



US 20120022157A1

(19) **United States**

(12) **Patent Application Publication**
Scharschmidt

(10) **Pub. No.: US 2012/0022157 A1**

(43) **Pub. Date: Jan. 26, 2012**

(54) **DOSING AND MONITORING PATIENTS ON
NITROGEN-SCAVENGING DRUGS**

(75) Inventor: **Bruce Scharschmidt**, South San
Francisco, CA (US)

(73) Assignee: **UCYCLYD PHARMA, INC.**,
Scottsdale, AZ (US)

(21) Appl. No.: **13/061,509**

(22) PCT Filed: **Aug. 27, 2009**

(86) PCT No.: **PCT/US09/55256**

§ 371 (c)(1),

(2), (4) Date: **Jun. 15, 2011**

Related U.S. Application Data

(63) Continuation-in-part of application No. PCT/US09/
30362, filed on Jan. 7, 2009, Continuation-in-part of
application No. 12/350,111, filed on Jan. 7, 2009.

(60) Provisional application No. 61/093,234, filed on Aug.
29, 2008, provisional application No. 61/093,234,
filed on Aug. 29, 2008.

Publication Classification

(51) **Int. Cl.**

A61K 31/216 (2006.01)

A61P 3/00 (2006.01)

G01N 33/00 (2006.01)

A61P 13/12 (2006.01)

(52) **U.S. Cl. 514/533; 514/532; 73/61.41**

(57) **ABSTRACT**

The invention provides a method for determining a dose and dosing schedule, and making dose adjustments of patients taking PBA prodrugs as nitrogen scavengers to treat nitrogen retention states, including ammonia accumulation disorders as well as chronic renal failure, by measuring urinary excretion of phenylacetylglutamine and/or total urinary nitrogen. The invention provides methods to select an appropriate dosage of a PBA prodrug based on the patient's dietary protein intake, or based on previous treatments administered to the patient. The methods are applicable to selecting or modifying a dosing regimen for a subject receiving an orally administered waste nitrogen scavenging drug, and to monitoring patients receiving such drugs.

Human Nitrogen Retention States: Hereditary (UCDs) And Acquired (Cirrhosis) Liver Disease And Chronic Renal Failure (CRF)

