

TŘETÍ DODATEK KE SMLOUVĚ O KLINICKÉM HODNOCENÍ

Třetí dodatek („**Dodatek**“) ke Smlouvě o klinickém hodnocení, uzavřené s účinností od 19. září 2022 a pozměněné Dodatkem č. 1 ze dne 21. července 2023 a Dodatkem č. 2 ze dne 2. ledna 2025 (společně dále jen „**Smlouva**“), mezi **Fakultní nemocnicí Hradec Králové**, Sokolská 581, 500 05 Hradec Králové - Nový Hradec Králové, Česká republika, IC: 00179906, DIC: CZ00179906, zastoupenou [REDACTED] („**Poskytovatel zdravotních služeb**“) a [REDACTED] (**IV. Interní hematologická klinika**, zaměstnanec Poskytovatele zdravotních služeb („**Hlavní zkoušející**“) a **AbbVie, s. r. o.**, Metronom Business Center, Bucharova 2817/13, Stodůlky, 158 00 Praha 5, Česká republika, IČ: 24148725, DIČ: CZ24148725, zastoupená Mgr. Janem Balzerem, Country Clinical Operations Manager, 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. Na základě přijetí dodatku k Protokolu (**PV7BA5**) a zahrnutí dodatečných procedur, Rozpočet stanovený v Příloze A Smlouvy se zrušuje v celém svém rozsahu a nahrazuje se příloženou Přílohou A. Zde připojená Příloha A nabývá účinnosti k datu, ke kterému budou zajištěna veškerá schválení regulatorních úřadů a zároveň bude Dodatek uveřejněn v registru smluv.

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 Smlouvy v plné platnosti a účinnosti během trvání Smlouvy.

THIRD AMENDMENT TO THE CLINICAL STUDY AGREEMENT

Third Amendment (the “**Amendment**“) to that certain Clinical Study Agreement effective 19 August 2022, amended by Amendment no. 1 as of 21 July 2023 and Amendment no. 2 as of 2. January 2025 (collectively the “**Agreement**“), between **Fakultní nemocnice Hradec Králové**, Sokolská 581, postcode 500 05 Nový Hradec Králové, Czech Republic, Company ID: 00179906, Tax ID: CZ00179906, represented by [REDACTED] (the “**Provider of Medical Services**“) and [REDACTED] (**IV. Hematology Clinic**, employee of Provider of Medical Services (the “**Principal Investigator**“) 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 Mgr. Jan Balzer, Country Clinical Operations Manager, 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. Pursuant to Protocol Amendment (**PV7BA5**) and inclusion of additional procedures the Budget set forth in Exhibit A of the Agreement shall be deleted in its entirety and replaced with the attached Exhibit A. Exhibit A attached hereto shall be effective from the date that all required regulatory approvals are secured and the Amendment is published in Contracts Registry.

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.

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Tento Dodatek nabývá platnosti okamžikem podpisu všech smluvních stran a účinnosti okamžikem uveřejnění dle zákona č. 340/2015 Sb., o registru smluv. Poskytovatel zdravotních služeb vyžaduje zaslat společností AbbVie revidovanou a písemně odsouhlasenou finální verzi dodatku ve strojově čitelném formátu s podbarveným (redigovaným) textem, který společnost AbbVie považuje za obchodní tajemství dle ust. § 504 zákona č. 89/2012 Sb., občanského zákoníku. Společnost AbbVie považuje za své obchodní tajemství následující informace: přehled plateb a plánovaný počet subjektů hodnocení na daném pracovišti, jména a funkce pověřených osob k podpisu smluv vyjma statutárních zástupců. Tyto informace jsou běžně nedostupné veřejně či v příslušných obchodních kruzích a pro společnost AbbVie konkurenčně významné. Uveřejnění takových osobních údajů a obchodních tajemství by tak mohlo poškodit zájmy společnosti AbbVie. Poskytovatel zdravotních služeb je povinen získat souhlas společnosti AbbVie před uveřejněním redigovaného dodatku nad rámec podbarveného textu ze strany společnosti AbbVie.

Předpokládaná hodnota Smlouvy ve znění tohoto Dodatku představuje **29.774.555,- Kč**.

This Amendment shall enter into force at the moment of signature of all parties and effective at the time of publication pursuant to Act No. 340/2015 Coll., on the register of contracts. The Provider of Medical Services requires AbbVie to send AbbVie a revised and approved final version of the Amendment in a machine-readable format with colored (redacted) text that AbbVie considers to be a trade secret in accordance with Section 504 of Act No. 89/2012 Coll., Civil Code. AbbVie considers the following information to be a trade secret: a summary of payments and the planned number of evaluators in a given workplace, the names and functions of the persons authorized to sign contracts, excluding statutory representatives. This information is not normally available publicly or in relevant business circles and is competitively relevant to AbbVie. The disclosure of such personal information and trade secrets could harm AbbVie's interests. The Provider of Medical Services is required to obtain AbbVie's consent before AbbVie publishes a redacted Amendment beyond the colorized text

Anticipated value of the Agreement amended by the Amendment is **CZK 29,774,555.00**

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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..

AbbVie s.r.o.

Fakultní nemocnice Hradec Králové

By/Podepsal: _____

By/Podepsal: _____

Name/Jméno: _____

Name/Jméno: _____

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

Title/Funkce: Director / ředitel

Date/Datum: 29.9.2025

Date/Datum: 8.10.2025

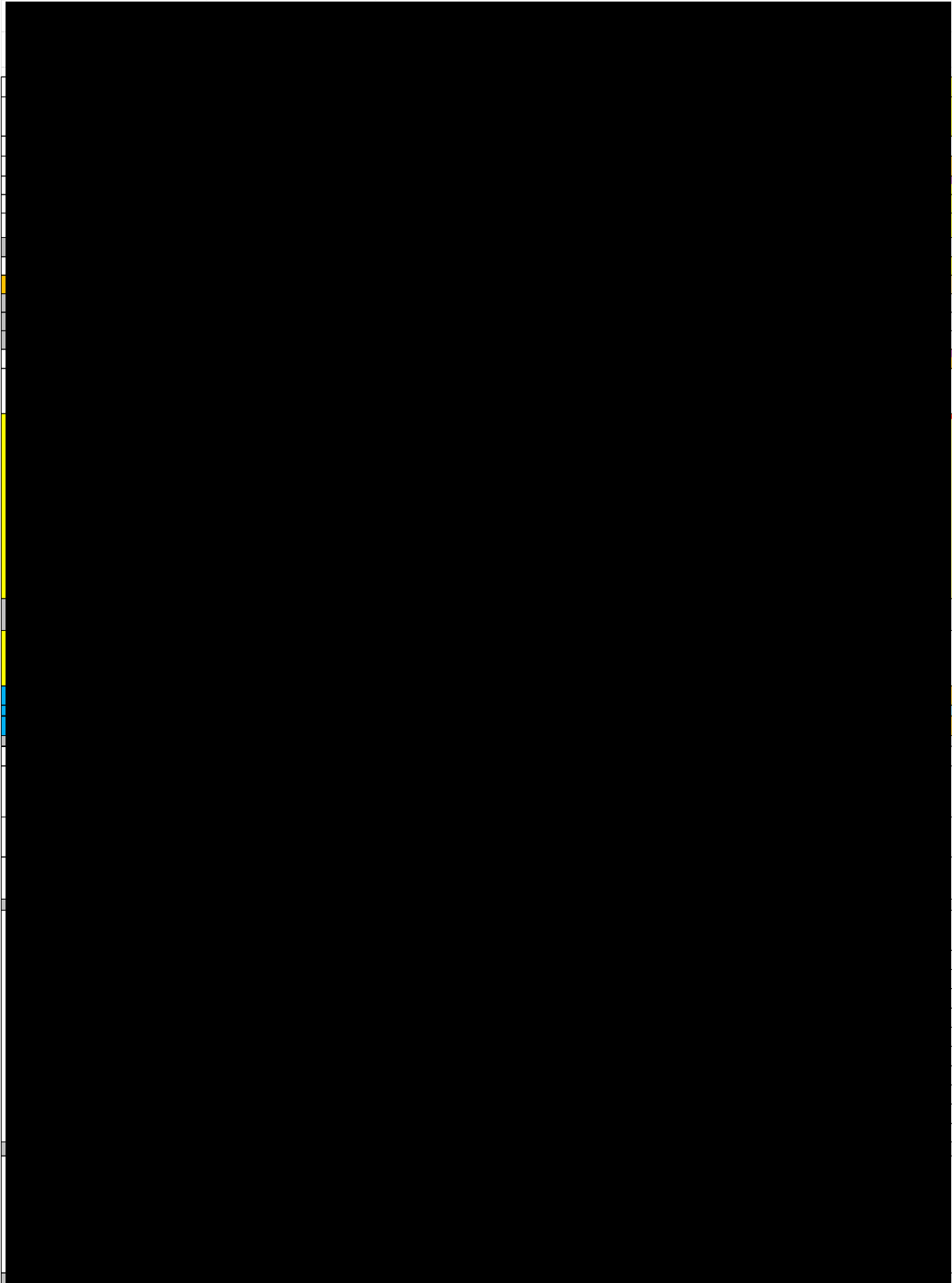
By/Podepsal: _____

Name/Jméno: _____

Title/Funkce: Principal Investigator / Hlavní zkoušející

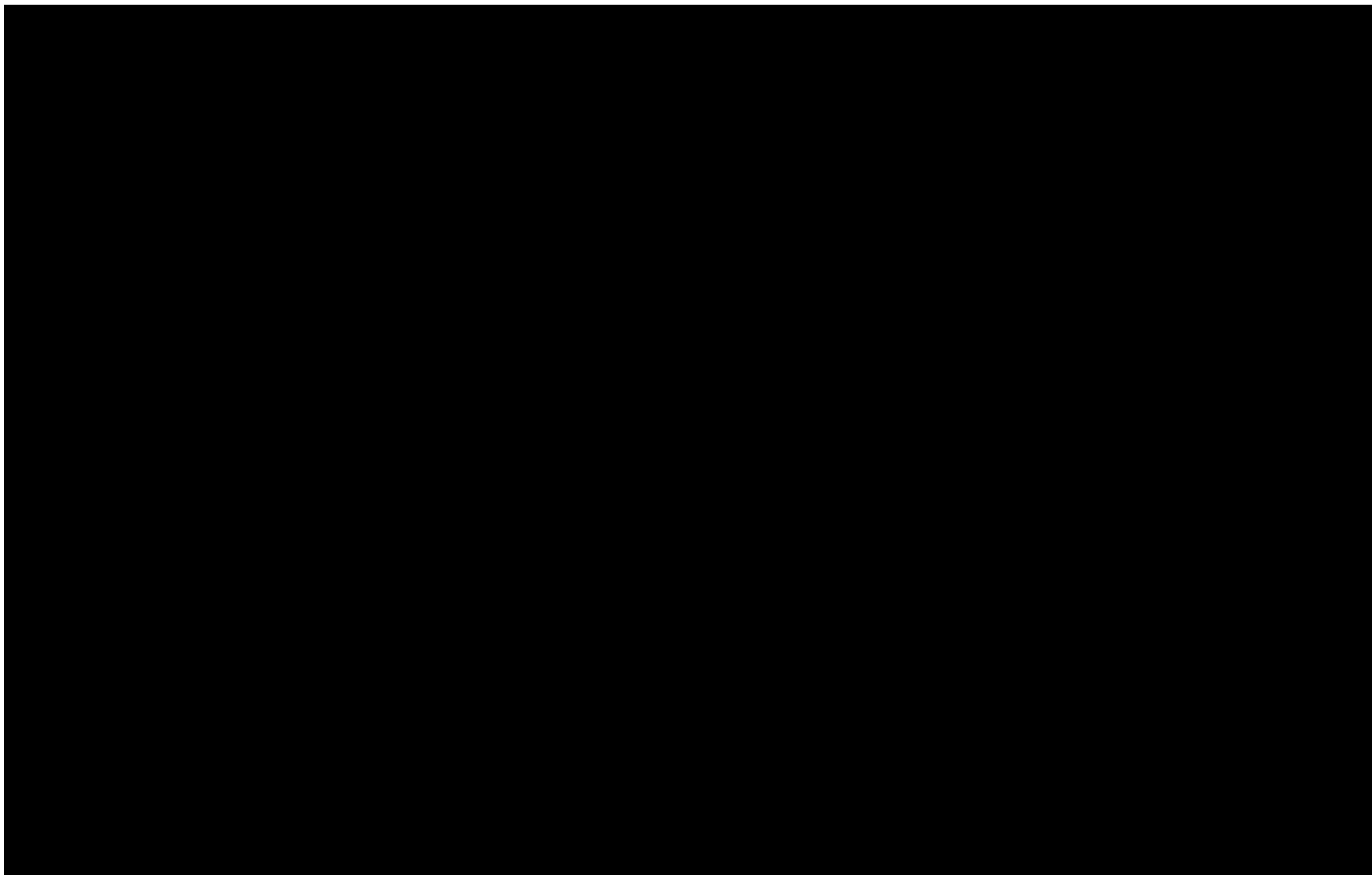
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Attachment 1 to Exhibit A



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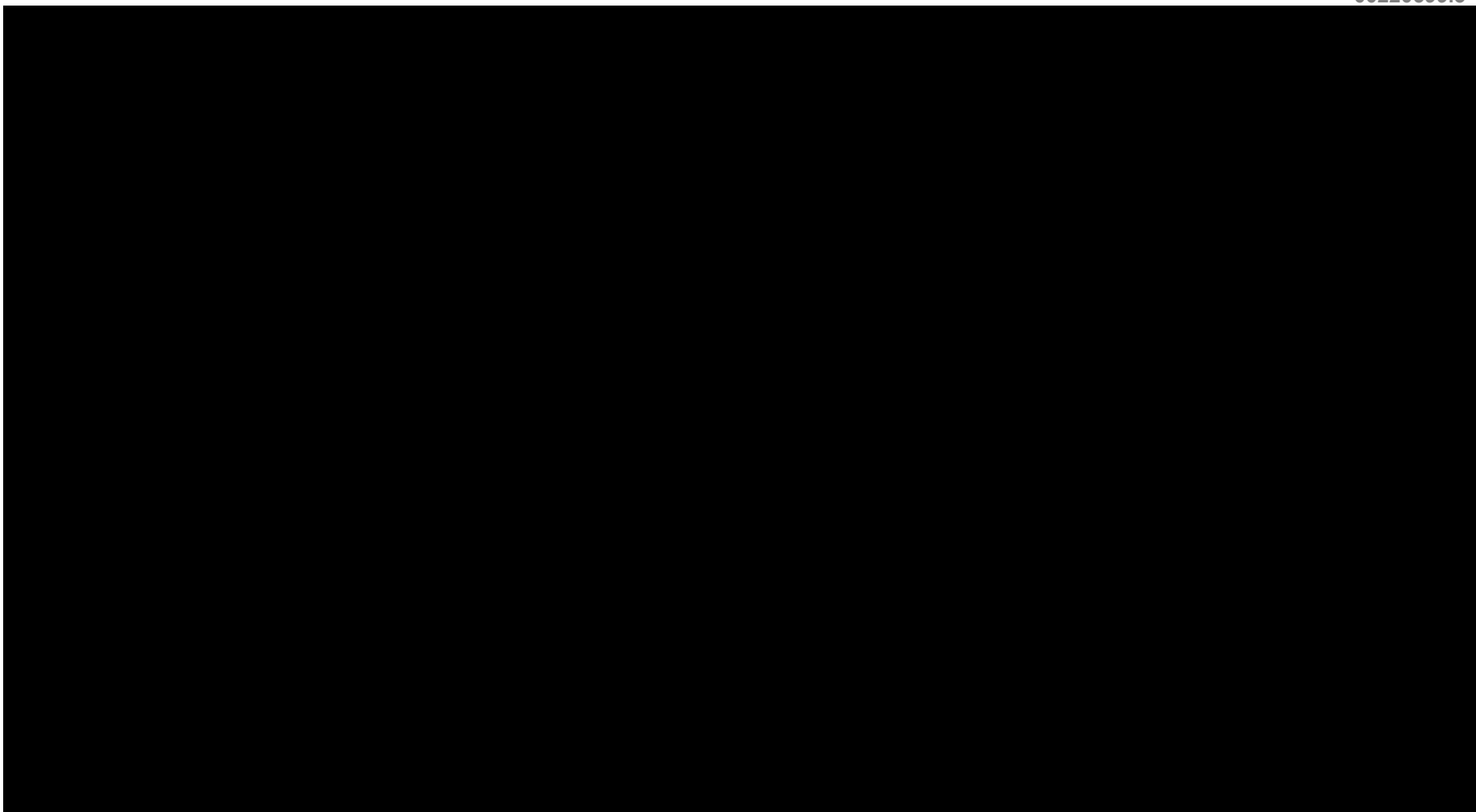
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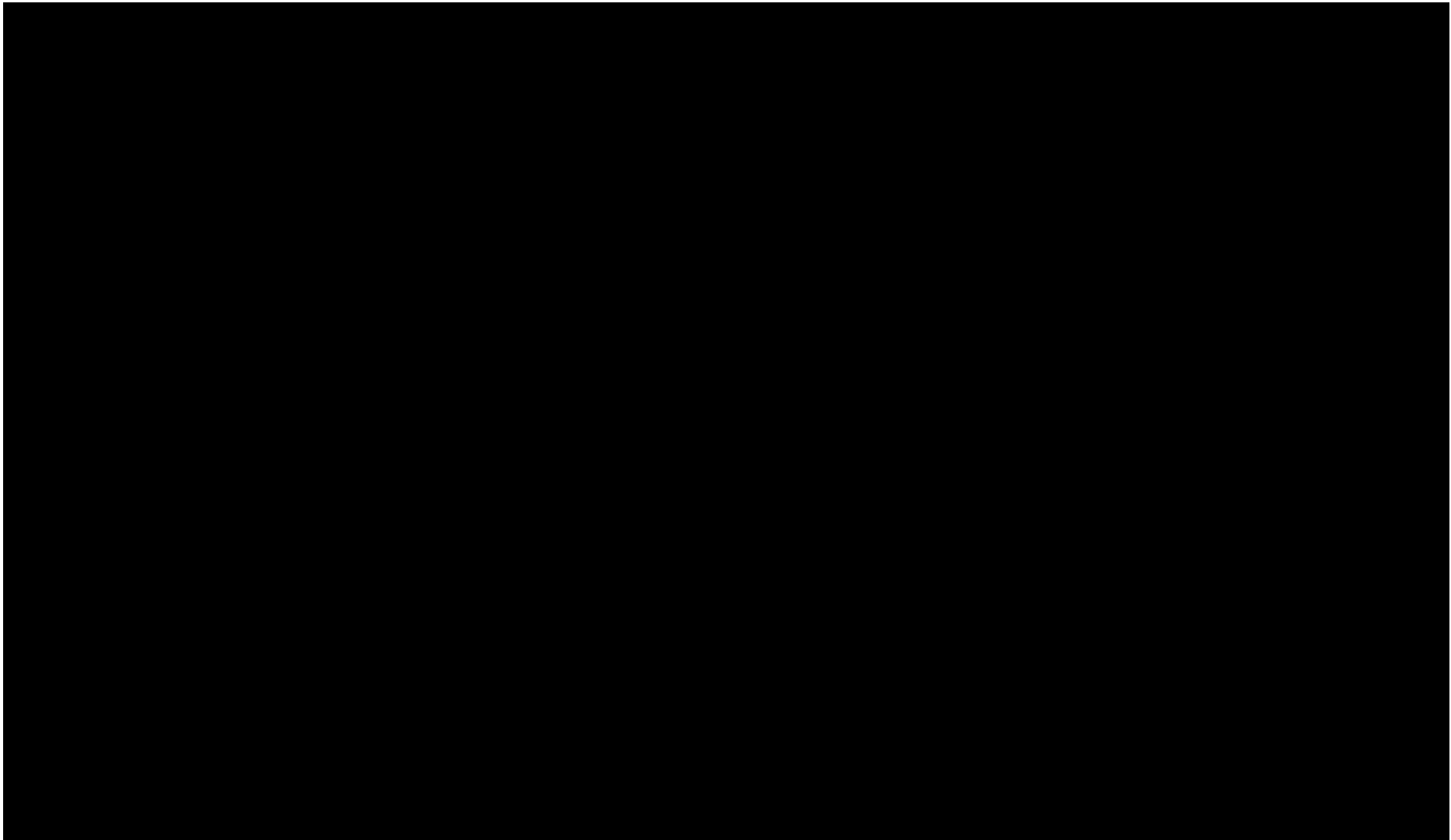
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Attachment 2 to Exhibit A



