

R13/371236



Australian Government

Department of Health and Ageing
Therapeutic Goods Administration

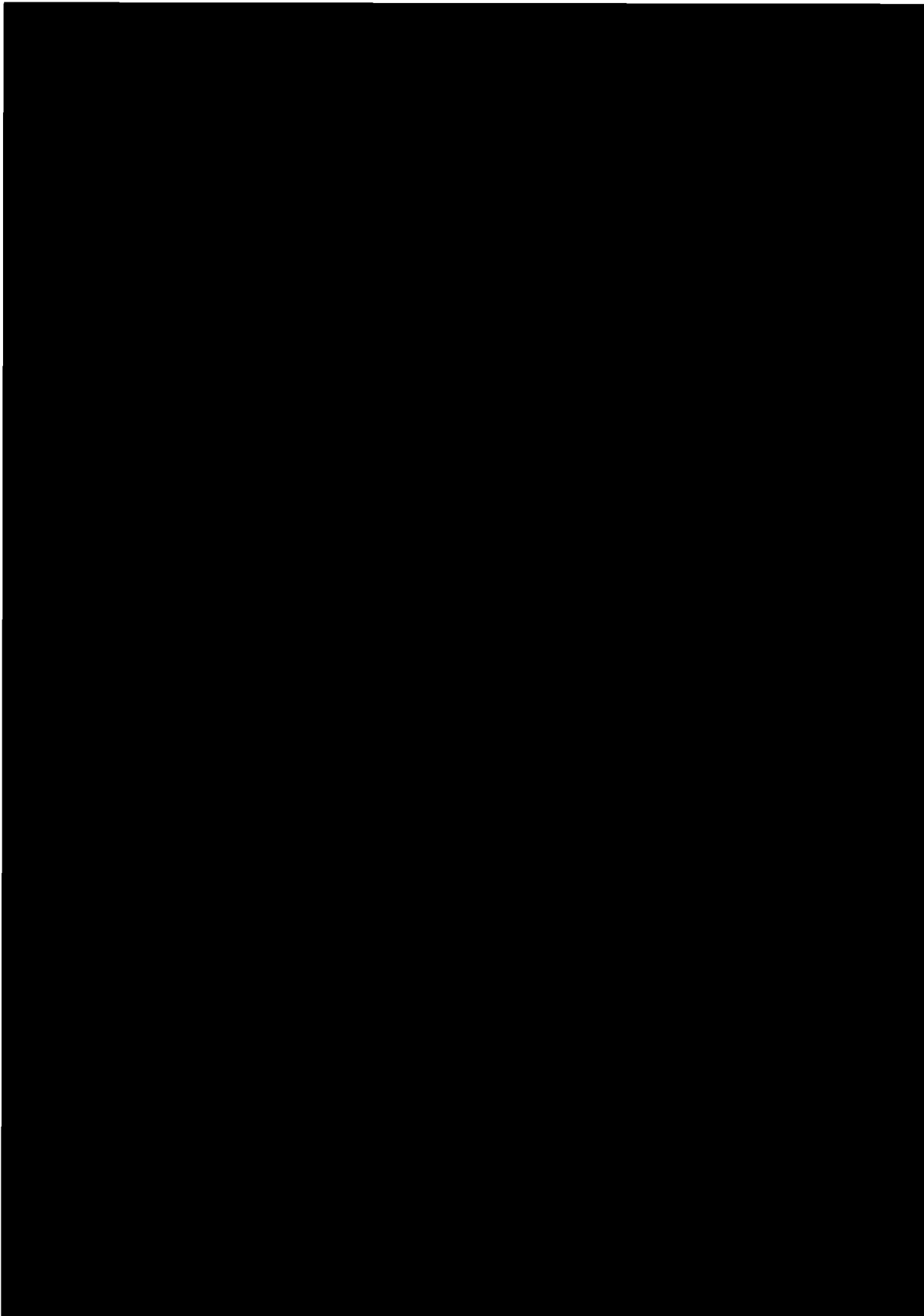
Advisory Committee on the Safety of Medicines

Ratified Minutes

16th Meeting – 8 March 2013

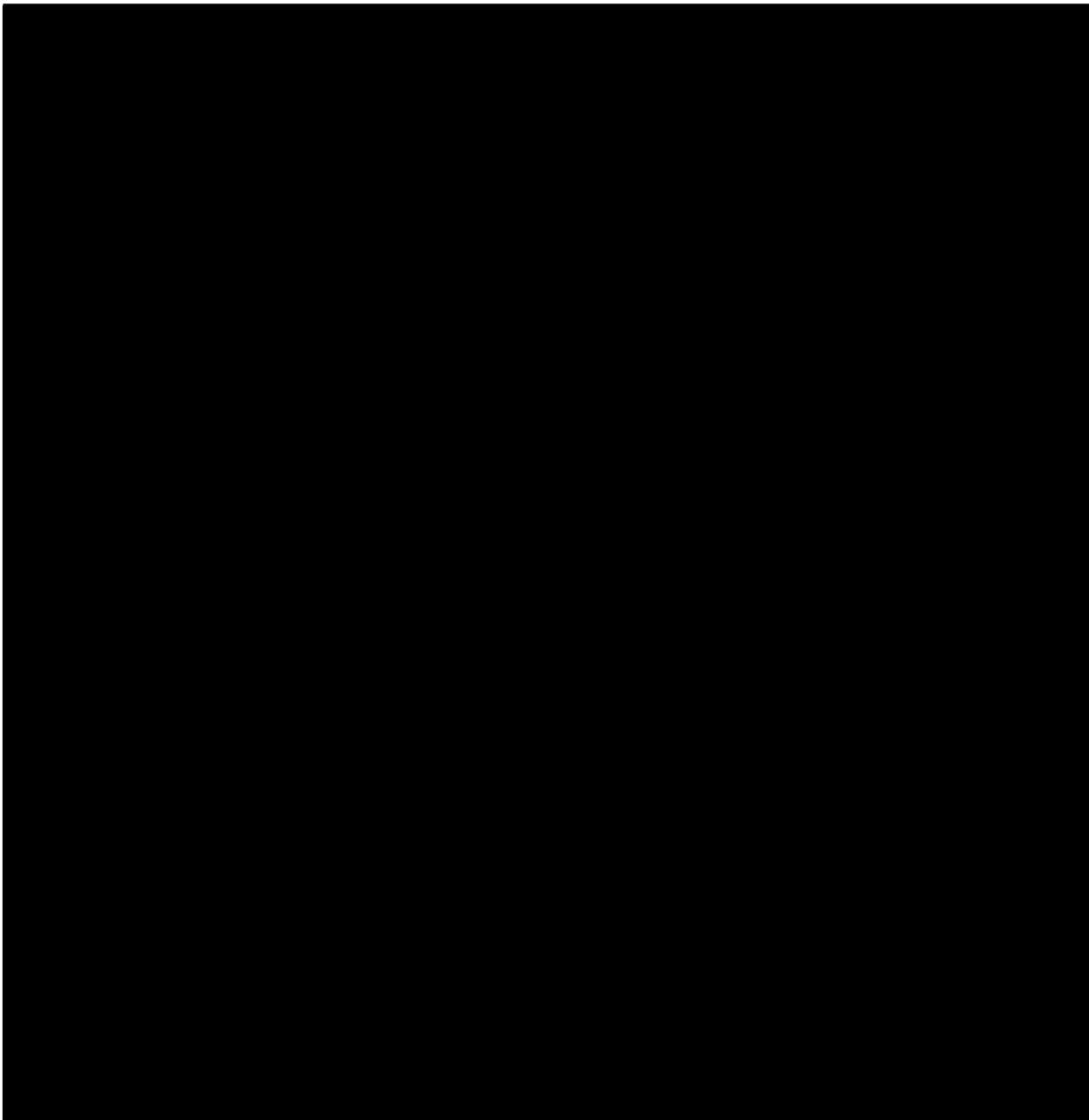
TGA Health Safety
Regulation

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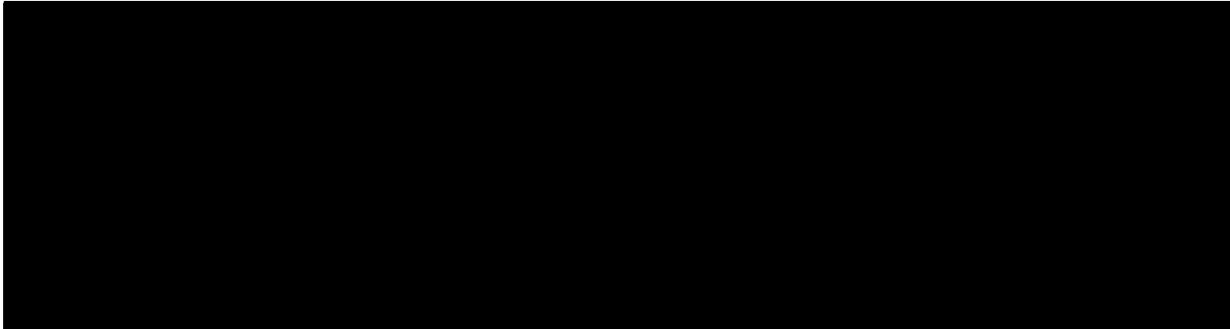


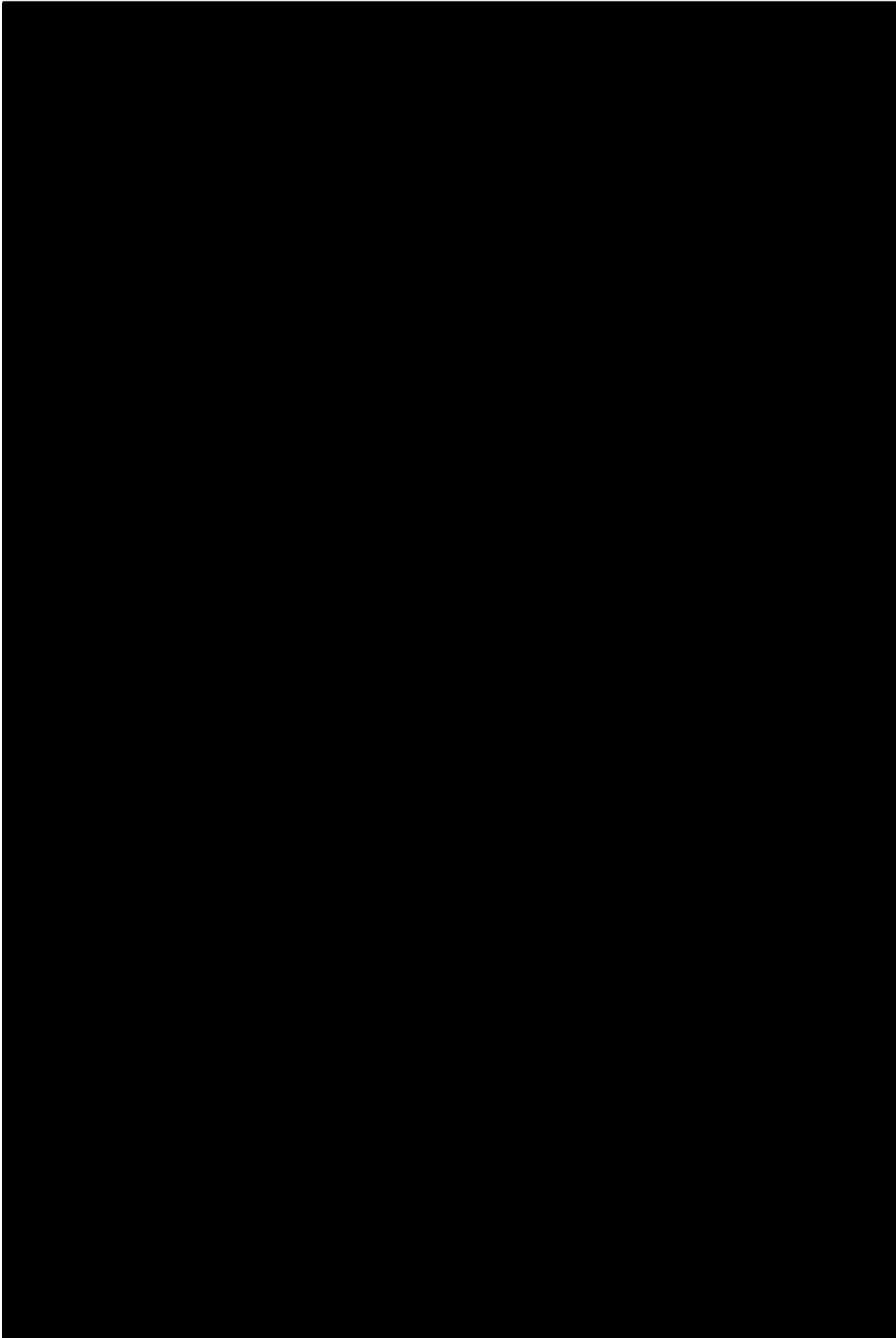


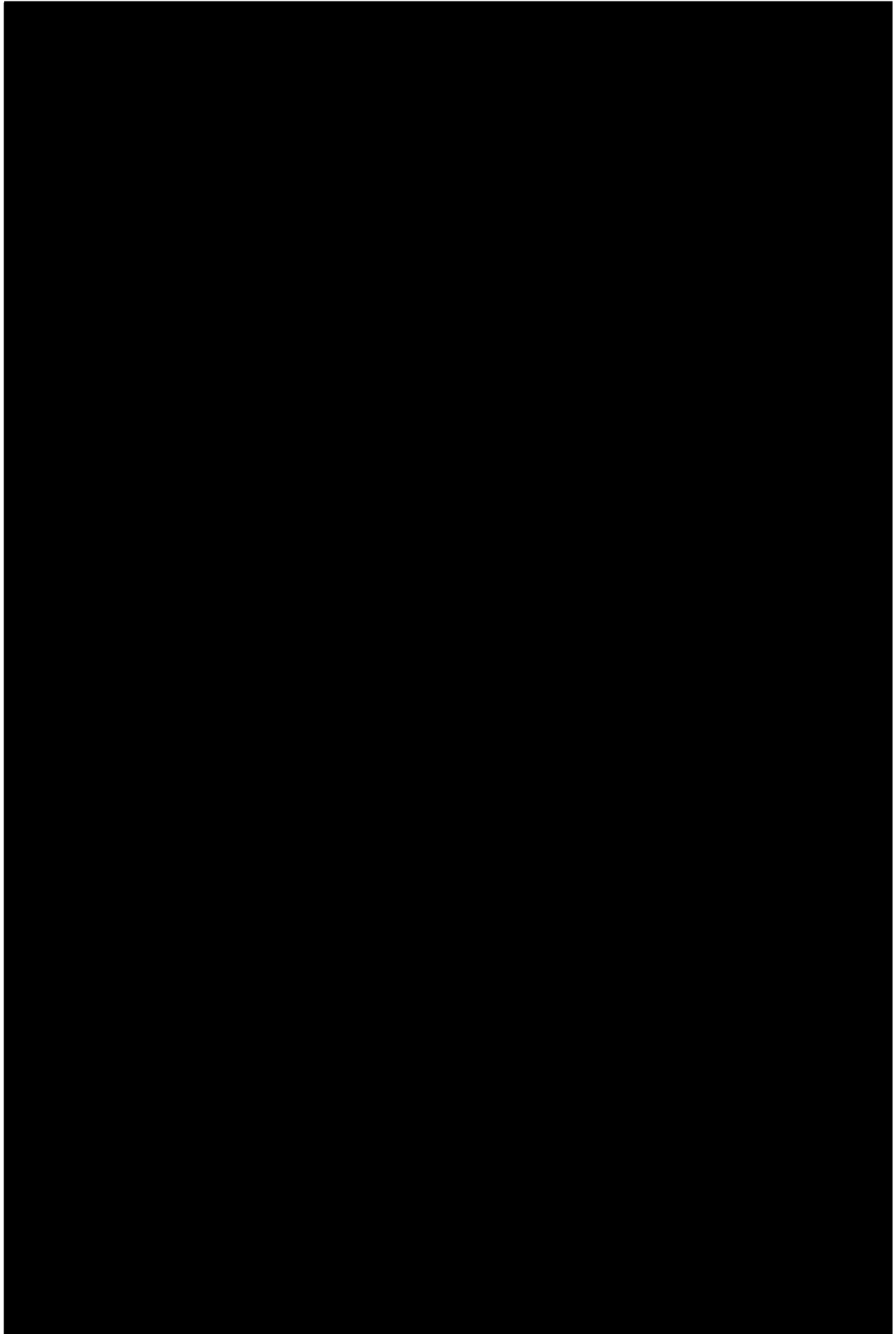
- TGA staff:** Dr John Skerritt: TGA National Manager (items 3.1 4.5-4.7)
Dr Jane Cook: Head, Office of Product Review
Dr Bronwen Harvey: Head, Signal Investigation Unit (items 3.1, 4.5-4.7)
Dr Rona Hiam: Section Head, Risk Management Plan Evaluation Section (items 4.1-4.4)
Dr Kaye Robertson: Medical Officer, Office of Product Review (items 3.1, 4.6, 4.7)
- Secretariat:** Dr Katherine Gray: Secretary (a/g), Office of Product Review
Mr Jason Ng: Secretariat, Office of Product Review
Ms Kushani Chandrasena: Secretariat, Office of Product Review

