

Microbial Commercial Activity Notice
40 C.F.R. § 725.155

to the

U.S. Environmental Protection Agency
Office of Pollution Prevention and Toxics
Chemical Control Division
New Chemicals Notice Management Branch

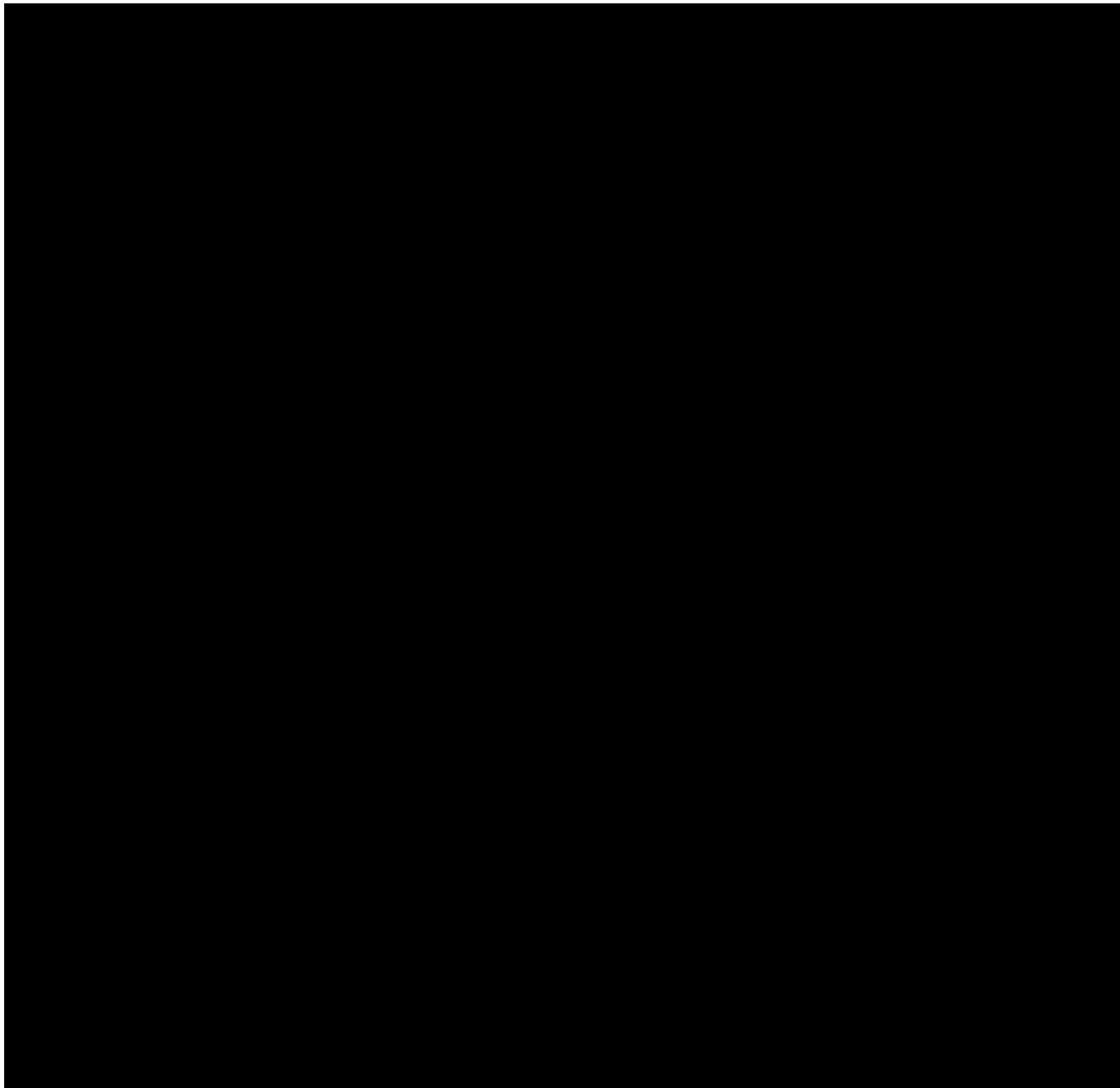
TS Number: [REDACTED]

Submitter:

[REDACTED]
[REDACTED]
[REDACTED]

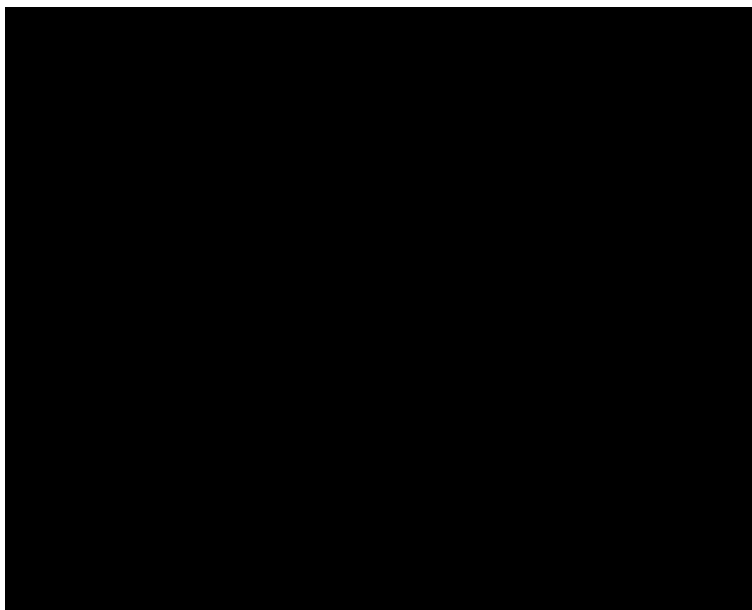
Submitted to:

TSCA Document Processing Center (7407)
Room L-100
Office of Pollution Prevention and Toxics
U.S. Environmental Protection Agency
1200 Pennsylvania Ave., N.W.
Washington, D.C. 20460



1. CERTIFICATION OF INFORMATION

I certify that to the best of my knowledge and belief: The company named in this submission intends to manufacture, import, or process for a commercial purpose, other than in small quantities solely for research and development, the microorganism identified in this submission. All information provided in the submission is complete and truthful as of the date of this submission. I am including with this submission all test data in my possession or control and a description of all other data known to or reasonably ascertainable by me as required by 40 C.F.R. § 725.160 or § 725.260.

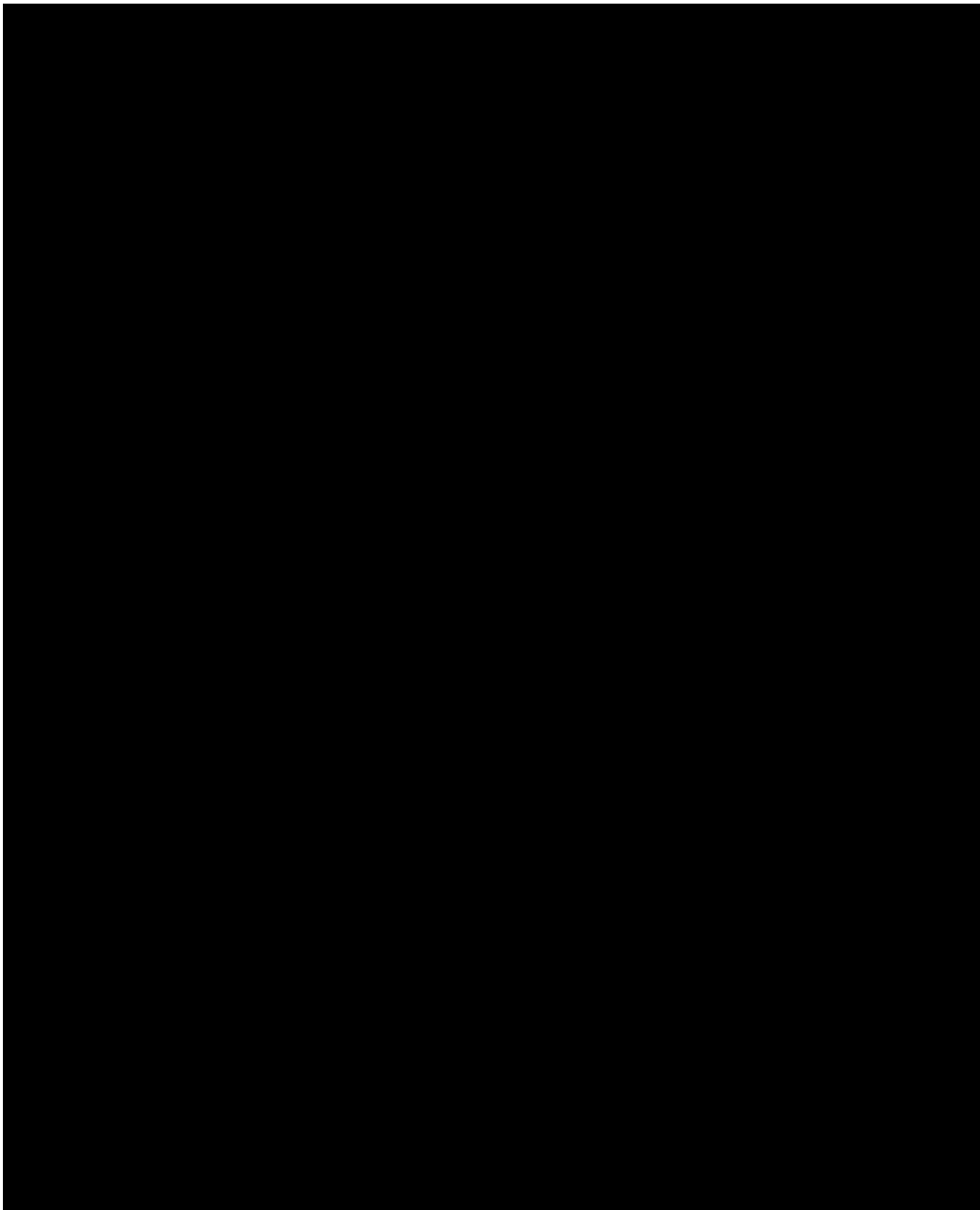


2. SUBSTANTIATION OF CONFIDENTIALITY

The following information is claimed confidential: Submitter Identity, Microorganism Identity, Process Information, Use, and Internal Company Documents (excluding health and safety studies). The following information is provided to substantiate the need to maintain the confidential business information (CBI) status of these aspects of this submission, in accordance with 40 C.F.R. § 725.94.

A. Harmful effects to competitive position.

[REDACTED]



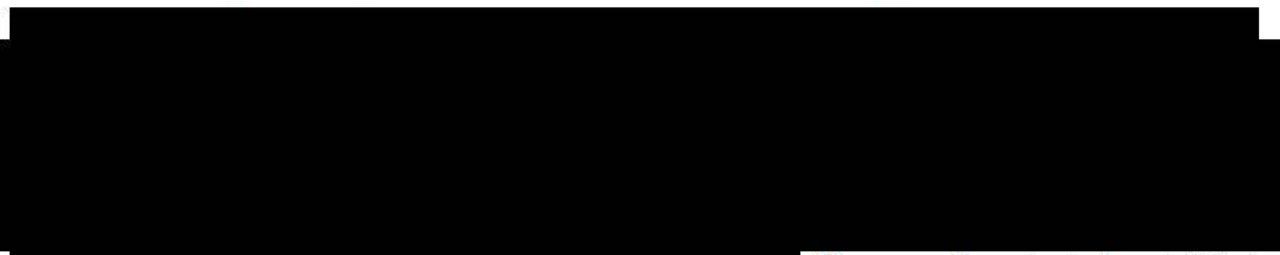
B. Identity kept confidential. The company has securely guarded information related to microorganism identity, such as process information, use, and internal company documents. These safeguards ensure that the commercial utility of this information cannot be discovered by others. All employees sign a Non-disclosure agreement upon hire. Files are kept in locked and secure areas and facilities using microorganisms have restricted, "need to know" access. The research facility that stores small-repository size volumes of the MCAN strains is only accessible to those with the key code password. Their associated DNA is destroyed such that it cannot be identified in the waste streams from the site. The experiment data is only accessible via personal logins specific to employees with a need-to-know.

The innovation does not leave the site of testing or production in a form which is accessible to the public or its competitors. The company takes steps to impede product analysis by competitors so they cannot access the innovation in any form that would be comparable to the form used by the company.

The company has disclosed information claimed confidential to outside legal counsel subject to attorney-client privilege and third parties who protect its confidential status and have received information under a non-disclosure agreement. There are no other outside disclosures or intent to disclose this information more broadly in the future.

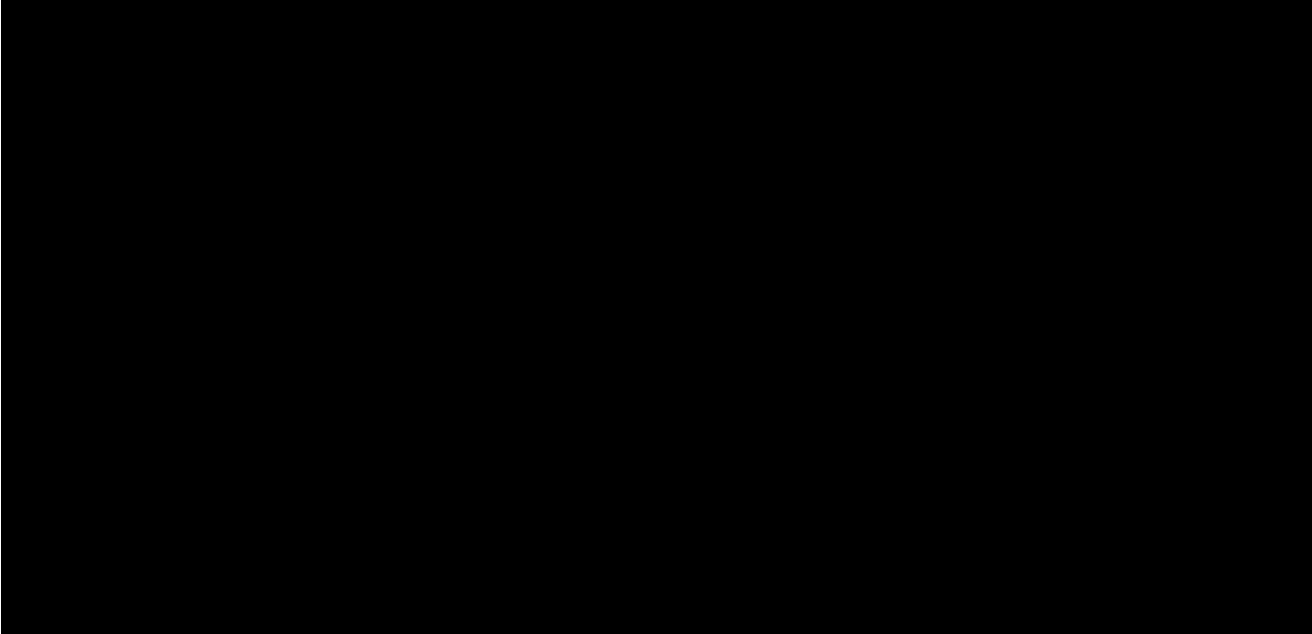
C. Federal law public disclosure requirements. The data contained within, is not required to be disclosed.

D. Information claimed as confidential within public documents. Some of the information in this filing have appeared in public documents. The fact that the company exists is known, that the

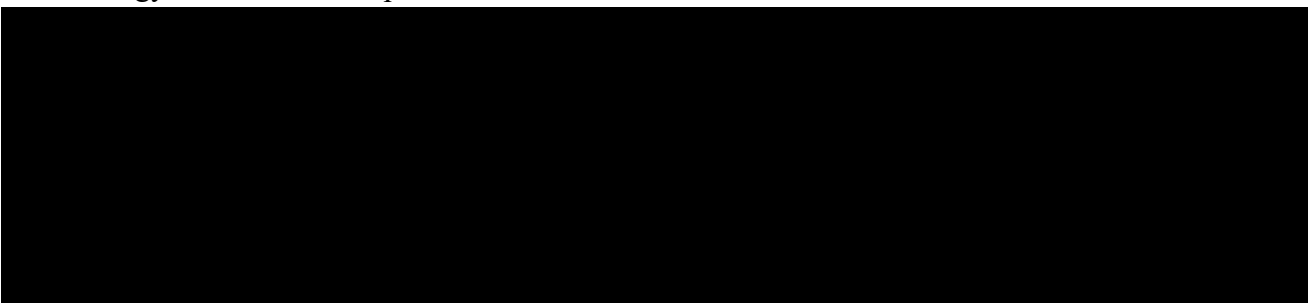


However, the patents do not defeat CBI claims for the information claimed herein as CBI. In EPA's Confidential Business

Information Claims under the Toxic Substances Control Act (TSCA); Final Rule (RIN 2070-AK68), Response to Comments Document (May 2023), EPA confirmed that patents do not defeat disclosure where it may lack key details on steps about the creation of the substance or the manner in which it is presented makes it difficult to discern which substance is of commercial value.