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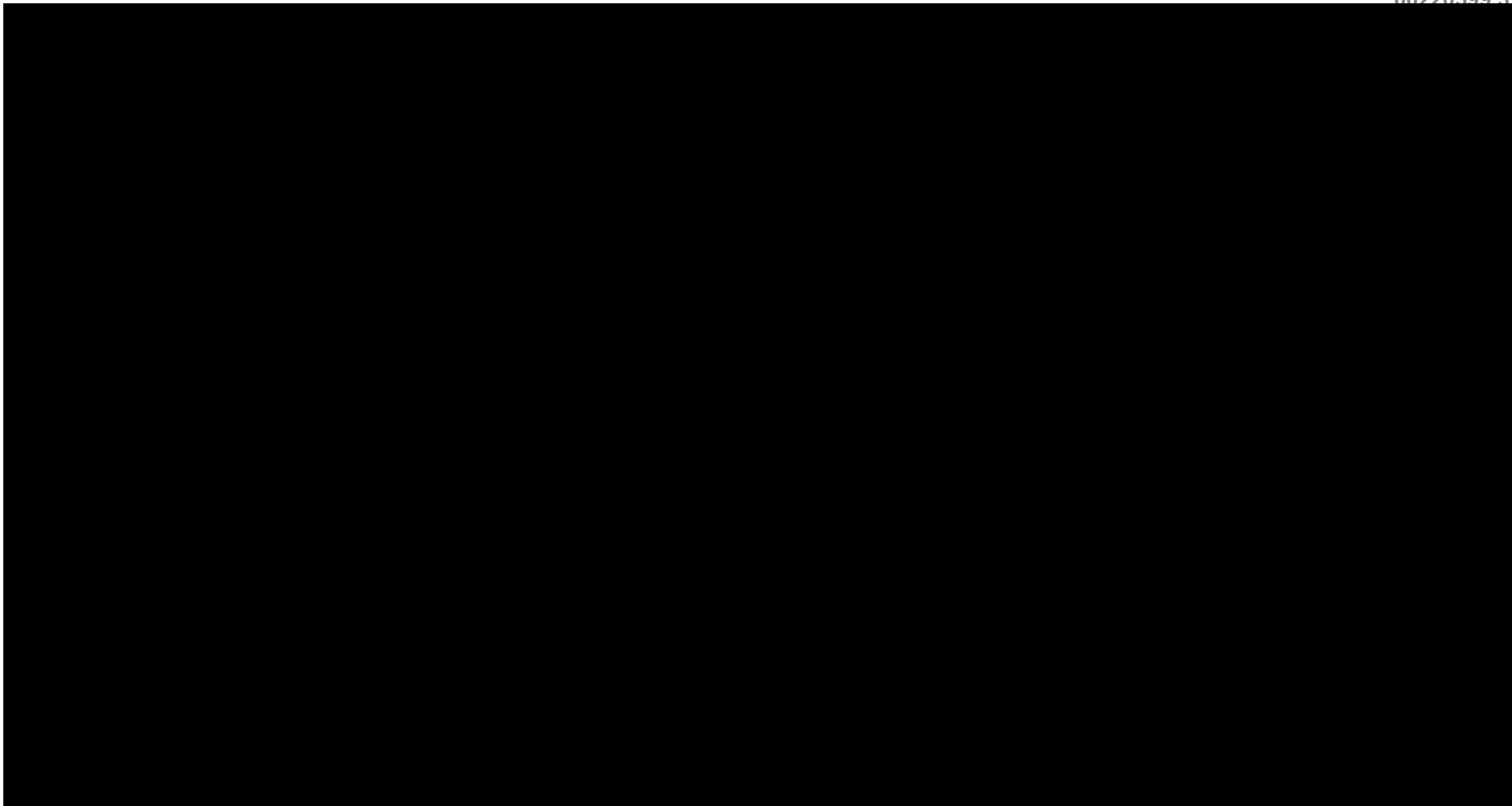
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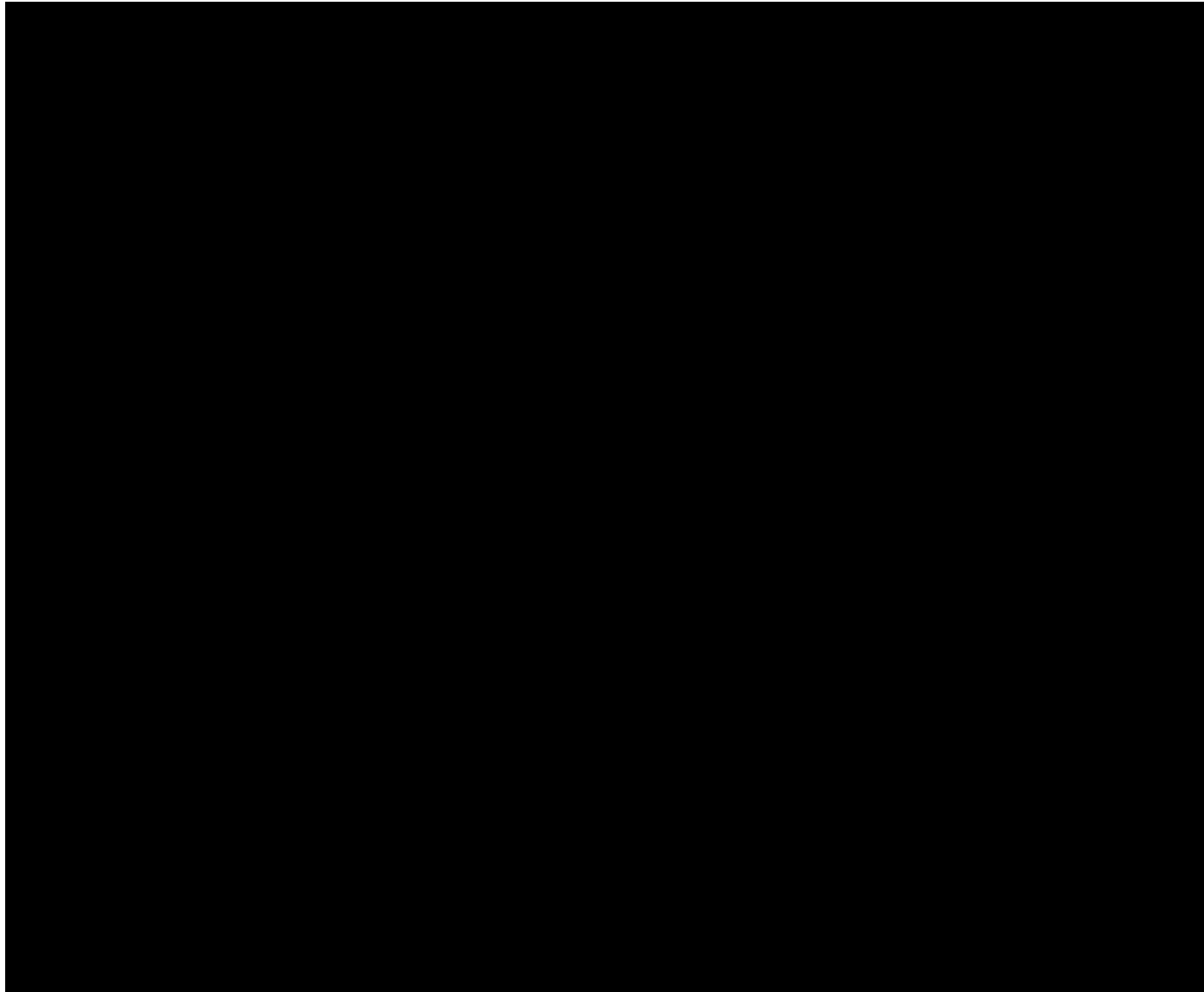
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Attachment 3 to Exhibit A



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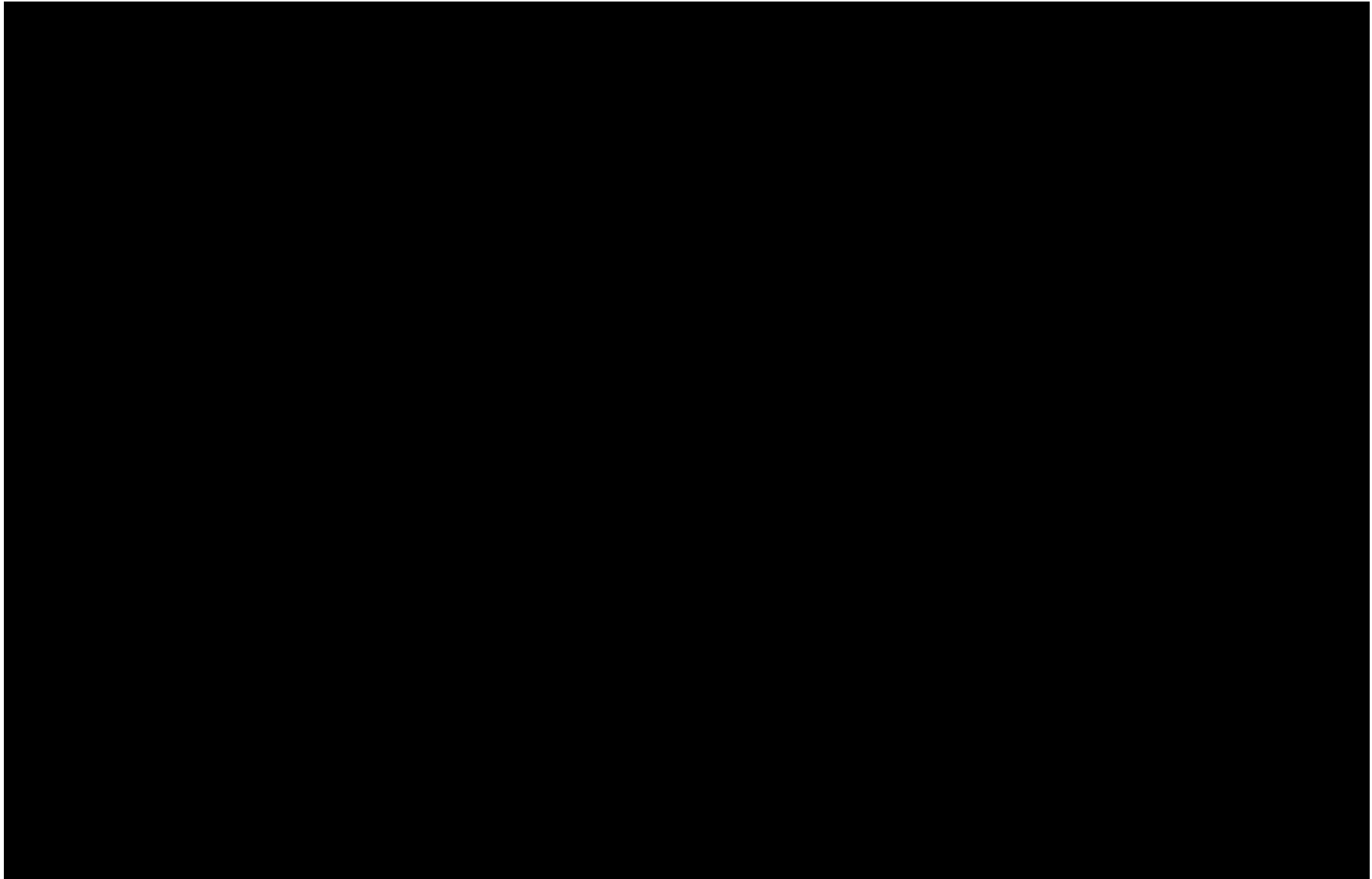
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Attachment 4 to Exhibit A



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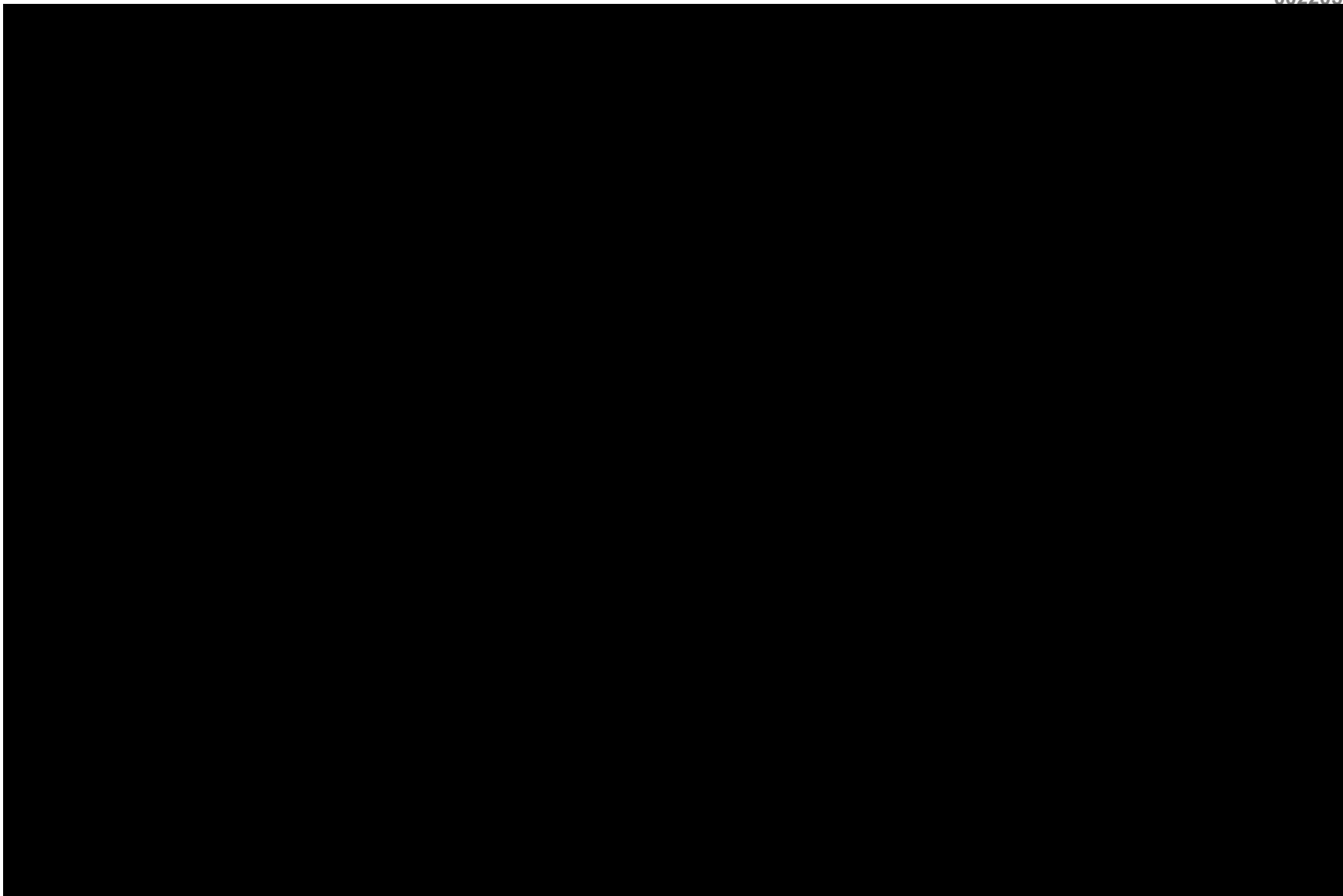
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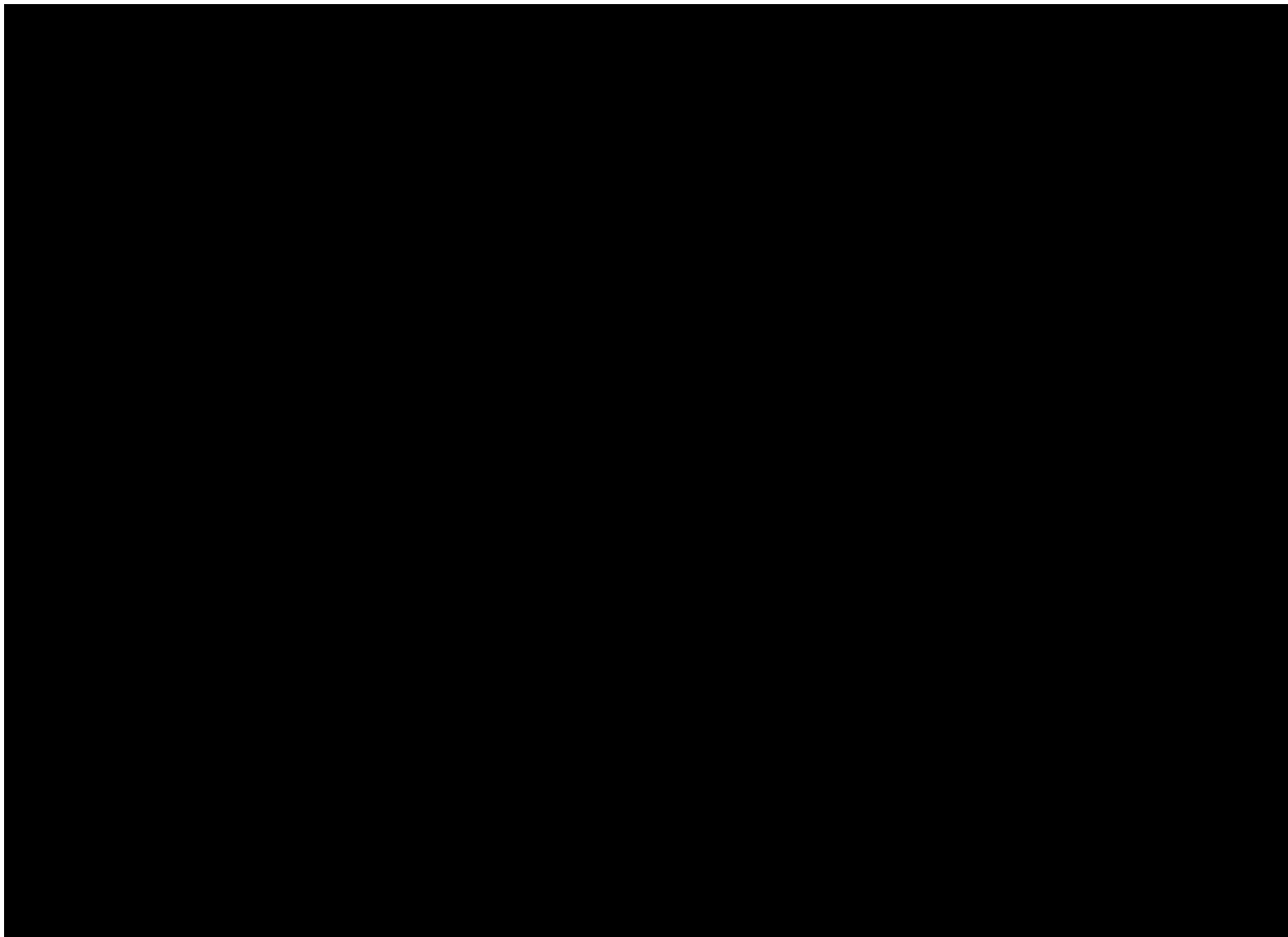
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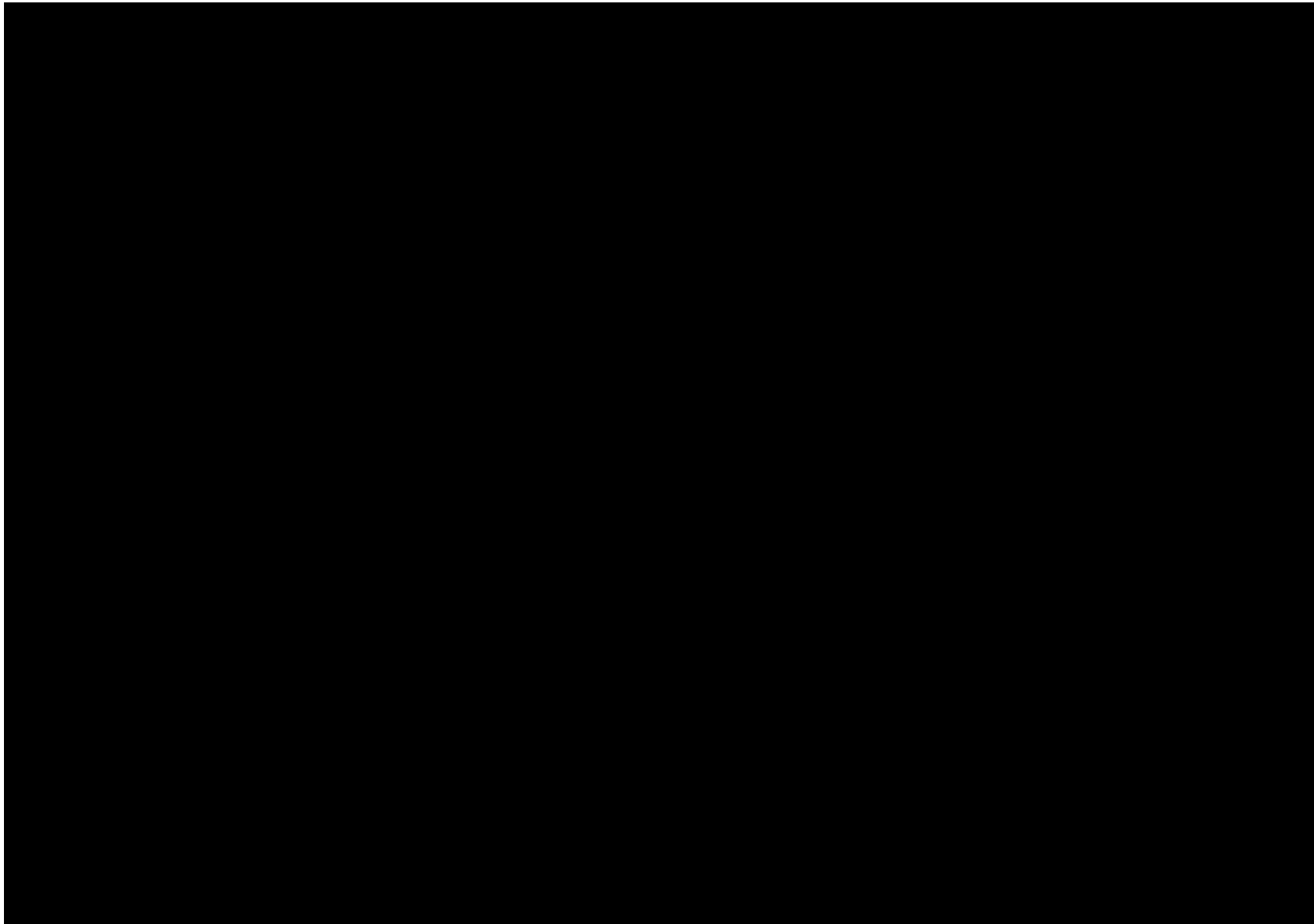
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Attachment 5 to Exhibit A