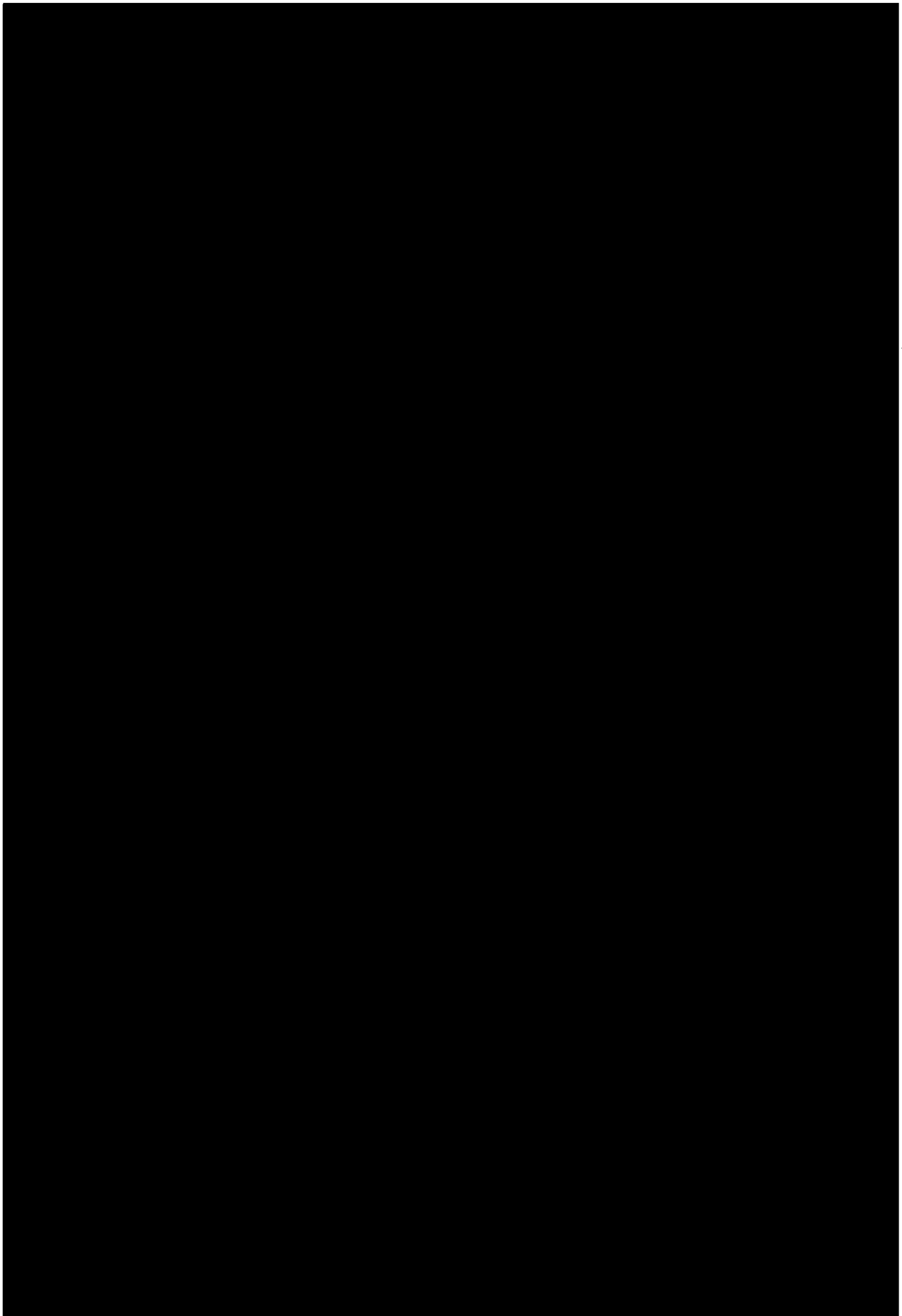


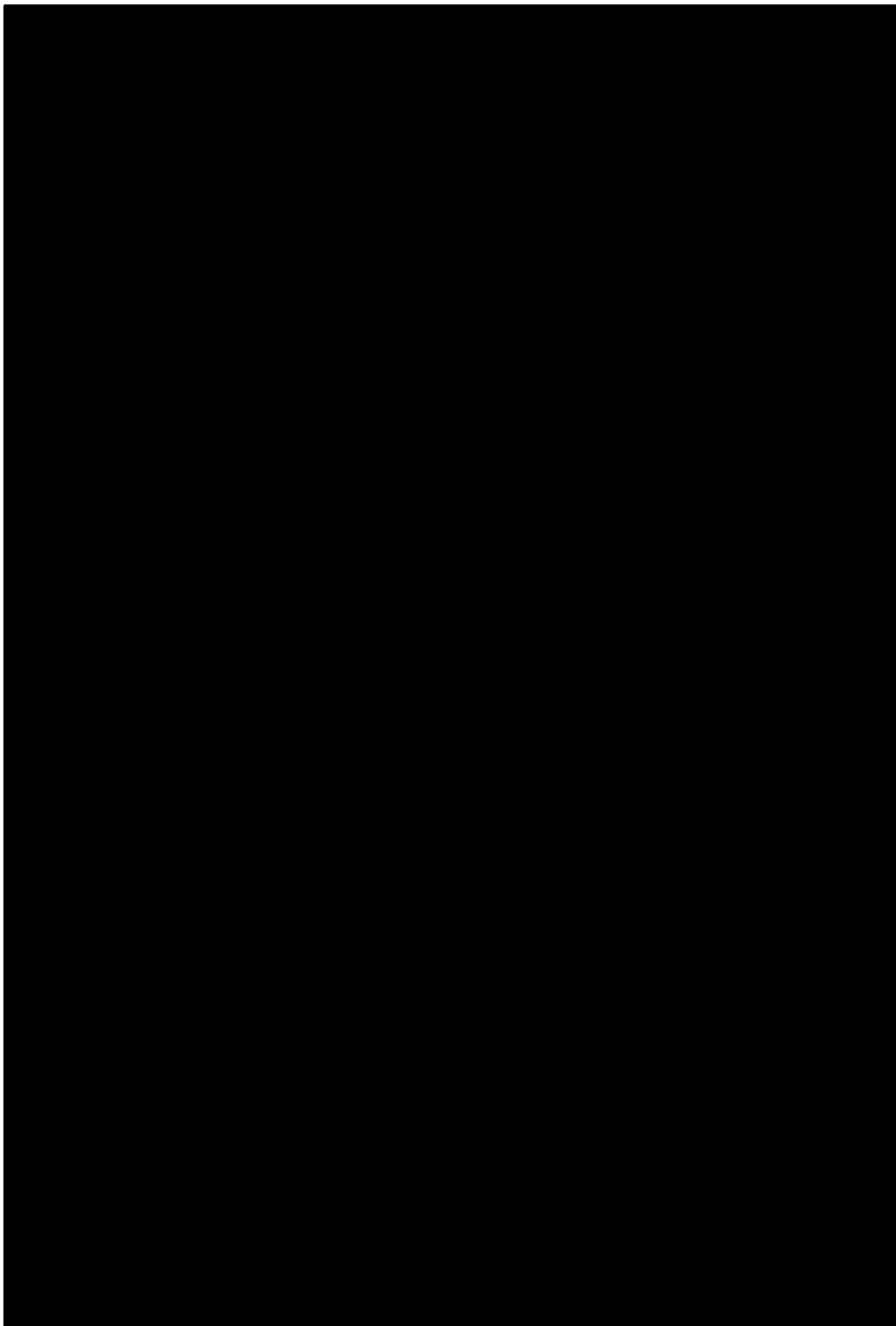
- Meeting 1, 5 March 2010, Item 6.3: The report from the *Psychiatric Drug Safety Expert Advisory Panel (PDSEAP)*.
 - Complete –OPR staff have finalised negotiations with the sponsors of each innovator product and are finalising the outstanding actions. A summary of all actions taken was provided to the members at Item 2.2 of the agenda papers.

