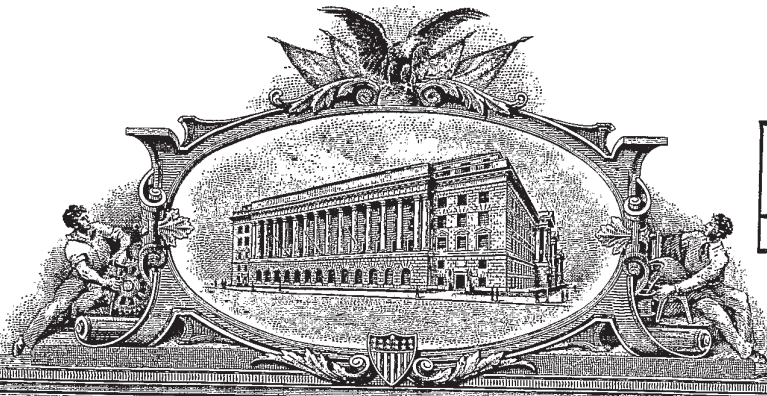


REC'D 26 JUL 2004  
WIPO PCT

PA 1178182



# THE UNITED STATES OF AMERICA

**TO ALL TO WHOM THESE PRESENTS SHALL COME:**

**UNITED STATES DEPARTMENT OF COMMERCE**

**United States Patent and Trademark Office**

**June 03, 2004**

**THIS IS TO CERTIFY THAT ANNEXED HERETO IS A TRUE COPY FROM THE RECORDS OF THE UNITED STATES PATENT AND TRADEMARK OFFICE OF THOSE PAPERS OF THE BELOW IDENTIFIED PATENT APPLICATION THAT MET THE REQUIREMENTS TO BE GRANTED A FILING DATE UNDER 35 USC 111.**

**APPLICATION NUMBER: 60/541,247**

*US/04/9387*

**FILING DATE: February 04, 2004**

**PRIORITY DOCUMENT  
SUBMITTED OR TRANSMITTED IN  
COMPLIANCE WITH  
RULE 17.1(a) OR (b)**

**By Authority of the  
COMMISSIONER OF PATENTS AND TRADEMARKS**



*N. Williams*  
**N. WILLIAMS**

**Certifying Officer Merck 2046  
Hopewell v Merck**

PATENT APPLICATION SERIAL NO. \_\_\_\_\_

U.S. DEPARTMENT OF COMMERCE  
PATENT AND TRADEMARK OFFICE  
FEE RECORD SHEET

02/09/2004 FMETEKI1 00000018 60541247

01 FC:1005

160.00 0P

PTO-1556  
(5/87)

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



19281 U.S. PTO

Customer Number 2 1 8 3 9

Approved for use through 10/31/2002. OMB 0651-0037  
Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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)

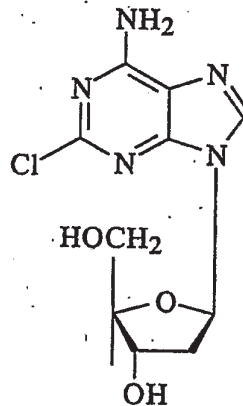
## ORAL FORMULATIONS OF CLADRIBINE

### 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

# Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

## Real-Time Litigation Alerts



Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

## Advanced Docket Research



With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

## Analytics At Your Fingertips



Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

## API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

## LAW FIRMS

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

## FINANCIAL INSTITUTIONS

Litigation and bankruptcy checks for companies and debtors.

## E-DISCOVERY AND LEGAL VENDORS

Sync your system to PACER to automate legal marketing.