

PRVNÍ DODATEK KE SMLouvĚ O KLINICKÉM HODNOCENÍ

První dodatek („**Dodatek**“) ke Smlouvě o klinickém hodnocení, uzavřené s účinností od 3. ledna 2023 („**Smlouva**“), mezi **Všeobecná fakultní nemocnice v Praze**, U Nemocnice 499/2, Praha 2, 128 08 Česká republika, IČ: 00064165, zastoupenou [REDACTED]

[REDACTED] na základě plné moci ze dne 7.6.2019 („**Zdravotnické zařízení**“) a **AbbVie, s. r. o.**, Metronom Business Center, Bucharova 2817/13, Stodůlky, 158 00 Praha 5, Česká republika, IČ: 24148725, DIČ: CZ24148725, zastoupenou [REDACTED]

[REDACTED], na základě plné moci („**AbbVie**“) na poskytování služeb uvedených v Protokolu č. **M22-132** s názvem „**Otevřená studie fáze 1b/2 hodnotící bezpečnost a toleranci epcoritamabu v kombinaci s antineoplastickými látkami/immunoterapií u osob s non-Hodgkinovým lymfomem**“

S ohledem na řádné plnění tohoto Dodatku a v souladu s podmínkami Smlouvy, se smluvní strany dohodly pozměnit Smlouvu následovně:

1. Rozpočet stanovený v Příloze A Smlouvy se zrušuje v celém svém rozsahu a nahrazuje se příloženou Přílohou A.

Pojmy, jež zde nejsou definovány jinak, mají stejný význam, který je jim připisován ve Smlouvě. Kromě podmínek, které se výslovně změnily tímto Dodatkem, zůstávají všechny ostatní podmínky této Smlouvy v plné platnosti a účinnosti během trvání této Smlouvy.

Registr smluv - Poskytovatel zdravotních služeb uveřejní do dvou pracovních dnů ode dne podpisu verzi Dodatku, kterou mu za tímto účelem připraví a poskytne AbbVie nejpozději v den podpisu Dodatku, a to v strojově čitelném formátu v elektronické podobě zasláním na emailovou adresu okh@vfn.cz. Pokud AbbVie danou povinnost nesplní, je Poskytovatel zdravotních služeb oprávněn uveřejnit Dodatek sám. Hodnota Smlouvy ve znění Dodatku činí [REDACTED].

FIRST AMENDMENT TO THE CLINICAL STUDY AGREEMENT

First Amendment (the „**Amendment**“) to that certain Clinical Study Agreement effective 03 January 2023 („**Agreement**“), between **Všeobecná fakultní nemocnice v Praze**, U Nemocnice 499/2, Praha 2, 128 08 Czech Republic, ID: 00064165, represented by [REDACTED]

[REDACTED] based on power of attorney dated as of 7 June 2019 (the „**Institution**“) and **AbbVie s.r.o.**, Metronom Business Center, Bucharova 2817/13, Stodůlky, 158 00 Praha 5, Czech Republic, ID: 24148725, VAT ID: CZ24148725, represented by [REDACTED]

[REDACTED], upon power of attorney („**AbbVie**“) for services relating to Protocol No. **M22-132** entitled „**Phase 1b/2, Open Label Study to Evaluate Safety and Tolerability of Epcoritamab in Combination with Anti-Neoplastic Agents/Immunotherapies in Subjects with Non-Hodgkin Lymphoma**“.

Subject to the full execution of this Amendment and in accordance with the terms of the Agreement, the parties hereby agree to amend the Agreement, as follows:

1. The Budget set forth in Exhibit A of the Agreement shall be deleted in its entirety and replaced with the attached Exhibit A.

Terms not otherwise defined herein shall have the meanings ascribed to such terms in the Agreement. Except as specifically amended by this Amendment, all other terms and conditions of the Agreement shall continue in full force and effect during the term of the Agreement.

Contracts Registry – Provider of Medical Services shall publish a redacted version of the Amendment, prepared and sent by AbbVie up to the date of its execution at the latest in a machine readable format, electronic form, by sending it to following e-mail: okh@vfn.cz, within two business days from the date of its execution. Should AbbVie fail to meet this obligation, Provider of Medical Services may publish the Amendment at its disposal. Value of the Agreement amended by the Amendment is CZK [REDACTED].

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NA DŮKAZ ČEHOŽ každá smluvní strana prostřednictvím svých řádně zmocněných zástupců uvedla tuto smlouvu v platnost svým podpisem.	IN WITNESS WHEREOF , each of the parties has caused this Amendment to be executed by its authorized representative in its name and on its behalf.
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AbbVie s.r.o.

Všeobecná fakultní nemocnice

By/Podepsal: _____

By/Podepsal: _____

Name/Jméno: _____

Name/Jméno: _____

Title/Funkce: Country Clinical Operations Manager
Upon the power of attorney/Na základě
plné moci

_____ náměstek pro vědu, výzkum a
výuku

Date/Datum: _____

Date/Datum: _____

_____, Principal Investigator of this Study hereby represent, that I have perused Protocol of the Study and all documents submitted by AbbVie for performance of the Study. I have reviewed the terms of this Agreement between AbbVie s.r.o. and Všeobecná fakultní nemocnice v Praze and shall comply with all obligations set forth in it that pertain to Principal Investigator and shall comply with obligations pertaining to investigator in ICH-GCP.

_____ hlavní zkoušející této Studie tímto potvrzuji, že jsem se seznámil s protokolem Studie a všemi dokumenty předanými AbbVie k provedení klinického hodnocení. Byl jsem seznámen s podmínkami této smlouvy uzavřené mezi AbbVie s.r.o. a Všeobecnou fakultní nemocnicí v Praze a budu dodržovat povinnosti v ní stanovené hlavnímu zkoušejícímu či povinnosti vyplývající pro zkoušejícího ze Správné klinické praxe (ICH-GCP).

By/Podepsal: _____

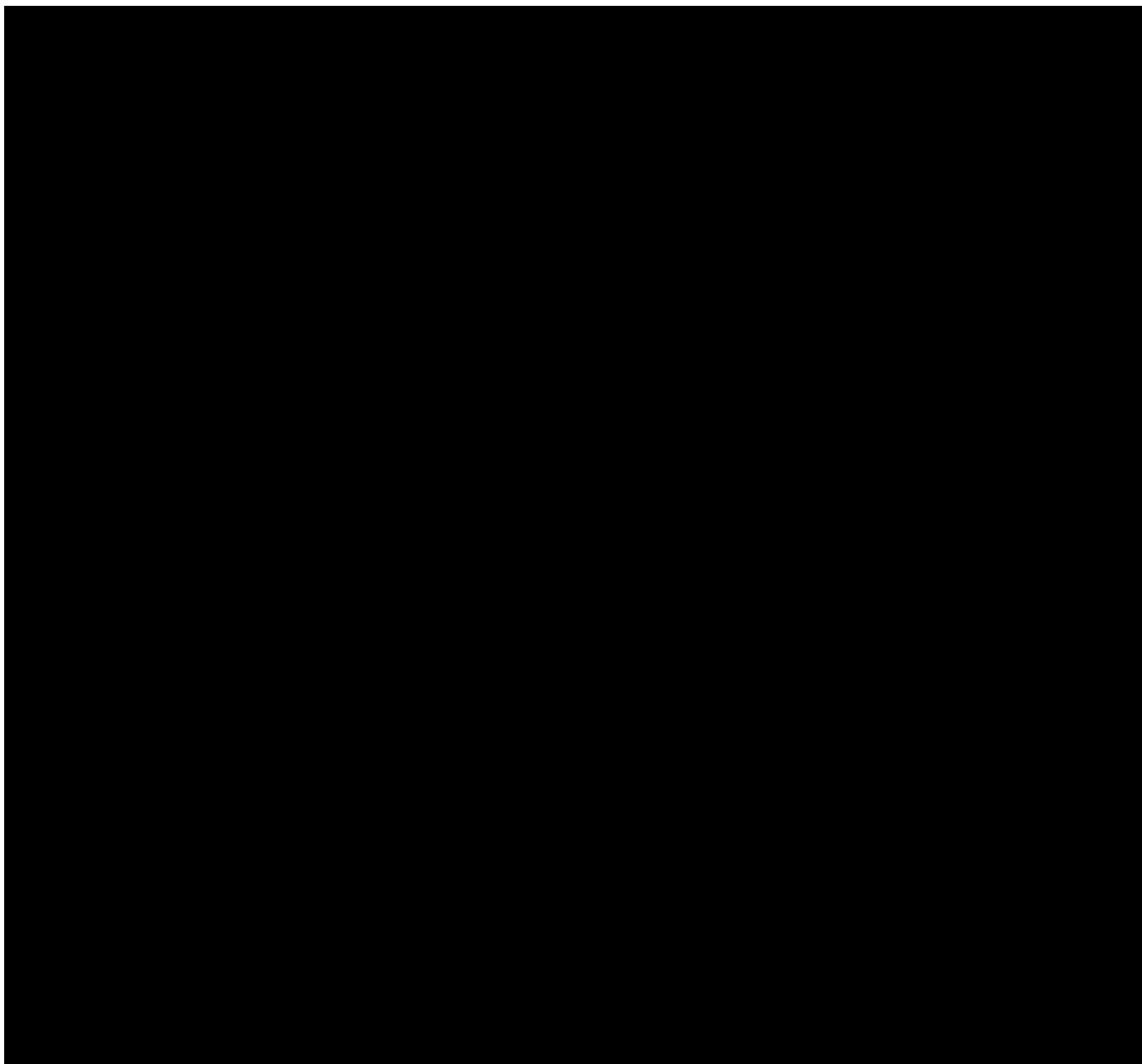
Name/Jméno: _____

Title/Funkce: Principal Investigator / Hlavní zkoušející

Date/Datum: _____

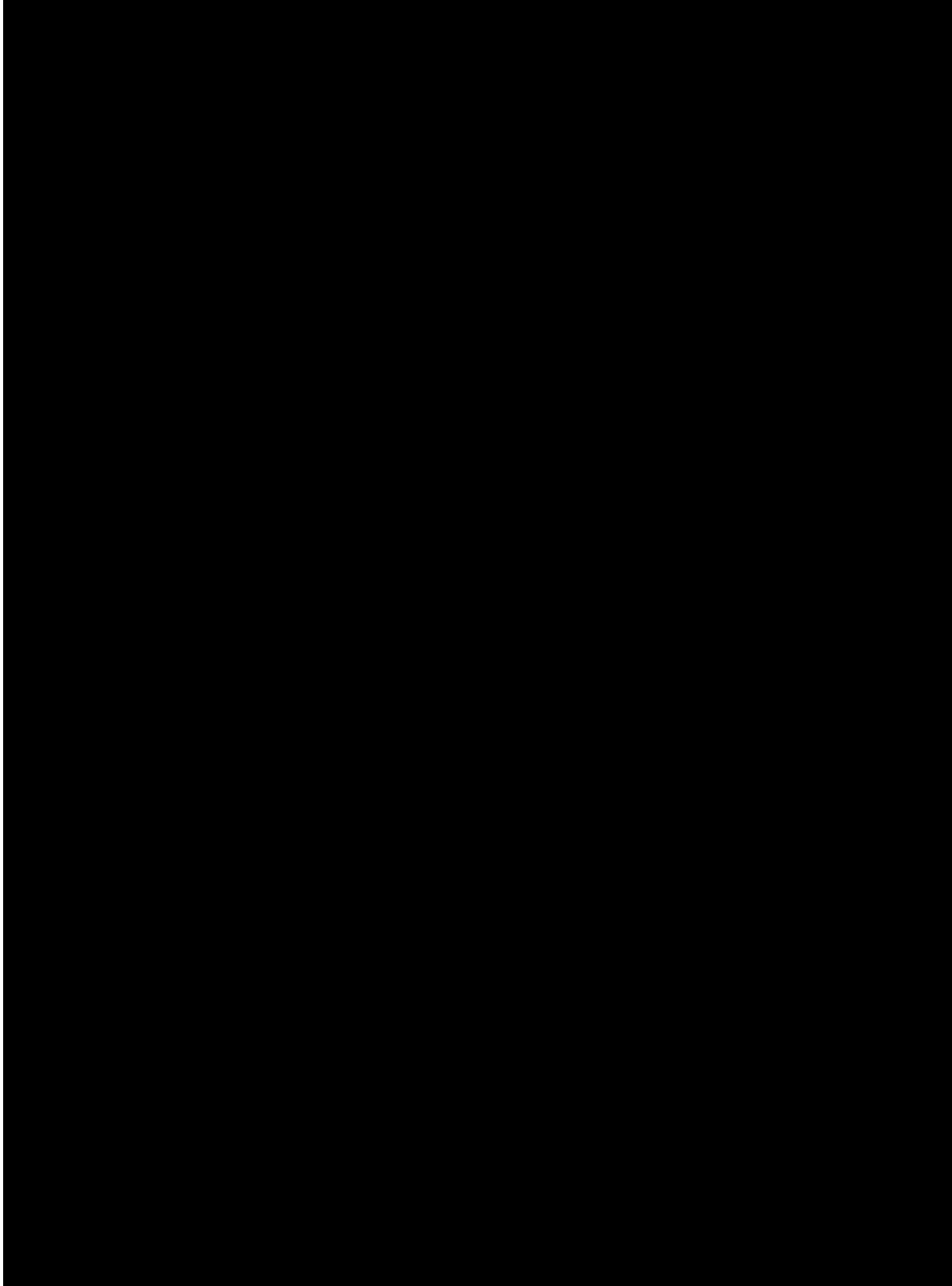
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Exhibit A – INSTITUTION
STUDY BUDGET

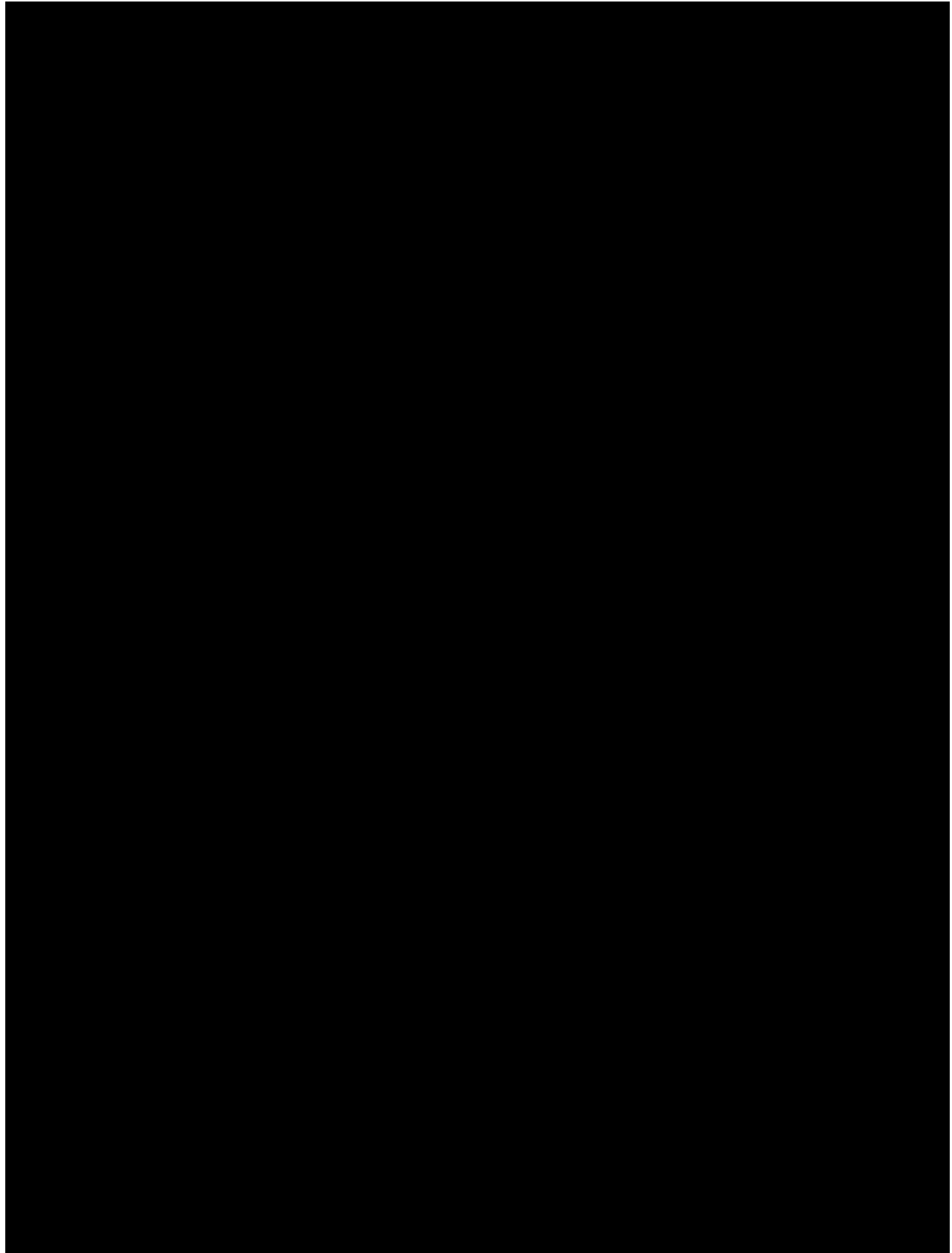


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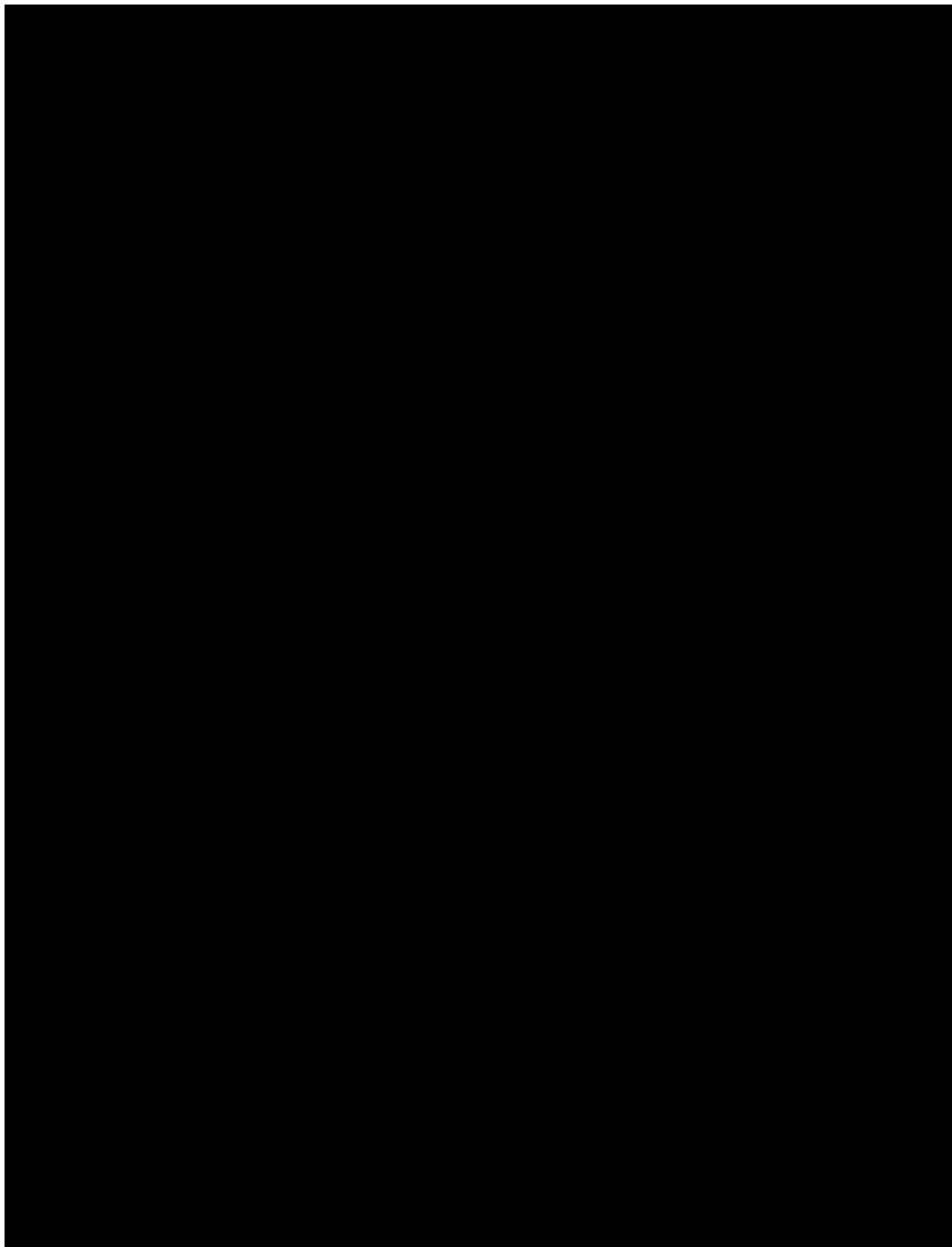
Attachment 1 to Exhibit A



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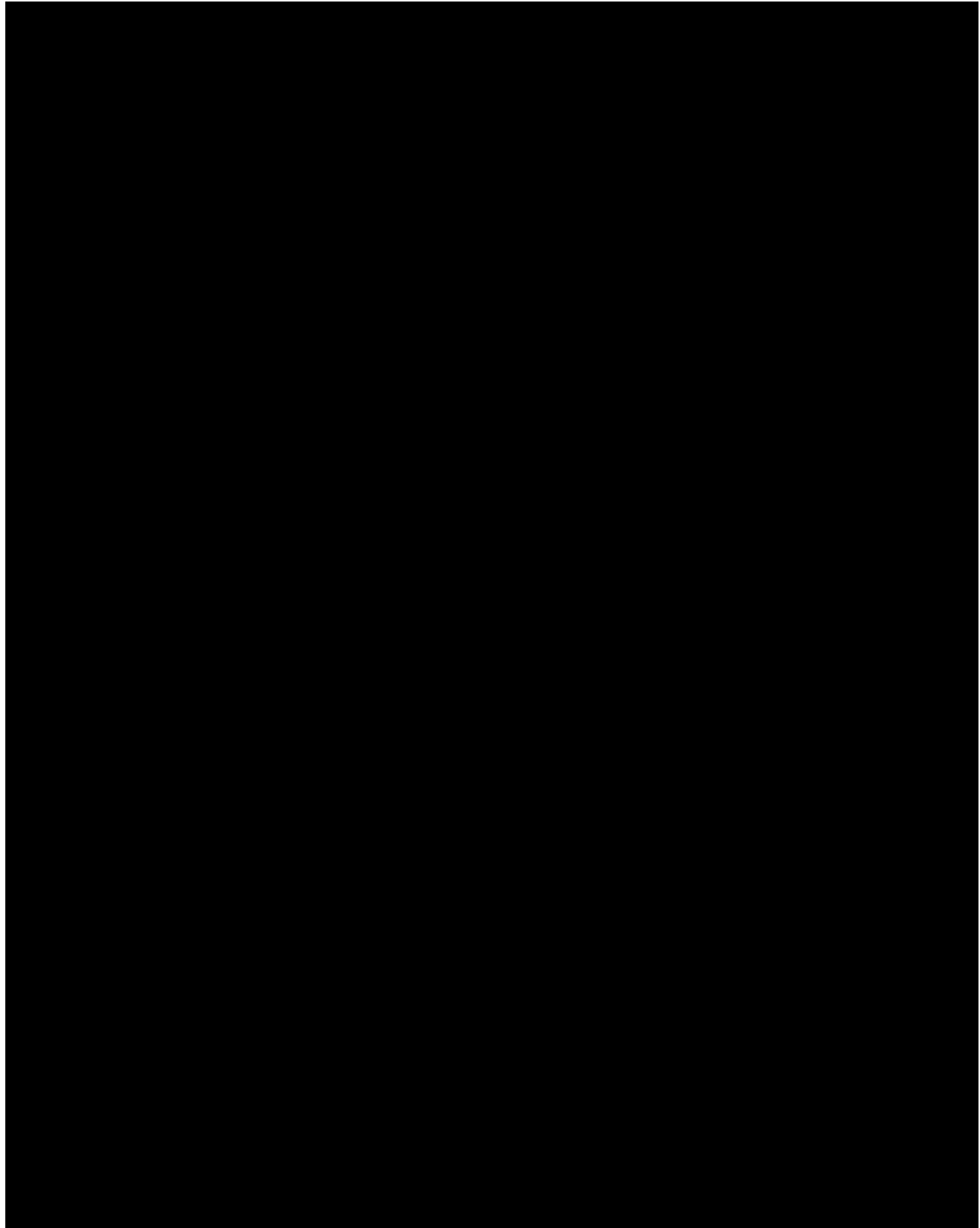


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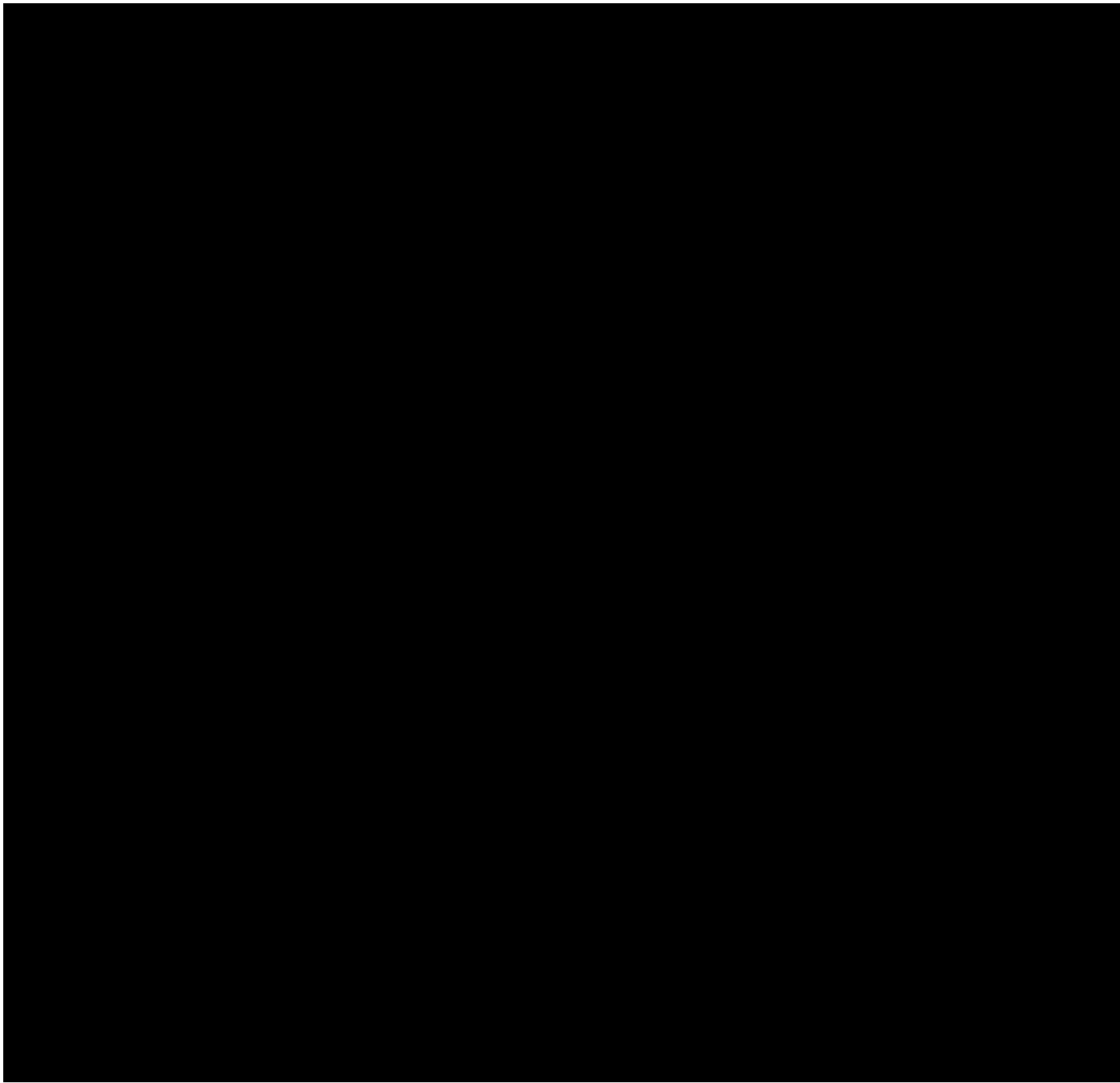