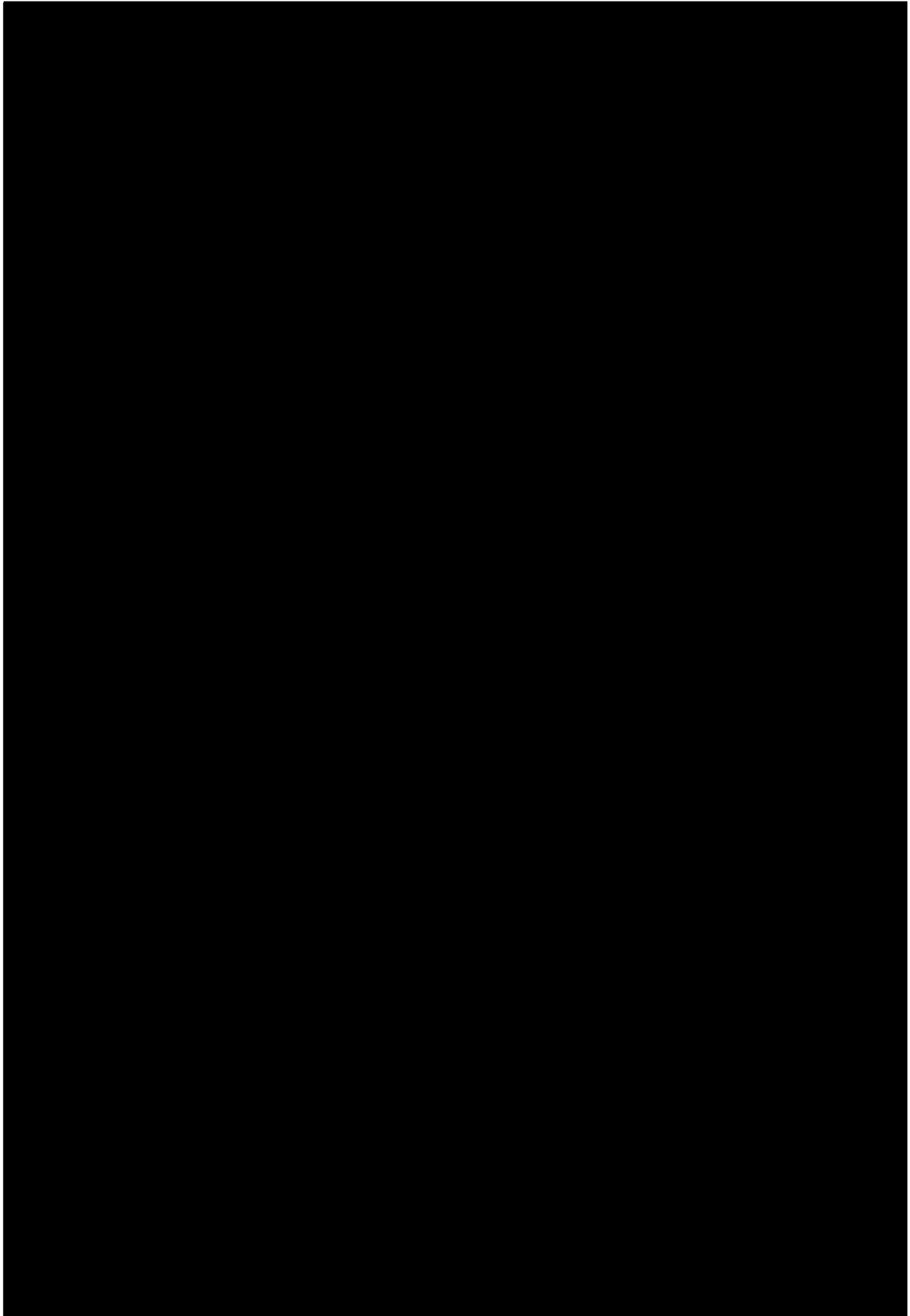


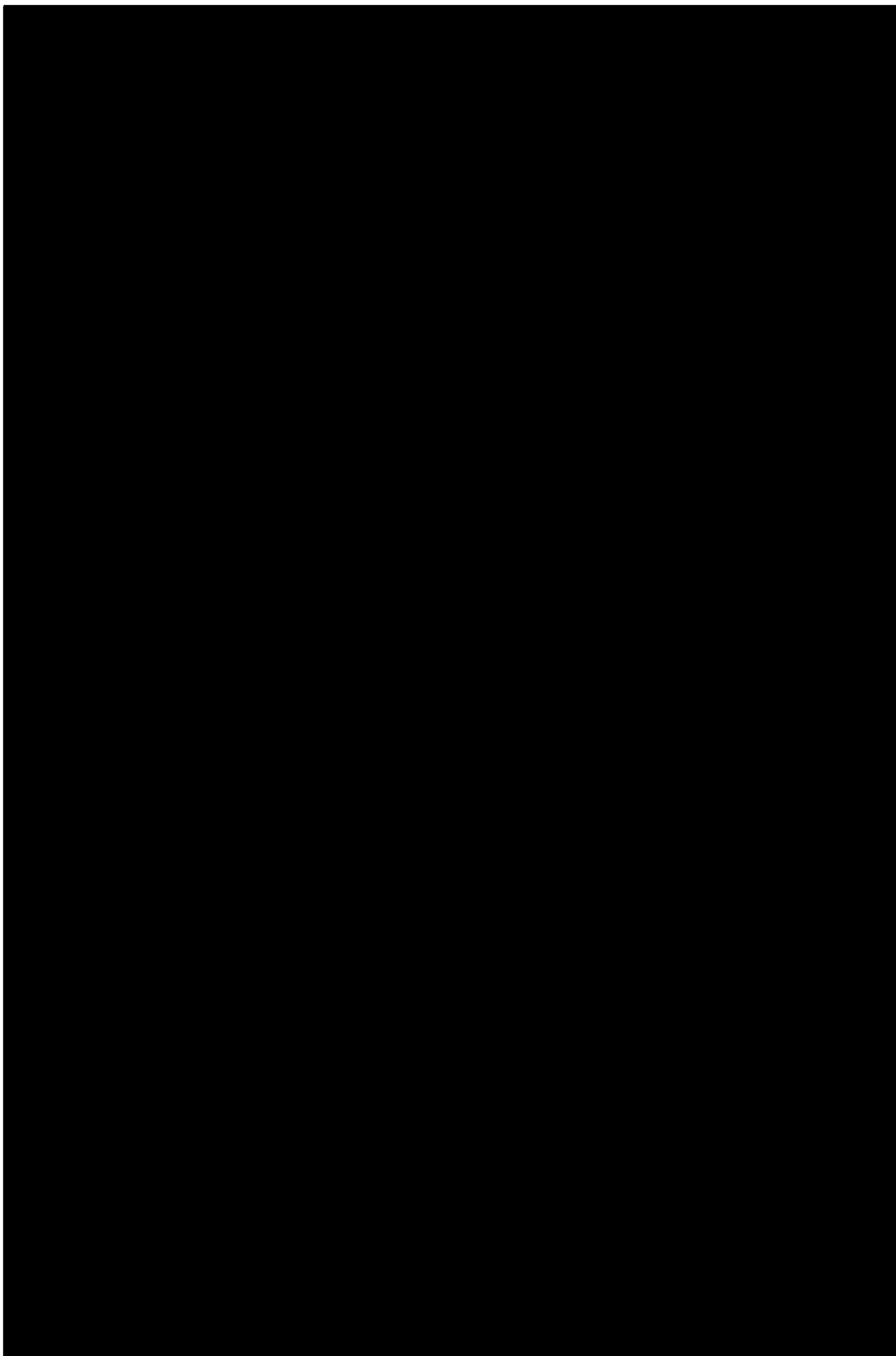


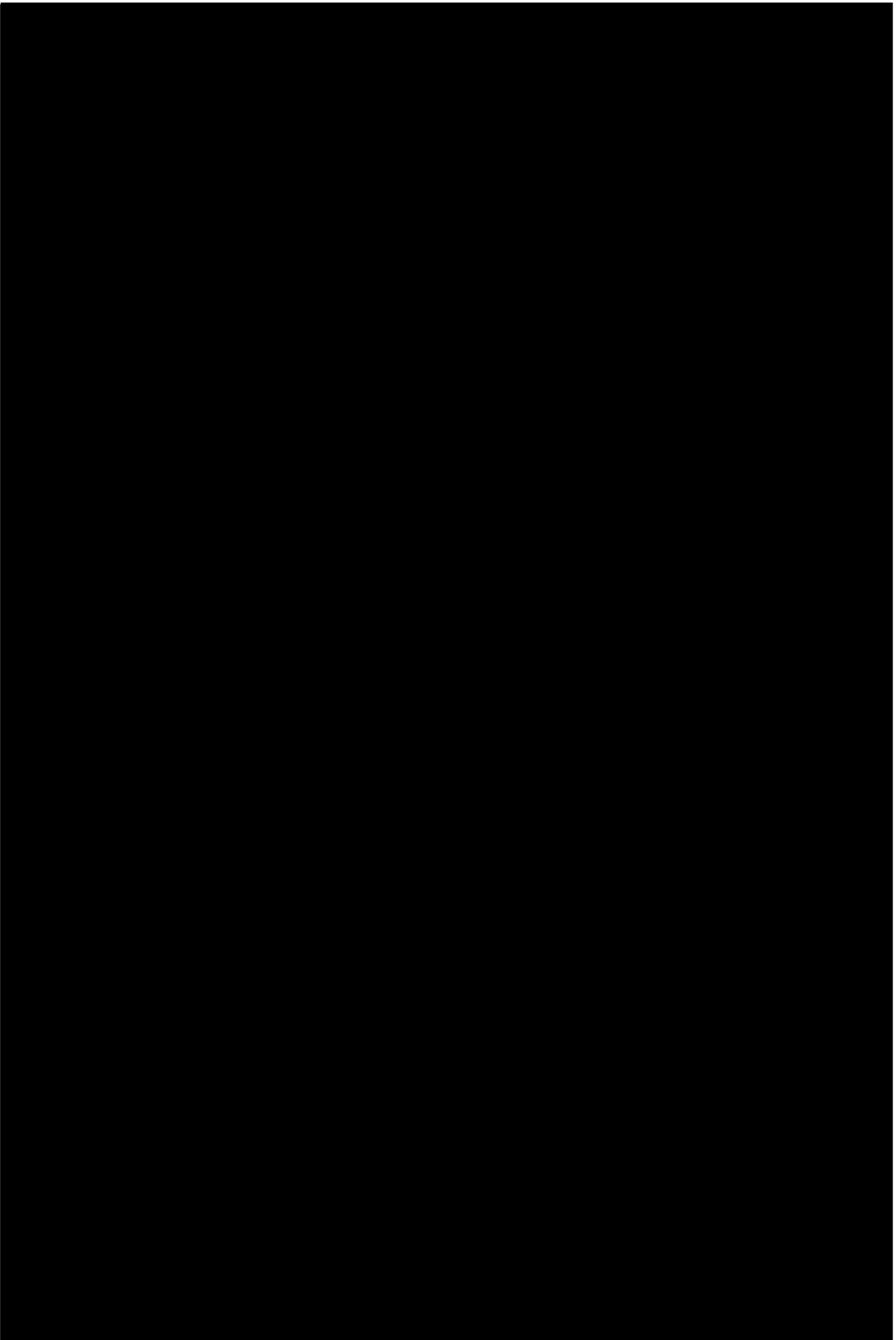


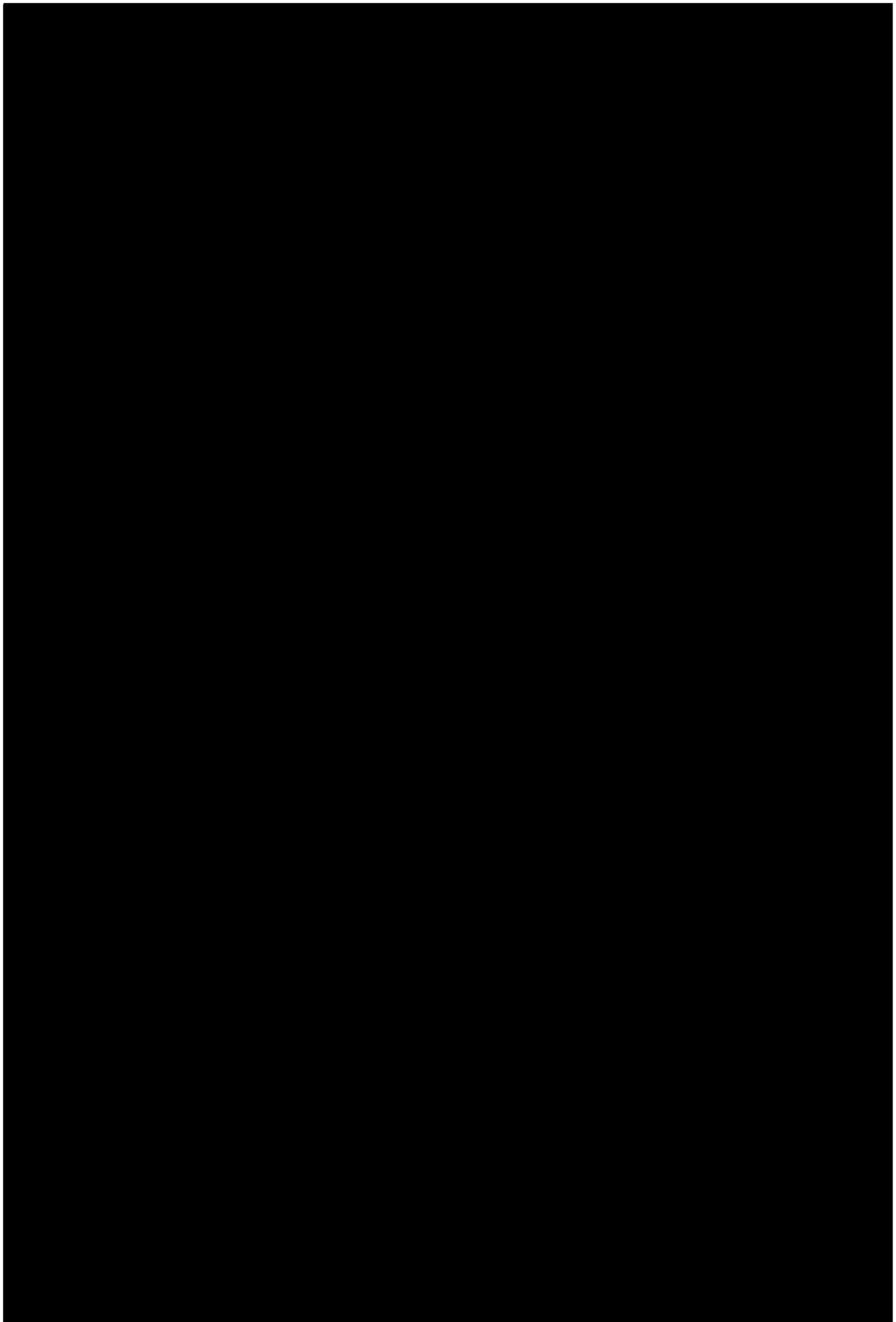


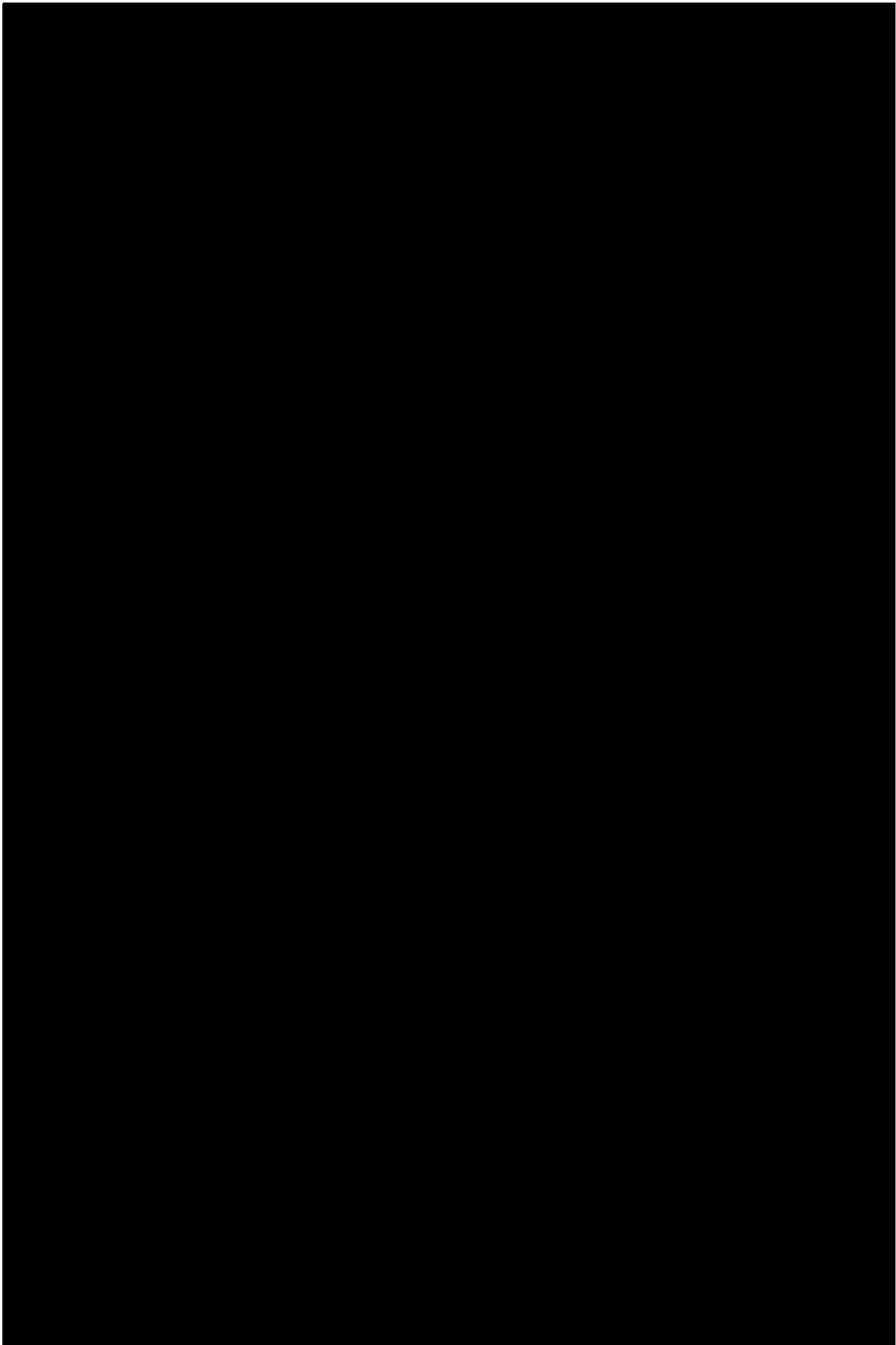


