IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re:	**U.S. Patent No. 5,654,301**
Inventor:	KOHN, Harold et al.
Issue Date:	August 5, 1997
For:	AMINO ACID DERIVATIVE ANTICONVULSANT
Assignee:	Research Corporation Technologies, Inc.
Date:	December 23, 2008
Attorney Docket:	32555-0002-2
NDA:	**NDA 22-254 (VIMPAT® injection)**

Mail Stop Hatch-Waxman PTE
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

APPLICATION FOR EXTENSION OF PATENT
TERM UNDER 35 U.S.C. §156

Commissioner for Patents:

Applicant, Research Corporation Technologies, Inc., a non-profit corporation organized and existing under the laws of Delaware, and having a principal place of business at 5210 E. Williams Circle, Suite 240, Tucson, Arizona 85711-4410, represents that it is the owner of the entire interest in and to U.S. Patent No. 5,654,301, granted to Harold Kohn and Darrell Watson for "Amino Acid Derivative Anticonvulsant," as reflected in the assignment document recorded by the U.S. Patent and Trademark Office on January 12, 1993 at Reel 006433, Frame 0347. Attached at **Exhibit A** is a Power of Attorney document appointing the undersigned patent attorney as legal representative of Applicant.

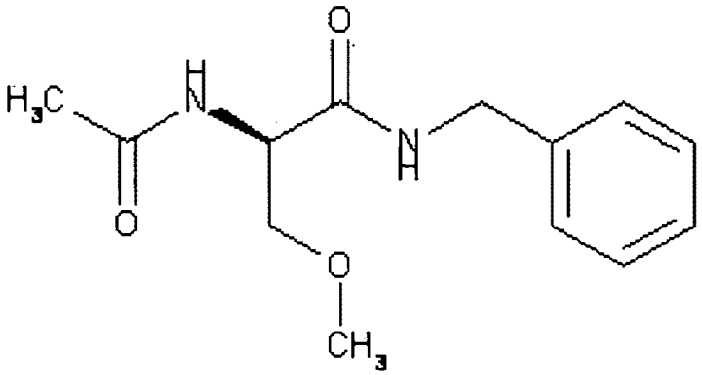
Schwarz Biosciences, Inc. ("Schwarz"), a corporation of the state of Delaware and having a place of business at 1209 Orange St., Wilmington, DE 19801, is the owner of a New Drug Application ("NDA") for VIMPAT® injection, NDA number NDA 22-254. Schwarz

Pharma AG ("SPAG"), having its registered office at Alfred-Nobel Strasse 10, 40789 Monheim, Germany, has exclusive license rights under U.S. Patent No. 5,654,301 to lacosamide, R-2-Acetamido-N-benzyl-3-methoxypropionamide. Schwarz and SPAG are related companies, being wholly owned by UCB S.A., which has its registered office at Allée de la Recherche 60, 1070 Brussels, Belgium. Attached at **Exhibit B** is a Letter of Reliance document granting to the Applicant from Schwarz the right to rely upon NDA 22-254 and the activities of SPAG and its predecessors in interest supporting FDA approval of VIMPAT® injection for purposes of obtaining any and all patent term extensions available in conjunction with the approval of VIMPAT® injection.

Applicant, acting through its duly authorized attorney, hereby submits this application for extension of patent term under 35 U.S.C. §156, based upon the approval by the Food and Drug Administration for commercial marketing or use of VIMPAT® injection, since the active ingredient of VIMPAT® injection is lacosamide and lacosamide falls within the ambit of the claims of U.S. Patent No. 5,654,301. The information contained in this Application and its Exhibits is provided in accordance with the rules promulgated by the U.S. Patent and Trademark Office at 37 CFR §§1.710-1.785 and presented in the manner set forth at 37 CFR §1.740.

1. A Complete Identification Of The Approved Product As By Appropriate Chemical And Generic Name, Physical Structure Or Characteristics

The approved product, VIMPAT® injection, contains lacosamide as its active ingredient and is indicated for adjunctive therapy in the treatment of partial-onset seizures in patients with epilepsy aged 17 years and older when oral administration is temporarily not feasible. The IUPAC chemical name of lacosamide is (R)-2-acetamido-N-benzyl-3-methoxypropionamide. Lacosamide has the empirical formula $C_{13}H_{18}N_2O_3$, and has a molecular weight of 250.30. Lacosamide is present in VIMPAT® injection in the form of a single (R)-enantiomer, and has the structural formula:



Lacosamide is prepared as a white to light yellow powder that is sparingly soluble in acetonitrile and ethanol. The approved product is formulated for intravenous injection as a clear, colorless, sterile solution containing 10 mg lacosamide per mL for intravenous infusion. One 20 mL vial contains 200 mg of lacosamide, plus inactive ingredients sodium chloride and water for injection. Hydrochloric acid is used for pH adjustment, giving VIMPAT® injection a pH of 3.5 to 5.0. The initial recommended dosage regimen is 100 mg of lacosamide infusion per day, and dosage can be increased, such as at weekly intervals of 100 mg/day, until a maintenance dose of 200 to 400 mg/day (based upon individual patient response and tolerability) is reached.