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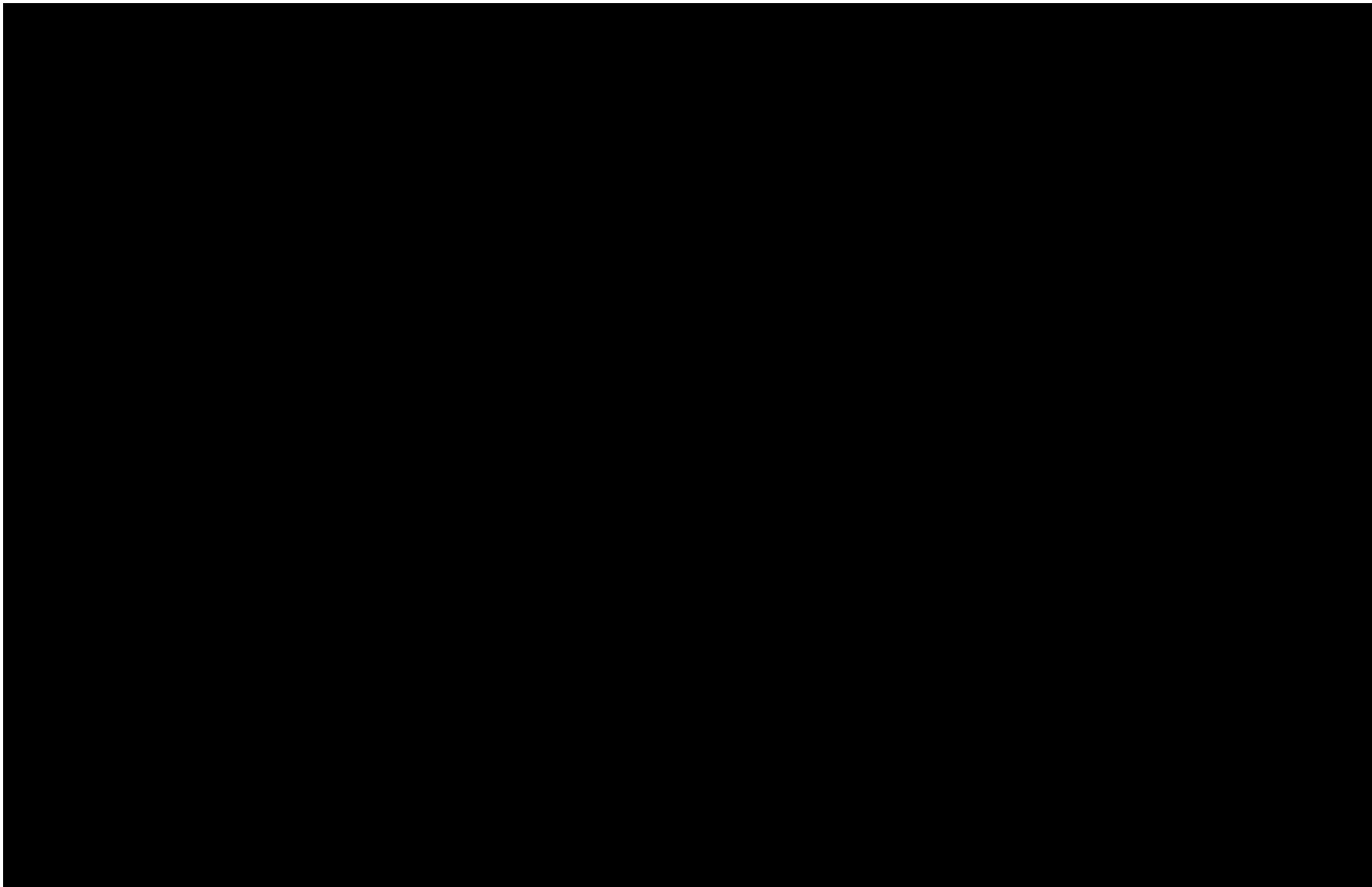
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Attachment 6 to Exhibit A



