

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

GNOSIS S.P.A., GNOSIS BIORESEARCH S.A., AND
GNOSIS U.S.A., INC.
Petitioners

v.

SOUTH ALABAMA MEDICAL SCIENCE FOUNDATION
Patent Owner

Case IPR 2013-00116
U.S. Patent No. 5,997,915

Case IPR 2013-00118
U.S. Patent No. 6,673, 381

Case IPR 2013-00119
U.S. Patent No. 7,172,778

DECLARATION OF SAMUEL STRADA, Ph.D.

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I, Samuel Strada, pursuant to 37 C.F.R. § 42.53, declare as follows:

I. INTRODUCTION

1. I am the Dean of the College of Medicine, Professor of Pharmacology, and President of the South Alabama Medical Science Foundation (“SAMSF”) at the University of South Alabama College of Medicine.

2. This declaration is based on my personal knowledge and/or information provided to me by employees of SAMSF.

3. I have been the Dean of the College of Medicine continuously beginning in October 2005 to present, and I have been with the University of South Alabama for 30 years as of July 2013. I started at the University as chairman of the Department of Pharmacology in 1983. I have been President of SAMSF since 1993.

4. In my role at the College of Medicine, I am responsible for the academic and research programs and other related support activities, which includes overseeing 18 academic departments and multiple other units.

5. In addition, I have consulted for a number of accreditation boards and scientific review panels and have participated in a number of professional organizations related to my area of specialty and medical education and biomedical science more broadly.

II. BACKGROUND

6. I have a Bachelor's of Pharmacy and a Master's of Science in Pharmacology from University of Missouri in Kansas City and a Ph.D. in Pharmacology from Vanderbilt University. I received my Ph.D. in 1970.

7. After I received my Ph.D., I spent two years as a staff fellow at the National Institute of Mental Health in Washington, D.C., and then beginning in 1972, I spent 11 years on the faculty at the University of Texas Medical School at Houston, where I was a professor. After I left the University of Texas, I came to the University of South Alabama in 1983.

III. SAMSF BACKGROUND

8. SAMSF is a not-for-profit research 509(a)(3) foundation that was established to promote education and research at the University of South Alabama College of Medicine. It was established by the Board of Trustees in 1981.

9. By virtue of my position as Chairman of the Department of Pharmacology, I became a member of the board of SAMSF in 1983 when I joined the University. Within about 3 years of being there I was elected secretary of the board, so I was both an officer and a board member by about 1986. I was elected president after the founding president of the Foundation, who recruited me, retired around 1993.

10. SAMSF invests in research and development in various biomedical fields in hopes of encouraging the advancement of science and innovation at the University. SAMSF evaluates potential areas of research and invests its funds in areas that hold promise for scientific advancement and financial return to support the college's mission. This includes basic investigation research, translation, and clinical application of the research. If SAMSF is successful, it is able to develop the technology, obtain a patent, and eventually gain a return from licensing activities. SAMSF then re-invests the money received from the licenses back into the University and the Foundation. In effect, the revenues SAMSF generates from licensing its technology are reinvested to enhance further research and other activities within the University and in the long-term interests of the University, and the students and faculty at the University develop the technology that SAMSF evaluates as a potential area for a SAMSF investment.

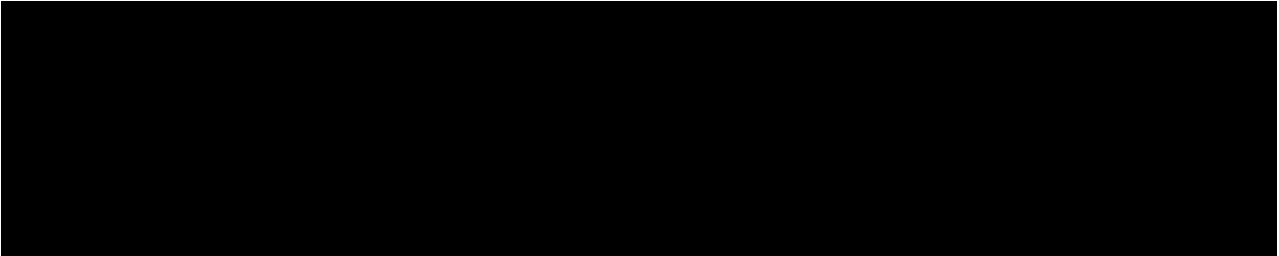
11. A particular technology is evaluated as a potential area for a SAMSF investment and it is determined whether it represents a technology opportunity that is potentially commercially viable. If we determine that the technology does have commercial applicability and a strong potential to provide a good return to the Foundation, we will follow through with an investment in the research and make efforts to secure patent rights using Foundation funds. If not, we relinquish the rights to the technology back to the inventors.

