[Billing Code 4140-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of an Exclusive Patent License: Development and Commercialization of Fenoterol and Certain Fenoterol Analogues for the Treatment of Cancer

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The National Institute on Aging, an institute of the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an Exclusive Patent License to practice the inventions embodied in the Patents and Patent Applications listed in the Supplementary Information section of this Notice to Paz Pharmaceuticals, LLC of the State of Delaware**.**

DATES: Only written comments and/or applications for a license which are received by the National Cancer Institute's Technology Transfer Center on or before [INSERT DATE FIFTEEN (15) DAYS FROM DATE OF PUBLICATION OF NOTICE IN THE FEDERAL REGISTER] will be considered.

ADDRESSES: Requests for copies of the patent applications, inquiries, and comments relating to the contemplated Exclusive Patent License should be directed to: Richard T. Girards, Jr., Esq., MBA, Senior Technology Transfer Manager, National Institutes of Health, NCI Technology Transfer Center by email (richard.girards@nih.gov) or phone (240-276-6825).

SUPPLEMENTARY INFORMATION:

Intellectual Property

E-205-2006: preparation of (R,R)-fenoterol and (R,R)-or (R,S)-fenoterol analogues and their use in treating congestive heart failure

1. United States Provisional Patent Application No. 60/837,161, filed 10 August 2006 (HHS Reference No. E-205-2006-0-US-01);
2. United States Provisional Patent Application No. 60/927,825, filed 03 May 2007 (HHS Reference No. E-205-2006-1-US-01);
3. United States Patent Application No. 12/376,945, filed 09 February 2009 (HHS Reference No. E-205-2006-2-US-13);
4. United States Patent No. 8,703,826, issued 22 April 2014 (HHS Reference No. E-205-2006-2-US-15);
5. United States Patent No. 9,522,871, issued 20 December 2016 (HHS Reference No. E-205-2006-2-US-19);
6. United States Patent No. 9,908,841, issued 06 March 2018 (HHS Reference No. E-205-2006-2-US-22);
7. United States Patent No. 10,308,591, issued 04 June 2019 (HHS Reference No. E-205-2006-2-US-26);
8. United States Patent No. 10,562,843, issued 18 February 2020 (HHS Reference No. E-205-2006-2-US-27);
9. International Patent Application No. PCT/US2007/075731, filed 10 August 2007 (HHS Reference No. E-205-2006-2-PCT-01);
10. Australia Patent No. 2007286051, issued 26 April 2013 (HHS Reference No. E-205-2006-2-AU-02);

11. Australia Patent No. 2013202127, issued 25 September 2014 (HHS Reference No. E-205-2006-2-AU-16)
12. Australia Patent Application No. 2014224073, filed 11 September 2014 (HHS Reference No. E-205-2006-2-AU-20)
13. Brazil Patent Application No. PI0716495-5, filed 18 June 2009 (HHS Reference No. E-205-2006-2-BR-03);
14. Canada Patent No. 2660707, issued 08 July 2014 (HHS Reference No. E-205-2006-2-CA-04);
15. China Patent No. 200780036155.9, issued 29 January 2014 (HHS Reference No. E-205-2006-2-CN-05);
16. China Patent Application No. 201310705914.3, filed 10 August 2007 (HHS Reference No. E-205-2006-2-CN-18);
17. European Patent No. 2064174, issued 26 October 2016 (HHS Reference No. E-205-2006-2-EP-06) and all of its national validations;
18. Hong Kong Patent Application No. 14107948.2, filed 04 August 2014 (HHS Reference No. E-205-2006-2-HK-21);
19. Israel Patent No. 196965, issued 30 January 2016 (HHS Reference No. E-205-2006-2-IL-07);
20. India Patent No. 266343, issued 28 April 2015 (HHS Reference No. E-205-2006-2-IN-08);
21. Japan Patent No. 5302194, issued 28 June 2013 (HHS Reference No. E-205-2006-2-JP-09);

22. Japan Patent Application No. 2013-129406, filed 20 June 2013 (HHS Reference No. E-205-2006-2-JP-17)
23. Korea (South) Patent No. 10-1378067, issued 19 March 2014 (HHS Reference No. E-205-2006-2-KR-10);
24. Mexico Patent No. 331996, issued 30 July 2015 (HHS Reference No. E-205-2006-2-MX-11);
25. Philippines Patent Application No. 1-2009-500267, filed 10 August 2007 (HHS Reference No. E-205-2006-2-PH-12);
26. South Africa Patent No. 2009/00938, issued 28 April 2010 (HHS Reference No. E-205-2006-2-ZA-14); and
27. any and all other U.S. and ex-U.S. patents and patent applications claiming priority to any one of the foregoing, now or in the future.