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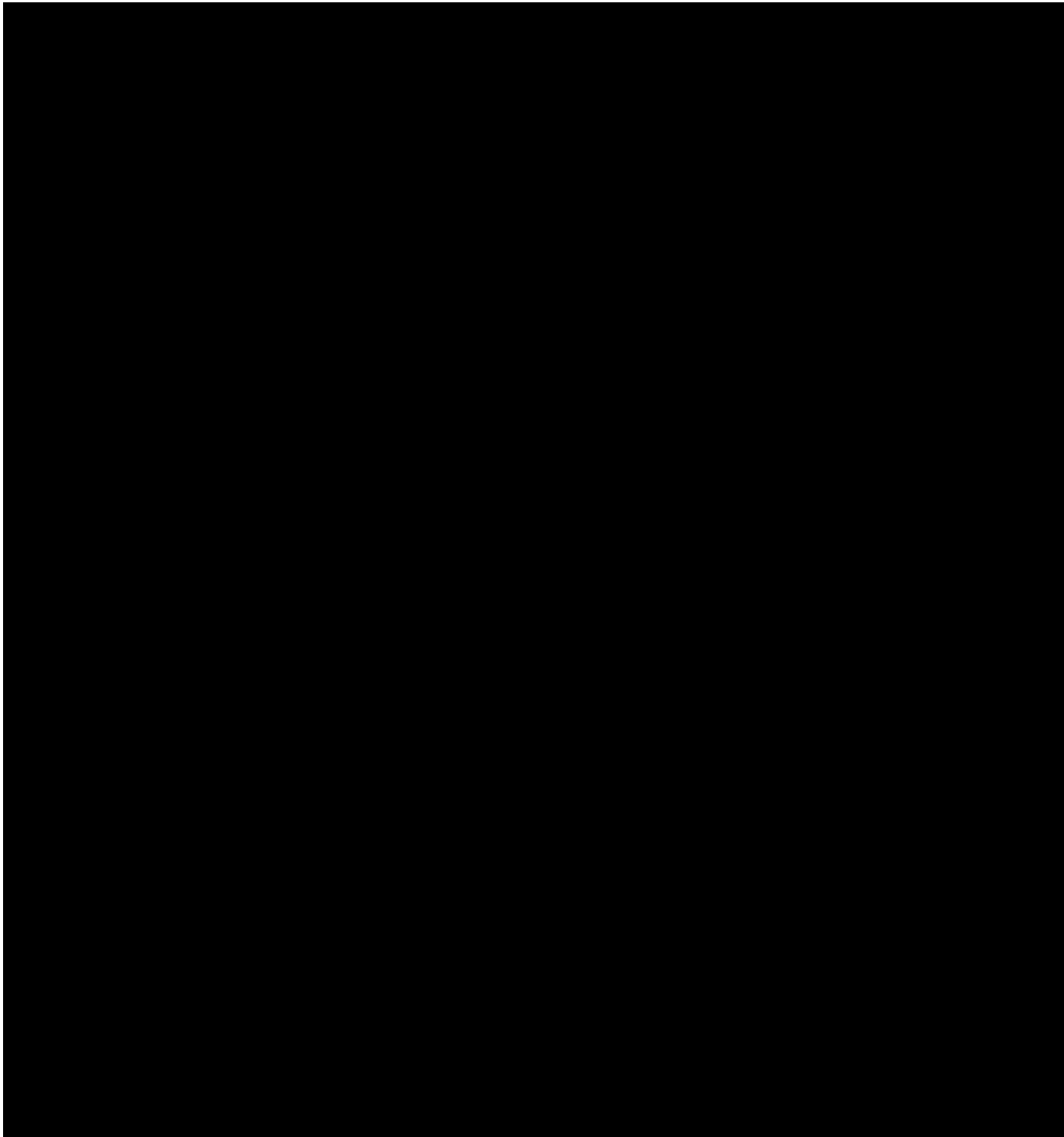
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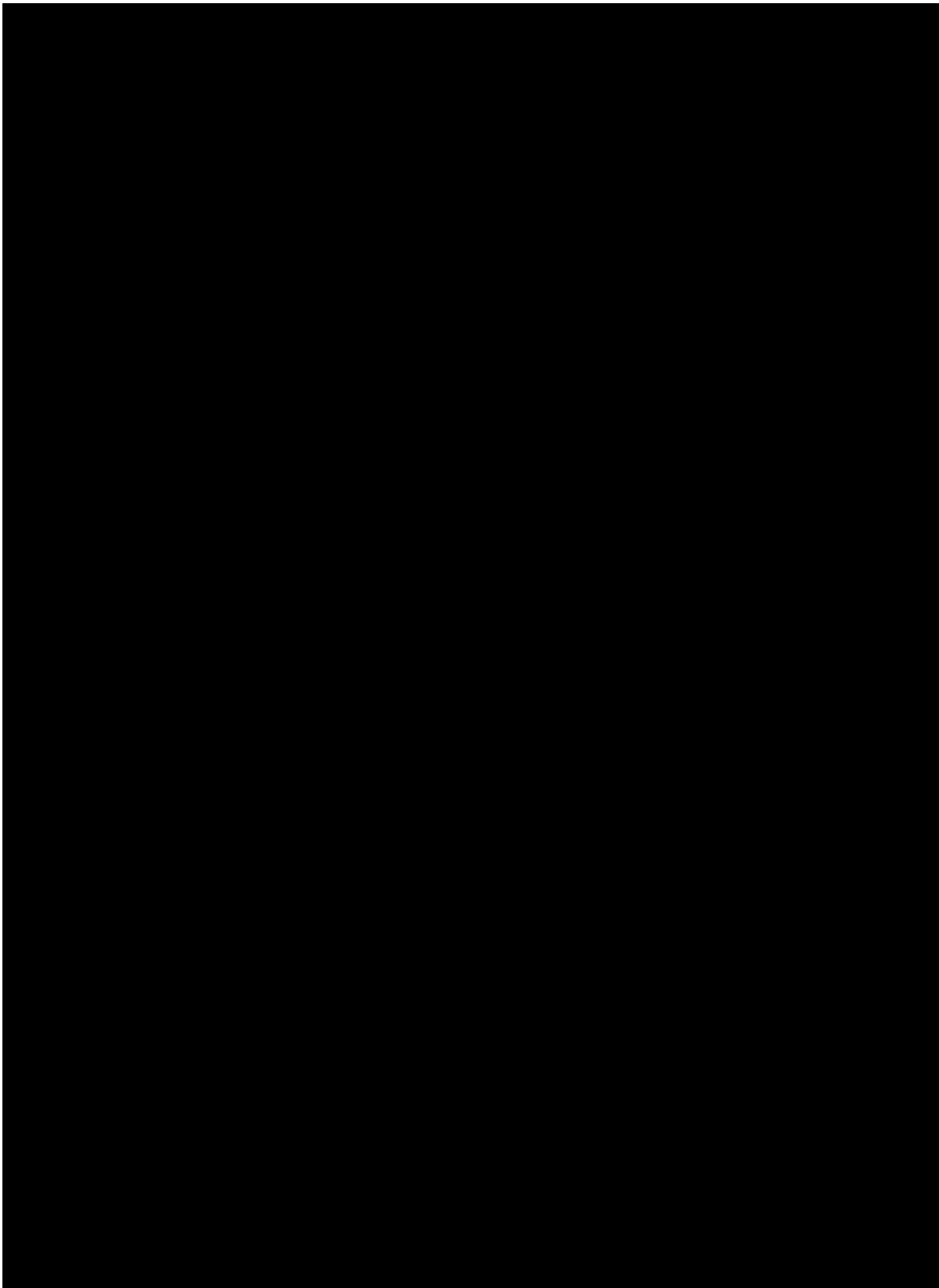


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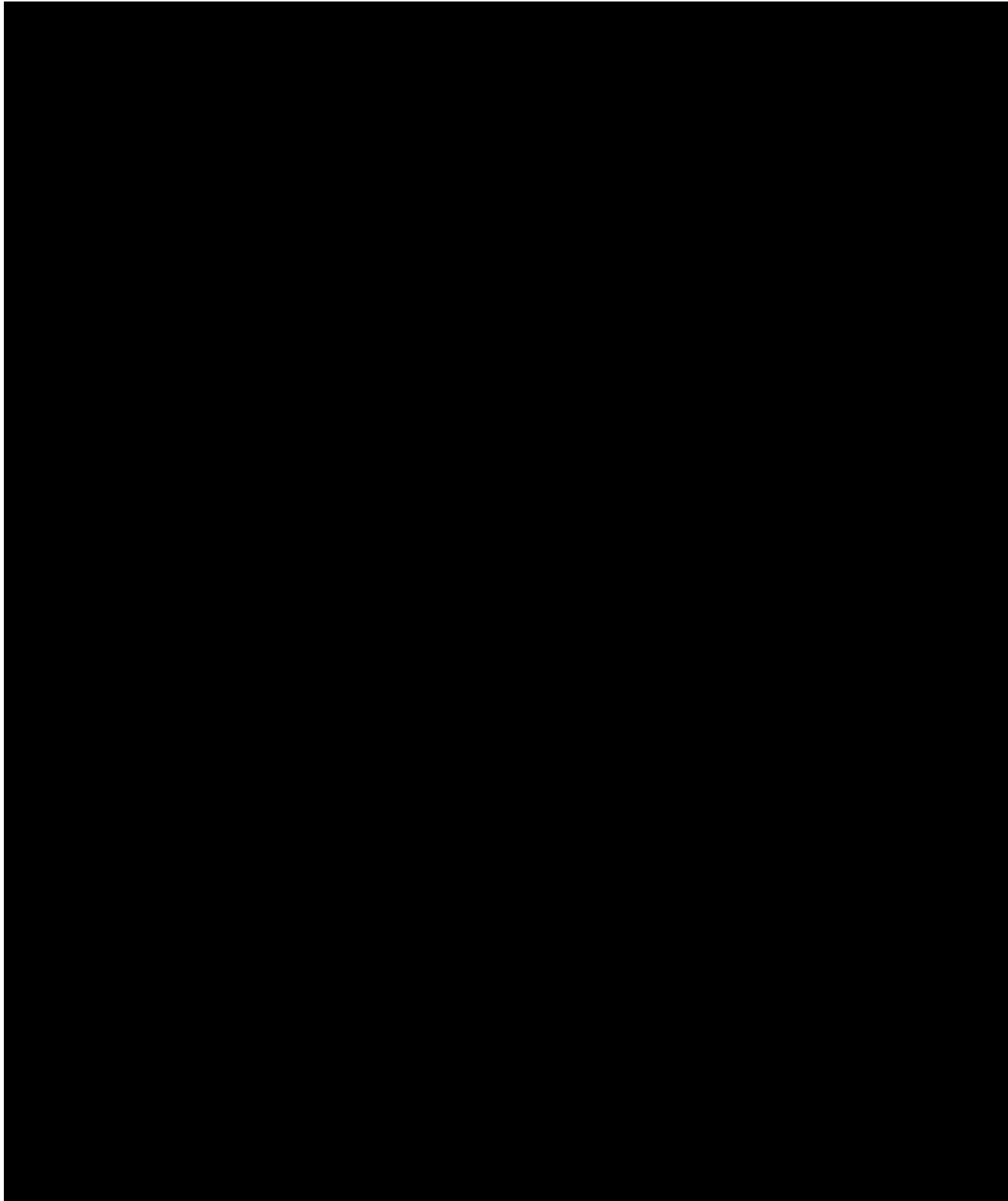


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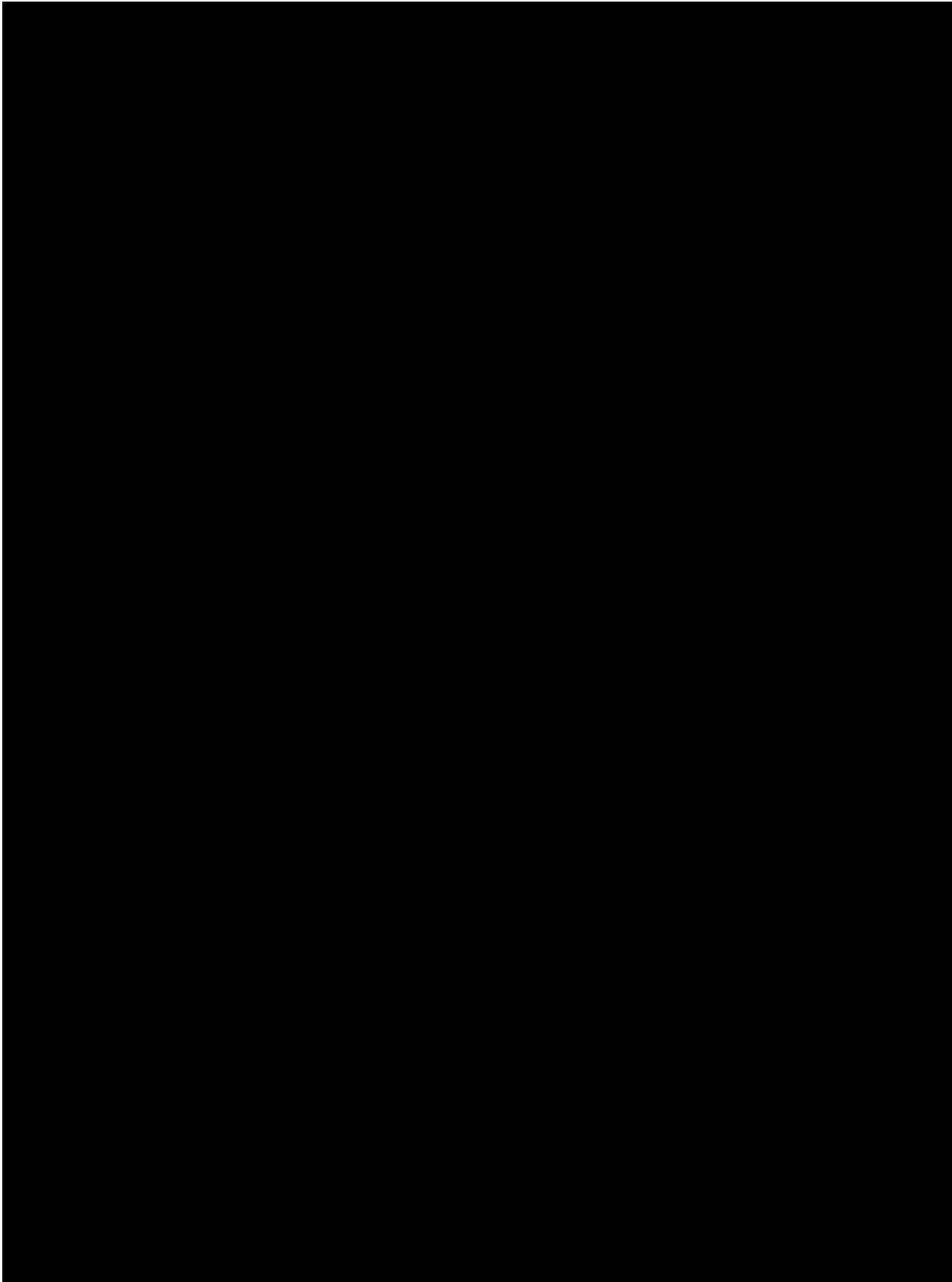


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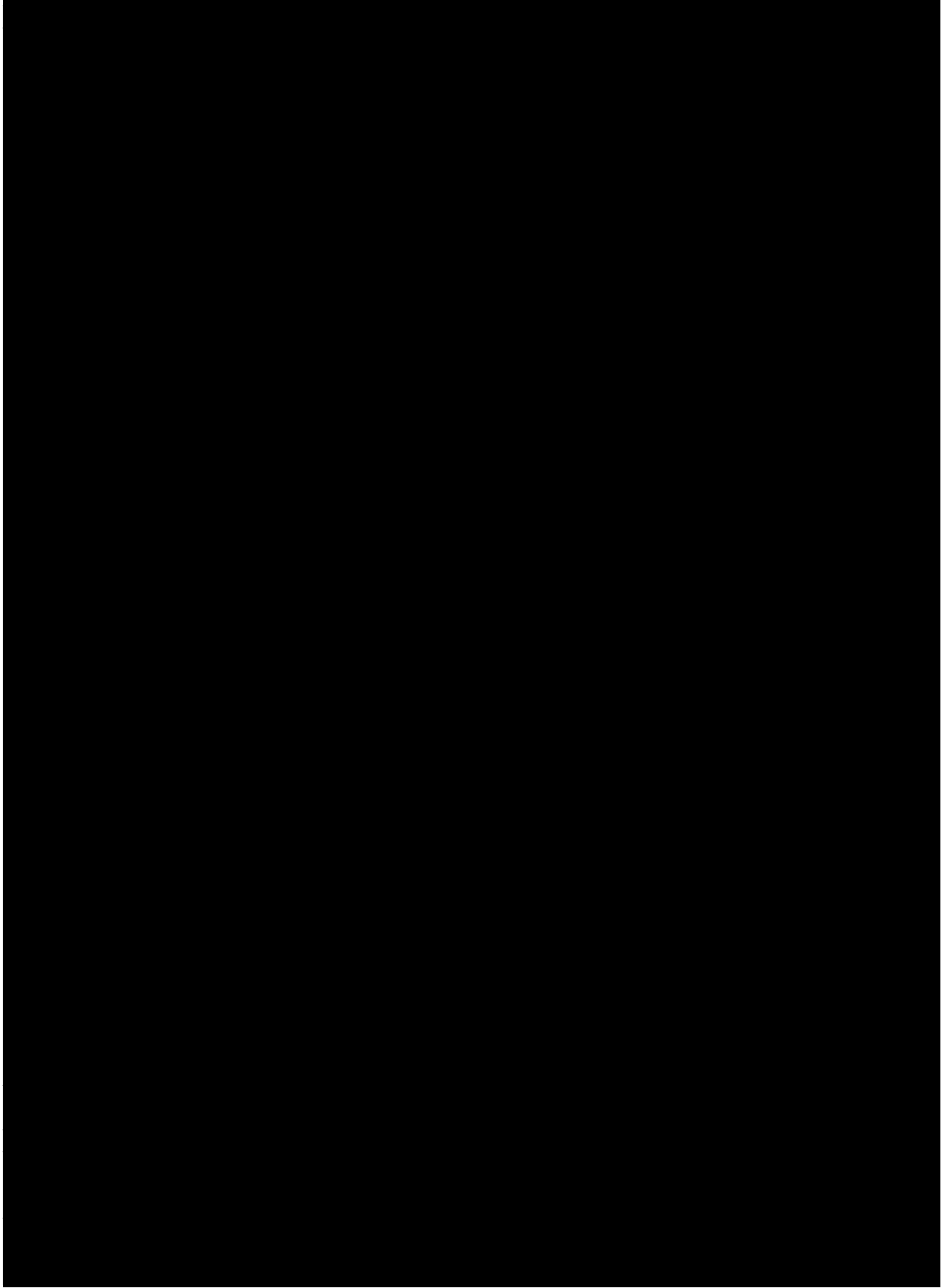


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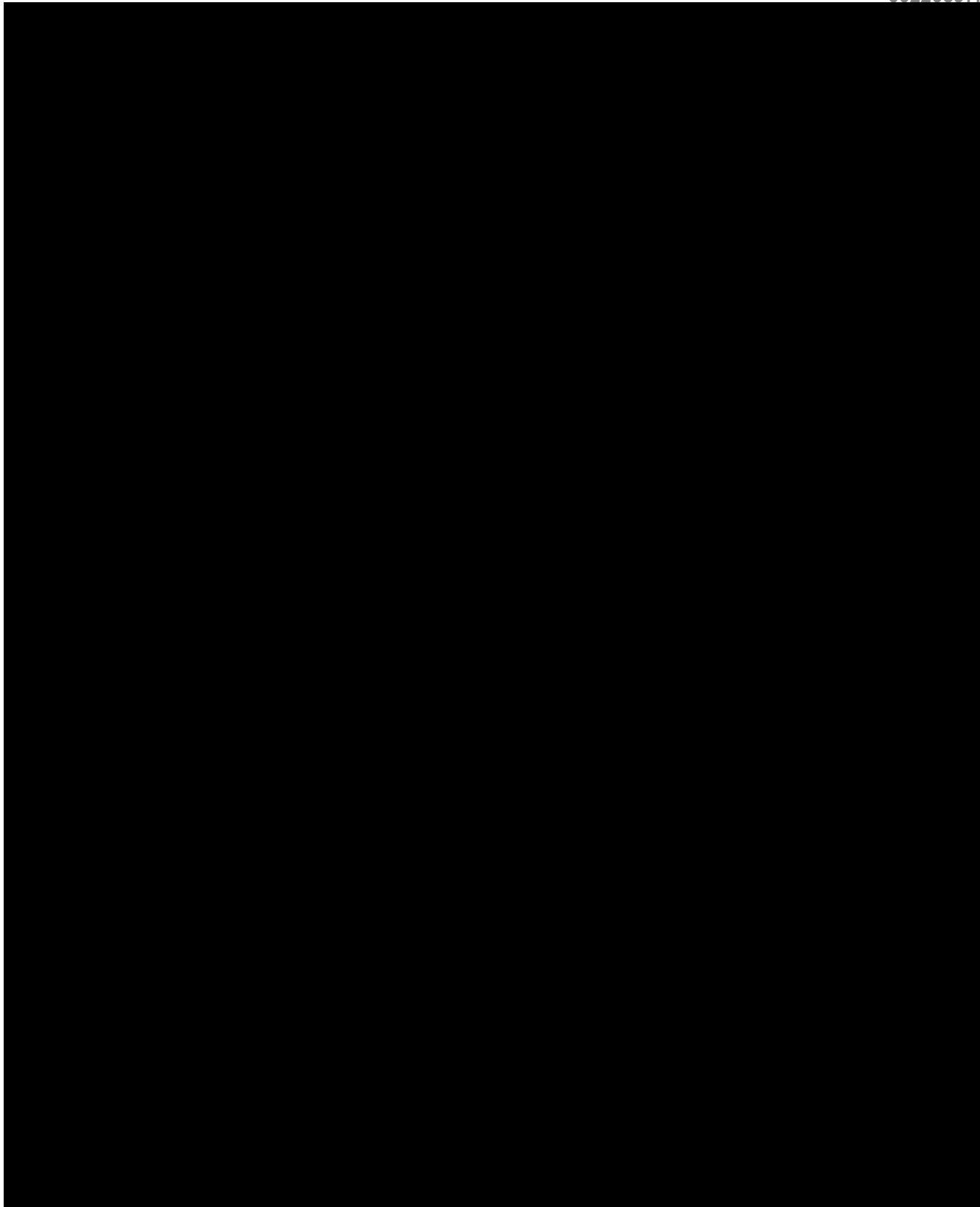
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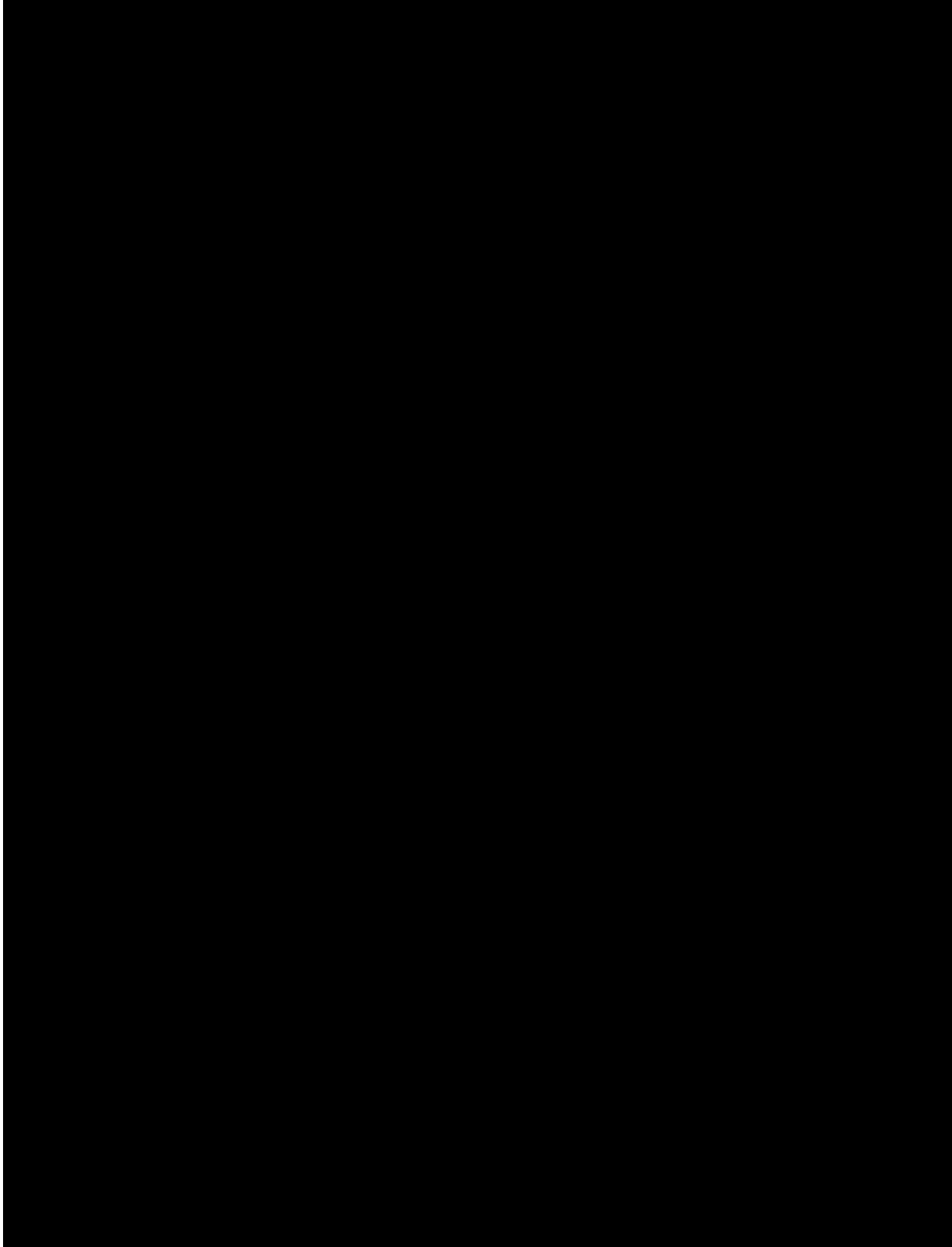


