Introduction to Patents

Rutgers University - Robert Wood Johnson Medical School
October 2, 2019

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Victor P. Ghidu
Patents and the Patent Process

• A patent provides a right to exclude

• What makes an invention patentable? The invention must...
  
  • Encompass “patentable subject matter”
  
  • Be useful
  
  • Be new
  
  • Be non-obvious
  
  • Be supported by a specification containing a written description of the invention, and of the manner and process of making and using it, in such terms as to enable any person skilled in the art to make and use the same, and also set forth the best mode* of carrying out the invention.
**Patents and the Patent Process**

- **Provisional Patent Application Filing**: 1 year
- **Non-Provisional Patent Application**: 20 years*
- **US and/or ex-US Patent Examination**: (3-5 years)
- **Patent Grant**: 1 year
- **Patent Expiration**: 20 years*

*Patent Term extended for:*
1. Patent office delays (PTA)
2. Regulatory Delays (PTE)
3. Pediatric Exclusivity (6 mos.)
Pregabalin (LYRICA) – Oral - Pfizer

- Launched in US in 2004;
- Indicated for the treatment of:
  - Neuropathic pain associated with diabetic peripheral neuropathy (DPN)
  - Postherpetic neuralgia (PHN)
  - Adjunctive therapy for the treatment of partial onset seizures in patients 4 years of age and older
  - Fibromyalgia
  - Neuropathic pain associated with spinal cord injury
• **Pregabalin (LYRICA) – Oral - Pfizer**

• *Protected by Orange Book listed patents – all expired.*

• *Protected by various regulatory exclusivities*

  • **Pediatric Exclusivity**
    • *Added 6 months to patent term*

  • **New Patient Population Exclusivity**
    • *Marketing exclusivity until 2022 for certain indications*
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**Exclusivity Data**

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United States Patent

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<th>Patent No.</th>
<th>6,001,876</th>
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<td>Date of Patent</td>
<td>Dec. 14, 1999</td>
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**Inventor:** Lakhdar Singh, Cambridgeshire, United Kingdom

**Assignee:** Warner-Lambert Company, Morris Plains, N.J.

**Title:** INOBUTYLGABA AND ITS DERIVATIVES FOR THE TREATMENT OF PAIN

**References Cited**

- **U.S. PATENT DOCUMENTS**
  - 5,563,175 10/1994 Silverman et al. 514/561

- **FOREIGN PATENT DOCUMENTS**
  - 9209996 6/1999 Itoh WIPO
  - 9220388 11/1993 Itoh WIPO

**Abstract**

The instant invention is a method of using certain glutamic acid and gamma-aminobutyric acid in a pa... 15 Claims, 18 Drawing Sheets

**Related U.S. Application Data**

- Provisional application No. 60/022,337, Jul. 24, 1996.

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**United States Patent**

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<th>Patent No.</th>
<th>US 6,197,819 B1</th>
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<td>Date of Patent</td>
<td>Mar. 6, 2001</td>
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**Inventors:** Silverman et al.

**Title:** GAMMA AMINO BUTYRIC ACID ANALOGS AND OPTICAL ISOMERS

**Assignee:** Northwestern University, Evanston, IL (US)

**Abstract**

- Subject to any disclaimer, the terms of this patent is extended or adjusted under 35 U.S.C. 154(a) by 0 days.

**Related U.S. Application Data**

- Continuation of application No. 08/364,313, filed on May 18, 1997, now abandoned, which is a continuation-in-part of application No. 07/880,380, filed on May 30, 1992, now abandoned, which is a continuation-in-part of application No. 07/618,962, filed on Nov. 27, 1990, now abandoned.
- 9209996 6/1999 Itoh WIPO
- 9220388 11/1993 Itoh WIPO

**Citations**

- Silverman et al., (1991) 3-alkyl-4-aminobutyric acids the
ISOBUTYLGLABABA AND ITS DERIVATIVES FOR THE TREATMENT OF PAIN

Inventor: Lakhbir Singh, Cambridgeshire, United Kingdom


Appl. No.: 09/043,358
PCT Filed: Jul. 16, 1997
PCT No.: PCT/US97/12390
§ 371 Date: Jul. 15, 1998
§ 102(e) Date: Jul. 15, 1998
PCT Pub. No.: WO98/03167
PCT Pub. Date: Jan. 29, 1998

Related U.S. Application Data
Provisional application No. 60/022,337, Jul. 24, 1996.

References Cited
U.S. PATENT DOCUMENTS
5,563,175 10/1996 Silverman et al. ................. 514/561

FOREIGN PATENT DOCUMENTS
9323383 11/1993 WIPO .