<u>E-013-2010: use of fenoterol and fenoterol analogues in the treatment of glioblastomas and astrocytomas</u>

1. United States Provisional Patent Application No. 61/312,642, filed 10 March 2010 (HHS Reference No. E-013-2010-0-US-01);
2. United States Patent No. 9,492,405, issued 15 November 2016 (HHS Reference No. E-013-2010-0-US-08);
3. United States Patent No. 10,130,594, issued 20 November 2018 (HHS Reference No. E-013-2010-0-US-10);
4. United States Patent No. 10,617,654, issued 14 April 2020 (HHS Reference No. E-013-2010-0-US-15);

5. United States Patent Application No. 16/806,659, filed 02 March 2020 (HHS Reference No. E-013-2010-0-US-16);
6. International Patent Application No. PCT/US2011/027988, filed 10 March 2011 (HHS Reference No. E-013-2010-0-PCT-02);
7. Australia Patent No. 2011224241, issued 21 August 2014 (HHS Reference No. E-013-2010-0-AU-03);
8. Australia Patent No. 2014210656, issued 30 June 2016 (HHS Reference No. E-013-2010-0-AU-09);
9. Brazil Patent Application No. BR112012022552-9, filed 10 March 2011 (HHS Reference No. E-013-2010-0-BR-04);
10. Canada Patent No. 2791702, issued 29 May 2018 (HHS Reference No. E-013-2010-0-CA-05);
11. European Patent No. 2544676, issued 19 September 2018 (HHS Reference No. E-013-2010-0-EP-06) and all of its national validations;
12. Japan Patent No. 5837890, issued 13 November 2015 (HHS Reference No. E-013-2010-0-JP-07);
13. any and all other U.S. and ex-U.S. patents and patent applications claiming priority to any one of the foregoing, now or in the future.

<u>E-139-2012: methods of regulating cannabinoid receptor activity-related disorders and diseases</u>

1. United States Provisional Patent Application No. 61/651,961, filed 25 May 2012 (HHS Reference No. E-139-2012-0-US-01);

2. United States Provisional Patent Application No. 61/789,629, filed 15 March 2013 (HHS Reference No. E-139-2012-1-US-01);
3. United States Patent Application No. 14/403,516, filed 24 November 2014 (HHS Reference No. E-139-2012-2-US-06);
4. United States Patent No. 10,130,593, issued 20 November 2018 (HHS Reference No. E-139-2012-2-US-11);
5. United States Patent No. 10,485,771, issued 26 November 2019 (HHS Reference No. E-139-2012-2-US-13);
6. United States Patent Application No. 16/600,234, filed 11 October 2019 (HHS Reference No. E-139-2012-2-US-14);
7. International Patent Application No. PCT/US2013/042457, filed 23 May 2013 (HHS Reference No. E-139-2012-2-PCT-01);
8. Australia Patent No. 2013266235, issued 21 September 2017 (HHS Reference No. E-139-2012-2-AU-02);
9. Canada Patent Application No. 2874655, filed 23 May 2013 (HHS Reference No. E-139-2012-2-CA-03);
10. European Patent No. 2854855, issued 27 April 2016 (HHS Reference No. E-139-2012-2-EP-04) and all of its national validations;
11. Japan Patent No. 6130495, issued 21 April 2017 (HHS Reference No. E-139-2012-2-JP-05);
12. any and all other U.S. and ex-U.S. patents and patent applications claiming priority to any one of the foregoing, now or in the future.

The patent and patent application rights in these inventions have been assigned and/or exclusively licensed to the government of the United States of America.

The prospective exclusive license territory may be worldwide and the fields of use may be limited to the following: the development, manufacture, distribution, sale and use for the treatment of cancer of one or more of fenoterol and its analogues, either in combination or not in combination with one or more other therapeutic agents.

These technologies disclose, e.g., the use of fenoterol and its analogues for regulating cannabinoid (CB) receptor activity-related disorders and disease, such as dysregulated CB receptors, including treating a disorder or disease. These diseases may include but are not limited to glioblastoma, hepatocellular carcinoma, liver cancer, colon cancer, and/or lung cancer, all of which may be associated with altered cannabinoid receptor activity. In one example, the technologies include administering to a subject having or at risk of developing a disorder or disease regulated by CB receptor activity an effective amount of fenoterol or one of its analogues to reduce one or more symptoms associated with the disorder or disease regulated by CB receptor activity.

This Notice is made in accordance with 35 U.S.C. § 209 and 37 C.F.R. § 404. The prospective exclusive license will be royalty bearing, and the prospective exclusive license may be granted unless within fifteen (15) days from the date of this published Notice, the National Cancer Institute receives written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. § 209 and 37 C.F.R. § 404.

In response to this Notice, the public may file comments or objections. Comments and objections, other than those in the form of a license application, will not be treated confidentially, and may be made publicly available.

License applications submitted in response to this Notice will be presumed to contain business confidential information and any release of information from these license applications will be made only as required and upon a request under the Freedom of Information Act, 5 U.S.C. § 552.

Dated: June 12, 2020. _____

Richard U. Rodriguez,

Associate Director,

Technology Transfer Center,

National Cancer Institute.

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