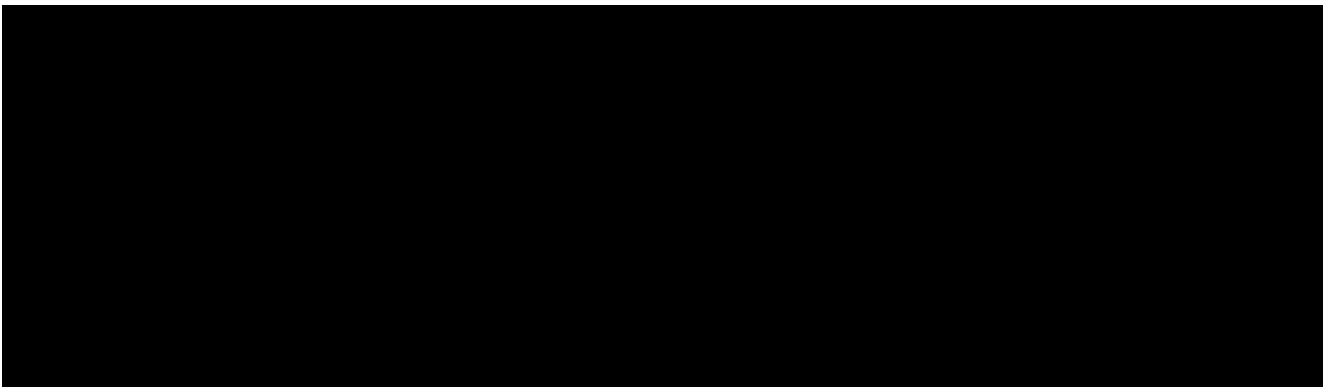
E. Period of confidentiality claim. We request that the confidentiality claims be held indefinitely. The claims should be held for the full ten years allowed by the law and it should renew until the technology is obsolete or public disclosed. Failure to hold the information as confidential



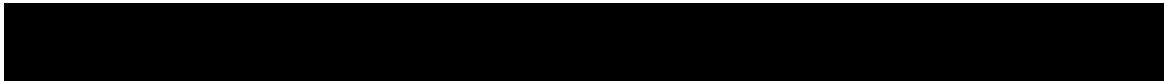
F. Confidentiality determination regarding information associated with this microorganism. The EPA, any Federal agency, or court has not made any confidentiality determination regarding information associated with this microorganism.

3. GENERAL INFORMATION

3.1 Purpose of this Submission



3.2 Contact Information



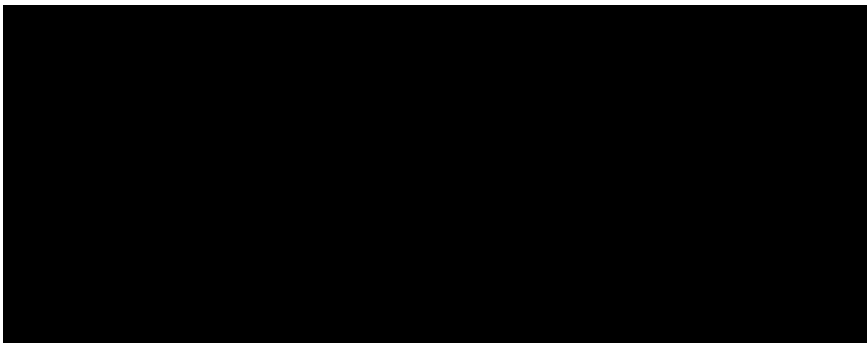
Submitter:

Address:

Contact:

Technical Contact:

Authorized Agent:



3.3 Generic Name

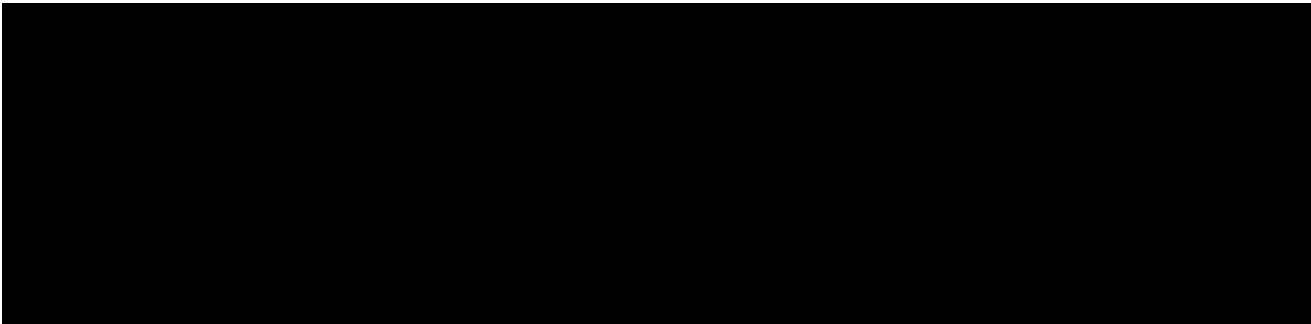
The generic name for both constructs in accordance with 40 C.F.R. § 725.85 is “Biopolymer producing modified microorganism, with chromosomally located modifications.”

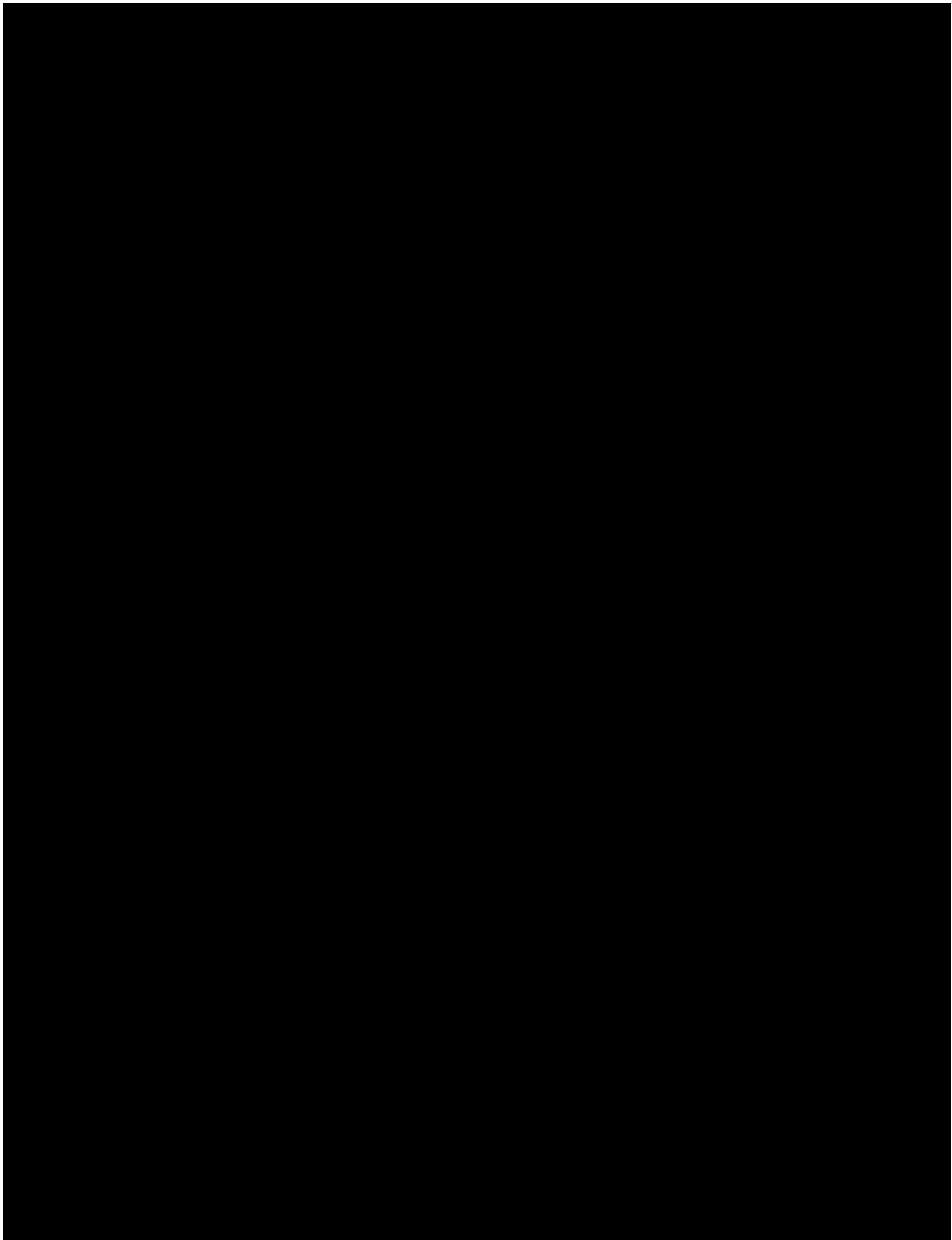
3.4 Generic Use Description

The generic use description for both constructs is “biopolymer production”.

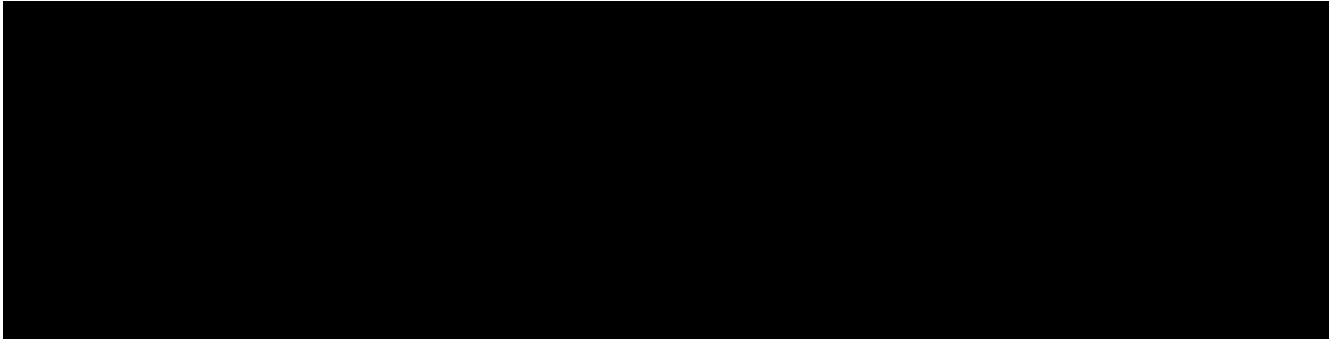
4. MICROORGANISM IDENTITY INFORMATION

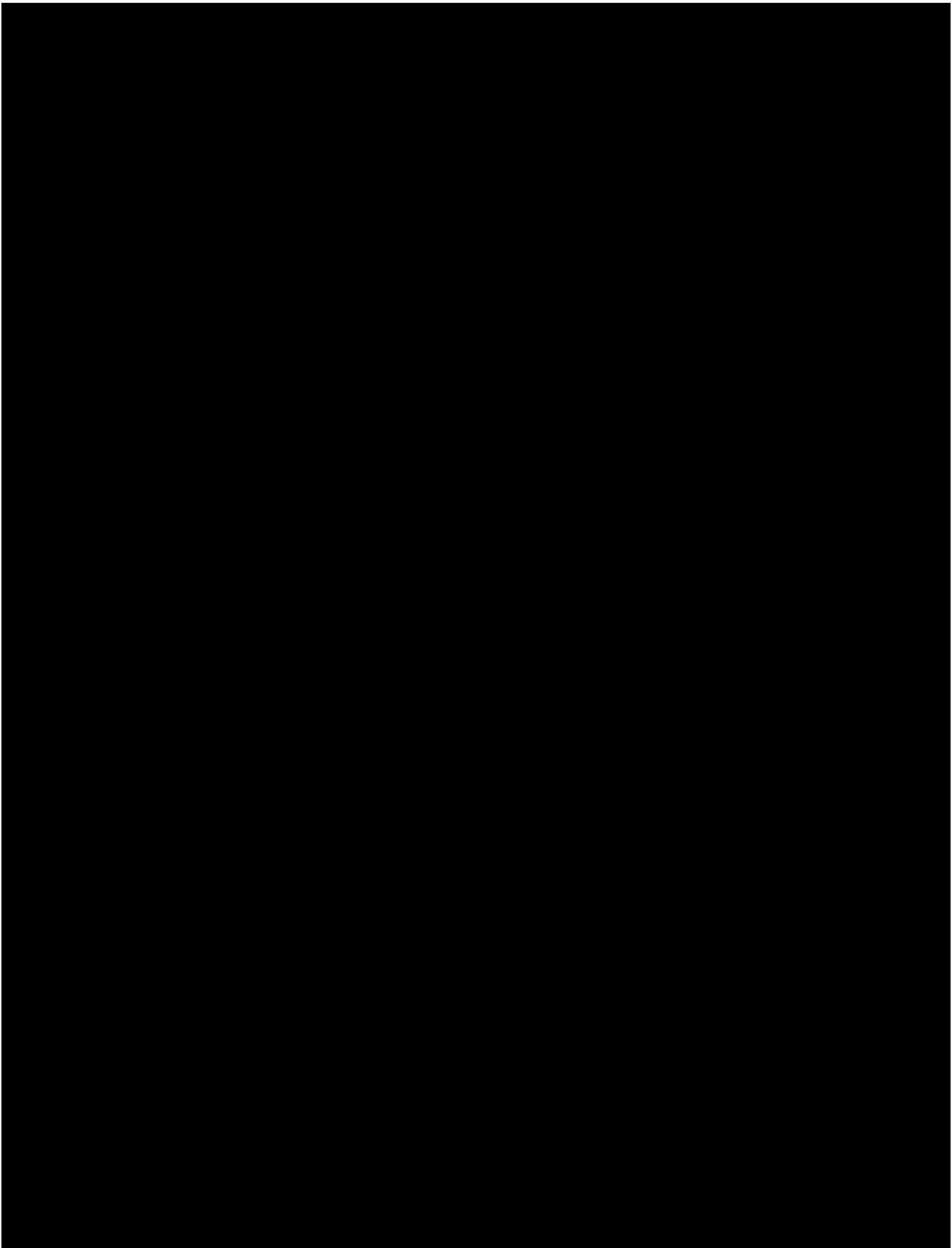
Description of the Recipient Microorganism

