

**DEPARTMENT OF HEALTH AND HUMAN SERVICES****National Institutes of Health****Prospective Grant of Exclusive License: The Development of Therapeutic Agents for the Treatment of Metastatic Breast Cancer and T-cell Lymphoma**

**AGENCY:** National Institutes of Health, Public Health Service, HHS.

**ACTION:** Notice.

**SUMMARY:** This is notice, in accordance with 35 U.S.C. 209(c)(1) and 37 CFR Part 404.7(a)(1)(i), that the National Institutes of Health, Department of Health and Human Services, is contemplating the grant to Birich Technologies, Inc., of an exclusive evaluation option license to practice the inventions embodied in the following U.S. Patent Applications (and all continuing applications and foreign counterparts): Serial No. 61/045,088 entitled, "COMPOSITIONS AND METHODS FOR DELIVERING INHIBITORY OLIGONUCLEOTIDES" [HHS Ref. E-051-2008/0-US-01]; Serial No. 61/333,512 entitled, "Peptide Inhibitors of Interferon Gamma and Interleukin 10 Signaling" [HHS Ref. E-167-2010/0-US-01]; and Serial No. 60/987,340 entitled, "Diagnostic and Therapeutic Applications of a p53 Isoform in Regenerative Medicine, Aging and Cancer" [HHS Ref. E-033-2008/0-US-01]. The patent rights in these inventions have been assigned or exclusively licensed to the Government of the United States of America.

The prospective exclusive evaluation option license territory may be worldwide, and the field of use may be limited to:

The use in humans of the peptide-based antisense delivery technology (ChemoArp) in conjunction with either (i) a peptide-based interleukin-10 (IL-10) inhibitor as a dual-biologic therapy to treat metastatic breast cancer, or ii) incorporating a p53 isoform antisense oligonucleotide as a single biologic therapy to treat T-cell lymphoma.

Upon the expiration or termination of the exclusive evaluation option license, Birich Technologies, Inc. will have the exclusive right to execute an exclusive commercialization license which will supersede and replace the exclusive evaluation option license with no greater field of use and territory than granted in the exclusive evaluation option license.

**DATES:** Only written comments or applications for a license (or both) which are received by the NIH Office of

Technology Transfer on or before October 30, 2012 will be considered.

**ADDRESSES:** Requests for copies of the patent application, inquiries, comments, and other materials relating to the contemplated exclusive evaluation option license should be directed to: Patrick McCue, Ph.D., Licensing and Patenting Manager, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852-3804; Telephone: (301) 435-5560; Facsimile: (301) 402-0220; Email: [mccuepat@mail.nih.gov](mailto:mccuepat@mail.nih.gov).

**SUPPLEMENTARY INFORMATION:** These inventions concern i) compositions and methods for targeted delivery of inhibitory nucleic acids to cells using a cell surface receptor ligand targeting domain and an inhibitory oligonucleotide-binding domain to efficiently deliver the antisense nucleic acid to cells that expresses the cell surface receptor that binds the ligand, ii) compositions that potently and selectively interfere with dimerization of interleukin-10 and binding of this protein to its receptor, and iii) compositions that inhibit *delta133p53*, a natural variant nucleic acid of tumor suppressor protein 53 (p53) that inhibits p53-dependent cell senescence.

The prospective exclusive evaluation option license is being considered under the small business initiative launched on 1 October 2011, and will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR Part 404.7. The prospective exclusive evaluation option license, and a subsequent exclusive commercialization license, may be granted unless the NIH 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 CFR Part 404.7 within fifteen (15) days from the date of this published notice.

Complete applications for a license in the field of use filed in response to this notice will be treated as objections to the grant of the contemplated exclusive evaluation option license. Comments and objections submitted to this notice will not be made available for public inspection and, to the extent permitted by law, will not be released under the *Freedom of Information Act*, 5 U.S.C. 552.

Dated: October 9, 2012.

