABN which is a DIV of 10/117,709 04/05/2002 PAT 7,211,267 which claims benefit of 60/325,489 09/26/2001 and claims benefit of 60/281,916 04/05/2001 ** FOREIGN APPLICATIONS ***** ** IF REQUIRED, FOREIGN FILING LICENSE GRANTED ** 11/28/2011						
Foreign Priority claimed <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No 35 USC 119(a-d) conditions met <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No Verified and /SUSAN T. TRAN/ Acknowledged Examiner's Signature		<input type="checkbox"/> Met after Allowance Initials	STATE OR COUNTRY PA	SHEETS DRAWINGS 1	TOTAL CLAIMS 20	INDEPENDENT CLAIMS 1
ADDRESS HOFFMANN & BARON, LLP 6900 JERICHO TURNPIKE SYOSSET, NY 11791 UNITED STATES						
TITLE METHODS OF TREATING ACNE						
FILING FEE RECEIVED 1940	FEES: Authority has been given in Paper No. _____ to charge/credit DEPOSIT ACCOUNT No. _____ for following:		<input type="checkbox"/> All Fees <input type="checkbox"/> 1.16 Fees (Filing) <input type="checkbox"/> 1.17 Fees (Processing Ext. of time) <input type="checkbox"/> 1.18 Fees (Issue) <input type="checkbox"/> Other _____ <input type="checkbox"/> Credit			