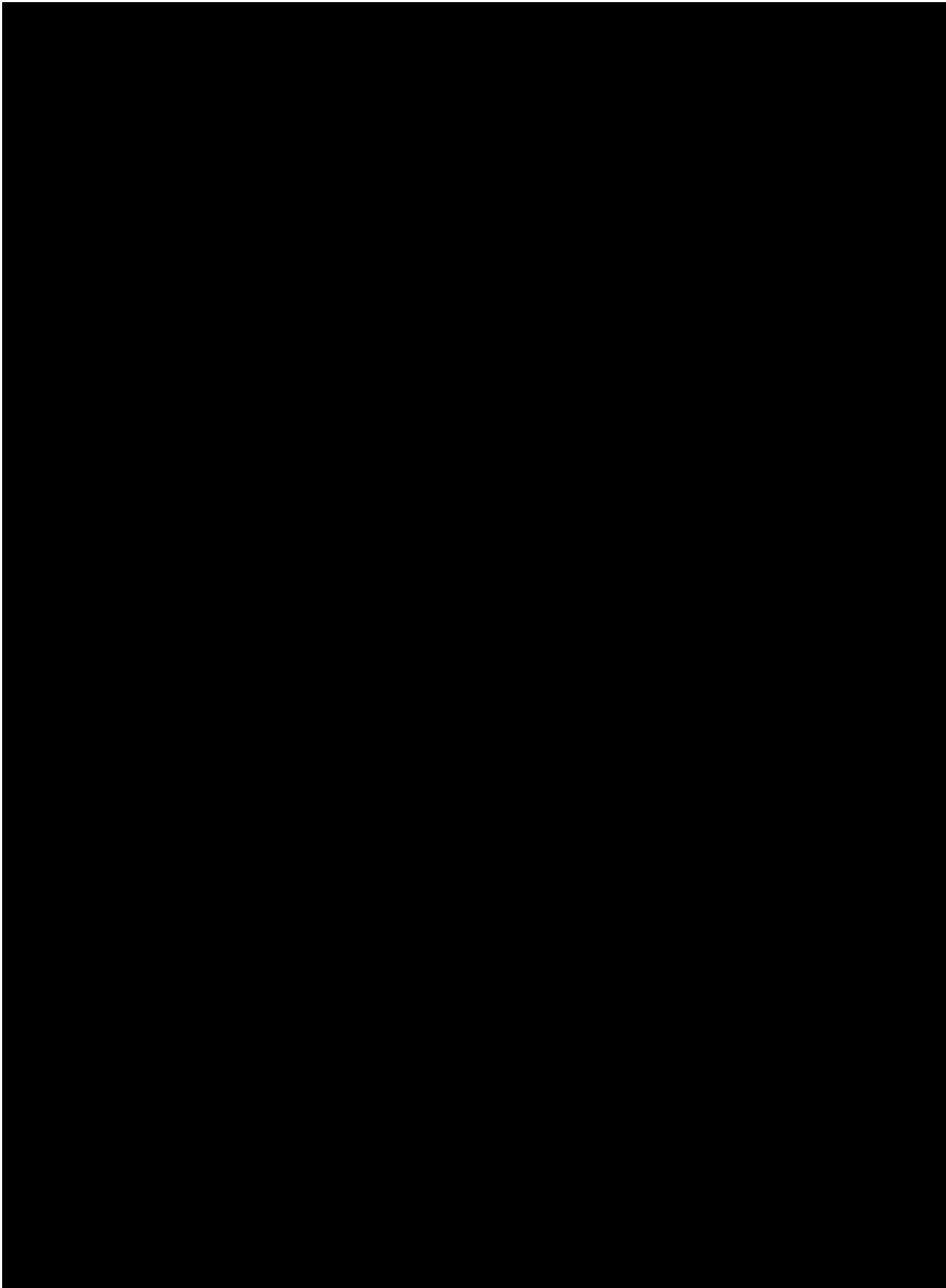


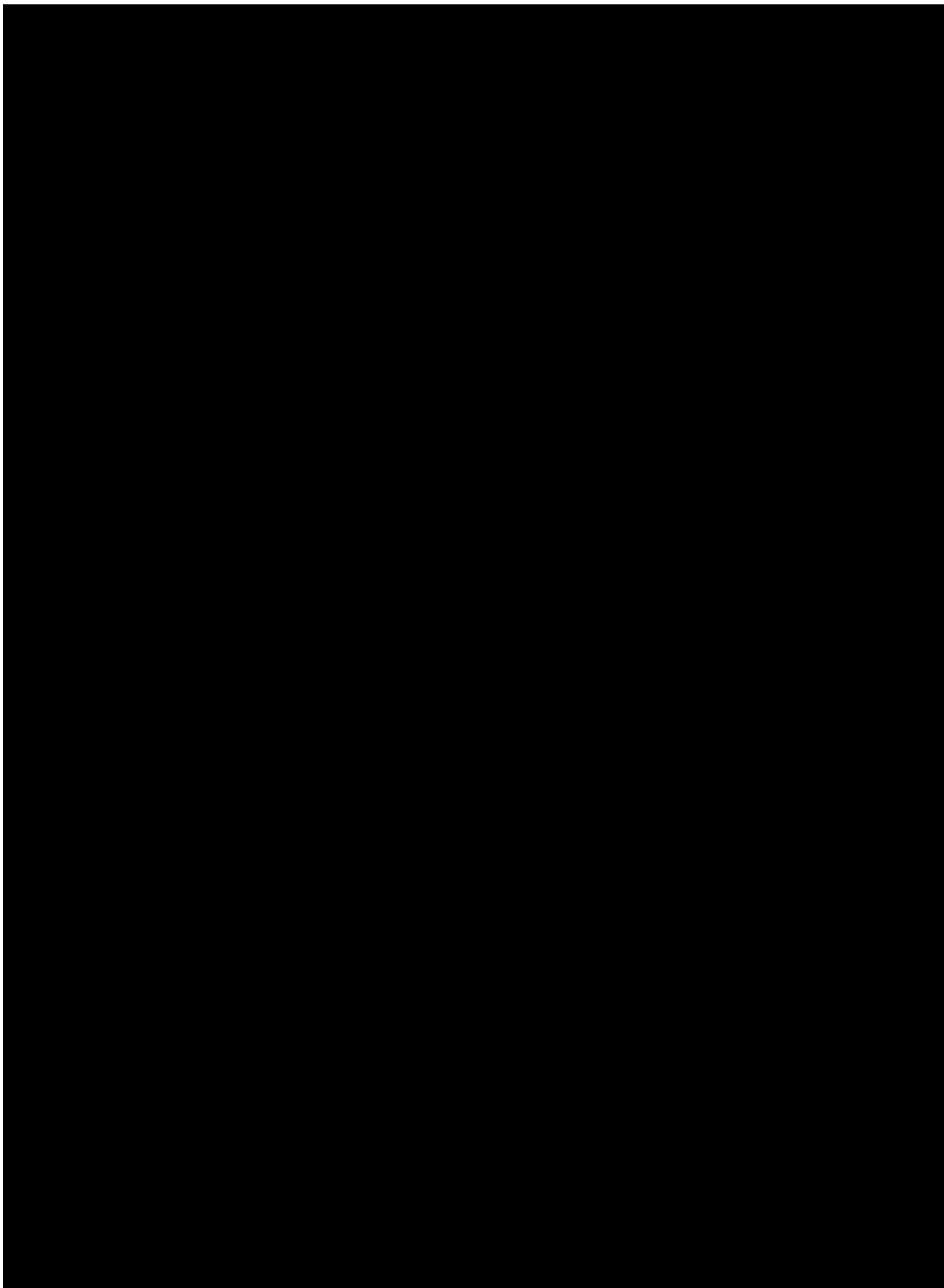


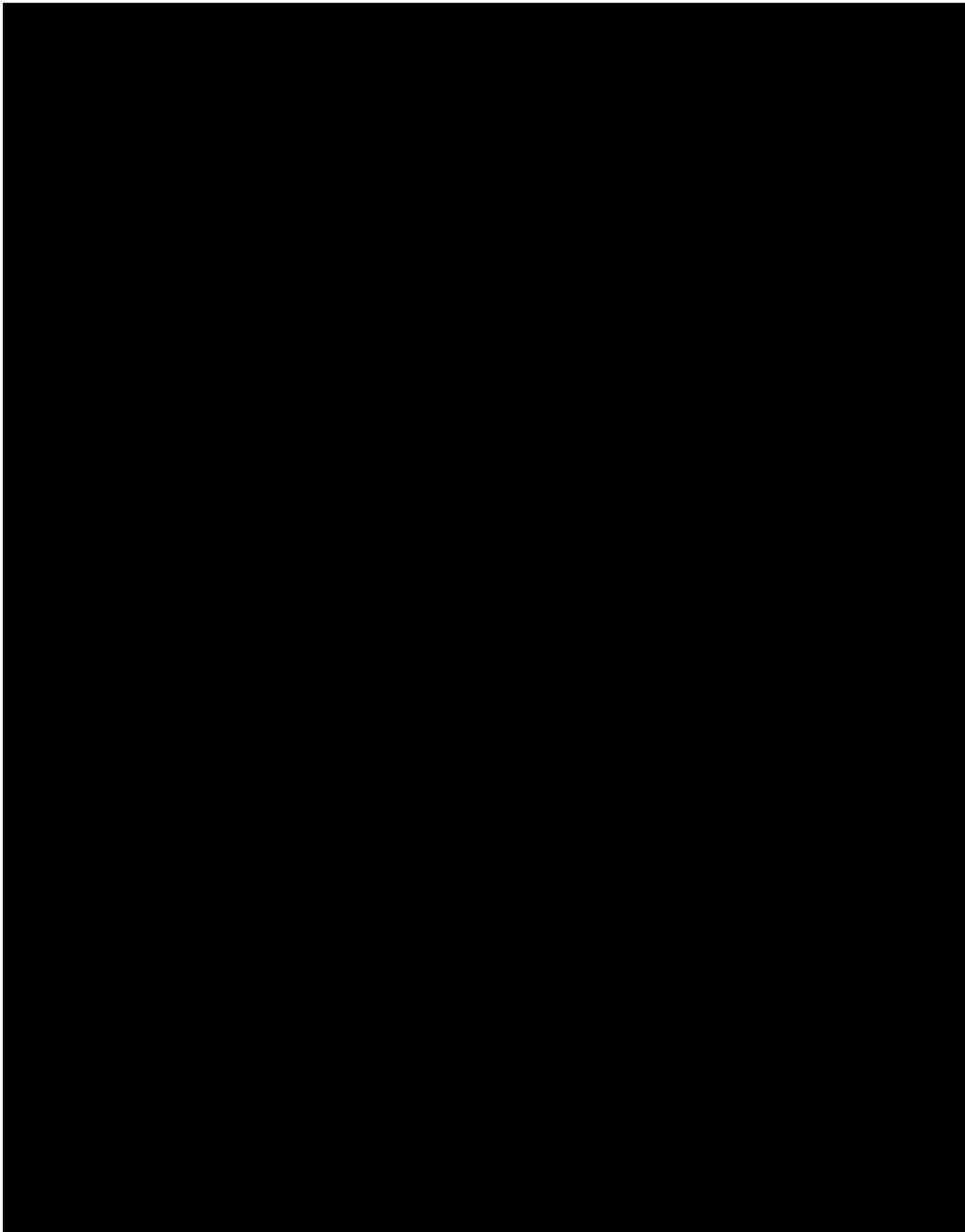
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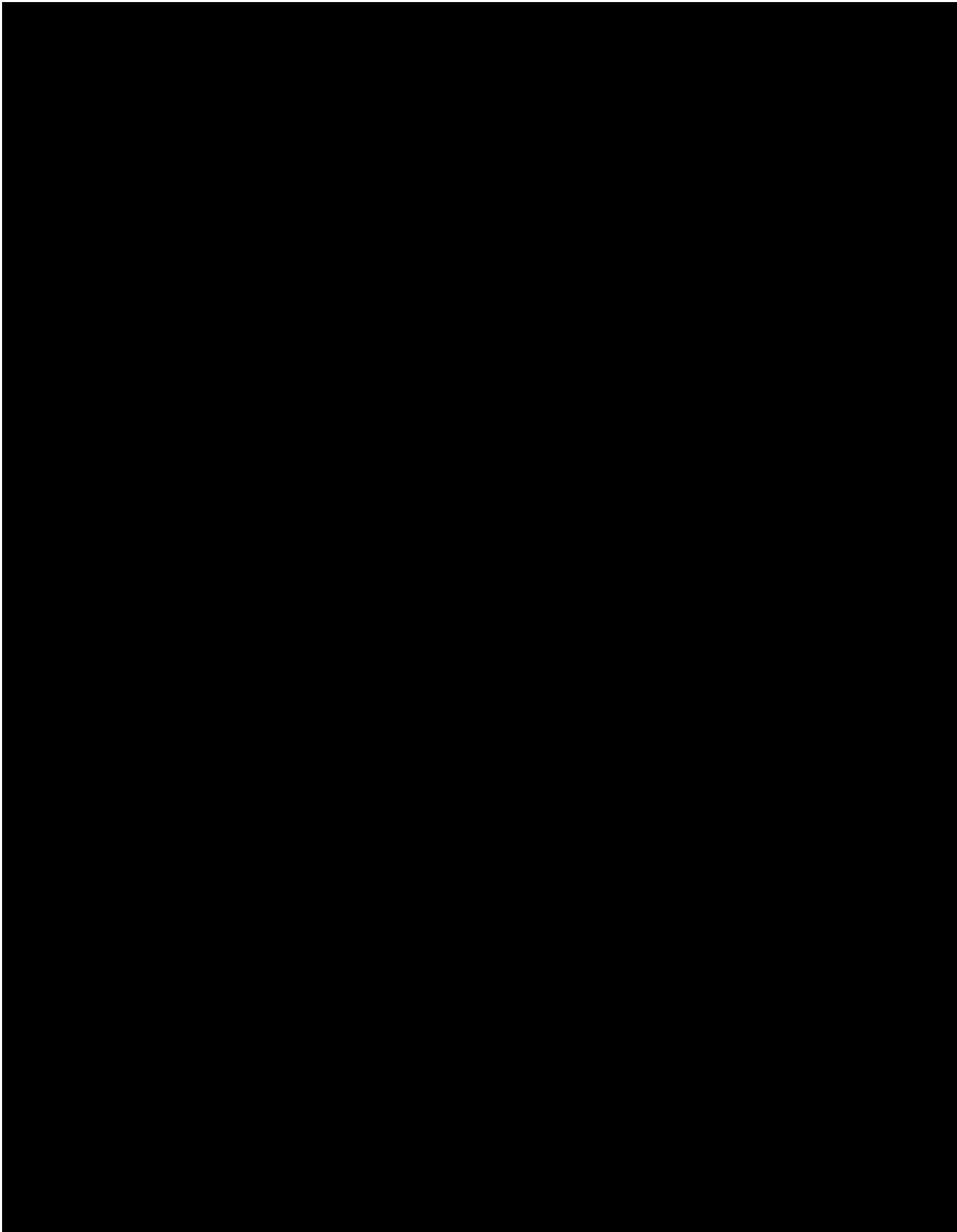


