Cancer Moonshot Pilot Program/Patents 4 Patients

UNITED STATES
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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:

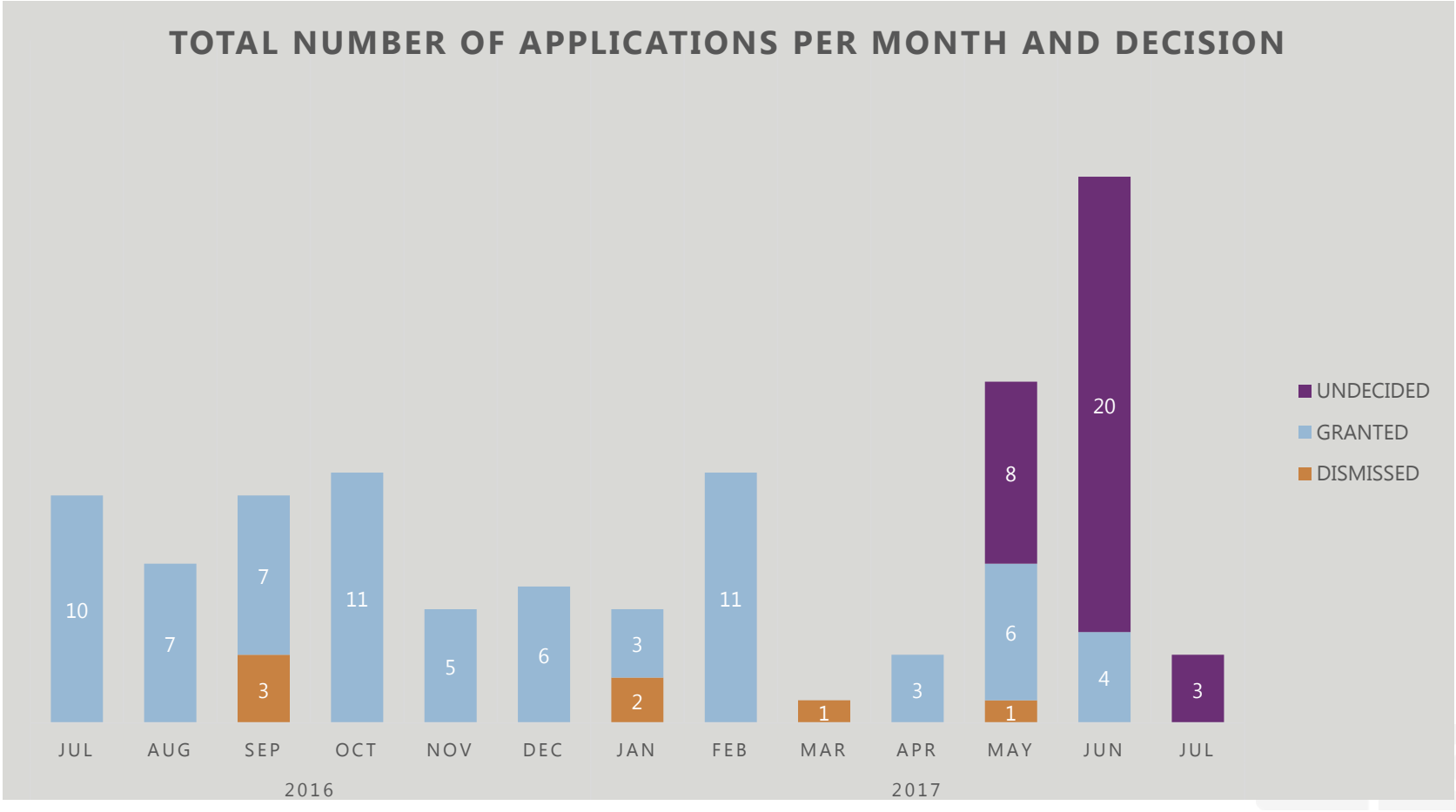
- If multiple inventions are found in the application, the examiner may make a restriction requirement in accordance with current restriction practice.
  - Must follow the procedure for telephonic restriction practice set forth in MPEP § 812.01.
  - Applicants must make a telephonic election without 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

