Records processed under FOIA Request 2016-8070; Released by CDRH on 10/5/2017

K141165

3shape

May 27, 2014

FDA CDRH DMC
JUN 0 1 2015
Received

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center - WO66-G609
10903 New Hampshire Avenue
Silver Spring, Maryland 20993-0002

Re: 510(k) Submission

Att.: Document Mail Clerk

This is to notify you of the intention by 3Shape A/S to manufacture and market the below device:

Type of 510(k) submission: Traditional

Proprietary Name: 3Shape Abutment Designer™ Software

Device Common Name: Abutment Designer

510(k) submitter: 3Shape A/S, Holmens Kanal 7, DK-1060 Copenhagen K, Tel.: +45 7027 2620, Fax.: +45 7027 2621

Contact Person: Ms. Hanne Nielsen, Regulatory Affairs Manager, Tel.: +45 7027 2620

Establishment Registration Number: 3005940400

Manufacturers Registration No.: 10023901

Classification Name: Endosseous Dental Implant Abutment

Regulation No.: 872.3630

Classification: Class II

Panel: Dental

Product Code: NHA

Submission copies: 2 (eCopy and paper). The eCopy is an exact duplicate of the paper copy.

Promotional Material: Labeling examples and preliminary copies of the user documentation are enclosed.

Substantial Equivalence: The 3Shape Abutment Designer™ Software is similar in design and function to the Sirona Dental CAD/CAM System (K100152).

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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3shape

27 May 2015

Basis for the Submission: New device

Prior Submissions: K133457 WD001
CPT1200130 – Letter from the Agency
I120810 – Pre-submission

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Design and Use of the Device

The device is intended for prescription use (21 CFR 801 Subpart D).

The device is software only.

Best regards,
3Shape A/S

Hanne Nielsen
Regulatory Affairs Manager

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Form Approved OMB No 0910 0511 Expiration Date April 30, 2016 See Instructions for OMB Statement

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION **MEDICAL DEVICE USER FEE COVER SHEET**	PAYMENT IDENTIFICATION NUMBER: (b)(4) [redacted] Write the Payment Identification number on your check.

A completed cover sheet must accompany each original application or supplement subject to fees. If payment is sent by U.S. mail or courier, please include a copy of this completed form with payment. Payment and mailing instructions can be found at: http://www.fda.gov/oc/mdufma/coversheet.html

1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code)	2. CONTACT NAME
3SHAPE AS Holmens Kanal 7, floors 4 KOBENHAVN 1060 DK	Hanne Nielsen 2.1 E-MAIL ADDRESS hanne.nielsen@3shape.com 2.2 TELEPHONE NUMBER (include Area code) 45-70272620 2.3 FACSIMILE (FAX) NUMBER (Include Area code)
1.1 EMPLOYER IDENTIFICATION NUMBER (EIN)	

3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following web site: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm345263.htm

Select an application type:	3.1 Select a center
[X] Premarket notification(510(k)); except for third party	[X] CDRH
[ ] 513(g) Request for Information	[ ] CBER
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4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status)

[ ] YES, I meet the small business criteria and have submitted the required qualifying documents to FDA

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[ ] YES [X] NO

PAPERWORK REDUCTION ACT STATEMENT
Public reporting burden for this collection of information is estimated to average 18 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the address below.

Department of Health and Human Services, Food and Drug Administration, Office of Chief Information Officer, 8455 Colesville Road, COLE-14-14253 Silver Spring, MD 20993-0002
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(b)(4) [redacted] 27-Feb-2015

Form FDA 3601 (05/13)

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Online Payment

Step 3: Confirm Payment 1 | 2 | **3**

Thank you.
Your transaction has been successfully completed.

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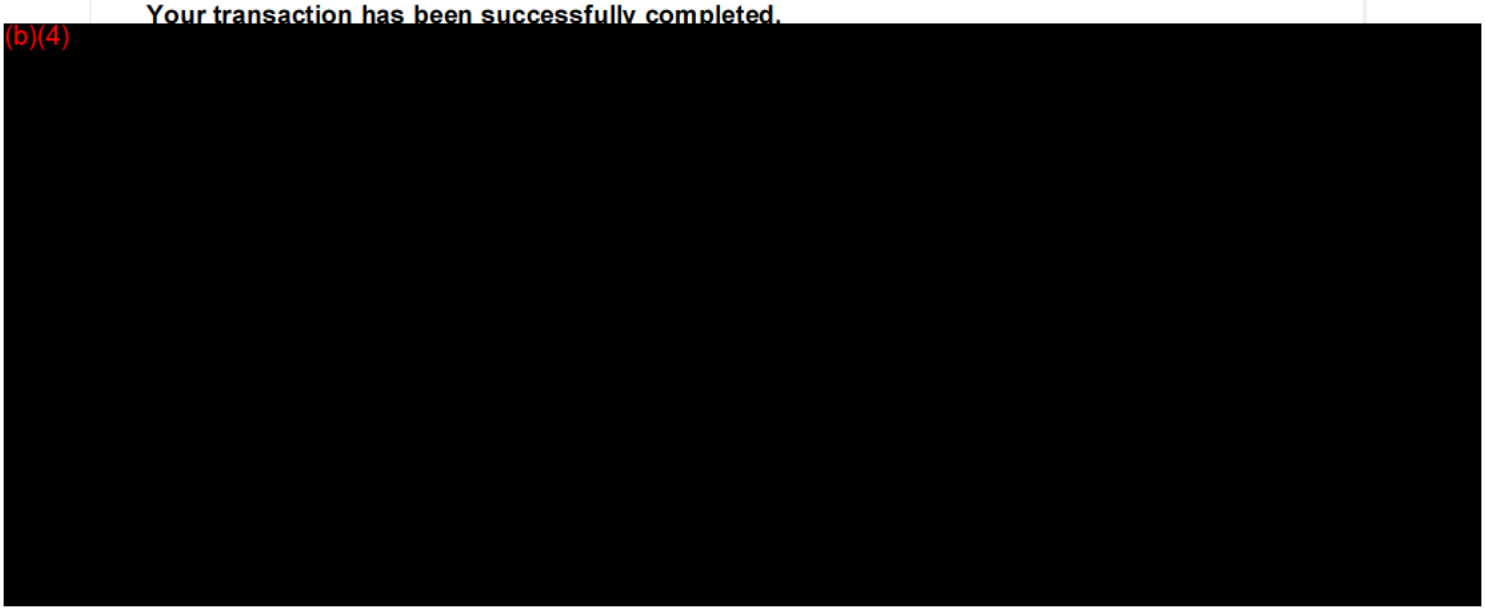

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

Device Name
3Shape Abutment Designer™ Software

Indications for Use *(Describe)*
The 3Shape Abutment Designer™ Software is intended for designing endosseous dental implant abutments based on digital scans of 3D models.
Intended users are Dental Practitioners and Dental Laboratory staff.
Intended Operational Environment is Dental Laboratories.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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Device Common Name: Abutment Designer

510(k) submitter: 3Shape A/S, Holmens Kanal 7, DK-1060 Copenhagen K, Tel.: +45 7027 2620, Fax.: +45 7027 2621

Contact Person: Ms. Hanne Nielsen, Regulatory Affairs Manager, Tel.: +45 7027 2620

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REVISION LEVEL HISTORY **VOL 011**

REVISION LEVEL HISTORY **11-1**

UNRESOLVED ANOMALIES **VOL 012**

UNRESOLVED ANOMALIES **12-1**

LABELING **VOL 013**

LABELING **13-1**

3SHAPE DENTAL SYSTEM SOFTWARE BROCHURE (EXCERPT) APPENDIX 13 1 (5 PAGES)
MANUAL DS-2.15.2.0-A-EN VERSION (EXCERPT) APPENDIX 13 2 (62 PAGES)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2016-8070; Released by CDRH on 10/5/2017

510(K) SUMMARY – Traditional 510(K)

Submitter Information

A Company Name:	3Shape A/S
B Company Address:	Holmens Kanal 7 DK-1060 Copenhagen K
C Company Phone: Company Fax:	+45 7027 2620 +45 7027 2621
D Contact Person:	Hanne Nielsen Regulatory Affairs Manager
E Date Summary Prepared:	May 27, 2015

Device Identification

A Trade/proprietary Name:	3Shape Abutment Designer™ Software
B Common Name:	Abutment Designer
C Device Classification Name:	Endosseous Dental Implant Abutment
C Regulation Number:	872.3630
C Classification:	Class II
D Product Code:	NHA

Predicate Device

The 3Shape Abutment Designer™ Software has equivalent intended use and technical characteristics as the Sirona Dental CAD/CAM System (K100152).

3Shape Abutment Designer™ Software does not provide any physical parts that can come into contact with the patient.

Therefore, the differences between the Device and the predicates do not raise additional concerns concerning the Device's safety and effectiveness.

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Intended Use

The 3Shape Abutment Designer™ Software is intended for designing endosseous dental implant abutments based on digital scans of 3D models.

Device Description

The 3Shape Abutment Designer™ Software receives scan data containing topographical characteristics of real teeth, dental impressions, or stone models. The software provides the user with the ability to create matching endosseous dental implant abutments using computer aided design.

The output of the device is a computer file containing the abutment(s) in digital form which can be used by 3rd party providers of milling machines and/or rapid prototyping machines to manufacture physical abutments.

The 3Shape Abutment Designer™ Software can be run on properly configured "off-the-shelf" PC hardware running Microsoft® Windows and using a standard keyboard and mouse.

Scientific Concept

The underlying scientific concept is the use of CAD/CAM technology for the optical acquisition of the topographical characteristics of dental impressions, and models and the design of individual mesostructures using recorded data (CAD).

Materials Used

Software. Not applicable.

Physical Properties

Software. Not applicable.

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Summary of the technological characteristics

The 3Shape Abutment Designer™ is a software only device programmed in (b)(4) and has the following PC/laptop requirements:

Item	Minimum Requirements	Recommended
OS	Windows 7 32-bit Professional*	Windows 7 64-bit Professional
RAM	4GB	8GB (16GB)
Video Card	512MB DirectX 10 (1GB DirectX 10) NVIDIA GeForce	1GB DirectX 11 (2GB DirectX 11) NVIDIA GeForce
Available HDD Space	250GB	500GB (1TB)
CPU	Intel Core i5 or equivalent	Intel Core i7 or equivalent
Monitor resolution	1440 x 900 pixels	1920 x 1080 pixels
3D Mouse	None	3DConnexion SpaceMouse™ Pro
Network	Internet connection	
USB ports	USB 2.0 port for 3Shape desktop scanner	
Mouse	Mouse with wheel button support	

Nonclinical Testing

Software, hardware, and integration verification and validation testing was performed in accordance with the FDA Guidance Document "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" (Issued on May 11, 2005).

Prior to release, verification and validation testing of the 3Shape Abutment Designer™ Software has been completed using the approved acceptance criteria: Each user need has its own validation acceptance criteria; each specification has its own verification acceptance criteria; bug verification consists in ensuring issue is not reproducible; issues reported by beta partners must be reviewed and handled appropriately; beta partners must report functionality to be an improvement over previous version.

The validation suite includes validation of implemented mitigations related to device hazards identified in the risk management procedures.

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All test results have been reviewed and approved, showing the 3Shape Abutment Designer™ Software to be safe and effective.

Clinical Testing

Clinical testing is not a requirement and has not been performed.

Conclusion

Based on a comparison of intended use, indications, construction materials, principle of operations, features and technical data, and the test results, the 3Shape Abutment Designer™ Software is found to be as safe and effective as the Predicate Devices. Intended use and performance is found to be substantially equivalent to the Predicate Devices.

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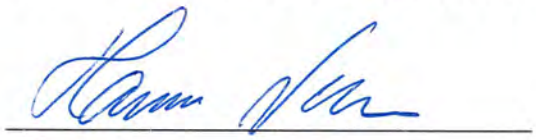
3shape

Premarket Notification Truthful And Accurate Statement

[As Required by 21 CFR 807.87(k)]

I certify that, in my capacity as Regulatory Affairs Manager of 3Shape A/S, I believe to the best of my knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.



(Signature)

Hanne Nielsen

MAY 27, 2015

(Date)

_____

*(Premarket Notification [510(k)] Number)

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Proposed Labelling

The 3Shape Abutment Designer™ Software is a prescription device and is exempt from needing adequate directions for lay use.

The following labelling is included (please see "VOL 013 Labelling" of this submission):

- PDF copy of User Manual
- Dental System™ Brochure

The application is for download only, and hence there is no CD label.

Device Specific Requirements

There are no applicable requirements in a device specific regulation.

Special Controls Document

The 3Shape Abutment Designer™ Software falls into the following product group:

NHA

The guidance document entitled "Class II Special Controls Guidance Document: Root Form Endosseous Dental Implants and Endosseous Dental Implant Abutments" serve as the special control.

The Guidance Document lists the below labelling requirements.

Requirement	**Referenced in**
Labelling in sufficient detail to satisfy the requirements of 21 CFR 807.87(e)	Online help Safety and Setup Guide
Provide users with a surgical manual along with the instructions for use	N/A The 3Shape Abutment Designer ™ Software is not used in surgery
Provide all relevant precautions and warnings in the professional labelling	Online help Safety and Setup Guide
Precautions or warnings that relate to unpackaging or sterility	N/A The 3Shape Abutment Designer ™ Software is a software device and not supplied sterile.
If any parts are provided non sterile we recommend that you provide sterilization instructions	N/A The 3Shape Abutment Designer ™ Software is a software device and not supplied sterile.
If patient labelling is appropriate, we recommend that you follow Guidance on Medical Device Patient Labelling; Final Guidance for Industry and FDA Reviewers	N/A 3Shape Abutment Designer ™ Software is a prescription device and patient labeling is not required.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Specifications

1. Device Description

The 3Shape Abutment Designer ™ Software falls under the device specific FDA guidance document "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, May 11 2005".

Thus, a narrative description of the Device, indications for use, principles of operation, power source, composition, and other information necessary to understand the device can be found under the Volume "VOL 003 Software Description" in the document "001 Software Description" included in this submission.

The 3Shape Abutment Designer ™ Software does not include any physical part(s), therefore a physical description is not included in this submission.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Substantial Equivalence Comparison

1. Predicates

The 3Shape Abutment Designer™ Software has the same intended uses and technical characteristics as the Sirona Dental CAD/CAM System (K100152) as listed in "Table 1: Predicate"

Table 1: Predicate

Predicate	Manufacturer	510(k) number	Product code
Dental CAD/CAM System	Sirona	K100152	NHA*

* Endosseous dental implant abutments, 21CFR872.3630

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2. Intended Use Comparison

2.1. 3Shape Abutment Designer™ Software

The Device's Intended Use, Intended users, and Intended Operational is stated in the "VOL 001 Administrative Documents" volume of this submission and reproduced here:

> *"The 3Shape Abutment Designer™ Software is intended for designing endosseous dental implant abutments based on digital scans of 3D models.*
>
> *Intended users are Dental Practitioners and Dental Laboratory staff.*
>
> *Intended Operational Environment is Dental Laboratories."*

In the following sections, the similarities with the predicate are discussed.

2.2. Dental CAD/CAM System

The predicate's Intended Use can be extracted from the FDA 510(k) Premarket Notification Database:

> *"The Sirona Dental CAD/CAM System is intended for use in partially or fully edentulous mandibles and maxillae in support of single or multiple-unit cement retained restorations. The system consists of three major parts: TiBase, InCoris mesostructure, and CAD/CAM software. Specifically, the InCoris mesostructure and TiBase components make up a two-piece abutment which is used in conjunction with endosseous dental implants to restore the function and aesthetics in the oral cavity.*
>
> *The InCoris mesostructure may also be used in conjunction with the Camlog Titanium base CAD/CAM (types K2244.xxxx) (K083496) in the Canmlog Implant System. The CAD/CAM software is intended to design and fabricate the InCoris mesostructure. The InCoris mesostructure and TiBase two-piece abutment is compatible with the following implants systems:*
>
> *[List of compatible implant systems omitted for brevity]*

Underlined segments indicate similarity with 3Shape Abutment Designer™ Software.

Note, the predicate is a CAD/CAM System bundled with physical two piece abutments; the 3Shape Abutment Designer™ Software is CAD/CAM only.

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3. Characteristics Comparison

A Characteristics Comparison can be seen in "Table 2: Substantial Equivalence Chart".

Table 2: Substantial Equivalence Chart

Feature name	3Shape Abutment Designer ™ Software	Sirona Dental CAD/CAM System (K100152)
Graphical UI	Yes	Yes
Windows OS platform	Yes	Yes
Uses standard PC hardware	Yes	Yes
Digitally imports topography of teeth by 3D Scan	Yes	Yes
Uses 3D CAD design tools	Yes	Yes
Custom abutment design	Yes	Yes
Screw retained design	Yes	Yes
Implant Bar design	Yes	Yes
Export to remote milling machine by internet	Yes	Yes
Network Protocol	Internet/TCP IP	Internet/TCP IP
Intended users	Dental practitioners and dental labs	Dental practitioners and dental labs
Output type	Computer file	Computer file
Device submission includes pre manufactured prosthetics*	No	Yes

* Endosseous dental implant abutments as per 21CFR872.3630

4. Conclusion

The 3Shape Abutment Designer™ Software and the predicate only deviate significantly in the cases where the predicate is bundled with a physical dental implant abutment. 3Shape Abutment Designer™ Software does not provide any physical parts that can come into contact with the patient.

The differences between the 3Shape Abutment Designer™ Software and the predicate do not raise additional concerns with respect to the safety and effectiveness of the 3Shape Abutment Designer™ Software.

Based on the information presented, we conclude Substantial Equivalence between the predicate and the 3Shape Abutment Designer™ Software.

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Biocompatibility

Biocompatibility

The 3Shape Abutment Designer™ Software has no patient contacting components and thus biocompatibility requirements do not apply.

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EMC and Electrical Safety

EMC and Electrical Safety

The 3Shape Abutment Designer ™ Software has no patient or user contacting components as it is a software device. EMC and Electrical Safety evaluation is therefore not applicable.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Shelf Life

Shelf Life

The 3Shape Abutment Designer ™ Software is a software device and thus shelf life requirements do not apply.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Sterilization

Sterilization

The 3Shape Abutment Designer ™ Software is a software device and thus sterilization requirements do not apply.

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Corrosion Testing

The 3Shape Abutment Designer™ Software is a software device only. Corrosion Testing is therefore not applicable.

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Implant to Abutment Compatibility

The 3Shape Abutment Designer™ Software is a software device only.

The output of the device is a computer file containing the abutment(s) in digital form which can be used by 3rd party providers of milling machines and/or rapid prototyping machines to manufacture physical abutments. The 3Shape Abutment Designer™ Software does not provide any means of creating physical abutments, nor does it consist of any physical parts.

A digital representation of the Implant is required for the software to work, but only to ensure the Abutment will fit on the Seating Geometry / Interface of the Implant. The 3Shape Abutment Designer™ does not provide any means to design, alter, or manufacture any part of the Implant including, but not limited to, the abutment to implant interface.

Correct compatibility with the digital representation of the Implant is validated as described in the "VOL 10 Verfication and Validation" Volume of this submission.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Material Composition

Material Identity

The 3Shape Abutment Designer ™ Software is a software device only. Material Identity is therefore not applicable.