Primary Examiner—James H. Reamer
Attorney, Agent, or Firm—Elizabeth M. Anderson

ABSTRACT
The instant invention is a method of using certain analogs of glutamic acid and gamma-aminobutyric acid in pain therapy.

15 Claims, 18 Drawing Sheets
What is claimed is:

1. A method for treating pain comprising administering a therapeutically effective amount of a compound of Formula 1

\[
\begin{array}{c}
  R_3 R_2 \\
  H_2N\text{CCH}_2\text{COOH} \\
  R_1 \\
\end{array}
\]

or a pharmaceutically acceptable salt, diastereomer, or enantiomer thereof wherein

R₁ is a straight or branched alkyl of from 1 to 6 carbon atoms, phenyl, or cycloalkyl of from 3 to 6 carbon atoms;

R₂ is hydrogen or methyl; and

R₃ is hydrogen, methyl, or carboxyl to a mammal in need of said treatment.

2. A method according to claim 1 wherein the compound administered is a compound of Formula 1 wherein R₃ and R₂ are hydrogen, and R₁ is \(-(\text{CH}_2)_0-2-i\ C_4\text{H}_9\) as an (R), (S), or (R,S) isomer.

3. A method according to claim 1 wherein the compound administered is named (S)-3-(aminomethyl)-5-methyloxanolic acid and 3-aminomethyl-5-methyloxanolic acid.

4. A method according to claim 1 wherein the pain treated is inflammatory pain.

5. A method according to claim 1 wherein the pain treated is neuropathic pain.

6. A method according to claim 1 wherein the pain treated is cancer pain.

7. A method according to claim 1 wherein the pain treated is postoperative pain.

8. A method according to claim 1 wherein the pain treated is phantom limit pain.

9. A method according to claim 1 wherein the pain treated is bums pain.

10. A method according to claim 1 wherein the pain treated is gout pain.

11. A method according to claim 1 wherein the pain treated is osteoarthritic pain.

12. A method according to claim 1 wherein the pain treated is trigeminal neuralgia pain.

13. A method according to claim 1 wherein the pain treated is acute herpetic and postherpetic pain.

14. A method according to claim 1 wherein the pain treated is causalgia pain.

15. A method according to claim 1 wherein the pain treated is idiopathic pain.
(54) GAMMA AMINO BUTYRIC ACID ANALOGS AND OPTICAL ISOMERS

(75) Inventors: Richard B. Silverman, Morton Grove, II. (US); Ryszard Andruszkiewicz, Sopot (PL)

(73) Assignee: Northwestern University, Evanston, IL (US)

(45) Date of Patent: Mar. 6, 2001

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

(21) Appl. No.: 08/420,905
(22) Filed: Apr. 11, 1995

Related U.S. Application Data

(63) Continuation of application No. 08/064,285, filed on May 18, 1993, now abandoned, which is a continuation-in-part of application No. 07/886,080, filed on May 20, 1992, now abandoned, which is a continuation-in-part of application No. 07/618,692, filed on Nov. 27, 1990, now abandoned.


The ‘819 Patent’s Life

First Application
Nov. 27, 1990
(Abandoned)

Second Application
May 20, 1992
(Abandoned)

Third Application
May 18, 1993
(Abandoned)

Fourth Application
Apr. 11, 1995

Fourth Application
Issues
Mar. 6, 2001

Due to Expire
Mar. 6, 2018!!!!

Patent Received PTE
300 days
Due to Expire
Dec. 30, 2018

Patent Received Pediatric Exclusivity
6 Mos.
Due to Expire
Jun. 30, 2019
What is claimed is:

1. A compound of the formula S-(+)-4-amino-3-(2-methylpropyl) butanoic acid as a single optical isomer.
2. 4-amino-3-(2-methylpropyl) butanoic acid, or a pharmaceutically acceptable salt thereof.
3. A pharmaceutically acceptable salt of S-(+)-(4)-amino-3-(2-methylpropyl) butanoic acid, said salt being present as a single optical isomer.

4. A pharmaceutical composition comprising a compound any one of claims 1 or 3, together with a pharmaceutically acceptable carrier.

* * * * *
• **Pregabalin (LYRICA) – Oral - Pfizer**
  
  • *Launched in US in 2004*
  
  • *First Generic Paragraph IV Certifications filed in 2008*
  
  • *Patents Expired Jun. 30, 2019*
  
  • *First Group of Generics Approved in Jul. 19, 2019*
1. What are the differences, if any, in the claims between the two patents.

2. If you think there are differences, how does the scope of exclusivity differ between the claims in the ‘876 patent vs. the claims in the ‘819 patent?

3. Which patent do you think is “stronger”?

4. With regard to pharmaceuticals, are patents good, bad, a necessity, a cost of doing business, or something in between?
Thank You!

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