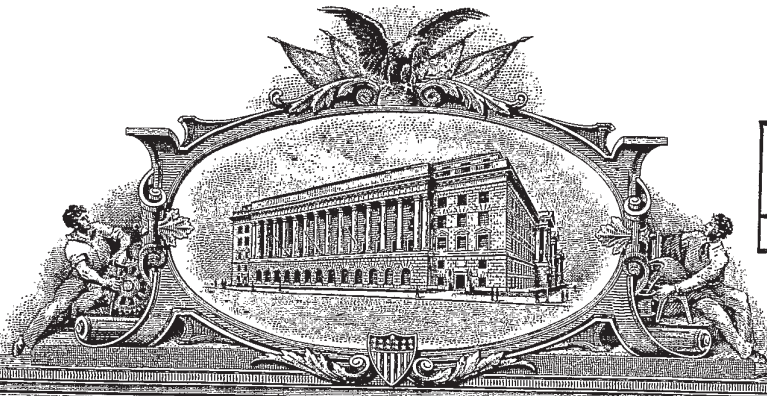


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APPLICATION NUMBER: 60/541,247

US/04/9387

FILING DATE: February 04, 2004

**PRIORITY DOCUMENT
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U.S. DEPARTMENT OF COMMERCE
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FEE RECORD SHEET

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PTO-1556
(5/87)

*U.S. Government Printing Office: 2001 — 481-697/59173



19281 U.S. PTO

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Approved for use through 10/31/2002. OMB 0651-0037
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22990 U.S. PTO
60/541247



PROVISIONAL APPLICATION FOR PATENT COVER SHEET

This is a request for filing a PROVISIONAL APPLICATION FOR PATENT under 37 C.F.R. § 1.53(c).

Docket Number		033935-005		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)	
BODOR		Nicholas		S.		10101 Collins Avenue, #4A Bal Harbour, Florida 33154	
<input type="checkbox"/> Additional inventors are being named on the ___ separately numbered sheets attached hereto.							
TITLE OF THE INVENTION (500 characters max)							
ORAL FORMULATIONS OF CLADRIBINE							
CORRESPONDENCE ADDRESS							
Burns, Doane, Swecker & Mathis, L.L.P. Customer Number 2 1 8 3 9 Post Office Box 1404 Alexandria							
STATE		Virginia		ZIP CODE		22313-1404	
				COUNTRY		United States of America	
ENCLOSED APPLICATION PARTS (check all that apply)							
<input checked="" type="checkbox"/> Specification		Number of Pages 28		<input checked="" type="checkbox"/> Other (specify)		Claims 1-45 (7 pgs.), Abstract (1 pg.)	
<input checked="" type="checkbox"/> Drawing(s)		Number of Sheets 1					
<input type="checkbox"/> Application Data Sheet. See 37 CFR 1.76							
METHOD OF PAYMENT OF FILING FEES FOR THIS PROVISIONAL APPLICATION FOR PATENT (check one)							
<input type="checkbox"/> Applicant claims small entity status. See 37 C.F.R. § 1.27.				PROVISIONAL FILING FEE AMOUNT(S)		<input type="checkbox"/> \$80.00 (2005)	
<input checked="" type="checkbox"/> A check or money order is enclosed to cover the Provisional filing fees.						<input checked="" type="checkbox"/> \$160.00 (1005)	
<input checked="" type="checkbox"/> The Director is hereby authorized to charge any deficiency in filing fees or credit any overpayment to Deposit Account No. 02-4800. This paper is submitted in duplicate.							

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:

BURNS DOANE
BURNS DOANE SWECKER & MATHIS LLP
INTELLECTUAL PROPERTY LAW

PROVISIONAL APPLICATION FOR PATENT
COVER SHEET

Page 1

Respectfully submitted,

SIGNATURE Mary Katherine Baumeister DATE February 4, 2004
TYPED or PRINTED NAME Mary Katherine Baumeister Registration No. 26,254
(if appropriate)

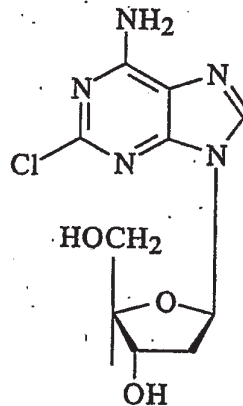
ORAL FORMULATIONS OF CLADRIBINE

FIELD OF THE INVENTION

The invention relates to a composition comprising a complex cladribine-cyclodextrin complex formulated into a solid oral dosage form and to a method for enhancing the oral bioavailability of cladribine.

BACKGROUND OF THE INVENTION

Cladribine, which is an acid-labile drug, has the chemical structure as set forth below:



It is also known as 2-chloro-2'-deoxyadenosine or 2-CdA. Cladribine exists as a white, nonhygroscopic, crystalline powder, consisting of individual crystals and of crystalline aggregates.

Cladribine is an antimetabolite which has use in the treatment of lymphoproliferative disorders. It has been used to treat experimental leukemias such as L1210 and clinically for hairy cell leukemia and chronic lymphocytic leukemia as well as Waldenstrom's macroglobulinaemia. It has also been used as an immunosuppressive agent and as a modality for the treatment of a variety of

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