**Richard U. Rodriguez,**

*Director, Division of Technology Development & Transfer, Office of Technology Transfer, National Institutes of Health.*

[FR Doc. 2012-25170 Filed 10-12-12; 8:45 am]

**BILLING CODE 4140-01-P**

**DEPARTMENT OF HOMELAND SECURITY**

[Docket No. DHS-2012-0056]

**National Infrastructure Advisory Council**

**AGENCY:** National Protection and Programs Directorate, DHS.

**ACTION:** Committee Management; Notice of an open Federal Advisory Committee Meeting.

**SUMMARY:** The National Infrastructure Advisory Council (NIAC) will meet Tuesday, October 16, 2012, at the United States Access Board, 1331 F Street NW., Suite 800, Washington, DC 20004. The meeting will be open to the public.

**DATES:** The NIAC will meet Tuesday, October 16, 2012, from 1:30 p.m. to 4:30 p.m. The meeting may close early if the committee has completed its business. For additional information, please consult the NIAC Web site, [www.dhs.gov/NIAC](http://www.dhs.gov/NIAC), or contact the NIAC Secretariat by phone at (703) 235-2888 or by email at [NIAC@hq.dhs.gov](mailto:NIAC@hq.dhs.gov).

**ADDRESSES:** United States Access Board, 1331 F Street NW., Suite 800, Washington, DC 20004.

For information on facilities or services for individuals with disabilities or to request special assistance at the meeting, contact the person listed under **FOR FURTHER INFORMATION CONTACT**, below as soon as possible.

To facilitate public participation, we are inviting public comment on the issues to be considered by the Council as listed in the **SUMMARY** section below. Comments must be submitted in writing no later than October 11, 2012, and must be identified by "DHS-2012-0056" and may be submitted by any one of the following methods:

- **Federal eRulemaking Portal:** [www.regulations.gov](http://www.regulations.gov). Follow the instructions for submitting written comments.
- **Email:** [NIAC@hq.dhs.gov](mailto:NIAC@hq.dhs.gov). Include the docket number in the subject line of the message.
- **Fax:** (703) 603-5098.
- **Mail:** Nancy Wong, National Protection and Programs Directorate, Department of Homeland Security, 245 Murray Lane SW., Mail Stop 0607, Arlington, VA 20598-0607.

**Instructions:** All written submissions received must include the words "Department of Homeland Security" and the docket number for this action. Written comments received will be posted without alteration at [www.regulations.gov](http://www.regulations.gov), including any personal information provided.

**Docket:** For access to the docket to read background documents or comments received by the NIAC, go to [www.regulations.gov](http://www.regulations.gov).

Members of the public will have an opportunity to provide oral comments after the presentation of the report from the Regional Resilience Working Group. We request that comments be limited to the issues listed in the meeting agenda and previous NIAC studies. All previous NIAC studies can be located at [www.dhs.gov/NIAC](http://www.dhs.gov/NIAC). Relevant public comments may be submitted in writing or presented in person for the Council to consider. Comments received by Nancy Wong after October 11, 2012, will still be accepted and reviewed by the members, but not necessarily by the time of the meeting. In-person presentations will be limited to 3 minutes per speaker, with no more than 30 minutes for all speakers. Parties interested in making in-person comments should register no later than 15 minutes prior to the beginning of the meeting at the meeting location.

**FOR FURTHER INFORMATION CONTACT:** Nancy Wong, National Infrastructure Advisory Council Designated Federal Officer, Department of Homeland Security, telephone (703) 235-2888.

**SUPPLEMENTARY INFORMATION:** Notice of this meeting is given under the Federal Advisory Committee Act, 5 U.S.C. App. (Pub. L. 92-463). The NIAC shall provide the President through the Secretary of Homeland Security with advice on the security of the critical infrastructure sectors and their information systems.

The NIAC will meet to discuss issues relevant to the protection of critical infrastructure as directed by the President. At this meeting, the Council will receive and discuss a presentation from the NIAC Regional Resilience Working Group documenting their work to date on the Regional Resilience Study, which includes the role and impact of critical infrastructure on regional resiliency, best regional practices and models, and the contribution of public private partnerships. The presentation will be posted no later than one week prior to the meeting on the Council's public Web page on [www.dhs.gov/NIAC](http://www.dhs.gov/NIAC). The Council will review and discuss the findings of the Working Group. Federal officials will provide further direction to the Council on the scope of the Working Group's study.

The Federal Advisory Committee Act requires that notices of meetings of advisory committees be announced in the **Federal Register** 15 days prior to the meeting date.