Chemical Composition and anticipated impurities

The 3Shape Abutment Designer ™ Software is a software device only. Chemical composition and anticipated impurities are therefore not applicable.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Mechanical Properties

The 3Shape Abutment Designer ™ Software is a software device only. Mechanical Properties are therefore not applicable.

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Modified Surfaces Information

The 3Shape Abutment Designer ™ Software is a software device only. Modified Surfaces Information is therefore not applicable.

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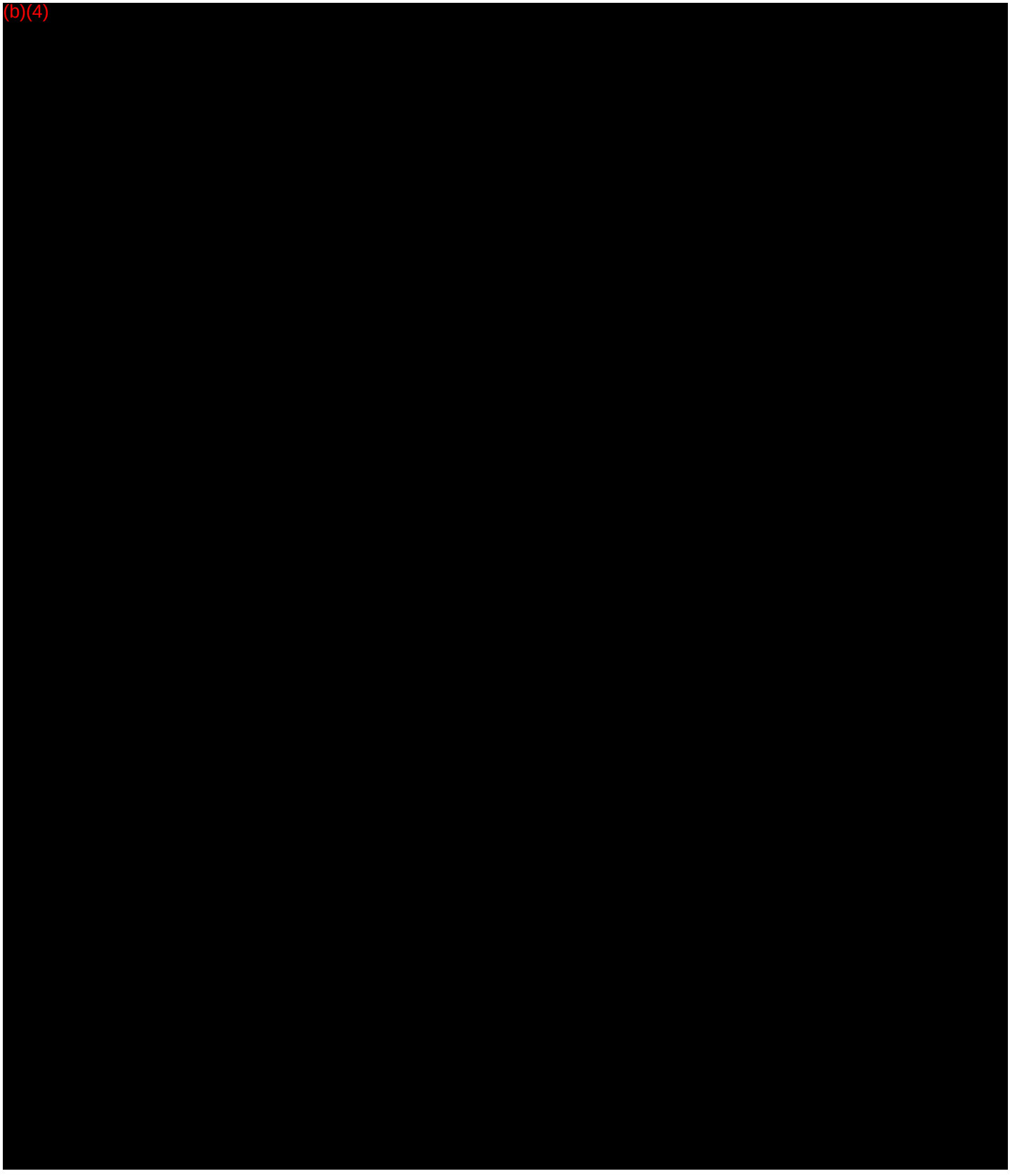
Deficiencies Previous Submission

(b)(4)



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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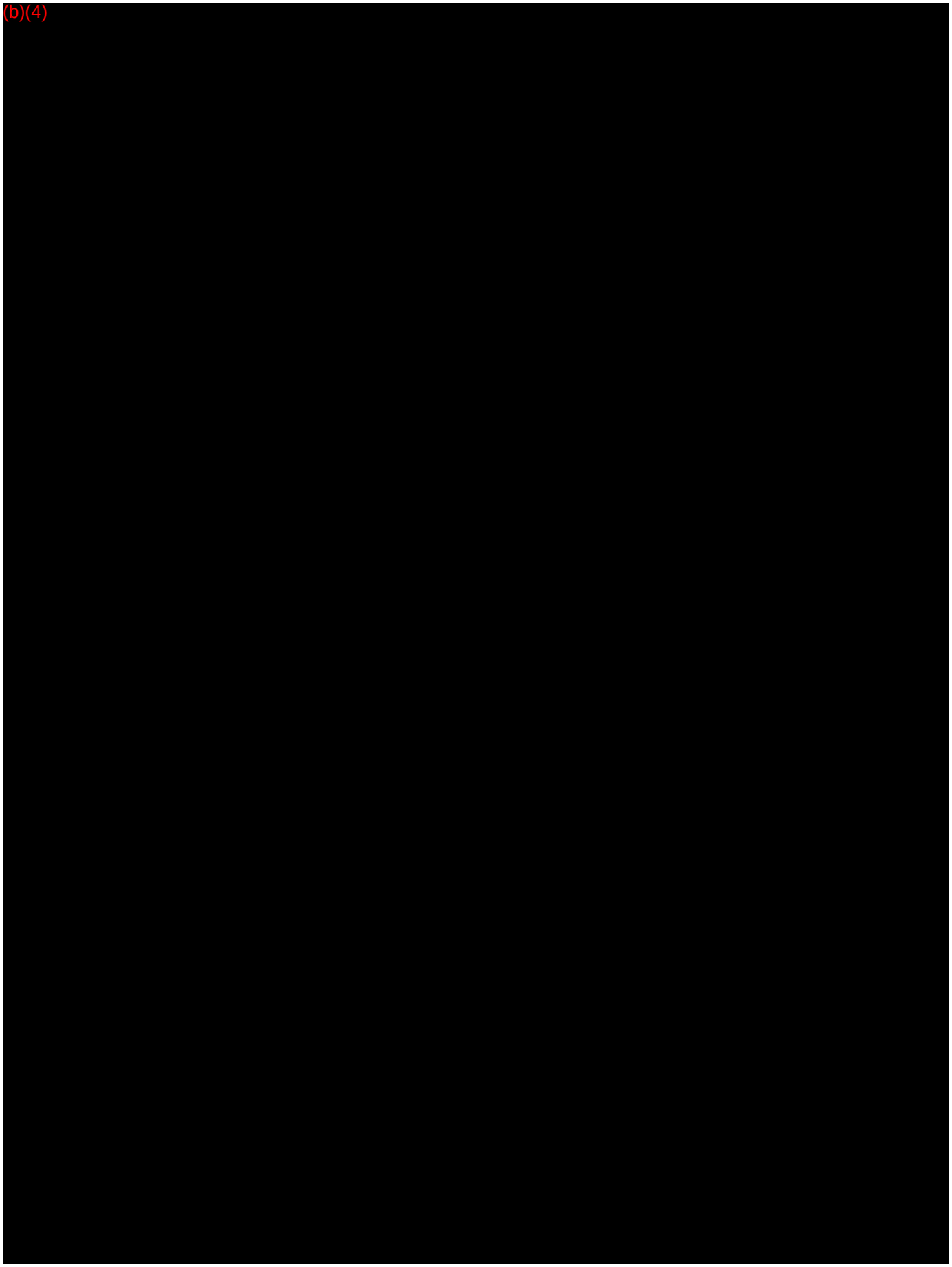
(b)(4)



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

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Applicable Voluntary Standards

A. Radiation control for Health and Safety Act

i. As the 3Shape Abutment Designer™ is a software only application this is not applicable.

B. CDRH – Recognized Voluntary Standards

i. There are not recognized voluntary standards applicable for the 3Shape Abutment Designer™

C. Standard Data Reports

i. A standard data report has been filled out for standards ISO 13485, ISO 14971 and IEC 62304, included as appendixes.

ii. Summary report tables are included in the standard data reports for standards ISO 13485, ISO 14971 and IEC 62304 are included as appendixes.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Contains Nonbinding Recommendations

Acceptance Checklist
for Traditional 510(k)s

(should be completed within 15 days of DCC receipt)

The following information is not intended to serve as a comprehensive review.

510(k) Number: _____ **Date Received by DCC:** _____

Lead Reviewer Name: _____ **Branch:** _____ **Division:** _____ **Office:** _____

Note: If an element is left blank on the checklist, it does not mean the checklist is incomplete; it means the reviewer did not assess the element during RTA and that element will be assessed during substantive review.

Preliminary Questions		
Answers in the shaded blocks indicate consultation with Center advisor is needed.	**Yes**	**No**
1. Is the product a device (per section 201(h) of the FD&C Act) or a combination product (per 21 CFR 3.2(e)) with a device constituent part subject to review in a 510(k)? If it appears not to be a device (per section 201(h) of the FD&C Act) or such a combination product, or you are unsure, consult with the CDRH Jurisdictional Officer or the CBER Office Jurisdiction Liaison to determine the appropriate action, and inform division management. *Provide a summary of the Jurisdictional Officer's/Liaison's determination.* If the product does not appear to be a device or such a combination product, mark "No."	X	
Comments:		
2. Is the application with the appropriate Center? If the product is a device or a combination product with a device constituent part, is it subject to review by the Center in which the submission was received? If you believe the application is not with the appropriate Center or you are unsure, consult with the CDRH Jurisdictional Officer or CBER Office Jurisdiction Liaison to determine the appropriate action and inform your division management. *Provide a summary of the Jurisdictional Officer's/Liaison's determination.* If application should not be reviewed by your Center mark "No."	X	
Comments:		
3. If a Request for Designation (RFD) was submitted for the device or combination product with a device constituent part and assigned to your center, identify the RFD # and confirm the following:	N/A	

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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a) **Is the device or combination product the same (e.g., design, formulation) as that presented in the RFD submission?** b) **Are the indications for use for the device or combination product identified in the 510(k) the same as those identified in the RFD submission?** If you believe the product or the indications presented in the 510(k) have changed from the RFD, or you are unsure, consult with the CDRH Jurisdictional Officer or appropriate CBER Jurisdiction Liaison to determine the appropriate action and inform your division management. *Provide summary of Jurisdictional Officer's/Liaison's determination.* If the answer to either question above is no, mark "No." If there was no RFD, skip this question.		
Comments:		
4. Is this device type eligible for a 510(k) submission? If a 510(k) does not appear to be appropriate (e.g., Class III type and PMA required, or Class I or II type and 510(k)-exempt), you should consult with the CDRH 510(k) Program Director or appropriate CBER staff during the acceptance review. If 510(k) is not the appropriate regulatory submission, mark "No."	X	
Comments:		
5. Is there a pending PMA for the same device with the same indications for use? If yes, consult division management and the CDRH 510(k) Program Director or appropriate CBER staff to determine the appropriate action.		X
Comments:		
6. If clinical studies have been submitted, is the submitter the subject of an Application Integrity Policy (AIP)? If yes, consult with the CDRH Office of Compliance/Division of Bioresearch Monitoring (OC/DBM - BIMO) or CBER Office of Compliance and Biologics Quality/Division of Inspections and Surveillance/Bioresearch Monitoring Branch (OCBQ/DIS/BMB) to determine the appropriate action. Check on web at http://www.fda.gov/ICECI/EnforcementActions/ApplicationIntegrityPolicy/ucm134453.htm.		N/A

If the answer to 1 or 2 appears to be "No," then stop review of the 510(k) and issue the "Original Jurisdictional Product" letter.
If the answer to 3a or 3b appears to be "No," then stop the review and contact the CDRH Jurisdictional Officer or CBER Office of Jurisdiction Liaison.
If the answer to 4 is "No", the lead reviewer should consult division management and other Center resources to determine the appropriate action.
If the answer to 5 is "Yes," then stop review of the 510(k), contact the CDRH 510(k) Staff and PMA Staff, or appropriate CBER staff.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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If the answer to 6 is "Yes," then contact CDRH/OC/DBM – BIMO or CBER/OCBQ/DIS/BMB, provide a summary of the discussion with the BIMO Staff, and indicate BIMO's recommendation/action.

Organizational Elements *Failure to include these items alone generally should not result in an RTA designation*		
	Yes	**No**
a. Submission contains Table of Contents	☒	☐
b. Each section is labeled (e.g., headings or tabs designating Device Description section, Labeling section, etc.)	☒	☐
c. All pages of the submission are numbered *All pages should be numbered in such a manner that information can be referenced by page number. This may be done either by consecutively numbering the entire submission, or numbering the pages within a section (e.g., 12-1, 12-2...).*	☒	☐
d. Type of 510(k) is identified– traditional, abbreviated, or special *If type of 510(k) is not designated, review as a traditional*	☒	☐
Comments:		

Elements of a Complete Submission (RTA Items) **(21 CFR 807.87 unless otherwise indicated)** Submission should be designated RTA if not addressed					
Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.					
	• Any "No" answer will result in a "Refuse to Accept" decision. • Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.		**Yes**	**N/A**	**No**
A.	**Administrative**				
	1.	All content used to support the submission is written in English (including translations of test reports, literature articles, etc.)	☒		☐
		Comments:			
	2.	Submission identifies the following (such as in CDRH Premarket Review Submission Cover Sheet (Form 3514) or 510(k) cover letter):	☒		☐
		a. Device trade name or proprietary name	☒		☐
		b. Device common name	☒		☐

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Elements of a Complete Submission (RTA Items) (21 CFR 807.87 unless otherwise indicated) Submission should be designated RTA if not addressed						
Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.						
	• Any "No" answer will result in a "Refuse to Accept" decision. • Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.			**Yes**	**N/A**	**No**
		c.	Device class and panel or Classification regulation or Statement that device has not been classified with rationale for that conclusion	☒		☐
		Comments:				
	3.	Submission contains Indications for Use Statement with Rx and/or OTC designated (see also 21 CFR 801.109) *Submitter should use format appropriate for the reviewing Center/Office (CDRH/ODE, CDRH/OIVD, CBER/OBRR, CBER/OCTGT). If not provided in correct format, request the correct format during substantive review.*		☒		☐
		Comments:				
	4.	Submission contains 510(k) Summary or 510(k) Statement *Either a) or b) must be answered "Yes" to be considered complete. Identify any missing element(s) in Comments.*		☒		☐
		a.	Summary contains all elements per 21 CFR 807.92 *See also 510(k) Summary Checklist*	☒	☐	☐
		b.	Statement contains all elements per 21 CFR 807.93	☐	☐	☐
		Comments: VOL_001				
	5.	Submission contains Truthful and Accuracy Statement per 21 CFR 807.87(k) *See recommended format. Select "Yes" if statement is present and includes the text in the recommended format, and is signed by a responsible person of the firm (not consultant).*		☒		☐
		Comments: VOL-001				

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Elements of a Complete Submission (RTA Items) (21 CFR 807.87 unless otherwise indicated) Submission should be designated RTA if not addressed						
Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.						
	• Any "No" answer will result in a "Refuse to Accept" decision. • Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.			**Yes**	**N/A**	**No**
	6.	Submission contains Class III Summary and Certification *See recommended content. Form should be signed by a responsible person of the firm, not a consultant. Select "N/A" only if submission is not a Class III 510(k).*		☐	☒	☐
		Comments:				
	7.	Submission contains clinical data *Select "N/A" if the submission does not contain clinical data. If "N/A" is selected, parts a and b below are omitted from the checklist.*		☐	☒	
		a.	Submission includes completed Financial Certification (FDA Form 3454) or Disclosure (FDA Form 3455) information for each covered clinical study included in the submission. *Select "N/A" if the submitted clinical data is not a "covered clinical study" as defined in the Guidance for Industry-Financial Disclosures by Clinical Investigators*	☐	☐	☐
		b.	Submission includes completed Certification of Compliance with requirements of ClinicalTrials.gov Data Bank (FDA Form 3674) (42 U.S.C. 282(j)(5)(B)) for each applicable device clinical trial included in the submission. *Select "N/A" if the submitted clinical data is not an "applicable device clinical trial" as defined in Title VIII of FDAAA, Sec. 801(j)*	☐	☐	☐
		Comments:				
	8.	If submission references use of a national or international standard as part of demonstration of substantial equivalence, submission contains complete Standards Data Report for 510(k)s (FDA Form 3654) *There should be a completed form for each referenced national or international standard.* *Select "N/A" only if submission does not reference any standards.*		☒	☐	☐

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.					
	• Any "No" answer will result in a "Refuse to Accept" decision. • Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.		**Yes**	**N/A**	**No**
		Comments:			
	9.	The submission identifies prior submissions for the same device for which FDA provided feedback related to the data or information needed to support substantial equivalence (e.g., submission numbers for Pre-Submission, IDE, prior not substantially equivalent (NSE) determination, prior 510(k) that was deleted or withdrawn) or states that there were no prior submissions for the subject device. *This information may be included in the Cover Letter (i.e., as a statement that there were no prior submissions for the device or a listing of the number(s) of the prior submissions). Alternatively, a list of submission numbers may be found in Section F (prior related submissions section) of the CDRH Coversheet form (Form 3514) to address this criterion. Please be advised that if this section of the form is left blank, it should not be considered a statement that there were no prior submissions.*	☒		☐
		a. If there were prior submissions, the submitter has identified where in the current submission any issues related to a determination of substantial equivalence outlined in prior communications are addressed. *To address this criterion, the submission may include a separate section with the prior submission number(s), a copy of the FDA feedback (e.g., letter, meeting minutes), and a statement of how or where in the submission this prior feedback was addressed. Note that the adequacy of how the feedback was addressed should be assessed during the substantive review.* For additional information regarding the Pre-Submission process, please refer to the Draft Guidance "Medical Devices: The Pre-Submission Program and Meetings with FDA Staff." (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm310375.htm). Once finalized, this guidance will represent the	☒	☐	☐

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	• Any "No" answer will result in a "Refuse to Accept" decision. • Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.			**Yes**	**N/A**	**No**
			Agency's current thinking on this topic. *Select "N/A" if the submitter states there were no prior submissions in criterion above.*			
		Comments: DEFICIENCIES PREVIOUS SUBMISSION IN VOL_001				
B.	**Device Description**					
	10.	a.	If there are requirements regarding the device description, such as special controls, in a device-specific regulation that are applicable to the device, the submission includes device description information to establish that the submitter has followed the device-specific requirement. *Select "N/A" if there are no applicable requirements in a device-specific regulation. Select "No" if the submission does not include a rationale for any omitted information. Note that the adequacy of how such requirements have been addressed should be assessed during the substantive review.*	☒	☐	☐
		b.	If there is a device-specific guidance, other than a special controls guidance document, applicable to the device, the submission includes device description information to establish that the submitter has addressed the recommendations or otherwise has met the applicable statutory or regulatory criteria through an alternative approach. *Select "N/A" if there is no applicable device-specific guidance. Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how recommendations in a device-specific guidance, etc., have been addressed should be assessed during the substantive review.*	☒	☐	☐
		Comments:				