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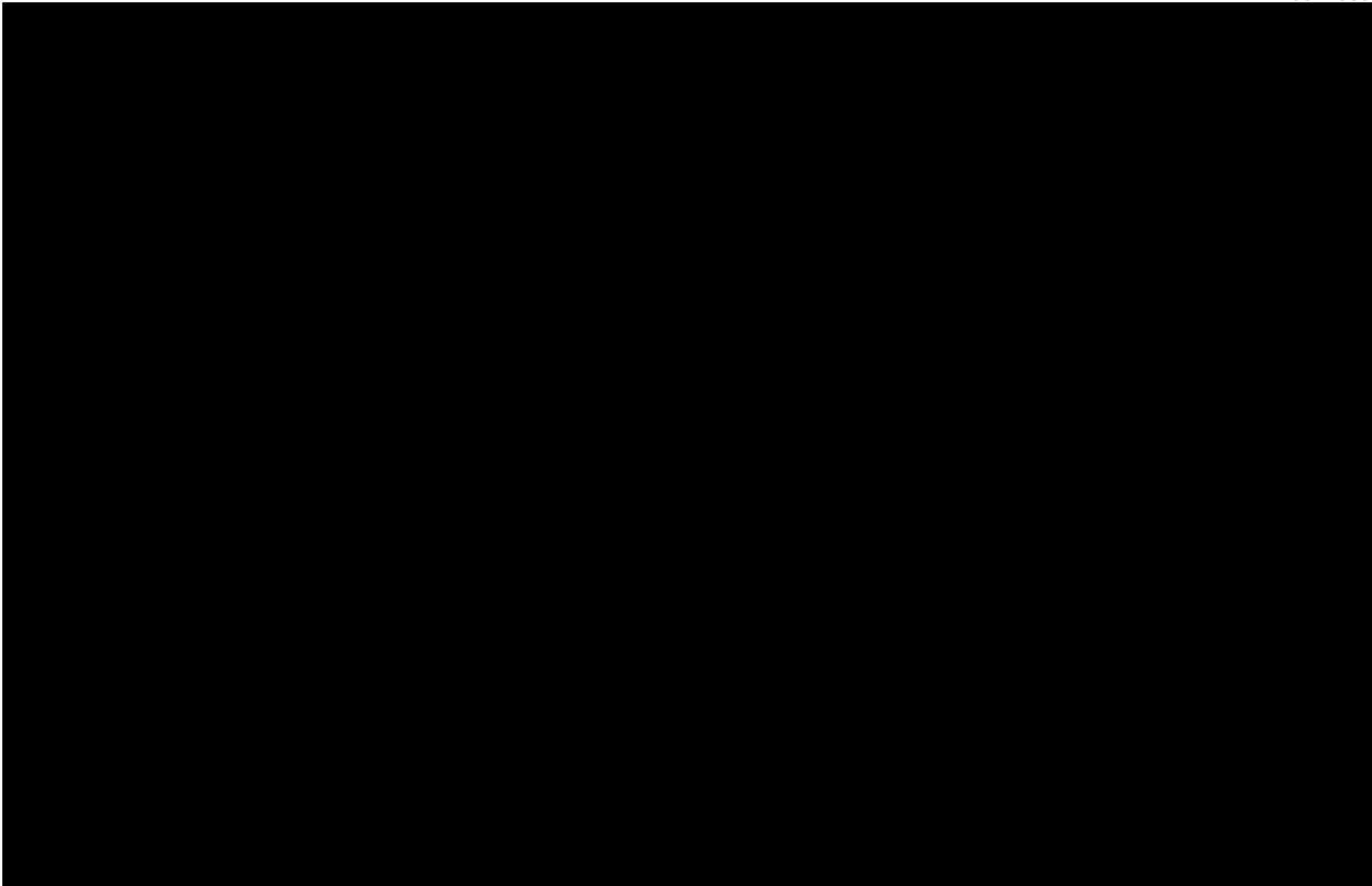
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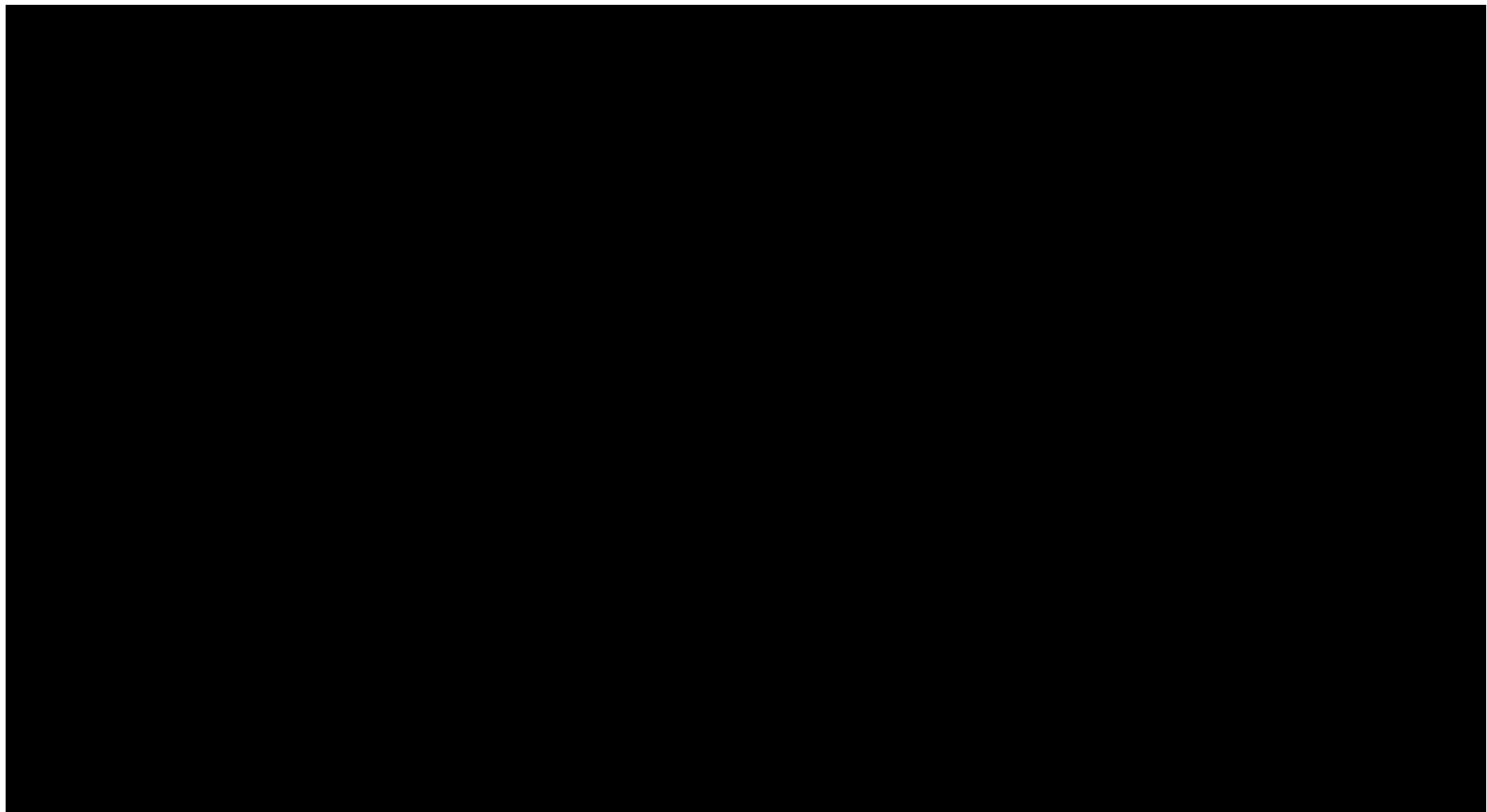
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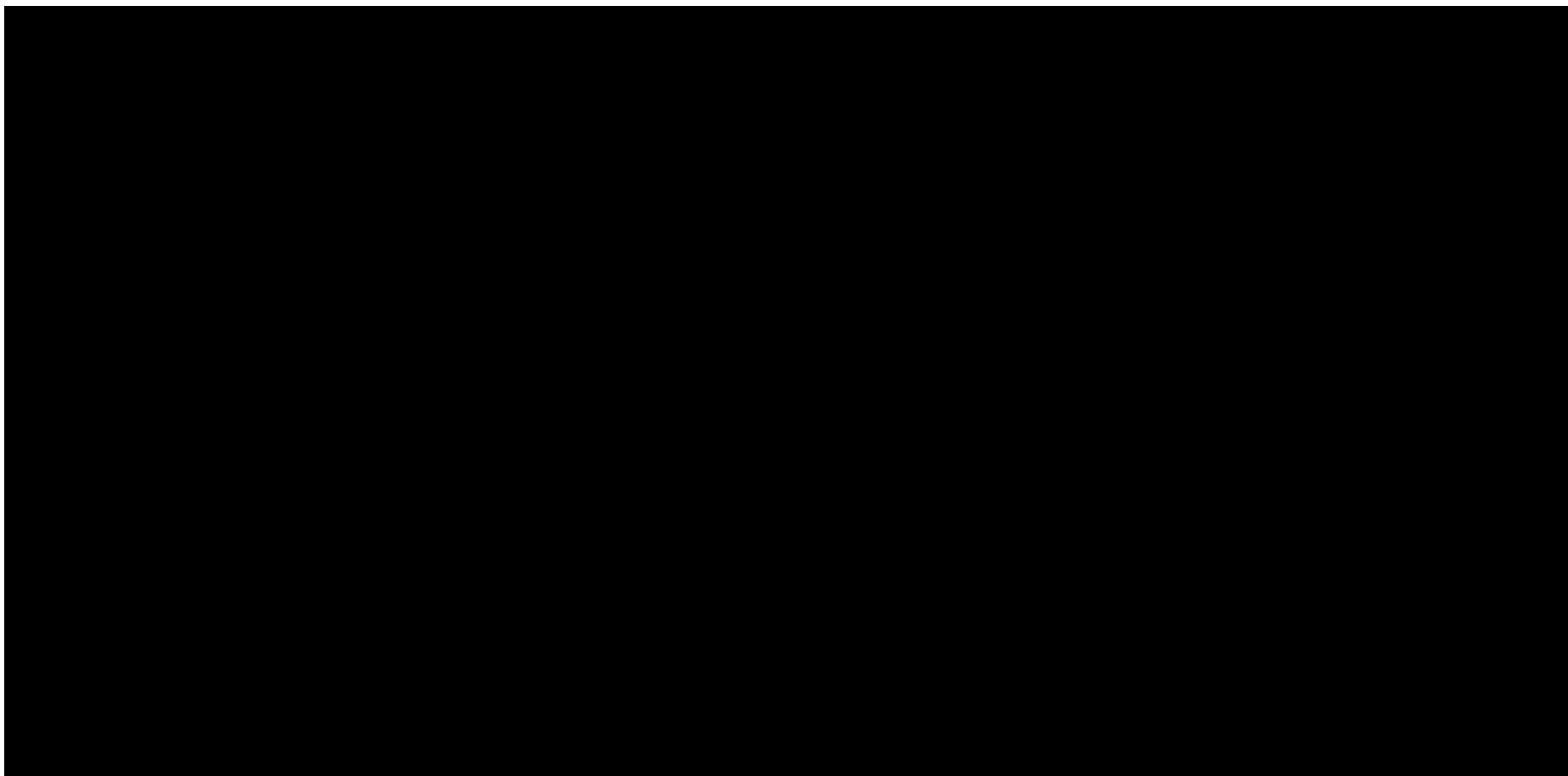
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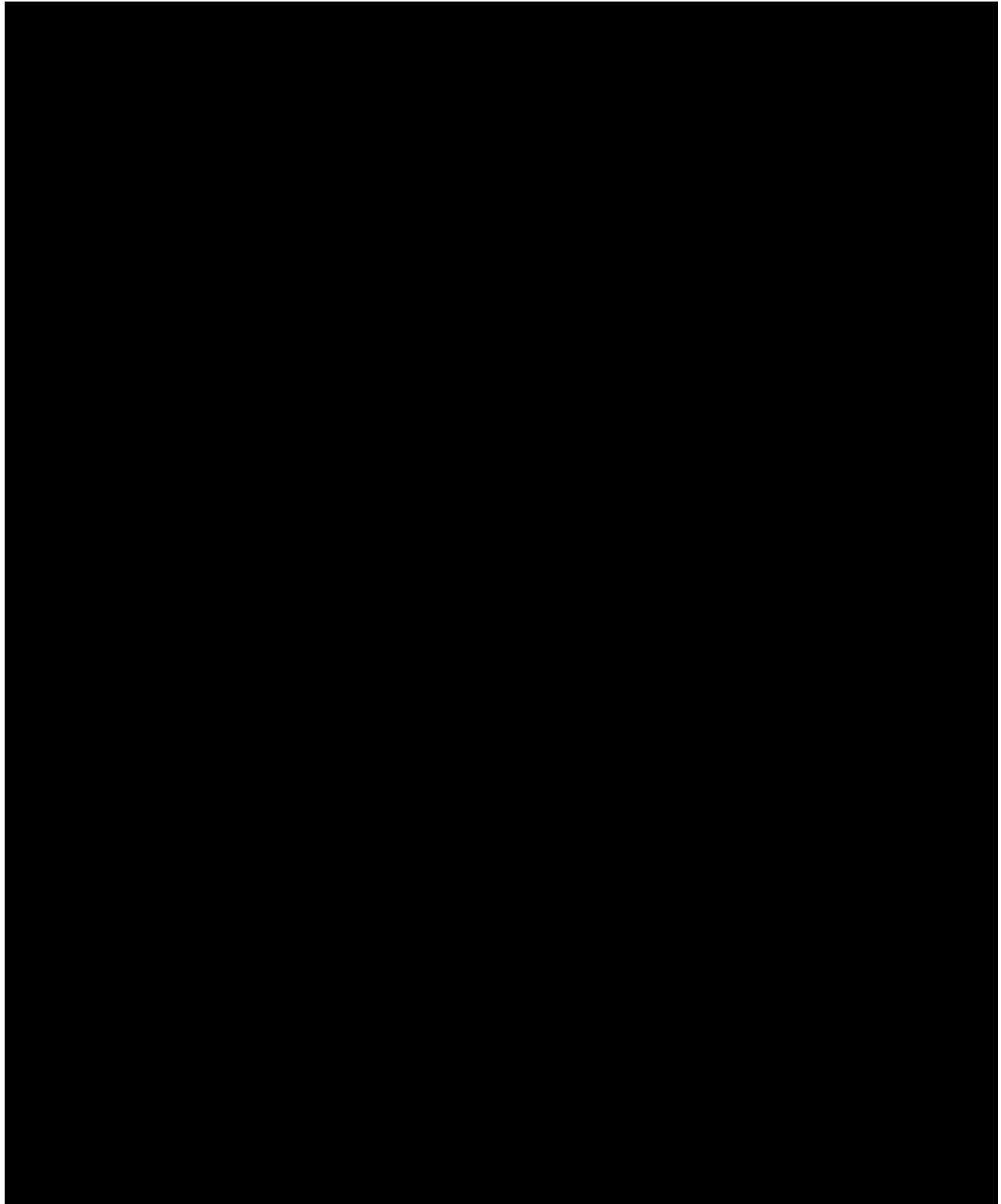
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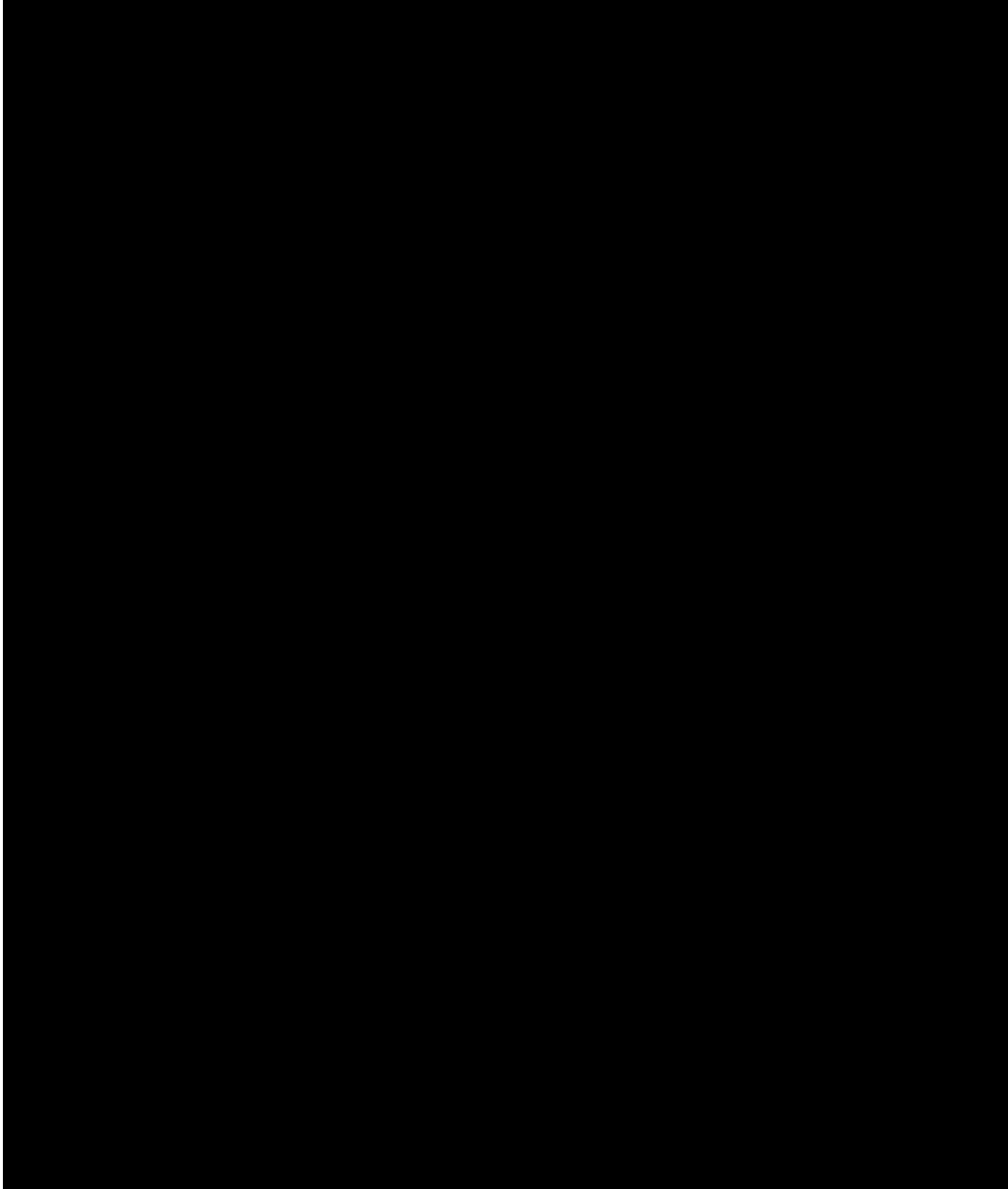
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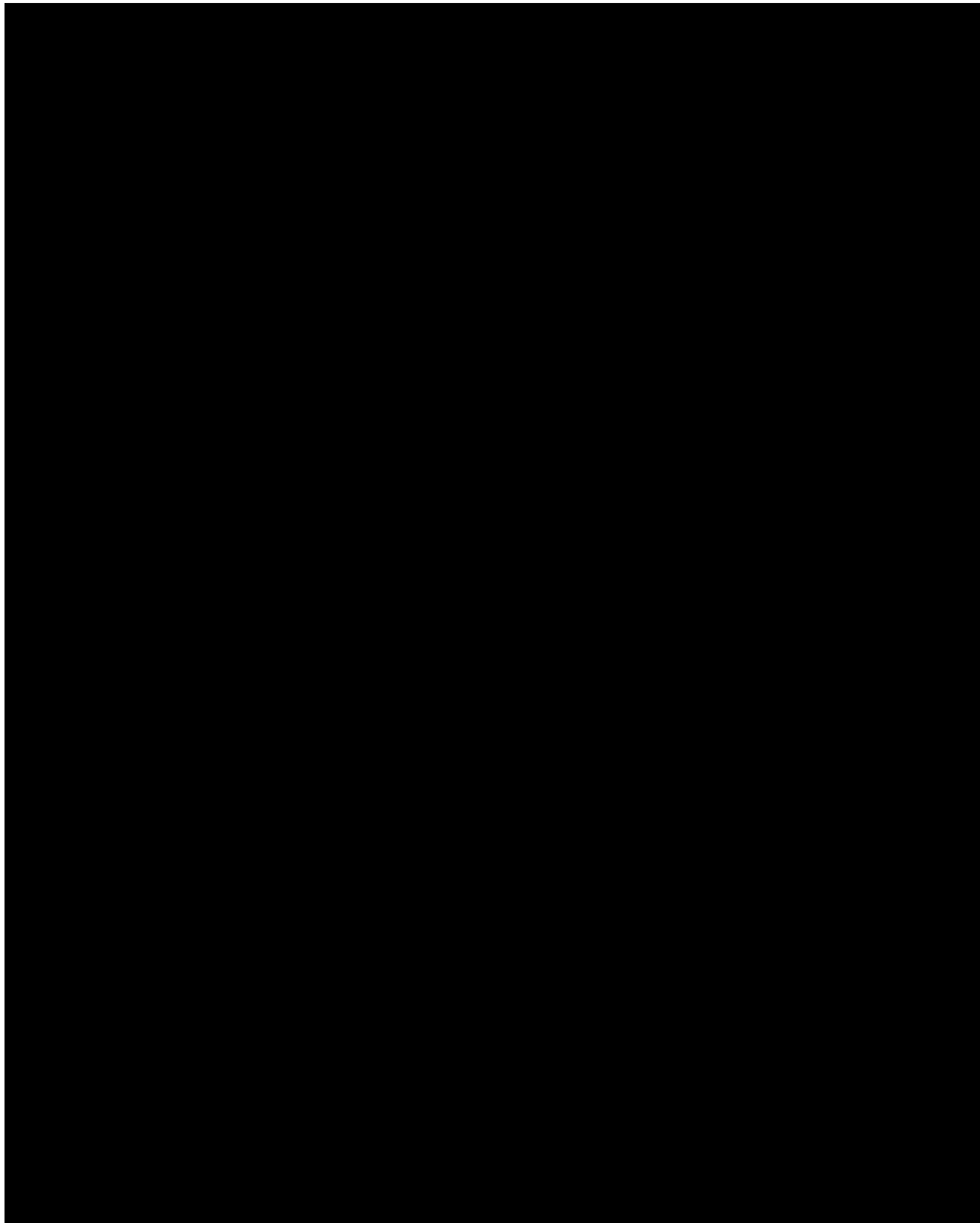
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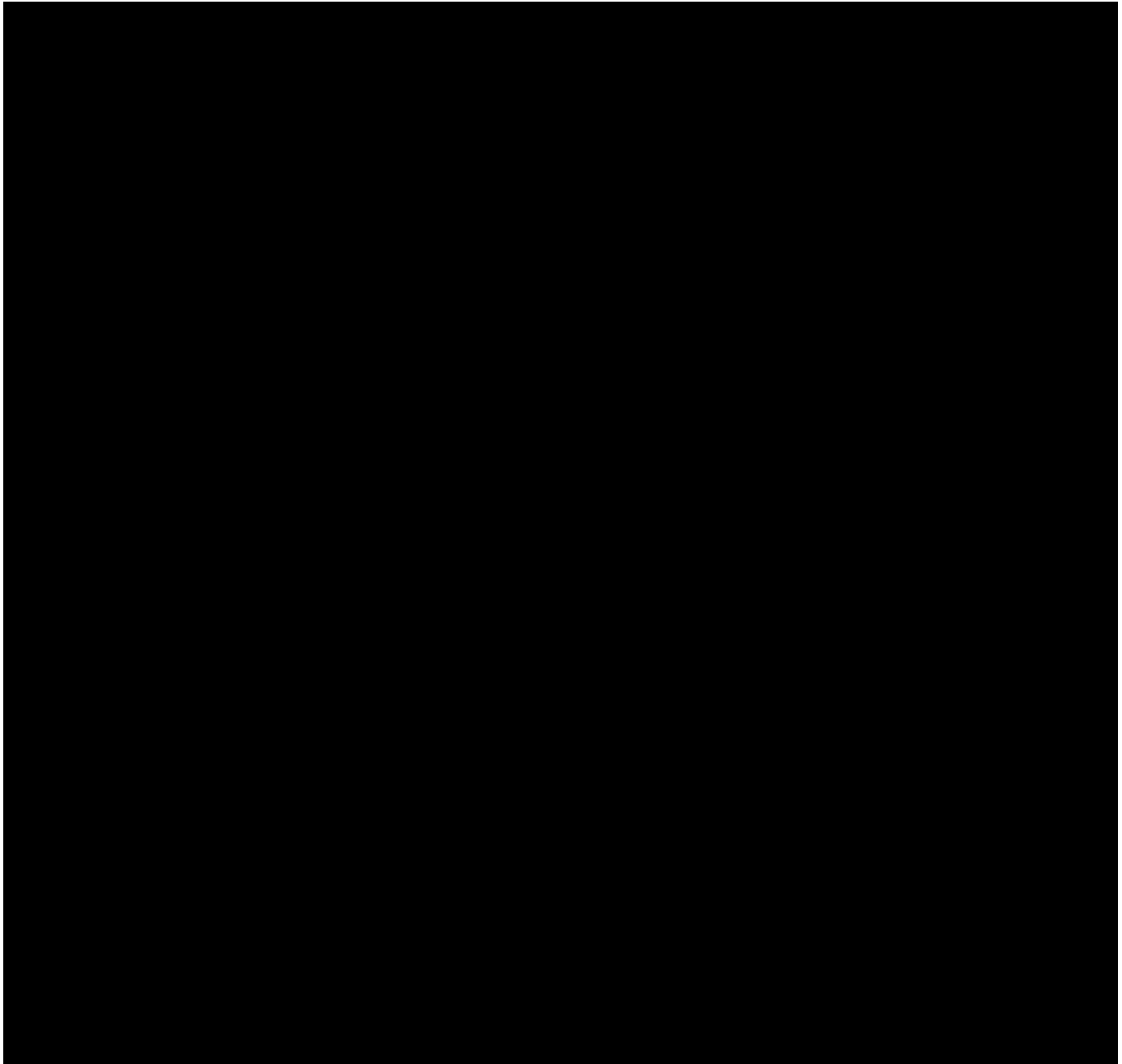
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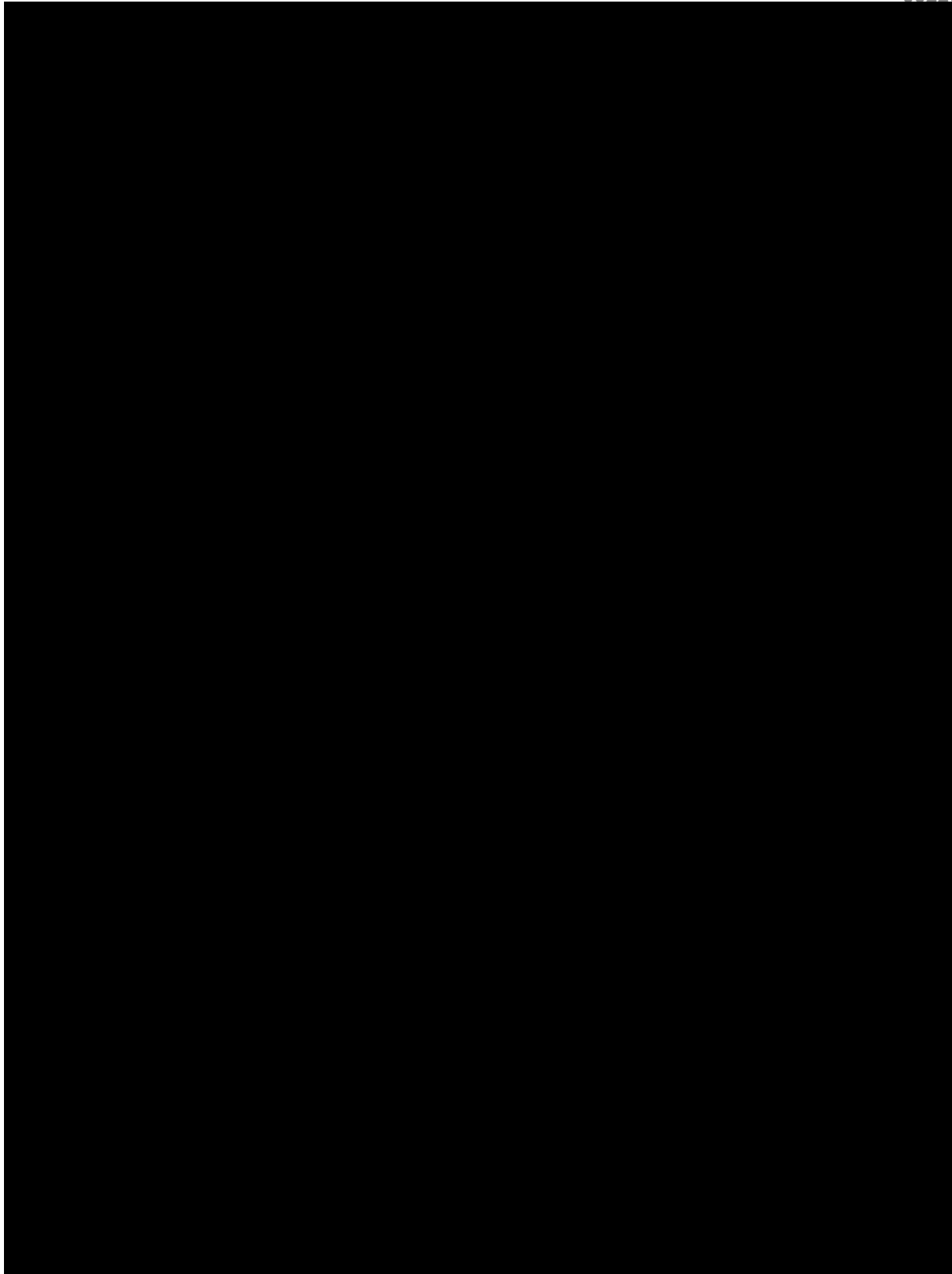