This notice of the NIAC meeting is published in the **Federal Register** with less than 15 days notice due to the complexity of the issues within the current study. Due to the complexities, the NIAC Working Group was not able to complete the interim finding of the report within this aggressive time line. Waiting for the full 15 day notice period to conduct the meeting will delay the discussion of the report. In order to not delay the continuation of this important study, this meeting is being announced with less than 15 days notice.

#### Meeting Agenda

- I. Opening of Meeting
- II. Roll Call of Members
- III. Opening Remarks and Introductions
- IV. Approval of July 17, 2012, minutes
- V. NIAC Presentation on Regional Resilience Working Group
- VI. Public Comment: Discussion Limited to Meeting Agenda Items and Previous NIAC Studies
- VII. Closing Remarks

#### Information on Services for Individuals With Disabilities

For information on facilities or services for individuals with disabilities or to request special assistance at the meeting, contact the NIAC Secretariat at (703) 235-2888 as soon as possible.

Dated: October 3, 2012.

**Nancy Wong,**

*Designated Federal Officer for the NIAC.*

[FR Doc. 2012-25176 Filed 10-12-12; 8:45 am]

**BILLING CODE 9110-9P-P**

## DEPARTMENT OF THE INTERIOR

### Fish and Wildlife Service

[FWS-R4-ES-2012-N236;  
FXES1113040000EA-123-FF04EF1000]

#### Endangered and Threatened Wildlife and Plants; Receipt of Application for Incidental Take Permit; Availability of Proposed Low-Effect Habitat Conservation Plan; Primax Properties, LLC, Lake County, FL

**AGENCY:** Fish and Wildlife Service, Interior.

**ACTION:** Notice of availability; request for comment/information.

**SUMMARY:** We, the Fish and Wildlife Service (Service), have received an application from Primax Properties, LLC (applicant), for an incidental take permit (ITP). The applicant requests a 5-year ITP under the Endangered Species Act of 1973, as amended (Act). We request public comment on the permit application (#TE83714A-0) and

accompanying proposed habitat conservation plan (HCP), as well as on our preliminary determination that the plan qualifies as low-effect under the National Environmental Policy Act (NEPA). To make this determination, we used our environmental action statement and low-effect screening form, which are also available for review.

**DATES:** To ensure consideration, please send your written comments by November 14, 2012.

**ADDRESSES:** If you wish to review the application and HCP, you may request documents by email, U.S. mail, or phone (see below). These documents are also available for public inspection by appointment during normal business hours at the office below. Send your comments or requests by any one of the following methods.

**Email:** [northflorida@fws.gov](mailto:northflorida@fws.gov). Use "Attn: Permit number TE83714A-0" as your message subject line.

**Fax:** David L. Hankla, Field Supervisor, (904) 731-3045, Attn.: Permit number TE83714A-0.

**U.S. mail:** David L. Hankla, Field Supervisor, Jacksonville Ecological Services Field Office, Attn: Permit number TE83714A-0, U.S. Fish and Wildlife Service, 7915 Baymeadows Way, Suite 200, Jacksonville, FL 32256.

**In-person drop-off:** You may drop off information during regular business hours at the above office address.

**FOR FURTHER INFORMATION CONTACT:** Erin M. Gawera, telephone: (904) 731-3121; email: [erin\\_gawera@fws.gov](mailto:erin_gawera@fws.gov).

#### SUPPLEMENTARY INFORMATION:

##### Background

Section 9 of the Act (16 U.S.C. 1531 et seq.) and our implementing Federal regulations in the Code of Federal Regulations (CFR) at 50 CFR part 17 prohibit the "take" of fish or wildlife species listed as endangered or threatened. Take of listed fish or wildlife is defined under the Act as "to harass, harm, pursue, hunt, shoot, wound, kill, trap, capture, or collect, or to attempt to engage in any such conduct" (16 U.S.C. 1532). However, under limited circumstances, we issue permits to authorize incidental take—i.e., take that is incidental to, and not the purpose of, the carrying out of an otherwise lawful activity.

Regulations governing incidental take permits for threatened and endangered species are at 50 CFR 17.32 and 17.22, respectively. The Act's take prohibitions do not apply to federally listed plants on private lands unless such take would violate State law. In addition to meeting other criteria, an incidental take permit's proposed actions must not