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	• Any "No" answer will result in a "Refuse to Accept" decision. • Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.			**Yes**	**N/A**	**No**
	11.	Descriptive information is present and consistent within the submission (e.g., the device description section is consistent with the device description in the labeling), including:				
		a.	A description of the principle of operation and mechanism of action for achieving the intended effect.	☒		☐
		b.	A description of proposed conditions of use, such as surgical technique for implants; anatomical location of use; user interface; how the device interacts with other devices; and/or how the device interacts with the patient.	☒		☐
		c.	A list and description of each device for which clearance is requested. *Select "N/A" if there is only one device or model. "Device" may refer to models, part numbers, or various sizes, etc.*	☐	☒	☐
		Comments:				
	12.	Submission contains representative engineering drawing(s), schematics, illustrations and/or figures of the device that are clear, legible, labeled, and include dimensions. *In lieu of drawings, schematics, etc. of each device to be marketed, "representative" drawings, etc. may be provided, where "representative" is intended to mean that the drawings, etc. provided capture the differences in design, size, and other important characteristics of the various models, sizes, or versions of the device(s) to be marketed.* *Select "N/A" if the submitter provided a rationale for why the submission does not contain engineering drawings, schematics, etc. (e.g., device is a reagent and figures are not pertinent to describe the device).*		☐	☒	☐
		Comments:				

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	13.	If device is intended to be marketed with multiple components, accessories, and/or as part of a system, *Select "N/A" if the device is not intended to be marketed with multiple components, accessories, and/or as part of a system.*			☐	
		a.	Submission includes a list of all components and accessories to be marketed with the subject device.	☒		☐
		b.	Submission includes a description (as detailed in item 11.a. and b. and 12 above) of each component or accessory. *Select "N/A" if the component(s)/accessory(ies) has been previously cleared, or is exempt, and the proposed indications for use are consistent with the cleared indications.*	☐	☒	☐
		c.	A 510(k) number is provided for each component or accessory that received a prior 510(k) clearance. *Select "N/A" if the submission states that the component(s)/ accessory(ies) does not have a prior 510(k) clearance or the component(s)/accessory(ies) is 510(k) exempt.*	☐	☒	☐
		Comments:				
C.	**Substantial Equivalence Discussion**					
	14.	Submitter has identified a predicate(s) device		☒		☐
		a.	Predicate's 510(k) number, trade name, and model number (if applicable) provided. For predicates that are preamendments devices, information is provided to document preamendments status. *Information regarding documenting preamendment status is available online (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidan*	☒		☐

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	• Any "No" answer will result in a "Refuse to Accept" decision. • Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.			**Yes**	**N/A**	**No**
			ce/ComplianceActivities/ucm072746.htm).			
		b.	The identified predicate(s) is consistent throughout the submission (i.e., the predicate(s) identified in the Substantial Equivalence section is the same as that listed in the 510(k) Summary (if applicable) and that used in comparative performance testing.	☒		☐
		Comments: VOL 001 – PAGE 1-12				
	15.	Submission includes a comparison of the following for the predicate(s) and subject device				
		a.	Indications for use	☒		☐
		b.	Technology, including features, materials, and principles of operation	☒		☐
		Comments: VOL 001 – PAGE 1-12				
	16.	Submission includes an analysis of why any differences between the subject device and predicate(s) do not render the device NSE (e.g., does not constitute a new intended use; and any differences in technological characteristics are accompanied by information that demonstrates the device is as safe and effective as the predicate and do not raise different questions of safety and effectiveness than the predicate), affect safety or effectiveness, or raise different questions of safety and effectiveness (see section 513(i)(1)(A) of the FD&C Act and 21 CFR 807.87(f)) *If there is no difference between the subject and predicate(s) with respect to indications for use or technology, this should be explicitly stated, in which case "N/A" should be selected. Select "No" only if the submission does not include an analysis of differences as described above or a statement that there are no differences. Note that the adequacy of the analysis should be assessed during the substantive review; only the presence of such an analysis is required for acceptance. In addition, note that due to potential differences in*			☒	☐	☐

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	• Any "No" answer will result in a "Refuse to Accept" decision. • Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.		**Yes**	**N/A**	**No**
		manufacturing that may not be known to the submitter, the fact that no differences are identified does not necessarily mean that no performance testing is needed.			
		Comments:			
D.	**Proposed Labeling (see also 21 CFR part 801)** *If in vitro diagnostic (IVD) device, criteria 17, 18, and 19 may be omitted. These criteria will be omitted from the checklist if "N/A" is selected. IVD labeling is addressed in section 21 below.*			☐	
	17.	Submission includes proposed package labels and labeling (e.g., instructions for use, package insert, operator's manual) that include a description of the device, its intended use, and the directions for use	☒		☐
		a. Indications for use are stated in labeling and are identical to Indications for Use form and 510(k) Summary (if 510(k) Summary provided)	☒		☐
		b. Submission includes directions for use that - include statements of all conditions, purposes or uses for which the device is intended (e.g., hazards, warnings, precautions, contraindications) (21 CFR 801.5) AND - Includes directions for layperson (see 21 CFR 801.5) OR submission states that device qualifies for exemption per 21 CFR 801 Subpart D	☒		☐
		Comments: VOL-013			
	18.	If indicated for prescription use, labeling includes the prescription use statement (see 21 CFR 801.109(b)(1)) or "Rx only" symbol [See also Alternative to Certain Prescription Device Labeling Requirements] *Select "N/A" if not indicated for prescription use.*	☒	☐	☐

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Contains Nonbinding Recommendations

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		Comments: FRONT PAGE IFU - VOL_013				
	19.	General labeling provisions				
		a.	Labeling includes name and place of business of the manufacturer, packer, or distributor (21 CFR 801.1)	☒		☐
		b.	Labeling includes device common or usual name (21 CFR 801.61) *Select "N/A" if device is for prescription use only.*	☐	☒	☐
		Comments:				
	20.	a.	If there are requirements regarding labeling, such as special controls, in a device-specific regulation that are applicable to the device, the submission includes labeling to establish that the submitter has followed the device-specific requirement. *Select "N/A" if there are no applicable requirements in a device-specific regulation. Select "No" if the submission does not include a rationale for any omitted information. Note that the adequacy of how such requirements have been addressed should be assessed during the substantive review.*	☐	☒	☐
		b.	If there is a device-specific guidance, other than a special controls guidance document, applicable to the device, the submission includes labeling to establish that the submitter has addressed the recommendations or otherwise has met the applicable statutory or regulatory criteria through an alternative approach. *Select "N/A" if there is no applicable device-specific guidance. Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how recommendations in a device-specific guidance have been addressed should be assessed during the substantive review.*	☐	☒	☐

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.						
	• Any "No" answer will result in a "Refuse to Accept" decision. • Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.			**Yes**	**N/A**	**No**
		c.	If there is a special controls document applicable to the device, the submission includes labeling to establish that the submitter has complied with the particular mitigation measures set forth in the special controls document or uses alternative mitigation measures but provides a rationale to demonstrate that those alternative measures identified by the firm will provide at least an equivalent assurance of safety and effectiveness. *Select "N/A" if there is no applicable special controls document. Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how mitigation measures in a special controls document have been addressed should be assessed during the substantive review.*	☐	☒	☐
		Comments:				
	21.	If the device is an in vitro diagnostic device, provided labeling includes all applicable information required per 21 CFR 809.10. *Select "N/A" if not an in vitro diagnostic device.*		☐	☒	☐
E.	**Sterilization** *If in vitro diagnostic (IVD) device and sterilization is not applicable, select "N/A." The criteria in this section will be omitted from the checklist if "N/A" is selected.*				☒	
	Submission states that the device and/or accessories are: (*one of the below must be checked*) ☐ provided sterile ☐ provided non-sterile but sterilized by the end user ☐ non-sterile when used This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination. *If "non-sterile when used" is selected, the sterility-related criteria below are omitted from*					☐

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	• Any "No" answer will result in a "Refuse to Accept" decision. • Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.			**Yes**	**N/A**	**No**
	the checklist. *If information regarding the sterility status of the device is not provided, select "No."*					
	Comments: STANDALONE SOFTWARE					
	22.	Assessment of the need for sterilization information				
		a.	Identification of device, and/or accessories, and/or components that are provided sterile.	☐	☐	☐
		b.	Identification of device, and/or accessories, and/or components that are end user sterilized	☐	☐	☐
		c.	Identification of device, and/or accessories, and/or components that are reusable and cleaning/disinfection instructions are provided.	☐	☐	☐
		Comments:				
	23.	If the device, and/or accessory, and/or a component is provided sterile: *Select "N/A" if no part of the device, accessories, or components is provided sterile, otherwise complete a-e below.*			☐	
		a.	Sterilization method is stated for each component (including parameters such as dry time for steam sterilization, radiation dose, etc.)	☐		☐
		b.	A description of method to validate the sterilization parameters (e.g., half-cycle method and full citation of FDA-recognized standard, including date) is provided for each proposed sterilization method. *Note, the sterilization validation report is not required.*	☐		☐
		c.	For devices sterilized using chemical sterilants such as ethylene oxide (EO) and hydrogen peroxide, submission states maximum	☐	☐	☐

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			levels of sterilant residuals remaining on the device and sterilant residual limits. *Select "N/A" if not sterilized using chemical sterilants.*			
		d.	Submission includes description of packaging and packaging contents (e.g., if multiple devices are included within the same package, Tyvek packaging, etc.)	☐		☐
		e.	Sterility Assurance Level (SAL) stated	☐		☐
		Comments:				
	24.	If the device, and/or accessory, and/or a component is end user sterilized: *Select "N/A" if no part of the device, accessories, or components are end user sterilized, otherwise complete a-d below.*			☐	
		a.	Sterilization method is stated for each component (including parameters such as dry time for steam sterilization, radiation dose, etc.)	☐		☐
		b.	A description of method to validate the sterilization parameters (e.g., half-cycle method and full citation of FDA-recognized standard, including date) is provided for each proposed sterilization method. *Note, the sterilization validation is not required.*	☐		☐
		c.	Submission includes description of packaging and packaging contents (e.g., if multiple devices are included within the same package, Tyvek packaging, etc.)	☐		☐
		d.	Submission includes sterilization instructions for end user	☐		☐
		Comments:				
	25.	a.	If there are requirements regarding sterility, such as special	☐	☐	☐

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			controls, in a device-specific regulation that are applicable to the device, the submission includes sterility information to establish that the submitter has followed the device-specific requirement. *Select "N/A" if there are no applicable requirements in a device-specific regulation. Select "No" if the submission does not include a rationale for any omitted information. Note that the adequacy of how such requirements have been addressed should be assessed during the substantive review.*			
		b.	If there is a device-specific guidance, other than a special controls guidance document, applicable to the device, the submission includes sterility information to establish that the submitter has addressed the recommendations or otherwise has met the applicable statutory or regulatory criteria through an alternative approach. *Select "N/A" if there is no applicable device-specific guidance. Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how recommendations in a device-specific guidance have been addressed should be assessed during the substantive review.*	☐	☐	☐
		c.	If there is a special controls document applicable to the device, the submission includes sterility information to establish that the submitter has complied with the particular mitigation measures set forth in the special controls document or uses alternative mitigation measures but provides a rationale to demonstrate that those alternative measures identified by the firm will provide at least an equivalent assurance of safety and effectiveness. *Select "N/A" if there is no applicable special controls document. Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how mitigation measures in a*			

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			special controls document have been addressed should be assessed during the substantive review.			
		Comments:				
F.	**Shelf Life**					
	26.	Proposed shelf life/ expiration date stated *Select "N/A" if the device is not provided sterile and the submitter states that storage conditions could not affect device safety or effectiveness.*		☐	☒	☐
		Comments:				
	27.	For sterile device, submission includes summary of methods used to establish that device sterility will remain substantially equivalent to that of the predicate through the proposed shelf life, or a rationale for why testing to establish shelf life is not applicable. *Select "N/A" if the device is not provided sterile.*		☐	☒	☐
		Comments:				
	28.	Submission includes summary of methods used to establish that device performance is not adversely affected by aging and therefore device performance will remain substantially equivalent to that of the predicate, or includes a rationale for why the storage conditions are not expected to affect device safety or effectiveness.		☐		☐
		Comments:				
G.	**Biocompatibility** *If in vitro diagnostic (IVD) device, select "N/A." The criteria in this section will be omitted from the checklist if "N/A" is selected.*				☒	
	Submission states that there: (*one of the below must be checked*) ☐ are					☐

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	☒ are not direct or indirect (e.g., through fluid infusion) patient-contacting components. This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination. *If "are not" is selected, the biocompatibility-related criteria below are omitted from the checklist. If information regarding whether the device is patient-contacting is not provided, select "No."*			
	Comments: VOL_001 PAGE 1-18			
	29. Submission includes list of patient-contacting device components and associated materials of construction, including identification of color additives, if present	☐		☐
	Comments:			
	30. Submission identifies contact classification (e.g., surface-contacting, less than 24 hour duration)	☐		☐
	Comments:			
	31. Biocompatibility assessment of patient-contacting components Submission includes: Test protocol (including identification and description of test article), methods, pass/fail criteria, and results provided for each completed test, OR a statement that biocompatibility testing is not needed with a rationale (e.g., materials and manufacturing/processing are identical to the predicate).	☐		☐
	Comments:			
H.	**Software**			

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2016-8070; Released by CDRH on 10/5/2017

Elements of a Complete Submission (RTA Items) (21 CFR 807.87 unless otherwise indicated) Submission should be designated RTA if not addressed				
Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.				
	• Any "No" answer will result in a "Refuse to Accept" decision. • Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.	**Yes**	**N/A**	**No**
	Submission states that the device: (*one of the below must be checked*) ☒ does ☐ does not contain software/firmware. This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination. *If "does not" is selected, the software-related criterion is omitted from the checklist. If information regarding whether the device contains software is not provided, select "No."*			☐
	Comments:			
	32. Submission includes a statement of software level of concern and rationale for the software level of concern	☒		☐
	Comments: VOL 002			
	33. All applicable software documentation provided based on level of concern identified by the submitter, as described in Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, or the submission includes information to establish that the submitter has otherwise met the applicable statutory or regulatory criteria through an alternative approach (i.e., the submitter has identified an alternate approach with a rationale).	☒		☐
	Comments: VOL 003 TO VOL 013			
I.	**EMC and Electrical Safety**			
	Submission states that the device: (*one of the below must be checked*) ☐ does ☒ does not require EMC and Electrical Safety evaluation.			☐

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2016-8070; Released by CDRH on 10/5/2017

Contains Nonbinding Recommendations

Elements of a Complete Submission (RTA Items) (21 CFR 807.87 unless otherwise indicated) Submission should be designated RTA if not addressed				
Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.				
	• Any "No" answer will result in a "Refuse to Accept" decision. • Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.	**Yes**	**N/A**	**No**
	This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination. *If "does not" is selected, the EMC-related and Electrical Safety-related criteria below are omitted from the checklist. If information regarding whether the device requires EMC and Electrical Safety evaluation is not provided, select "No."*			
	Comments: VOL - 001 PAGE 1-16			
	34. Submission includes evaluation of electrical safety (e.g., per IEC 60601-1, or equivalent FDA-recognized standard, and if applicable, the device-specific standard), OR submission includes electrical safety evaluation using methods or standards that are not FDA-recognized and submission includes information to establish that the submitter has otherwise met the applicable statutory or regulatory criteria through this alternative approach (i.e., the submitter has identified alternate methods or standards with a rationale).	☐		☐
	Comments:			
	35. Submission includes evaluation of electromagnetic compatibility (e.g., per IEC 60601-1-2 or equivalent FDA-recognized standard and if applicable, the device-specific standard) OR submission includes electromagnetic compatibility evaluation using methods or standards that are not FDA-recognized and submission includes information to establish that the submitter has otherwise met the applicable statutory or regulatory criteria through this alternative approach (i.e., the submitter has identified alternate methods or standards with a rationale).	☐		☐
	Comments:			

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Elements of a Complete Submission (RTA Items) (21 CFR 807.87 unless otherwise indicated) Submission should be designated RTA if not addressed					
Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.					
	• Any "No" answer will result in a "Refuse to Accept" decision. • Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.			**Yes**	**N/A**	**No**
J.	**Performance Data – General** *If in vitro diagnostic (IVD) device, select "N/A." The criteria in this section will be omitted from the checklist if "N/A" is selected. Performance data criteria relating to IVD devices will be addressed in Section K.*				☐	
	Comments:					
	36.	Full test report is provided for each completed test. A full test report includes: objective of the test, description of the test methods and procedures, study endpoint(s), pre- defined pass/fail criteria, results summary, conclusions, and an explanation of how the data generated from the test supports a finding of substantial equivalence. *Full test reports provided for all completed tests/evaluations (e.g., bench evaluations, comparative performance tests, etc.). Select "N/A" if the submission does not include performance data.*		☒	☐	☐
		Comments: VOL 010				
	37.	a.	If there are requirements regarding performance data, such as special controls, in a device-specific regulation that are applicable to the device, the submission includes performance data to establish that the submitter has followed the device-specific requirement. *Select "N/A" if there are no applicable requirements in a device-specific regulation. Select "No" if the submission does not include a rationale for any omitted information. Note that the adequacy of how such requirements have been addressed should be assessed during the substantive review.*	☐	☒	☐
		b.	If there is a device-specific guidance, other than a special controls guidance document, applicable to the device, the submission includes performance data to establish that the submitter has addressed the recommendations or otherwise has met the applicable statutory or regulatory criteria through an alternative	☐	☒	☐

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.						
	• Any "No" answer will result in a "Refuse to Accept" decision. • Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.			**Yes**	**N/A**	**No**
			approach. *Select "N/A" if there is no applicable device-specific guidance. Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how recommendations in a device-specific guidance have been addressed should be assessed during the substantive review.*			
		c.	If there is a special controls document applicable to the device, the submission includes performance data to establish that the submitter has complied with the particular mitigation measures set forth in the special controls document or uses alternative mitigation measures but provides a rationale to demonstrate that those alternative measures identified by the firm will provide at least an equivalent assurance of safety and effectiveness. *Select "N/A" if there is no applicable special controls document. Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how mitigation measures in a special controls document have been addressed should be assessed during the substantive review.*	☐	☒	☐
		Comments:				
	38.	If literature is referenced in the submission, submission includes: *Select "N/A" if the submission does not reference literature. Note that the applicability of the referenced article to support a substantial equivalence finding should be assessed during the substantive review; only the presence of a discussion is required to support acceptance.*			☒	
		a.	Legible reprints or a summary of each article	☐		☐
		b.	Discussion of how each article is applicable to support the	☐		☐