IV. SAMSF PATENTS

13. SAMSF holds a family of patents invented by June Ayling and Steve Bailey. I understand that these patents are the ones at issue in this proceeding. I signed an invention disclosure statement as a witness for the disclosure by Ayling and Bailey. I am also personally aware that we filed and were granted patents naming Ayling and Bailey as inventors, and that Ayling and Bailey assigned their patent rights to SAMSF. Those patent rights include at least U.S. Patent Number 5,997,915, (“the 915 patent”), U.S. Patent Number 6,673,381, (“the 381 patent”), and U.S. Patent Number 7,172,778 (“the 778 patent”) (collectively the “Bailey patents”). SAMSF has licensed the Bailey patents to Merck & Cie.

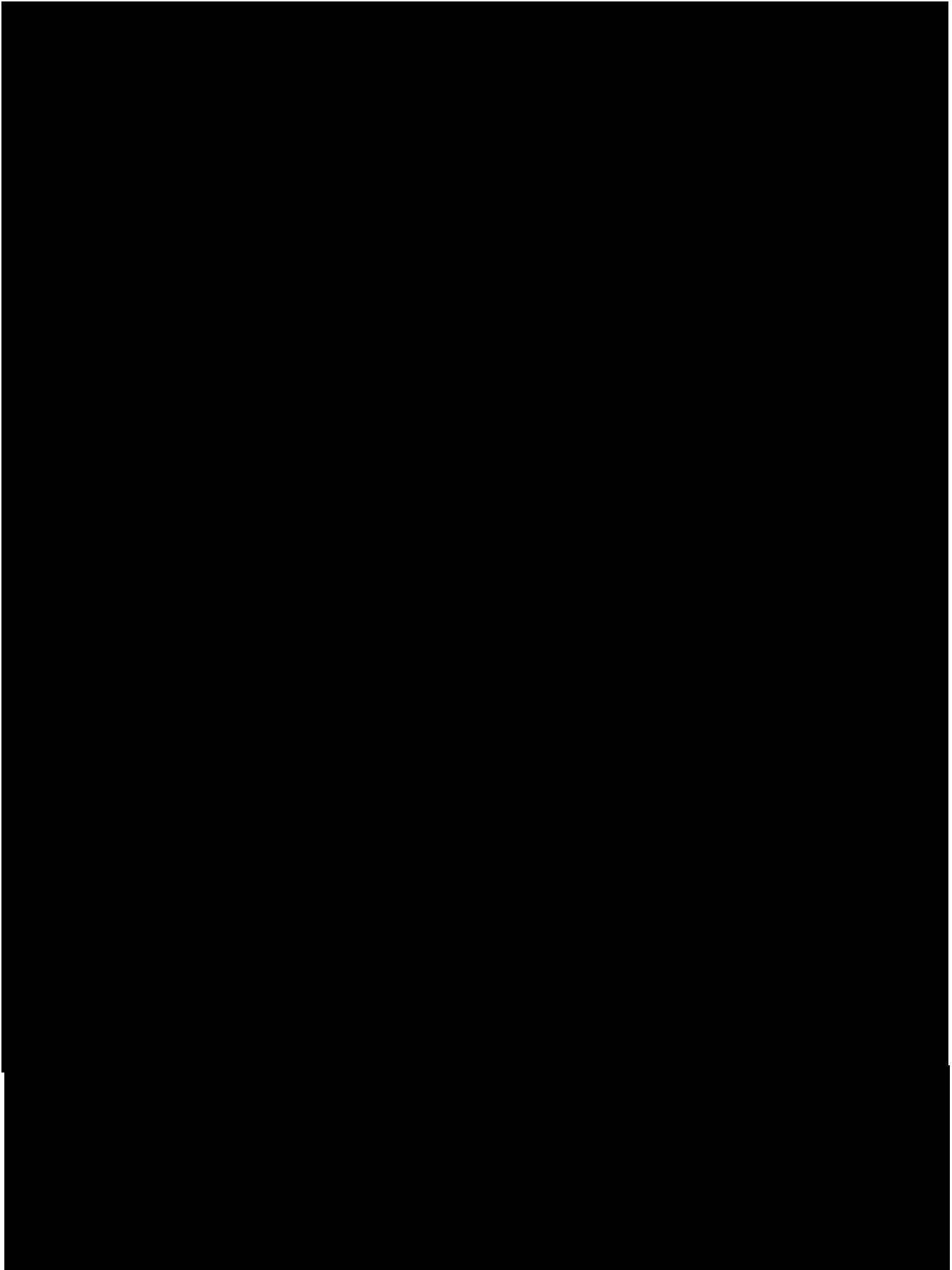
V. SAMSF-MERCK LICENSE

14. SAMSF evaluated the technology disclosed and claimed in the Bailey patents at an early stage to determine whether we believed there was a viable commercial path for the invention. We concluded there was and based on that, determined that we needed a licensing partner that would give us the best opportunity at creating a sound product that would be commercially successful and a good source of revenue generation.



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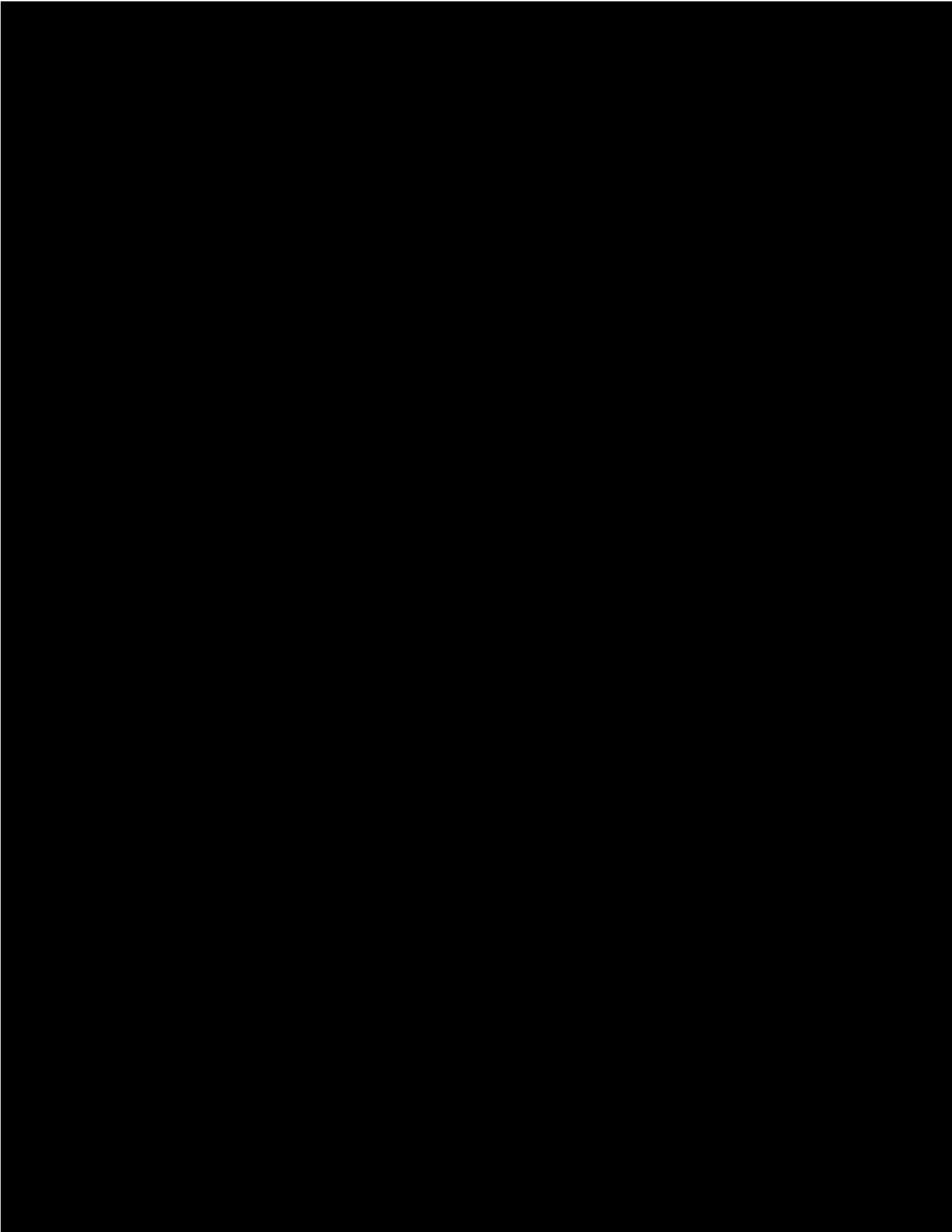