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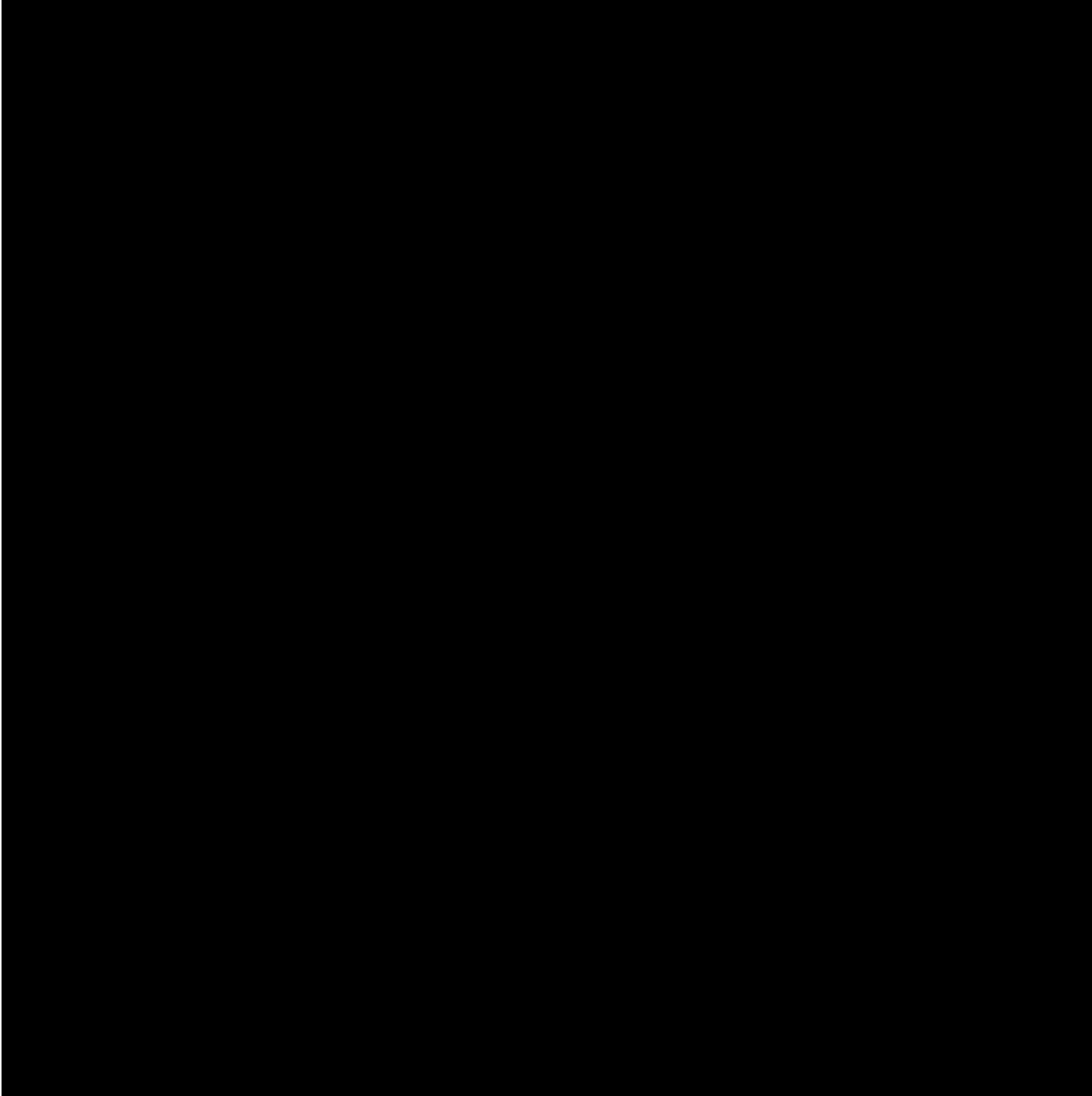


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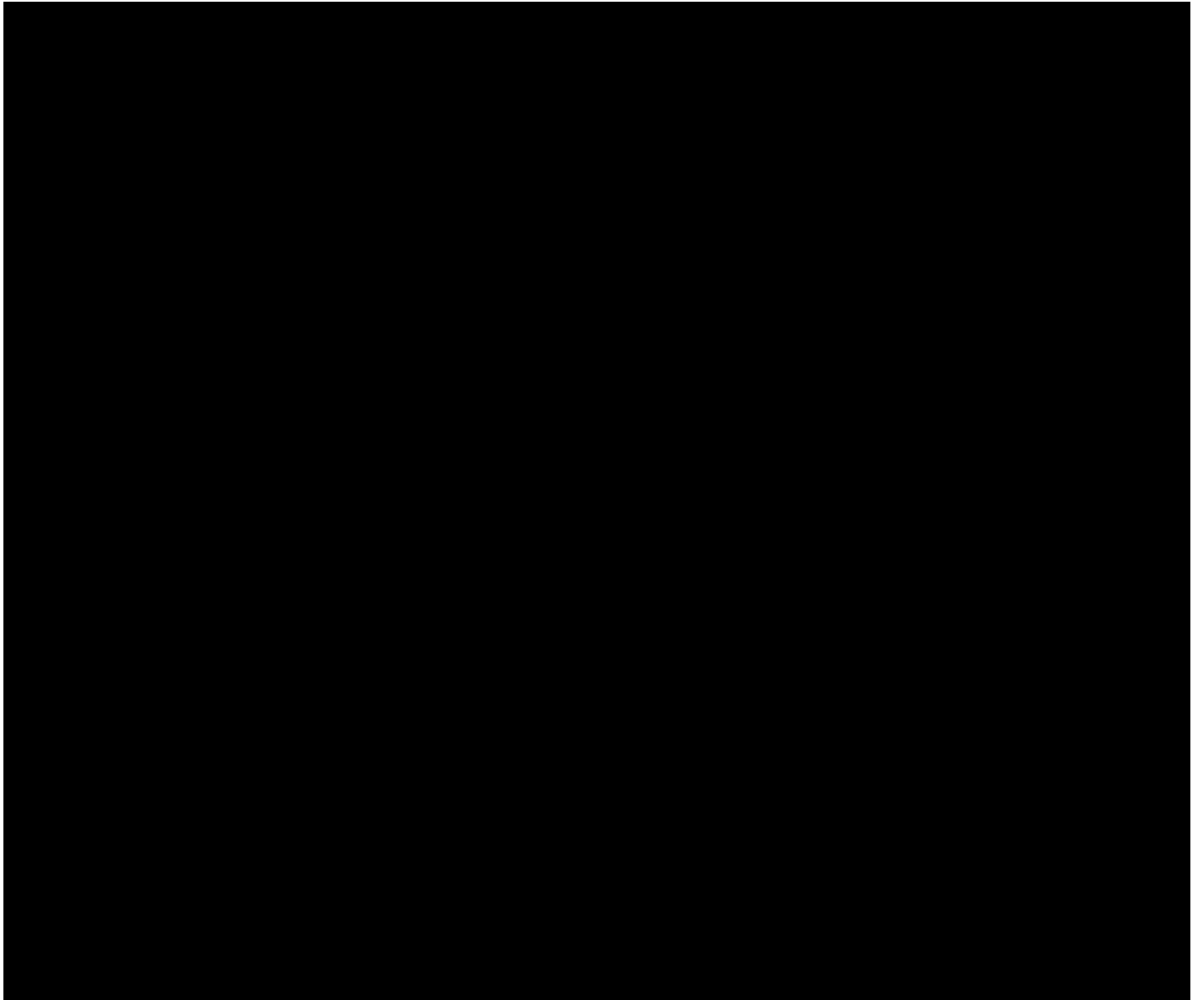
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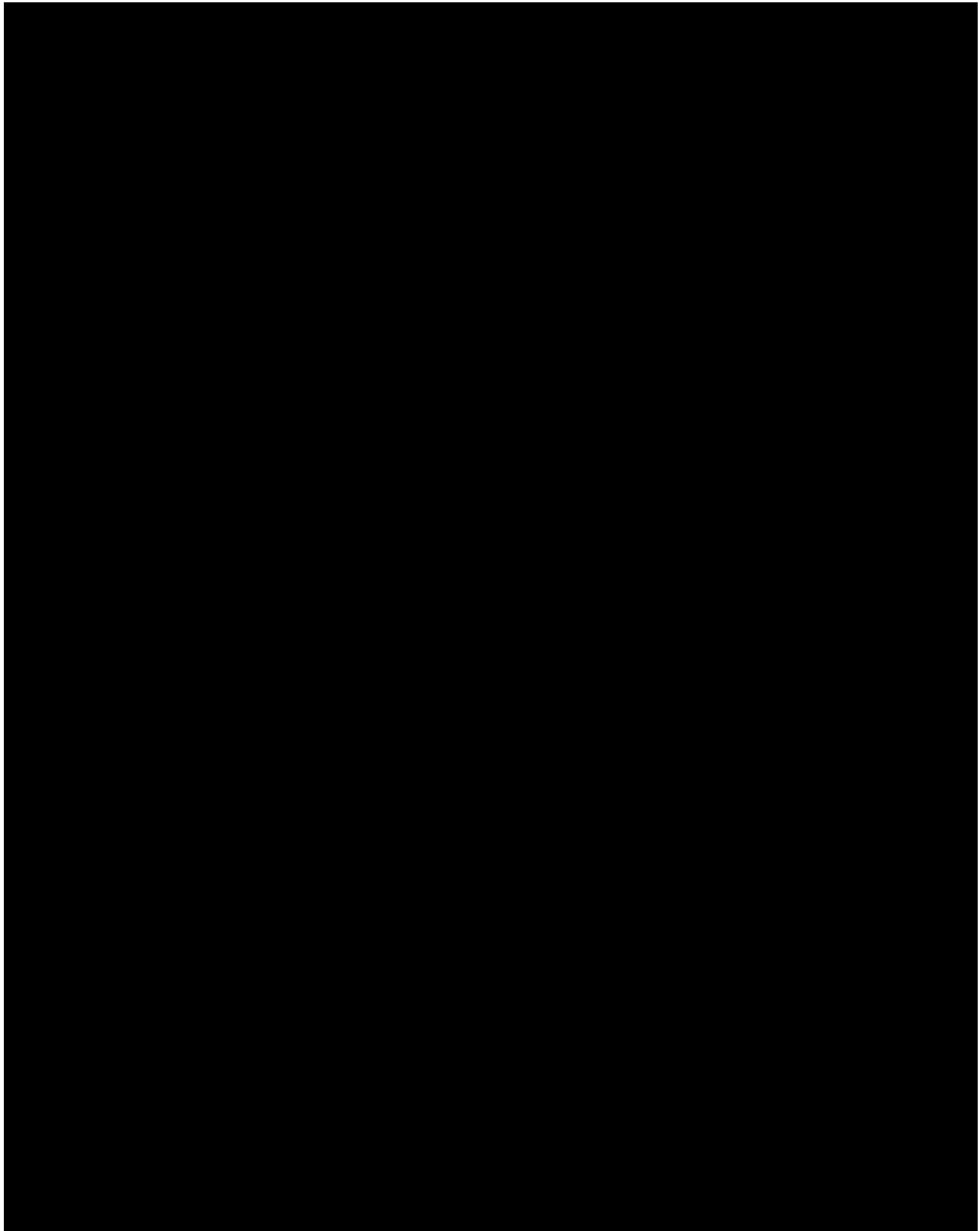


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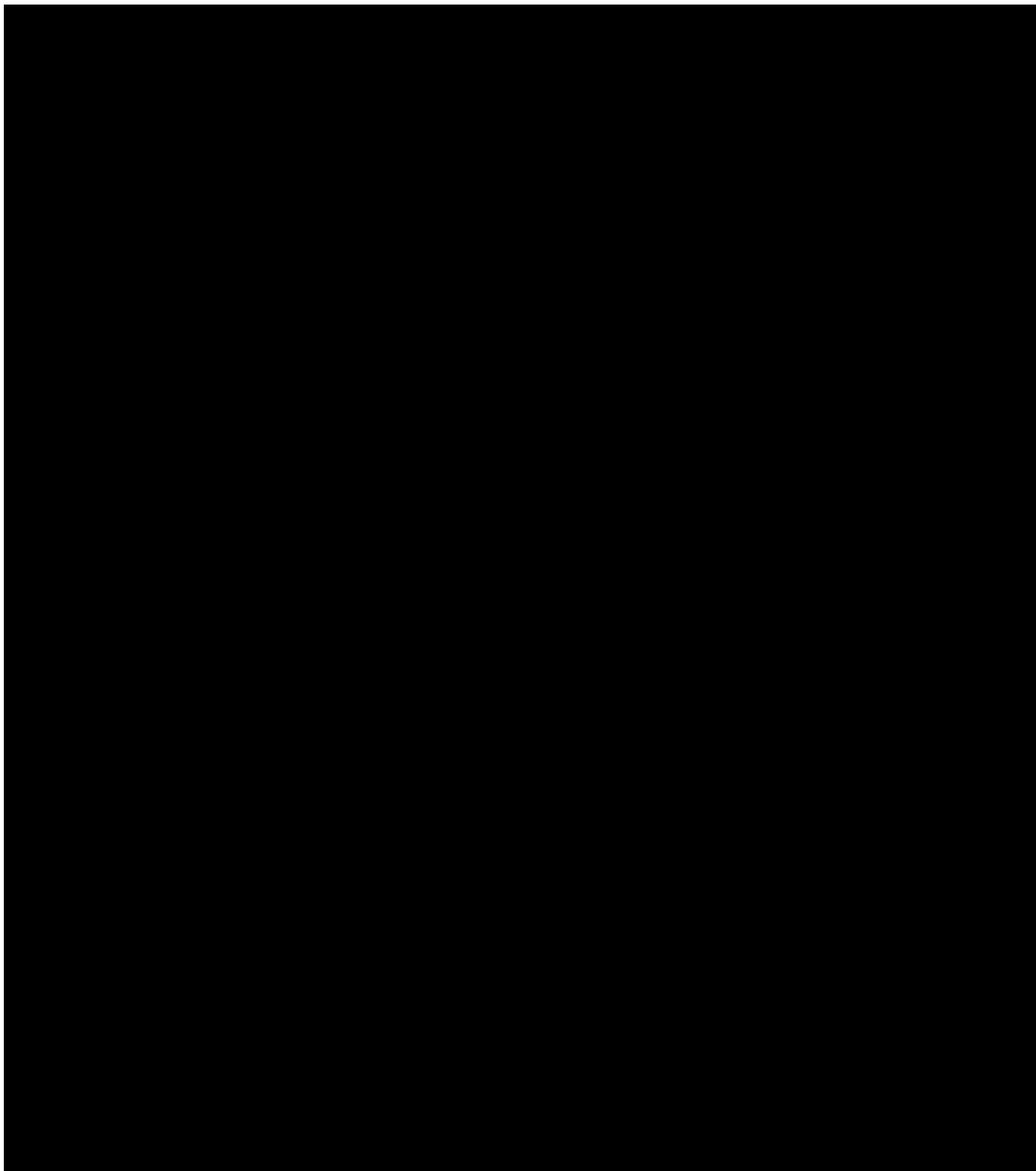


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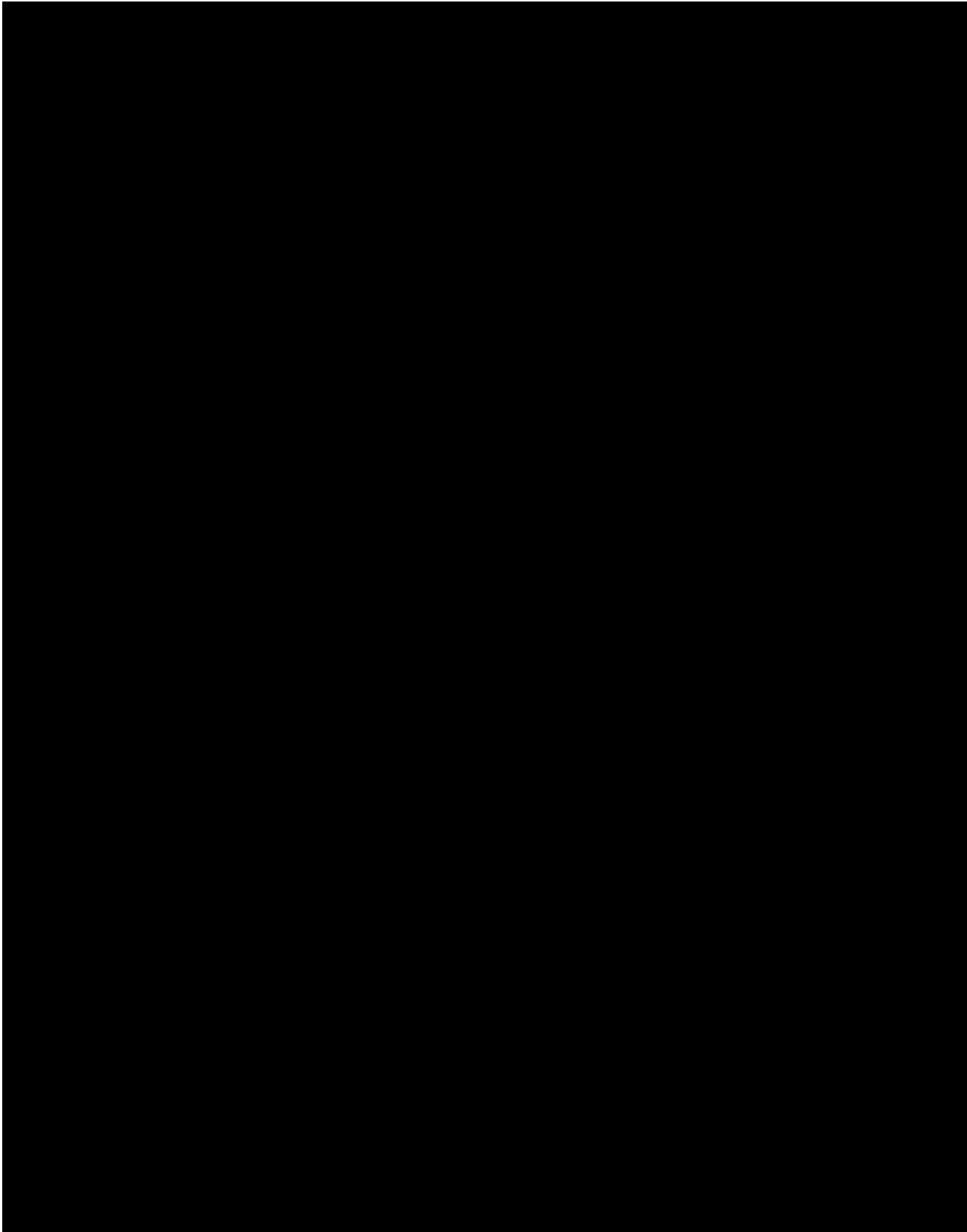
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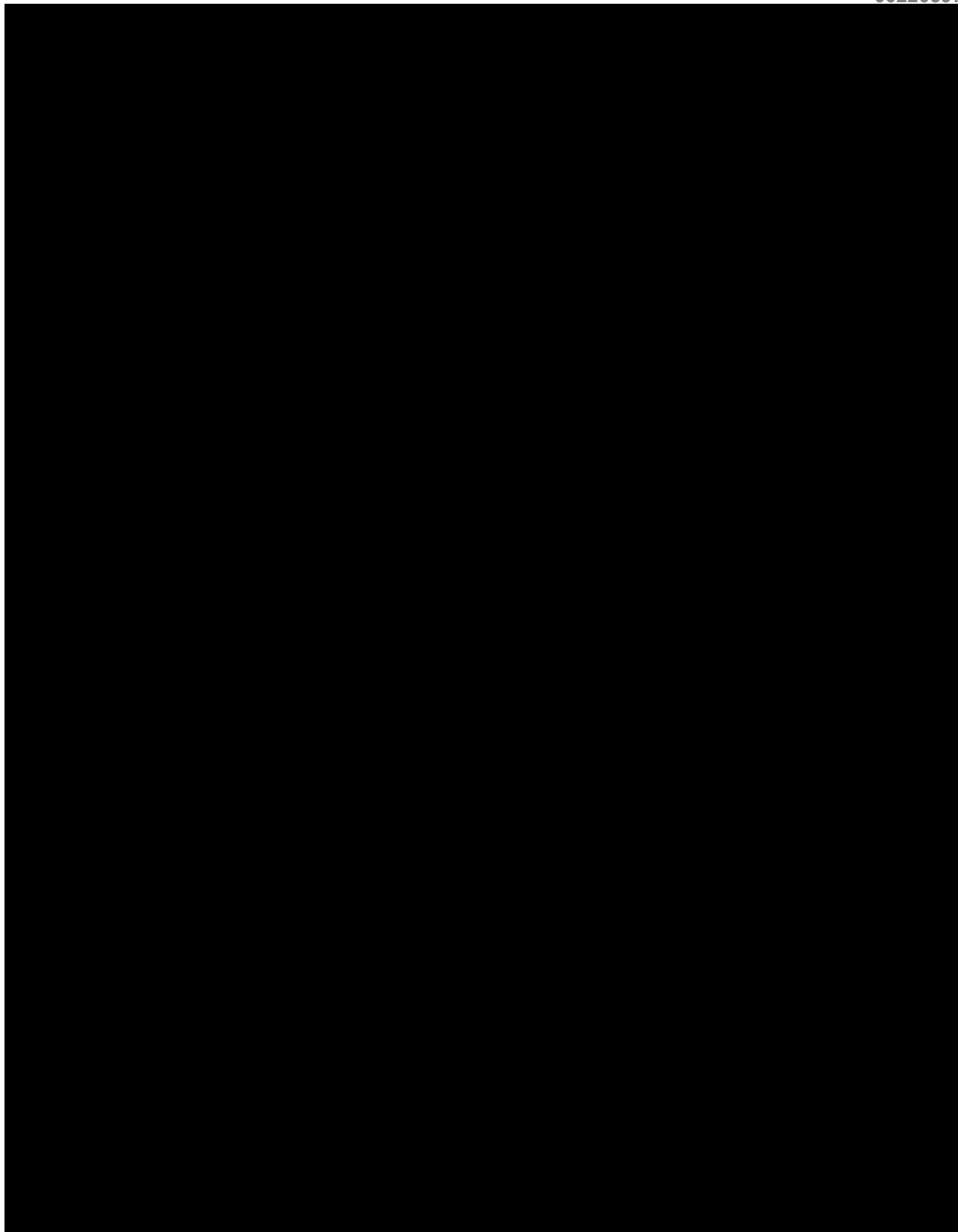
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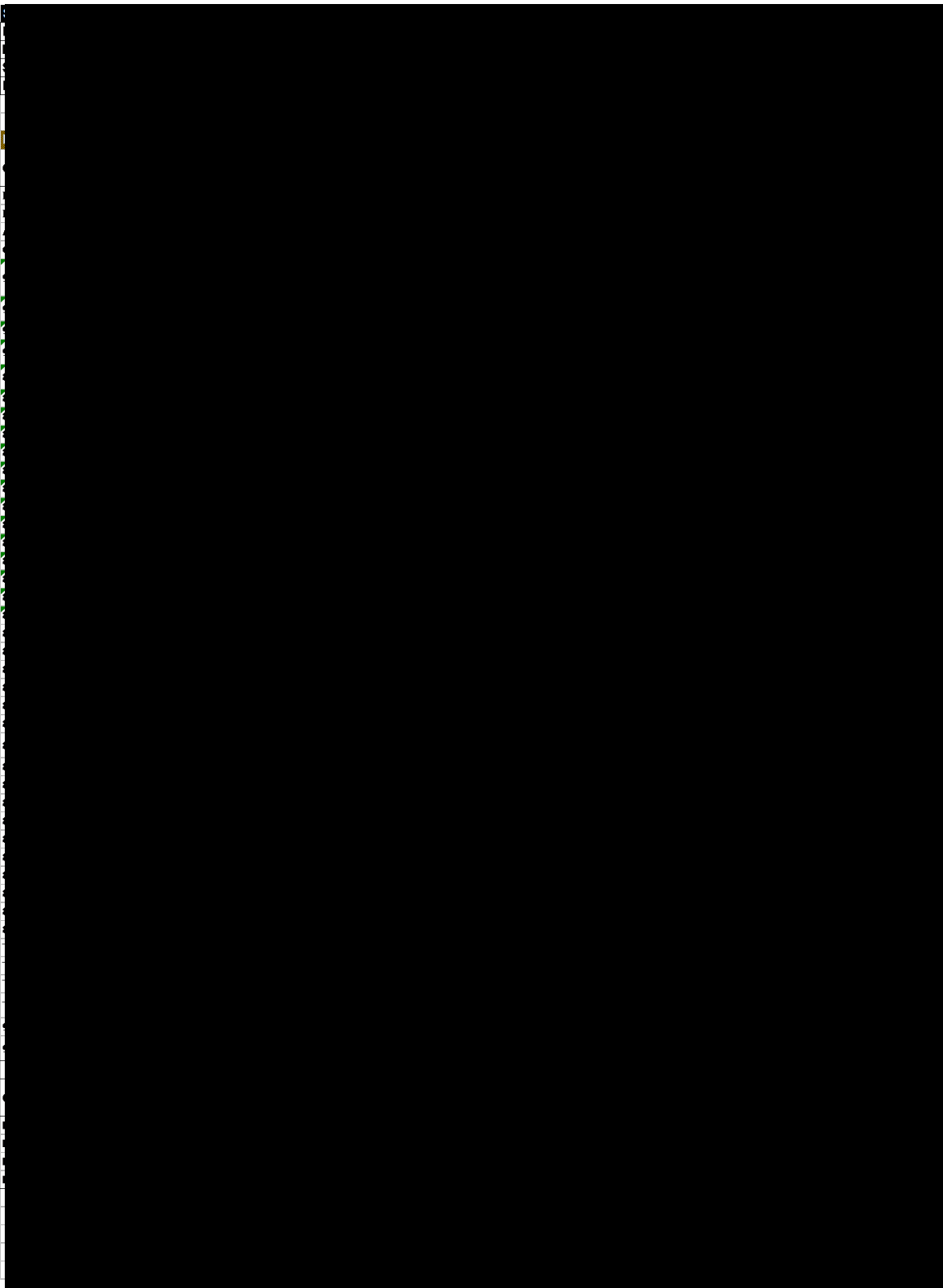