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.						
	• Any "No" answer will result in a "Refuse to Accept" decision. • Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.			**Yes**	**N/A**	**No**
			substantial equivalence of the subject device to the predicate.			
		Comments:				
	39.	For each completed nonclinical (i.e., animal) study conducted, *Select "N/A" if no animal study was conducted. Note that this section does not address biocompatibility evaluations, which are assessed in Section G of the checklist,*			☒	
		a.	Submission includes a study protocol which includes all elements as outlined in 21 CFR 58.120	☐		☐
		b.	Submission includes final study report which includes all elements outlined in 21 CFR 58.185	☐		☐
		c.	Submission contains a statement that the study was conducted in compliance with applicable requirements in the GLP regulation (21 CFR Part 58), or, if the study was not conducted in compliance with the GLP regulation, the submission explains why the noncompliance would not impact the validity of the study data provided to support a substantial equivalence determination.	☐		☐
		Comments:				
K.	**Performance Characteristics – In Vitro Diagnostic Devices Only (see also 21 CFR 809.10(b)(12))**					
	Submission indicates that device: (*one of the below must be checked*) ☐ is ☒ is not an in vitro diagnostic device (IVD). *If "is not" is selected, the performance data-related criteria below are omitted from the checklist.*					
	Comments:					

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Elements of a Complete Submission (RTA Items) (21 CFR 807.87 unless otherwise indicated) Submission should be designated RTA if not addressed						
Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.						
	• Any "No" answer will result in a "Refuse to Accept" decision. • Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.			**Yes**	**N/A**	**No**
	40.	Submission includes the following studies, as appropriate for the device type, including associated protocol descriptions, study results and line data:				
		a.	Precision/reproducibility	☐	☐	☐
		b.	Accuracy (includes as appropriate linearity; calibrator or assay traceability; calibrator and/or assay stability protocol and acceptance criteria; assay cut-off; method comparison or comparison to clinical outcome; matrix comparison; and clinical reference range or cutoff.	☐	☐	☐
		c.	Sensitivity (detection limits, LoB, LoD, LoQ where relevant for the device type).	☐	☐	☐
		d.	Analytical specificity	☐	☐	☐
		Comments:				
	41.	a.	If there are requirements regarding performance data, such as special controls, in a device-specific regulation that are applicable to the device, the submission includes performance data to establish that the submitter has followed the device-specific requirement. *Select "N/A" if there are no applicable requirements in a device-specific regulation. Select "No" if the submission does not include a rationale for any omitted information. Note that the adequacy of how such requirements have been addressed should be assessed during the substantive review.*	☐	☐	☐
		b.	If there is a device-specific guidance, other than a special controls guidance document, applicable to the device, the submission includes performance data to establish that the submitter has addressed the recommendations or otherwise has met the	☐	☐	☐

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.						
	• Any "No" answer will result in a "Refuse to Accept" decision. • Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.			**Yes**	**N/A**	**No**
			applicable statutory or regulatory criteria through an alternative approach. *Select "N/A" if there is no applicable device-specific guidance. Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how recommendations in a device-specific guidance have been addressed should be assessed during the substantive review.*			
		c.	If there is a special controls document applicable to the device, the submission includes performance data to establish that the submitter has complied with the particular mitigation measures set forth in the special controls document or uses alternative mitigation measures but provides a rationale to demonstrate that those alternative measures identified by the firm will provide at least an equivalent assurance of safety and effectiveness. *Select "N/A" if there is no applicable special controls document. Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how mitigation measures in a special controls document have been addressed should be assessed during the substantive review.*	☐	☐	☐
		Comments:				

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Records processed under FOIA Request 2016-8070; Released by CDRH on 10/5/2017

Form Approved: OMB No. 0910-0120; Expiration Date: 1/31/2017

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

IEC 62304 Medical Device Software - Software Life Cycle Processes, 08/20/2012

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#13-8	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☐	☒
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☐	☒
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☐	☒
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☒	☐
If yes, was the guidance document followed in preparation of this 510k?	☒	☐

Title of guidance: General Principles of Software Validation; Final Guidance for Industry and FDA Staff

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search for CDRH Guidance Documents can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2016-8070; Released by CDRH on 10/5/2017

EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
IEC 62304 Medical Device Software - Software Life Cycle Processes, 08/20/2012

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
4	Quality Management System	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
5	Software development process	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
6	Software maintenance process	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

◆ Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 1 hour per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE
IEC 62304 Medical Device Software - Software Life Cycle Processes, 08/20/2012

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
7	Software risk management process	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
8	Software configuration management process	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
9	Software problem resolution process	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

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Form Approved: OMB No. 0910-0120; Expiration Date: 1/31/2017

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ISO 14971 Medical devices - Application of Risk Management To Medical Devices 16/05/2012

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2] ?	☒	☐
FDA Recognition number [3]	#5-40	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☐	☒
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☐	☒
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☐	☒
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5] ?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
ISO 14971 Medical devices - Application of Risk Management To Medical Devices 16/05/2012

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
3	General requirements for risk management	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
4	Risk analysis	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
5	Risk evaluation	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

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PRAStaff@fda.hhs.gov

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Records processed under FOIA Request 2016-8070; Released by CDRH on 10/5/2017

EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE
ISO 14971 Medical devices - Application of Risk Management To Medical Devices 16/05/2012

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
6	Risk control	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
7	Evaluation of overall residual risk acceptability	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
8	Risk management report	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
9	Production and post-production information	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

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Form Approved: OMB No. 0910-0120; Expiration Date: 1/31/2017

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ISO 13485 Medical devices - Quality management systems - Requirements for regulatory proces, 2003-07-15

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2] ?	☐	☒
FDA Recognition number [3] # _____		
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☐	☒
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☐	☒
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☐	☒
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5] ?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search for CDRH Guidance Documents can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm

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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE
ISO 13485 Medical devices - Quality management systems - Requirements for regulatory proces, 2003-07-15

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
4	Quality management system	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
5	Management responsibility	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
6	Resource management	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

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This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 1 hour per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
ISO 13485 Medical devices - Quality management systems - Requirements for regulatory proces, 2003-07-15

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
7	Product realization	☒ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED ◆		
DESCRIPTION		
JUSTIFICATION		
8	Measurement, analysis and improvement	☒ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED ◆		
DESCRIPTION		
JUSTIFICATION		
		☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED ◆		
DESCRIPTION		
JUSTIFICATION		
		☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED ◆		
DESCRIPTION		
JUSTIFICATION		

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Level of concern

Level of Concern is determined by answering the key questions listed in Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, Table 1 and Table 2.

Table 1 Major Level of Concern

If the answer to any one question below is Yes, the Level of Concern for the Software Device is likely to be Major.
Does the Software Device qualify as Blood Establishment Computer Software? **No** (Blood Establishment Computer Software is defined as software products intended for use in the manufacture of blood and blood components or for the maintenance of data that blood establishment personnel use in making decisions regarding the suitability of donors and the release of blood or blood components for transfusion or further manufacture.)
Is the Software Device intended to be used in combination with a drug or biologic? **No**
Is the Software Device an accessory to a medical device that has a Major Level of Concern? **No**
Prior to mitigation of hazards, could a failure of the Software Device result in death or serious injury, either to a patient or to a user of the device? Examples of this include the following:
Does the Software Device control a life supporting or life sustaining function? **No**
Does the Software Device control the delivery of potentially harmful energy that could result in death or serious injury, such as radiation treatment systems, defibrillators, and ablation generators? **No**
Does the Software Device control the delivery of treatment or therapy such that an error or malfunction could result in death or serious injury? **No**
Does the Software Device provide diagnostic information that directly drives a decision regarding treatment or therapy, such that if misapplied it could result in serious injury or death? **No**
Does the Software Device provide vital signs monitoring and alarms for potentially life threatening situations in which medical intervention is necessary? **No**

Based on the above Dental application software is not Major Level of Concern.

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Table 2 Moderate Level of Concern

If the Software Device is not Major Level of Concern and the answer to any one question below is Yes, the Level of Concern is likely to be Moderate.
Is the Software Device an accessory to a medical device that has a Moderate Level of Concern? **No**
Prior to mitigation of hazards, could a failure of the Software Device result in Minor Injury, either to a patient or to a user of the device? **Yes**
Could a malfunction of, or a latent design flaw in, the Software Device lead to an erroneous diagnosis or a delay in delivery of appropriate medical care that would likely lead to Minor Injury? **No**

The answers to all of the questions in Table 1 are **No**, which is why Level of Concern for the 3shape Abutment Designer ™ Software is determined to be **Moderate**.

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Software Description

1. Introduction

The 3Shape Abutment Designer™ Software is intended for designing endosseous dental implant abutments based on digital scans of 3D models.

The output of the device is a computer file containing the abutment(s) in digital form which can be used by 3rd party providers of milling machines and/or rapid prototyping machines to manufacture physical abutments. The 3Shape Abutment Designer™ Software does not provide any means of creating physical abutments, nor does it consist of any physical parts.

The 3Shape Abutment Designer™ Software can be run on properly configured "off the shelf" PC hardware running Microsoft® Windows and using a standard keyboard and mouse.

The Software is implemented in the Delphi programming language.

For summary of functional requirements of the Software, see "VOL 005 Software Requirement Specification" of this submission.

Note: 3Shape Abutment Designer™ is an add on module to 3Shape Dental System™ which is classified as 872.3661 Optical Impression Systems for CAD/CAM, Product Code NOF (510(K) Exempt). Throughout this submission there will be references to 3Shape Dental System™, but only the documentation relevant to 3Shape Abutment Designer™ has been included.

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2. Intended Use and Operational Environment

The 3Shape Abutment Designer™ Software is intended for designing endosseous dental implant abutments based on digital scans of 3D models.

Intended users are Dental Practitioners and Dental Laboratory staff.

Intended Operational Environment is Dental Laboratories.

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3. Definitions

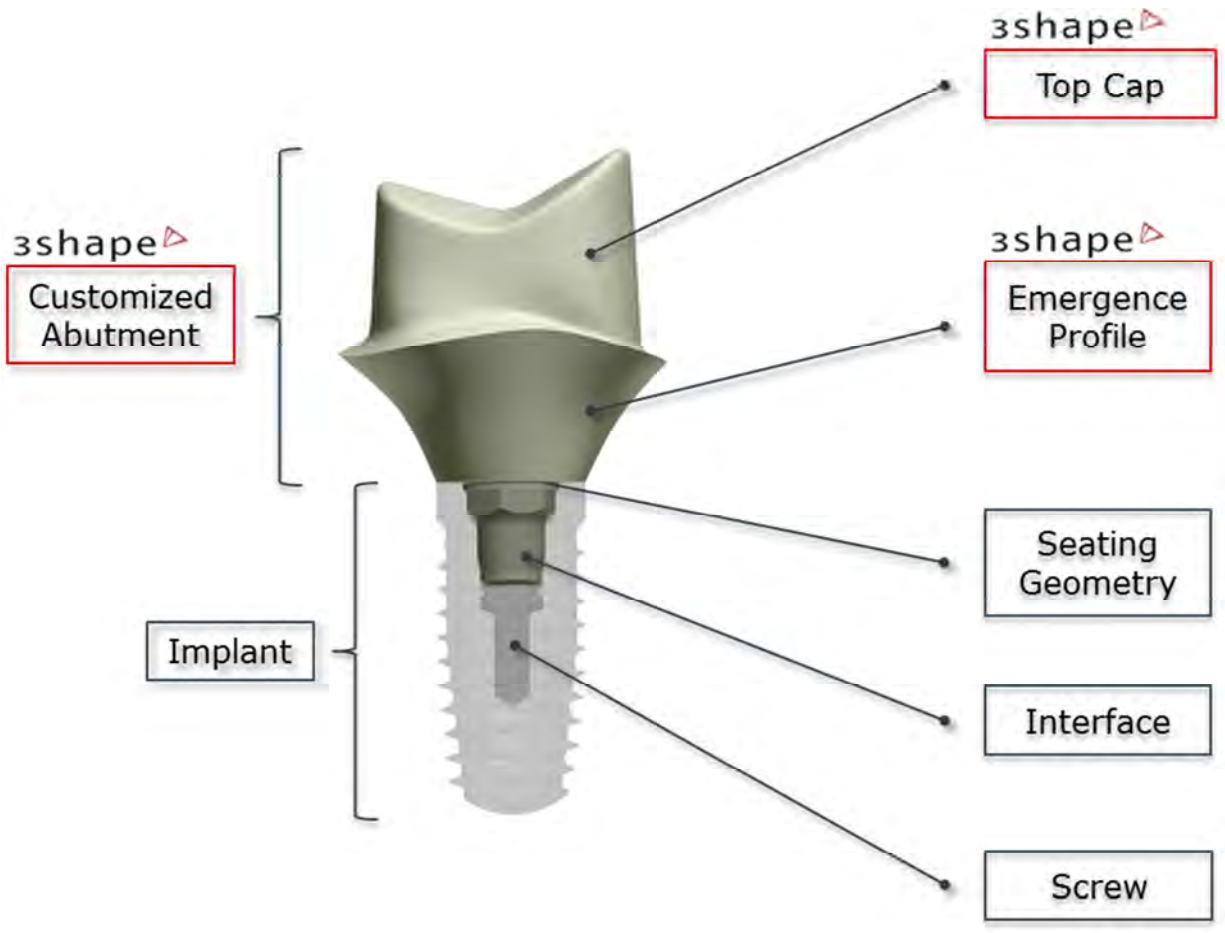
There are four types of Abutments supported by the 3Shape Dental System: Customized, Anatomical, Screw Retained Crown, and Wax up.

3Shape uses the term "Abutment" to denote all four types. Digitally created abutments are classified as an Endosseous dental implant abutment.

The 3Shape Abutment Designer™ only supports modification of the Abutment itself as exemplified on *Figure 1: Customized Abutment parts*.

A digital representation of the Implant is required for the software to work, but only to ensure the Abutment will fit on the Seating Geometry / Interface of the Implant. The 3Shape Abutment Designer™ does not provide any means to design, alter, or manufacture any part of the Implant including, but not limited to, the abutment to implant interface.

Figure 1: Customized Abutment parts



Terms used

The 3Shape Abutment Designer™ Software supports four types of Abutments however this only has impact on the initial guess of abutment shape as well as slight differences in the User Interface for designing the Abutment.

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There is no difference between the four types on abutment function, manufacturing requirements, output types, etc.

The output of any abutment designed is a computer file of the surface model.

Please find a detailed description in *Table 2: Abutment Types*

Table 2: Abutment Types

Type	**Description**
Customized Abutment	The Customized Abutment comes in 3 subtypes: Custom, Robotic, and Bar Interface. All provide the user with the ability to free hand modify the Top Cap and Emergence Profile as depicted on *Figure 1: Customized Abutment parts*. The Custom Abutment initial shape guess is based on an anatomic heuristic  The Robotic initial shape guess is based on a classic standard abutment.  The Bar Interface initial shape guess is based on a cylinder.

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Anatomical Abutment	This type of abutment comes with an initial shape guess that matches a crown. 
Screw Retained Crown	This type of abutment comes with an initial shape guess that can be used as a crown and has a screw hole in the centre. 
Wax up abutment	This type of abutment comes with an initial shape guess based on a scan of a wax model. Otherwise, it is equivalent to Anatomical abutment.

Also, throughout the submission the following terms are applicable.

Table 1: Terms

Term	**Definition**
Provider	Any creator of an Implant Library.
Implant Library	A digital representation of an Implant System
Implant System	A physical Dental Implant compatible with one of more abutments
Abutment	Endosseous dental implant abutment as regulated under 872.3630

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Milling Center	An industry term for a large scale provider of Milling and/or 3D Printing. Typically, the actual manufacturing is geographically centralized, which makes digital transfer of CAD designed surface files convenient. 3Shape does not own or operate any milling centers.
Local Milling	When the Dental Lab and milling machinery is co located. 3Shape does not manufacture or market milling machinery.

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4. Ensuring Regulatory Compliance of Abutments

Abutments are designed to interface with Dental Implants and 3Shape Abutment Designer™ requires a digital representation of the Dental Implant in order to create a functional Abutment.

The digital representations of Dental Implants (called Implant Systems) is collected in files called Implant Libraries.

In the U.S. only Abutments designed against Dental Implants with a 510(k) clearance are allowed in the 3Shape Abutment Designer™ (see *Design stops in the software* below).

Providers of Implant Libraries to be used in the U.S. must supply 3Shape with written documentation in order to have their Libraries activated in the software.

It is the responsibility of the Provider to ensure that the digital representation correctly represent the cleared physical parts.

Design stops in the software

(b)(4)

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Device Hazard Analysis

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3shape

PRODUCT RISK ASSESSMENT

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[redacted]

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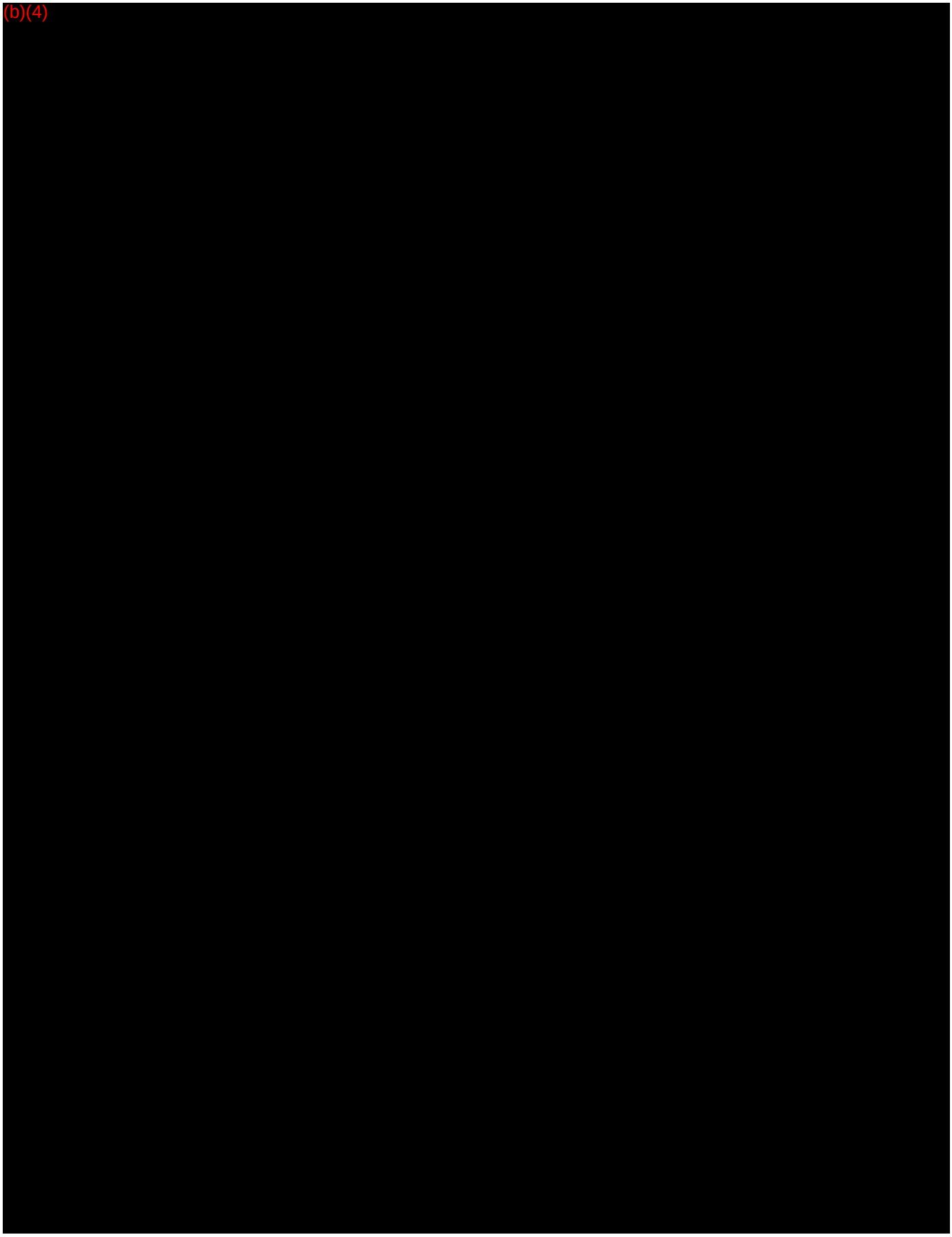

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Software Requirement Specification

1. Introduction

Please refer to the Software Requirement Specifications enclosed in this volume.