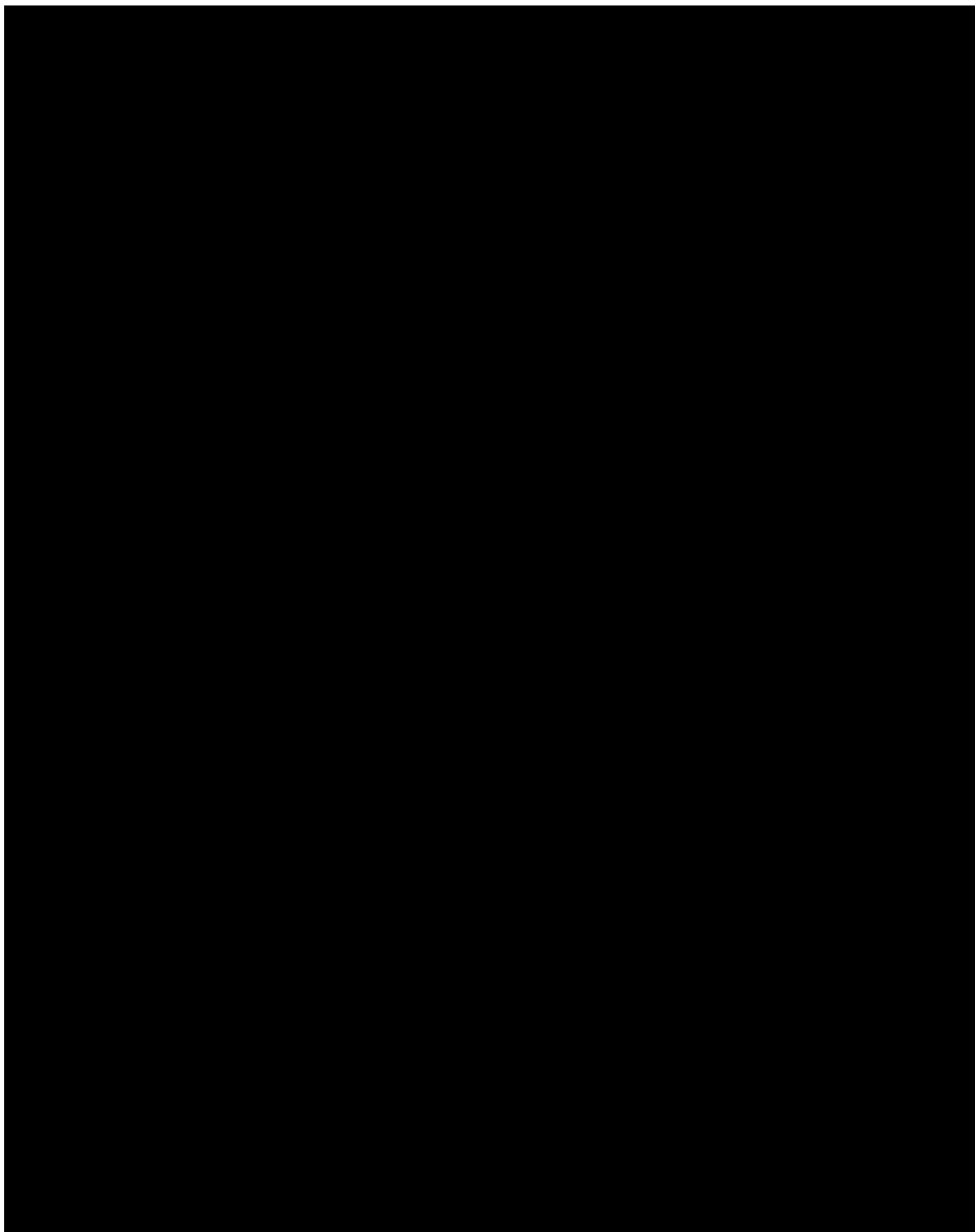
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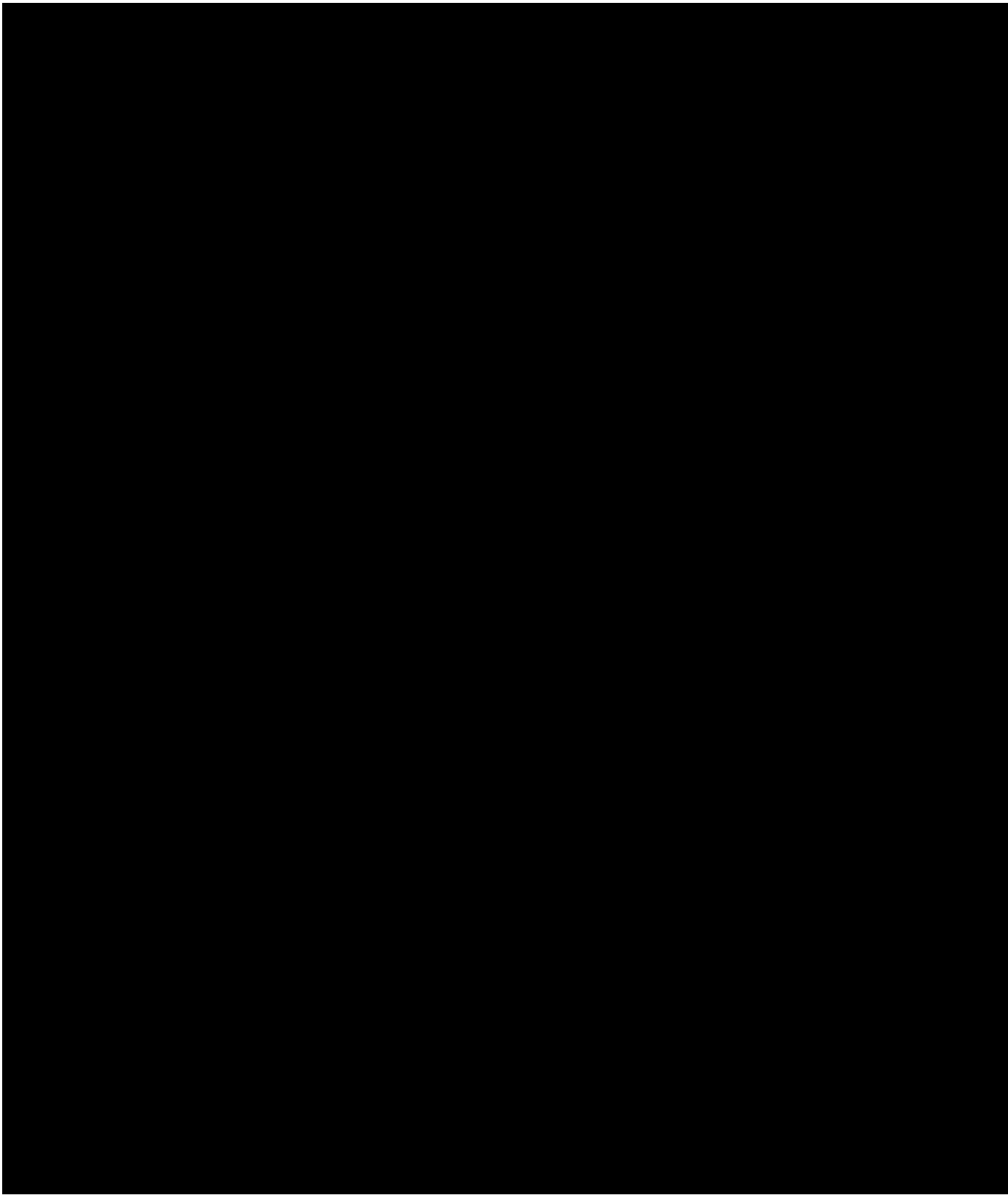
21. The SAMSF license to Merck was not precipitated by a lawsuit or the threat of a lawsuit between SAMSF and Merck.