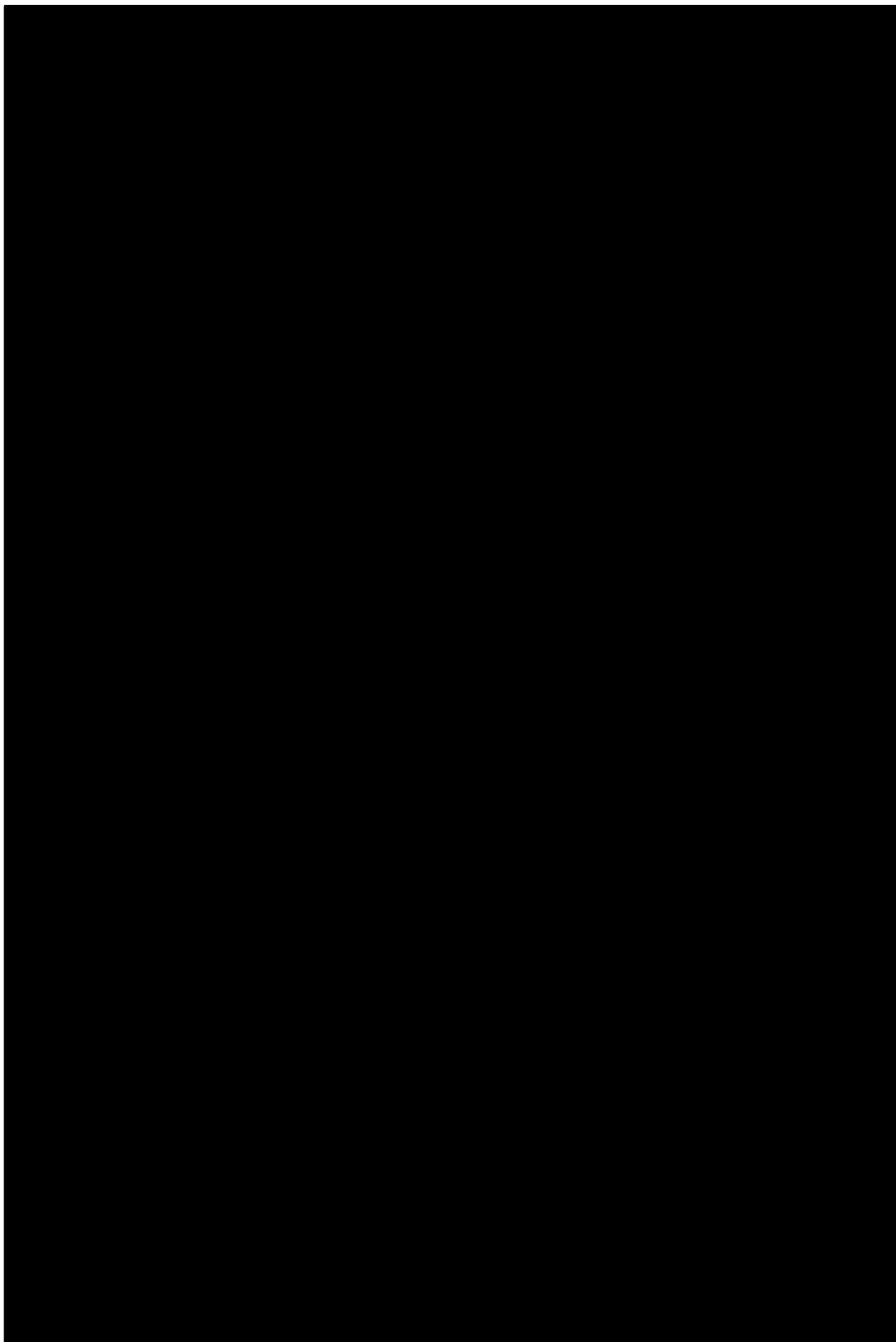


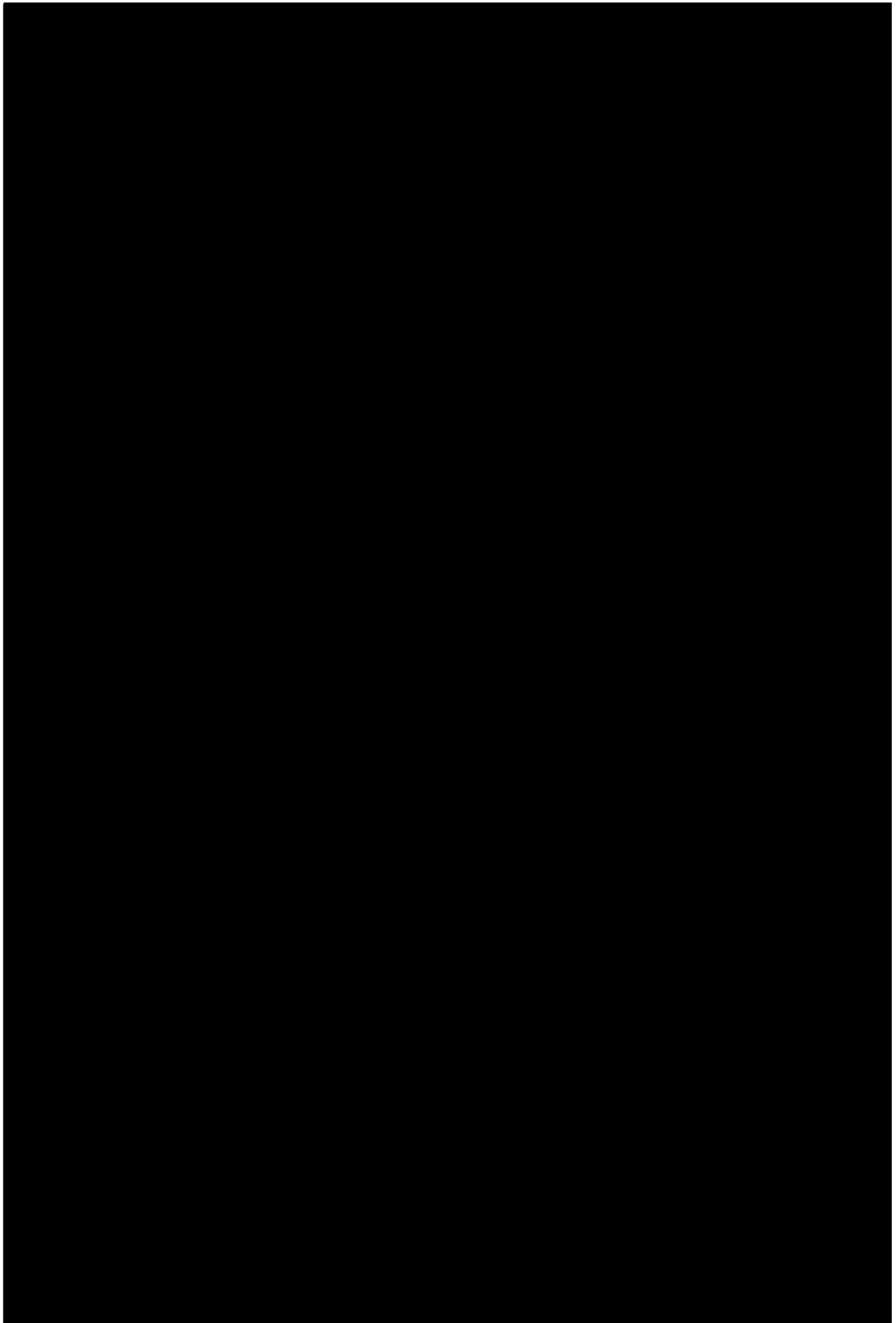


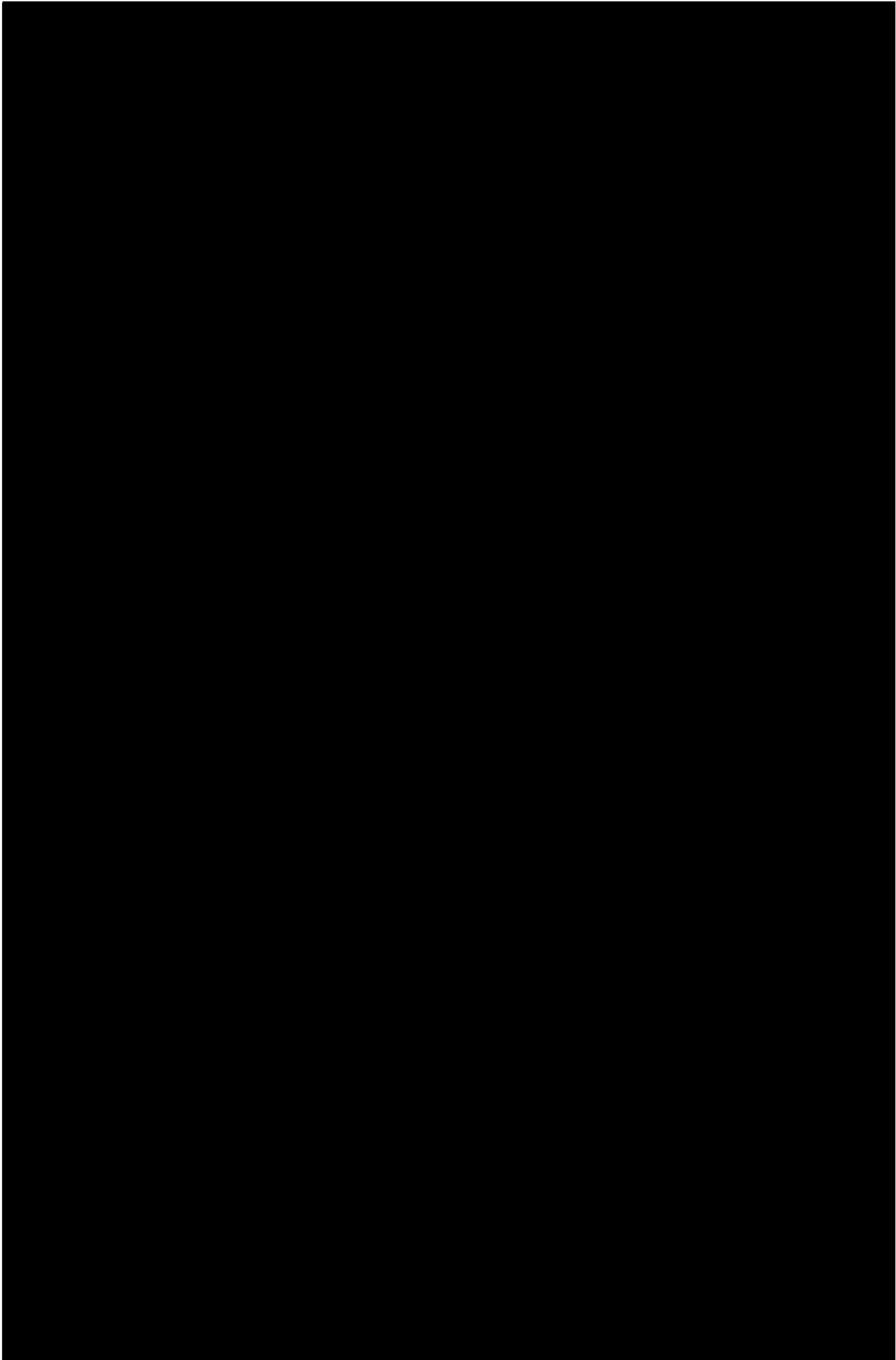


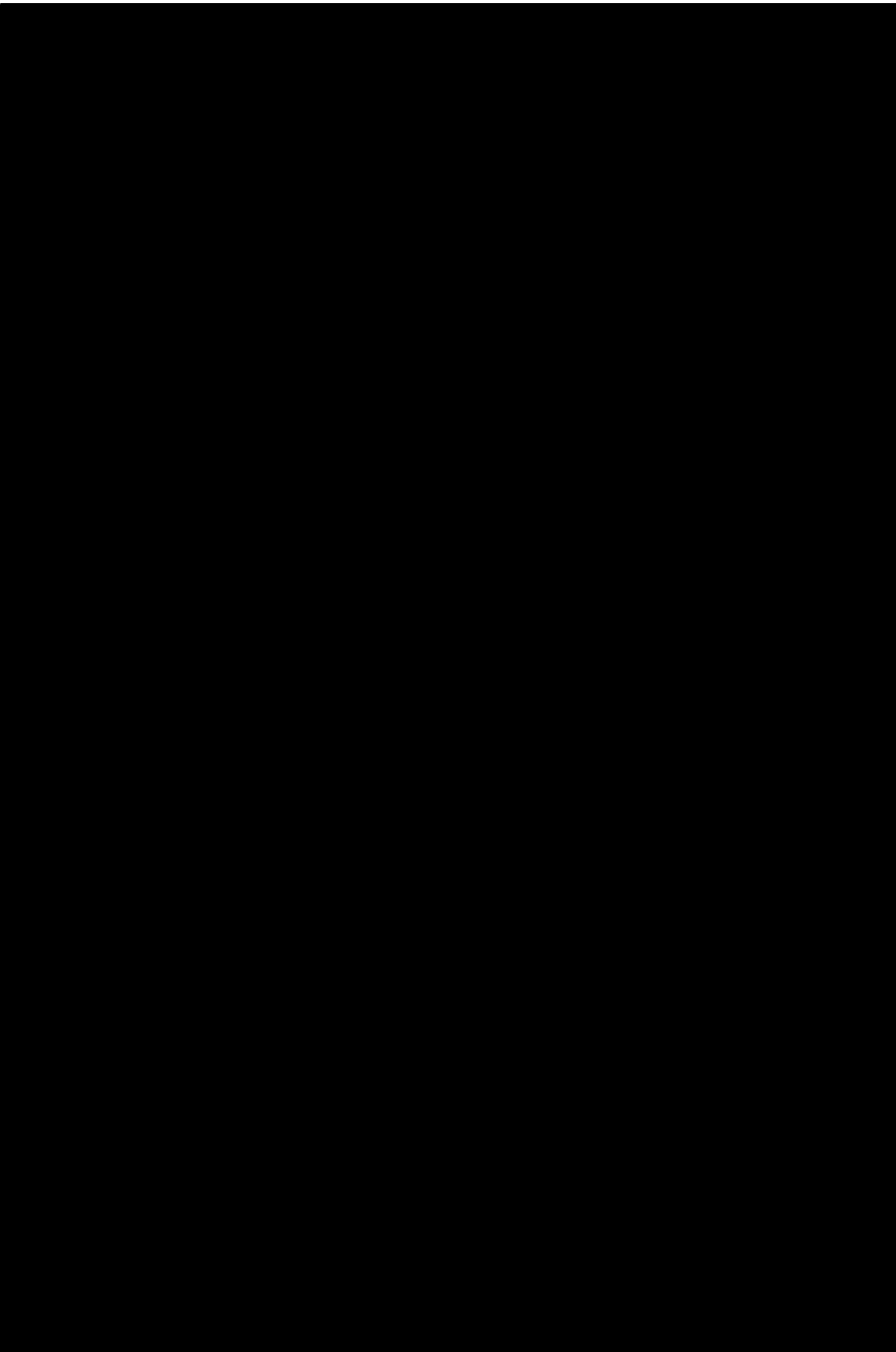