Please note that the Validation Protocol templates are included in the Requirement Specifications.

For links between the Requirements Specifications and the Software Specifications, please see "VOL 008 Traceability Analysis" enclosed in this submission.

Note: Some of these documents may have requirements referring to other areas than 3Shape Abutment Designer™. See the Trace matrix for reference to which requirements are relevant for 3Shape Abutment Designer™.

2. Table of Contents

(b)(4)

Configuration
Sending and receiving
Manufacturing Interfaces
User Manual
Material import export
Parametric Abutment Design
Wax-up Design
Implant Bars

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Requirement Specification – (b)(4)

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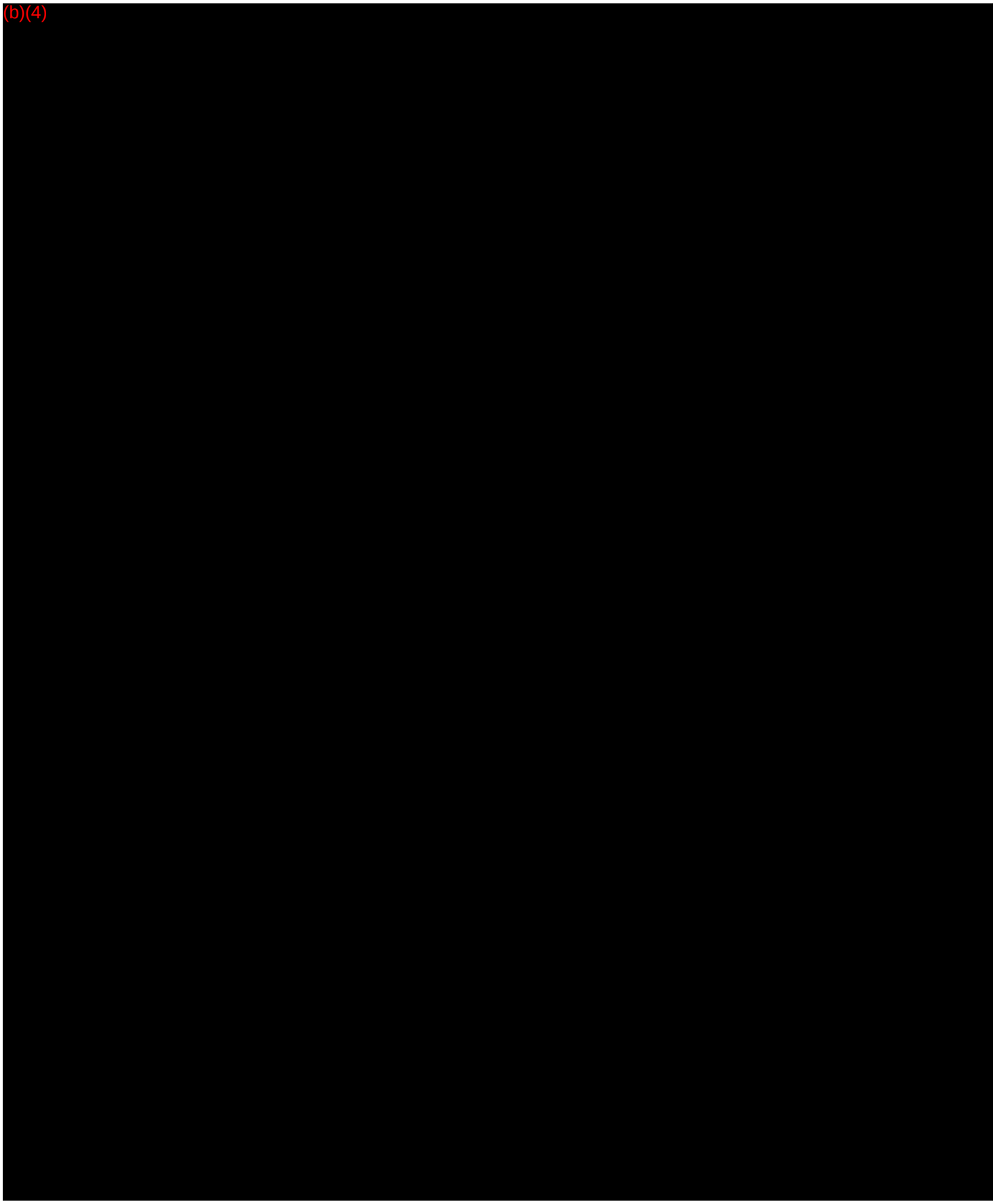

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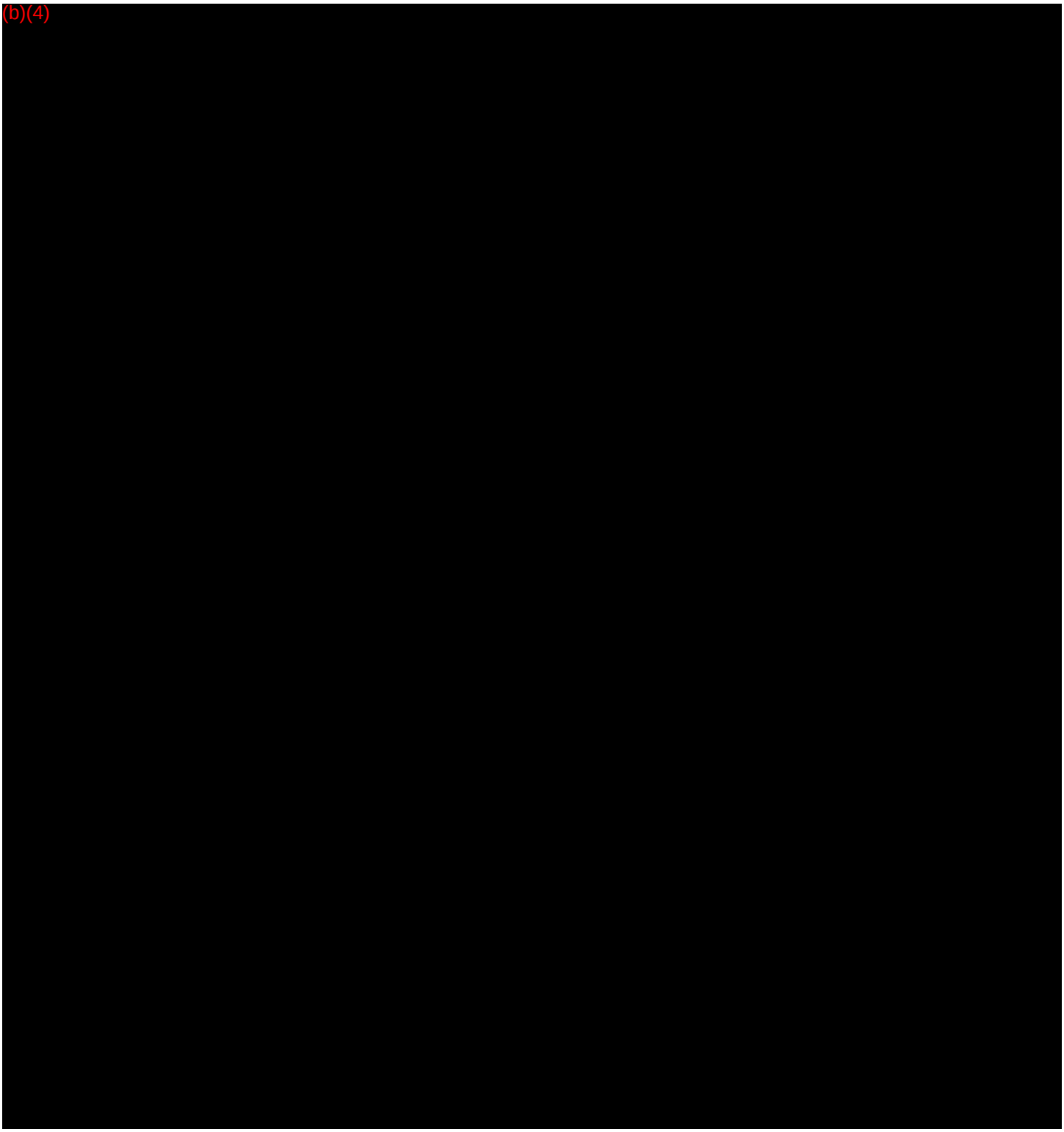

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Requirement Specification – (b)(4)

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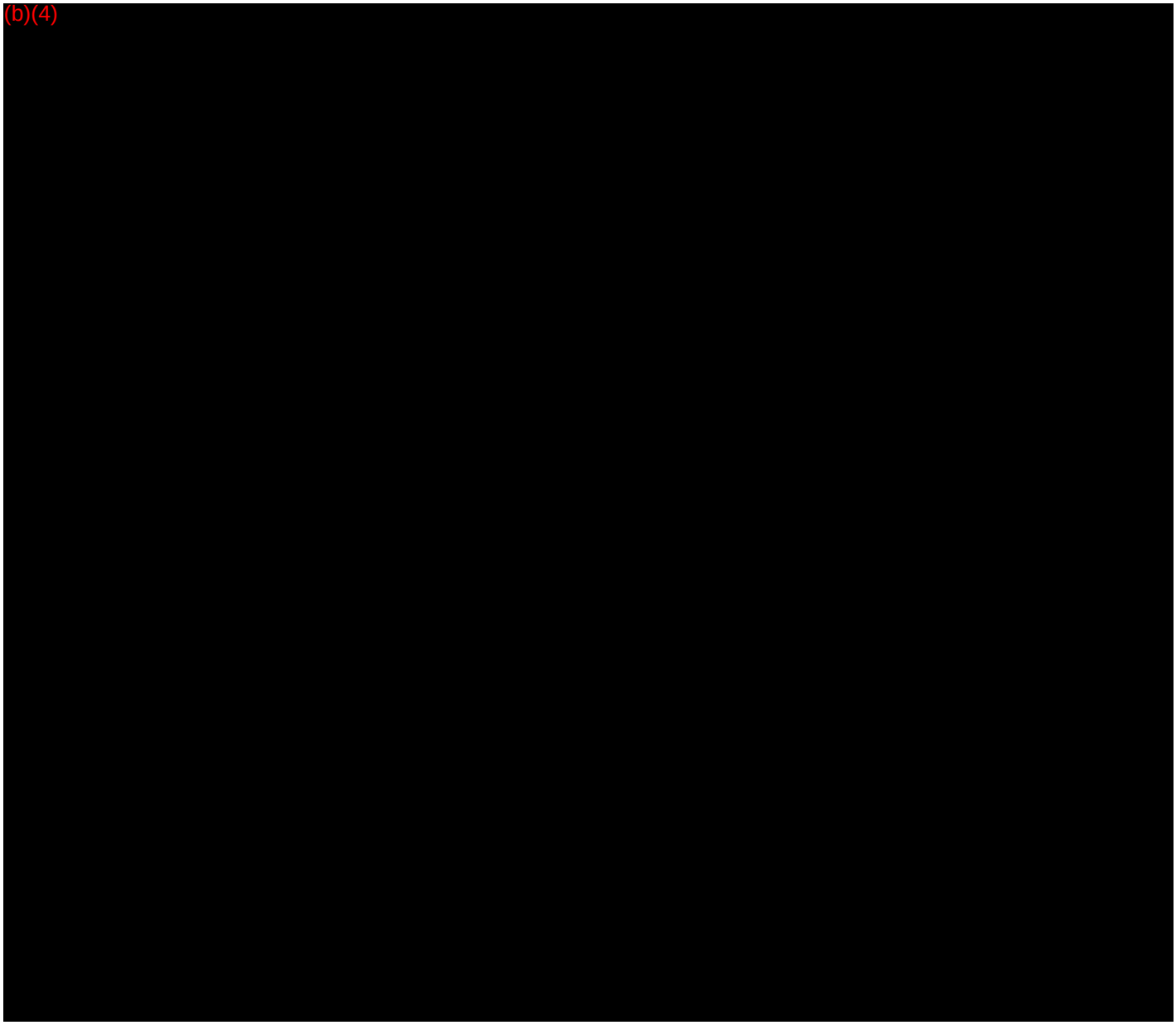

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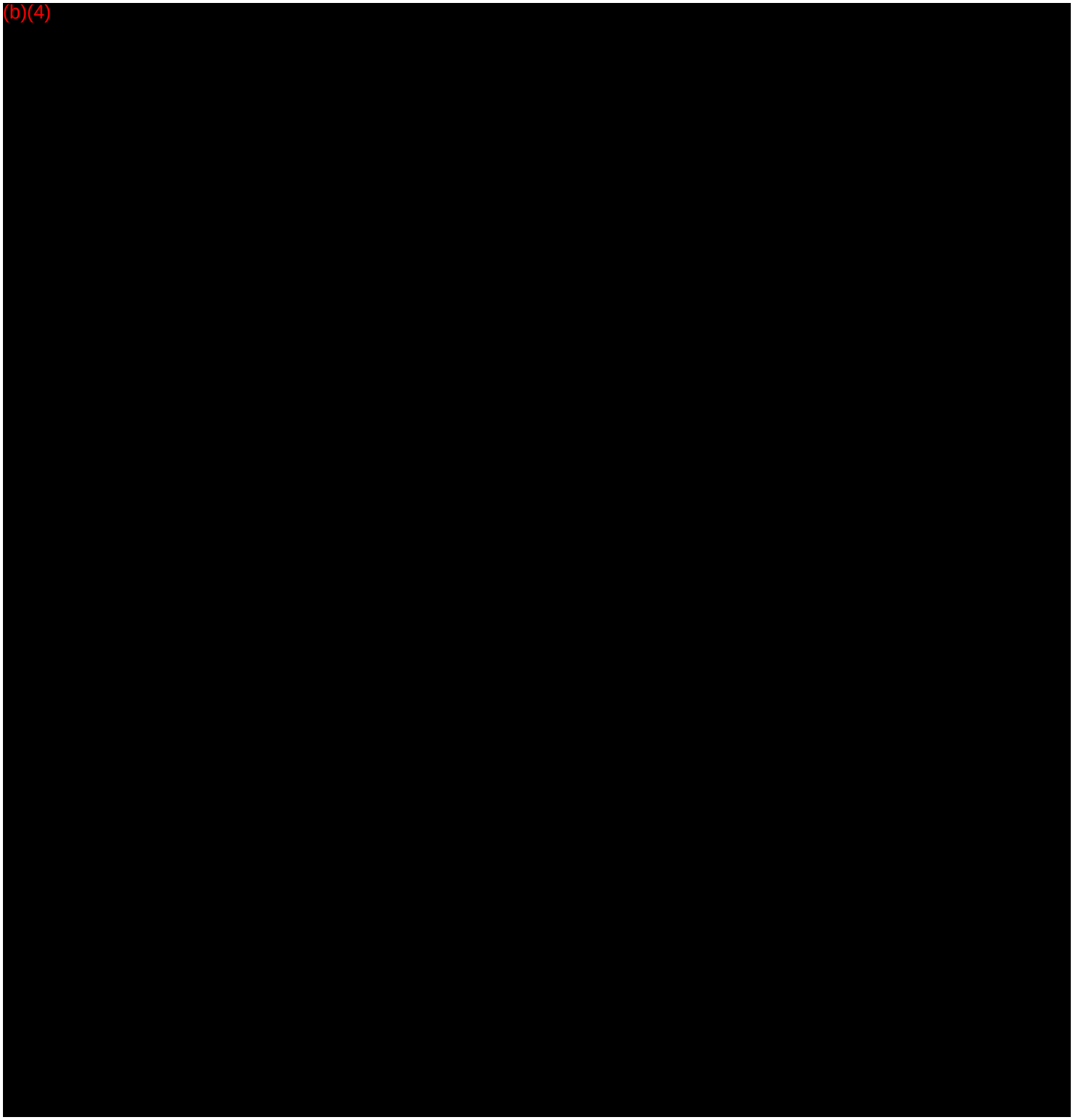

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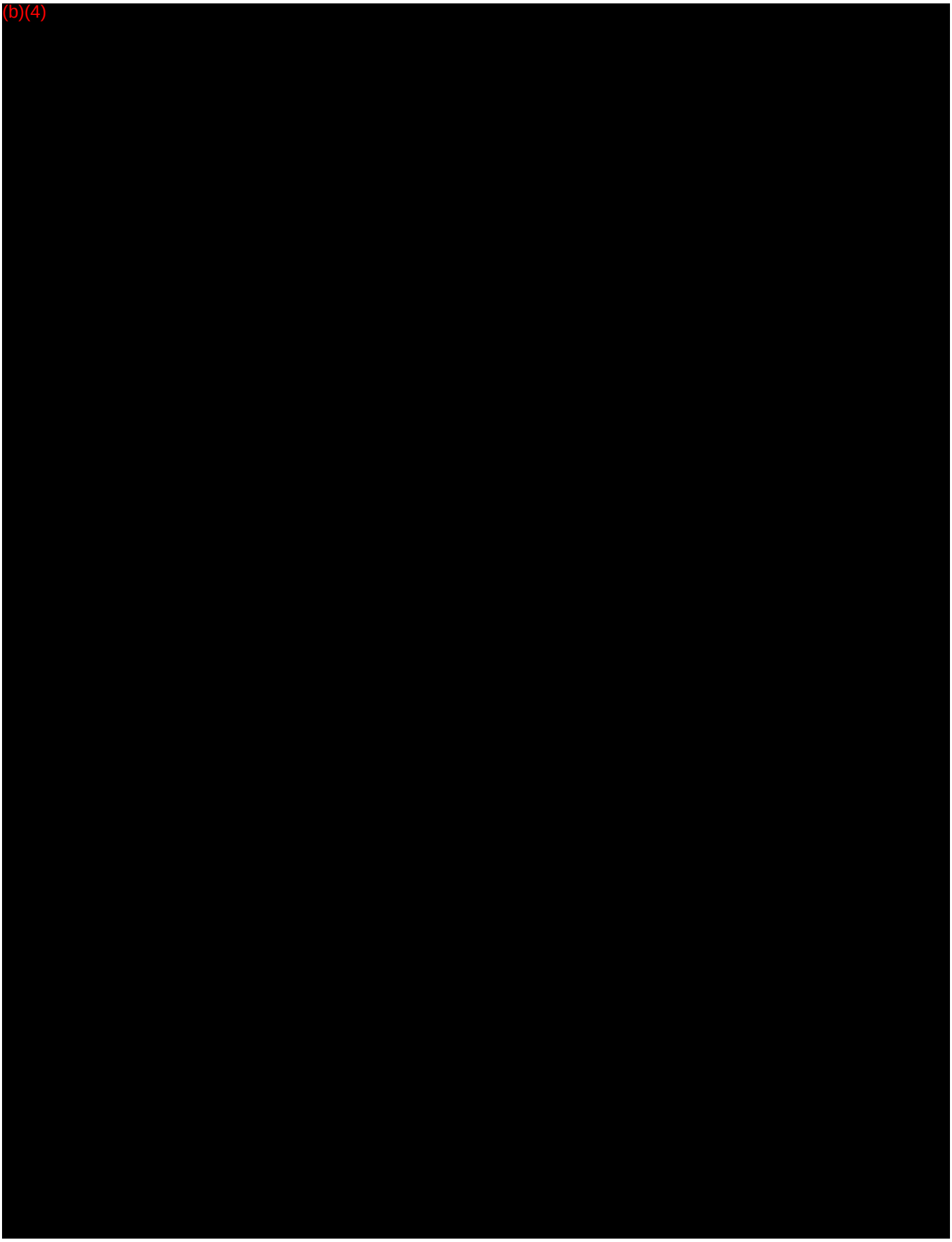

