Cancer Moonshot Pilot Program/Patents 4 Patients
Immunotherapy Pilot Program

• The United States Patent and Trademark Office implemented a pilot program (Patents 4 Patients) to provide for fast-track review of patent applications pertaining to cancer immunotherapy in support of the White House national $1 billion initiative to achieve ten years’ worth of cancer research in the next five years (“National Cancer Moonshot”).

• The objective of the pilot program was to complete the examination of the application within twelve months of special status being granted under the program.
Requirements

(1) Application type:
   - any application that has not received a first Office action,
   - any application where the petition is filed with a Request for Continued Examination (RCE), or
   - any application not under final rejection where the claimed cancer immunotherapy is the subject of an active Investigational New Drug (IND) application that has entered Phase II or Phase III (FDA) clinical trials.

(2) Three or fewer independent claims and twenty or fewer total claims.

(3) At least one method claim of treating a cancer using immunotherapy.

(4) File a Petition. See Form PTO/SB/443
Basic Requirements of Claim Construction

A method of treating, ameliorating, or preventing a malignancy..

• Steps must invoke (active) or achieve (passive) an immune response.
• Can include co-administration of biological adjuvants in combination with conventional therapies.
• Cancer vaccines (DNA, peptides, cells).
• Adoptive immunotherapies.
Prosecution

Requirement for Restriction:
• If multiple inventions are found in the application, the examiner may make a restriction requirement in accordance with current restriction practice.
  ▪ Must follow the procedure for telephonic restriction practice set forth in MPEP § 812.01.
  ▪ Applicants must make a telephonic election without traverse to a method of treating cancer using immunotherapy that meets the eligibility requirements.
  ▪ If Applicants cannot be reached after reasonable effort or applicant refuses to make a telephonic election, the examiner will treat the first group of claims to a method of treating a cancer using immunotherapy as constructively elected without traverse for examination.
Prosecution

Amendments:

• Any amendment to a non-final Office action will be considered non-responsive if it attempts to:
  ▪ Add claims which would result in more than three independent claims or more than twenty total claims.
  ▪ Add any multiple dependent claim.
  ▪ Present claims to a nonelected invention or an invention not previously claimed.
  ▪ Cancel all method claims to treating a cancer using immunotherapy.
Petition History

TOTAL NUMBER OF APPLICATIONS PER MONTH AND DECISION

- **JUL:** 10
- **AUG:** 7
- **SEP:** 7
- **OCT:** 11
- **NOV:** 5
- **DEC:** 6
- **JAN:** 3 (2 GRANTED, 1 DISMISSED)
- **FEB:** 11
- **MAR:** 1
- **APR:** 3
- **MAY:** 8 (6 GRANTED, 1 DISMISSED)
- **JUN:** 20 (8 GRANTED, 4 GRANTED, 4 DISMISSED)
- **JUL:** 3

Categories:
- **UNDECIDED**
- **GRANTED**
- **DISMISSED**
Art Unit Distribution
Status of Granted Petitions

Count of Applications Granted by Status

- Publications -- Issue Fee Payment Verified: 3
- Notice of Appeal Filed: 1
- Response after Final Action Forwarded to Examiner: 1
- Patented Case: 13
- Allowance Counted: 1
- Special New: 2
- Response to Non-Final Office Action Entered and Forwarded to...: 6
- Notice of Allowance Mailed -- Application Received in Office of...: 8
- Non Final Action Mailed: 22
- Non Final Action Counted, Not Yet Mailed: 2
- Final Rejection Mailed: 13
- Docketed New Case - Ready for Examination: 1
What is claimed is:

1. A method of treating cancer in a subject in need thereof, wherein the cancer comprises cells that express CD47, the method comprising administering to the subject an effective amount of an isolated anti-CD47 antibody molecule comprising a heavy chain complementarity determining region 1 (HCDR1) of the amino acid sequence set forth in SEQ ID NO: 7, a heavy chain complementarity determining region 2 (HCDR2) of the amino acid sequence set forth in SEQ ID NO: 8, a heavy chain complementarity determining region 3 (HCDR3) of the amino acid sequence set forth in SEQ ID NO: 9, a light chain complementarity determining region 1 (LCDR1) of the amino acid sequence set forth in SEQ ID NO: 10, a light chain complementarity determining region 2 (LCDR2) of the amino acid sequence set forth in SEQ ID NO: 11, and a light chain complementarity determining region 3 (LCDR3) of the amino acid sequence set forth in SEQ ID NO: 12.

2. The method of claim 1, wherein the anti-CD47 antibody molecule is administered in combination with a chemo-therapeutic agent or therapeutic antibody molecule.

3. The method of claim 1, wherein the anti-CD47 antibody molecule is administered in combination with an immunosuppressing antibody molecule.

4. The method of claim 3, wherein the immunosuppressing antibody molecule is an anti-CD9 antibody molecule, an anti-CD20 antibody molecule, or an anti-CD38 antibody molecule.

5. The method of claim 4, wherein the immunosuppressing antibody molecule is an anti-CD20 antibody molecule.

6. The method of claim 4, wherein the antibody molecule is rituximab.

7. The method of claim 1, wherein the cancer is a hematological cancer.

8. The method of claim 7, wherein the hematological cancer is selected from the group consisting of: acute lymphoblastic leukemia (ALL), T-ALL, B-ALL, acute myelogenous leukemia (AML), Non-Hodgkin lymphoma, B-lymphoblastic lymphoma/leukemia; B-cell chronic lymphocytic leukemia/small lymphocytic lymphoma, chronic lymphocytic leukemia (CLL), chronic myelogenous leukemia (CML), Burkitt's lymphoma, follicular lymphoma, SLL, and NHL.

9. The method of claim 1, wherein the anti-CD47 antibody molecule further comprises a wild type or mutant IgG1 heavy chain constant region.

10. The method of claim 14, wherein the IgG4 heavy chain constant region comprises one or both of the substitutions S228P and L235E.

11. The method of claim 1, wherein the anti-CD47 antibody molecule comprises a heavy chain of the amino acid sequence set forth in SEQ ID NO: 15, SEQ ID NO: 23, SEQ ID NO: 24, or SEQ ID NO: 25, and a light chain of the amino acid sequence set forth in SEQ ID NO: 16 or SEQ ID NO: 26.

12. The method of claim 1, wherein the anti-CD47 antibody molecule is administered in combination with a pharmacologically acceptable carrier or diluent.

13. The method of claim 1, wherein the anti-CD47 antibody molecule is administered intravenously.

14. The method of claim 1, wherein the anti-CD47 antibody molecule is administered in combination with a pharmaceutically acceptable carrier or diluent.

15. The method of claim 1, wherein the anti-CD47 antibody molecule is administered intravenously.
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