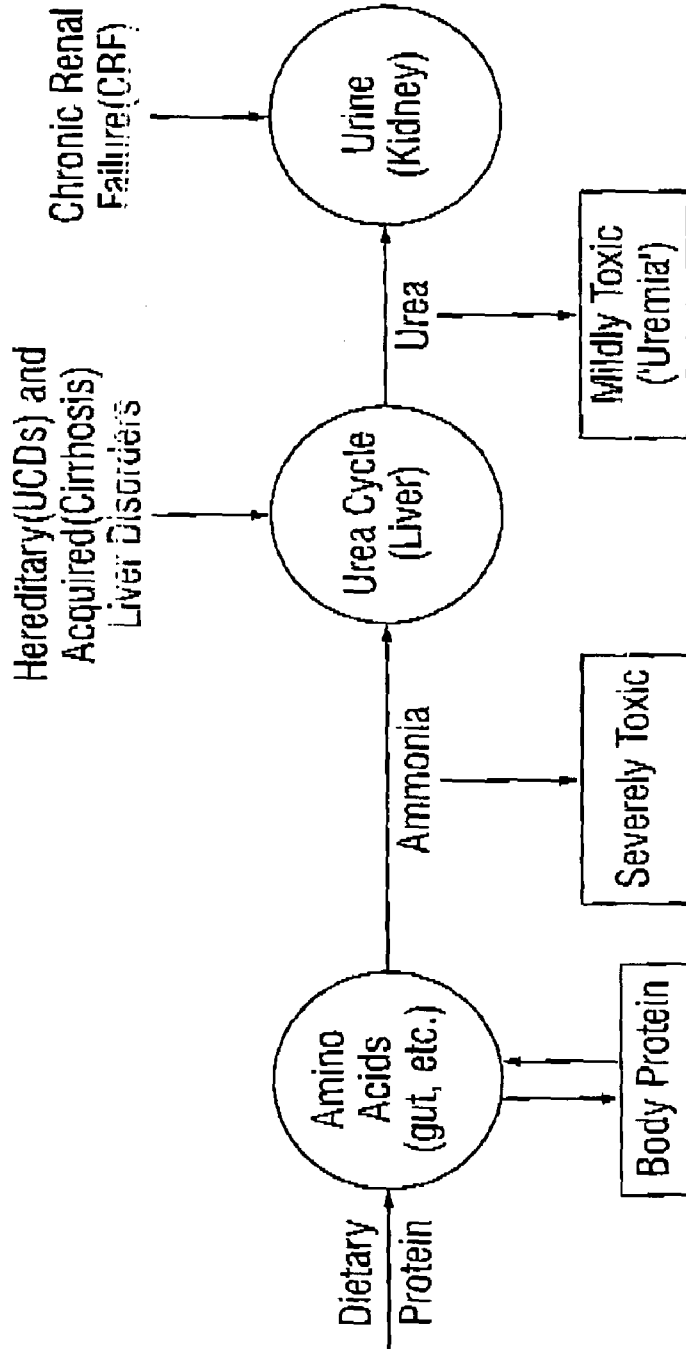


Figure 1a

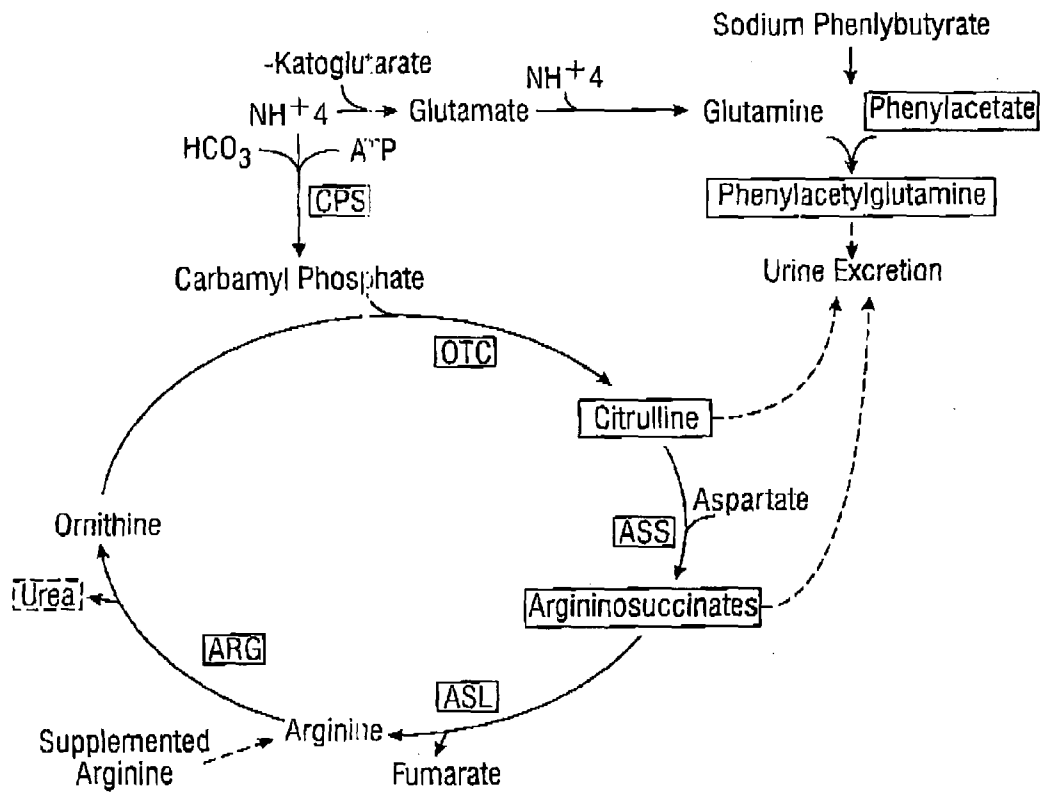
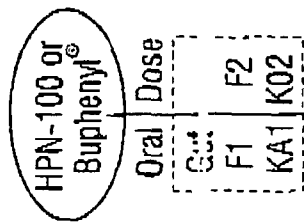


Figure 1b

PK/PD Modeling of PBA/PAA/PAGN/UPAGN

- Conventional Approach -



Note:
 This model only allows for conversion of PBA to PAA to PAGN in the systemic (labeled 'central') plasma compartment. Bioavailability and drug effect is assume to relate directly to plasma metabolite concentrations

