

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MILTENYI BIOMEDICINE GmbH and MILTENYI BIOTECH INC.
Petitioner

v.

THE TRUSTEES OF THE UNIVERSITY OF PENNSYLVANIA
Patent Owner

IPR Trial No. IPR2022-00855
U.S. Patent No. 9,540,445

DECLARATION OF THOMAS S. FLETCHER

I, Thomas S. Fletcher, make the following Declaration pursuant to 28 U.S.C. § 1746:

1. I am a partner at the law firm of Williams & Connolly LLP, Backup Counsel for Real Party in Interest and Licensee Novartis Pharma AG. I am a member of the bars of the State of California and the District of Columbia and registered to practice in front of the United States Patent and Trademark Office.
2. I submit this Declaration in connection with the above-identified *Inter Partes* Review proceeding of U.S. Patent No. 9,540,445 that has been instituted at the U.S. Patent and Trademark Office under 35 U.S.C §§ 311-319, 37 C.F.R. § 42.
3. Exhibit 2001 is a true and correct copy of Jason Fagone, *Has Carl June Found a Key to Fighting Cancer?*, PHILA. MAG. (Aug. 1, 2013), which was downloaded from NewsBank and can be accessed behind a paywall at the URL <https://www.newsbank.com/>. An exhibit label and page number have been added to the bottom right corner of this document, but no other alterations have been made.
4. Exhibit 2002 is a true and correct copy of Denise Grady, *An Immune System Trained to Kill Cancer*, N.Y. TIMES (Sept. 12, 2011), which was accessed via the URL <https://www.nytimes.com/2011/09/13/health/13gene.html> and printed to PDF. The article is now permanently accessible at the URL

<https://perma.cc/58EM-KPT5>. An exhibit label and page number have been added to the bottom right corner of this document, but no other alterations have been made.

5. Exhibit 2003 is a true and correct copy of Jasone Fagone, *Walt Keller, Leukemia Survivor, Has Passed*, PHILA. MAG. (Feb. 20, 2014), which was accessed via the URL <https://www.phillymag.com/news/2014/02/20/walt-keller-leukemia-survivor-obituary-1953-2014/> and printed to PDF. The article is now permanently accessible at the URL <https://perma.cc/5CL7-ZPHV>. An exhibit label and page number have been added to the bottom right corner of this document, but no other alterations have been made.
6. Exhibit 2004 is a true and correct copy of Gina Kolata, *A Cancer Treatment Makes Leukemia Vanish, but Creates More Mysteries*, N.Y. TIMES (Feb. 2, 2022), which was accessed via the URL <https://www.nytimes.com/2022/02/02/health/leukemia-car-t-immunotherapy.html> and printed to PDF. The article is now permanently accessible at the URL <https://perma.cc/UV2W-PGCN>. An exhibit label and page number have been added to the bottom right corner of this document, but no other alterations have been made.
7. Exhibit 2005 is a true and correct copy of Denise Grady, *In Girl's Last Hope, Altered Immune Cells Beat Leukemia*, N.Y. TIMES (Dec. 9, 2012), which was accessed via the URL <https://www.nytimes.com/2012/12/10/health/a->

breakthrough-against-leukemia-using-altered-t-cells.html and printed to PDF. The article is now permanently accessible at the URL <https://perma.cc/NUD3-B43D>. An exhibit label and page number have been added to the bottom right corner of this document, but no other alterations have been made.

8. Exhibit 2006 is a true and correct copy of Denise Grady, *F.D.A. Approves First Gene-Altering Leukemia Treatment, Costing \$475,000*, N.Y. TIMES (Aug. 30, 2017), which was accessed via the URL <https://www.nytimes.com/2017/08/30/health/gene-therapy-cancer.html> and printed to PDF. The article is now permanently accessible at the URL <https://perma.cc/6T4Q-9W8D>. An exhibit label and page number have been added to the bottom right corner of this document, but no other alterations have been made.
9. Exhibit 2007 is a true and correct copy of FOOD AND DRUG ADMIN., FDA APPROVAL BRINGS FIRST GENE THERAPY TO THE UNITED STATES (Aug. 30, 2017), which was accessed via the URL <https://www.fda.gov/news-events/press-announcements/fda-approval-brings-first-gene-therapy-united-states> and printed to PDF. The article is now permanently accessible at the URL <https://perma.cc/26LT-ESRX>. An exhibit label and page number have been added to the bottom right corner of this document, but no other alterations have been made.

10. Exhibit 2008 is a true and correct copy of FOOD AND DRUG ADMIN., BREAKTHROUGH THERAPY (Jan. 4, 2018), which was accessed via the URL <https://www.fda.gov/patients/fast-track-breakthrough-therapy-accelerated-approval-priority-review/breakthrough-therapy> and printed to PDF. The article is now permanently accessible at the URL <https://perma.cc/FE35-UMTZ>. An exhibit label and page number have been added to the bottom right corner of this document, but no other alterations have been made.

11. Exhibit 2009 is a true and correct copy of FOOD AND DRUG ADMIN., PRIORITY REVIEW (Jan. 4, 2018), which was accessed via the URL <https://www.fda.gov/patients/fast-track-breakthrough-therapy-accelerated-approval-priority-review/priority-review> and printed to PDF. The article is now permanently accessible at the URL <https://perma.cc/HCV8-DDH6>. An exhibit label and page number have been added to the bottom right corner of this document, but no other alterations have been made.

12. Exhibit 2010 is a true and correct certified copy of Barbara Savoldo et al., *CD28 costimulation improves expansion and persistence of chimeric antigen receptor-modified T cells in lymphoma patients*, 121 J. CLINICAL INVESTIGATION 1822 (2011), which was accessed via the URL <https://www.jci.org/articles/view/46110/pdf> and printed to PDF. The article

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