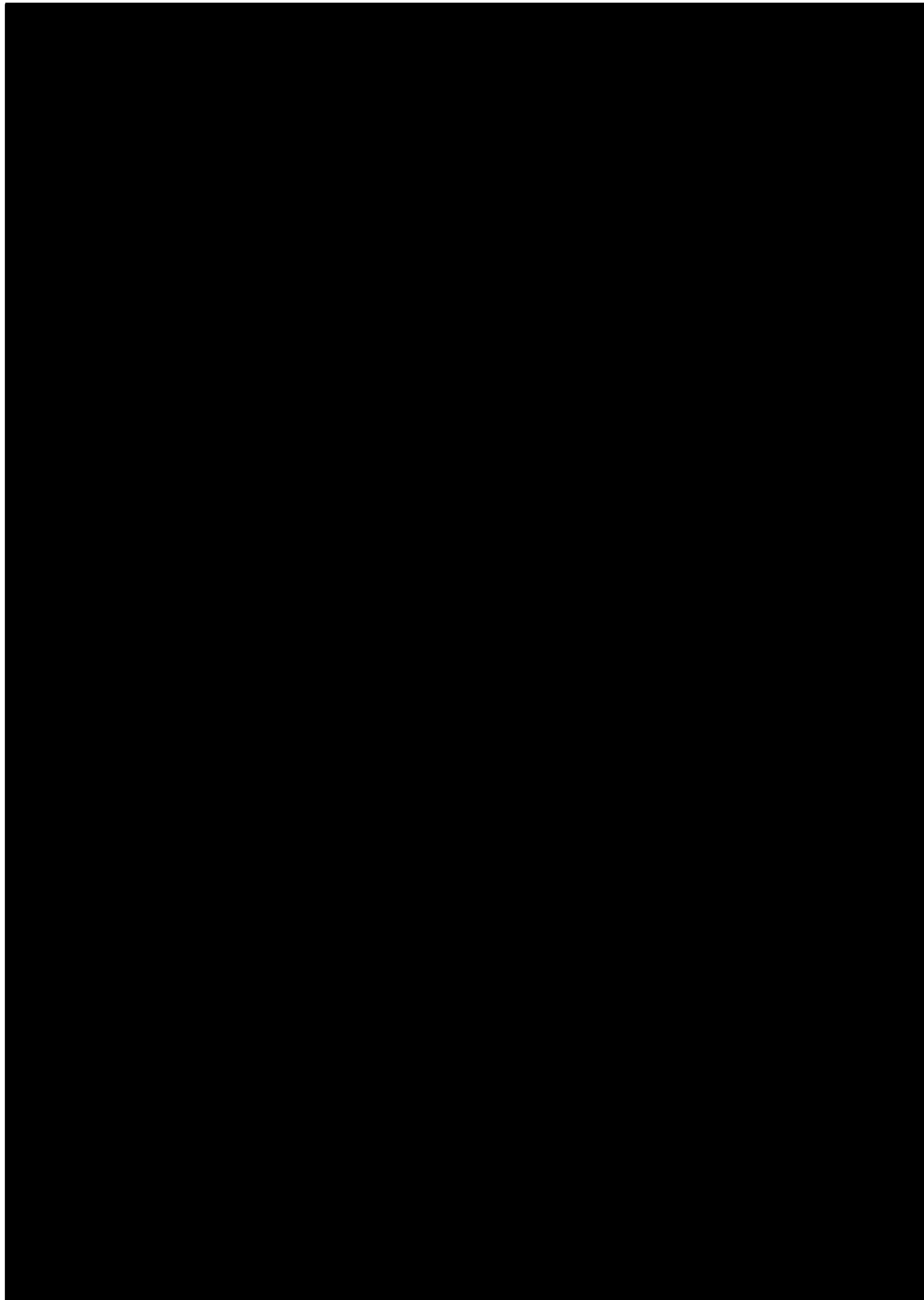


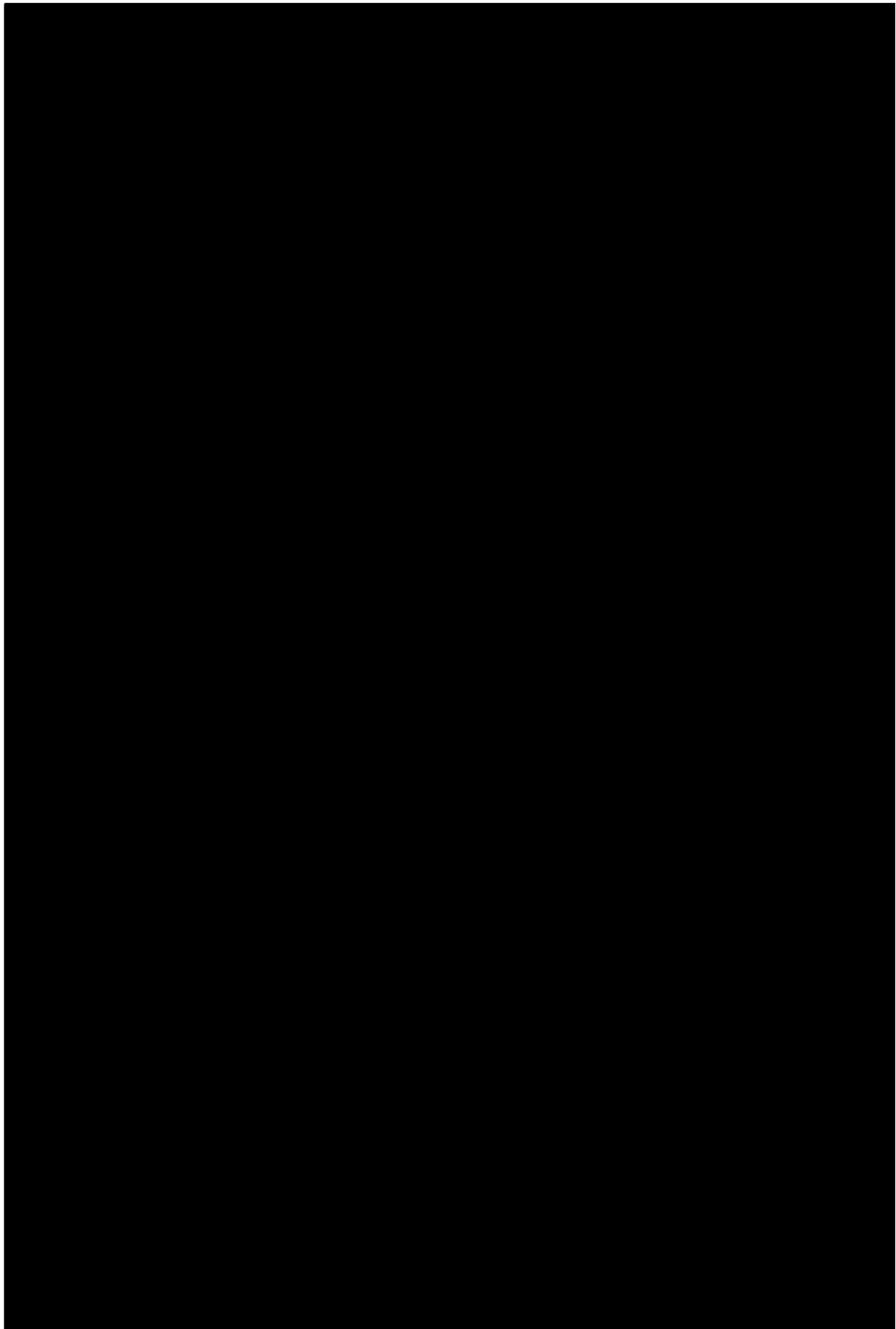


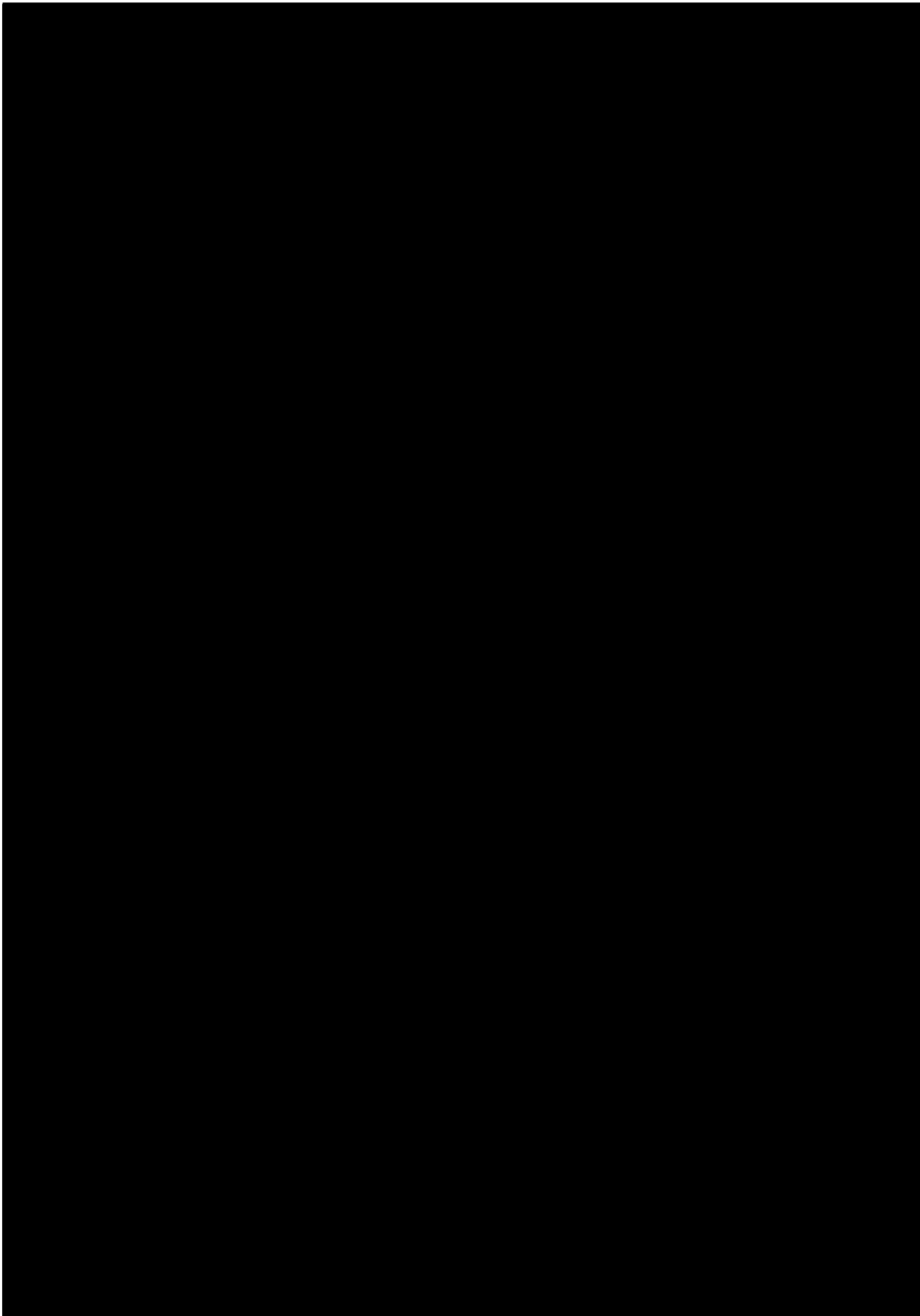


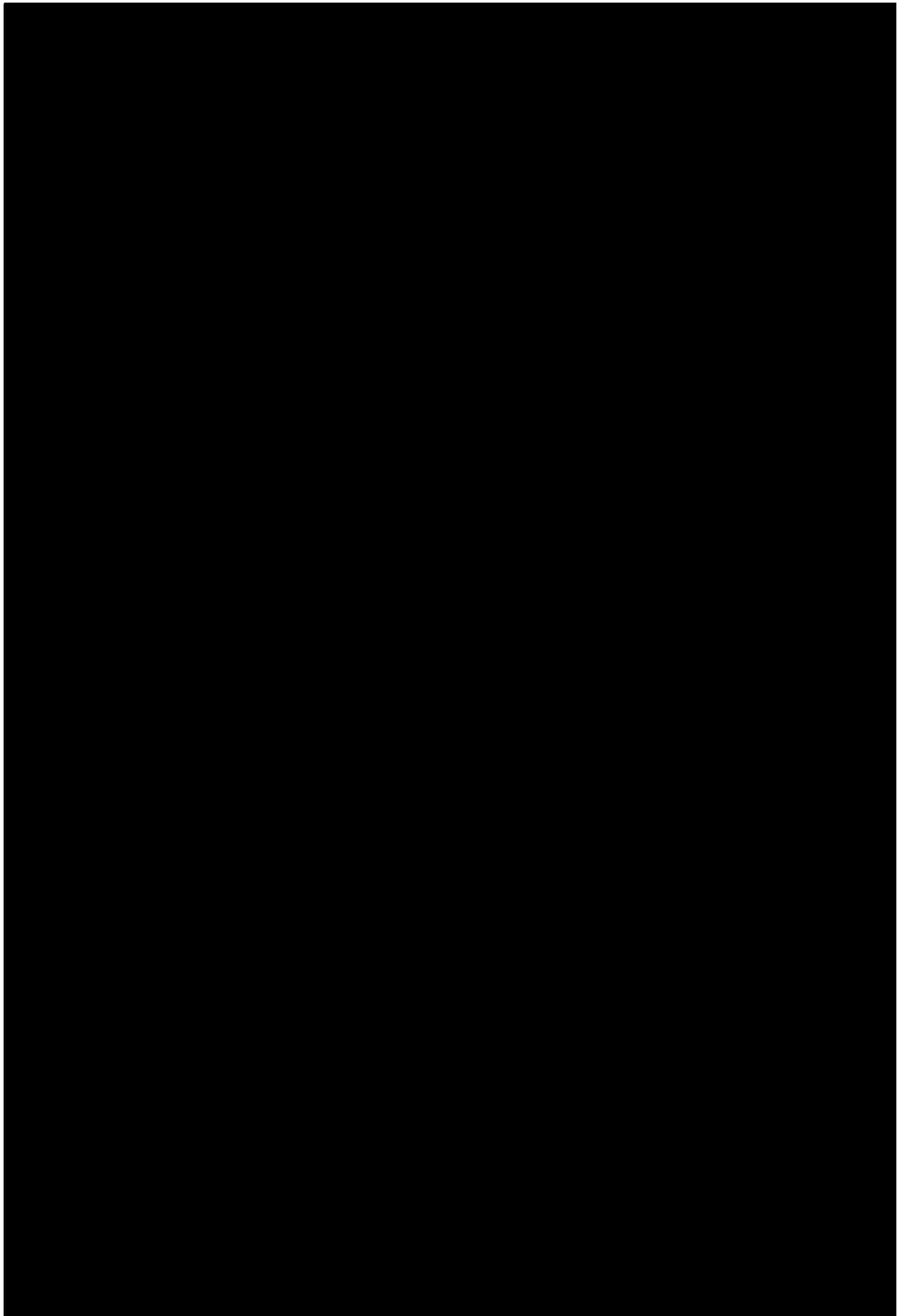


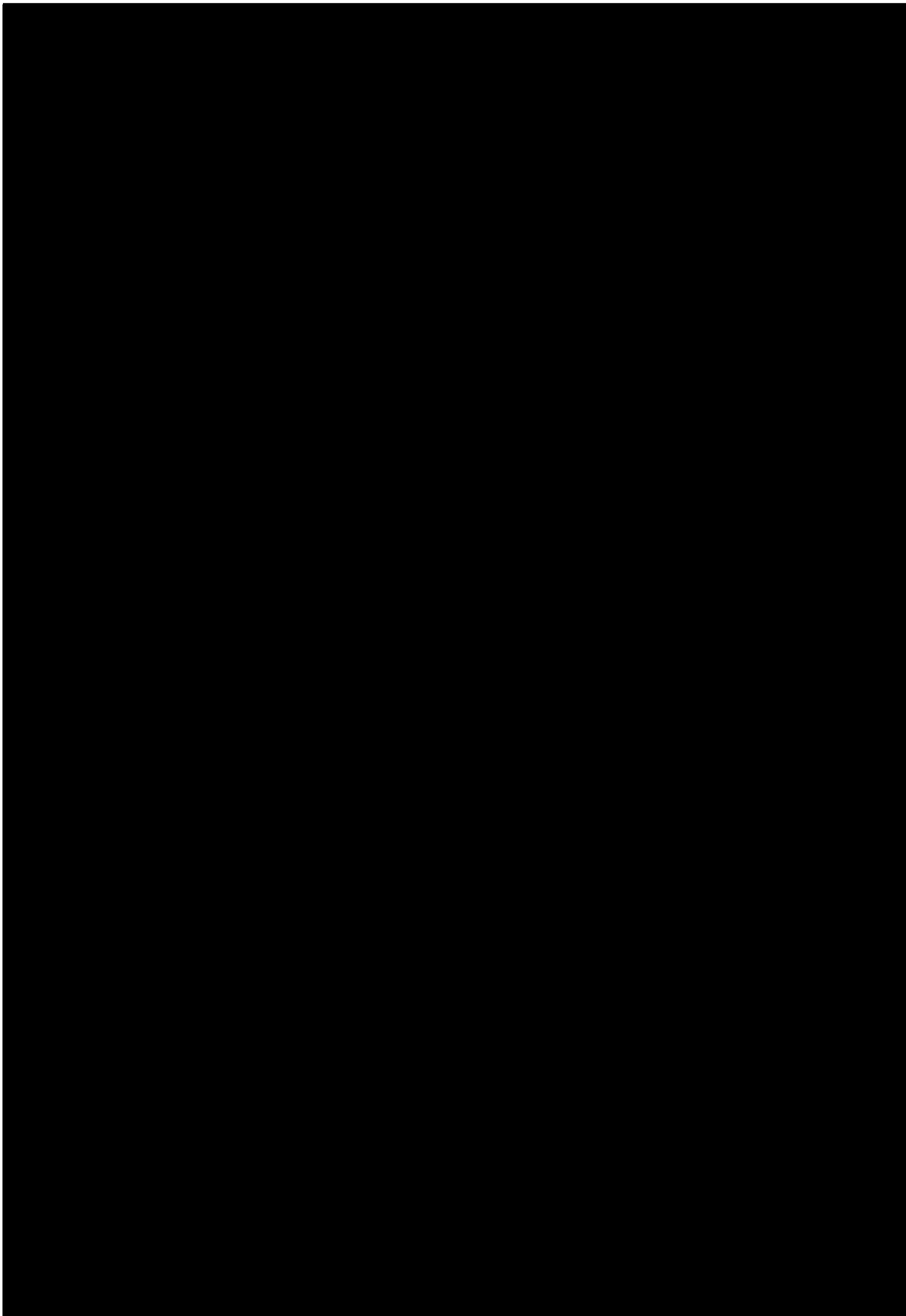