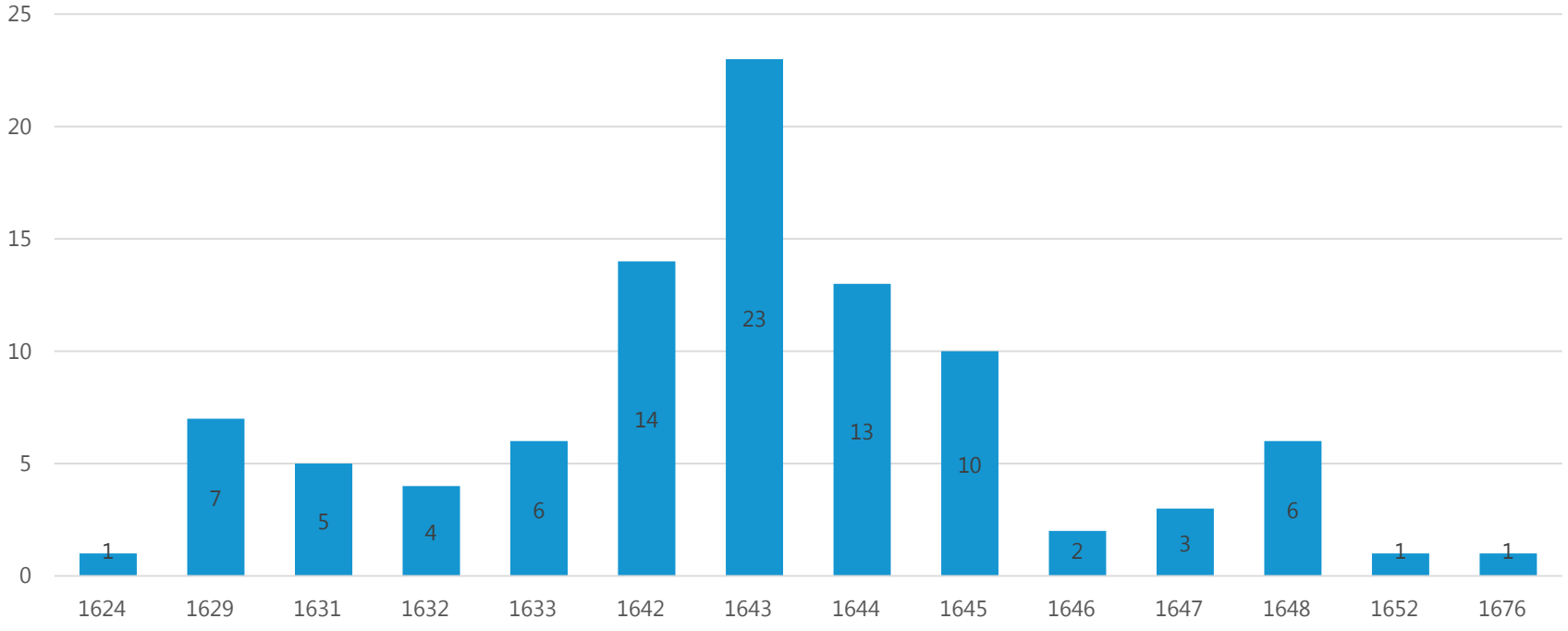
Amendments:

- 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.

