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PROVISIONAL APPLICATION FOR PATENT COVER SHEET

This is a request for filing a PROVISIONAL APPLICATION FOR PATENT under 37 CFR 1.53(c).

Express Mail Label No. EV 487328654 US

030805



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60/659679

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INVENTOR(S)		
Given Name (first and middle (if any))	Family Name or Surname	Residence (City and either State or Foreign Country)
Nachiappan	Chidambaram	High Point, North Carolina
Additional inventors are being named on the <u>1</u> separately numbered sheets attached hereto		
TITLE OF THE INVENTION (500 characters max):		
SOLVENT SYSTEM FOR ENHANCING THE SOLUBILITY OF PHARMACEUTICAL AGENTS		
Direct all correspondence to: CORRESPONDENCE ADDRESS		
<input checked="" type="checkbox"/> The address corresponding to Customer Number:		23579
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ENCLOSED APPLICATION PARTS (check all that apply)		
<input checked="" type="checkbox"/> Application Data Sheet. See 37 CFR 1.76	<input type="checkbox"/> CD(s), Number of CDs _____	
<input checked="" type="checkbox"/> Specification Number of Pages <u>19</u>	<input checked="" type="checkbox"/> Other (specify) <u>Return Postcard</u>	
<input type="checkbox"/> Drawing(s) Number of Sheets <u>0</u>		
Application Size Fee: If the specification and drawings exceed 100 sheets of paper, the application size fee due is \$250 (\$125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).		
METHOD OF PAYMENT OF FILING FEES AND APPLICATION SIZE FEE FOR THIS PROVISIONAL APPLICATION FOR PATENT		
<input type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27.	TOTAL FEE AMOUNT (\$)	
<input type="checkbox"/> A check or money order is enclosed to cover the filing fee and application size fee (if applicable).	\$200.00	
<input type="checkbox"/> Payment by credit card. Form PTO-2038 is attached		
<input checked="" type="checkbox"/> The Director is hereby authorized to charge the filing fee and application size fee (if applicable) or credit any overpayment to Deposit Account Number: <u>50-3129</u> . A duplicative copy of this form is enclosed for fee processing.		
The invention was made by an agency of the United States Government or under a contract with an agency of the United States Government.		
<input checked="" type="checkbox"/> No.		
<input type="checkbox"/> Yes, the name of the U.S. Government agency and the Government contract number are: _____		

SIGNATURE Rivka D. Monheit
 TYPED or PRINTED NAME Rivka D. Monheit
 TELEPHONE 404-879-2152

Date March 8, 2005
 REGISTRATION NO. 48,731
 (if appropriate)
 Docket Number: BAN 102

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This collection of information is required by 37 CFR 1.51. 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 1.11 and 1.14. This collection is estimated to take 8 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, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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PTO/SB/16 (12-04)

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First Named Inventor	Nachiappan Chidambaram	Docket Number	BAN 102
INVENTOR(S)/APPLICANT(S)			
Given Name (first and middle [if any])	Family or Surname	Residence (City and either State or Foreign Country)	
Aqeel	Fatmi	Greensboro, North Carolina	

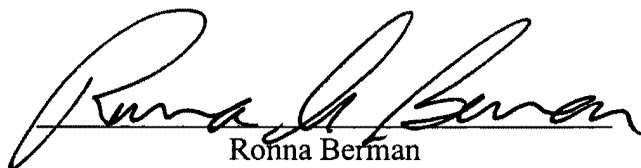
Number 2 of 2

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Title: "SOLVENT SYSTEM FOR ENHANCING THE SOLUBILITY OF PHARMACEUTICAL AGENTS"
By: Nachiappan Chidambaram and Aqeel Fatmi
Filed: March 8, 2005

CERTIFICATE OF MAILING UNDER 37 CFR §1.10

I hereby certify that this **PROVISIONAL APPLICATION**, and any documents referred to as attached therein, are being deposited with the United States Postal Service on this date, March 8, 2005, in an envelope as "Express Mail Post Office to Addressee" service under 37 CFR 1.10, Mailing Label Number EV 487328654 US, addressed to Commissioner for Patents, P. O. Box 1450, Alexandria, VA 22313-1450.


Ronna Berman

Date: March 8, 2005

UNITED STATES

PROVISIONAL PATENT APPLICATION

BY

NACHIAPPAN CHIDAMBARAM

AND

AQEEL FATMI

FOR

**SOLVENT SYSTEM FOR ENHANCING THE SOLUBILITY OF
PHARMACEUTICAL AGENTS**

**SOLVENT SYSTEM FOR ENHANCING THE SOLUBILITY OF
PHARMACEUTICAL AGENTS
FIELD OF THE INVENTION**

5 This invention is in the field of fill materials encapsulated in soft gelatin capsules.

BACKGROUND OF THE INVENTION

10 Filled one-piece soft gelatin capsules (“softgels”) have been widely used for years to encapsulate consumable materials such as vitamins and pharmaceuticals in a liquid vehicle or carrier. Because softgels have properties which are quite different from two-piece hardshell capsules, softgels are more capable of retaining a liquid fill material.

15 Not all liquids may be enclosed in a softgel capsule. Liquids containing more than about 20% water by weight are generally not enclosed in softgels, because the water tends to dissolve the gelatin shell. Other solvents such as propylene glycol, glycerin, low molecular weight alcohols, ketones, acids, amines, and esters all tend to degrade or dissolve the gelatin shell to some extent.

20 Softgels are also somewhat sensitive to pH, and generally require a pH in the encapsulated liquid from about 2.5 to about 7.5. Highly acidic liquids may hydrolyze the gelatin, resulting in leaks, while basic liquids may tan the gelatin, resulting in decreased solubility of the gelatin shell.

25 Pharmaceutical liquids are usually enclosed in softgels as either viscous solutions or suspensions. Suspensions are pharmaceutically less desirable because they can settle during manufacture, which leads to a less uniform product. In contrast, solutions provide the best liquid form for obtaining optimal “content uniformity” in a batch. Further, solutions typically provide a faster and more uniform absorption of an active agent than do suspensions.

30 Suitable softgel solutions, however, can be difficult to achieve. One constraint is size. Many pharmaceutical agents require volumes of solvent too large to produce a softgel capsule small enough to be taken by patients. The

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