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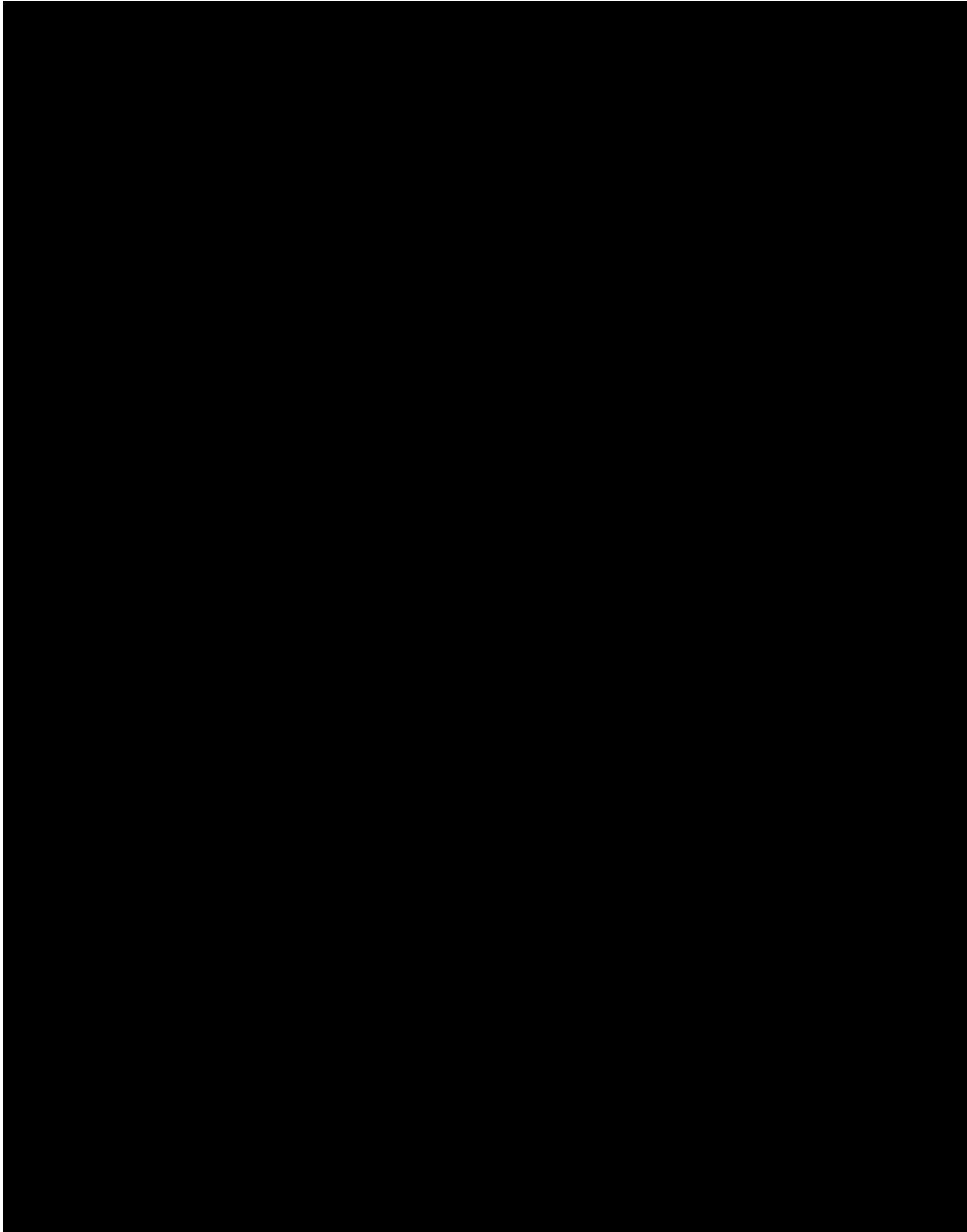


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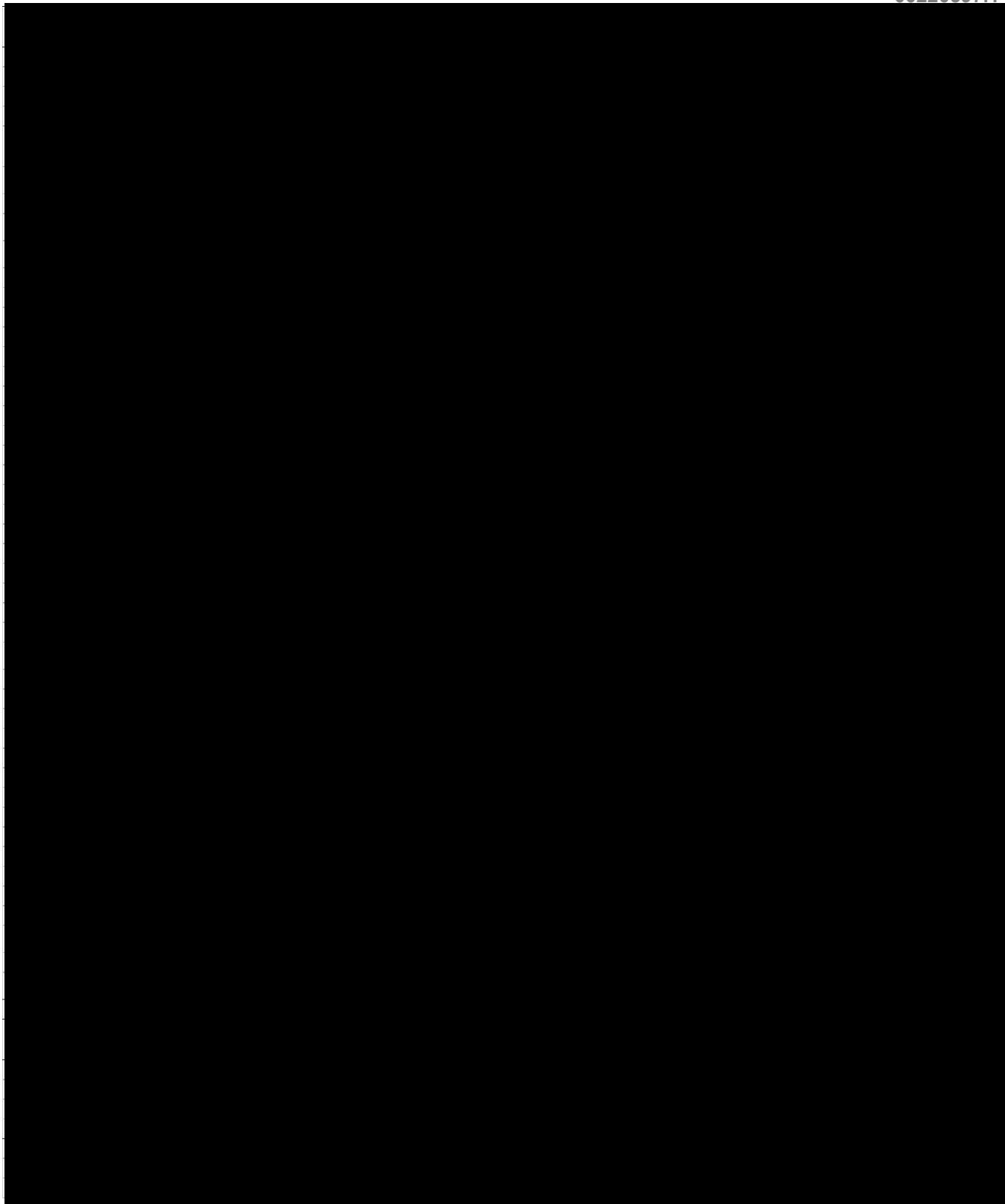
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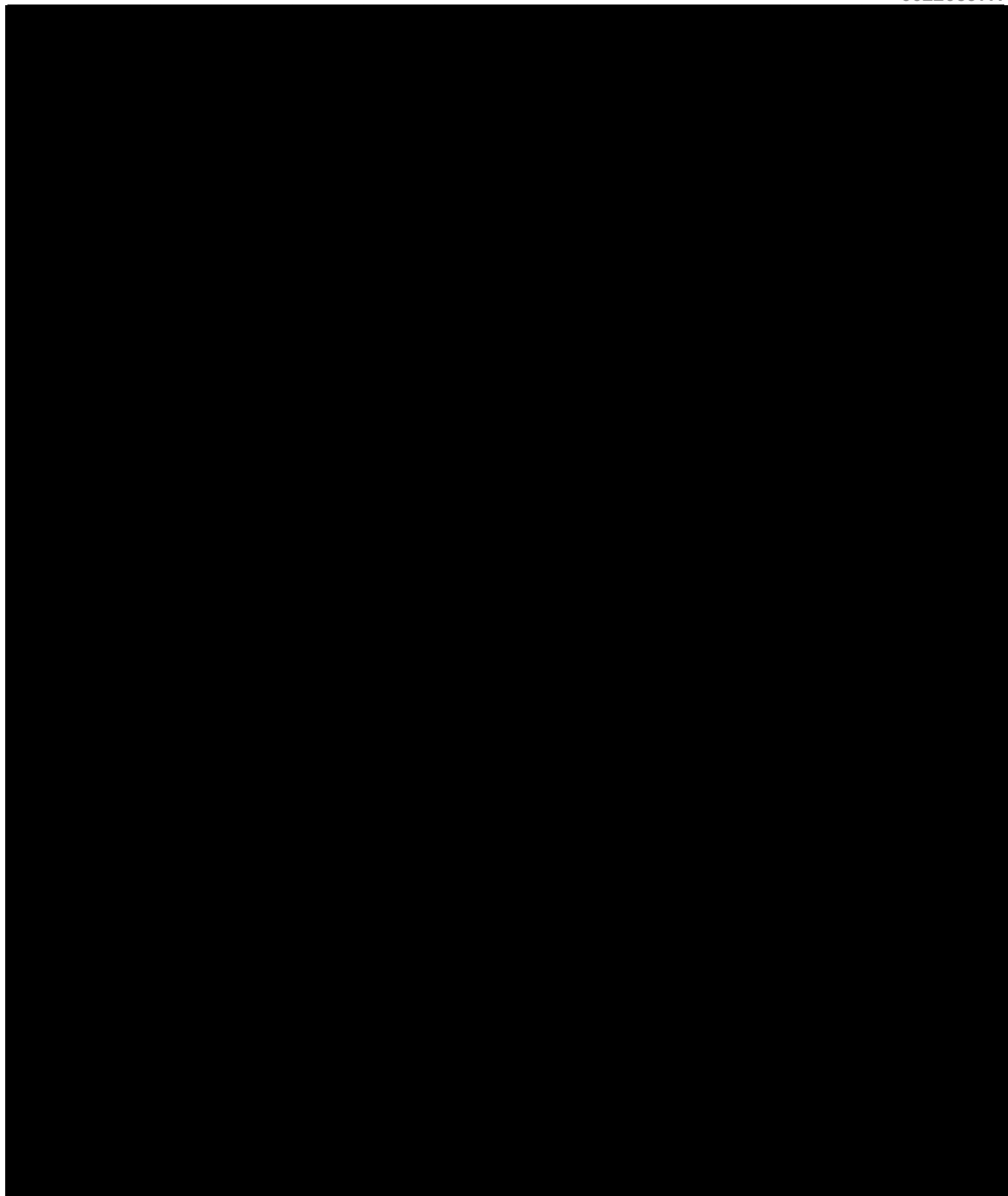
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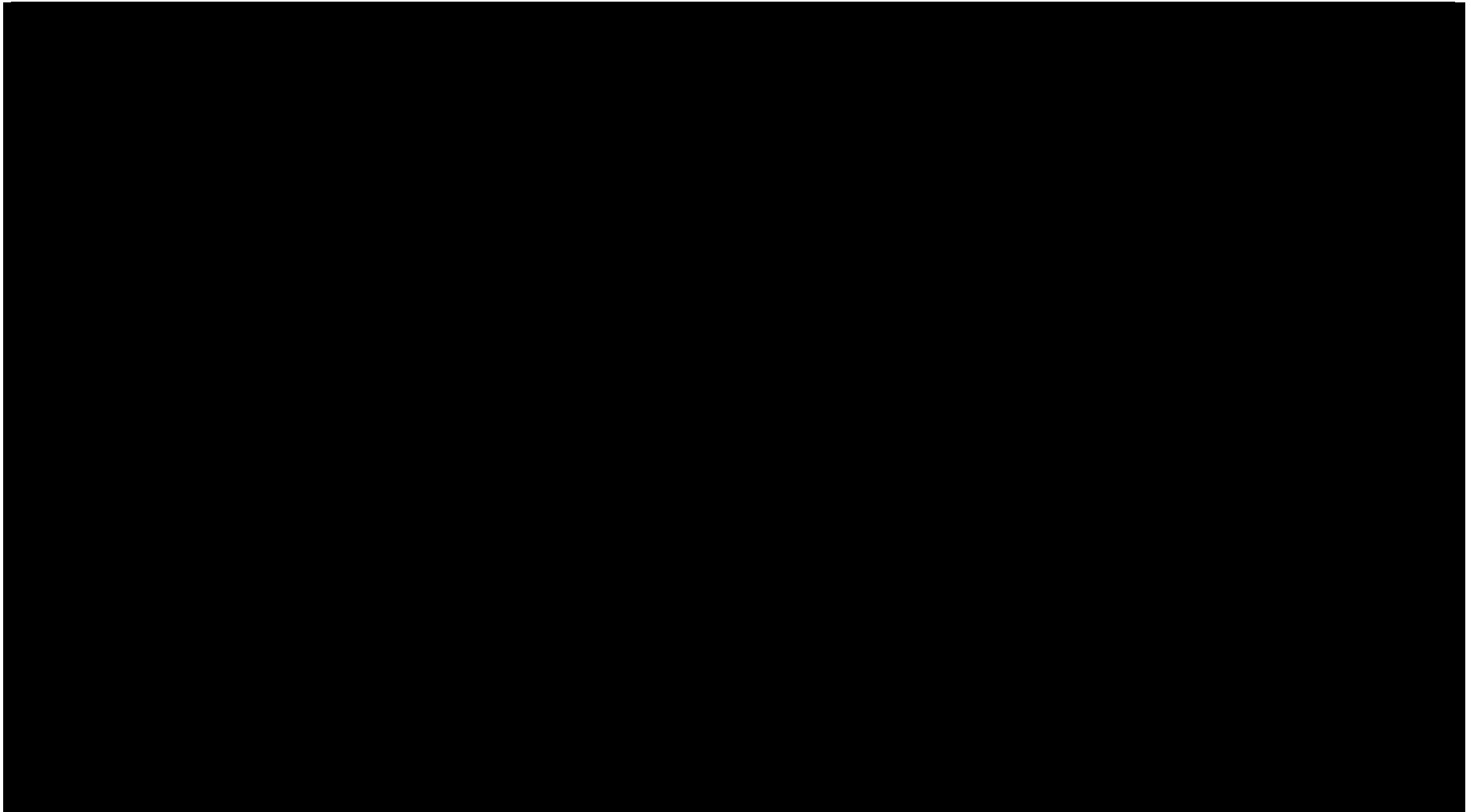


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Attachment 8 to Exhibit A



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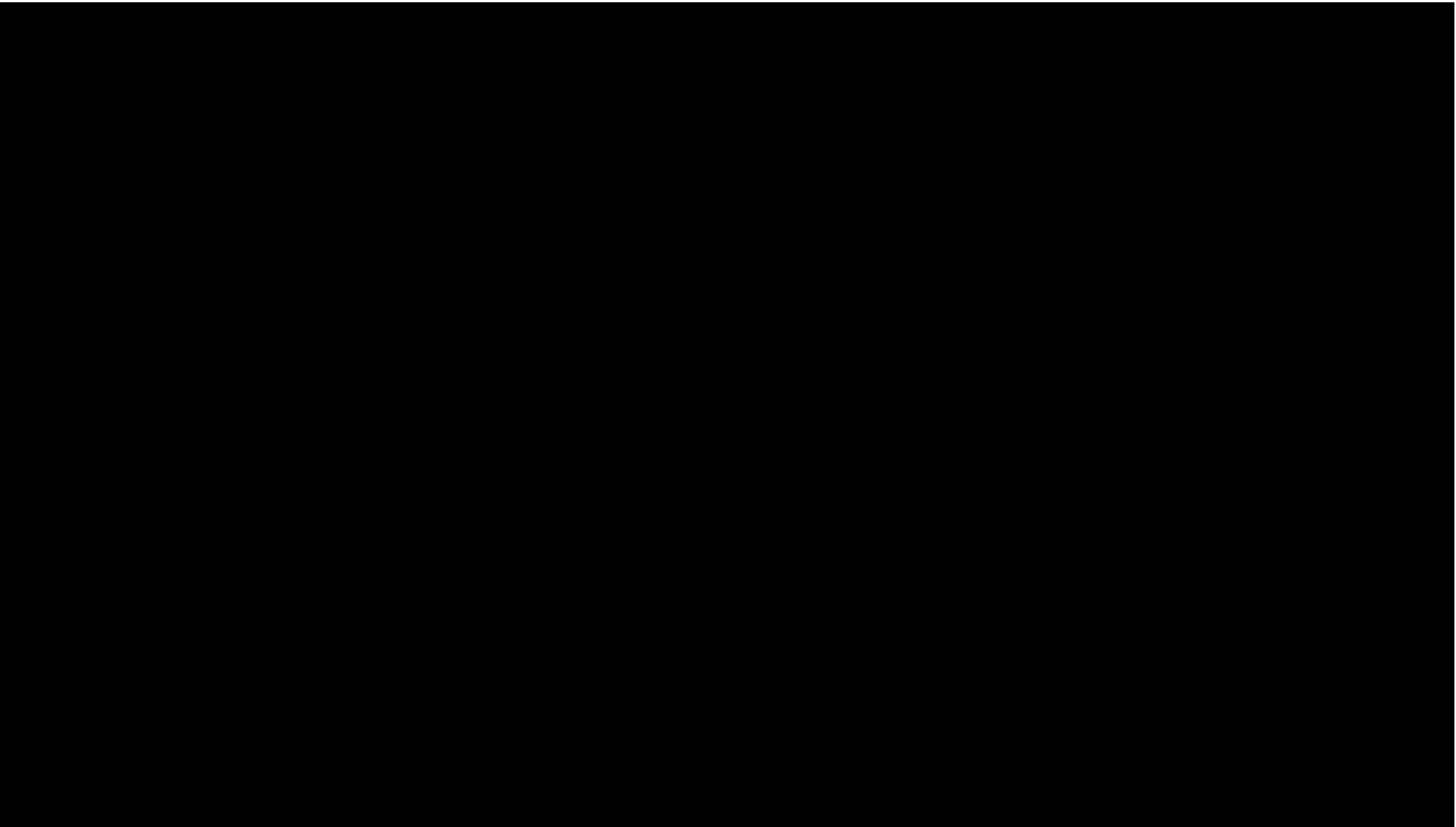
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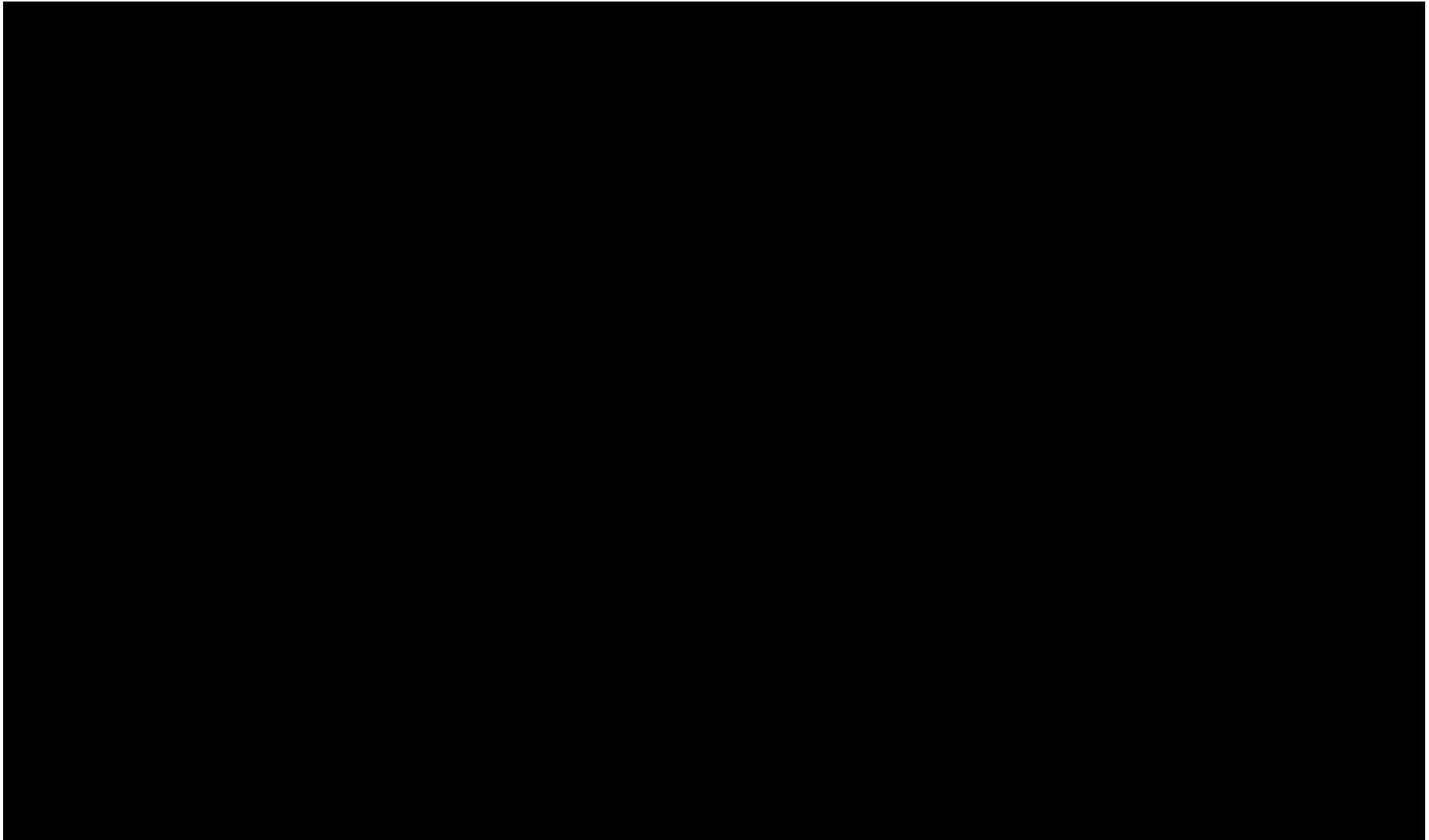
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Attachment 9 to Exhibit A