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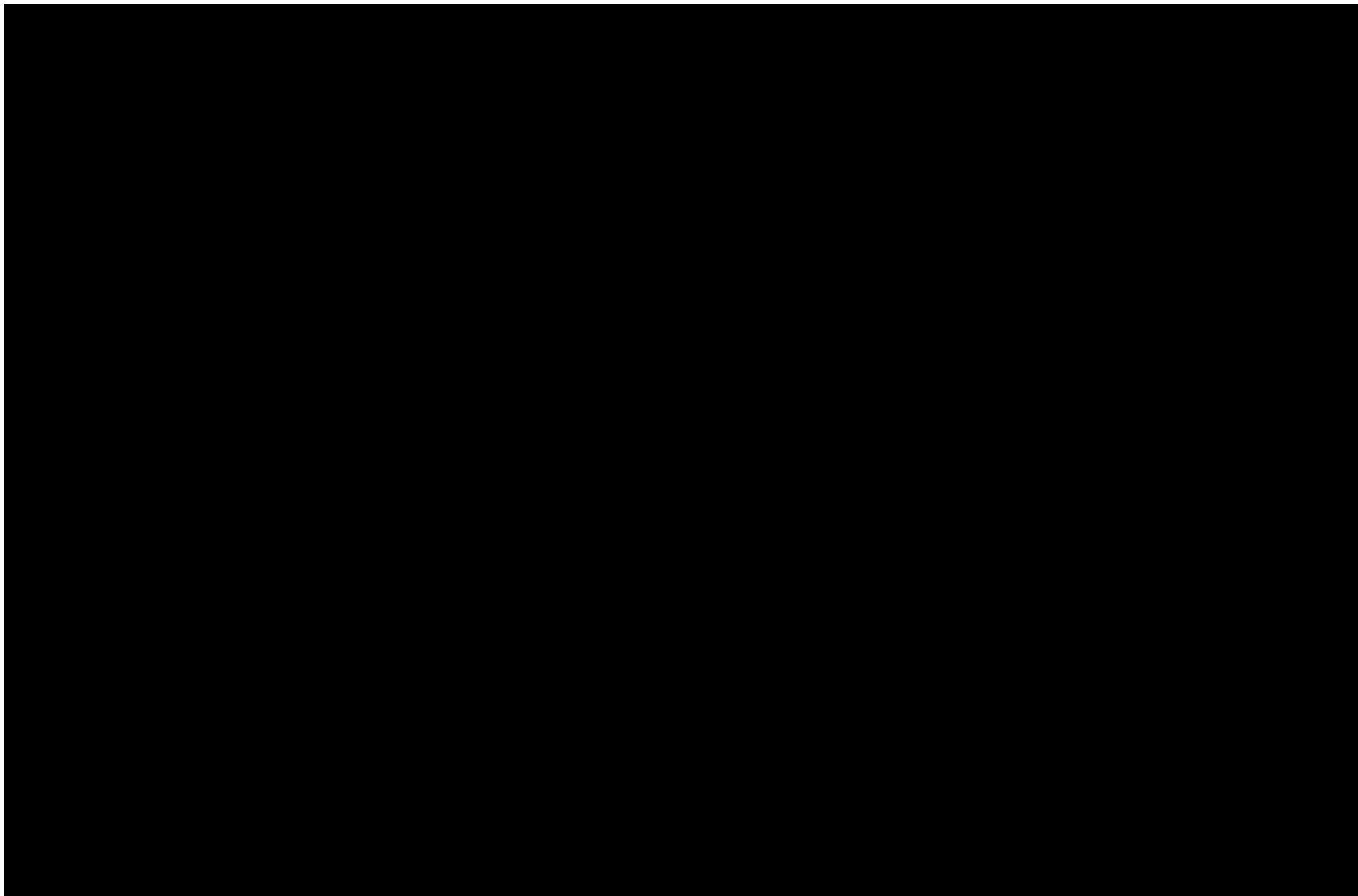
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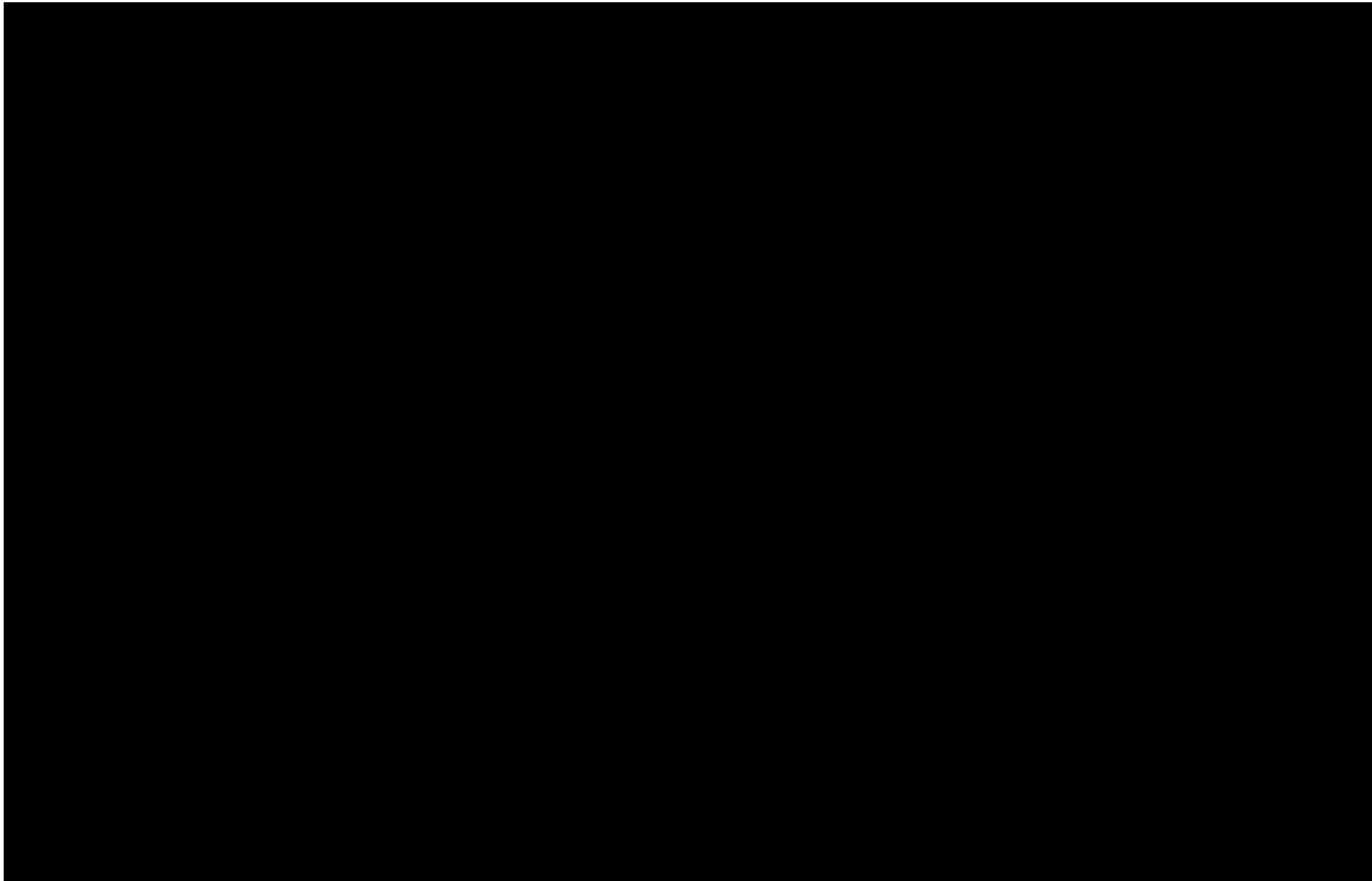
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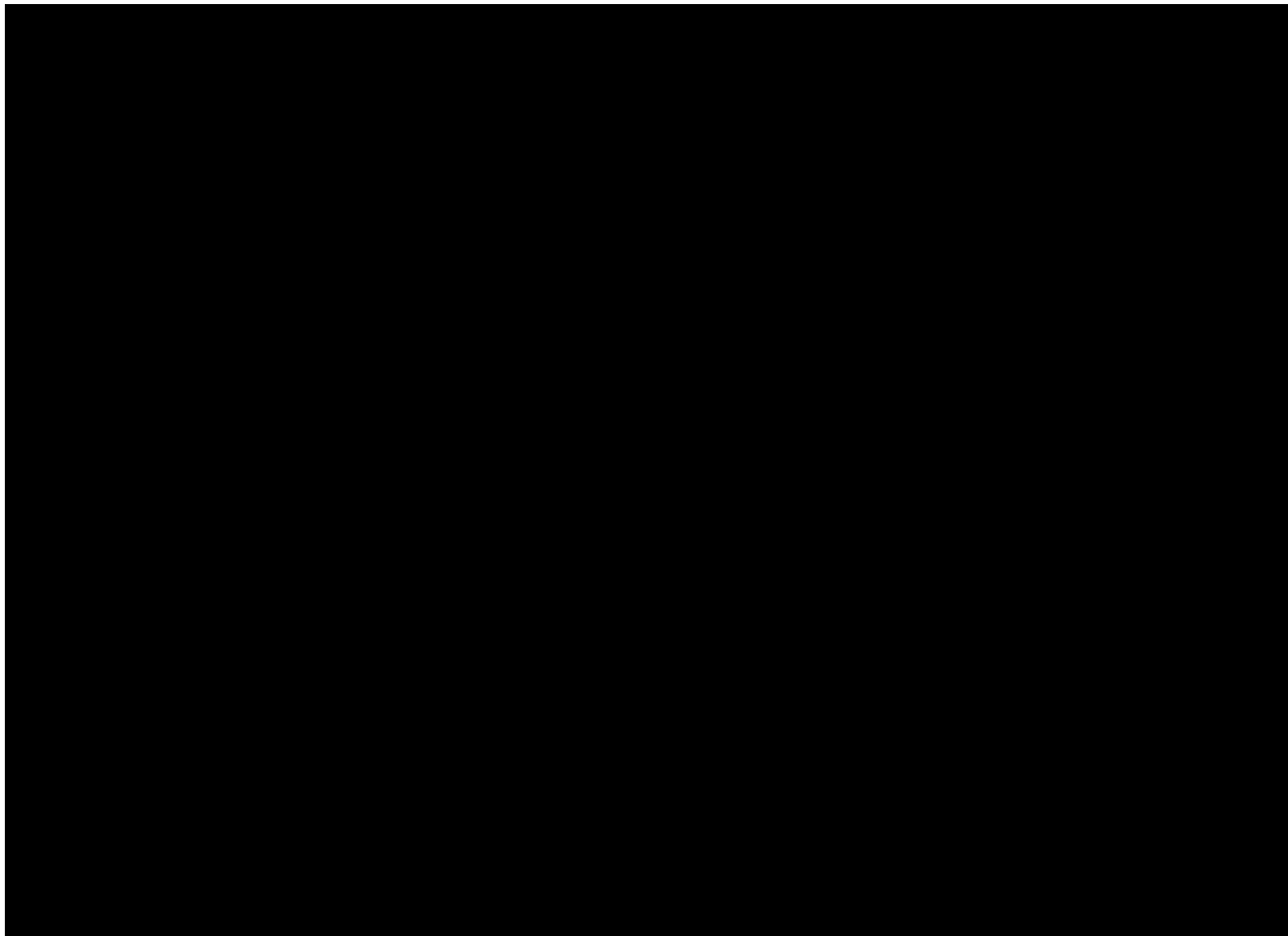
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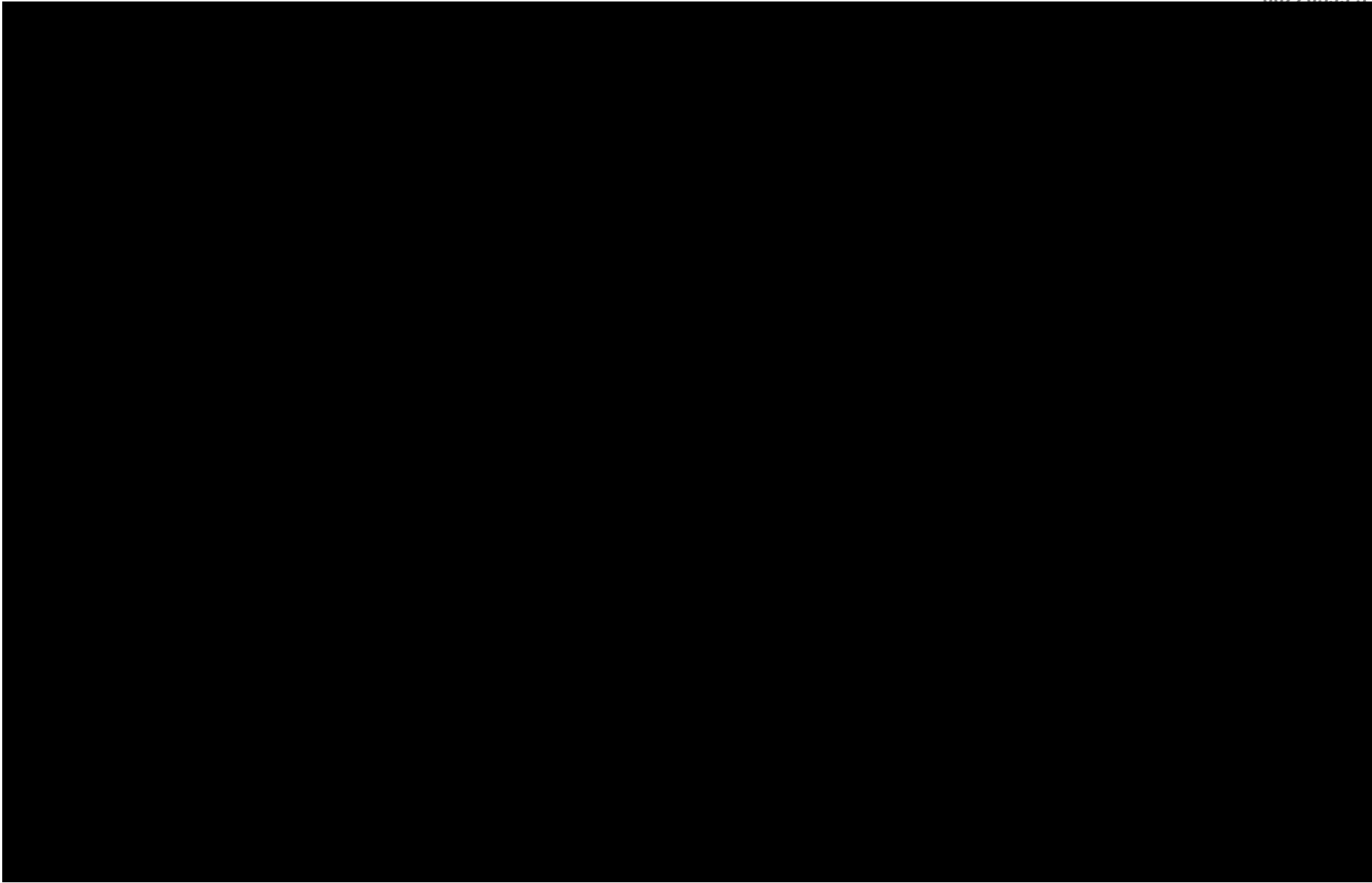
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Dodatek 2 k Příloze A