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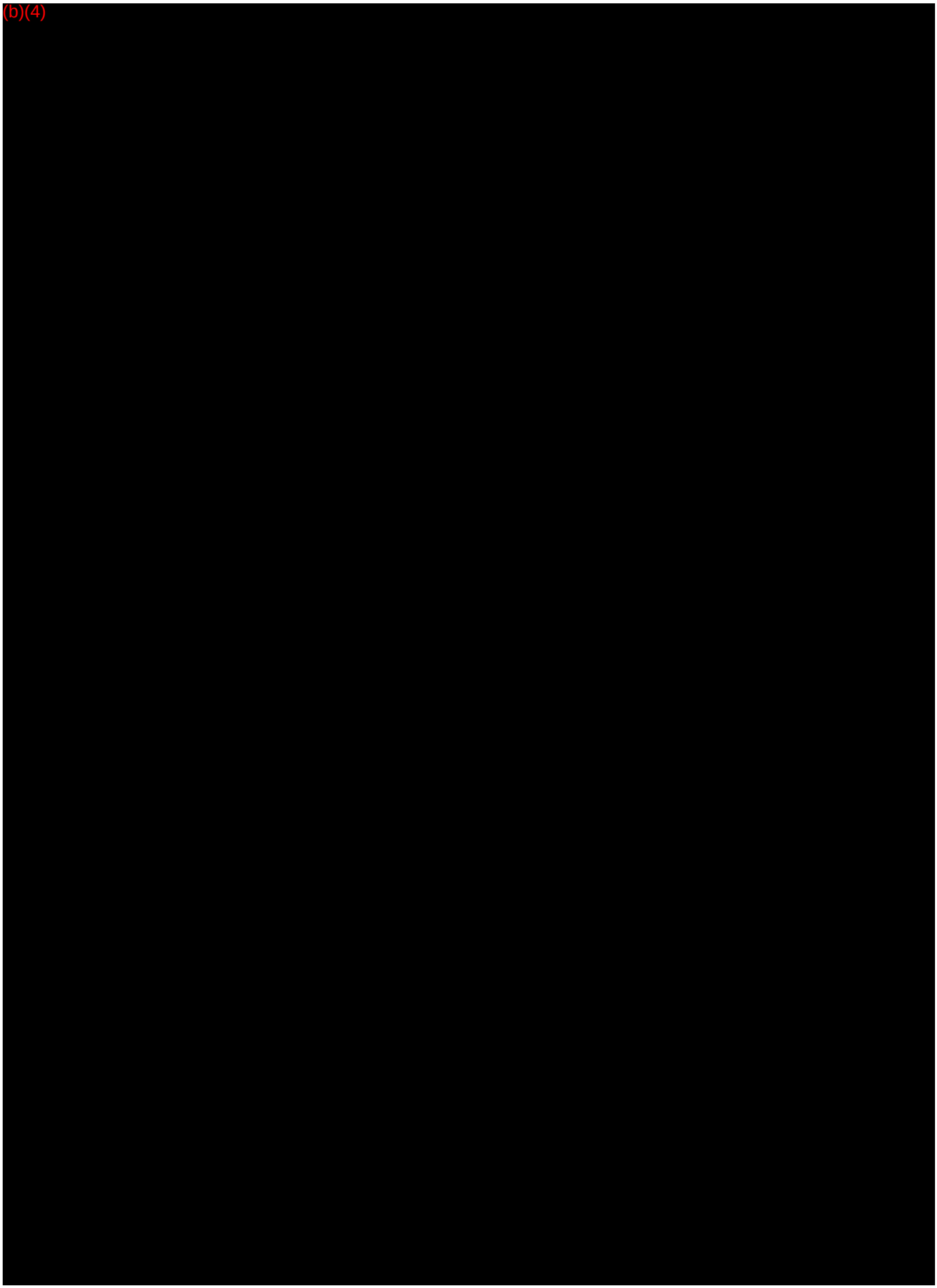

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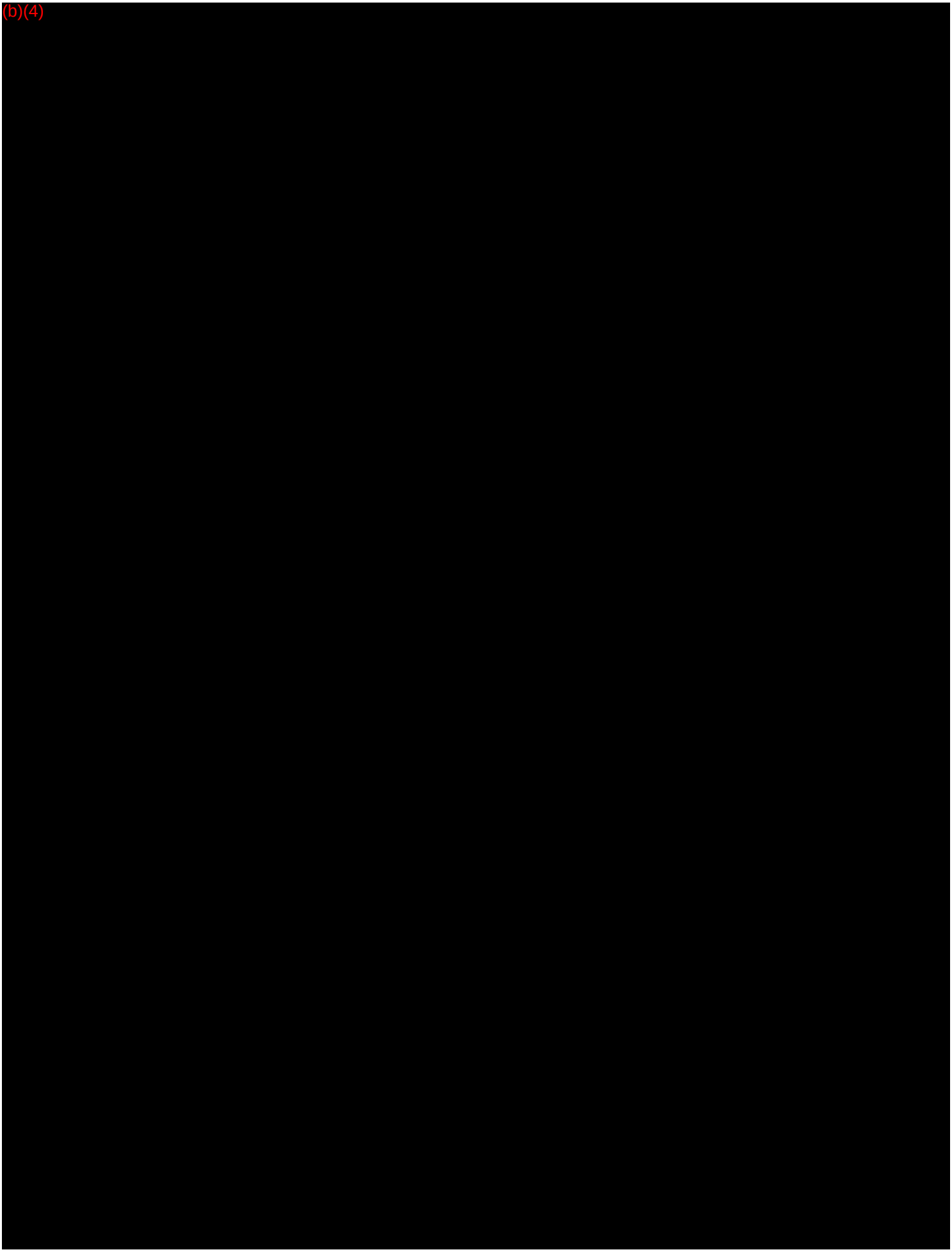

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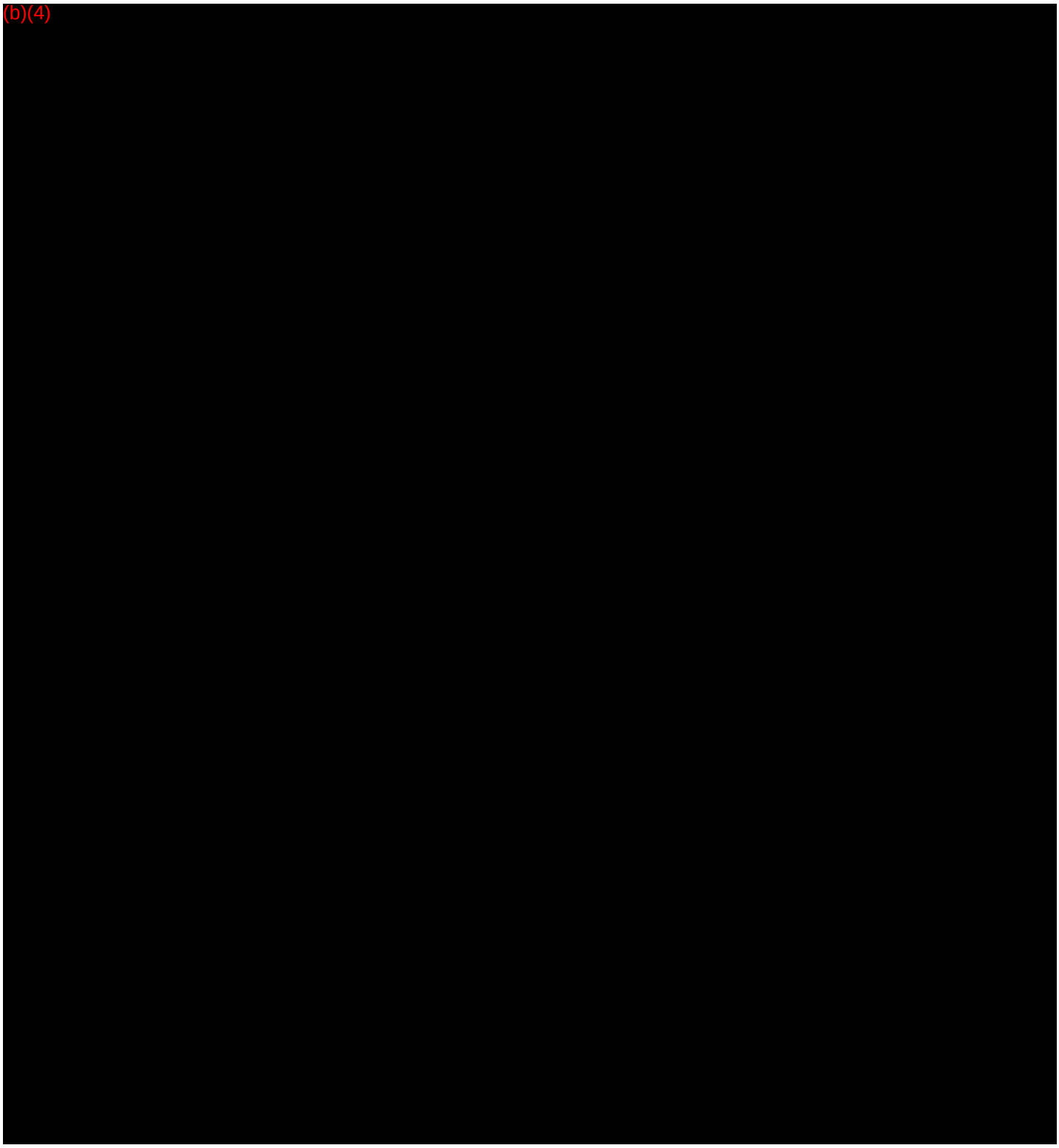

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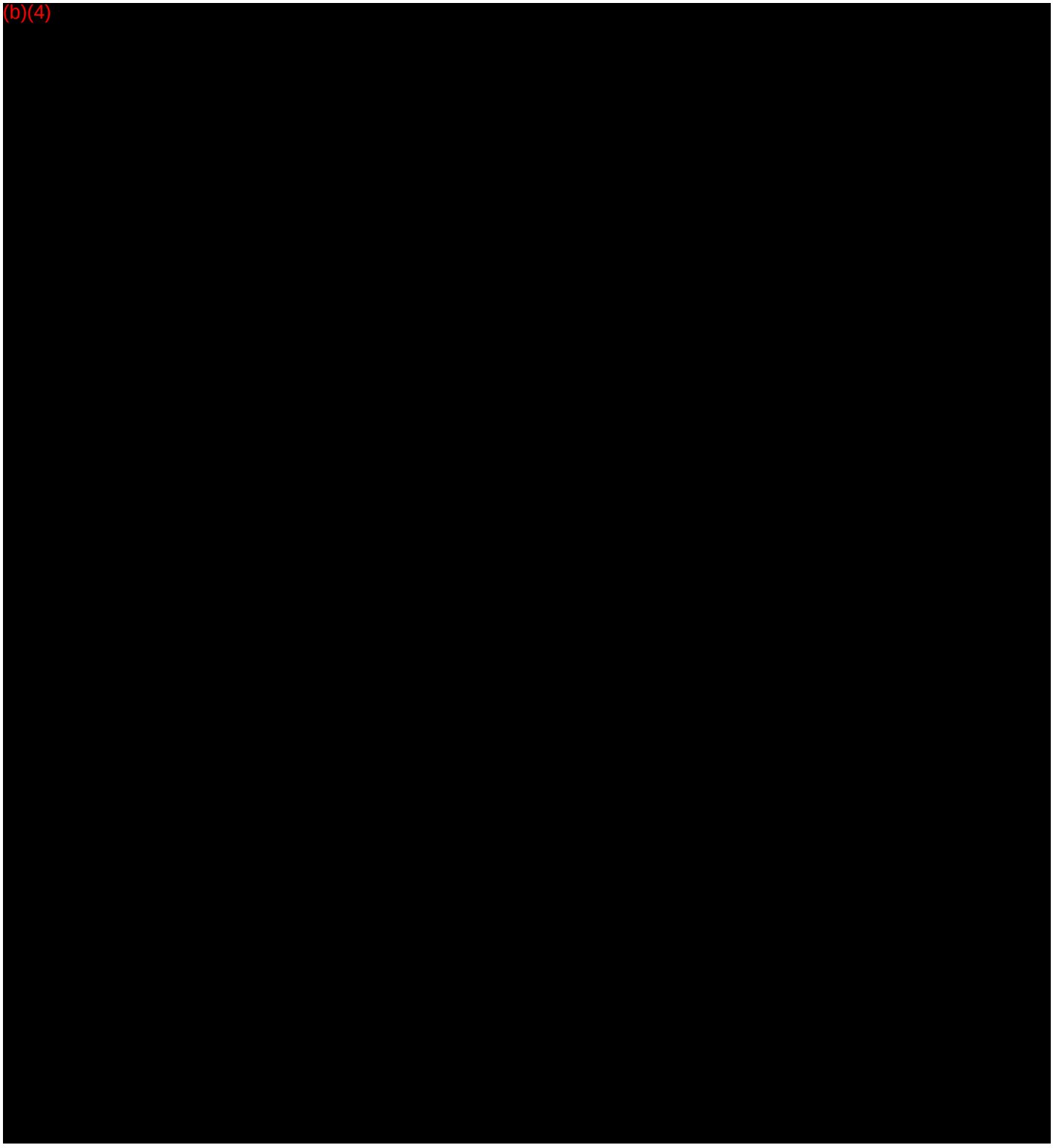

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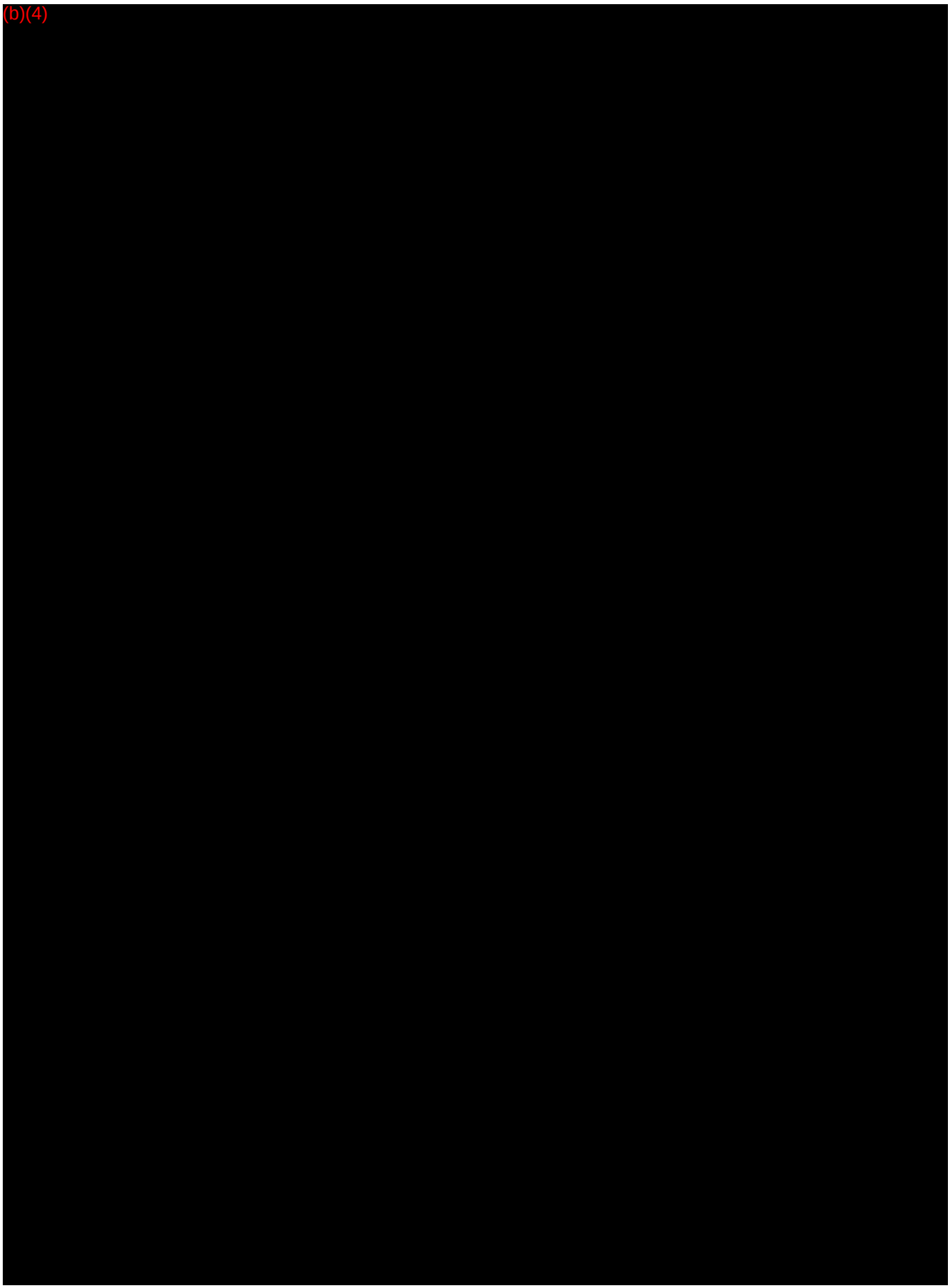