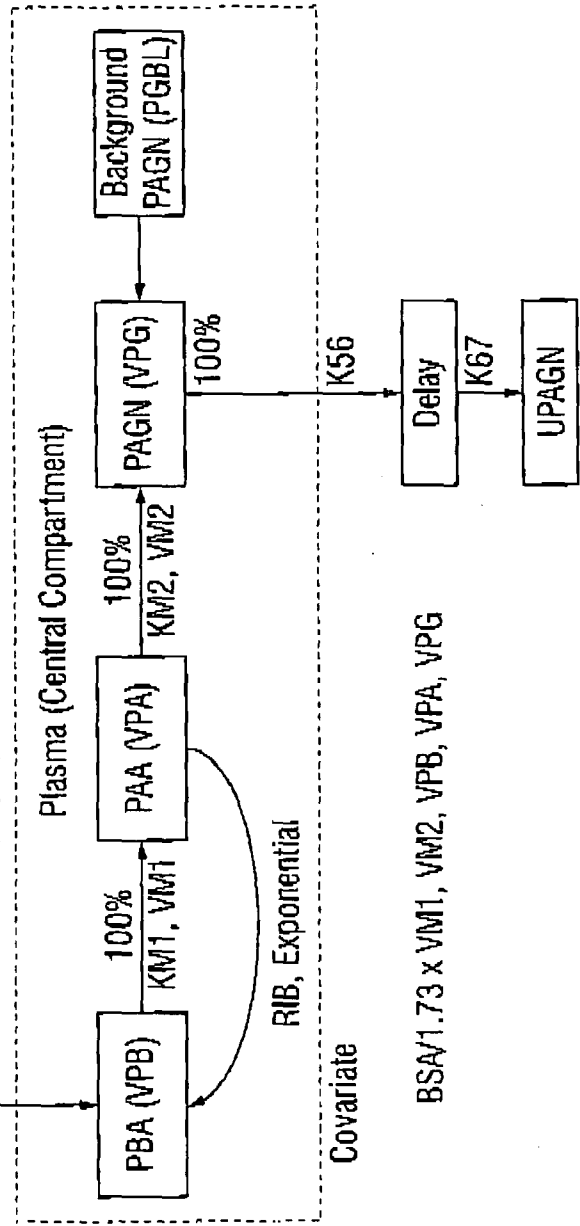


Figure 2

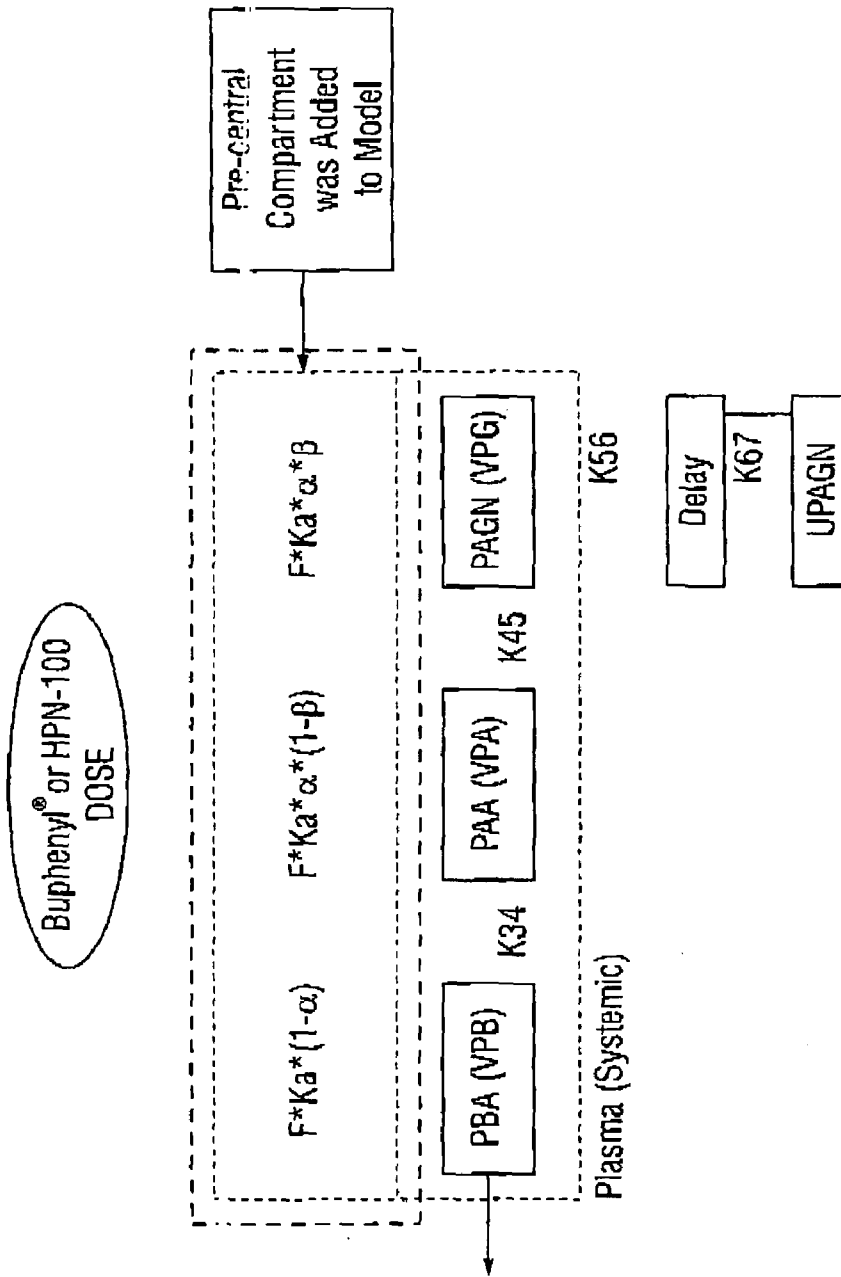


Figure 3

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.