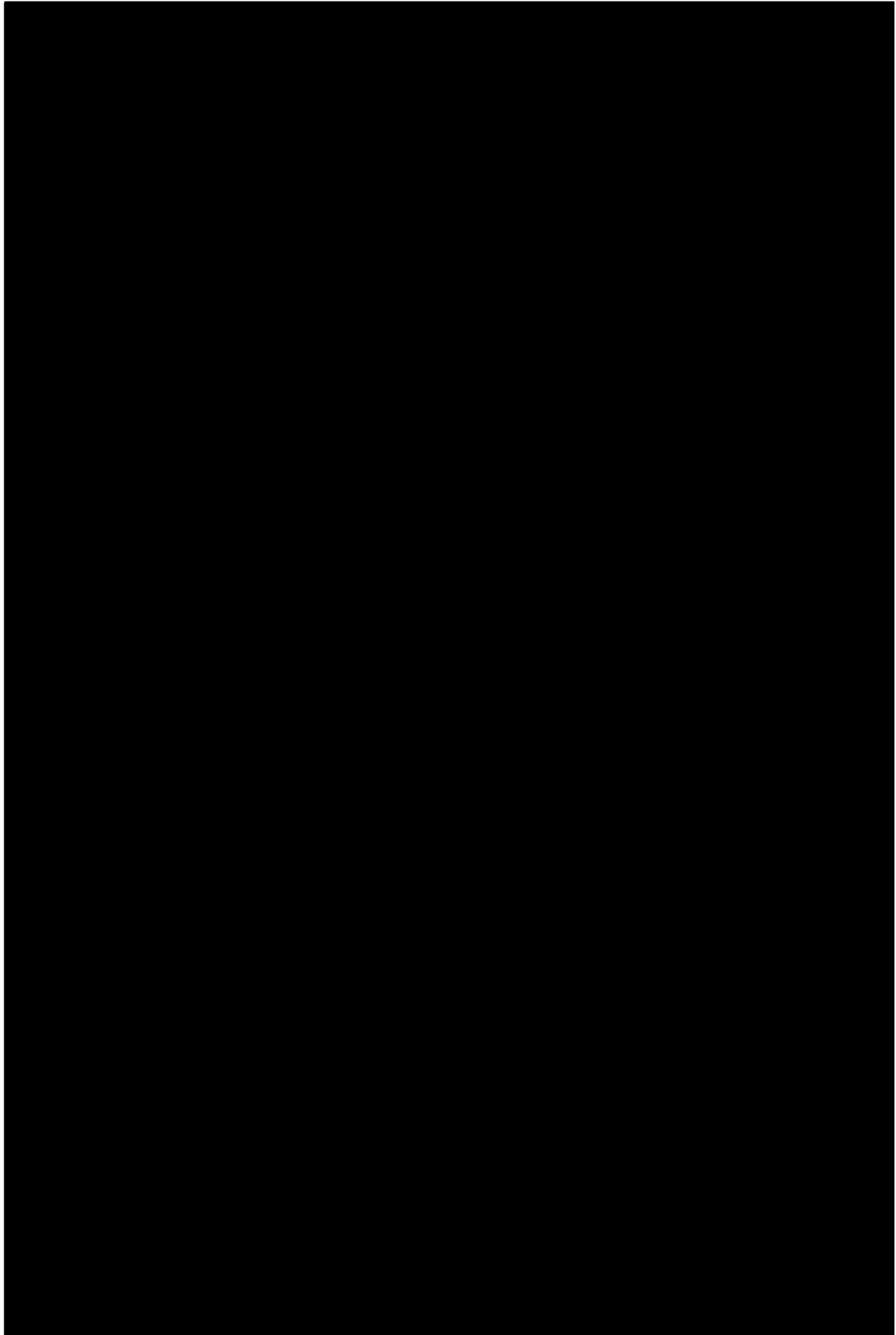


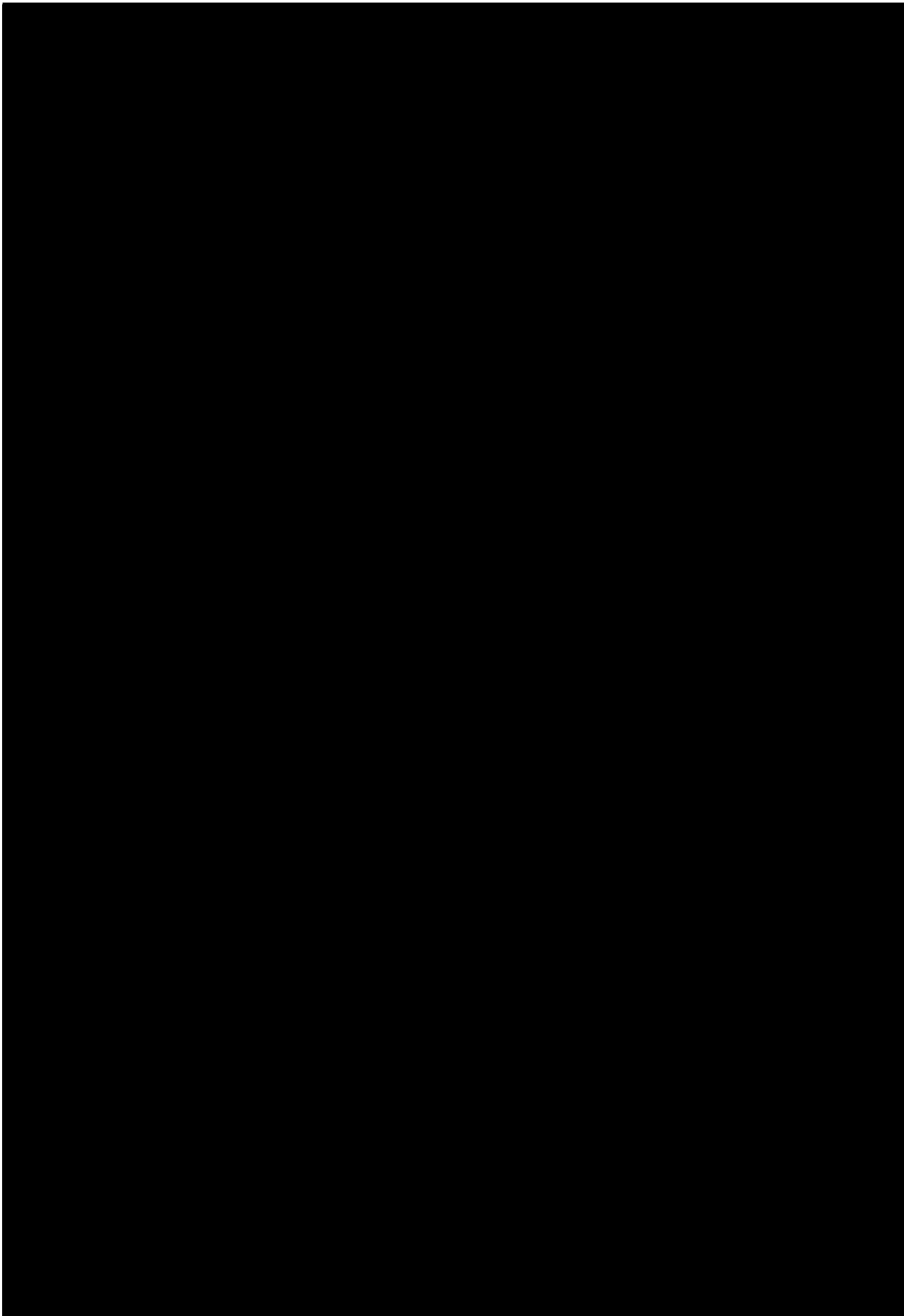


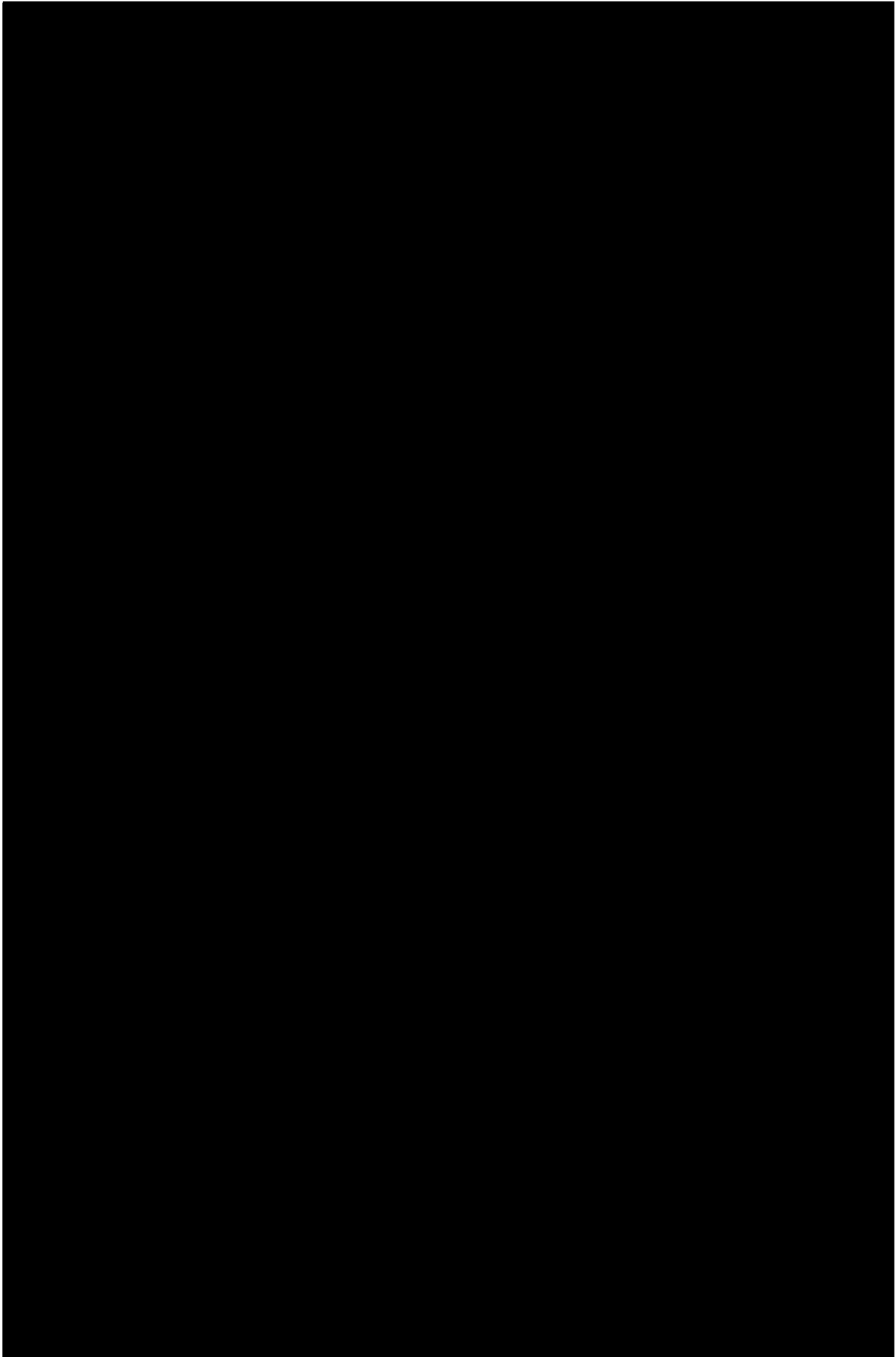


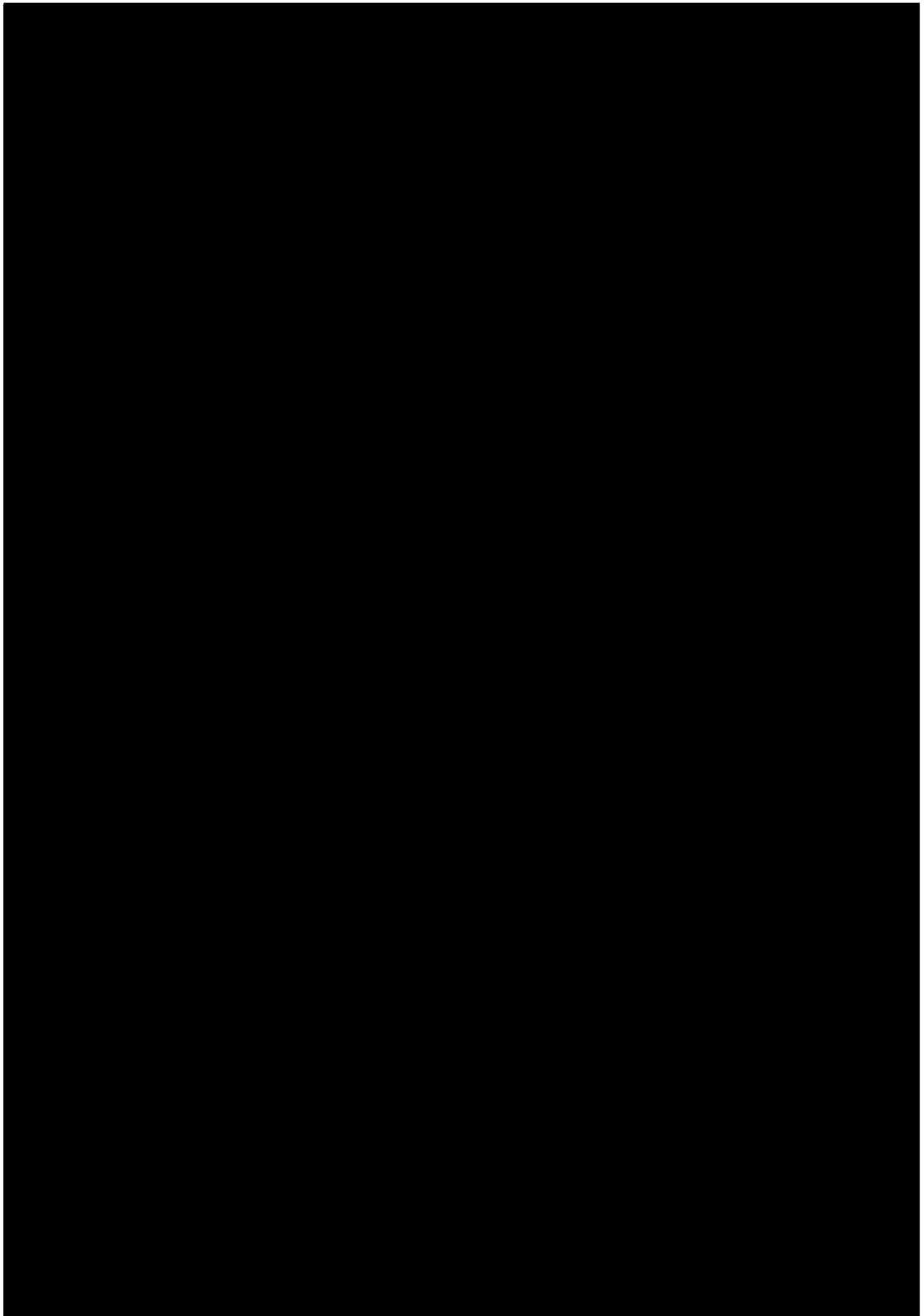