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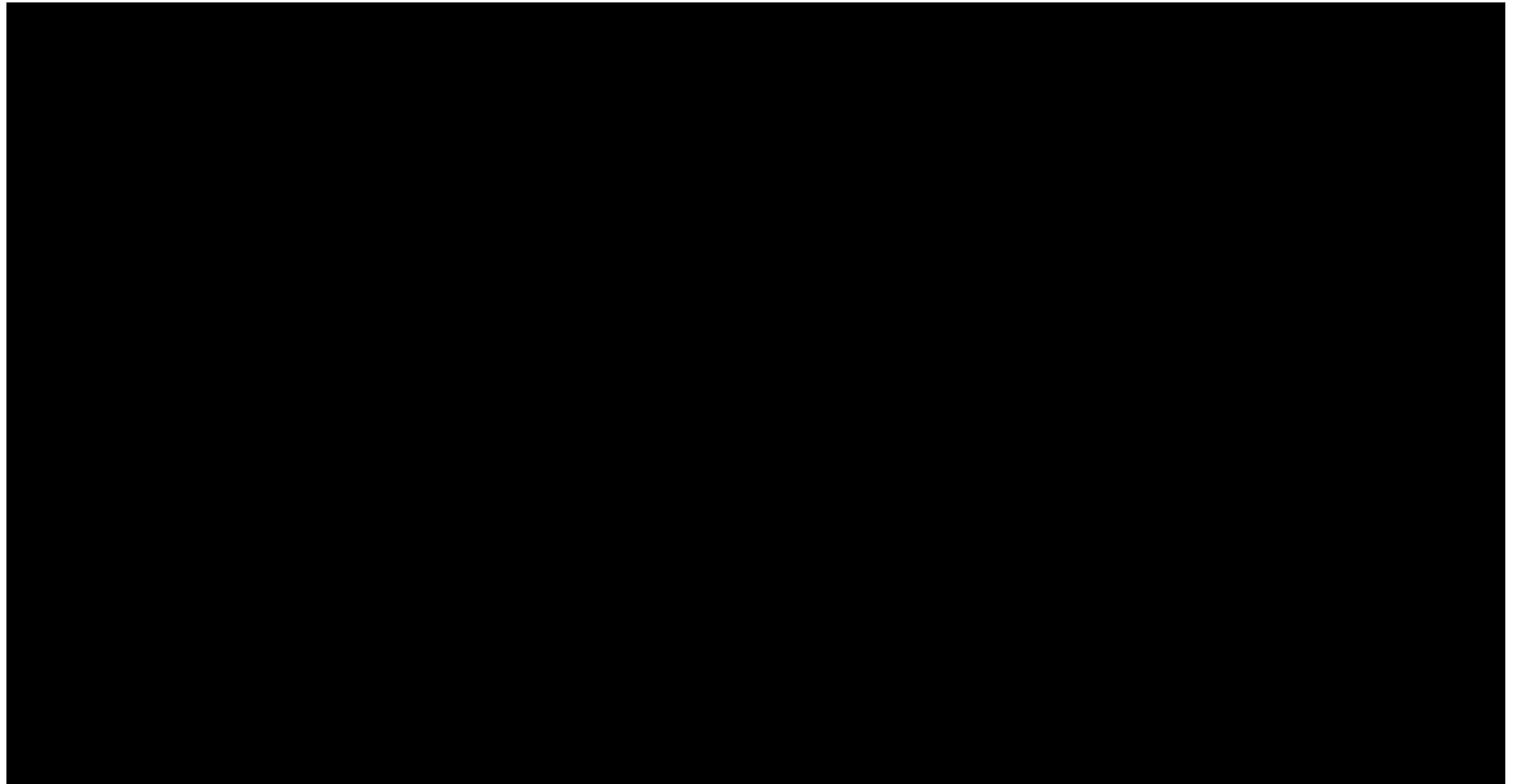
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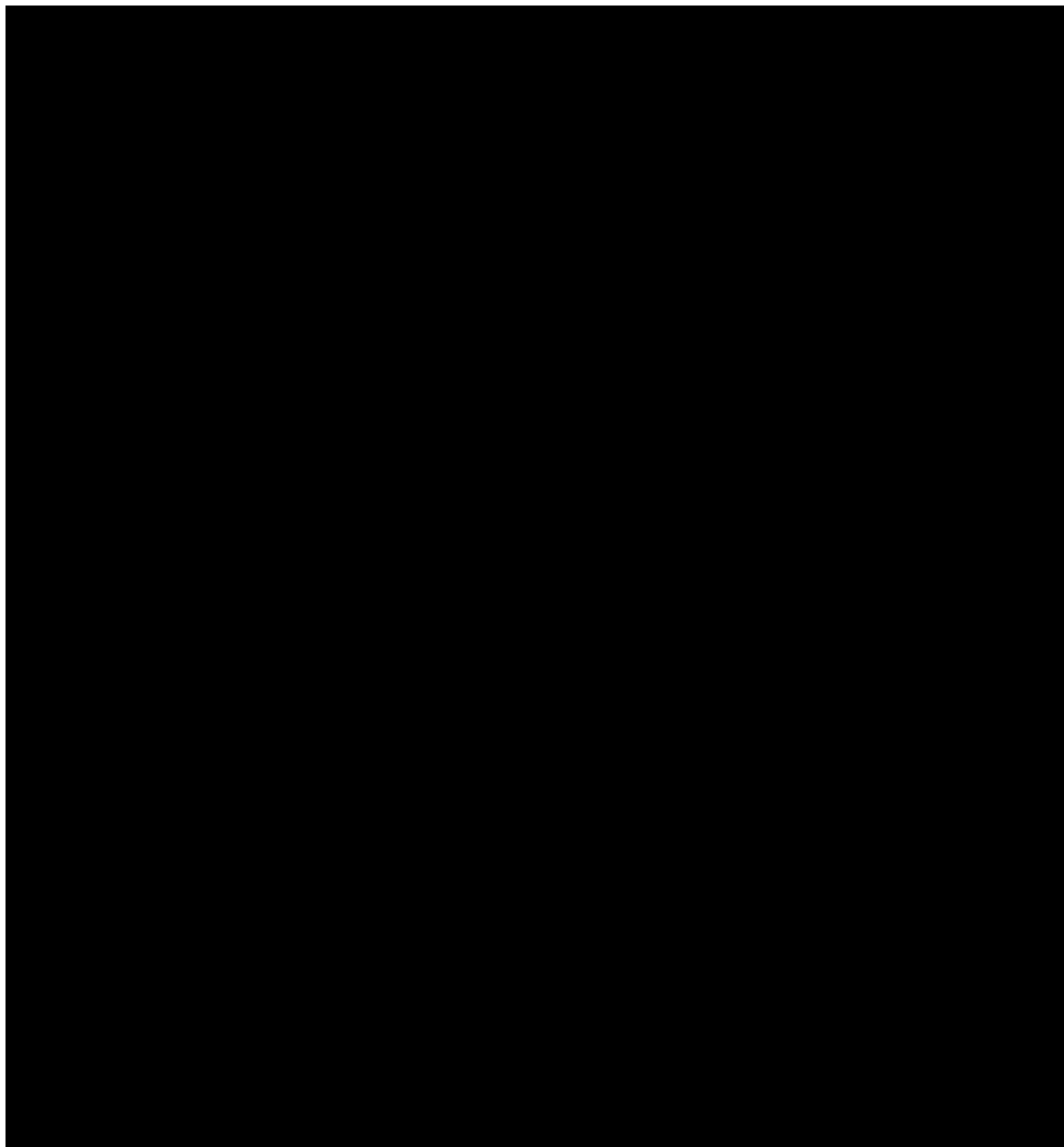
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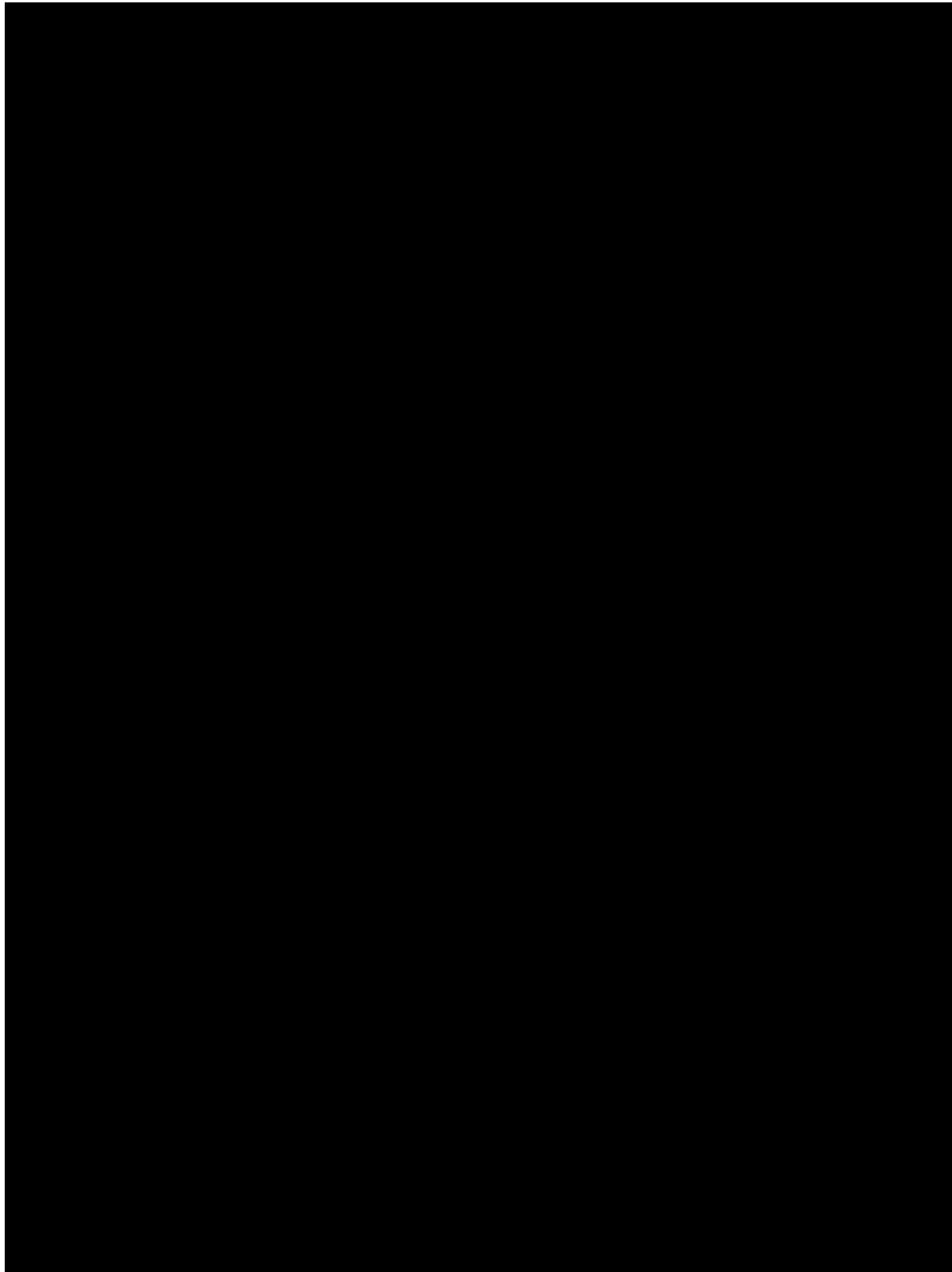
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Příloha A - ZDRAVOTNICKÉ ZAŘÍZENÍ
ROZPOČET STUDIE

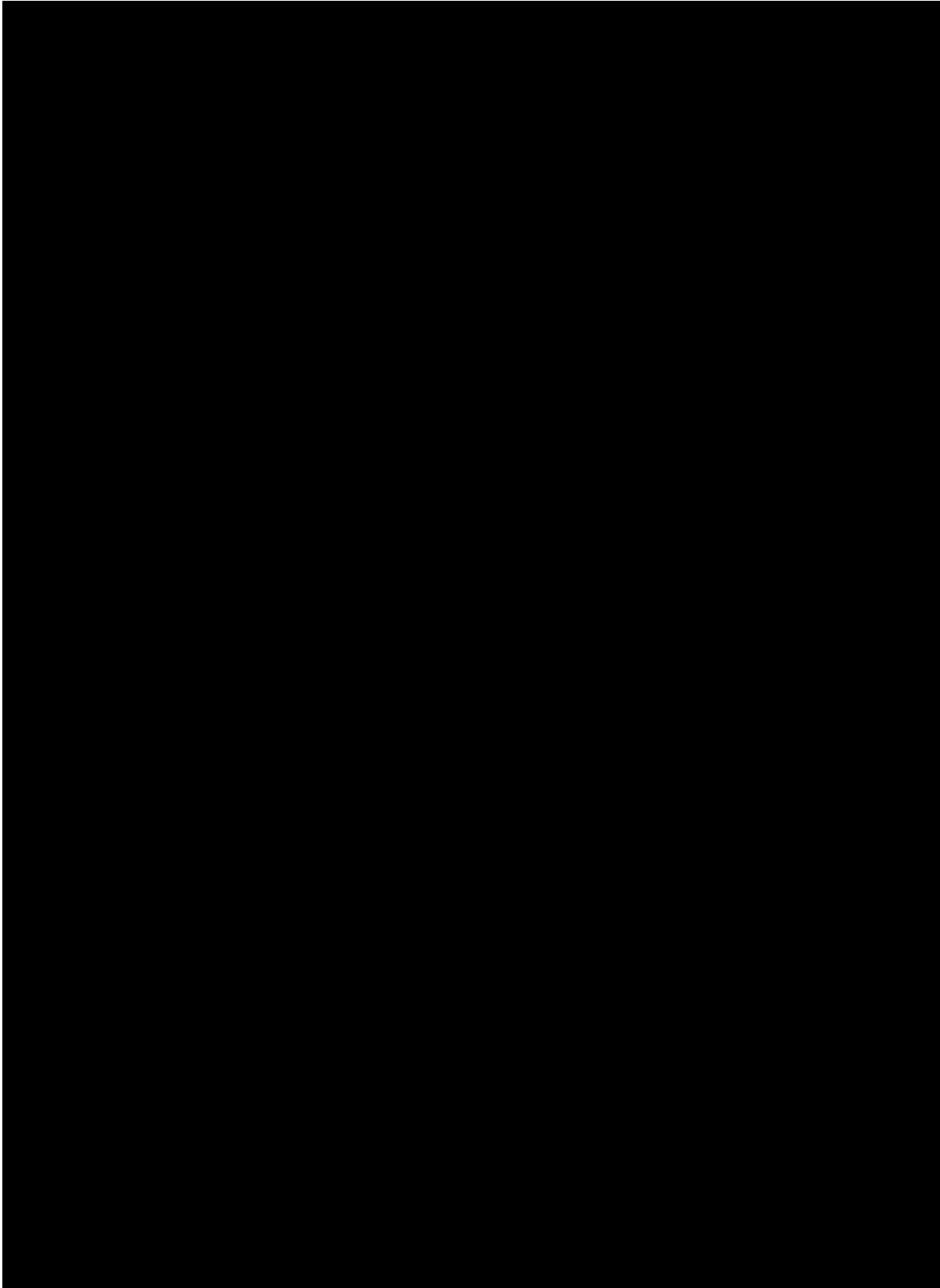


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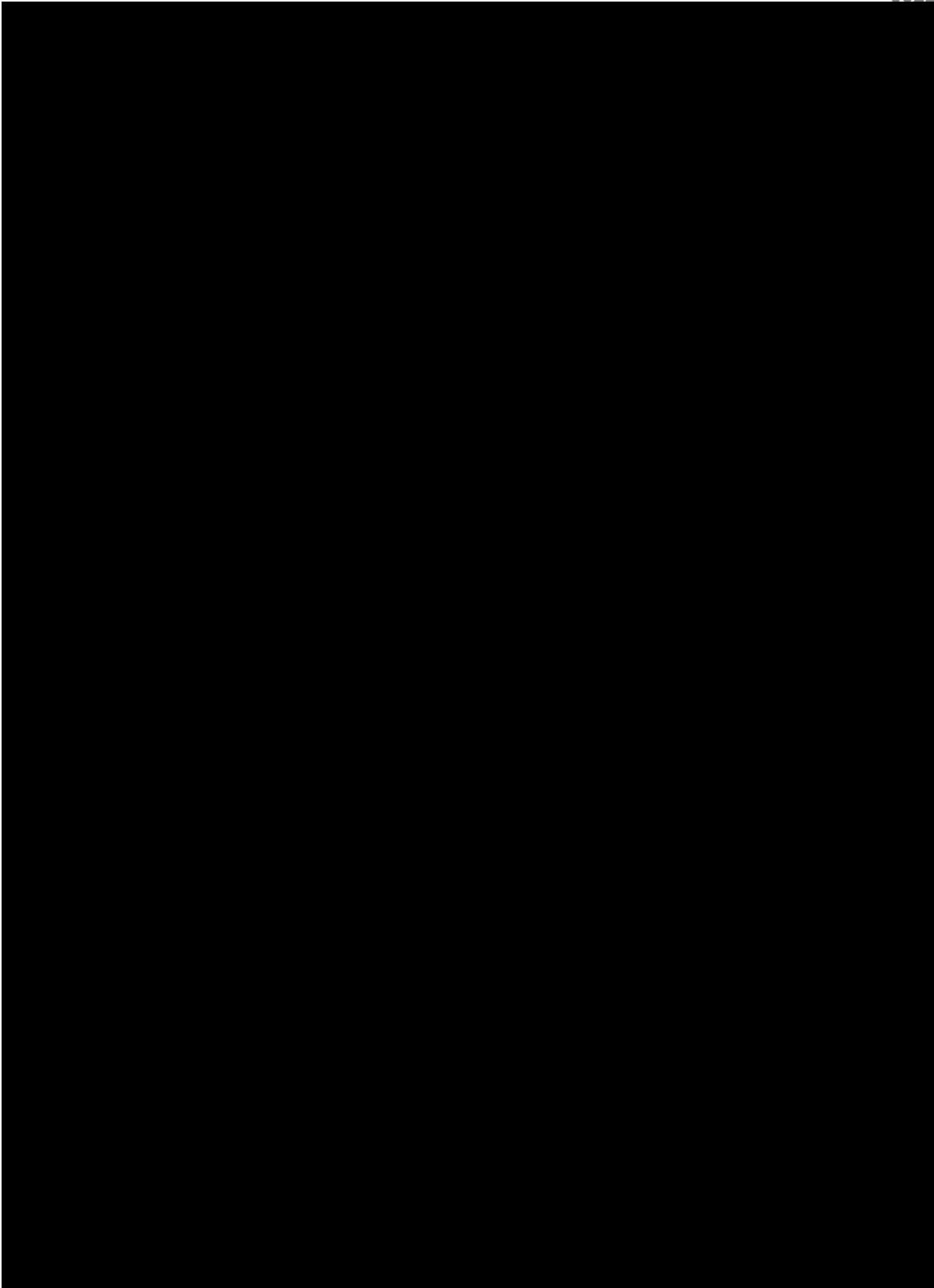
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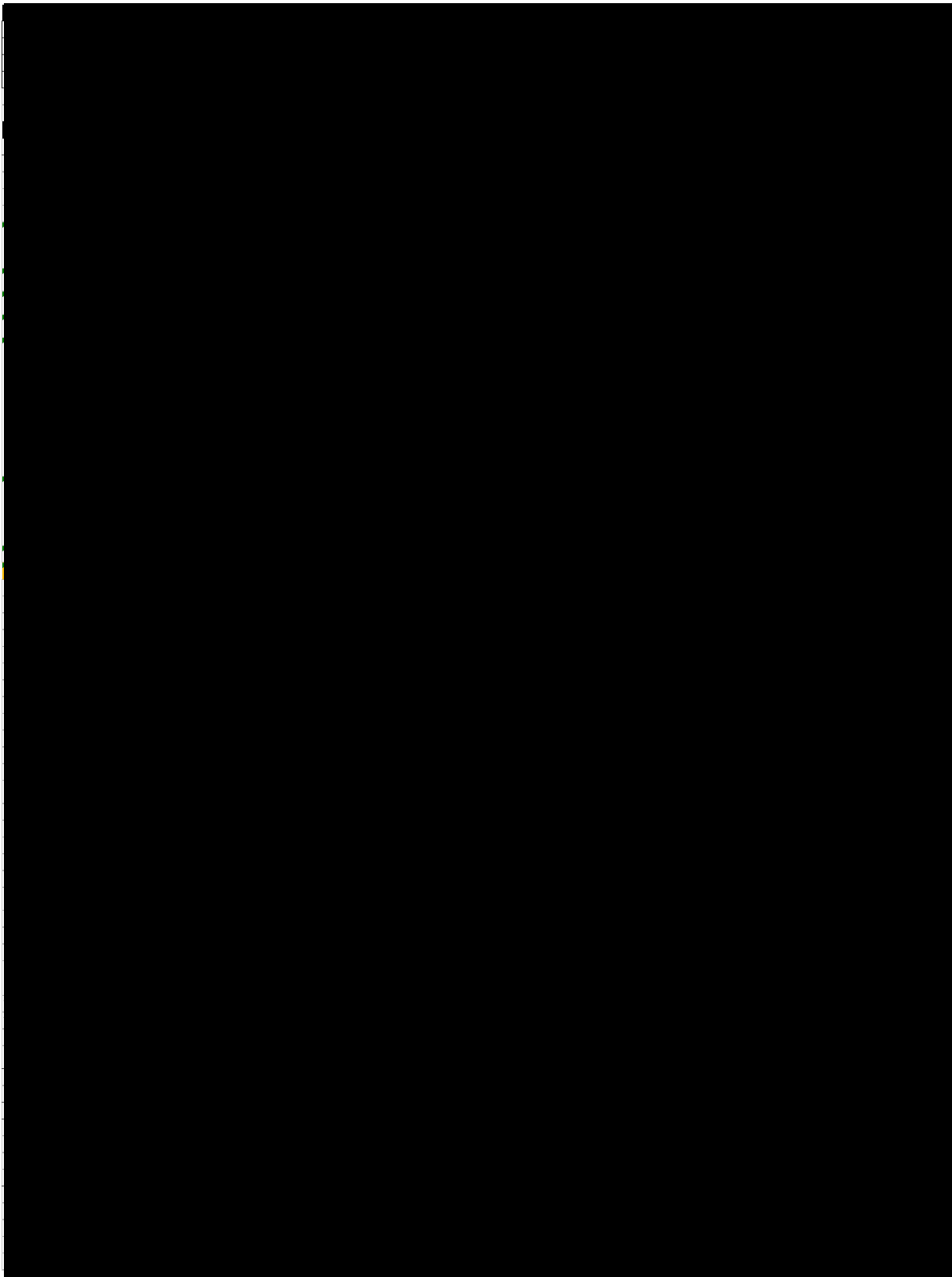


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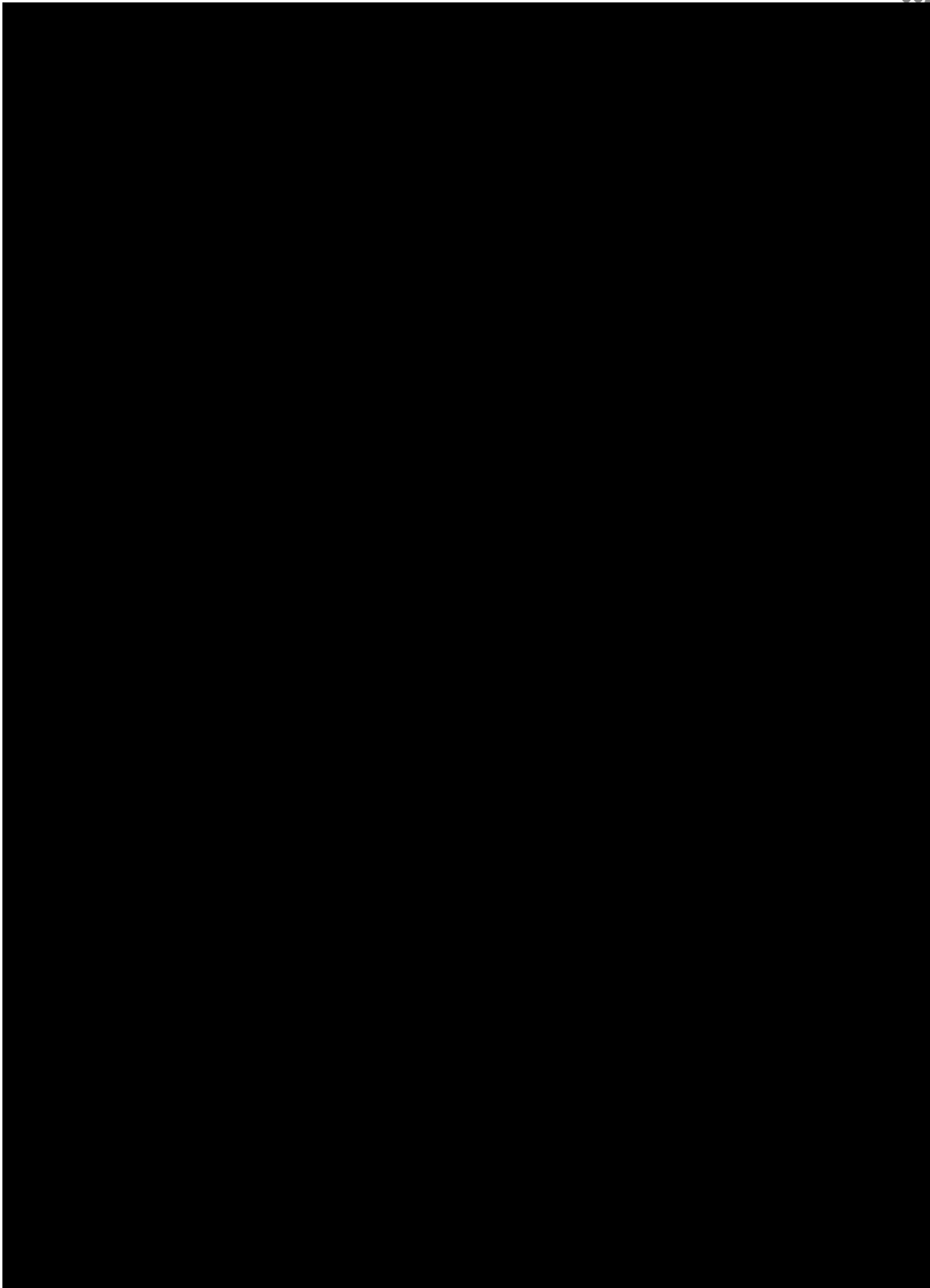