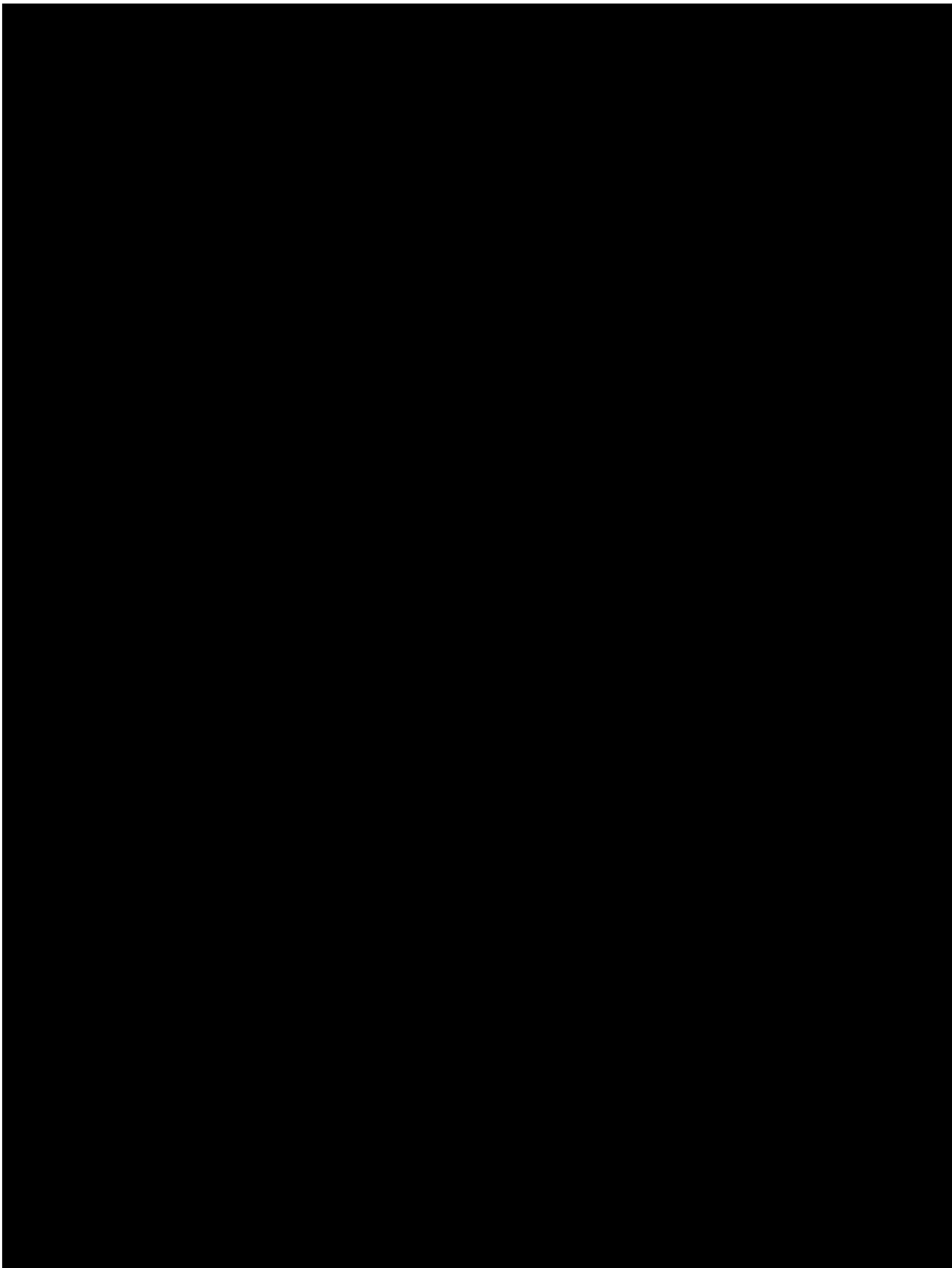


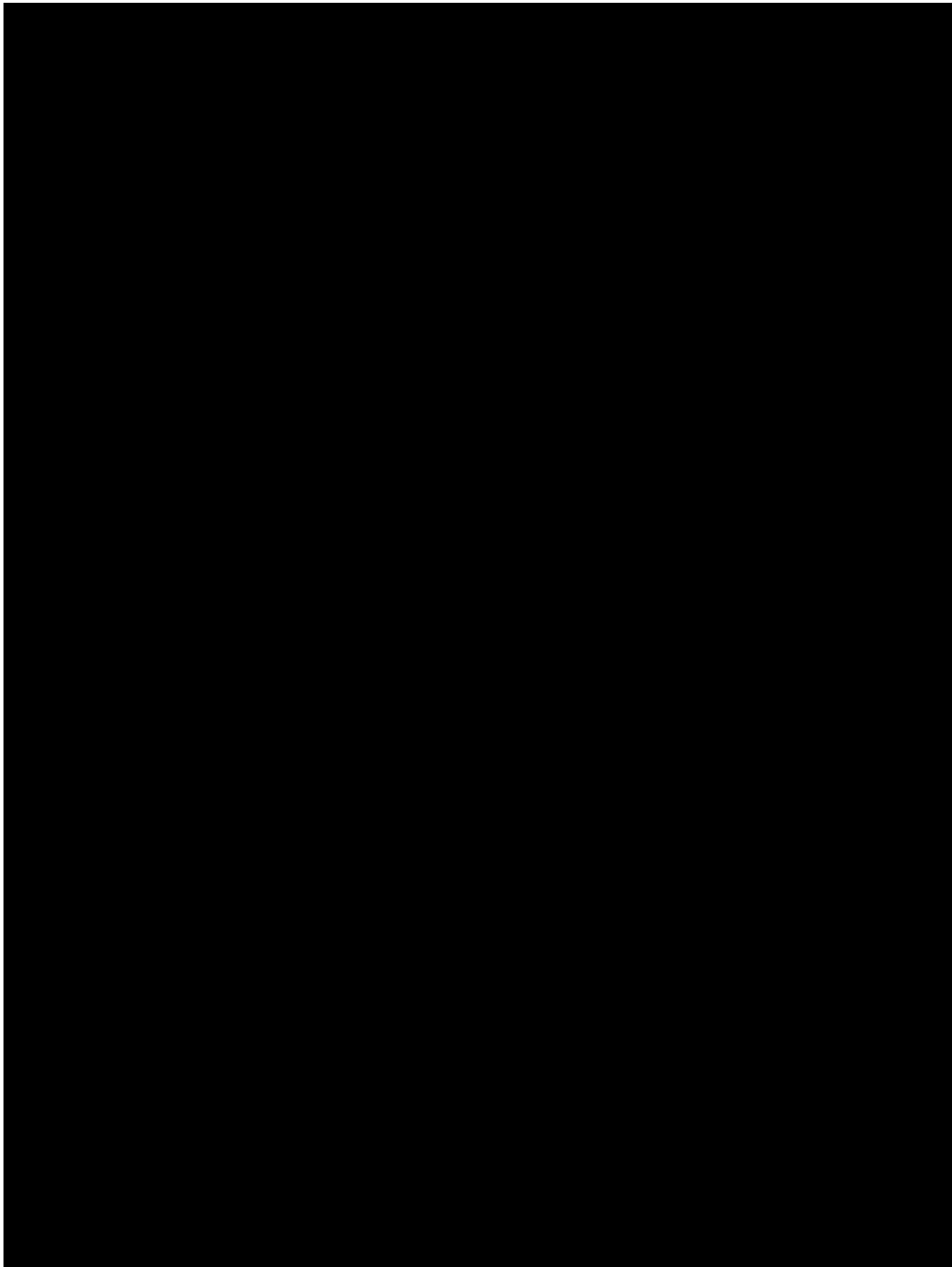


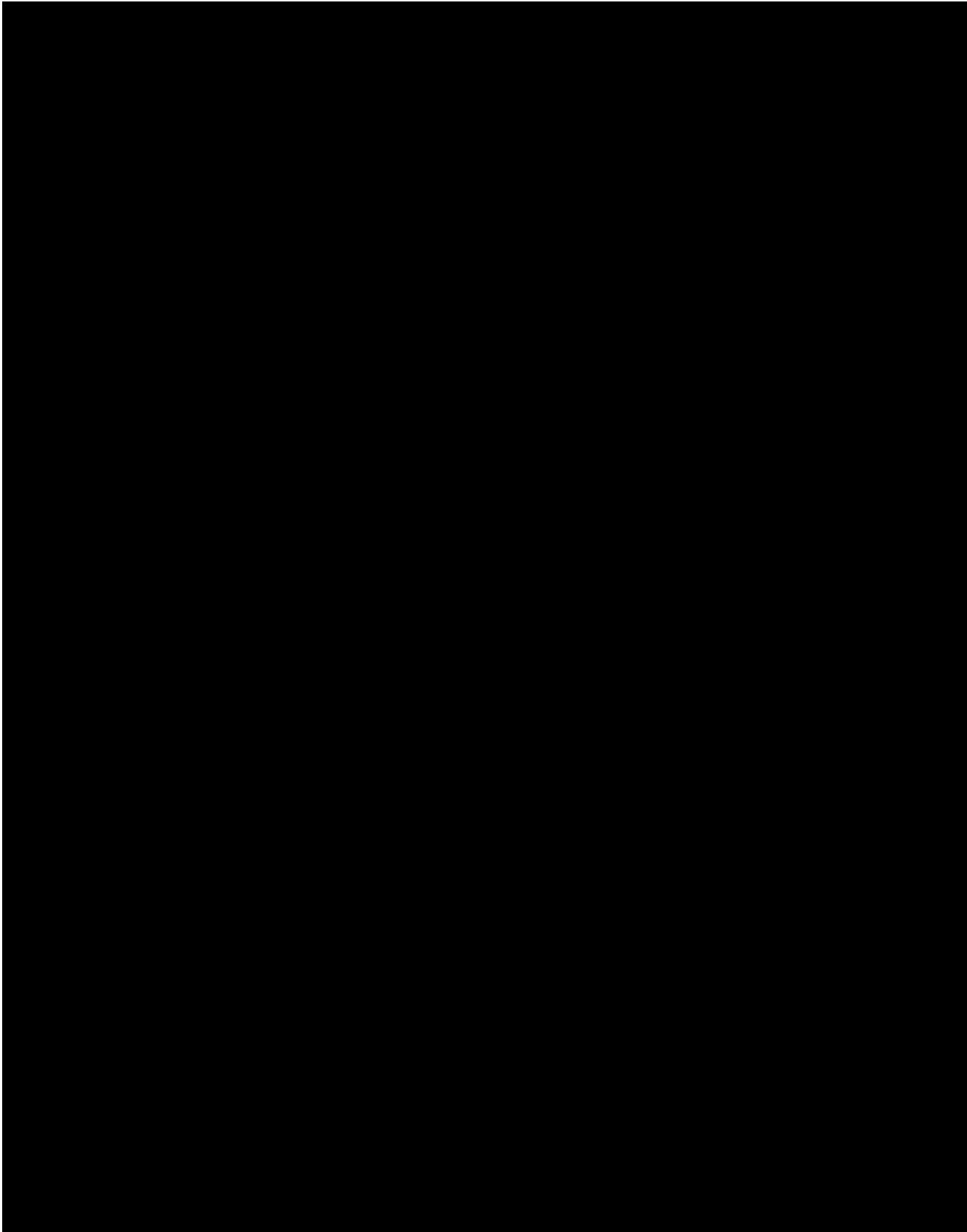


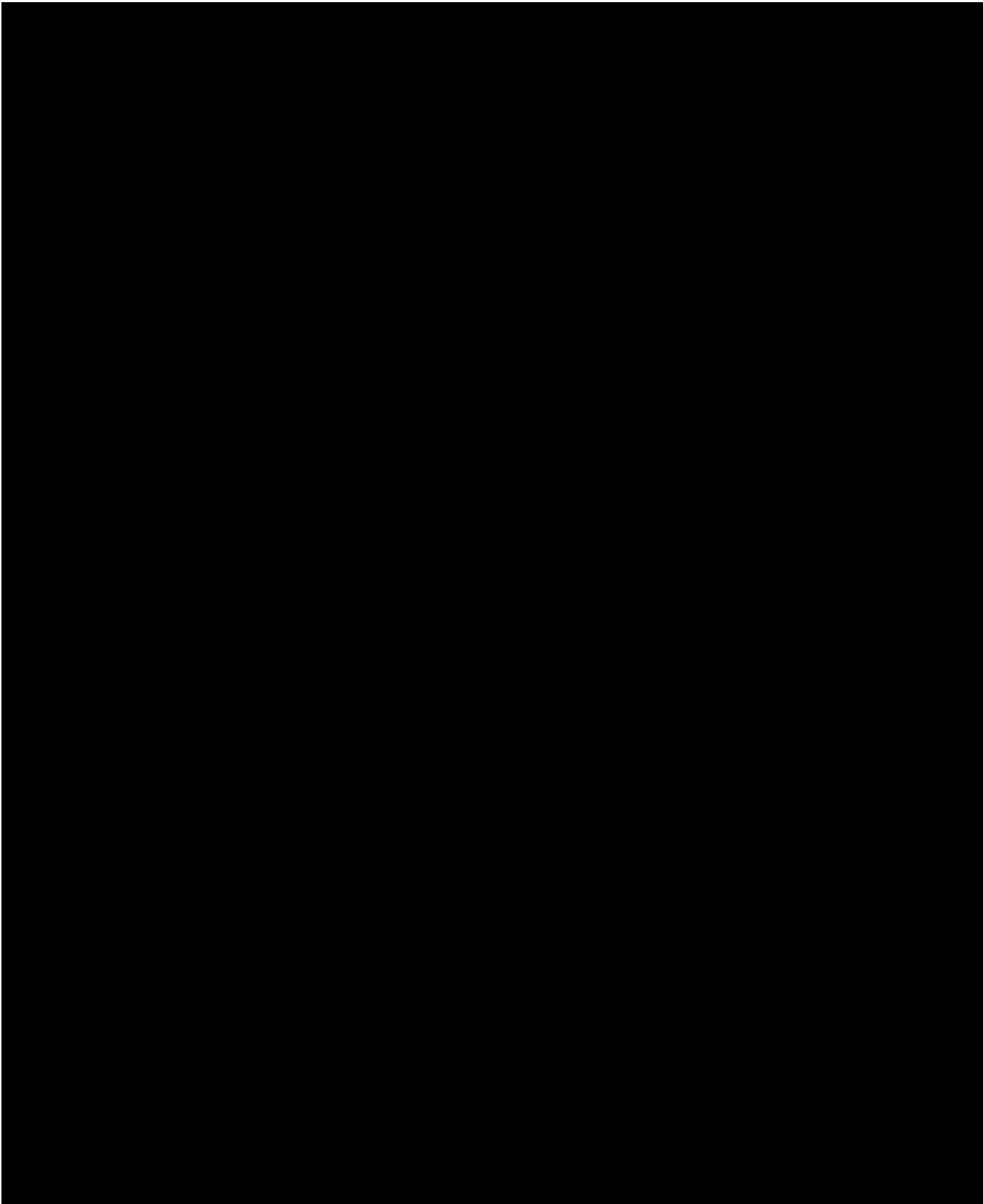


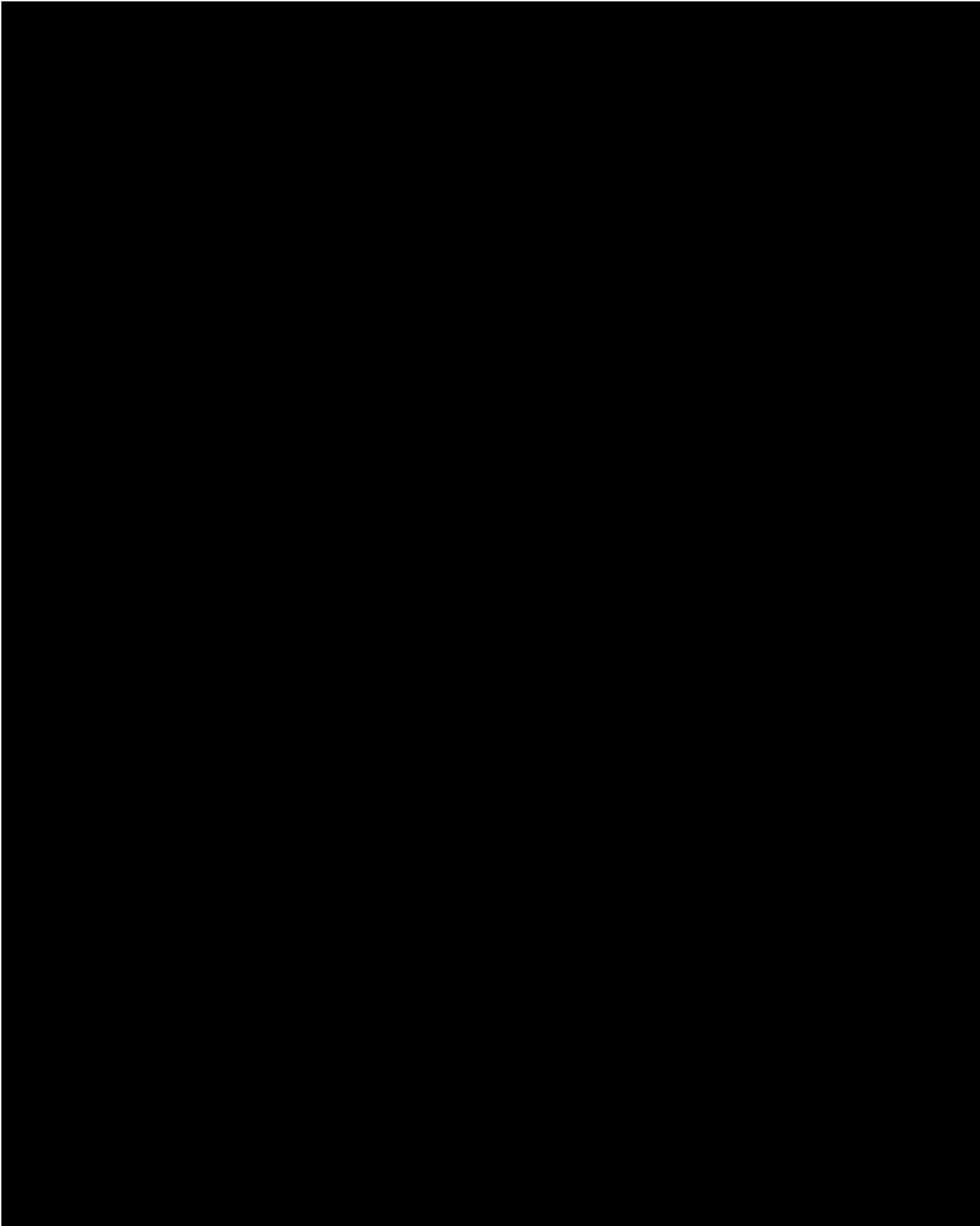