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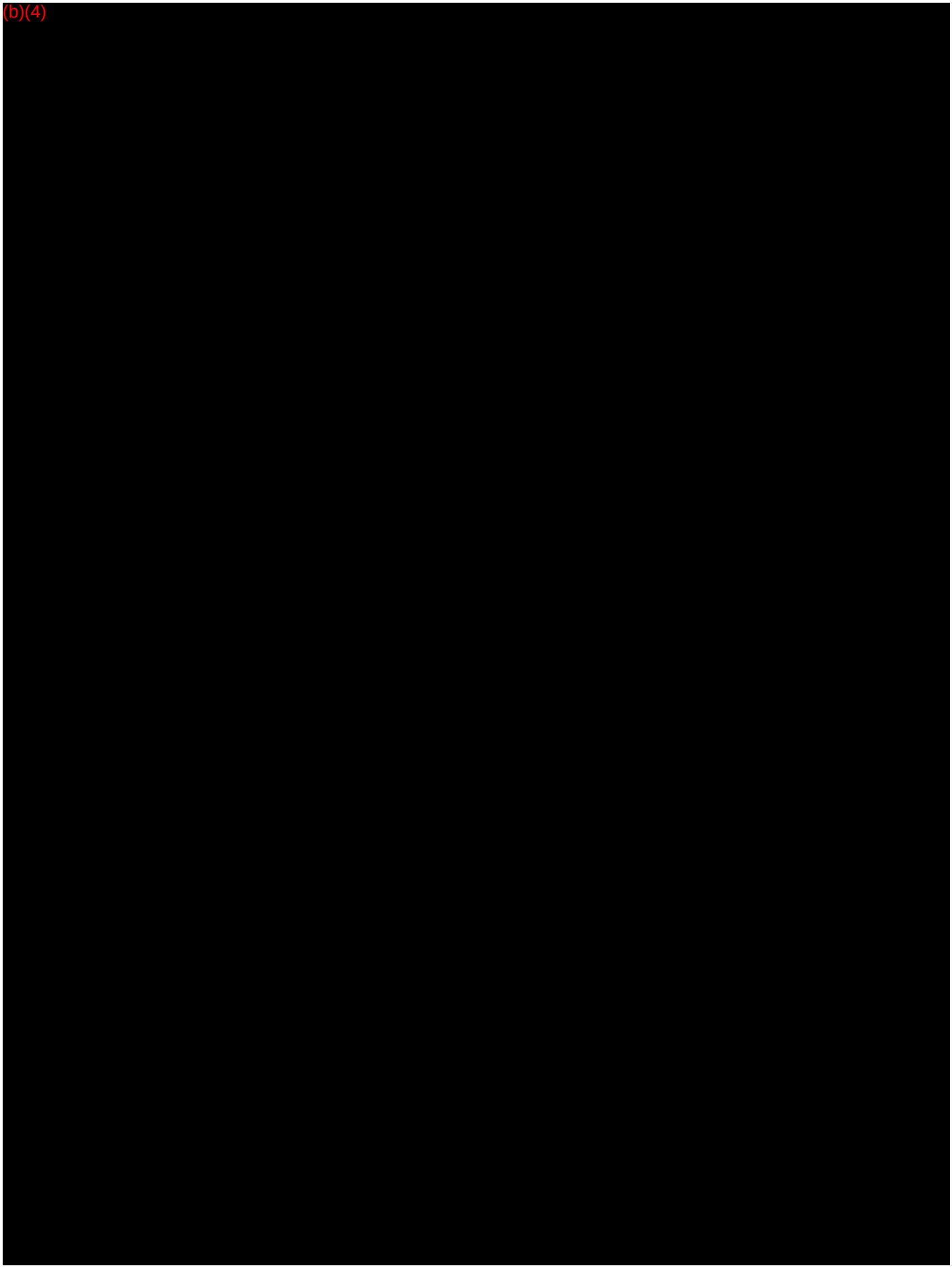

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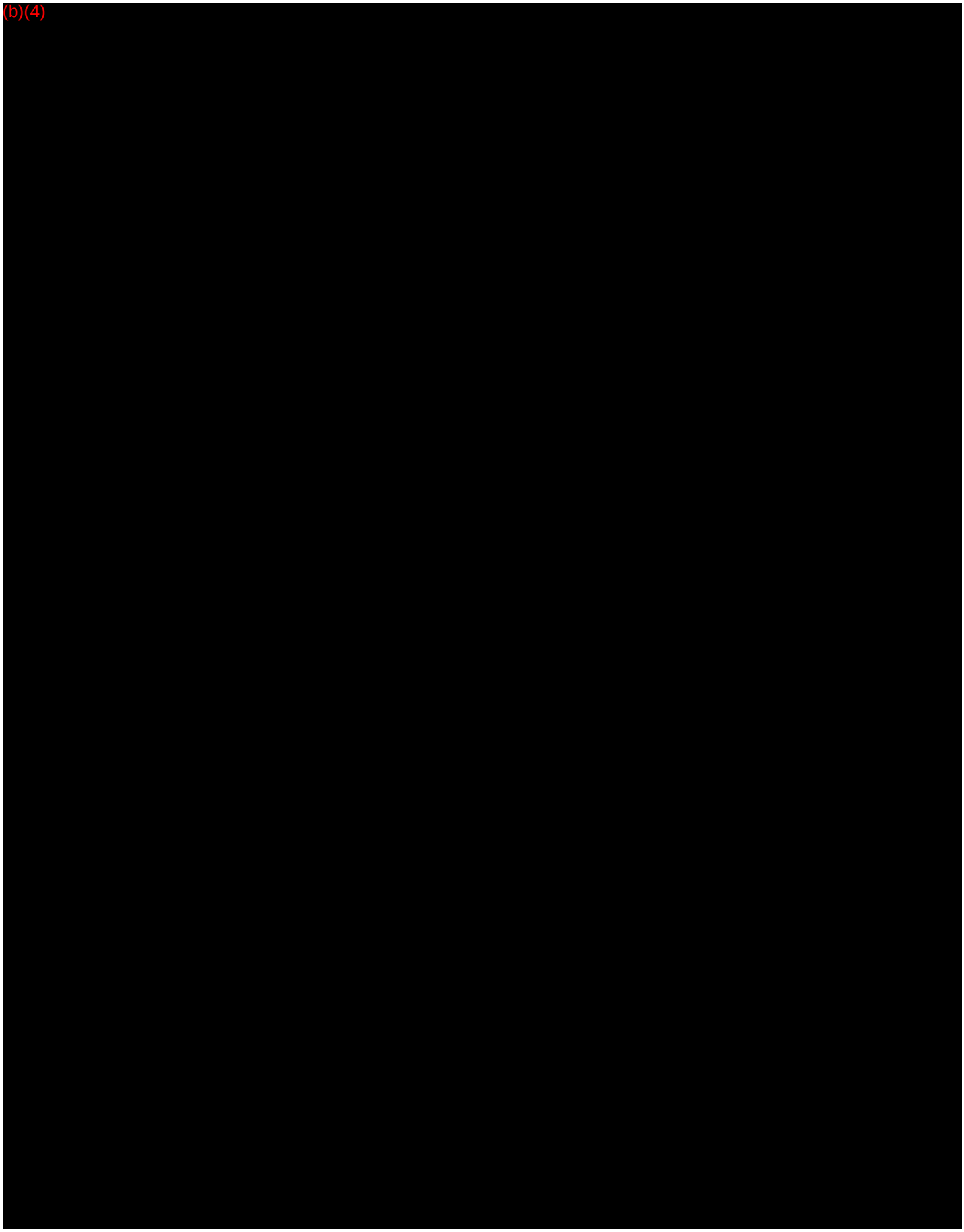

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Architecture Design Chart

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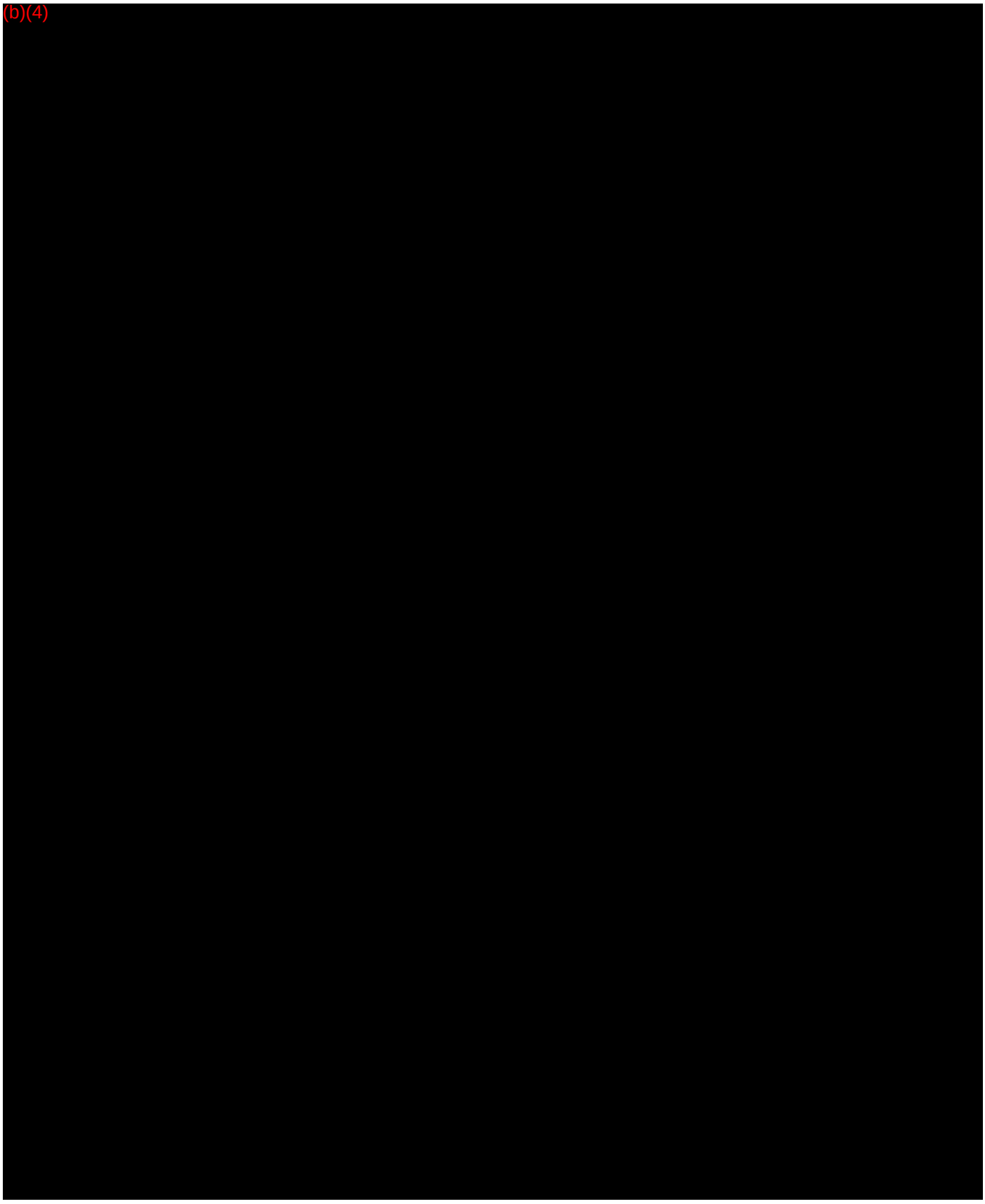

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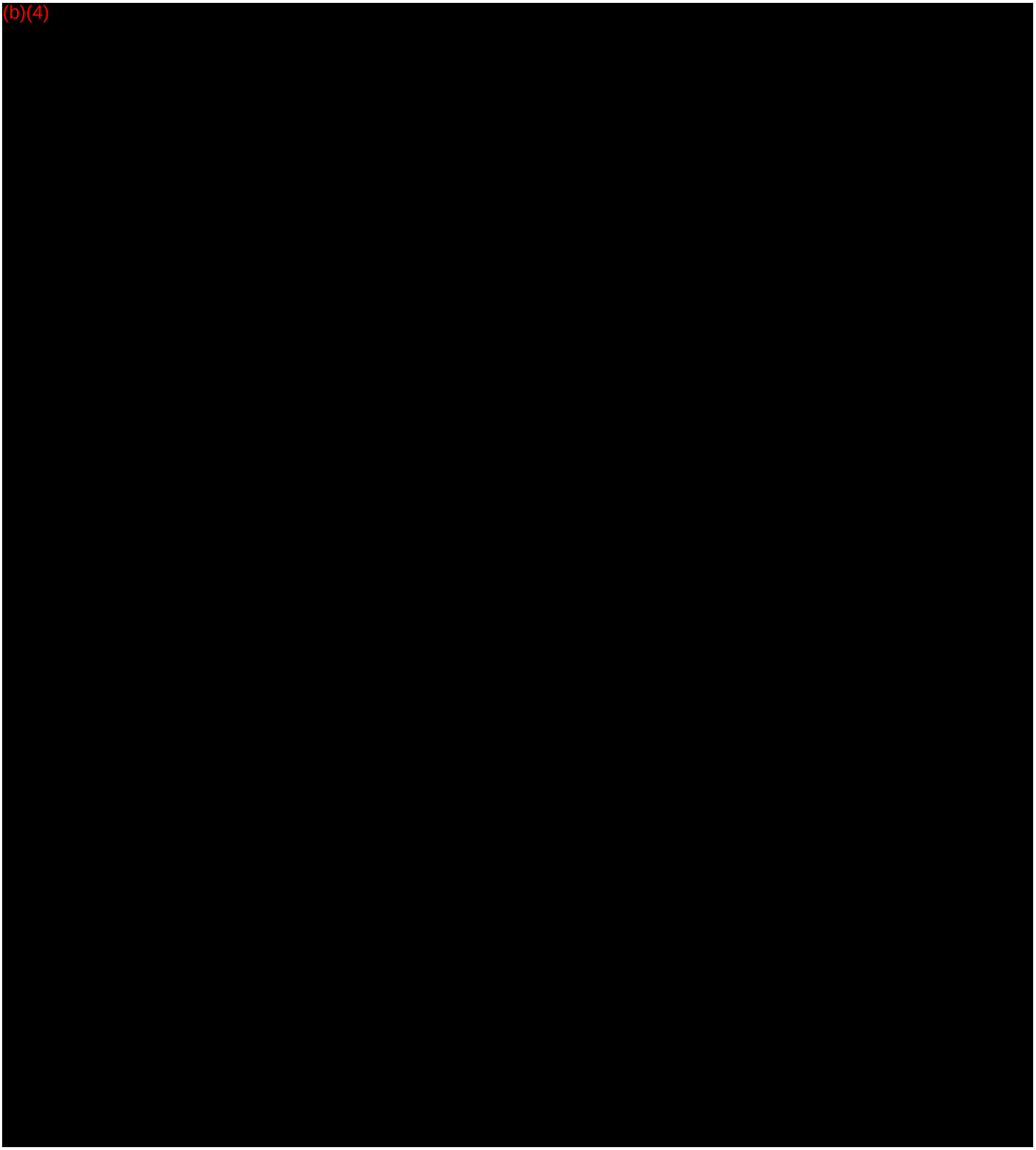

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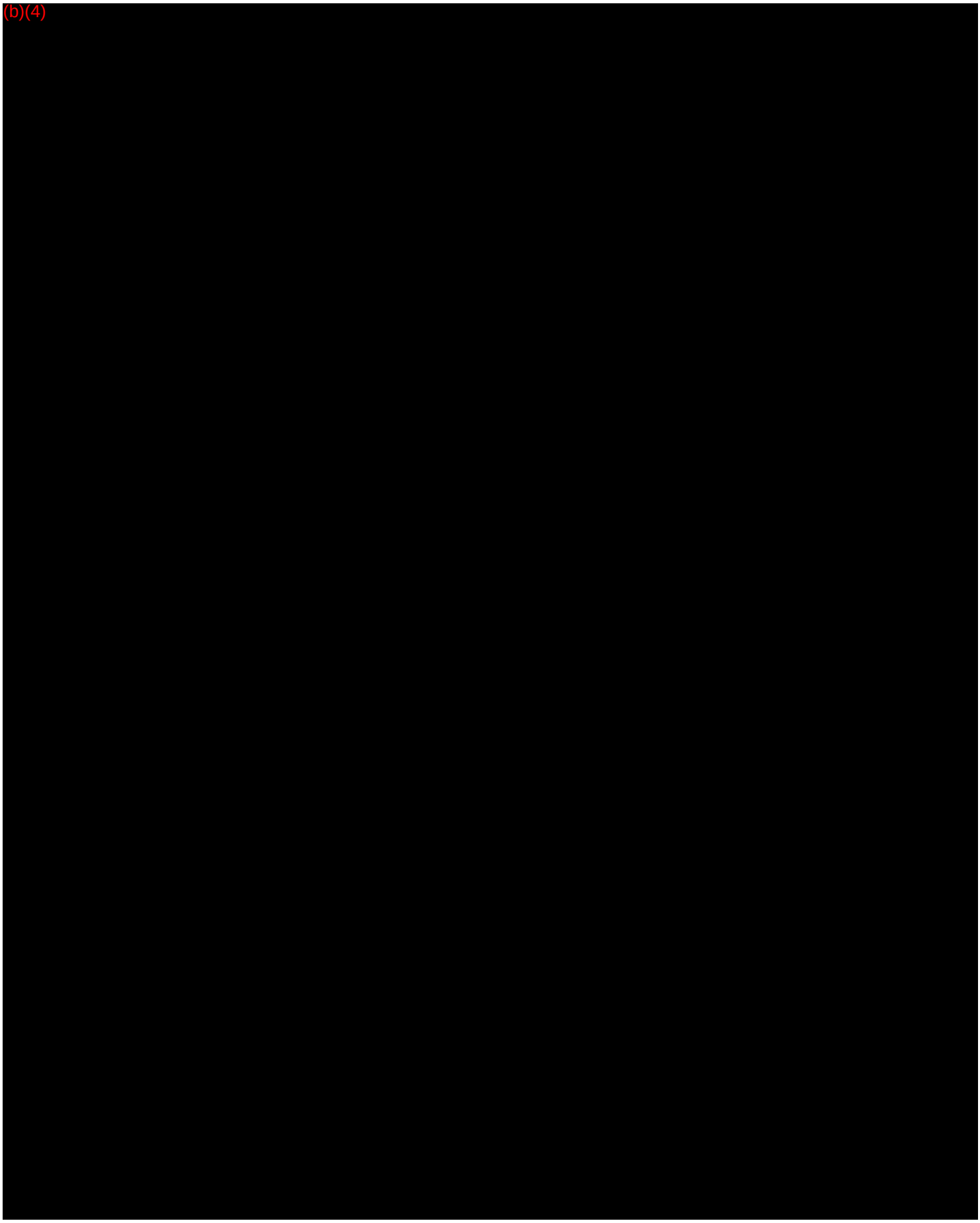

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Software Design Specification

1. Introduction

Please refer to the Software Design Specification enclosed in this volume.

