

PROVISIONAL APPLICATION COVER SHEET

This is a request for filing a PROVISIONAL APPLICATION under 37 CFR 1.53 (b)(2).

18351 U.S. PTO
09/15/03

19587 U.S. PTO
60/503137
09/15/03

Docket Number		D-3111P		Type a plus sign (+) inside this box -	+
INVENTOR(S)/APPLICANT(S)					
LAST NAME	FIRST NAME	MIDDLE INITIAL	RESIDENCE (CITY AND EITHER STATE OR FOREIGN COUNTRY)		
Acheampong Tang-Liu Chang Power	Andrew Diane James David	N. F.	Irvine, CA Newport Beach, CA Newport Beach, CA Trabuco Canyon, CA		
TITLE OF THE INVENTION (280 characters max)					
METHODS OF PROVIDING THERAPEUTIC EFFECTS USING CYCLOSPORIN COMPONENTS					
CORRESPONDENCE ADDRESS					
FRANK J. UXA 4 VENTURE, SUITE IRVINE, CA 92618					
STATE	CA	ZIP CODE	92618	COUNTRY	USA
ENCLOSED APPLICATION PARTS (check all that apply)					
X	Specification	Number of Pages	33	Small Entity Statement	
	Drawing(s)	Number of Sheets		Other(specify)	
METHOD OF PAYMENT (check one)					
	A check or money order is enclosed to cover the Provisional filing fee			PROVISIONAL FILING FEE AMOUNT (\$)	\$160.00
X	The Commissioner is hereby authorized to charge filing fees and credit deposit Account Number:		01-0885		

The invention was made by an agency of the United States Government or under a contract with an agency of the United States Government.

- No.
- Yes, the name of the U.S. Government agency and the Government contract number are: _____

I hereby appoint the following attorney(s) and/or agent(s) to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith

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Respectfully submitted,

SIGNATURE

FRANK J. UXA, REG. NO. 25,612

Date **SEPTEMBER 15, 2003**

- Additional inventors are being named on separately numbered sheets attached hereto

PROVISIONAL APPLICATION FILING ONLY

SEND TO: Commissioner of Patents, PO Box 1450, Alexandria, VA 22313-1450

DOCKET NO.: D-3111P

THE ENCLOSED PROVISIONAL PATENT APPLICATION OF ACHEAMPONG
ET AL IS BEING FILED IN ACCORDANCE WITH SECTION 37 CFR
1.10 BY EXPRESS MAIL AND SHOULD BE ACCORDED A FILING DATE

September 15, 2003

SEE THE EXPRESS MAIL CERTIFICATE ATTACHED TO THE APPLICATION.

D-3111P

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
PATENT

In re application of:
ACHEAMPONG ET AL.) Group Art Unit: N/A
Serial No. N/A) Examiner: N/A
Dated: Submitted herewith)
For: METHODS OF PROVIDING THERAPEUTIC)
EFFECTS USING CYCLOSPORIN)
COMPONENTS) ATTN: MS PROVISIONAL
PATENT APPLICATION

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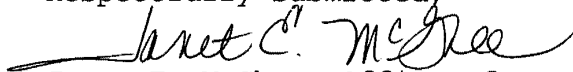
Date of Deposit: SEPTEMBER 15, 2003

I hereby certify that the following documents as identified below are being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.10 on the date indicated above and are addressed to the Commissioner for Patents, MS Provisional Patent Application, PO Box 1450, Alexandria, VA 22313-1450.

1. Provisional Application Cover Sheet;
2. Application Data Sheet
3. Application
4. Return receipt postcard.

The 4 above-identified documents are enclosed herewith.

Respectfully submitted,



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METHODS OF PROVIDING THERAPEUTIC EFFECTS
USING CYCLOSPORIN COMPONENTS

5 The present invention relates to methods of providing
desired therapeutic effects to humans or animals using
compositions including cyclosporin components. More
particularly, the invention relates to methods including
administering to an eye of a human or animal a
therapeutically effective amount of a cyclosporin component
10 to provide a desired therapeutic effect, preferably a
desired ophthalmic or ocular therapeutic effect.

The use of cyclosporin-A and cyclosporin A derivatives
to treat ophthalmic conditions has been the subject of
various patents, for example Ding et al U.S. Patent
15 5,474,979; Garst U.S. Patent 6,254,860; and Garst U.S.
6,350,442, this disclosure of each of which is incorporated
in its entirety herein by reference. In addition,
cyclosporin A compositions used in treating ophthalmic
conditions is the subject of a number of publications.
20 Such publications include, for example, "Blood
concentrations of cyclosporin a during long-term treatment
with cyclosporin a ophthalmic emulsions in patients with
moderate to severe dry eye disease," Small et al, *J Ocul
Pharmacol Ther*, 2002 Oct, 18(5):411-8; "Distribution of
25 cyclosporin A in ocular tissues after topical
administration to albino rabbits and beagle dogs,"
Acheampong et al, *Curr Eye Res*, 1999 Feb, 18(2):91-103b;
"Cyclosporine distribution into the conjunctiva, cornea,
lacrimal gland, and systemic blood following topical dosing
30 of cyclosporine to rabbit, dog, and human eyes," Acheampong
et al, *Adv Exp Med Biol*, 1998, 438:1001-4; "Preclinical
safety studies of cyclosporine ophthalmic emulsion,"

Angelov et al, *Adv Exp Med Biol*, 1998, 438:991-5;
"Cyclosporin & Emulsion & Eye," Stevenson et al,
Ophthalmology, 2000 May, 107(5):967-74; and "Two
5 multicenter, randomized studies of the efficacy and safety
of cyclosporine ophthalmic emulsion in moderate to severe
dry eye disease. CsA Phase 3 Study Group," Sall et al,
Ophthalmology, 2000 Apr, 107(4):631-9. Each of these
publications is incorporated in its entirety herein by
reference. In addition, cyclosporin A-containing oil-in-
10 water emulsions have been clinically tested, under
conditions of confidentiality, since the mid 1990's in
order to obtain U.S. Food and Drug Administration (FDA)
regulatory approval.

Examples of useful cyclosporin A-containing emulsions
15 are set out in Ding et al U.S. Patent 5,474,979. Example
1 of this patent shows a series of emulsions in which the
ratio of cyclosporin A to castor oil in each of these
compositions was 0.08 or greater, except for Composition B,
which included 0.2% by weight cyclosporin A and 5% by
20 weight castor oil. The Ding et al patent placed no
significance in Composition B relative to Compositions A,
C and D of Example 1.

Over time, it has become apparent that cyclosporin A
emulsions for ophthalmic use preferably have less than 0.2%
25 by weight of cyclosporin A. With cyclosporin A
concentrations less than 0.2%, the amount of castor oil
employed has been reduced since one of the functions of the
castor oil is to solubilize the cyclosporin A. Thus, if
reduced amounts of cyclosporin are employed, reduced
30 amounts of castor oil are needed to provide effective
solubilization of cyclosporin A.

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