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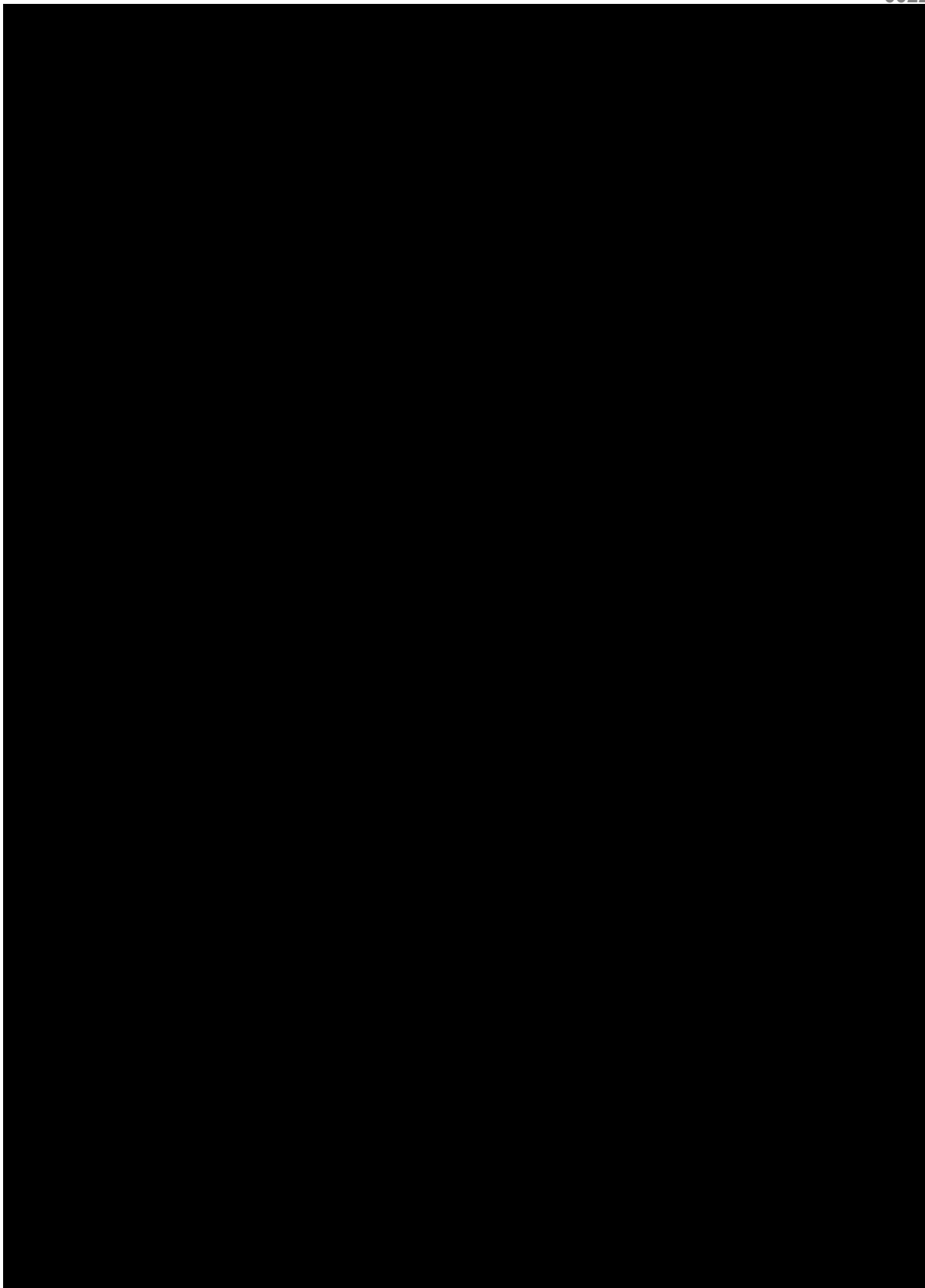
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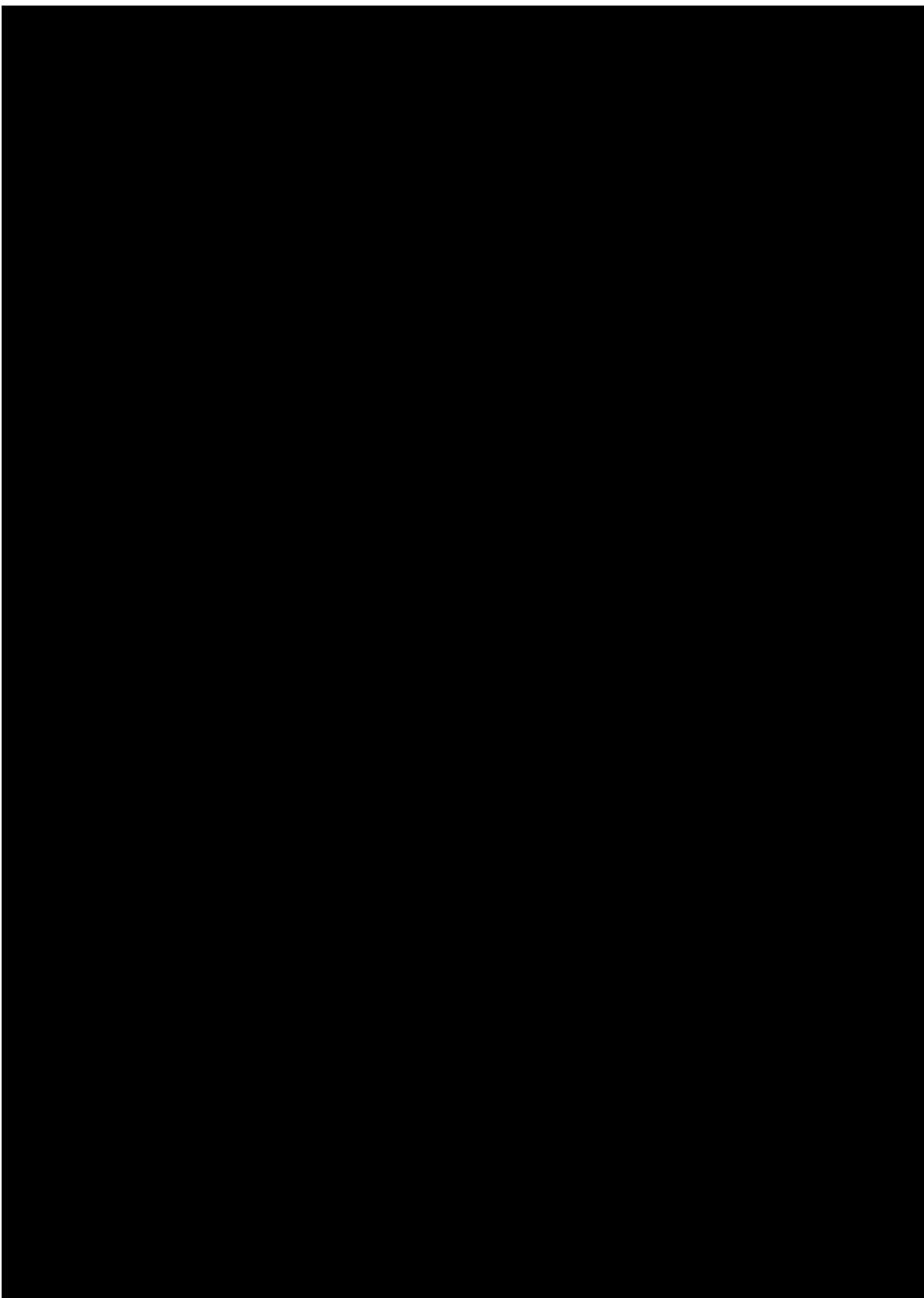
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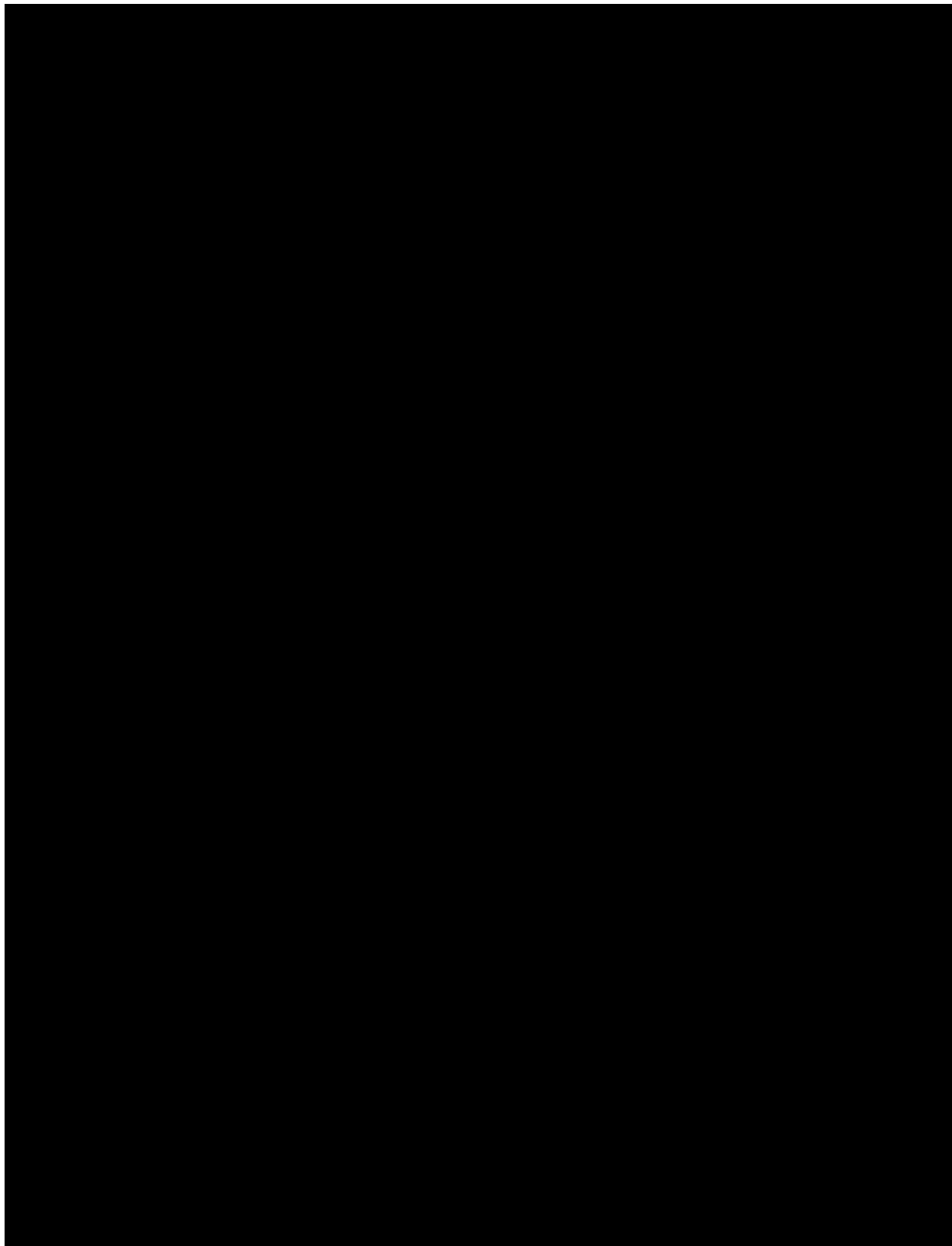


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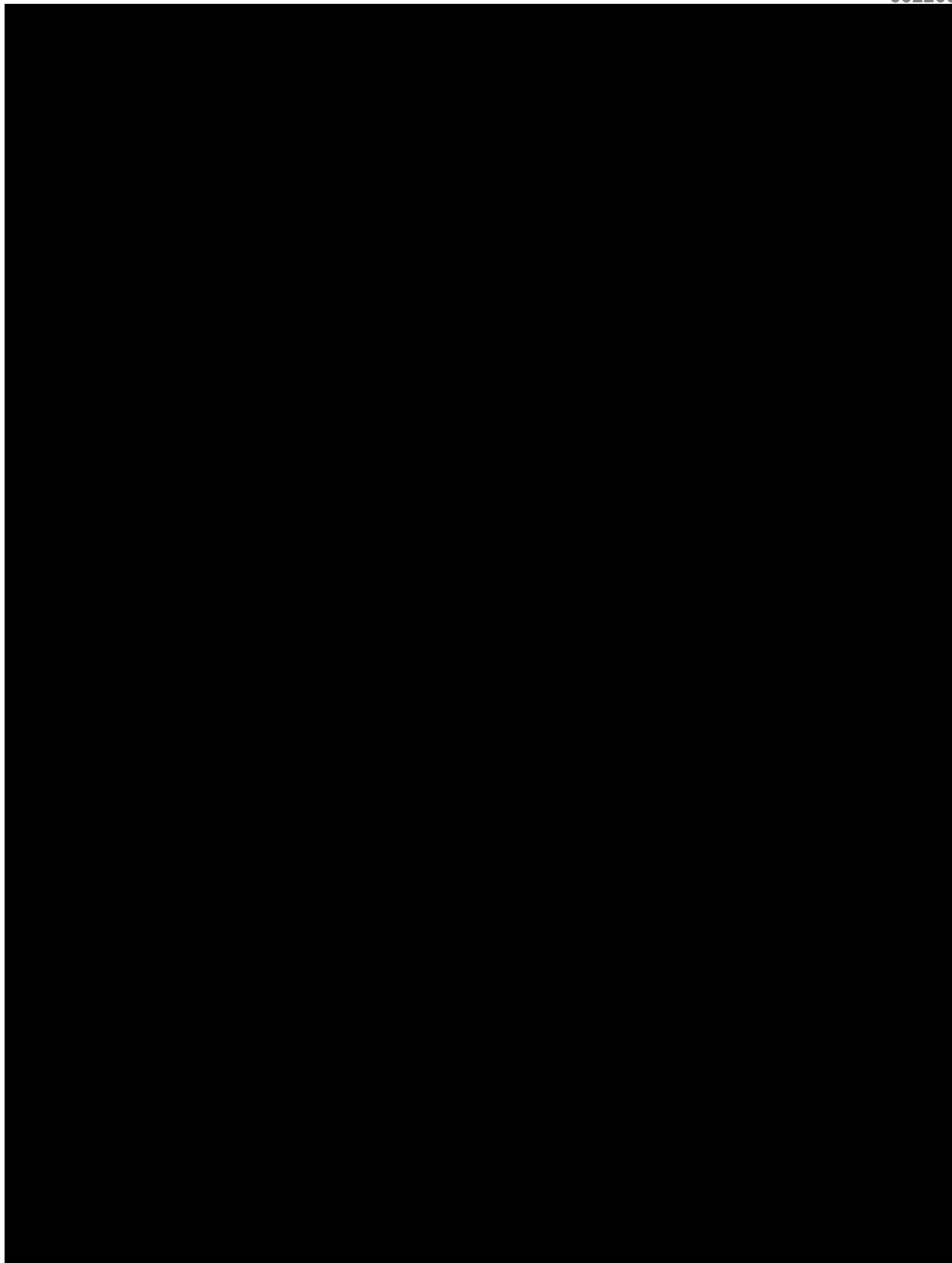


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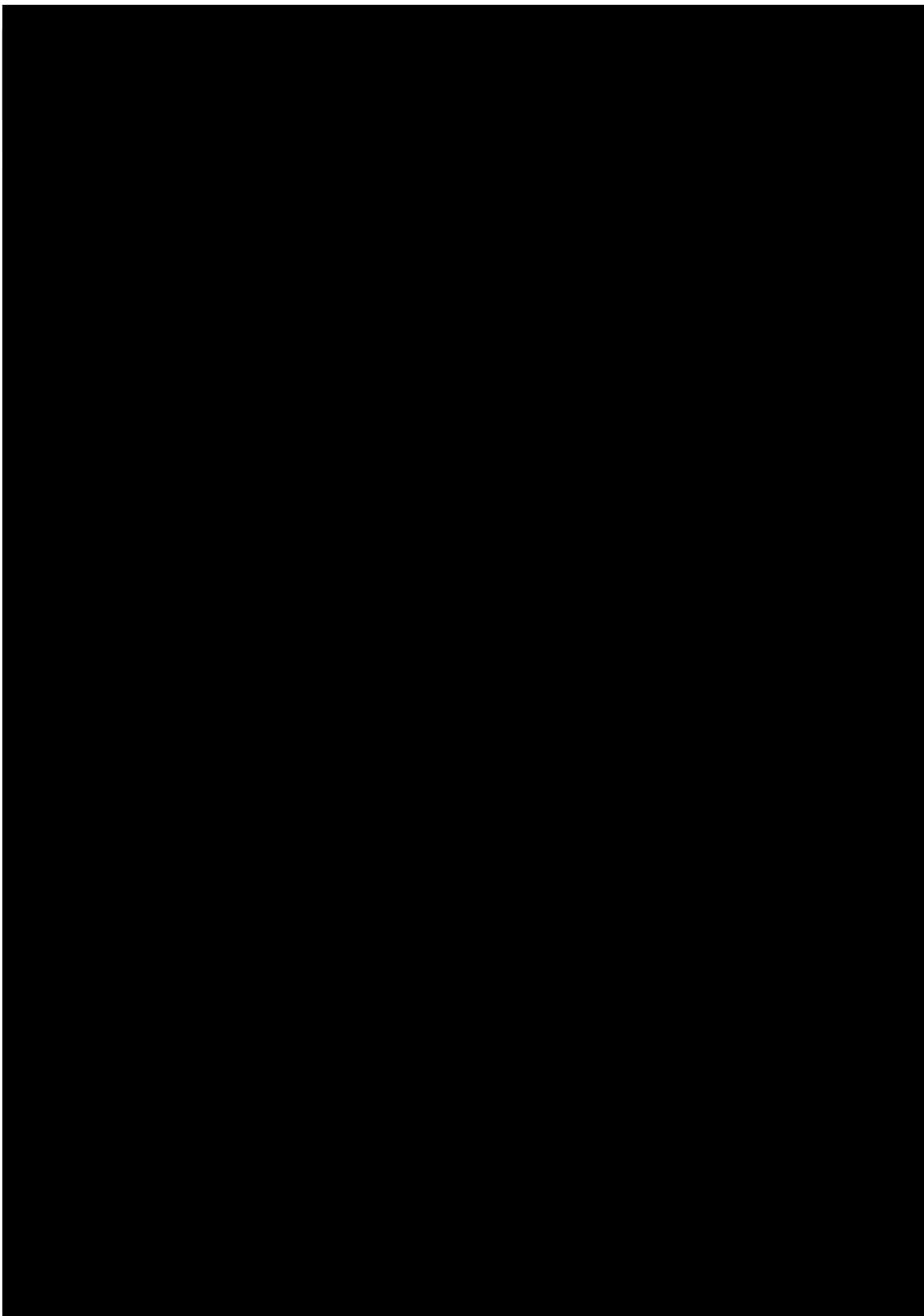


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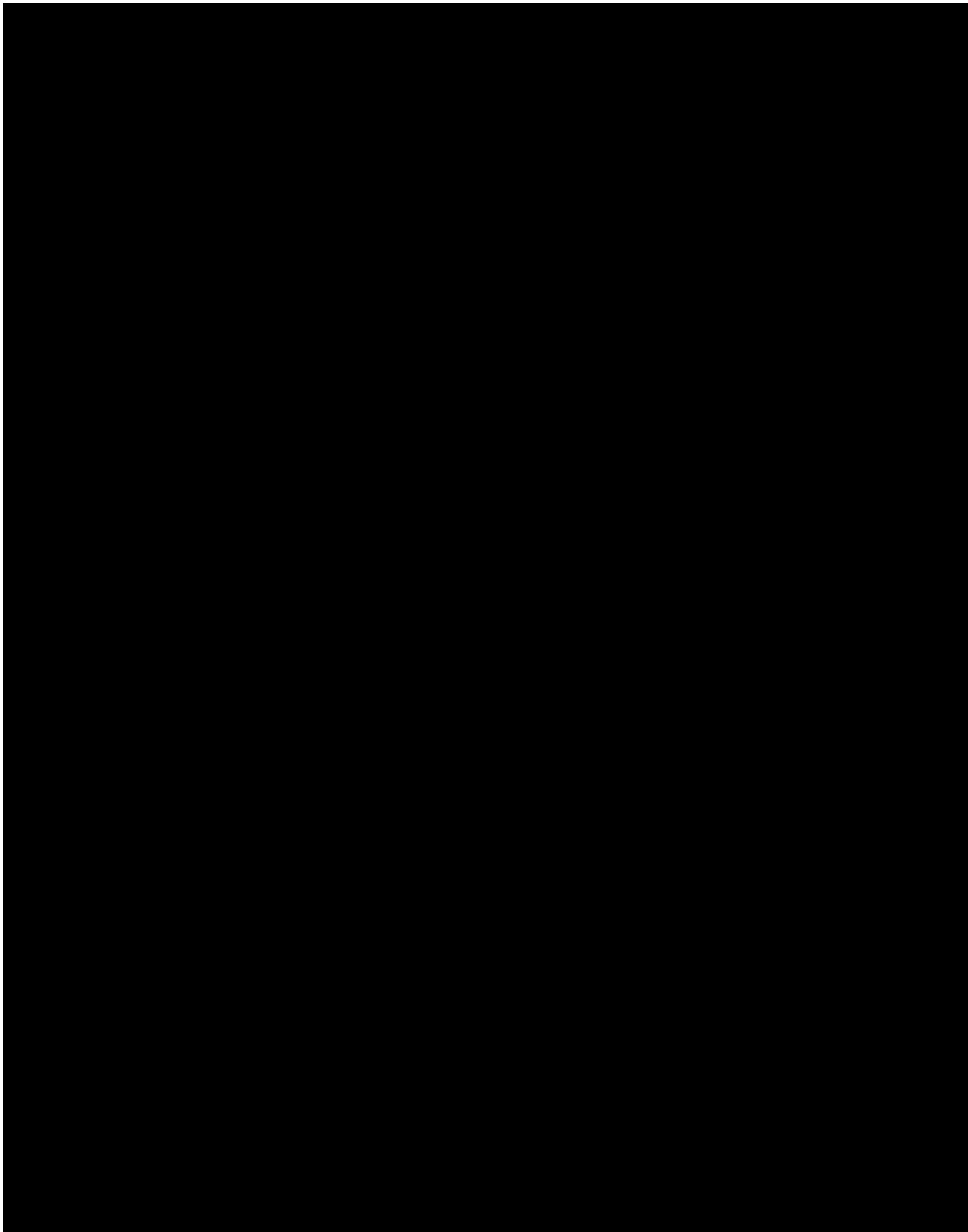


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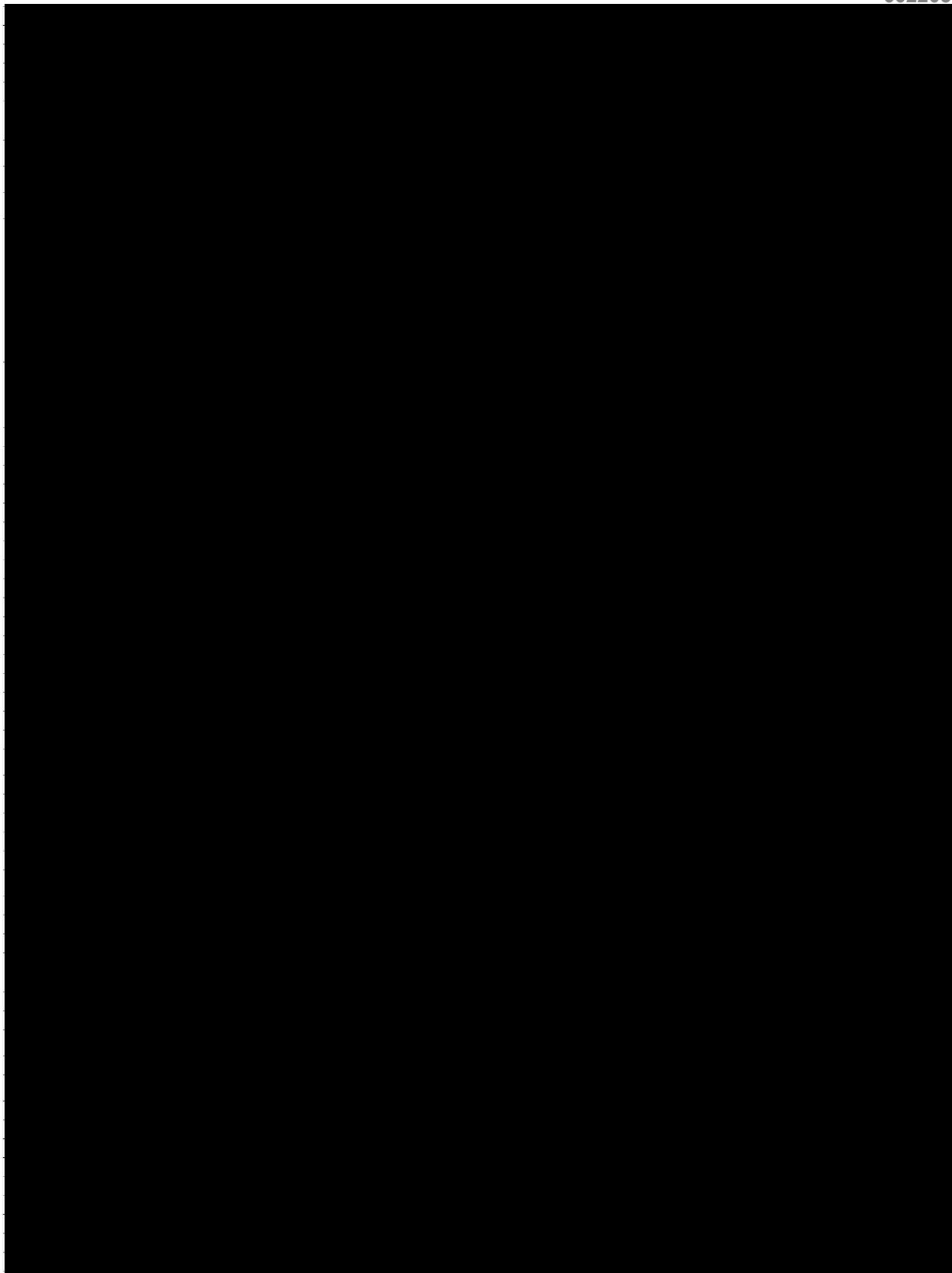
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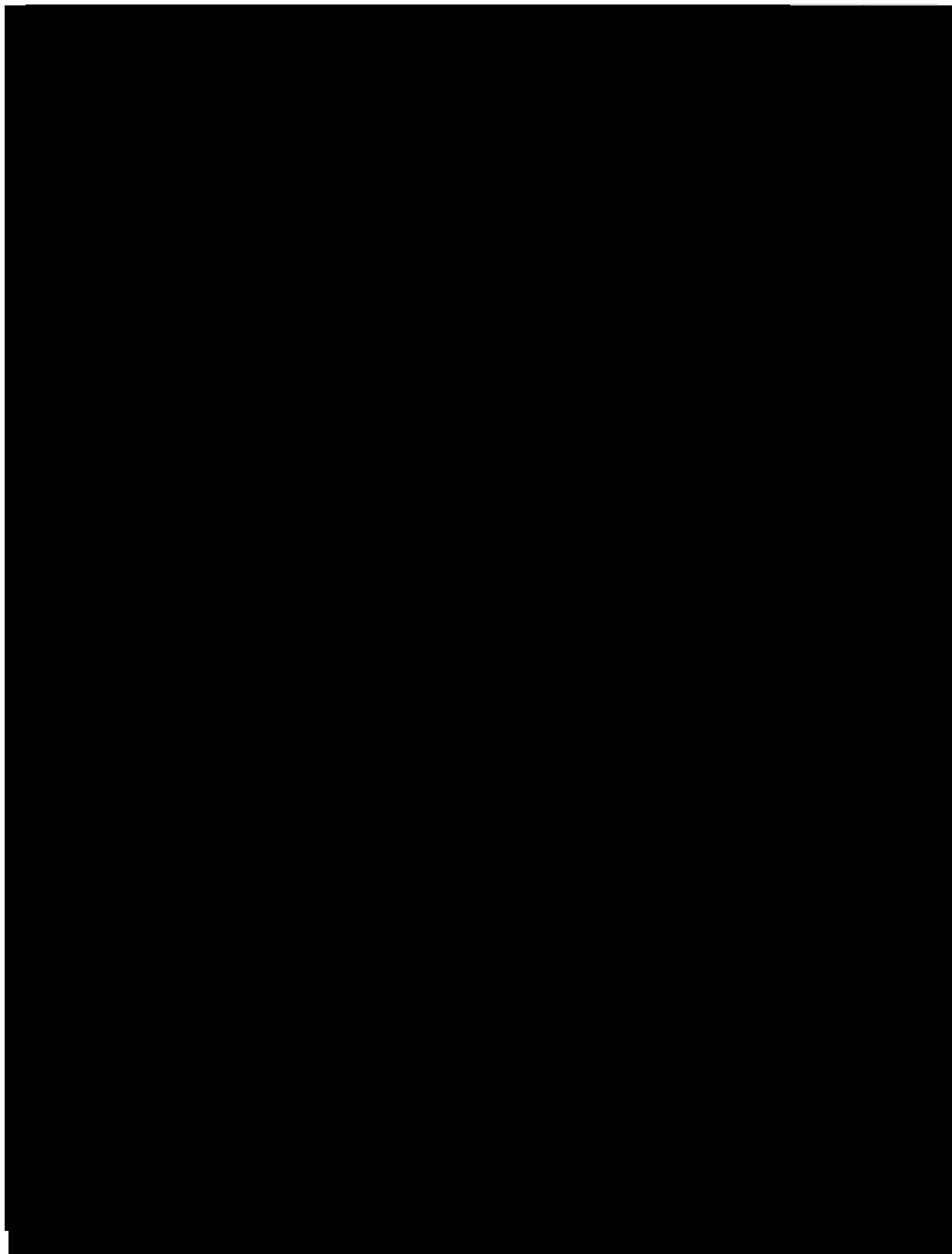