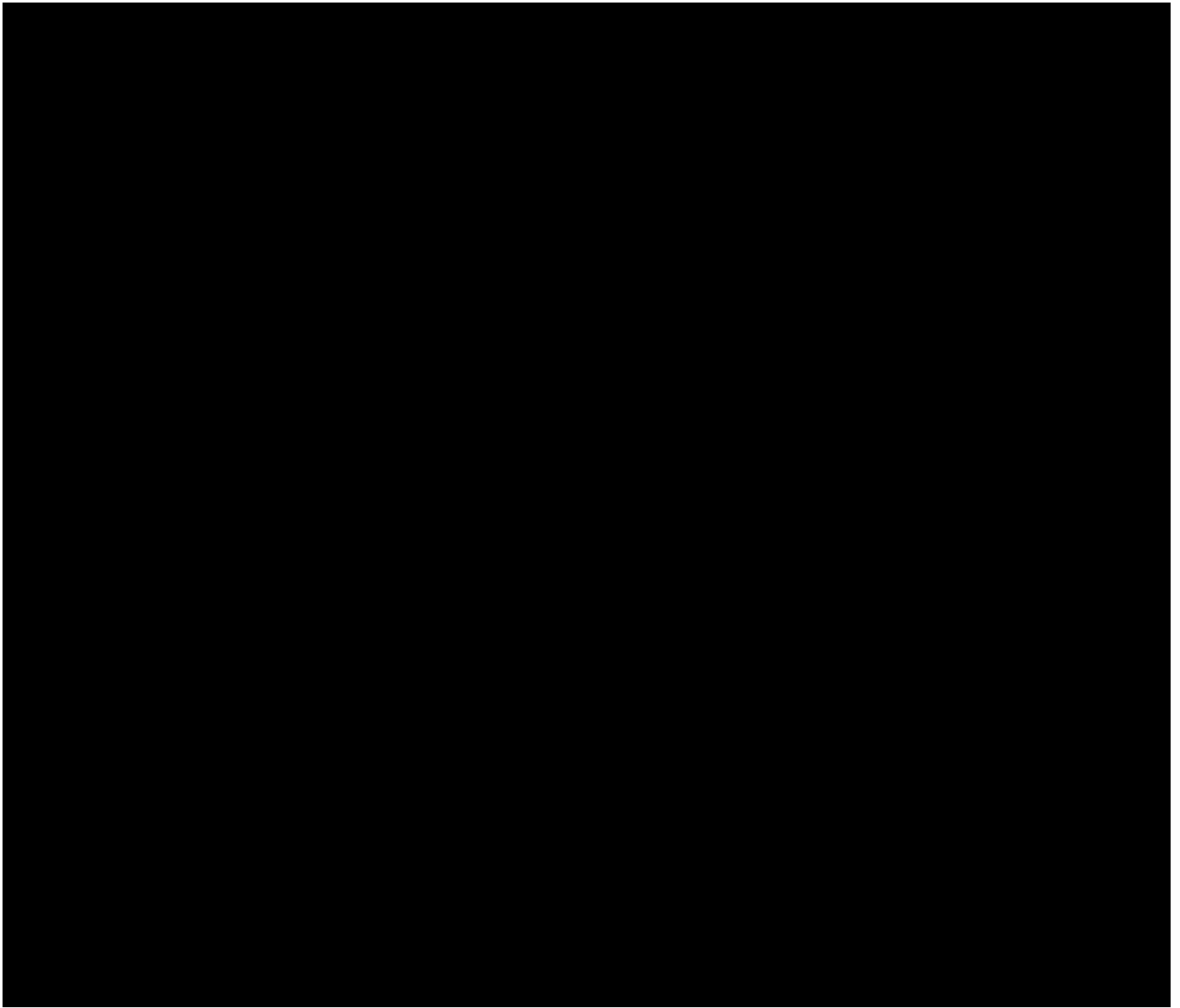
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31. I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

September 23, 2013

A handwritten signature in black ink, reading "Samuel J. Strada". The signature is written in a cursive style with a large initial 'S'.

Samuel J. Strada, Ph.D.