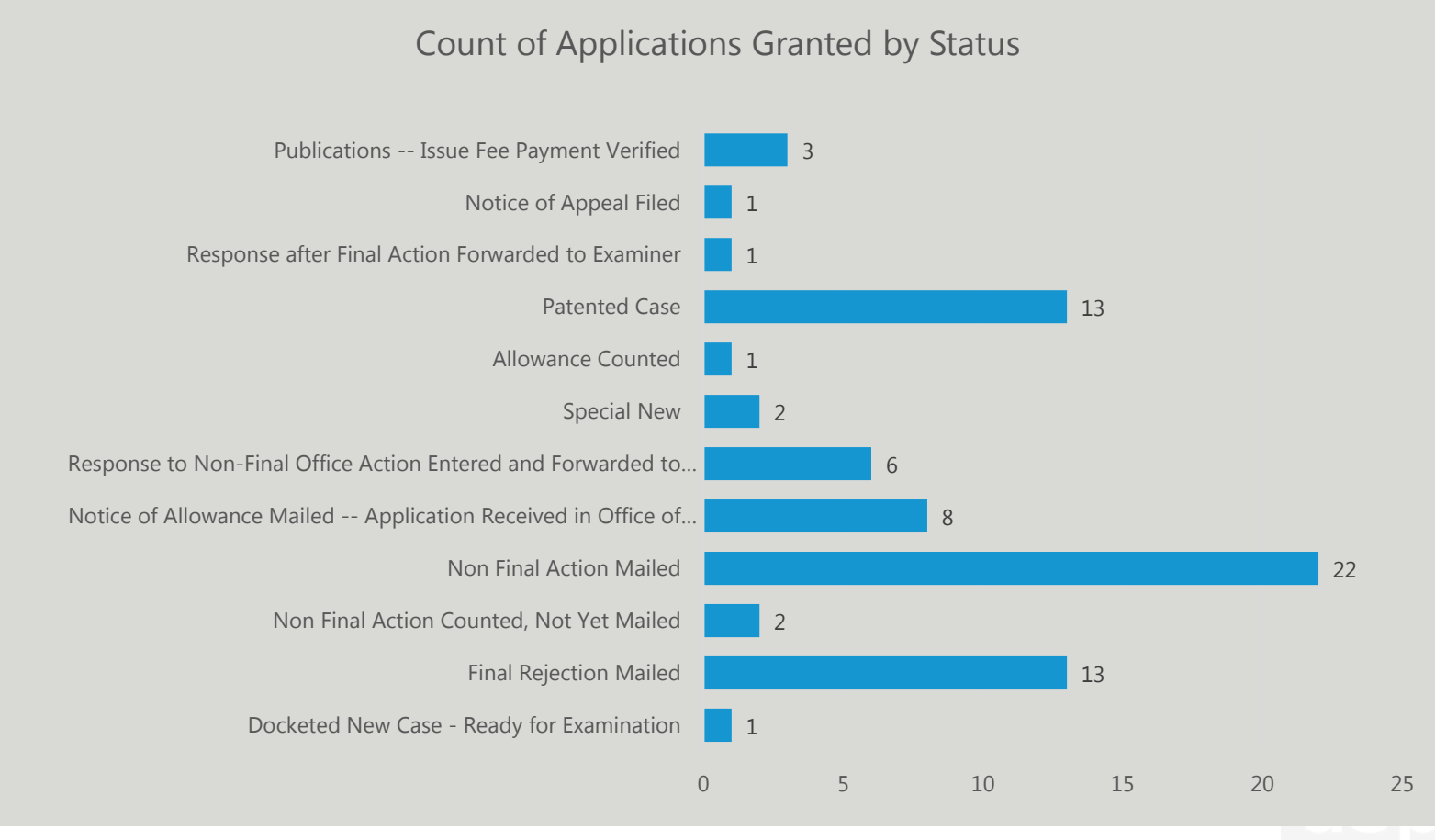
Petition History



Art Unit Distribution



Status of Granted Petitions



(12) **United States Patent**
Grosveld et al.

(10) **Patent No.: US 9,650,441 B2**
(45) **Date of Patent: May 16, 2017**

(54) **ANTI-CD47 ANTIBODIES AND METHODS OF USE**

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(*) 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.: **15/271,861**

(22) Filed: **Sep. 21, 2016**

(65) **Prior Publication Data**

US 2017/0081407 A1 Mar. 23, 2017

Related U.S. Application Data

(60) Provisional application No. 62/371,047, filed on Aug. 4, 2016, provisional application No. 62/221,446, filed on Sep. 21, 2015.