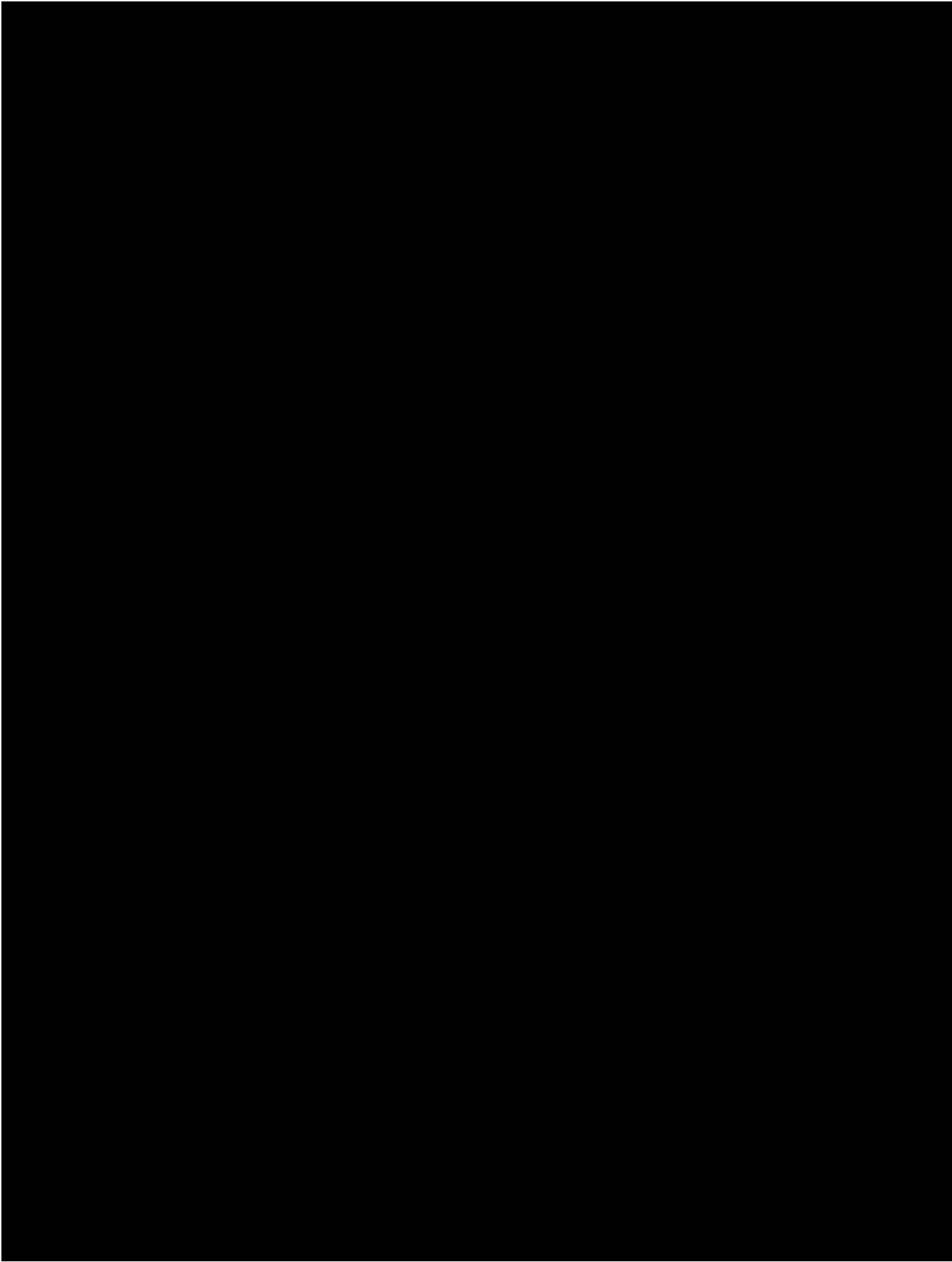


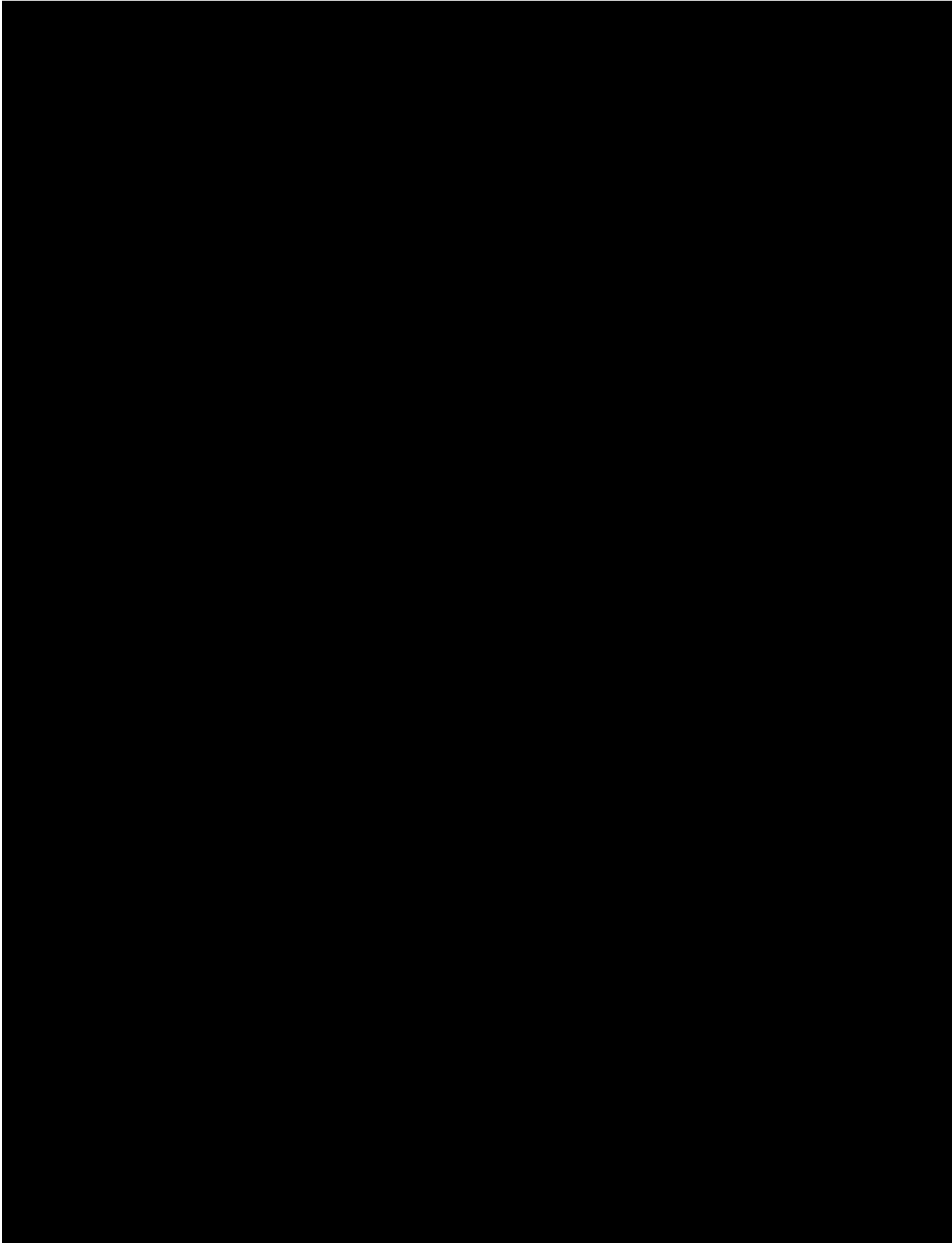


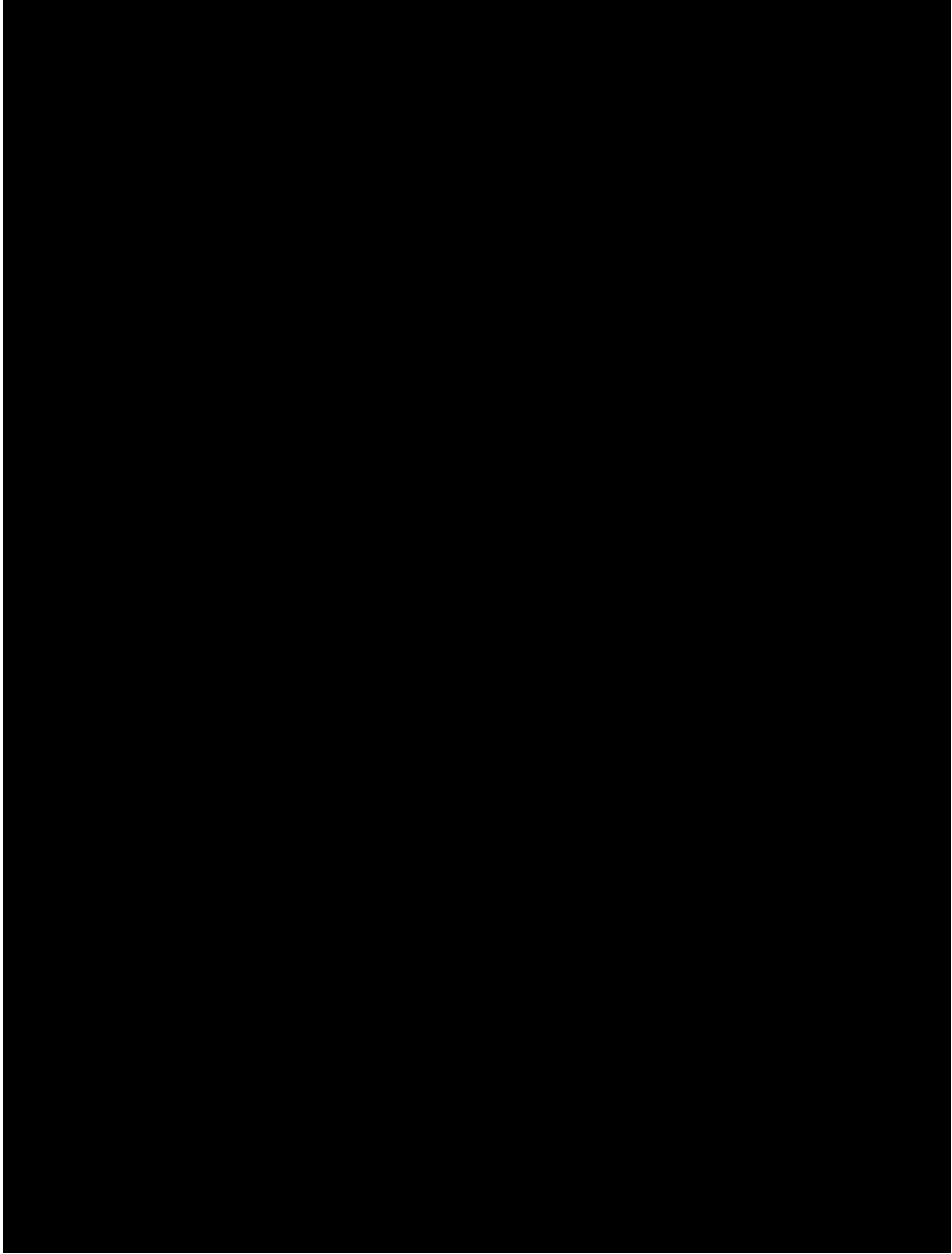


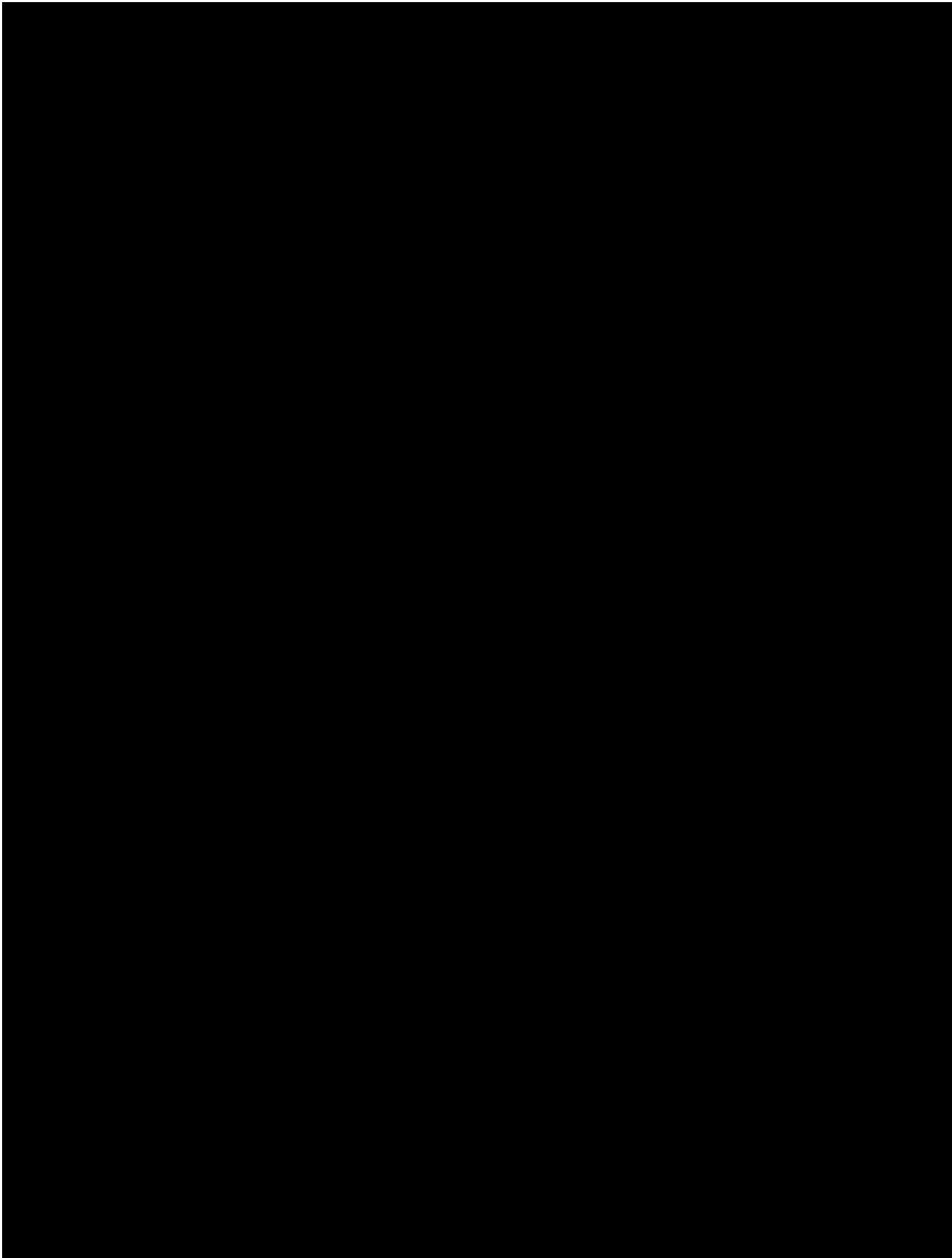


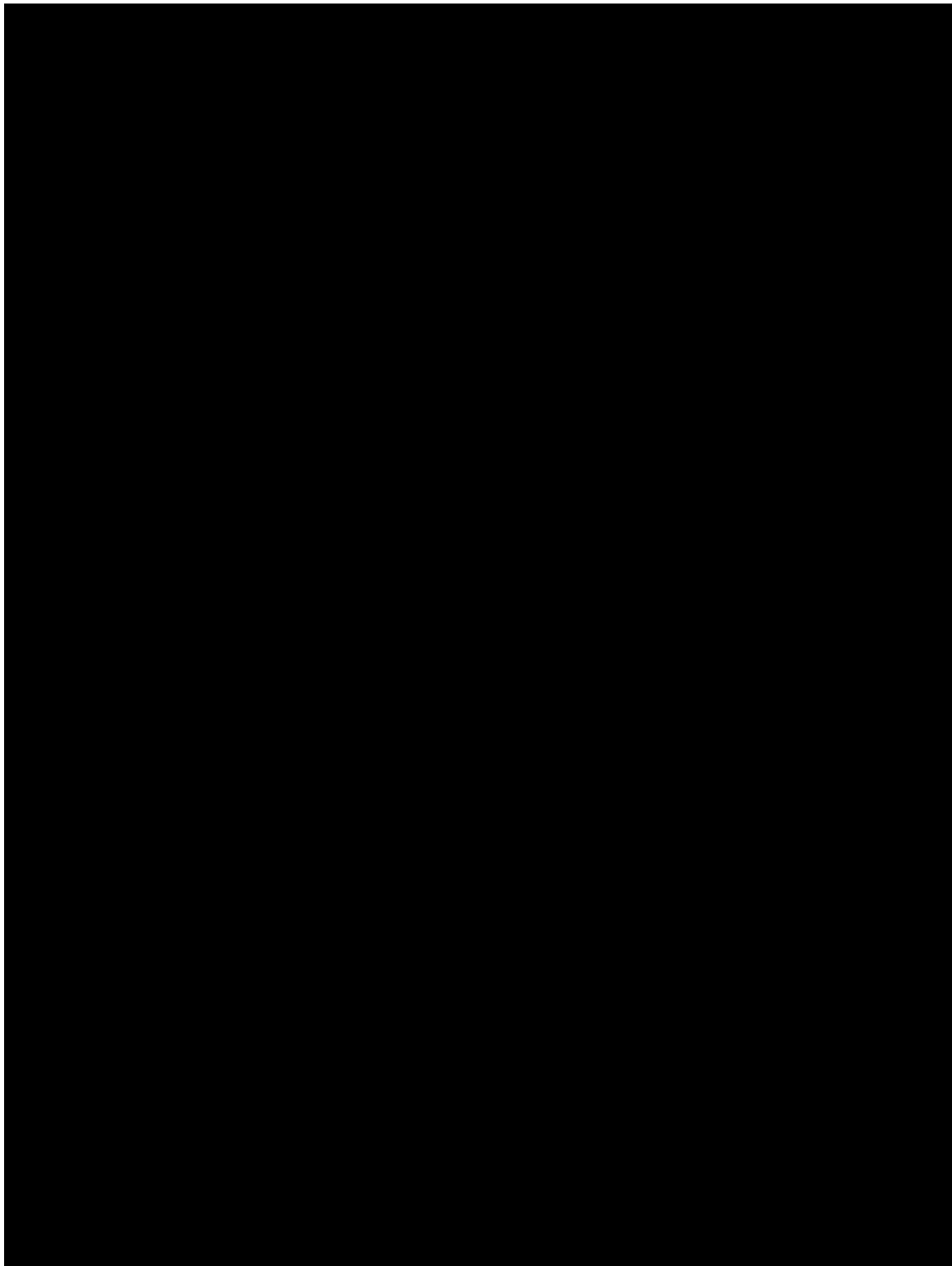


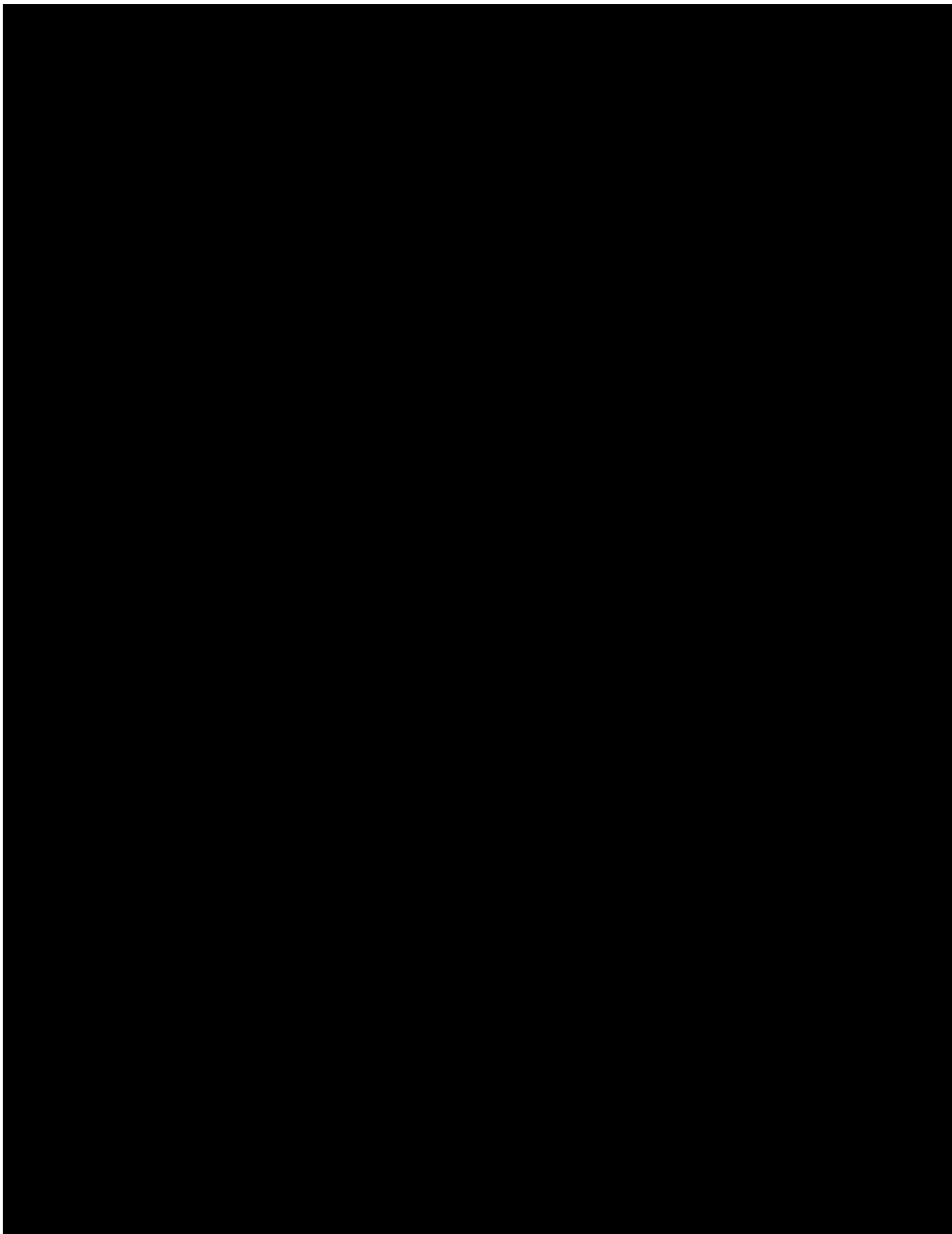


