



March 21, 2018

Ann M. Hammersla, J.D.  
Director  
Division of Extramural Inventions and Technology Resources  
Office of Policy for Extramural Research Administration  
Rockledge 1, Suite 310  
6705 Rockledge Drive  
Bethesda, Maryland 20892-7974  
Email: [hammerslaa@od.nih.gov](mailto:hammerslaa@od.nih.gov)

Dear Director Hammersla:

I am enclosing a memorandum and five attachments that describe two patents granted to James Griffin and assigned to the Dana-Farber Cancer Institute each with the same title:

Staurosporine derivatives as inhibitors of FLT3 receptor tyrosine kinase activity

Patents 7,973,031 and 8,222,244 are listed in the FDA Orange Book for the drug Rydapt (INN midostaurin), which is an expensive drug for the treatment of leukemia, including specifically acute myeloid leukemia (AML), myelodysplastic syndrome and advanced systemic mastocytosis (ASM).

The cost of Rydapt depends upon the indication and patient weight. For a typical patient, the cost for the treatment of AML is \$195,405 per year, and for ASM, \$390,811 per year. In both cases, the high cost is a barrier to access and a fiscal strain on health systems.

We believe both patents were based upon research funded by the NIH. Neither of the patents disclose federal funding.

Griffin has been working in the field of leukemia research since 1985 and has received over \$44 million in funding for 71 projects (and subprojects) where he was the principal investigator. Many of these NIH grants were during the time period of and on topics related to the patents at issue, including over \$15 million in grants between 1996-2001, leading up to the priority date of both patents, and over \$8 million in grants between 2009-2011, leading up to the filing date of the second patent. Griffin was the co-author of papers that describe the invention, refer specifically to midostaurin, and disclose NIH funding.

The memorandum asks the NIH to take title to the patents as a remedy for the failure by Griffin to acknowledge the NIH funding in the patent application, as required by law.

Sincerely,

A handwritten signature in blue ink that reads "Andrew S. Goldman".

Andrew S. Goldman, Esq.  
Counsel, Policy and Legal Affairs  
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A handwritten signature in blue ink that reads "James Love".

James Love, Director, KEI  
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Attachments:

MEMORANDUM: Rydapt (INN midostaurin): Failures to disclose government funding for patents granted to James Griffin and assigned to Dana-Farber Cancer Institute in the FDA Orange Book, KEI Series on inventors that fail to disclose U.S. government funding in patented inventions, March 21, 2018

ANNEX: James Griffin's 71 NIH Funded Projects  
ANNEX: Griffin's CA36167 Grants, from NIH REPORTER  
ANNEX: KEI-Briefing-Note-2018-1

Cc: The Honorable Daniel R. Levinson, Dan.Levinson@oig.hhs.gov