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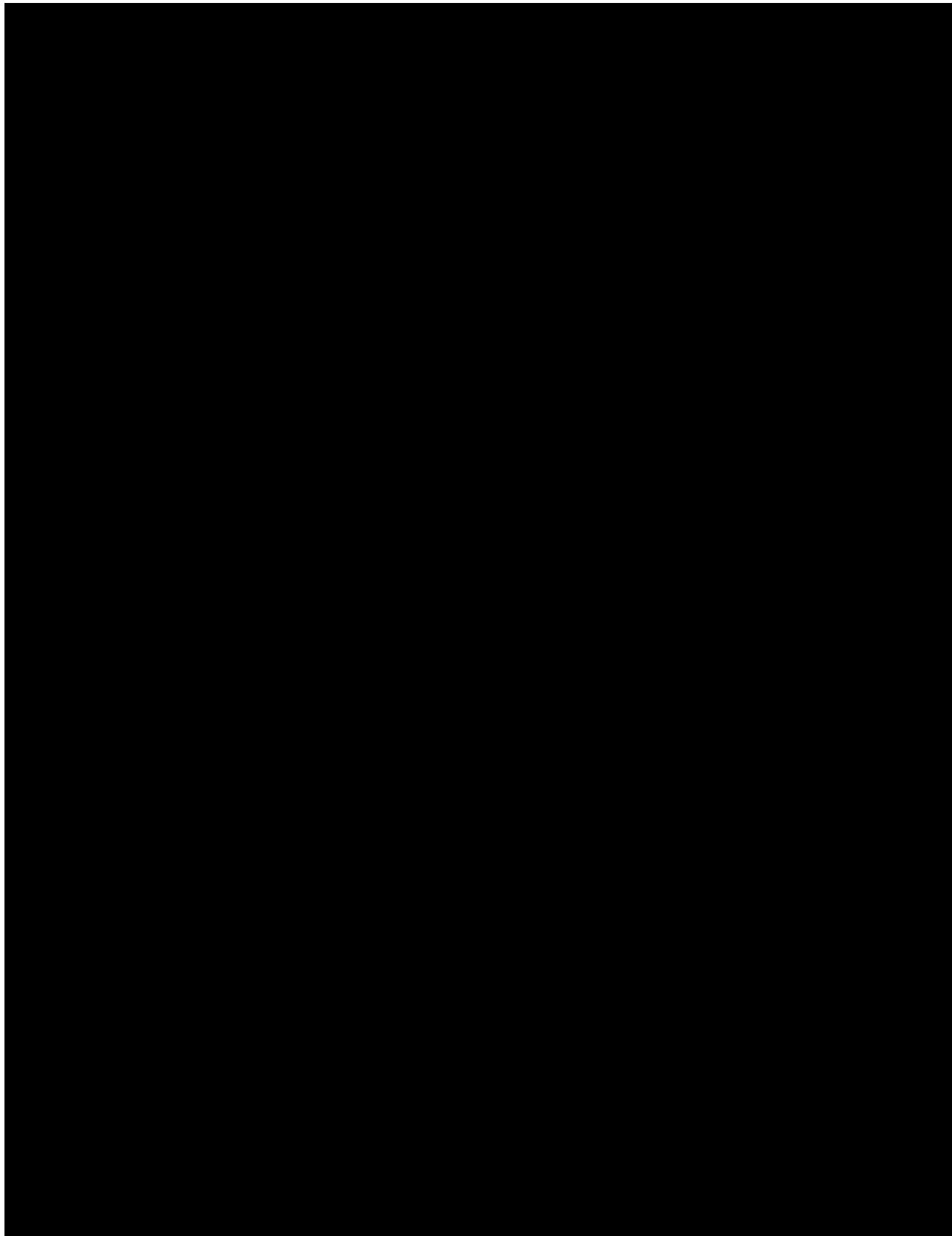


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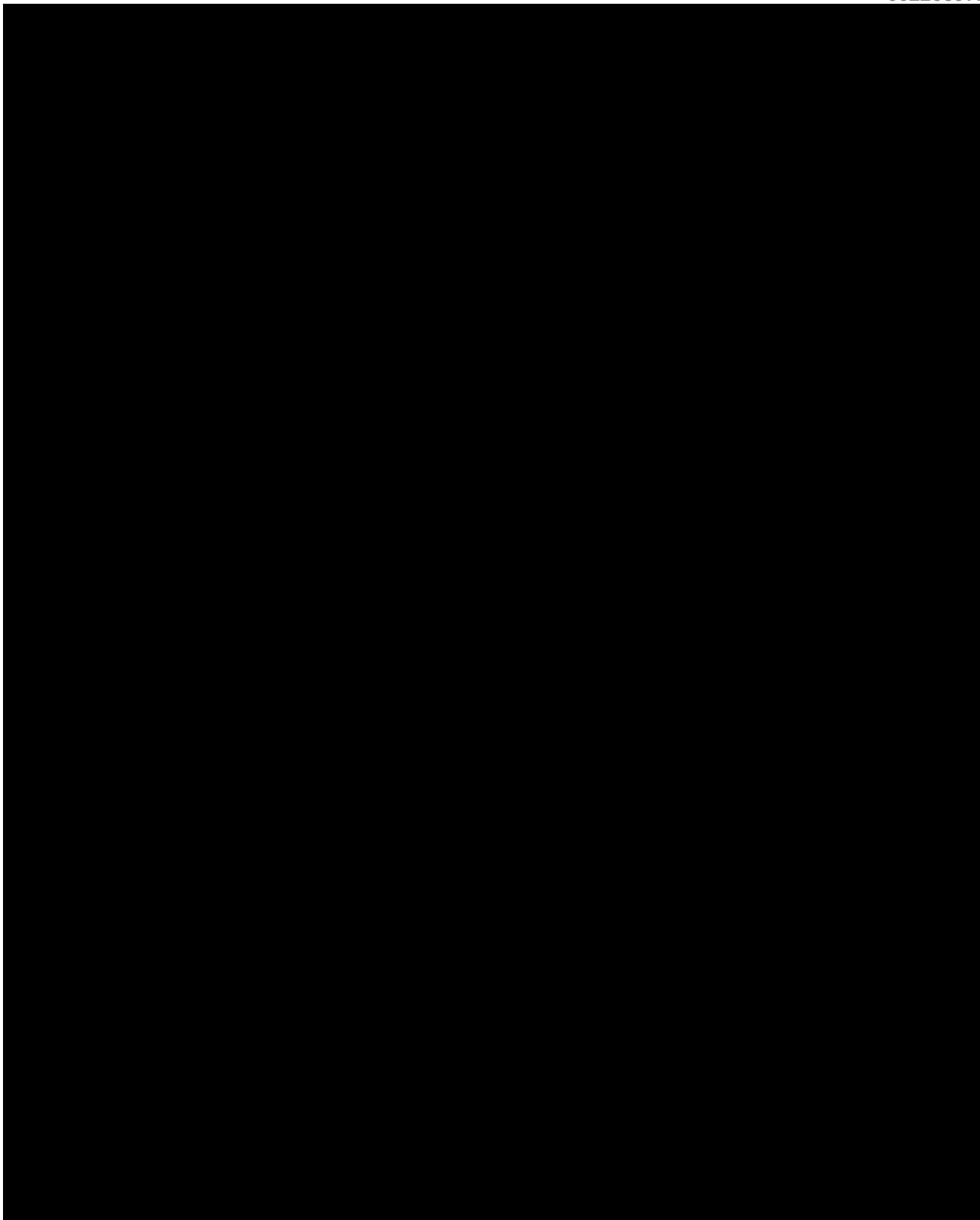
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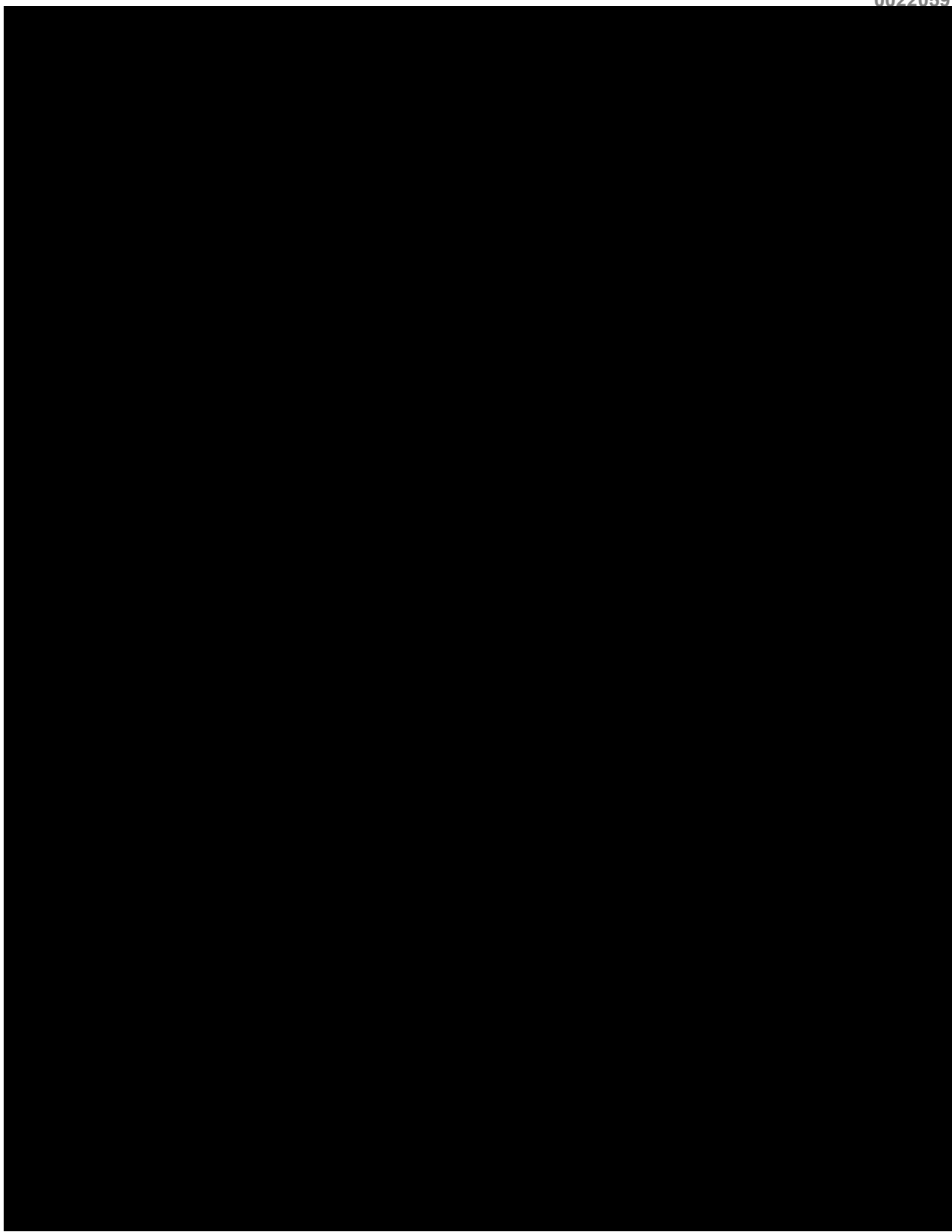
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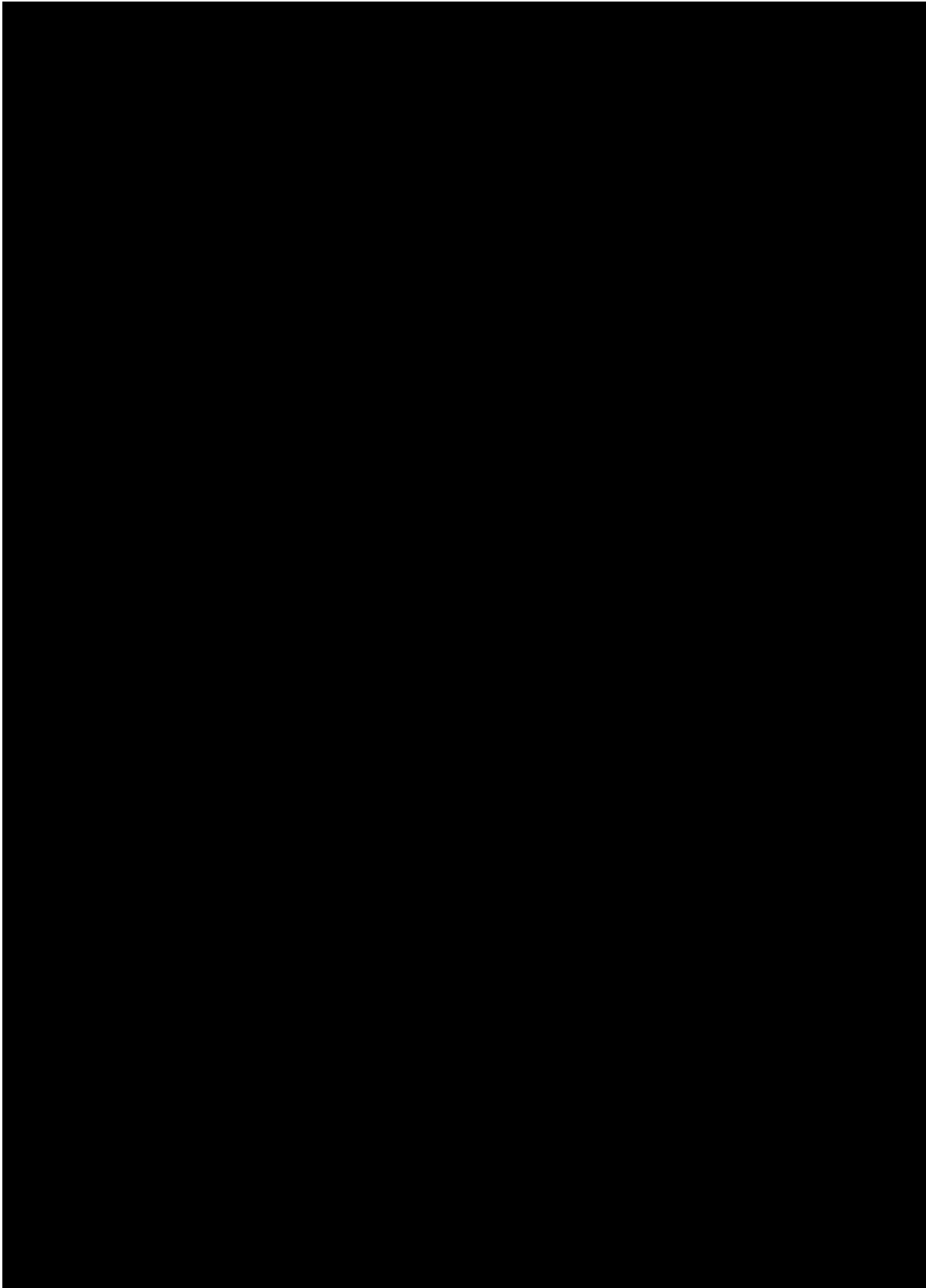


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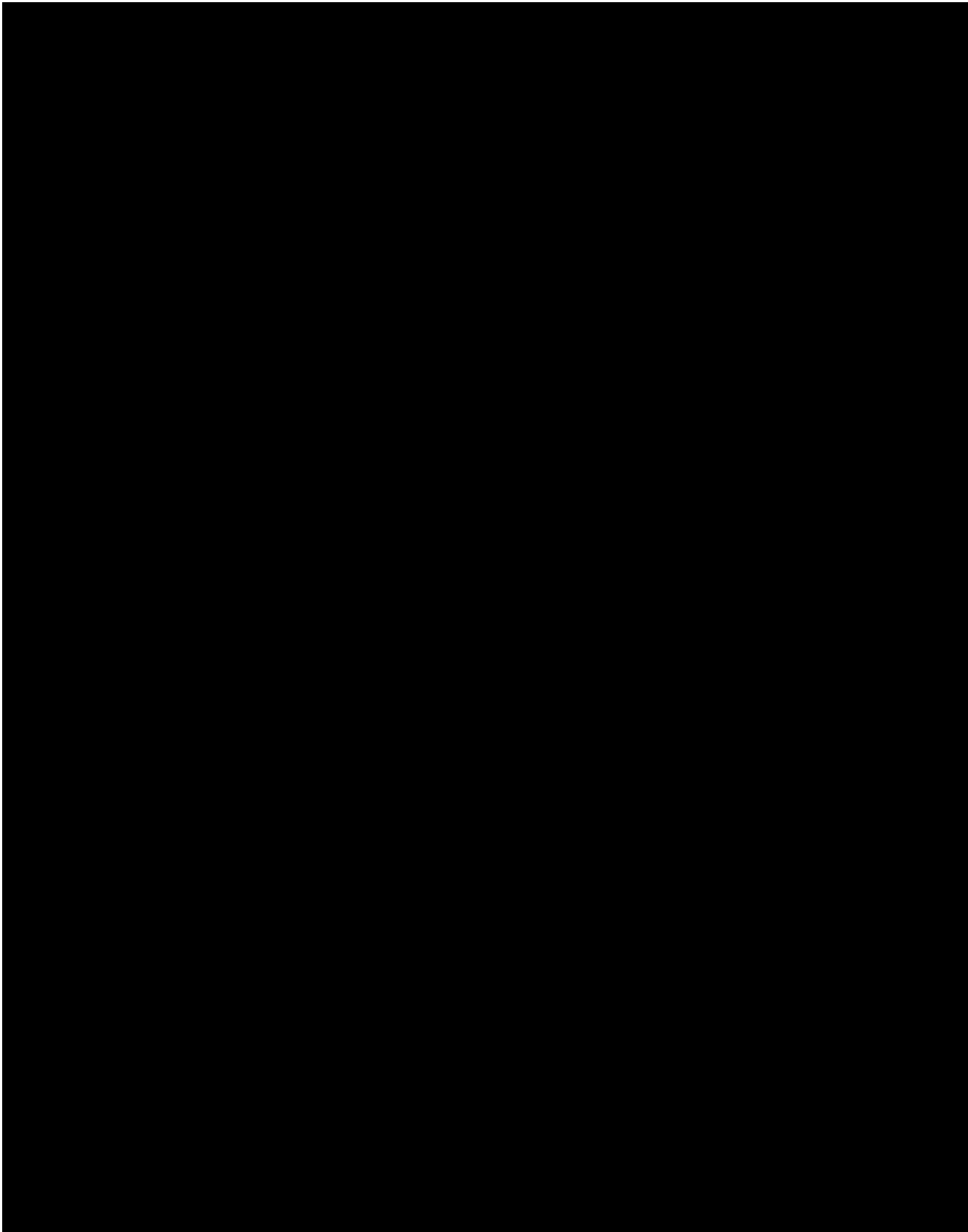
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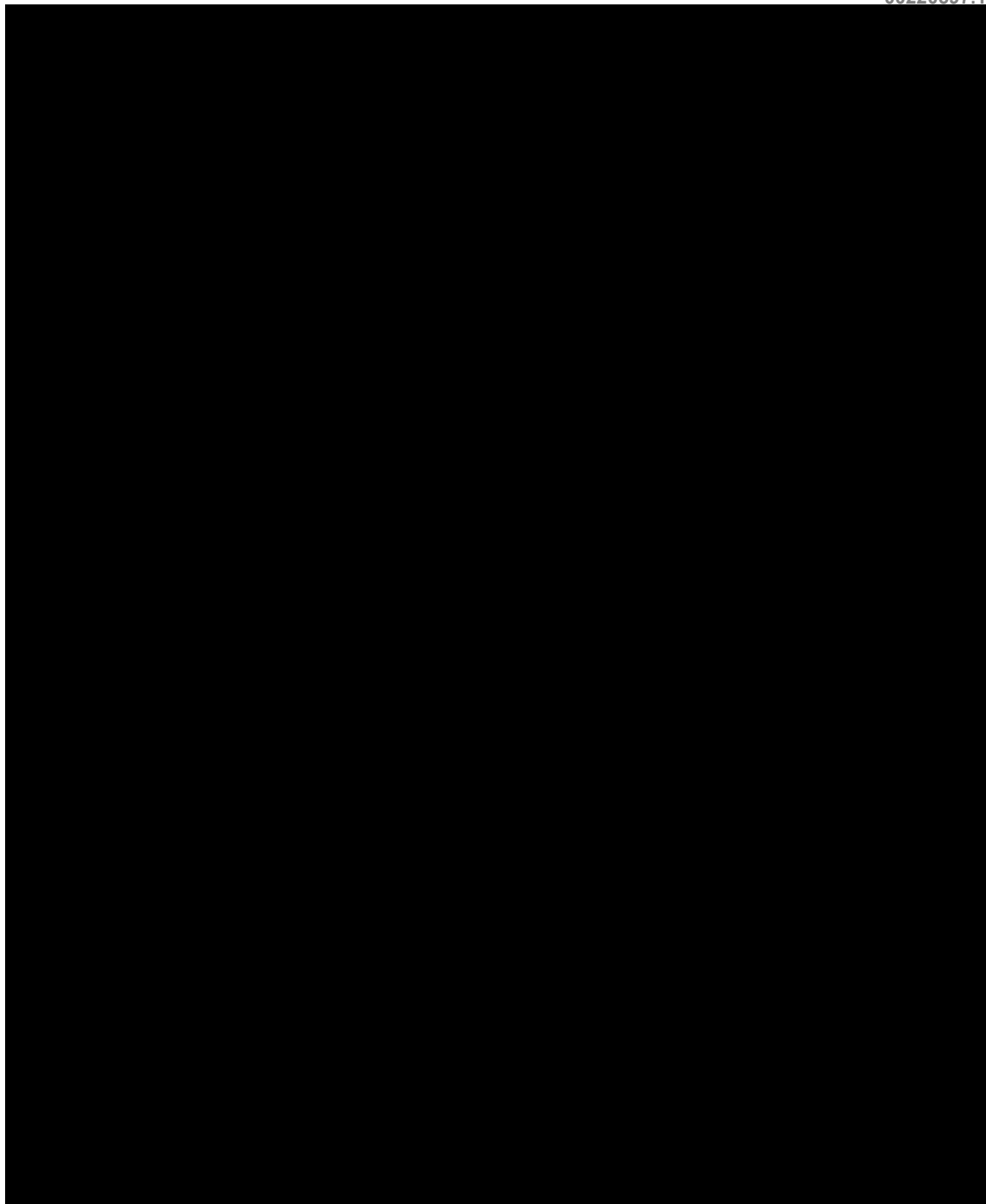
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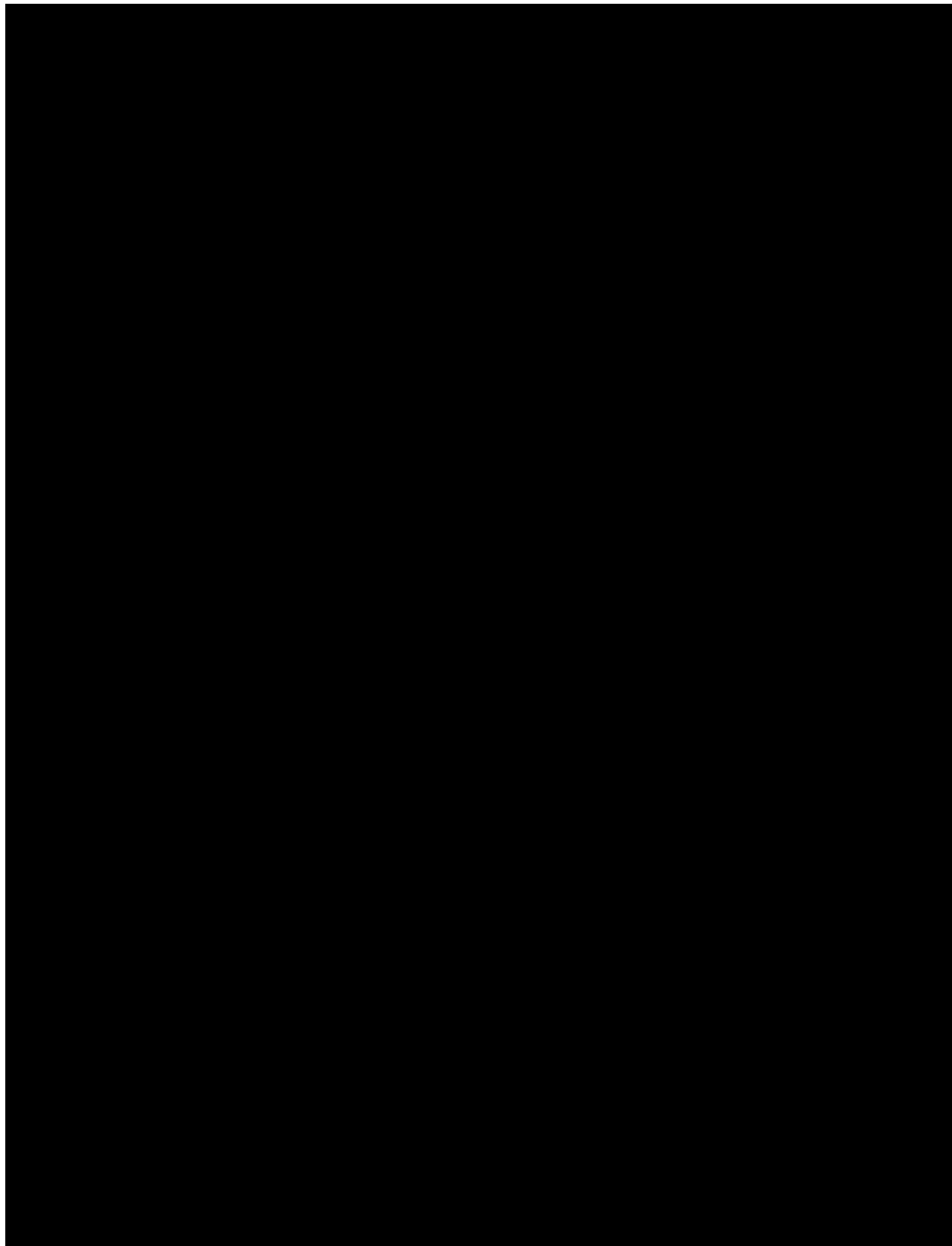