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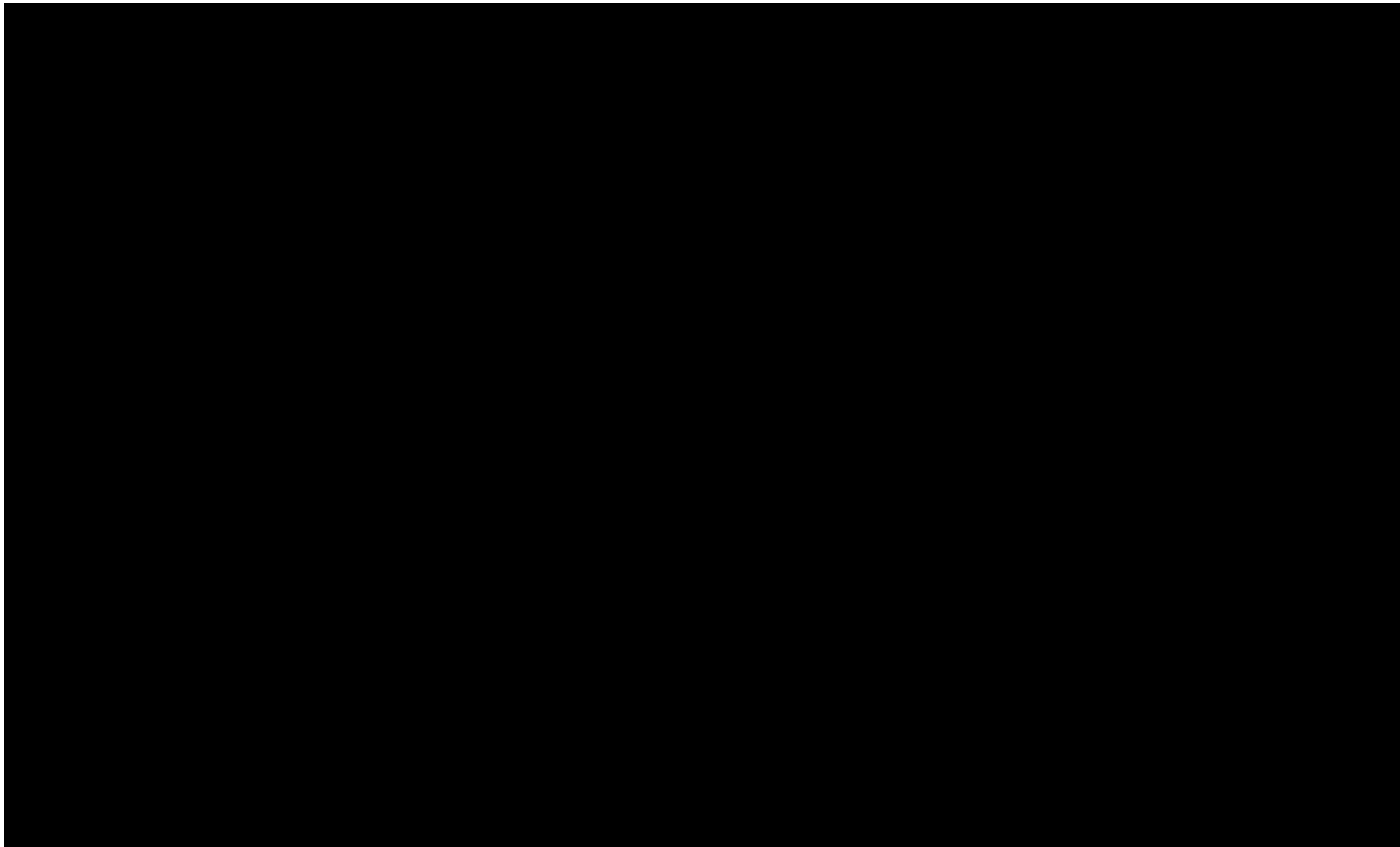
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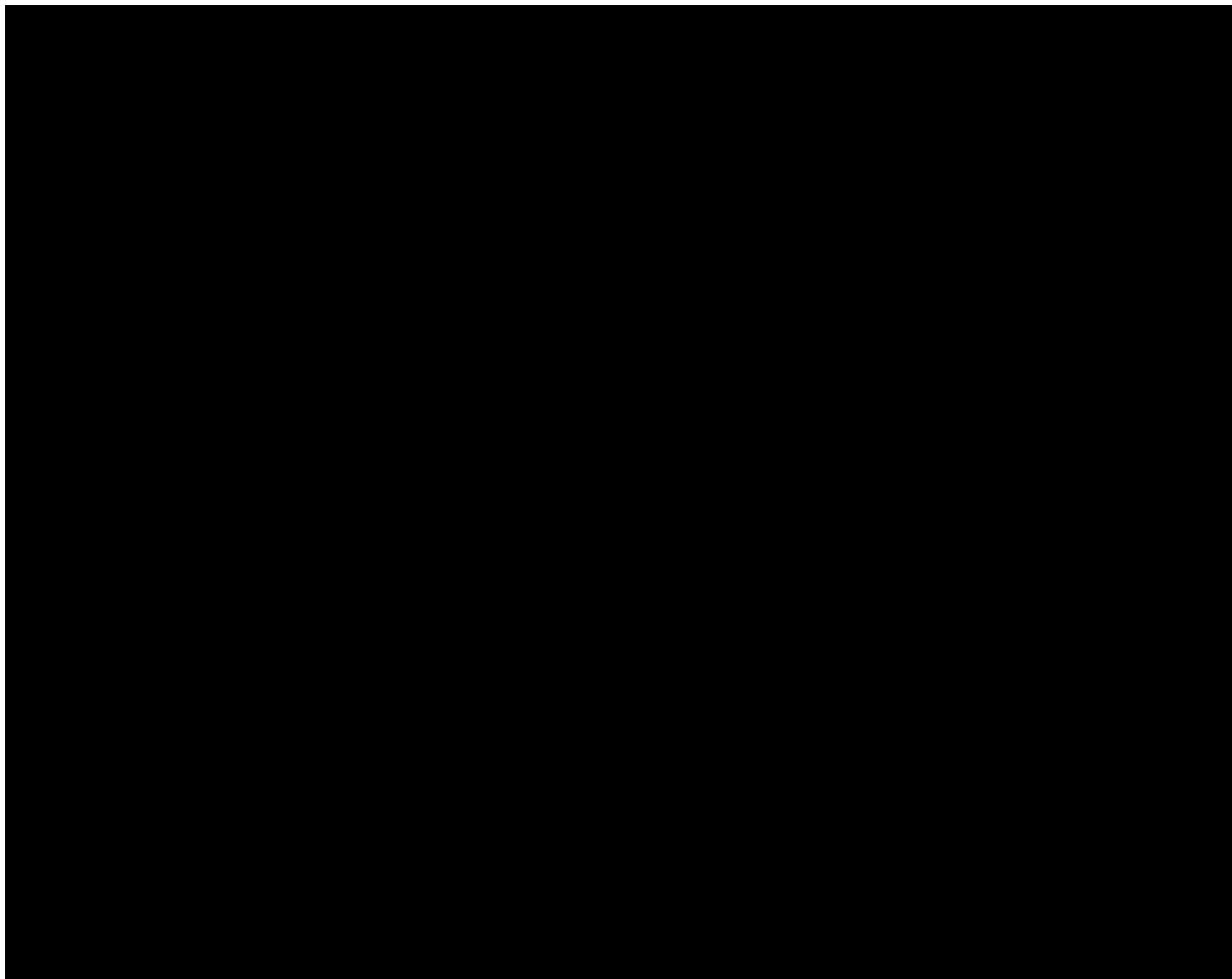
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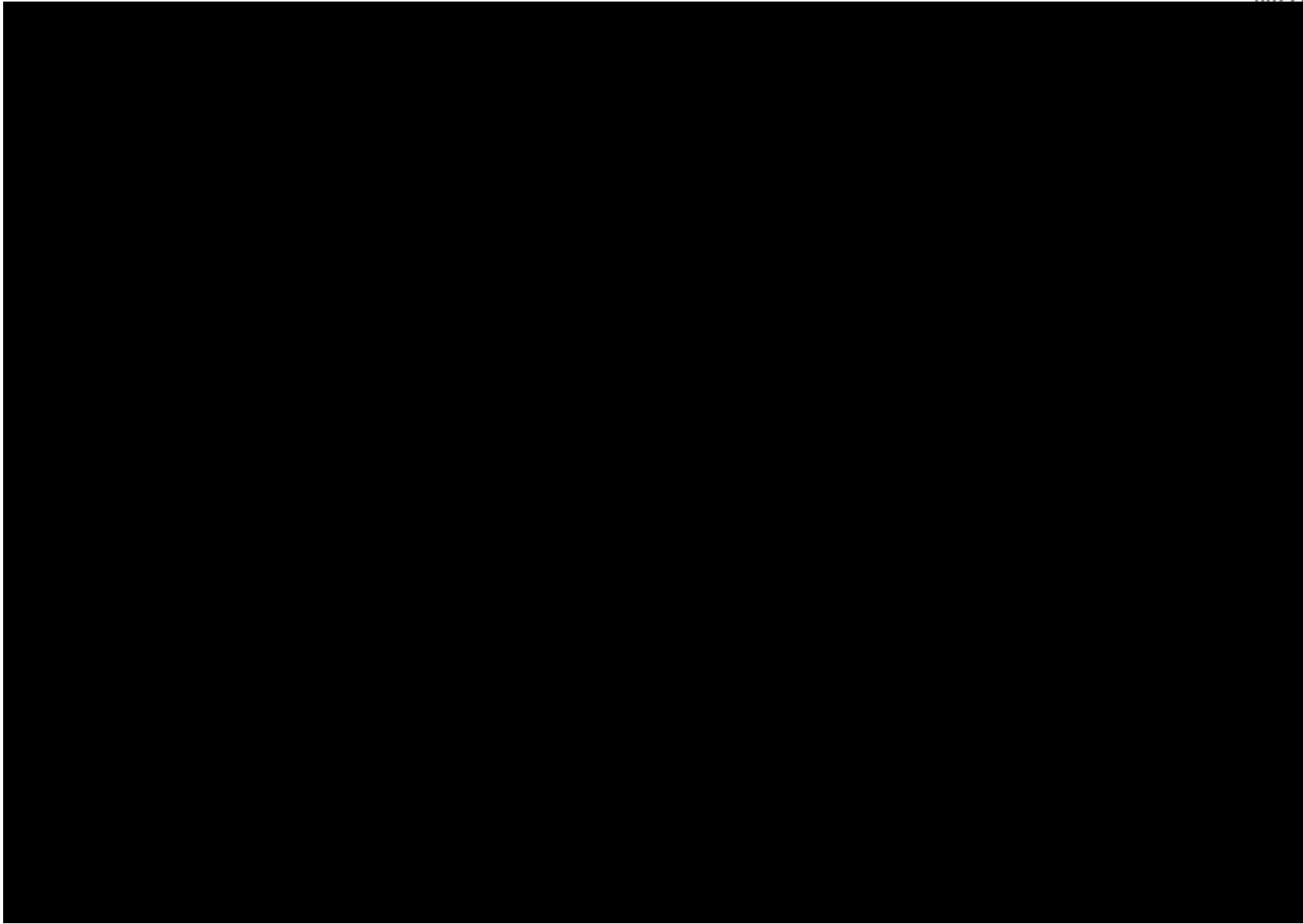
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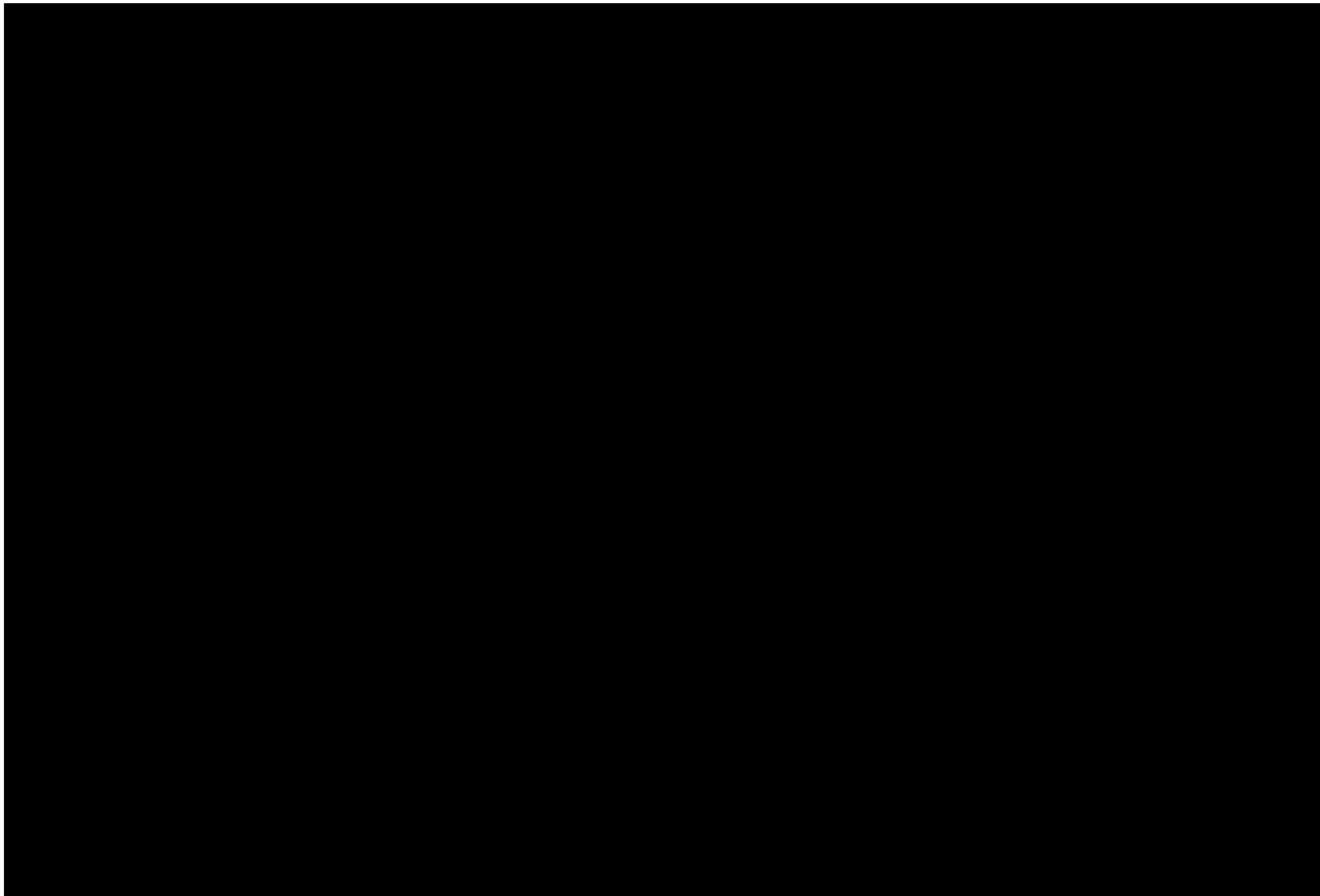
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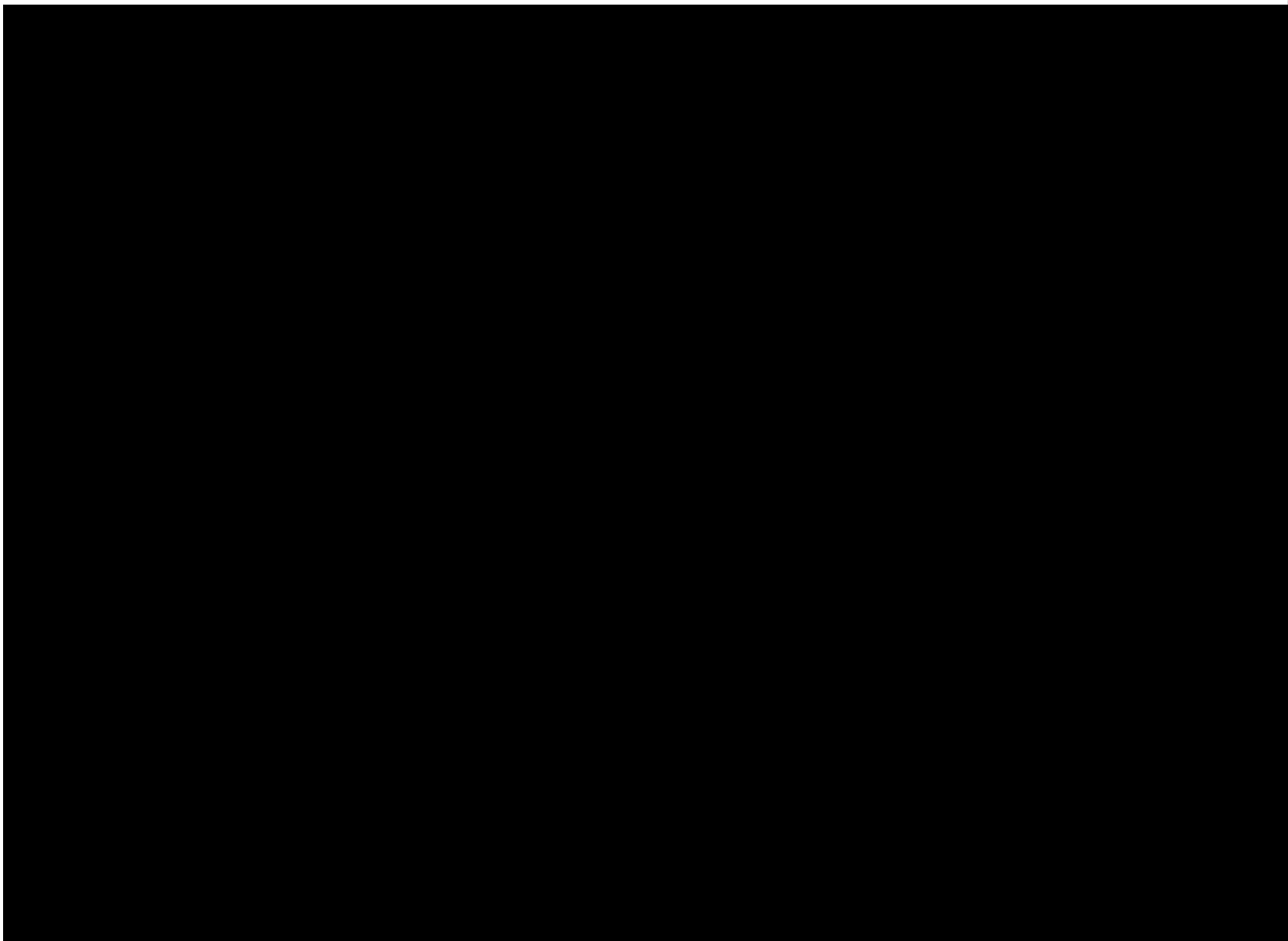
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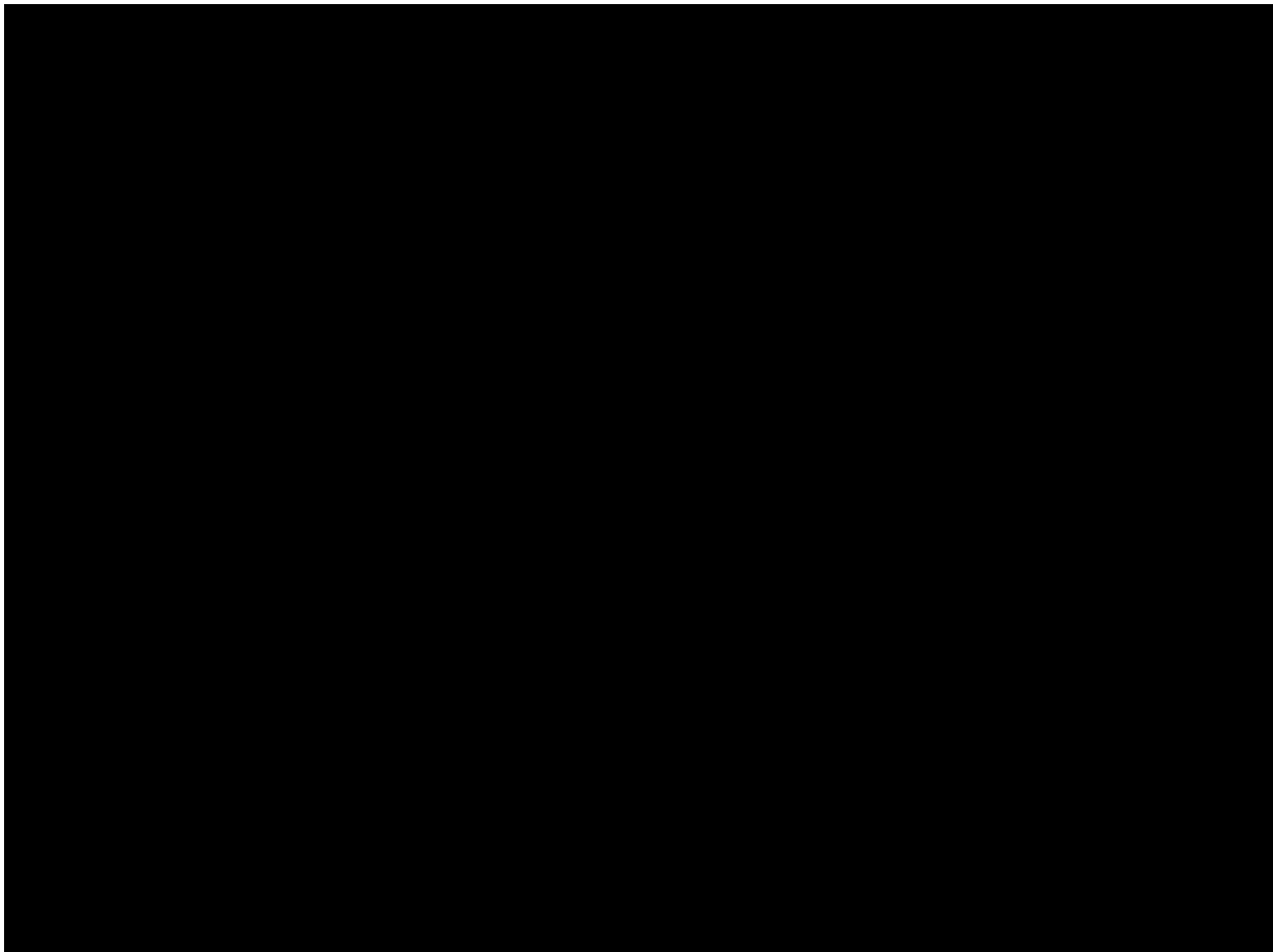
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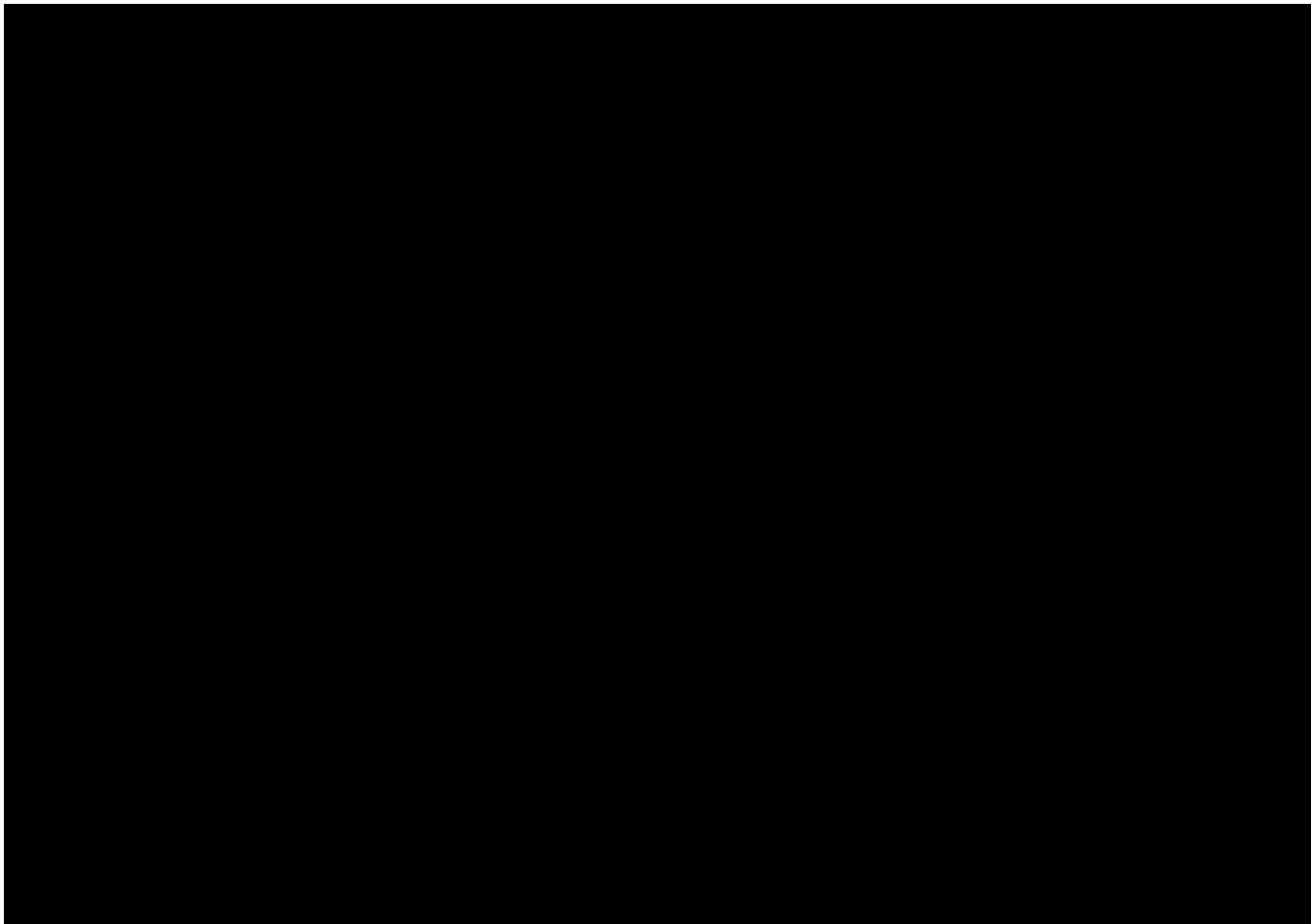
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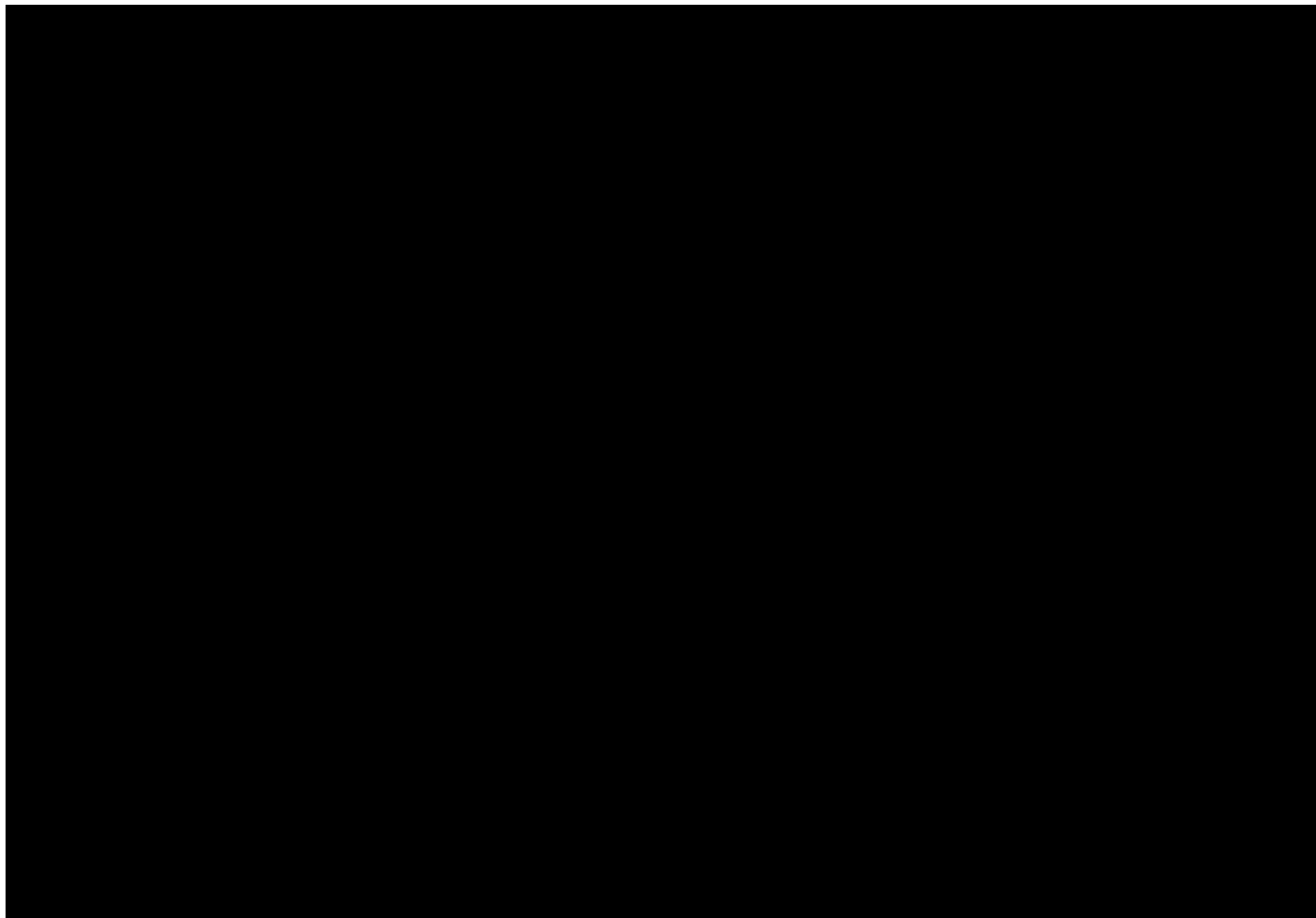
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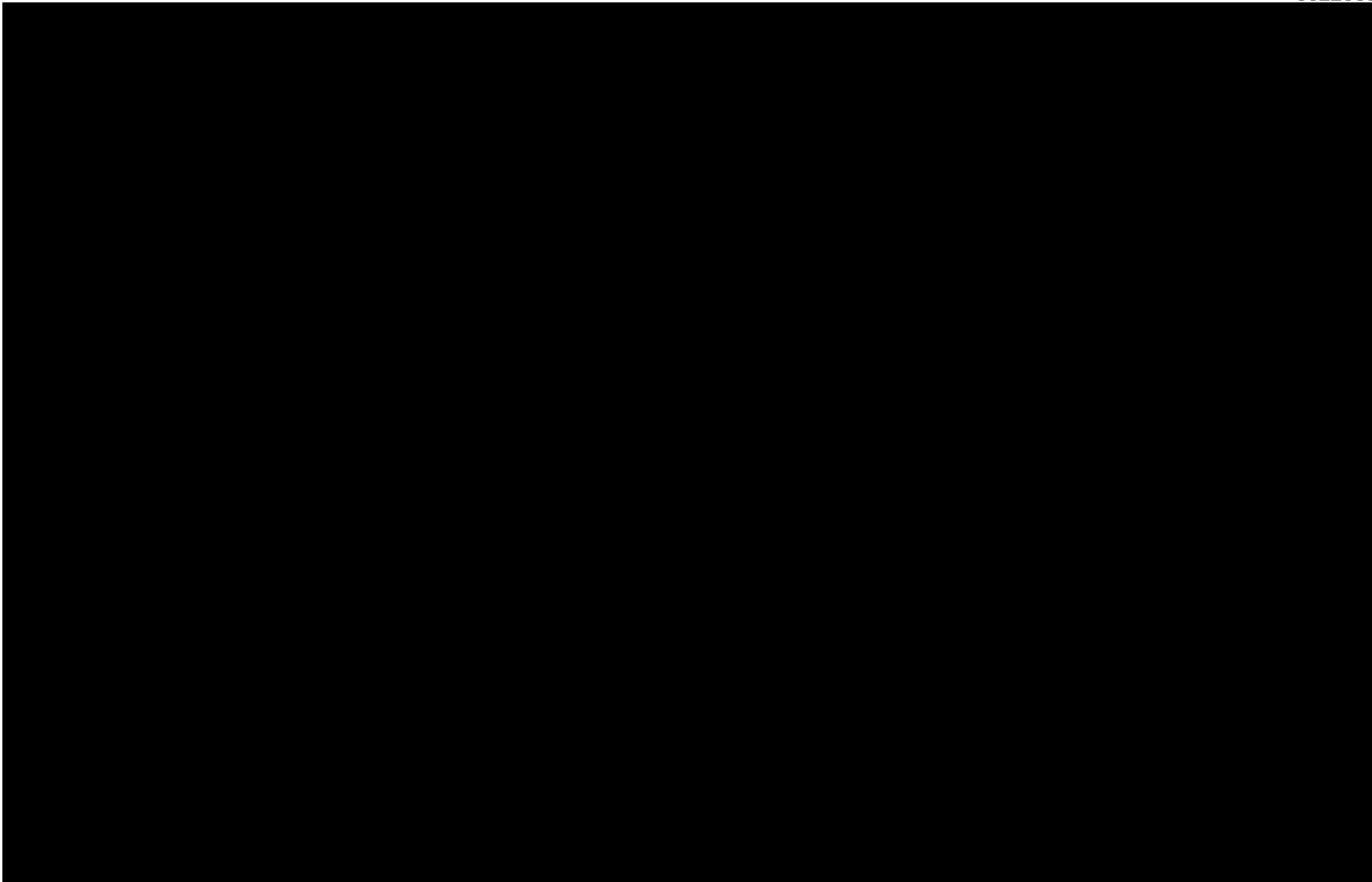
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Dodatek 6 k Příloze A