2. A Complete Identification Of The Federal Statute Including The Applicable Provisions Of Law Under Which The Regulatory Review Occurred

The approved product, VIMPAT® injection, was subject to regulatory review under Section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. §355).

3. An Identification Of The Date On Which The Product Received Permission For Commercial Marketing Or Use Under The Provision Of Law Under Which The Applicable Regulatory Review Period Occurred

The approved product, VIMPAT® injection, received permission for commercial marketing or use under Section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. §355) on October 28, 2008. A copy of a letter from the Food and Drug Administration ("FDA") indicating the date of approval is attached hereto at **Exhibit C**.

4. In The Case Of A Drug Product, An Identification Of Each Active Ingredient In The Product And As To Each Active Ingredient, A Statement That It Has Not Been Previously Approved For Commercial Marketing Or Use Under The Federal Food, Drug, and Cosmetic Act, The Public Health Service Act, Or The Virus-Serum-Toxin Act, Or A Statement Of When The Active Ingredient Was Approved For Commercial Marketing Or Use (Either Alone Or In Combination With Other Active Ingredients), The Use For Which It Was Approved, And The Provision Of Law Under Which It Was Approved

The active ingredient in VIMPAT® injection is lacosamide, which has not been previously approved for commercial marketing or use under the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act, or the Virus-Serum-Toxin Act.

5. A Statement That The Application Is Being Submitted Within The Sixty Day Period Permitted For Submission Pursuant to 37 CFR §1.720(f) And An Identification Of The Date Of The Last Day On Which The Application Could Be Submitted

This application is being submitted within the permitted sixty (60) day period, the last day of which is December 26, 2008.

6. A Complete Identification Of The Patent For Which An Extension Is Being Sought By The Name Of The Inventor, The Patent Number, The Date Of Issue, And The Date Of Expiration

The complete identification of the patent for which extension is sought is:

Inventors:	Harold Kohn, and Darrell Watson
Patent Number:	5,654,301
Issue Date:	August 5, 1997
Expiration Date:	August 5, 2014 (without extension under 35 U.S.C. §156)

7. A Copy Of The Patent For Which An Extension Is Being Sought, Including The Entire Specification (Including Claims) And Drawings

A complete copy of U.S. Patent No. 5,654,301 is annexed as **Exhibit D**.

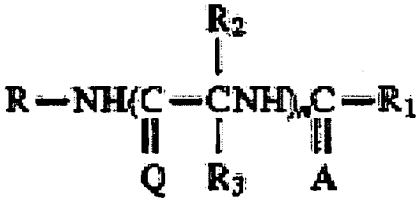
8. A Copy Of Any Disclaimer, Certificate of Correction, Receipt Of Maintenance Fee Payment, Or Reexamination Certificate Issued In The Patent

The patent for which extension is being sought has not been the subject of any disclaimer or reexamination certificate, but has had a certificate of correction duly issued by the

U.S. Patent and Trademark Office. A copy of the certificate of correction, dated November 27, 2001, is included at the end of the copy of U.S. Patent No. 6,654,301 annexed as **Exhibit D**. The first two scheduled maintenance fees for U.S. Patent 5,654,301 were duly paid on February 2, 2001 and December 3, 2004 by Applicant, and the next maintenance fee is due to be paid by February 6, 2009. Copies of the maintenance fee statements evidencing past payments are annexed as **Exhibit E**.

9. A Statement That The Patent Claims The Approved Product Or A Method Of Using Or Manufacturing The Approved Product, And A Showing Which Lists Each Applicable Patent Claim And Demonstrates The Manner In Which At Least One Such Patent Claim Reads On The Approved Product Or Method Of Using Or Manufacturing The Approved Product

U.S. Patent No. 5,654,301 claims the approved product, VIMPAT® injection. More specifically, claims 39-45 read on the approved product and claim the active ingredient of the final approved product lacosamide, claim 46 reads on the approved product and claims a composition comprising lacosamide, and claim 47 reads on methods that comprise using lacosamide for treatment of CNS (i.e., central nervous system) disorders. Claim 39, covering a compound, is compared to the approved product in the table below.

Patent Claim	Approved Product
39. A compound of the formula  or the pharmaceutically acceptable salts thereof wherein R is aryl, aryl lower alkyl, heterocyclic, heterocyclic lower alkyl, cycloalkyl or lower cycloalkyl lower alkyl, wherein R is unsubstituted or is substituted with at least one electron	The active ingredient of the approved product is lacosamide, which is (R)-2-acetamido-N-benzyl-3-methoxypropionamide. Lacosamide has the structural formula identified above in Section 1 of this application. Comparison of the structural formula above with that in claim 39 shows that the benzyl group at the far right of the structural formula identified above in Section 1 is an unsubstituted aryl lower alkyl and thus satisfies the claim's definition of "R." The $-CH_3$ group at the far left of the structure in Section 1 is a lower alkyl that satisfies the claim's definition of "R_1." The two double-bonded oxygen atoms satisfy

DOCKET ALARM

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.