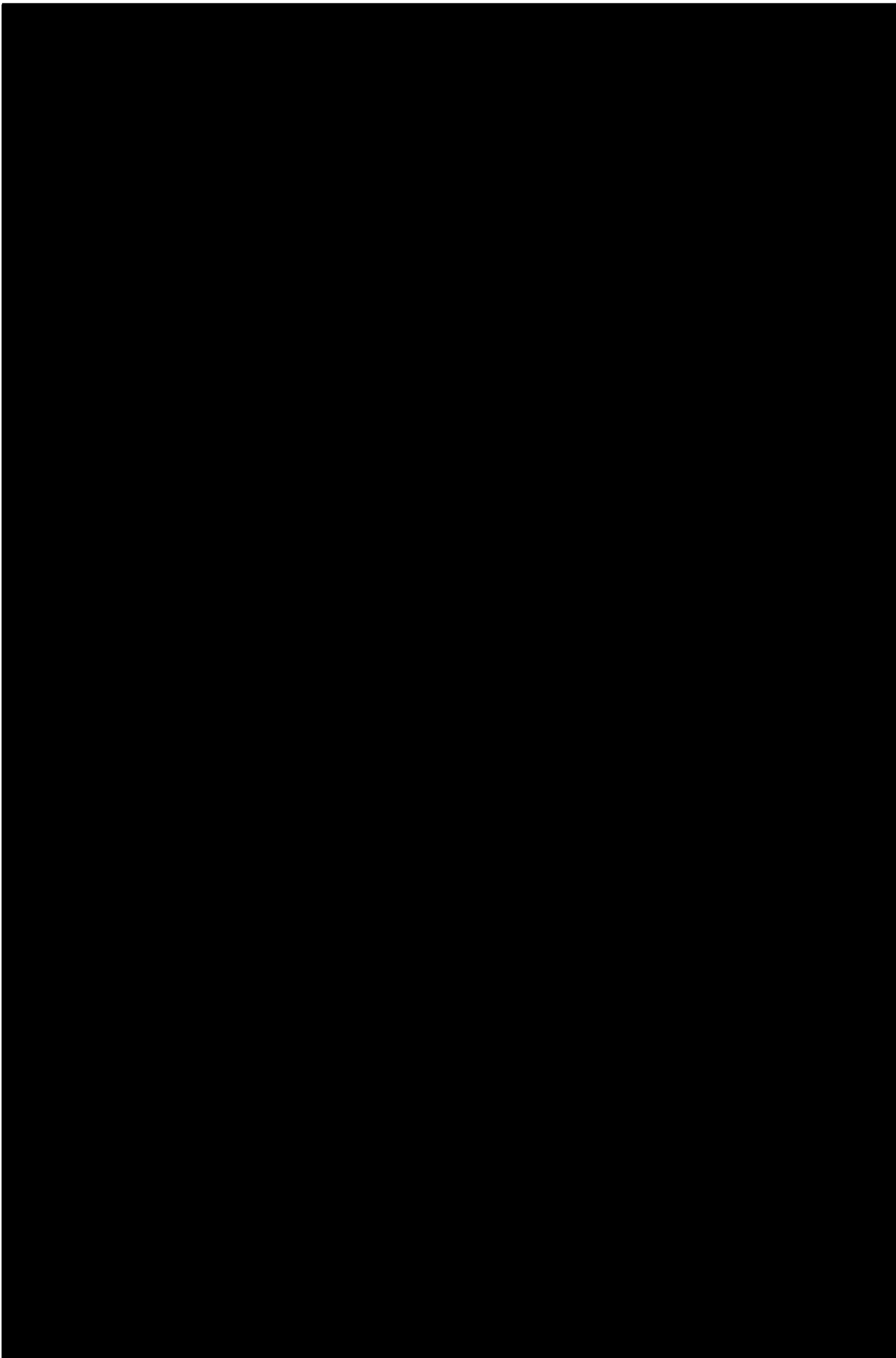


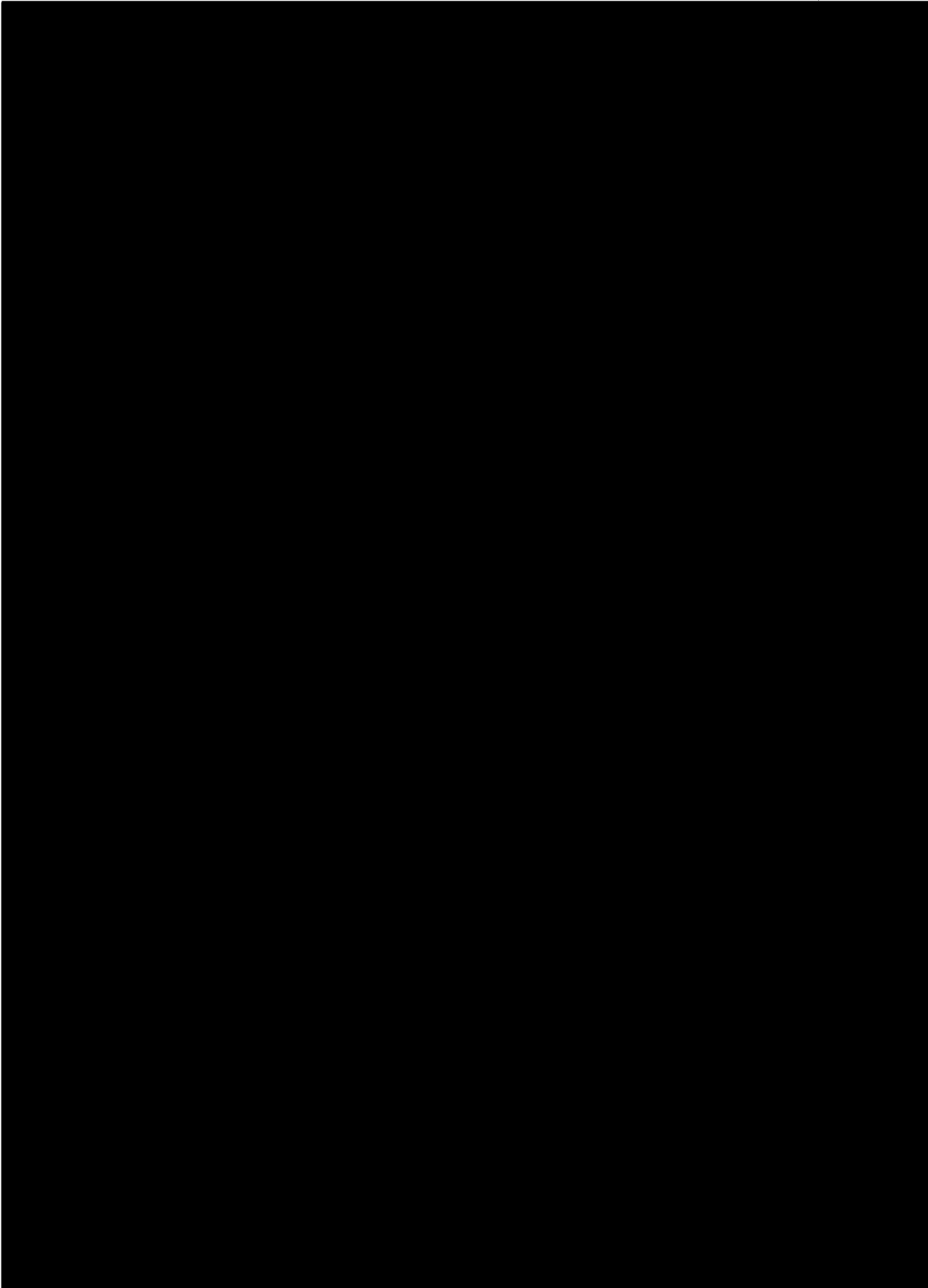


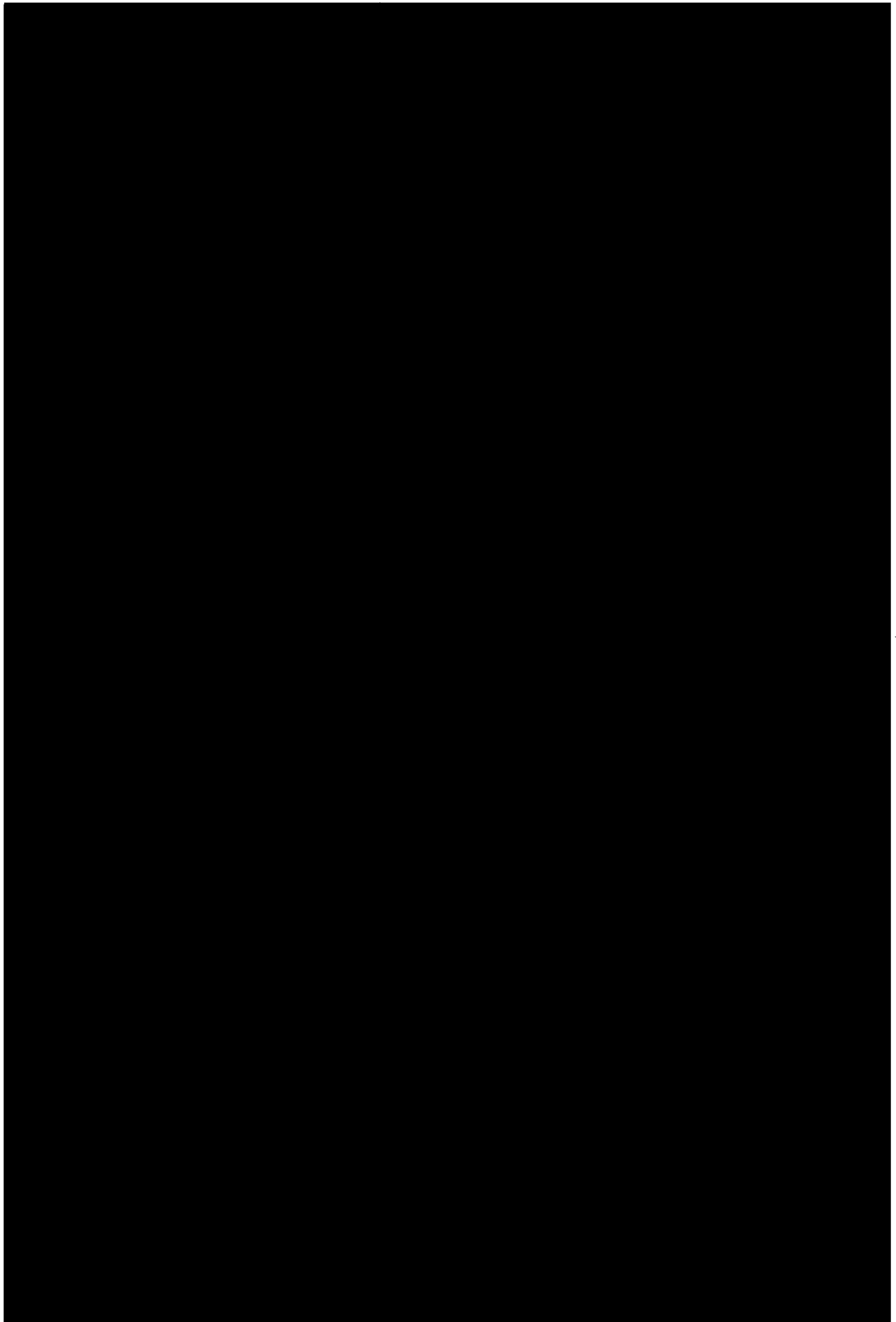


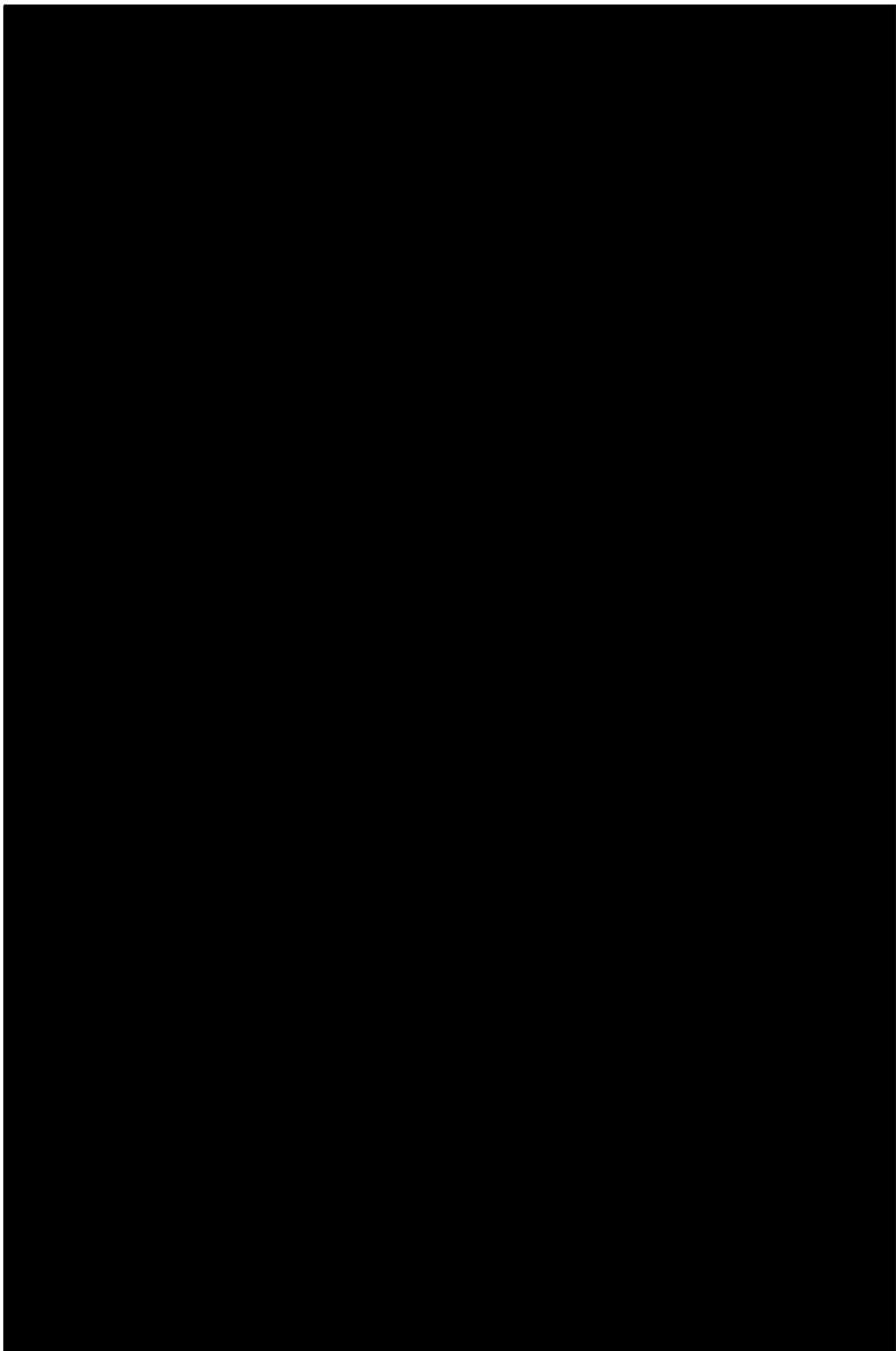


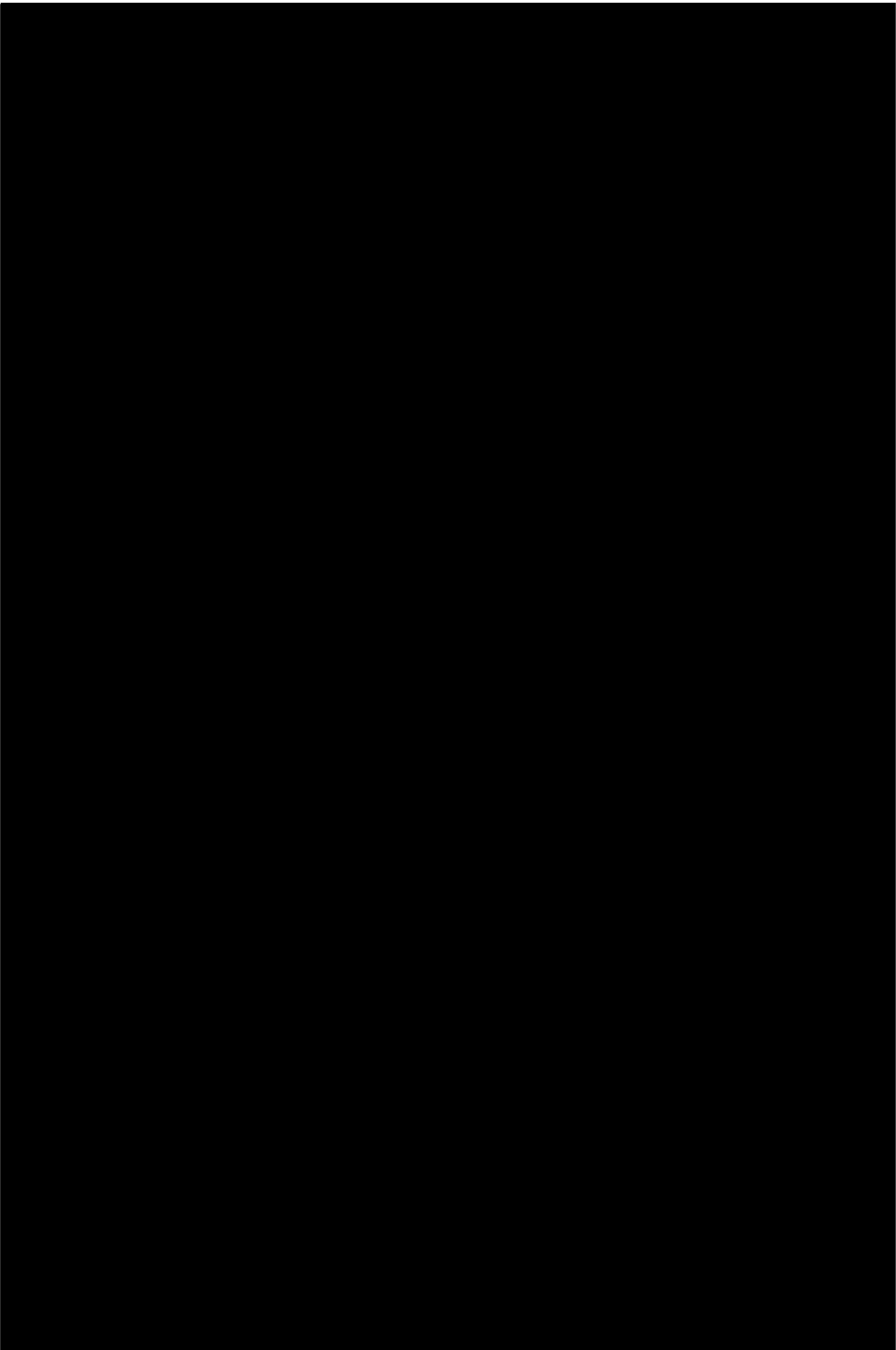