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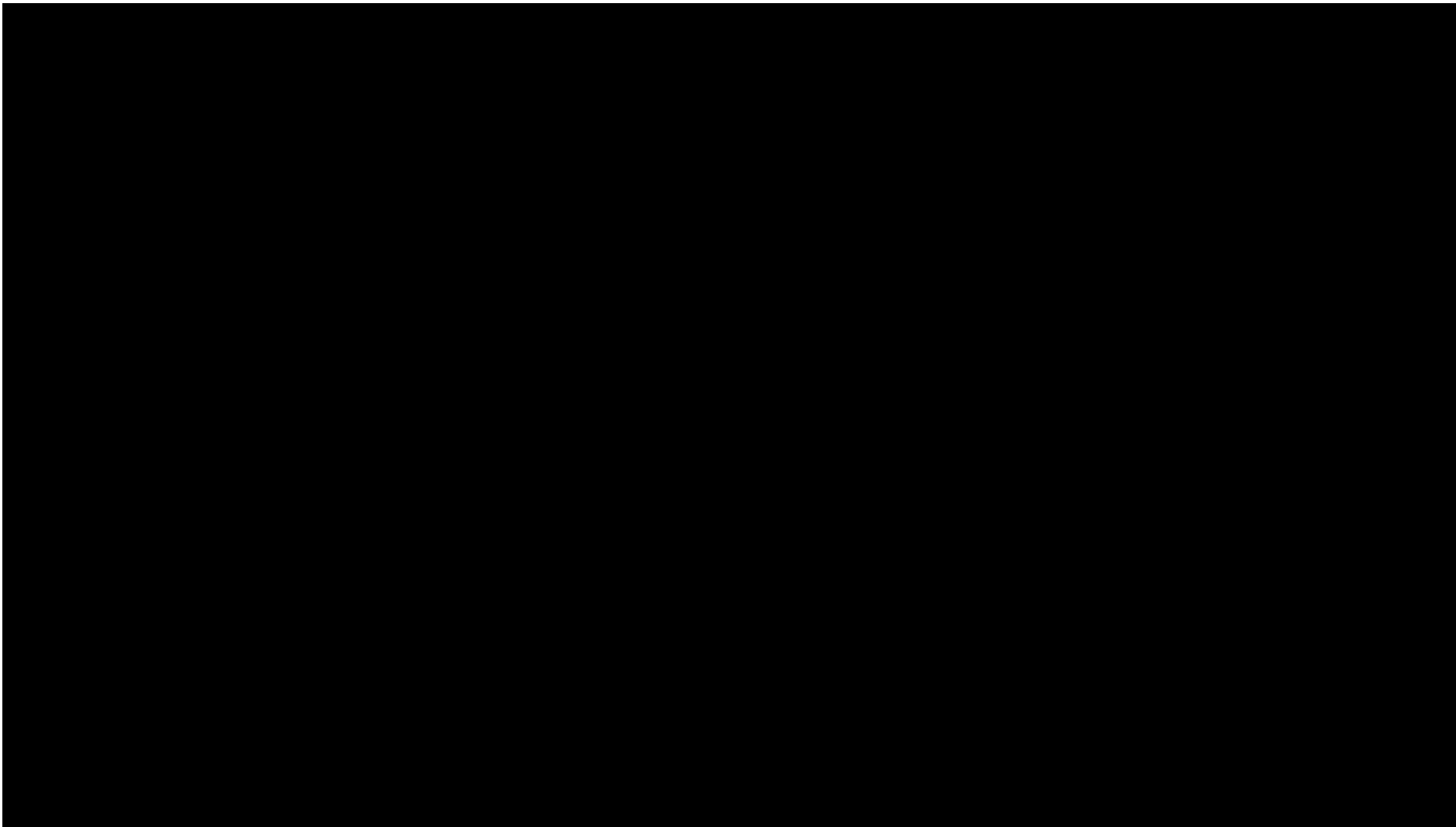
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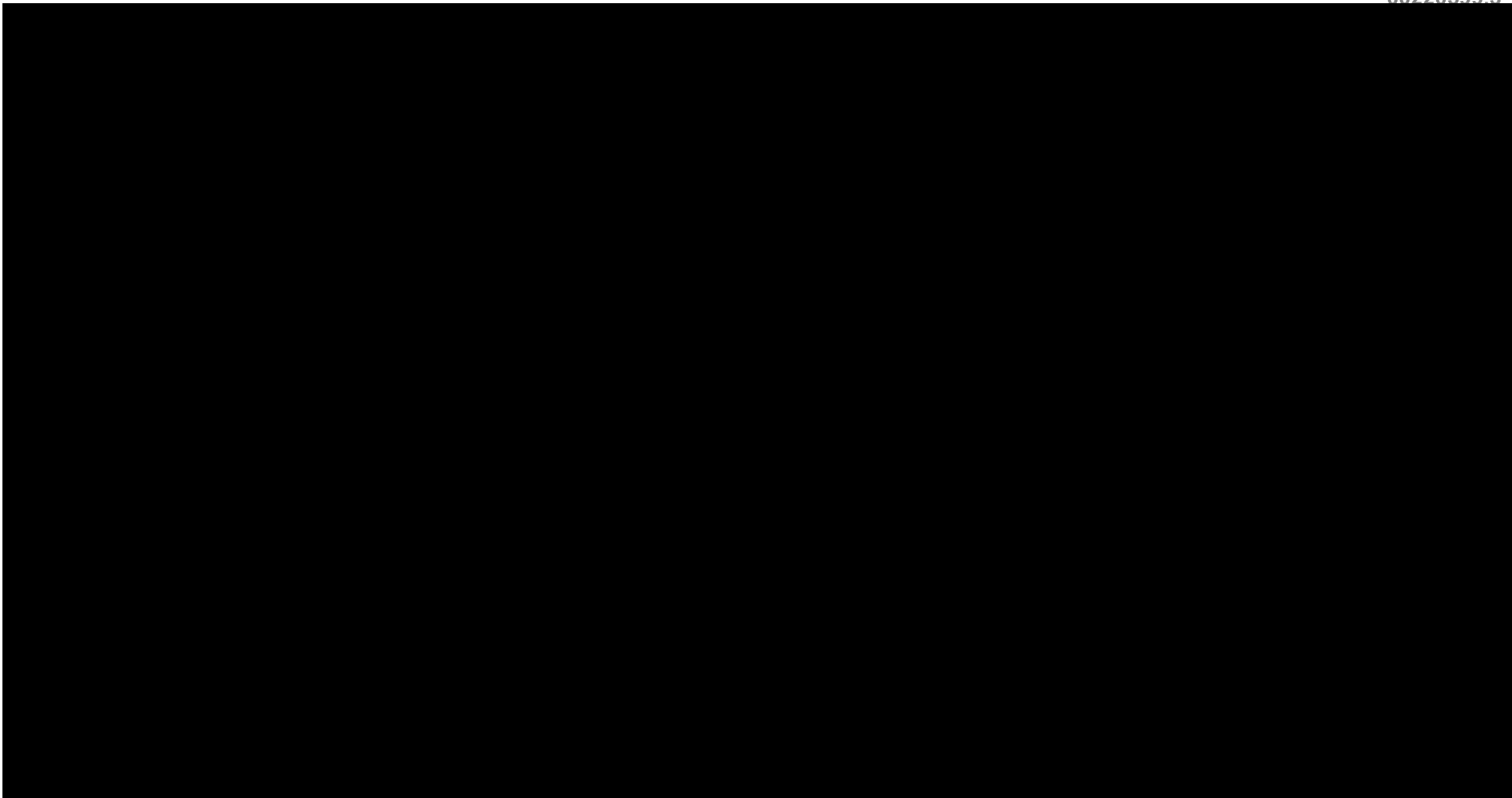
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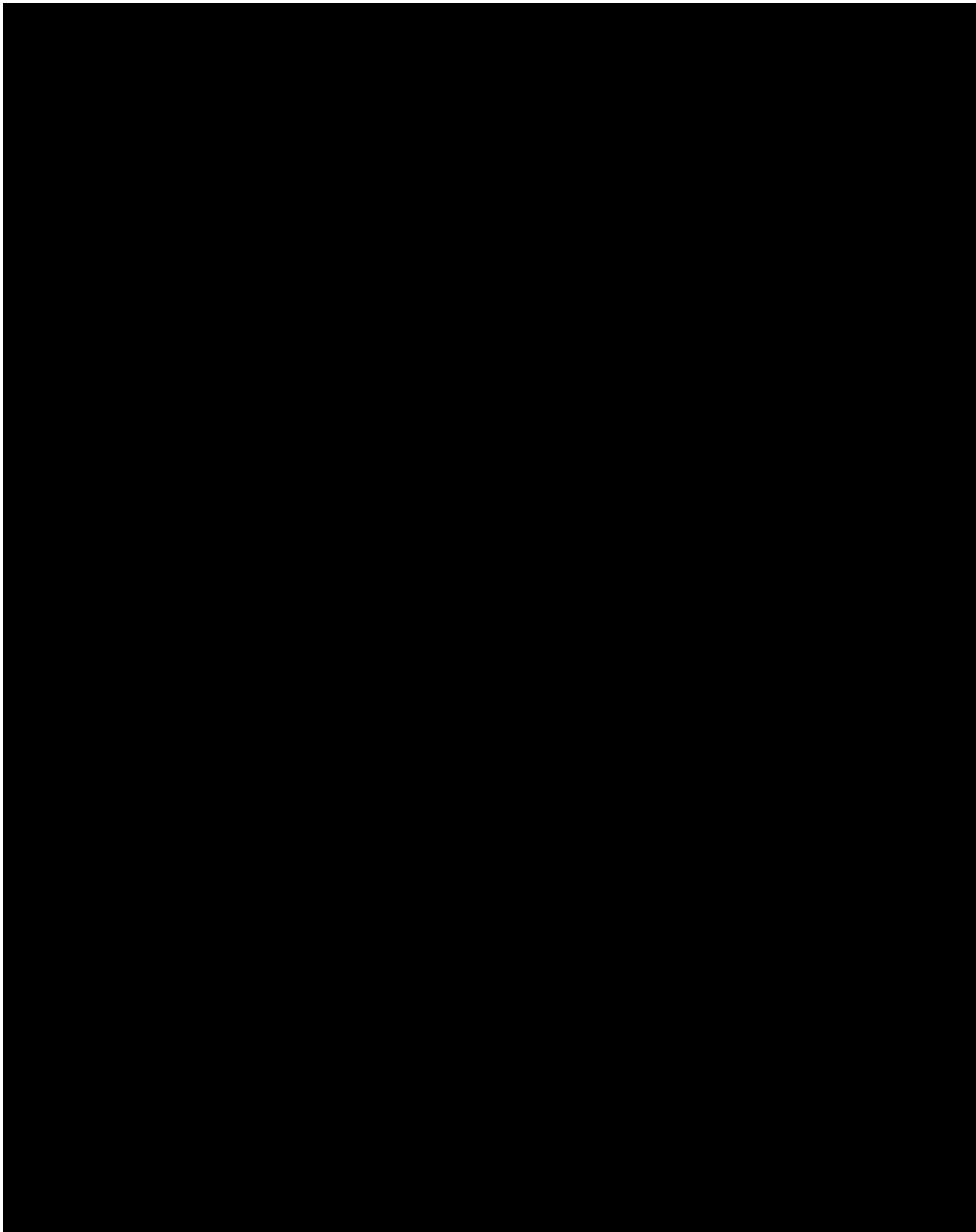
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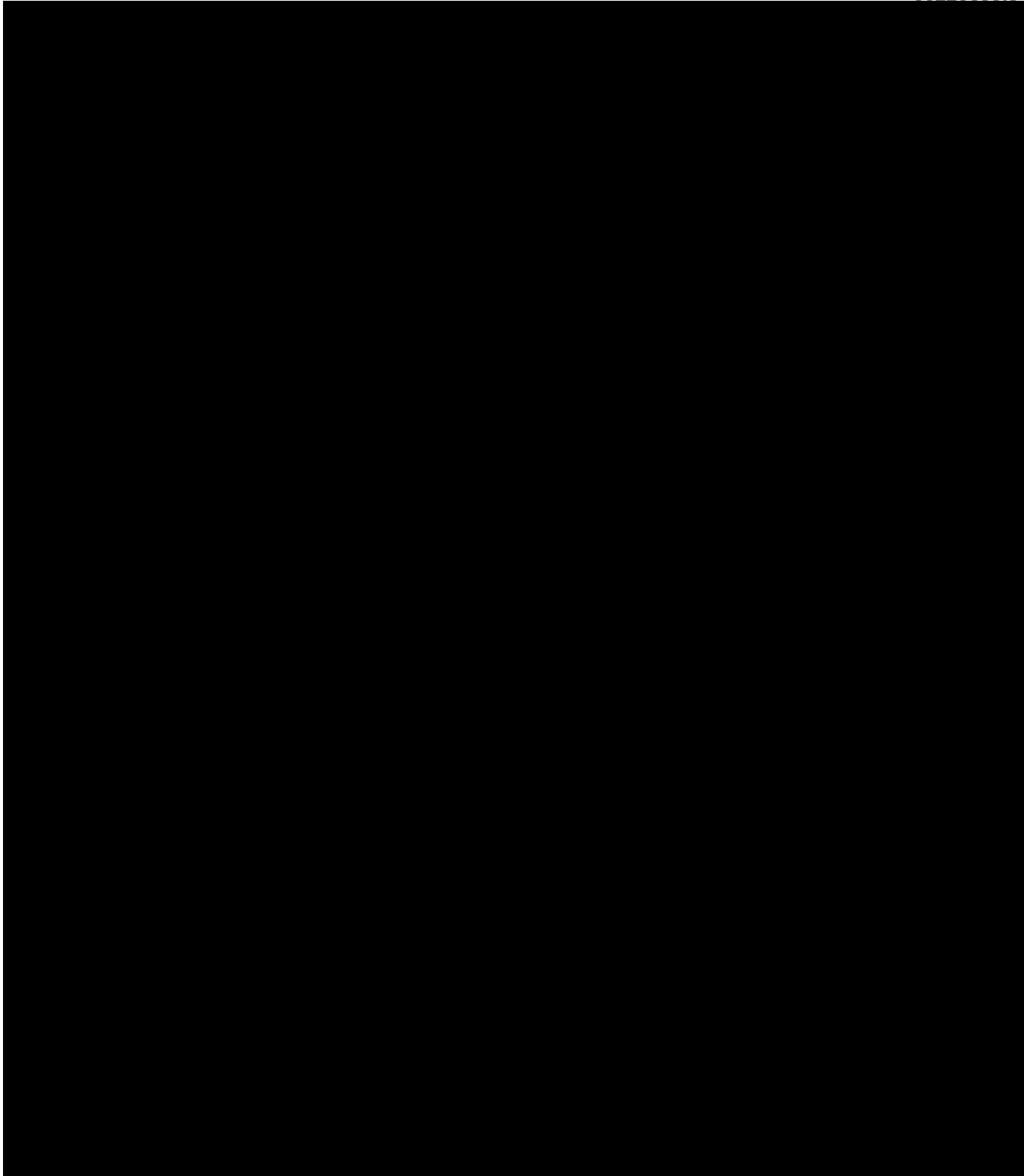
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Dodatek 8 k Příloze A