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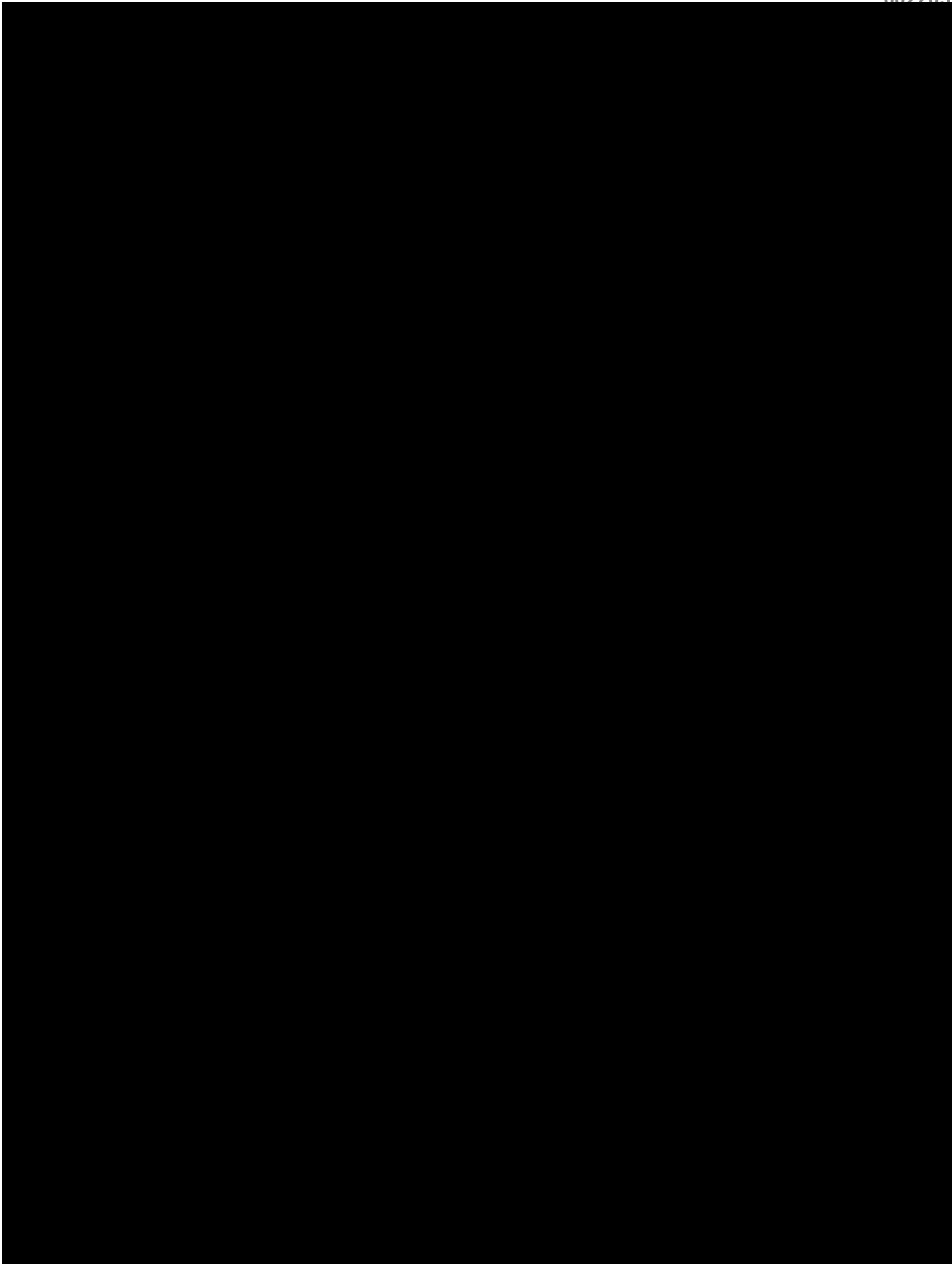


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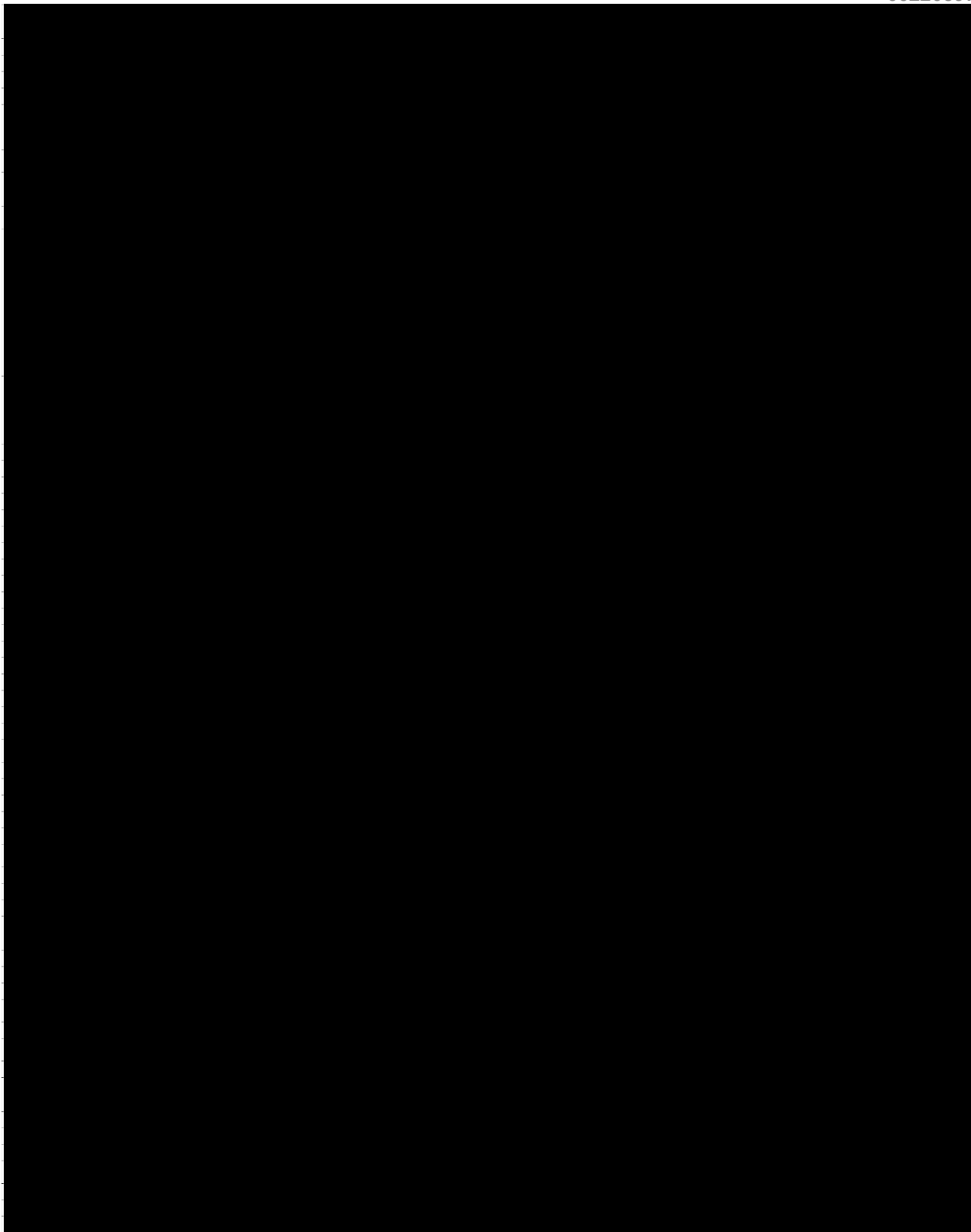
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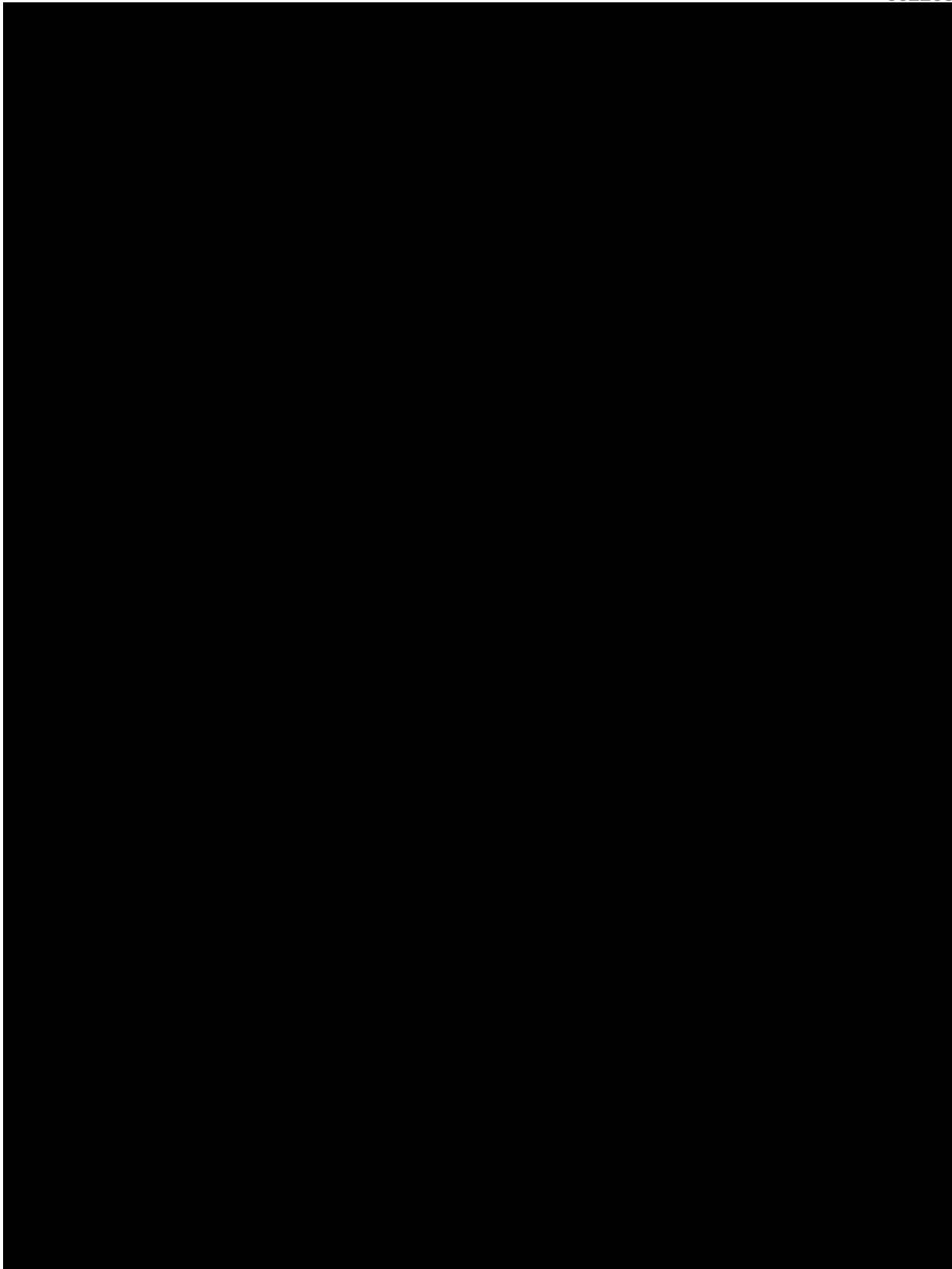
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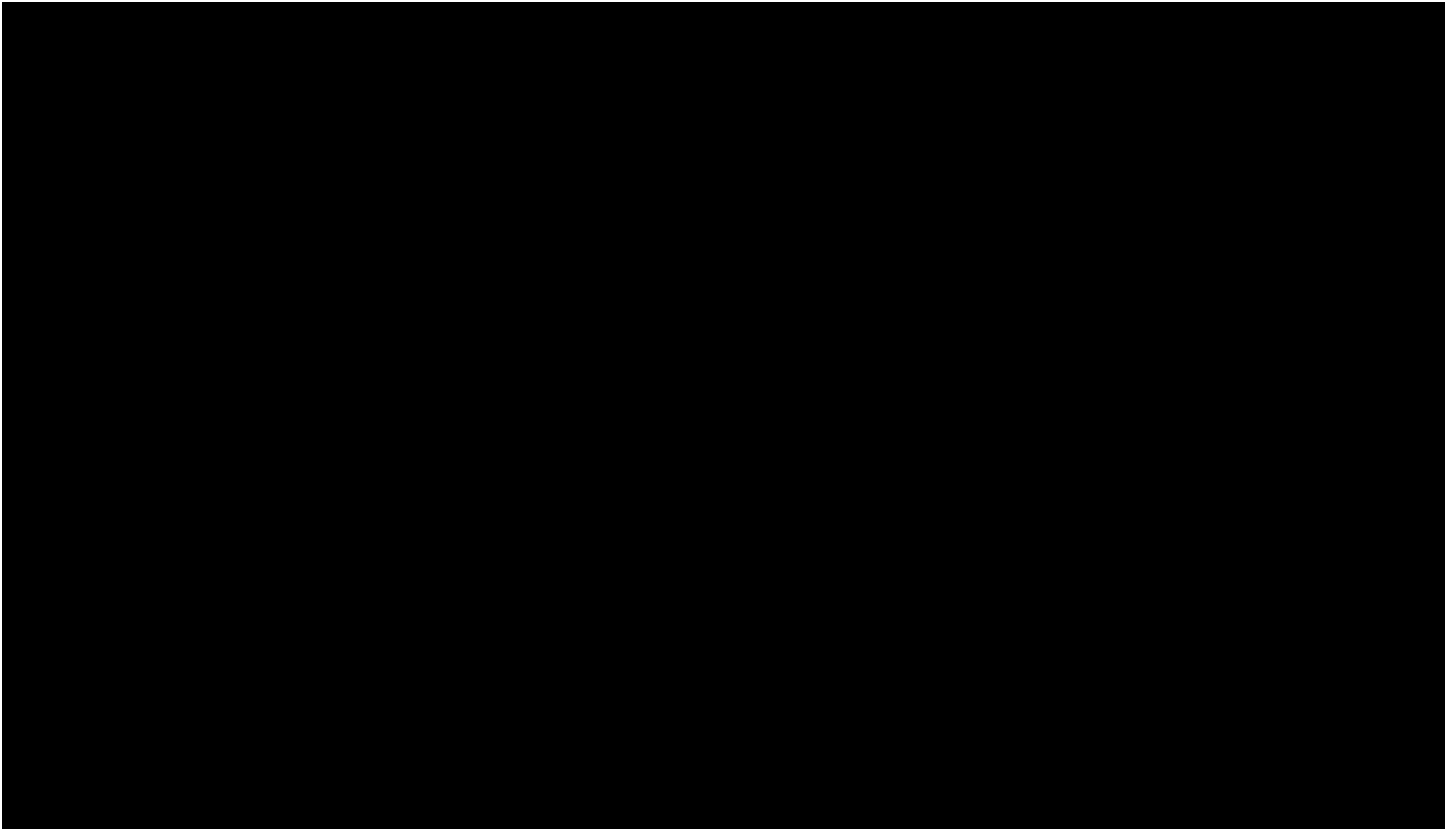


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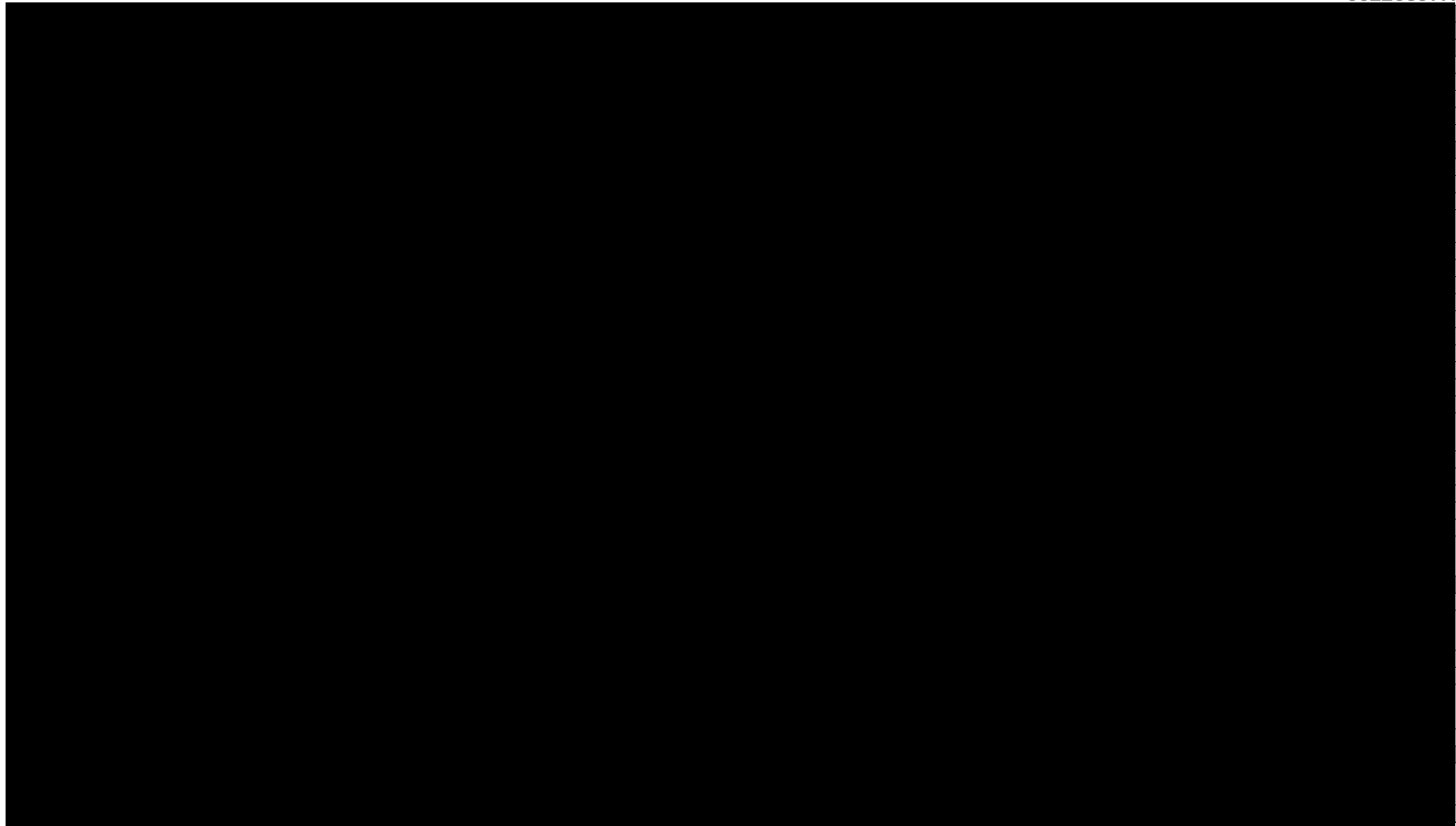


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Dodatek 8 k Příloze A



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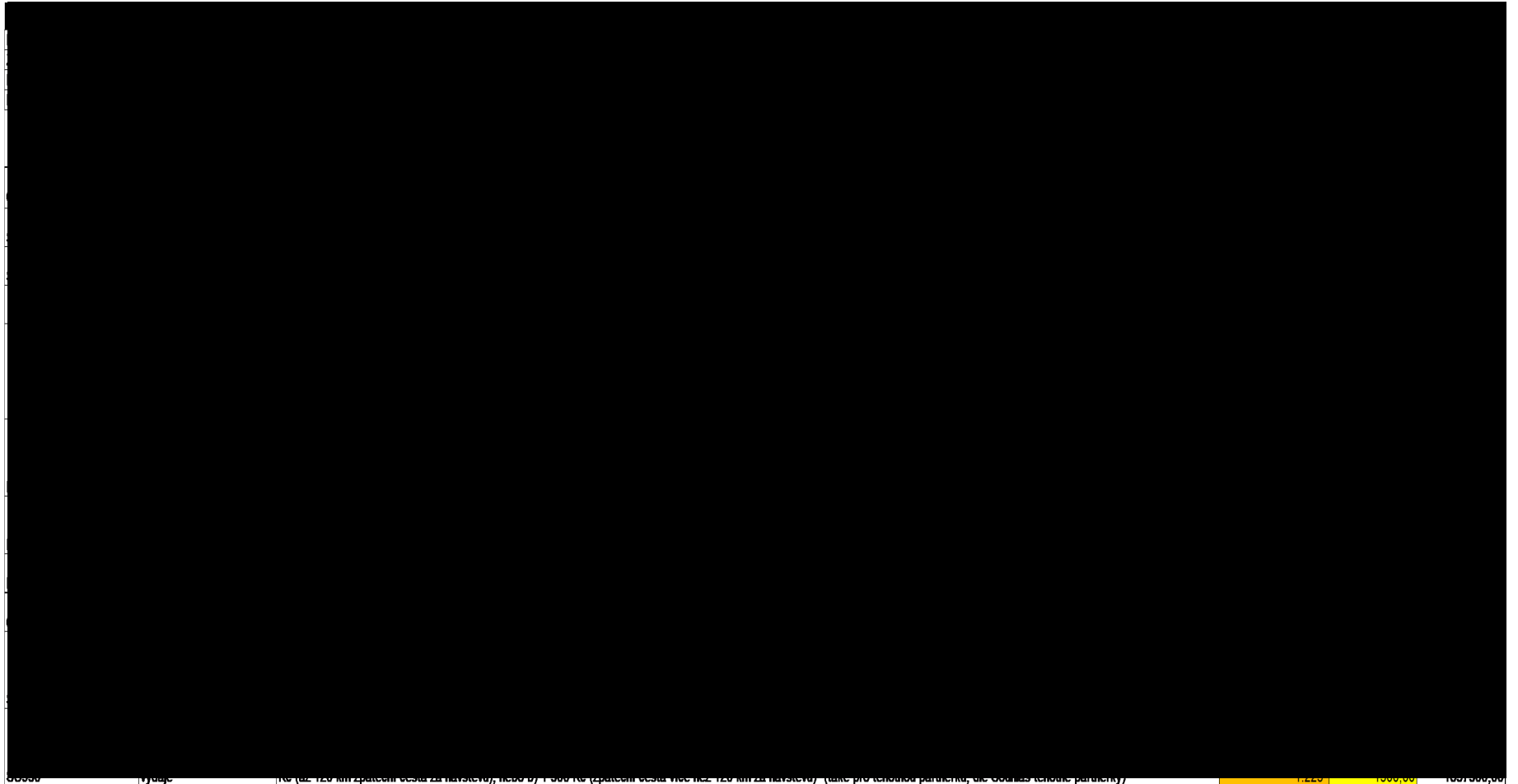
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Dodatek 9 k Příloze A



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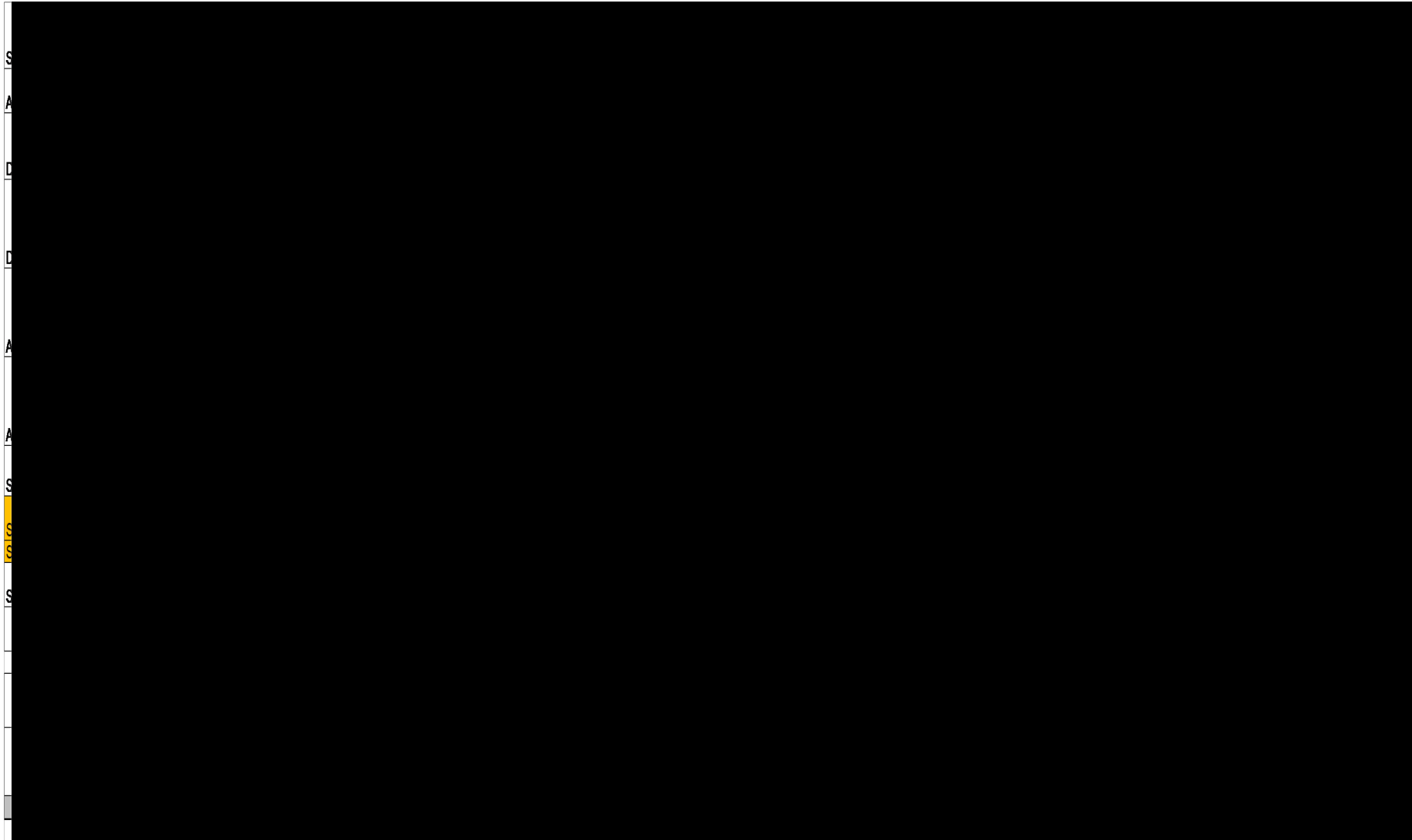
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