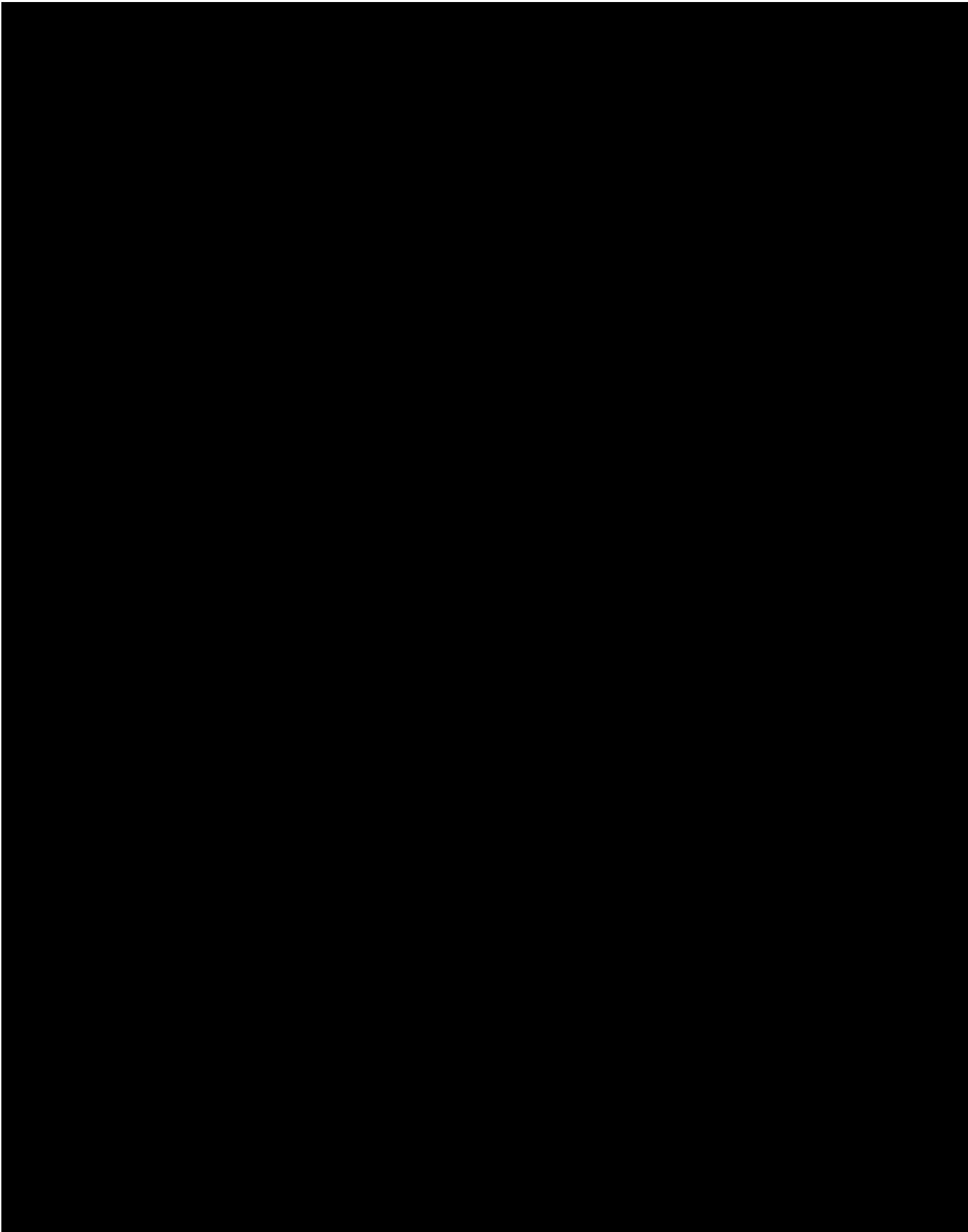


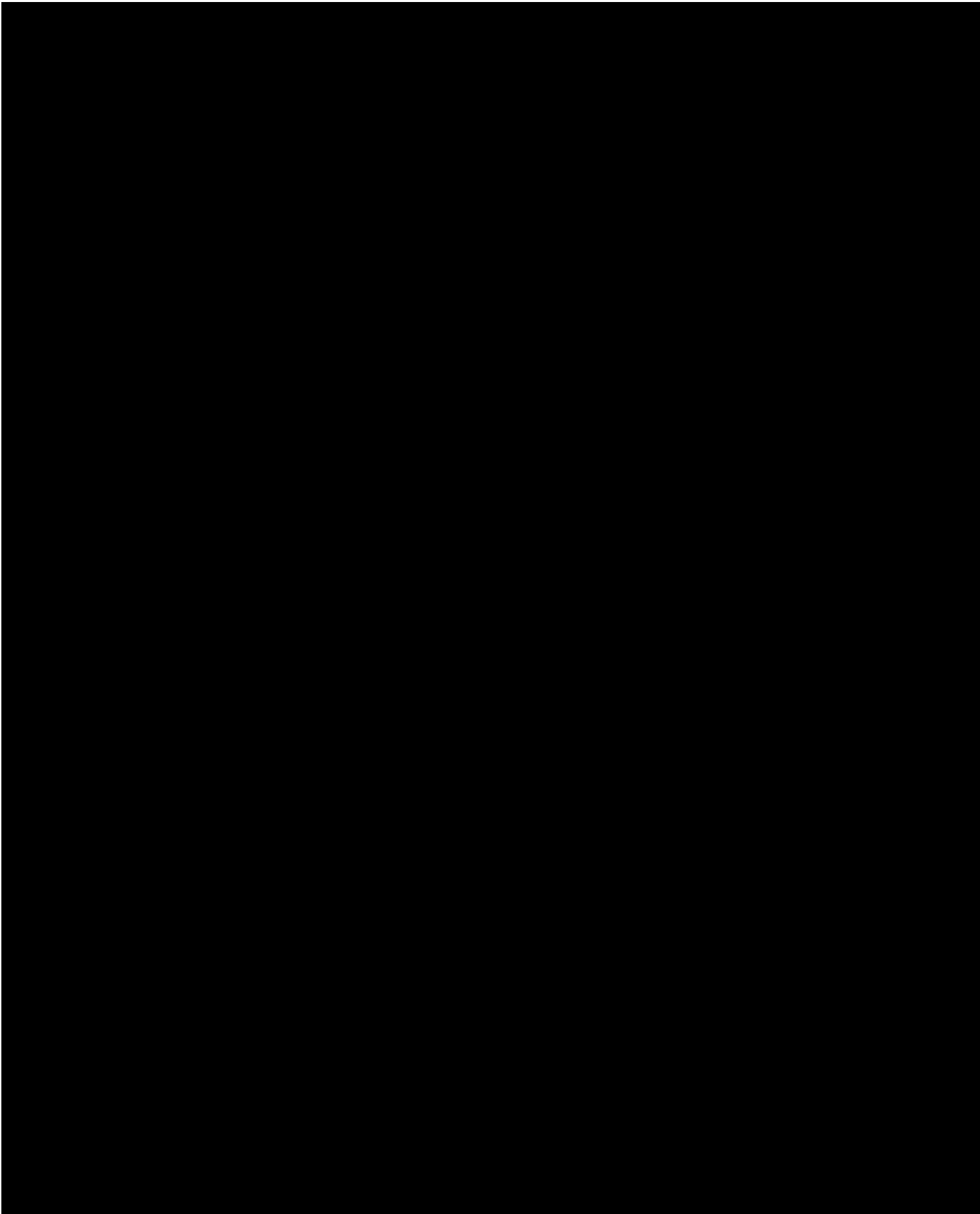


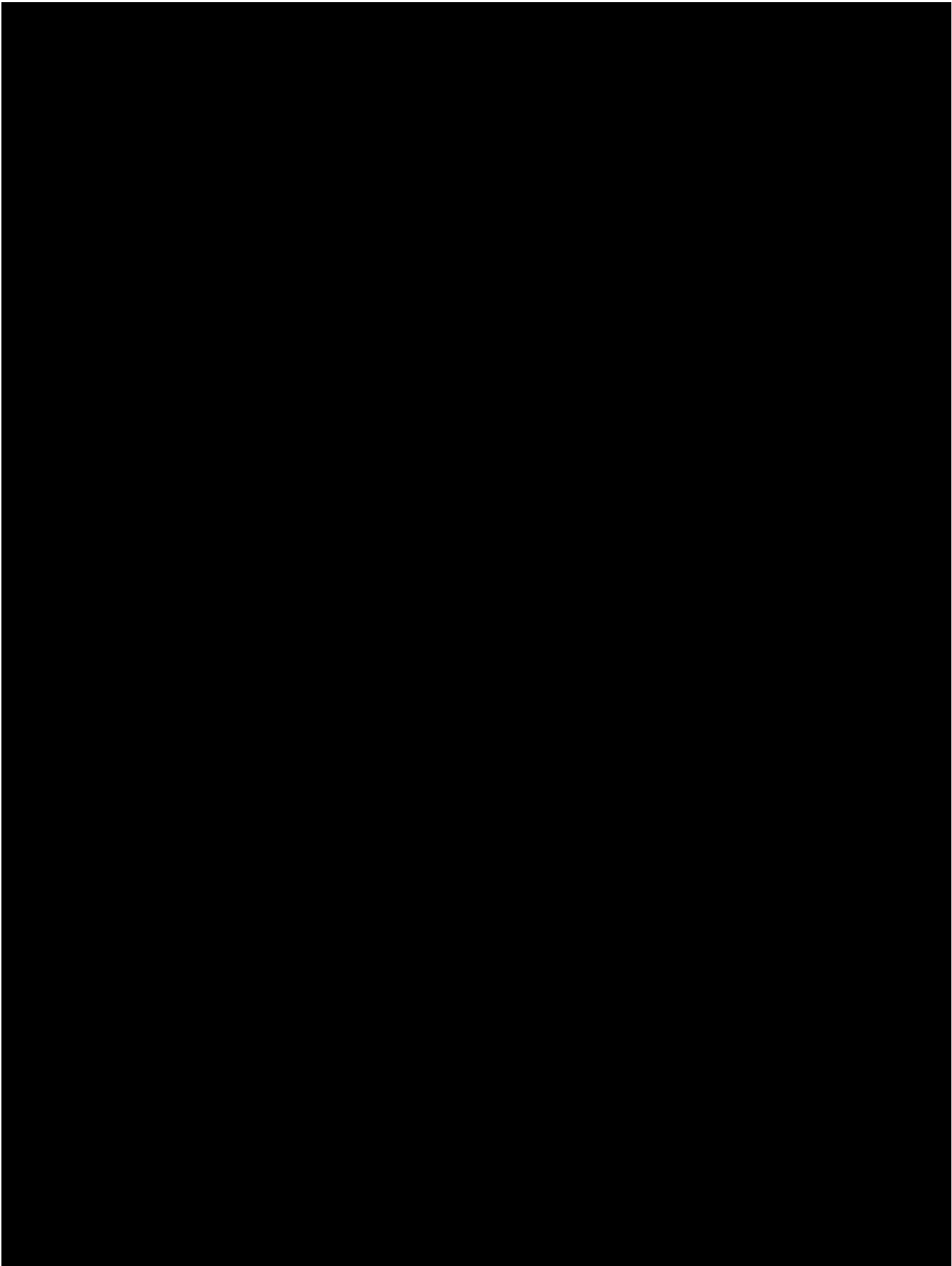


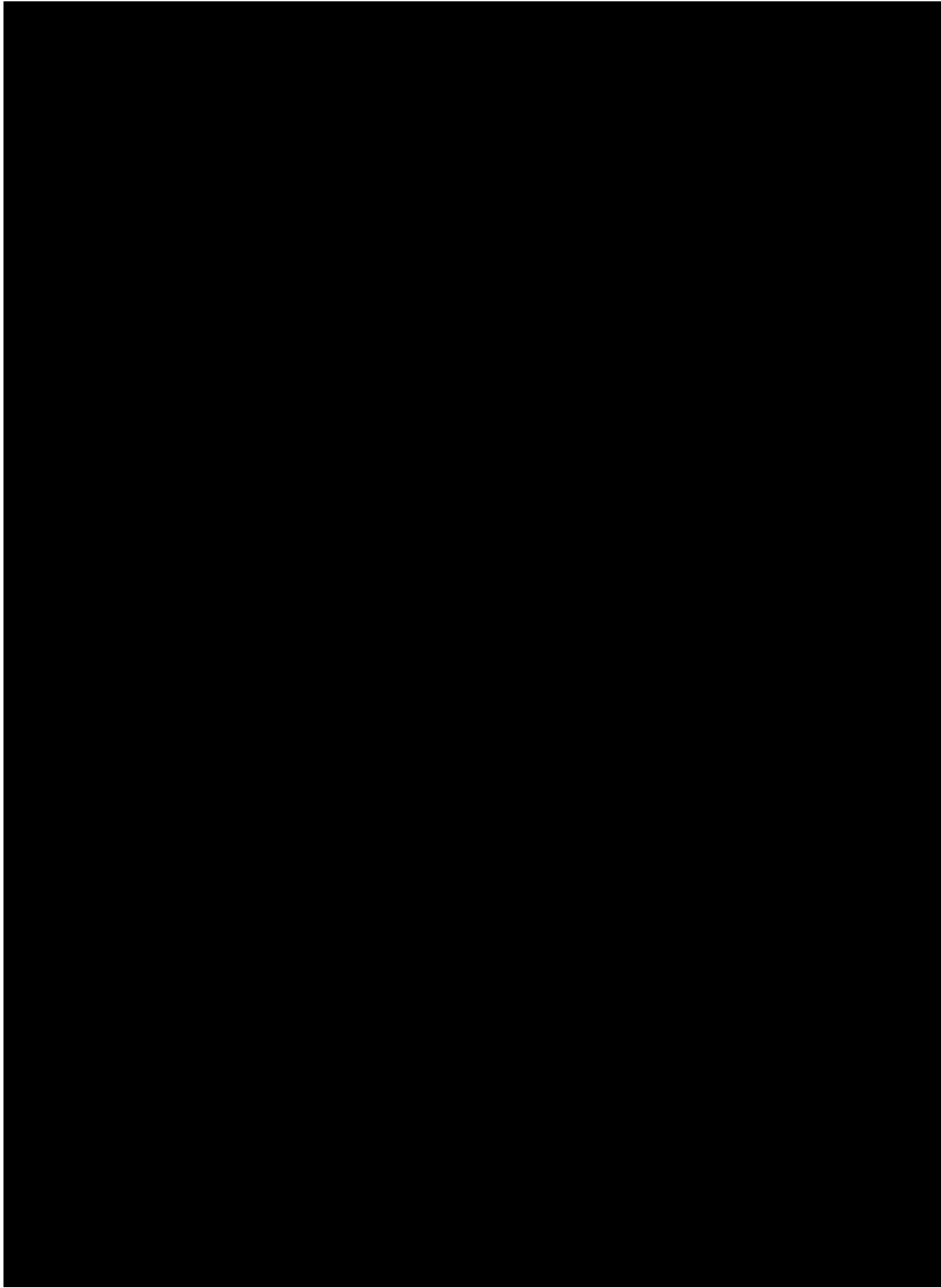


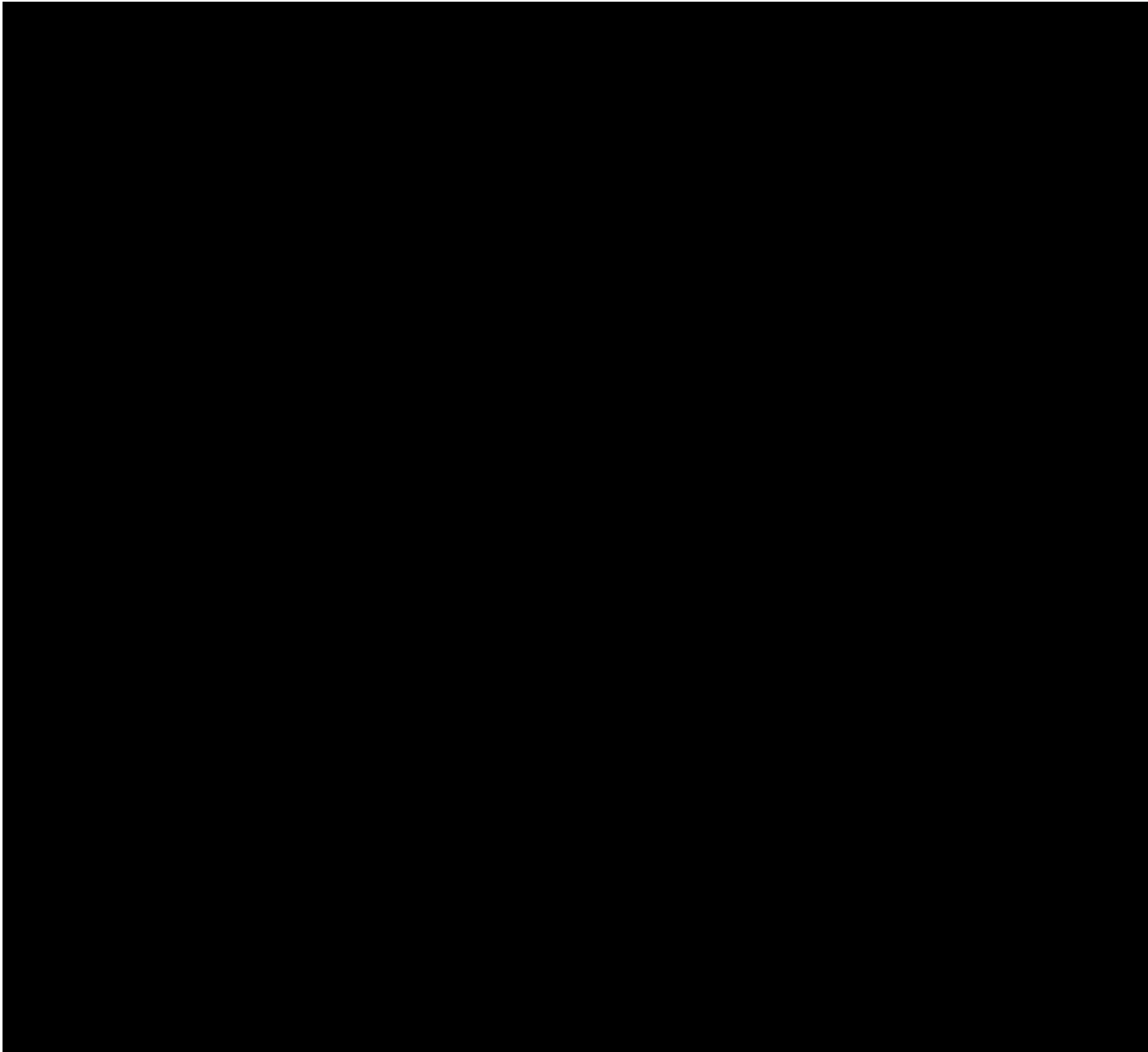