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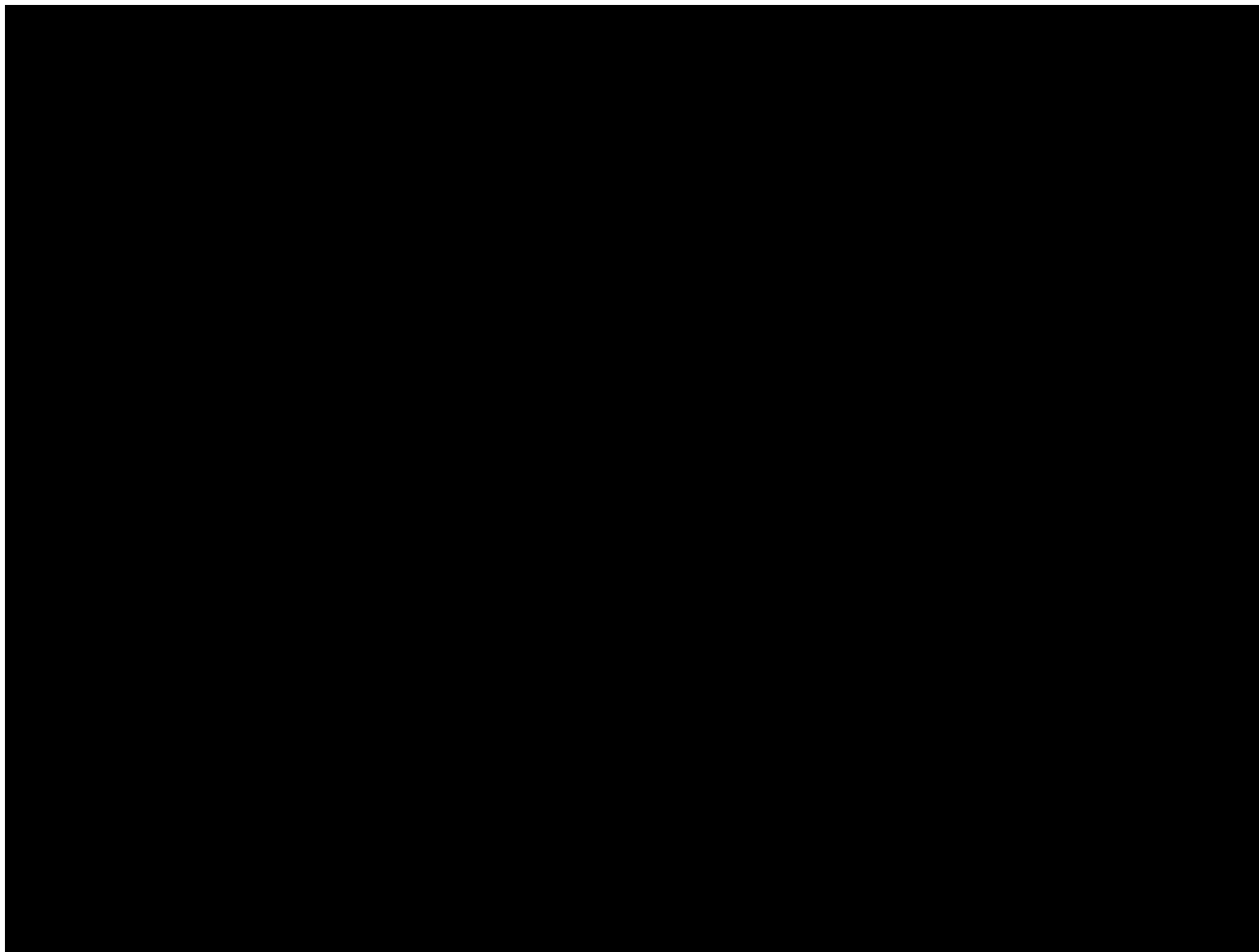
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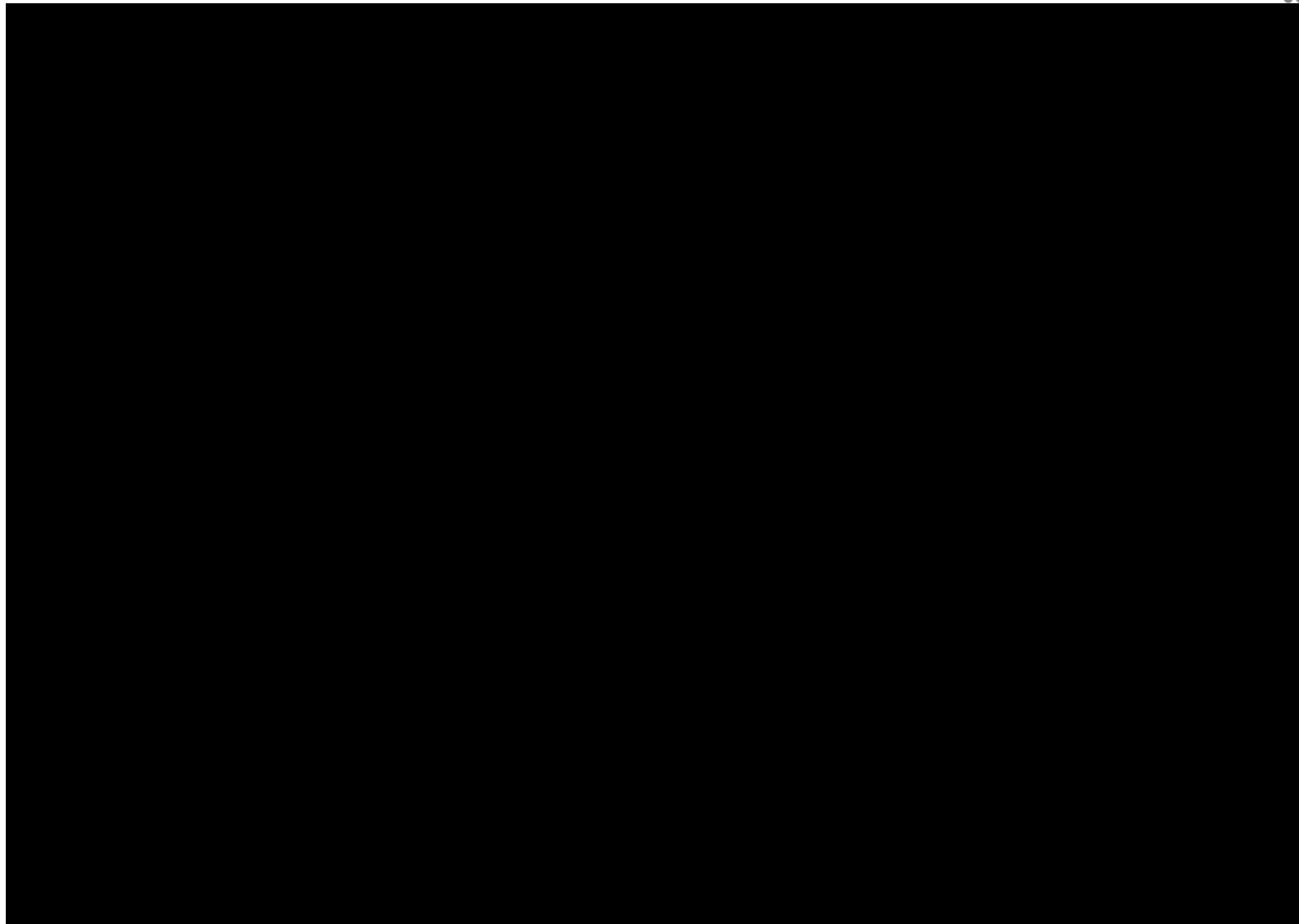
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Dodatek 9 k Příloze A



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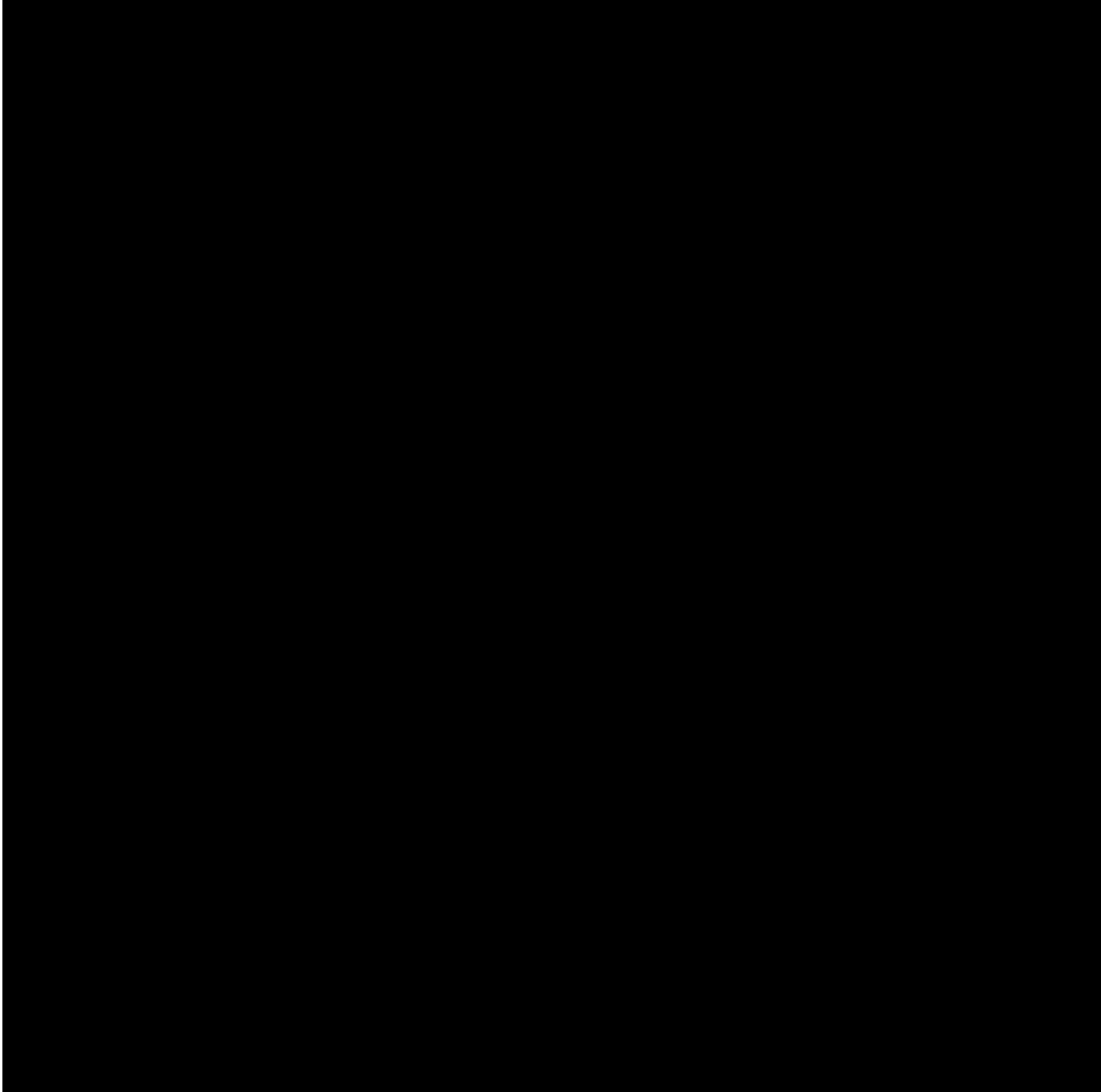
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Dodatek 10 k Příloze A



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