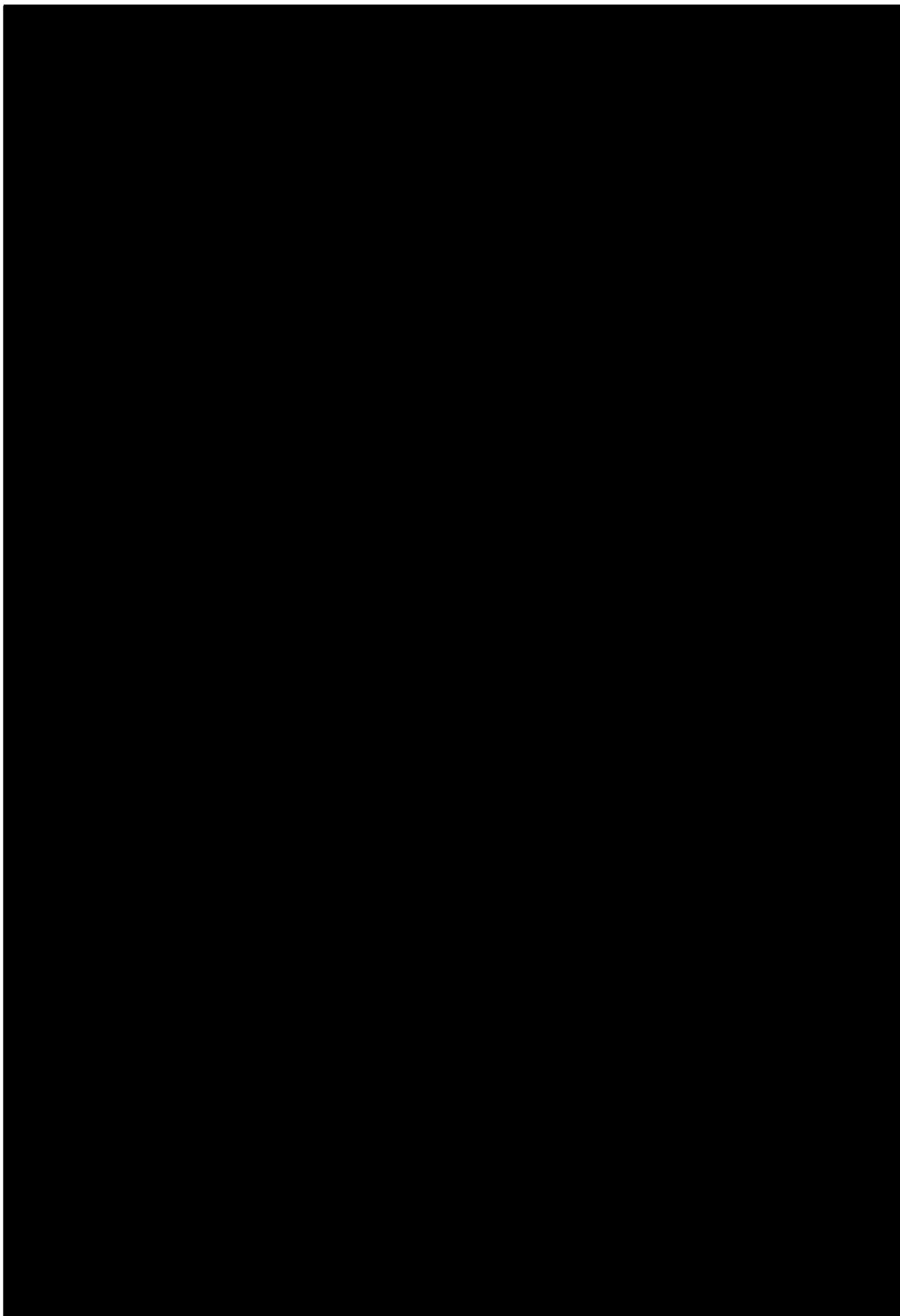


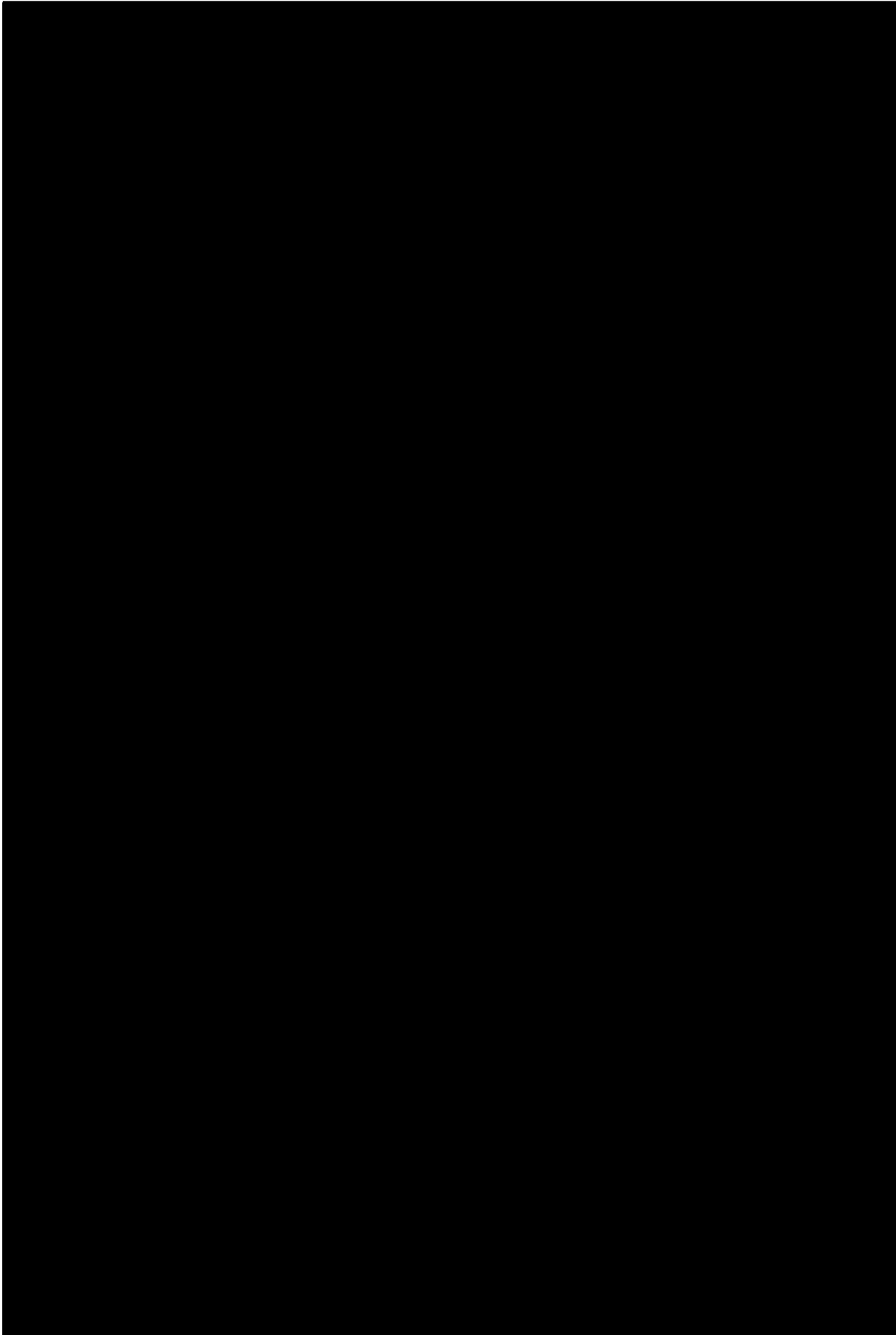


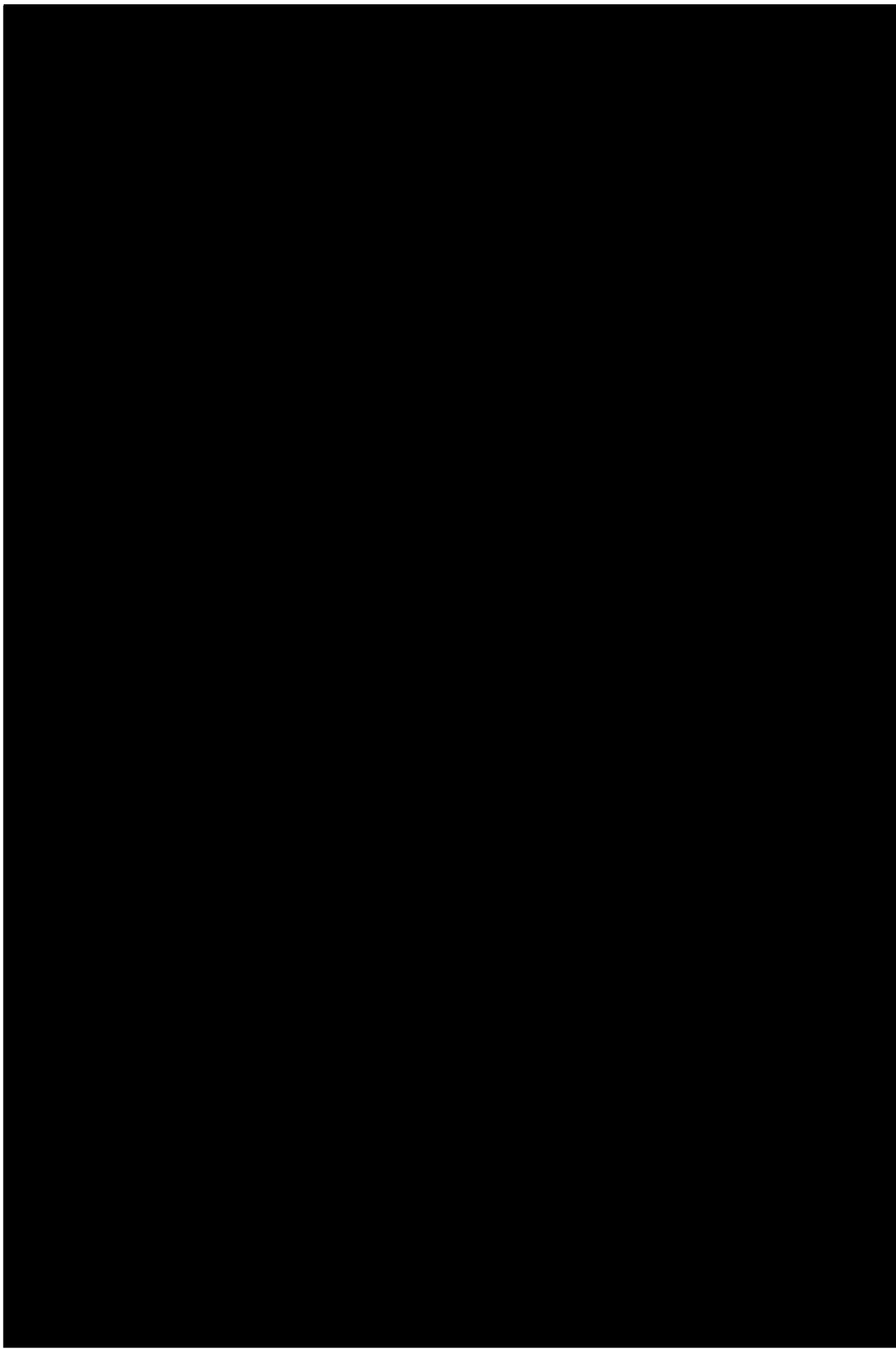














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