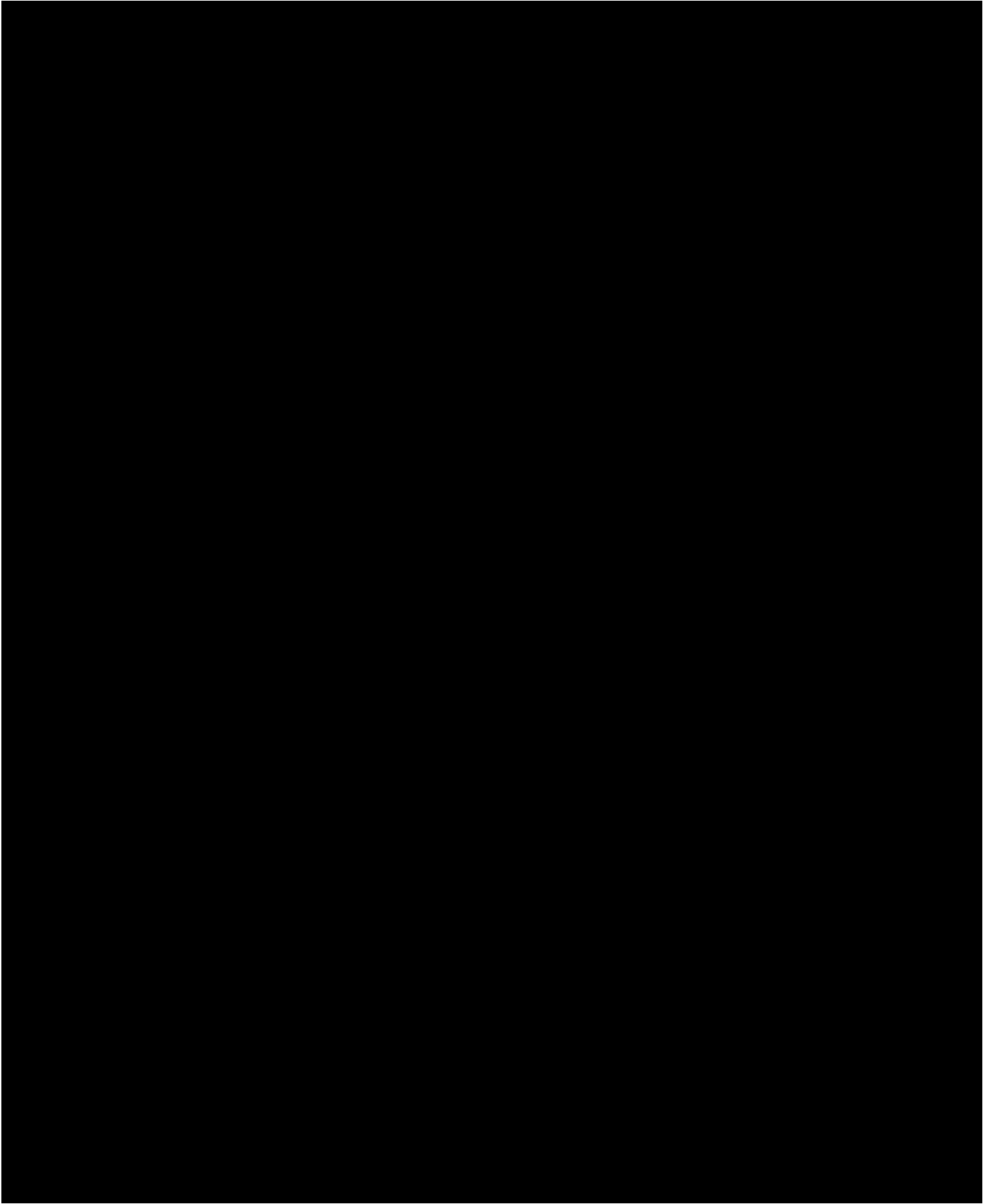


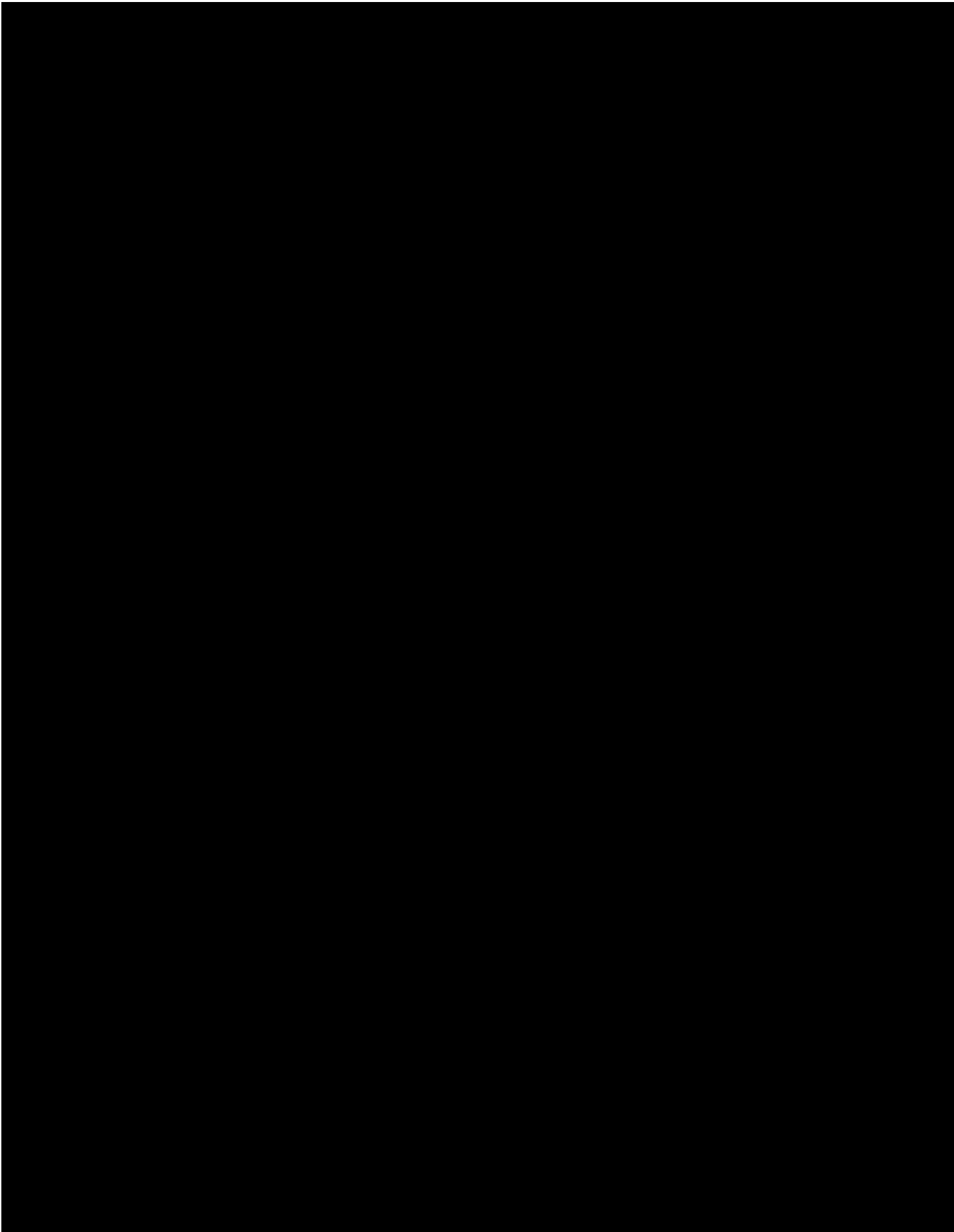


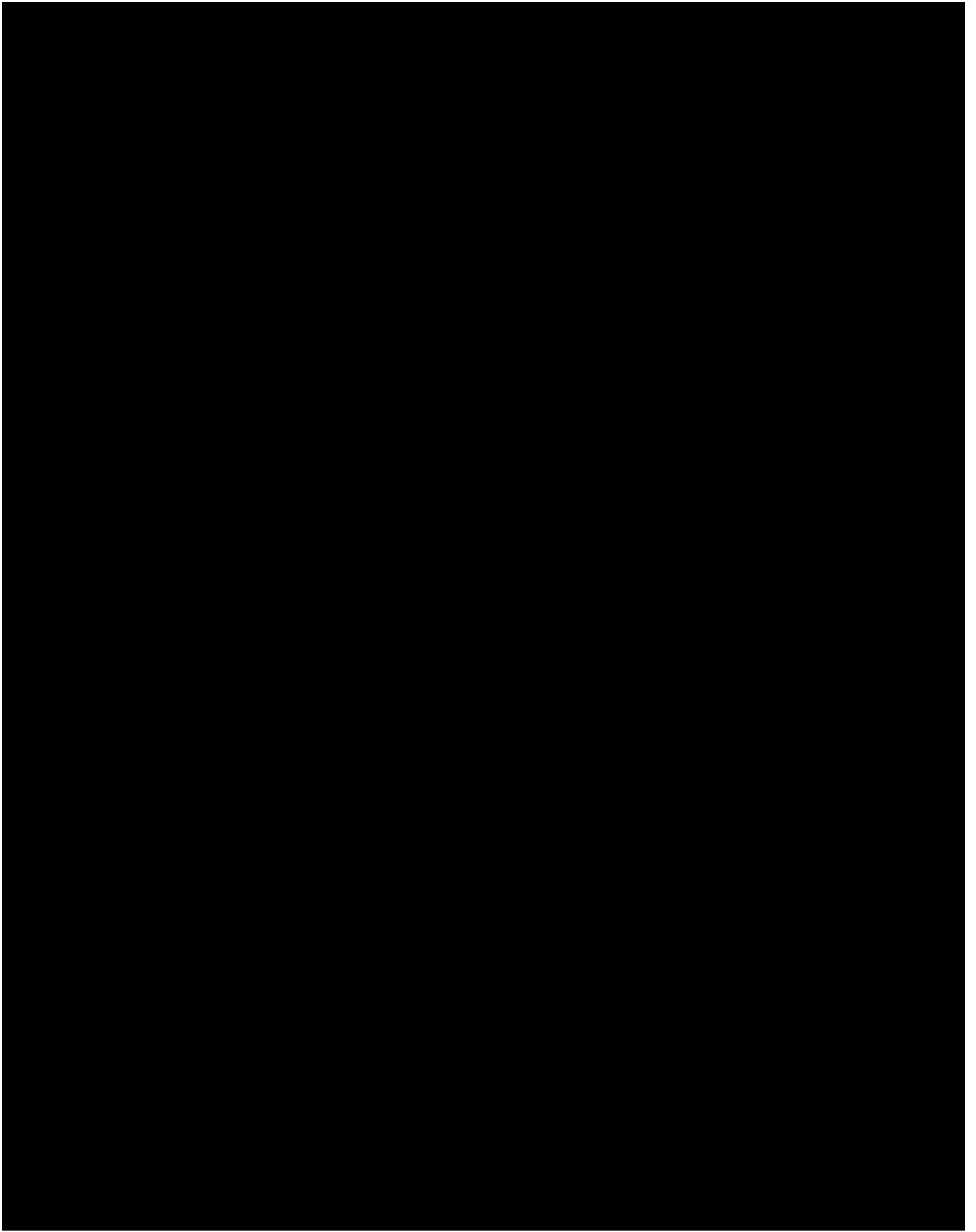


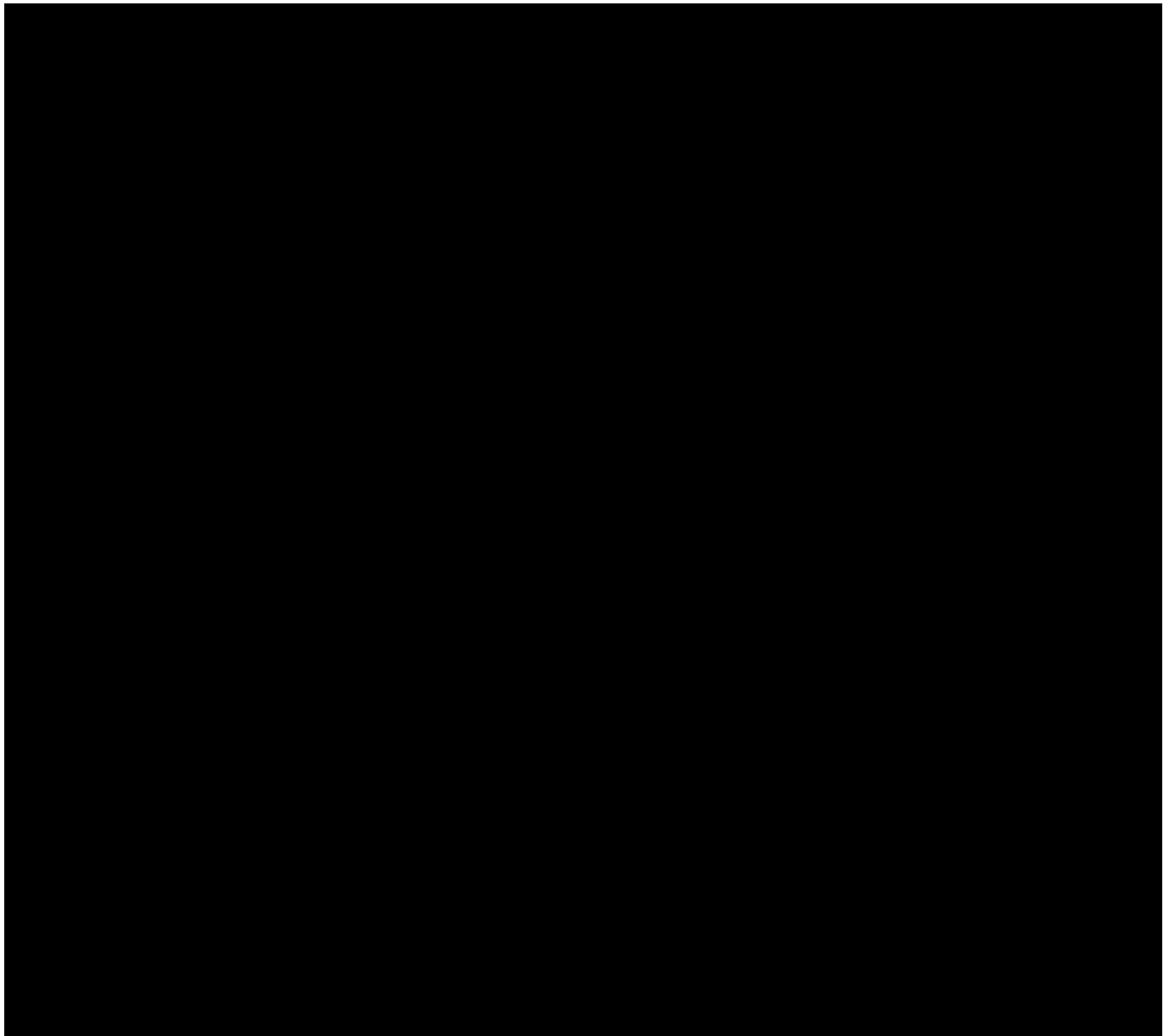


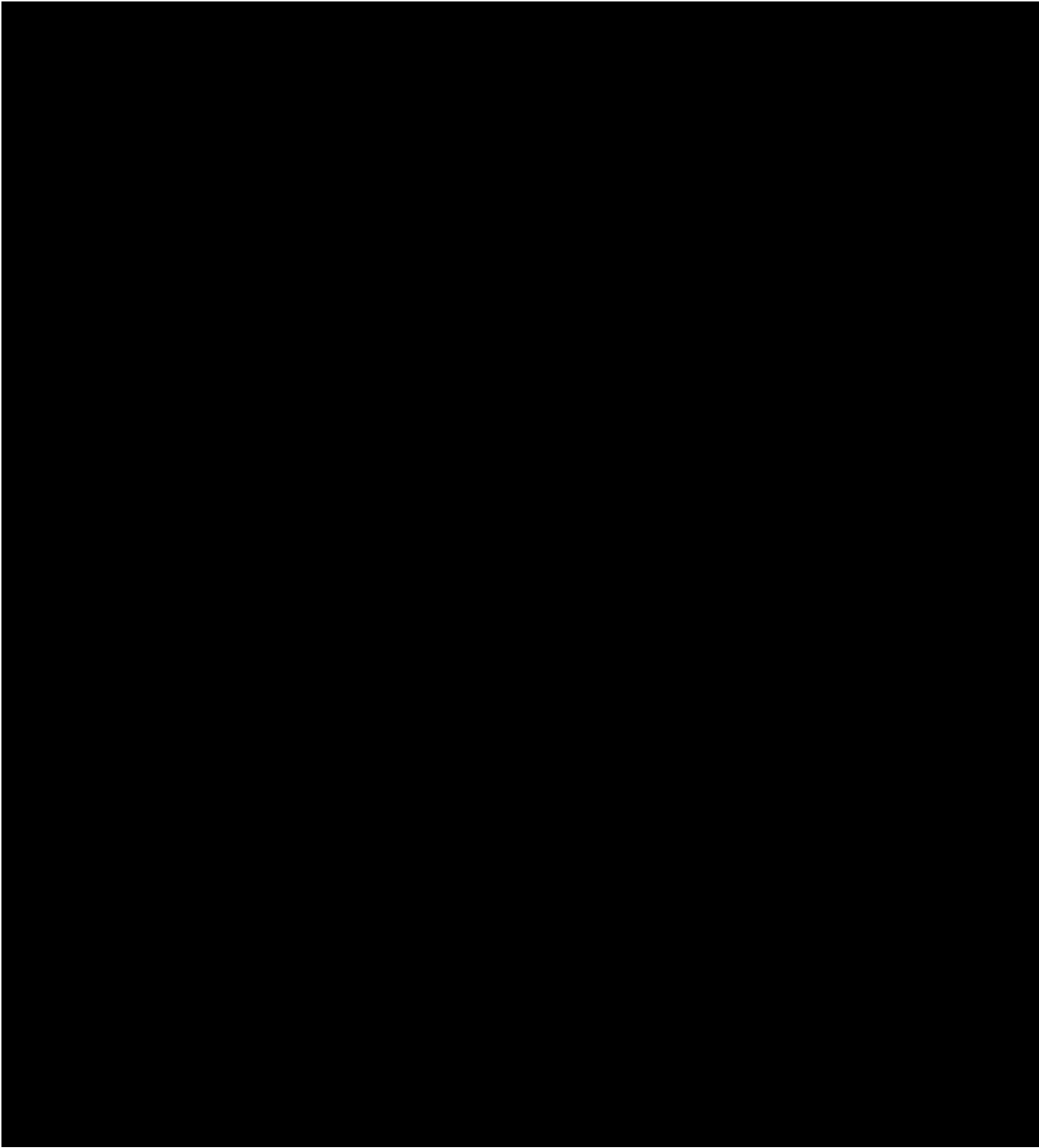


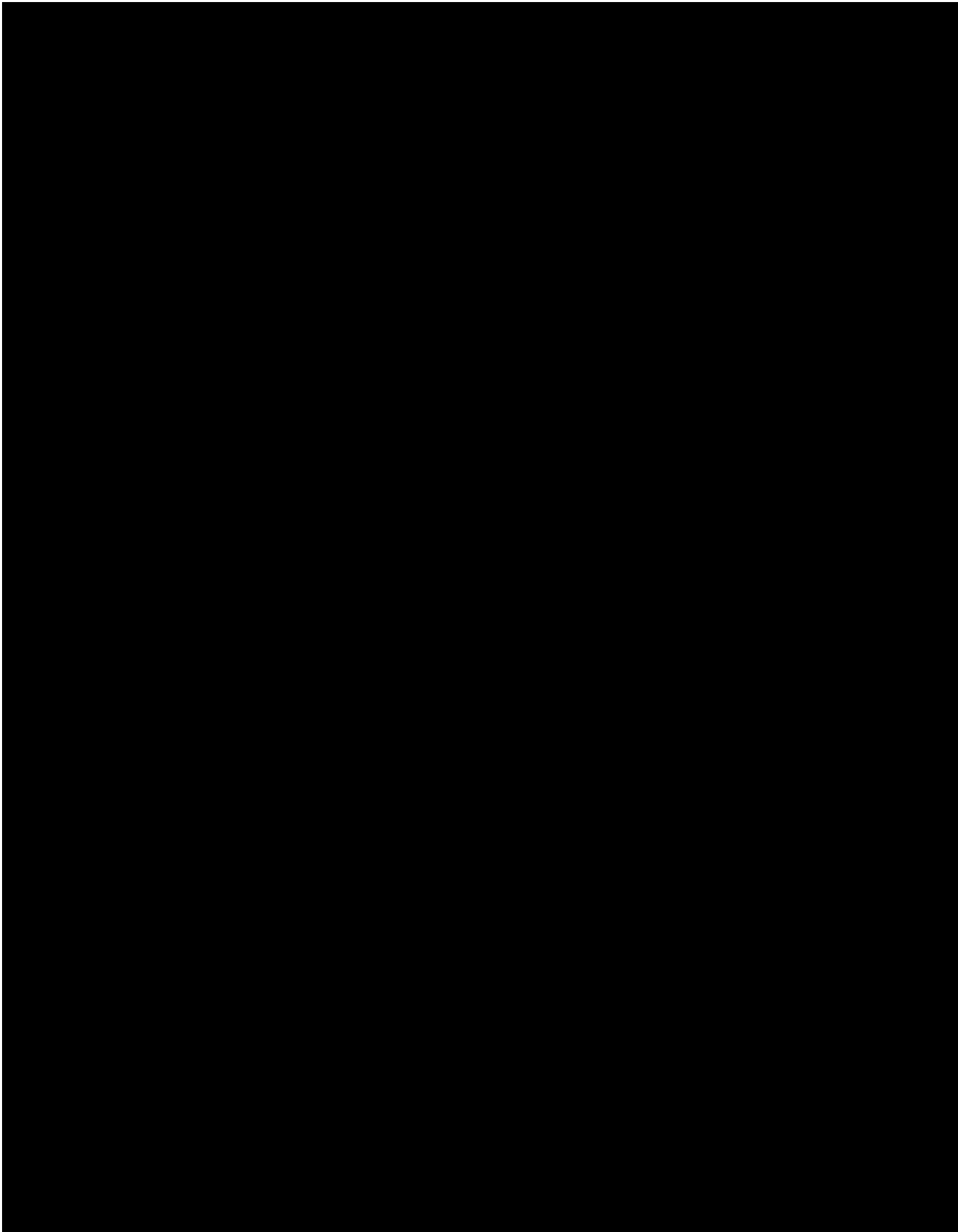