(51) **Int. Cl.**

A61K 39/395	(2006.01)
C07K 16/28	(2006.01)
A61K 39/00	(2006.01)

(52) **U.S. Cl.**

CPC ***C07K 16/2803*** (2013.01); ***C07K 16/2887*** (2013.01); *A61K 2039/507* (2013.01); *C07K 2317/24* (2013.01); *C07K 2317/52* (2013.01); *C07K 2317/56* (2013.01); *C07K 2317/565* (2013.01); *C07K 2317/73* (2013.01)

(58) **Field of Classification Search**

None

See application file for complete search history.

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(Continued)

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(57) **ABSTRACT**

Disclosed herein are anti-CD47 antibody molecules, their manufacture and use in treating disorders associated with CD47 expression, for example, certain hematological cancers and solid tumors.

20 Claims, 21 Drawing Sheets

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 (HC CDR1) of the amino acid sequence set forth in SEQ ID NO: 7, a heavy chain complementarity determining region 2 (HC CDR2) of the amino acid sequence set forth in SEQ ID NO: 8, a heavy chain complementarity determining region 3 (HC CDR3) of the amino acid sequence set forth in SEQ ID NO: 9, a light chain complementarity determining region 1 (LC CDR1) of the amino acid sequence set forth in SEQ ID NO: 10, a light chain complementarity determining region 2 (LC CDR2) of the amino acid sequence set forth in SEQ ID NO: 11, and a light chain complementarity determining region 3 (LC CDR3) 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 chemotherapeutic agent or therapeutic antibody molecule.

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

4. The method of claim **3**, wherein the opsonizing antibody molecule is an anti-CD19 antibody molecule, an anti-CD20 antibody molecule, or an anti-CD38 antibody molecule.

5. The method of claim **4**, wherein the opsonizing 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 i 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 leukemia/lymphoma; B-cell chronic lymphocytic leukemia/small lymphocytic lymphoma, chronic lymphocytic leukemia (CLL), chronic myelocytic leukemia (CML), Burkitt's lymphoma, follicular lymphoma, SLL, marginal zone lymphoma, CNS lymphoma, Richter's Syndrome, multiple myeloma, myelofibrosis, polycythemia vera, cutaneous T-cell lymphoma, MGUS, myelodysplastic syndrome (MDS), immunoblastic large cell lymphoma, precursor B-lymphoblastic lymphoma and anaplastic large cell lymphoma.

9. The method of claim **8**, wherein the hematological cancer is acute myelogenous leukemia (AML) or Burkitt's lymphoma.

10. The method of claim **1**, wherein the cancer is a solid tumor.

11. The method of claim **10**, wherein the cancer is a cancer of a tissue selected from the group consisting of: lung, pancreas, breast, liver, ovary, testicle, kidney, bladder, spine, brain, cervix, endometrium, colon/rectum, anus, esophagus, gallbladder, gastrointestinal tract, skin, prostate, pituitary, stomach, uterus, vagina, and thyroid.

12. The method of claim **1**, wherein the anti-CD47 antibody molecule comprises a heavy chain variable region (VH) of the amino acid sequence set forth in SEQ TD NO: 4 and a light chain variable region (VL) of the amino acid sequence set forth in SEQ ID NO: 6.

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

14. The method of claim **1**, wherein the anti-CD47 antibody molecule further comprises a wild type or mutant IgG4 heavy chain constant region.

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

16. 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.

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

18. The method of claim **1**, wherein the anti-CD47 antibody molecule is administered subcutaneously.

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

20. The method of claim **1**, wherein the cancer is selected from the group consisting of: pancreatic cancer, ovarian cancer, breast cancer, stomach cancer, colon cancer, prostate cancer, and uterine cancer.

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