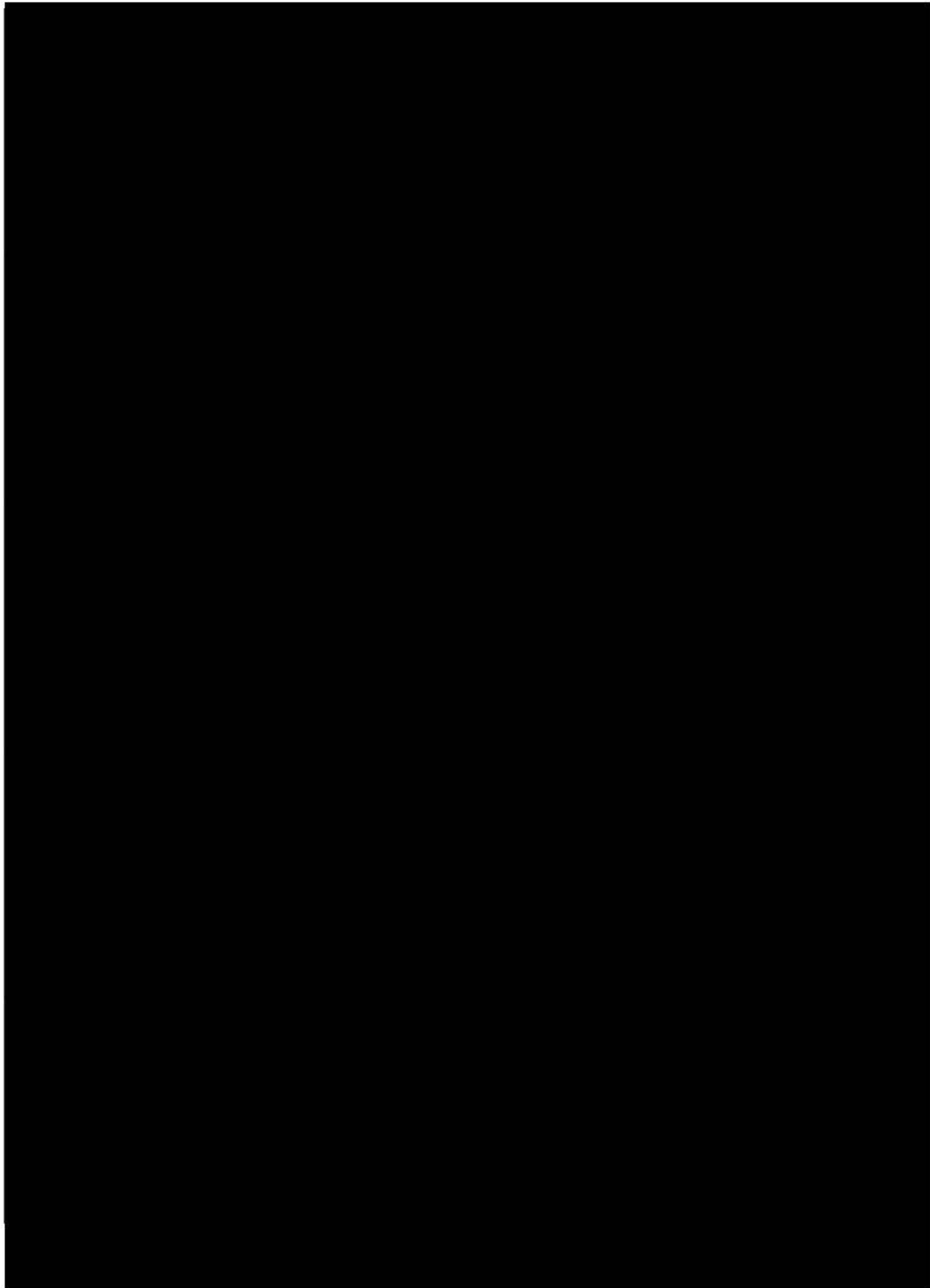


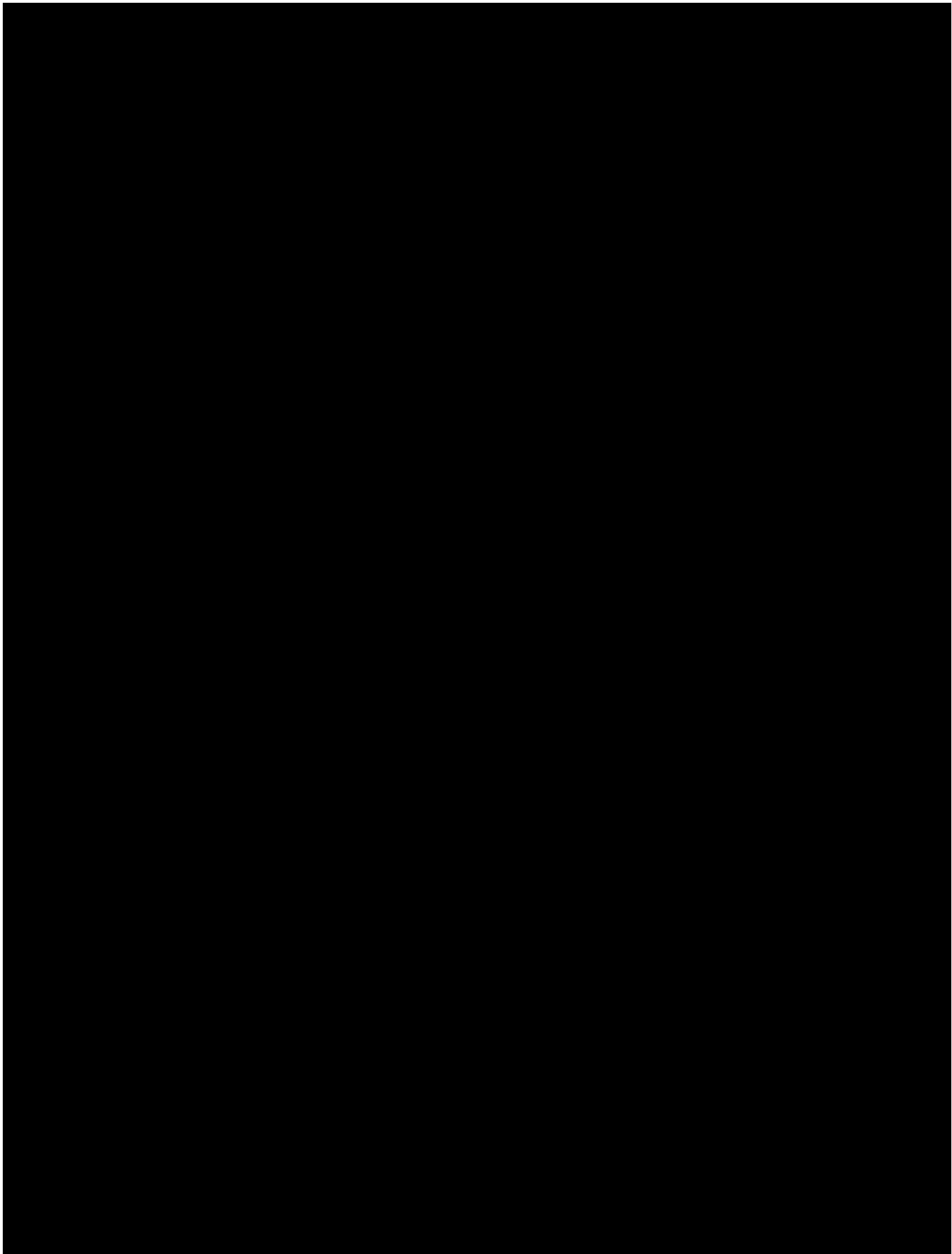


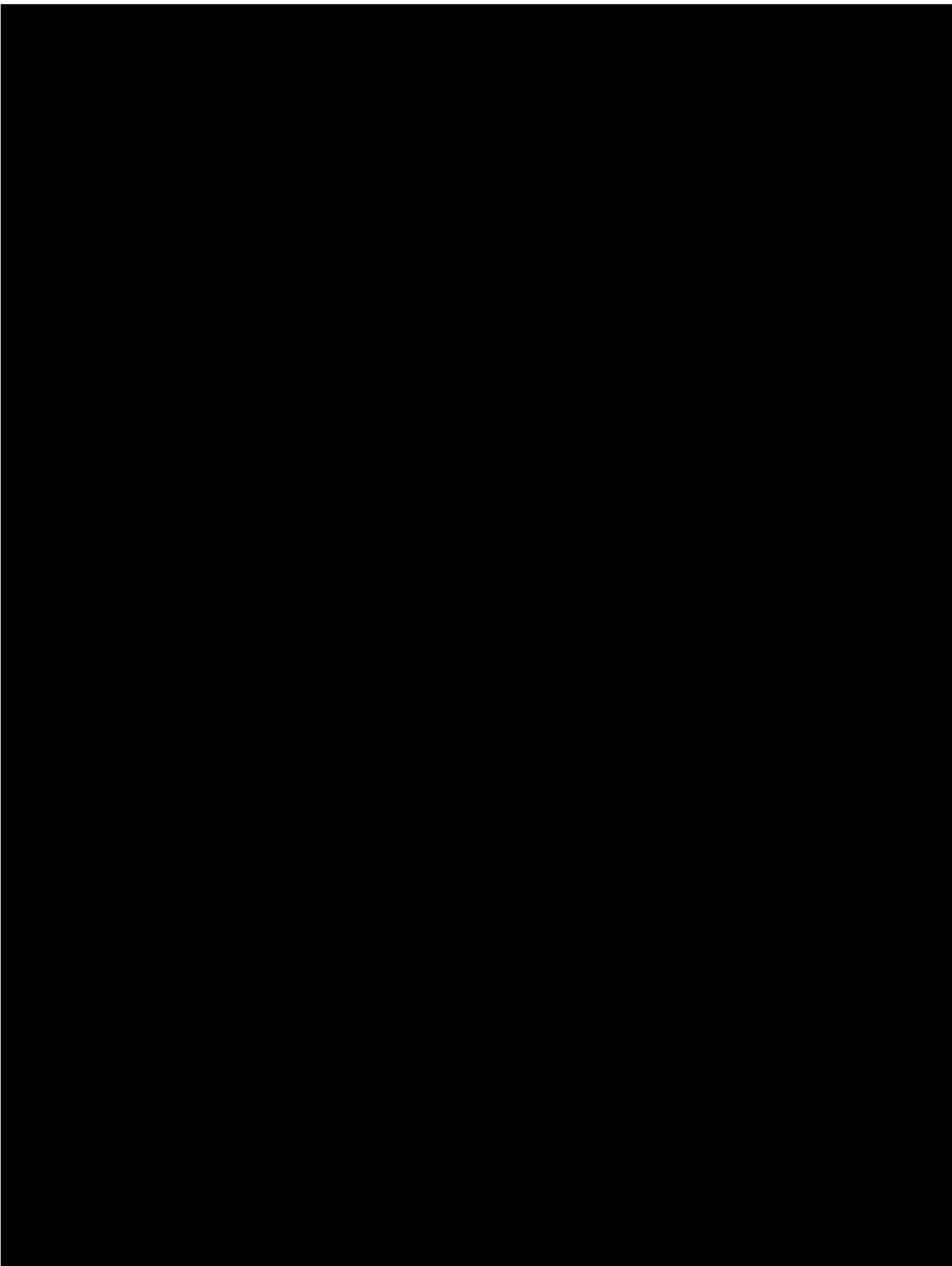


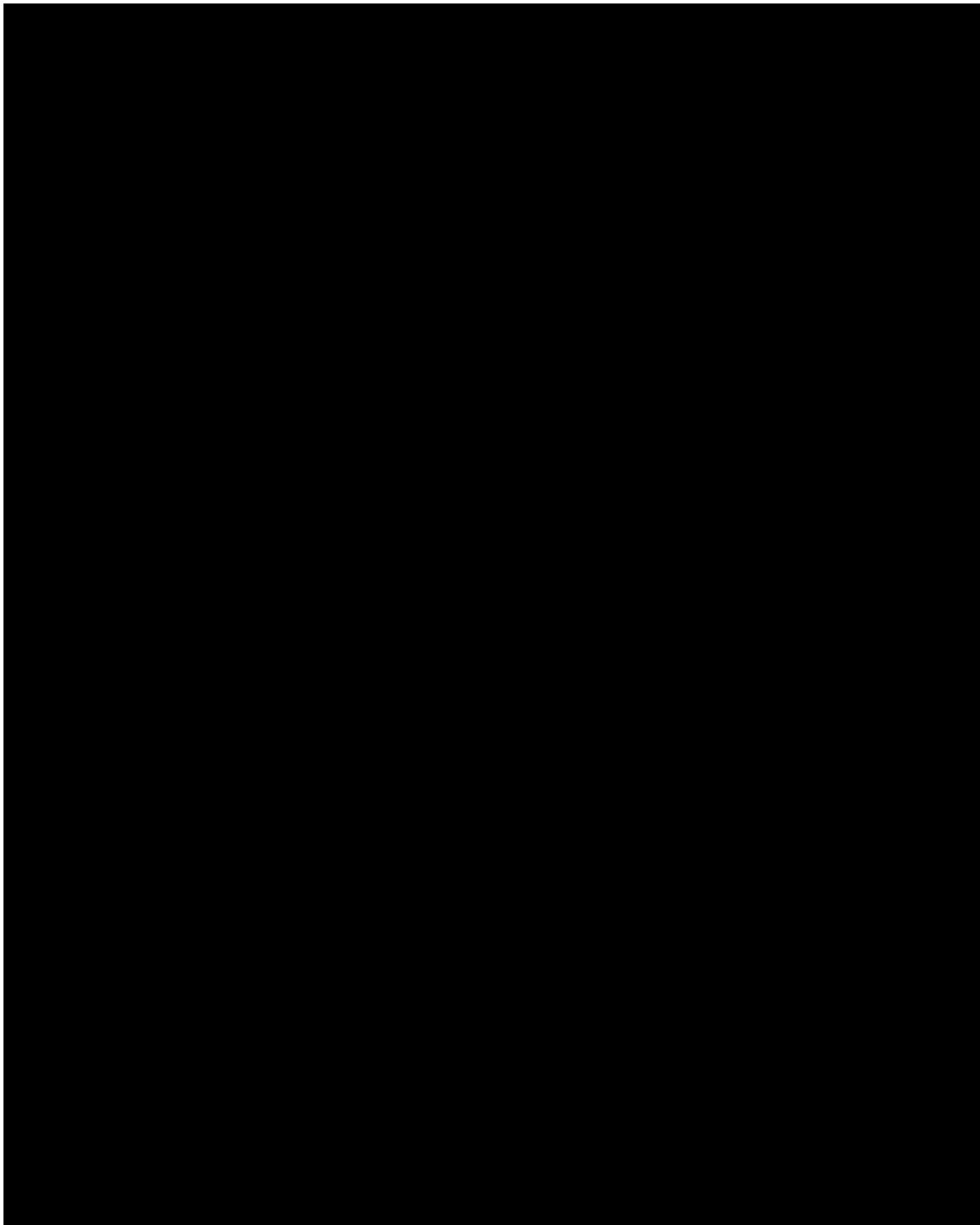












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