Please note that the Verification Protocol templates are included in the Software Specifications.

For links between the Requirements Specifications and the Software Specifications, please see "VOL 008 Traceability Analysis" enclosed in this submission.

2. Software Design Specification, Table of Contents

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Sending and receiving
Manufacturing Interfaces
User Manual
Material Import and Export
Abutment Design Configuration
Parametric Abutment Design
Wax up Design
Implant Bar Design
RawSTL Manufacturing Output

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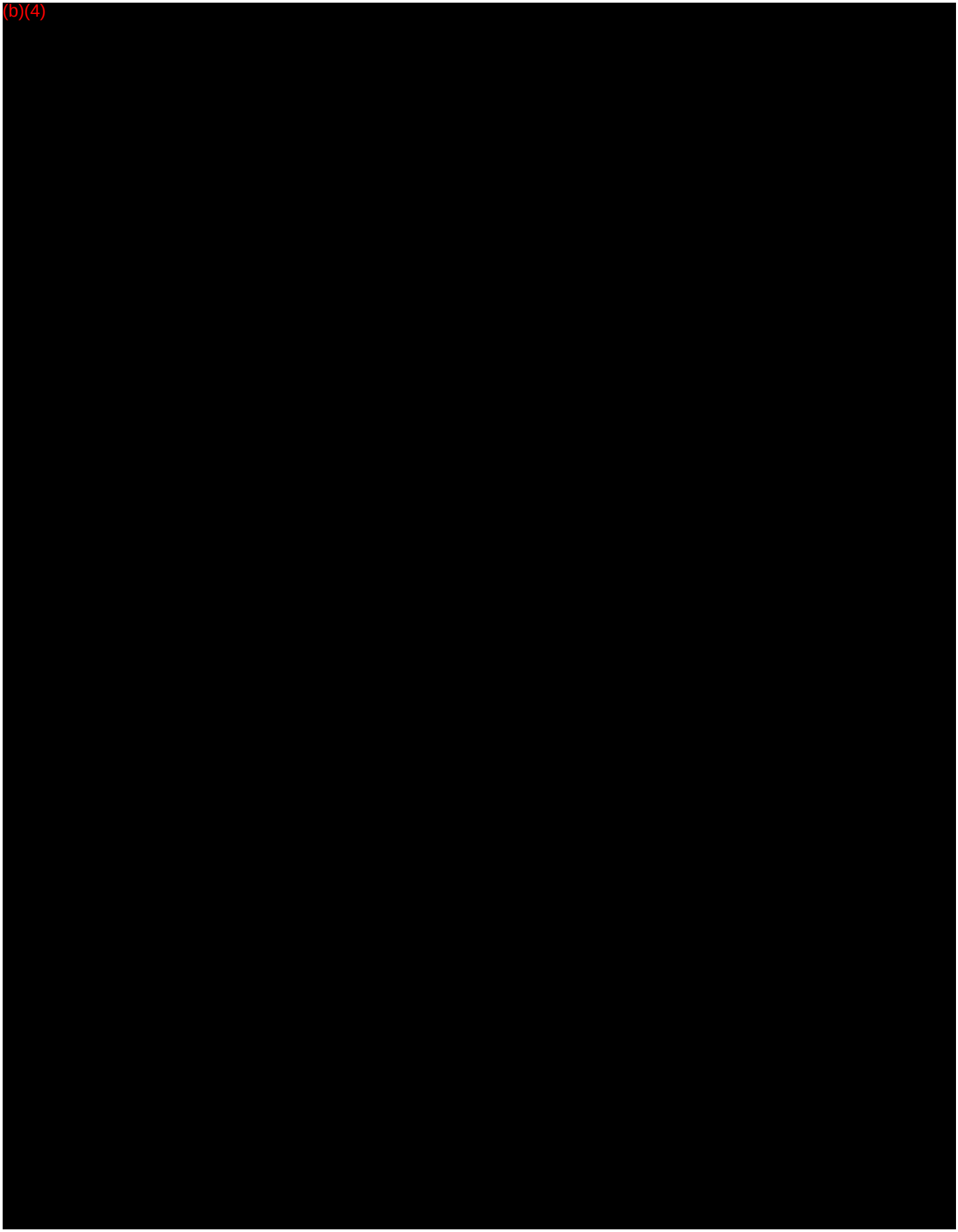

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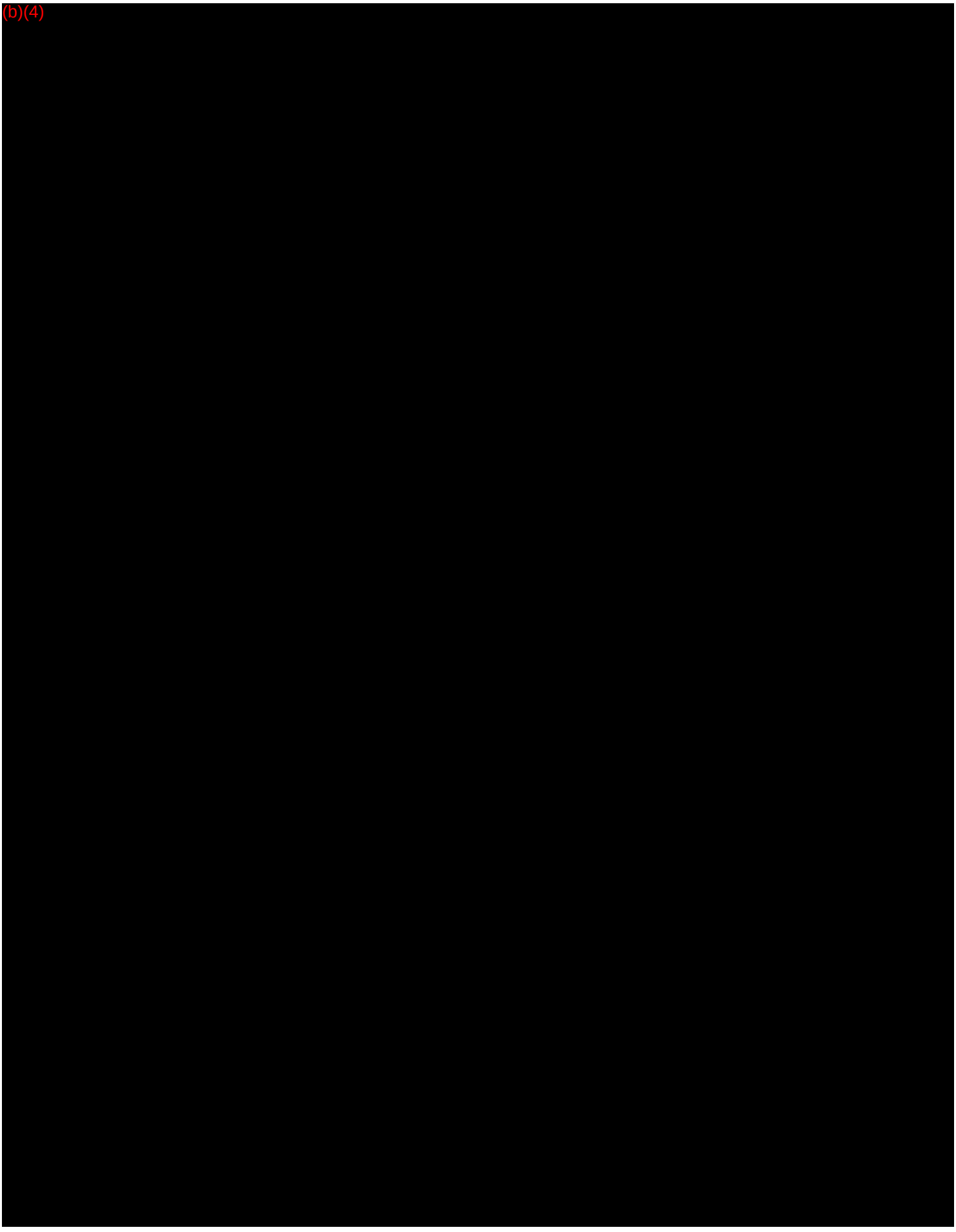

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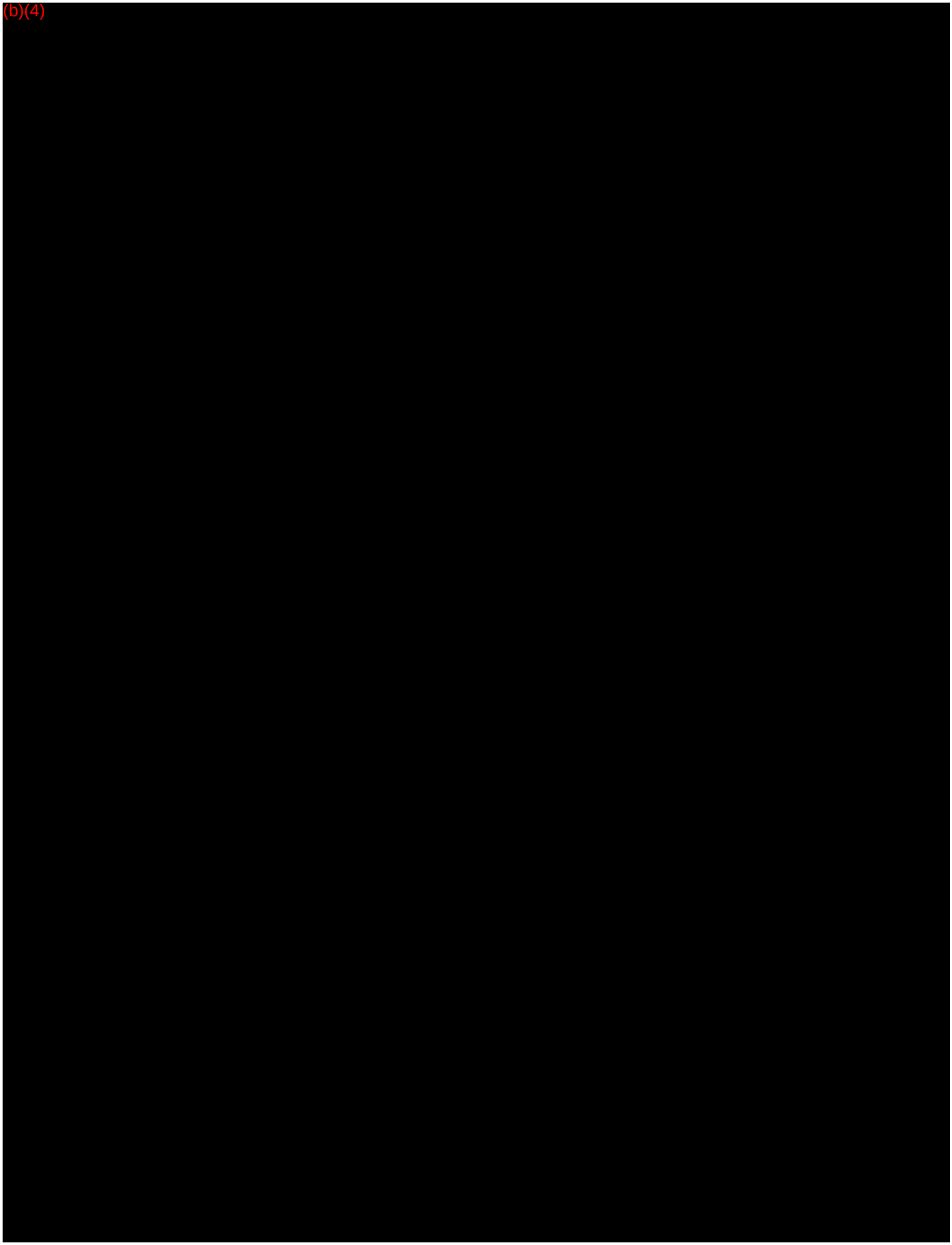

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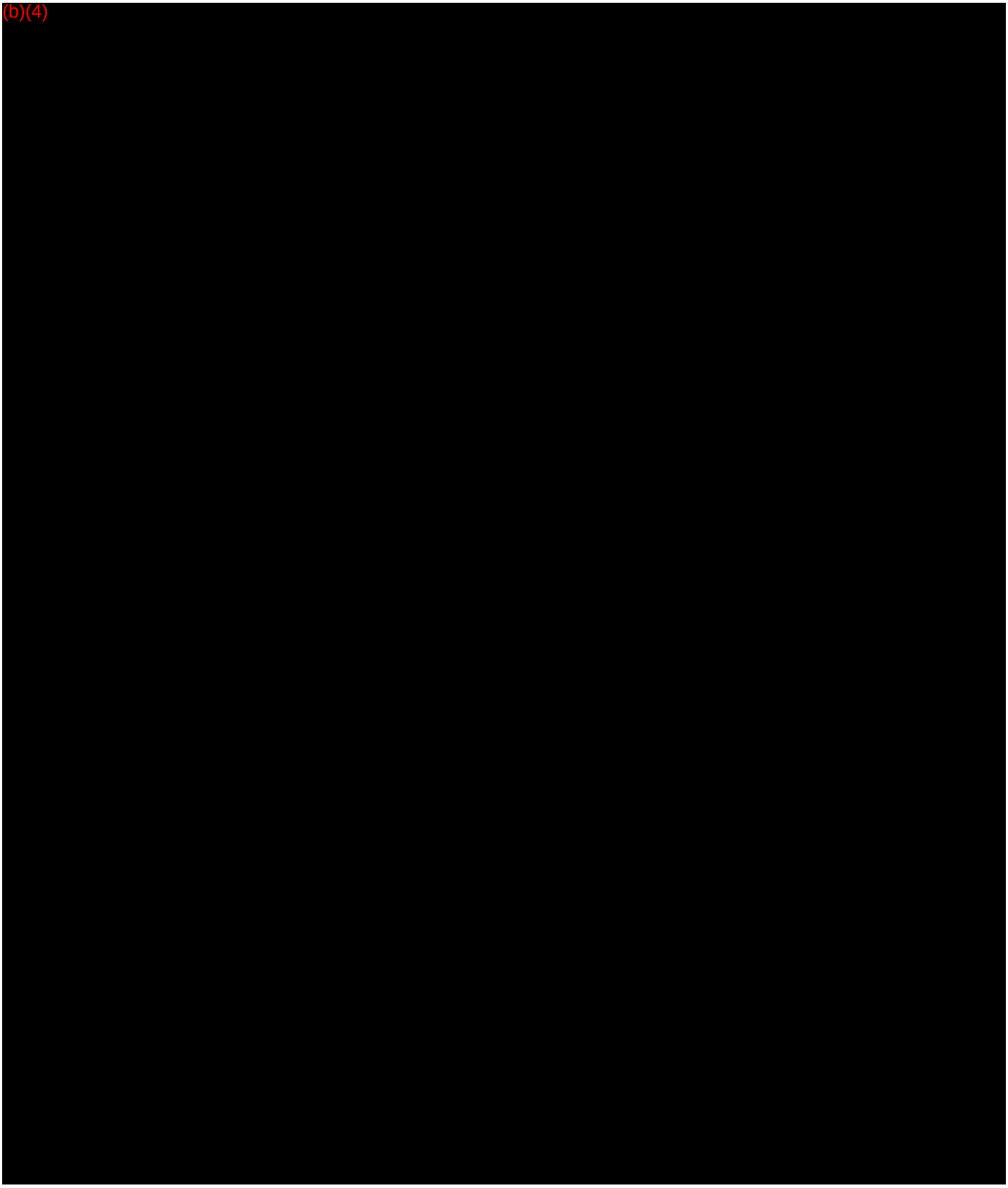

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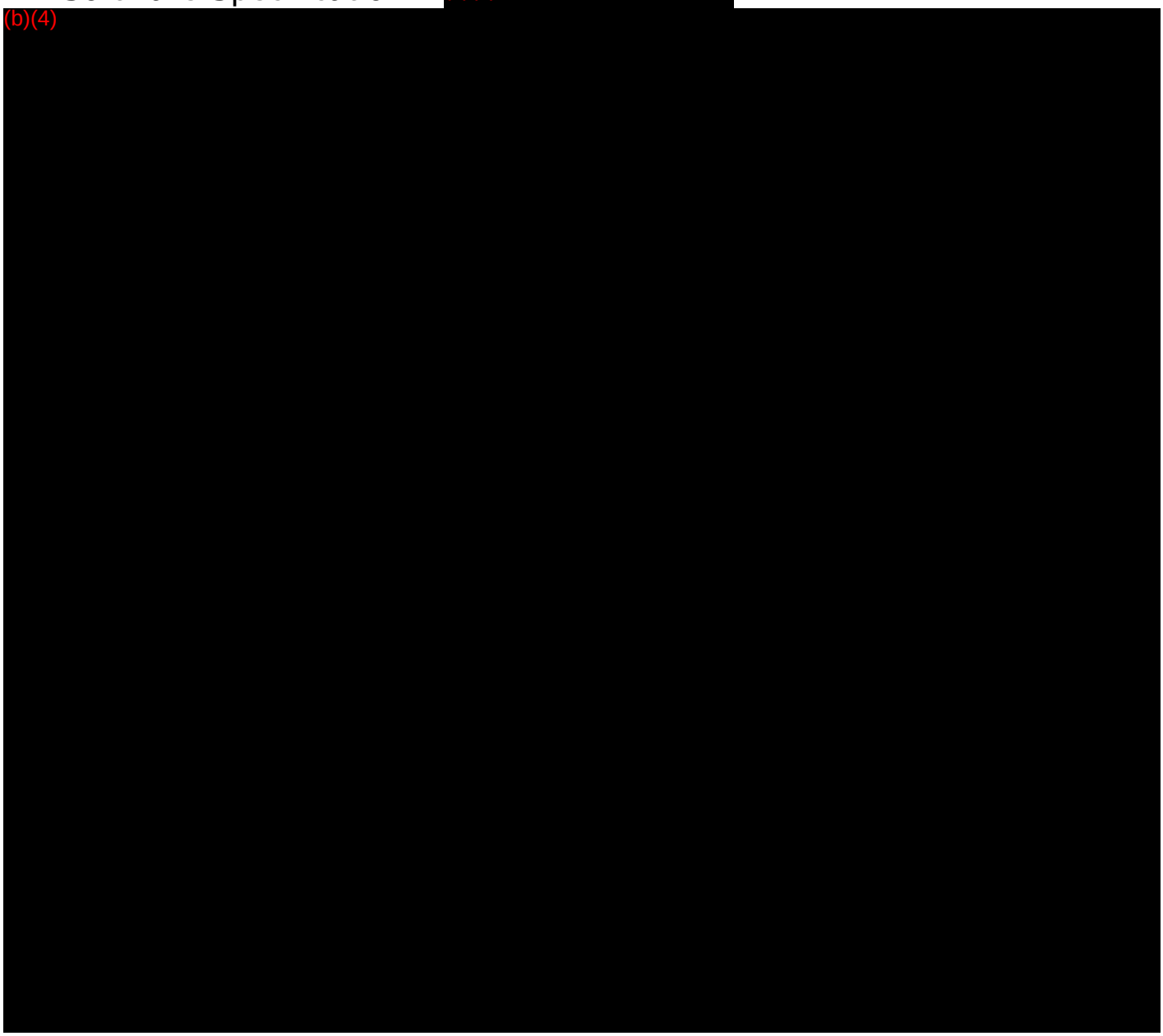

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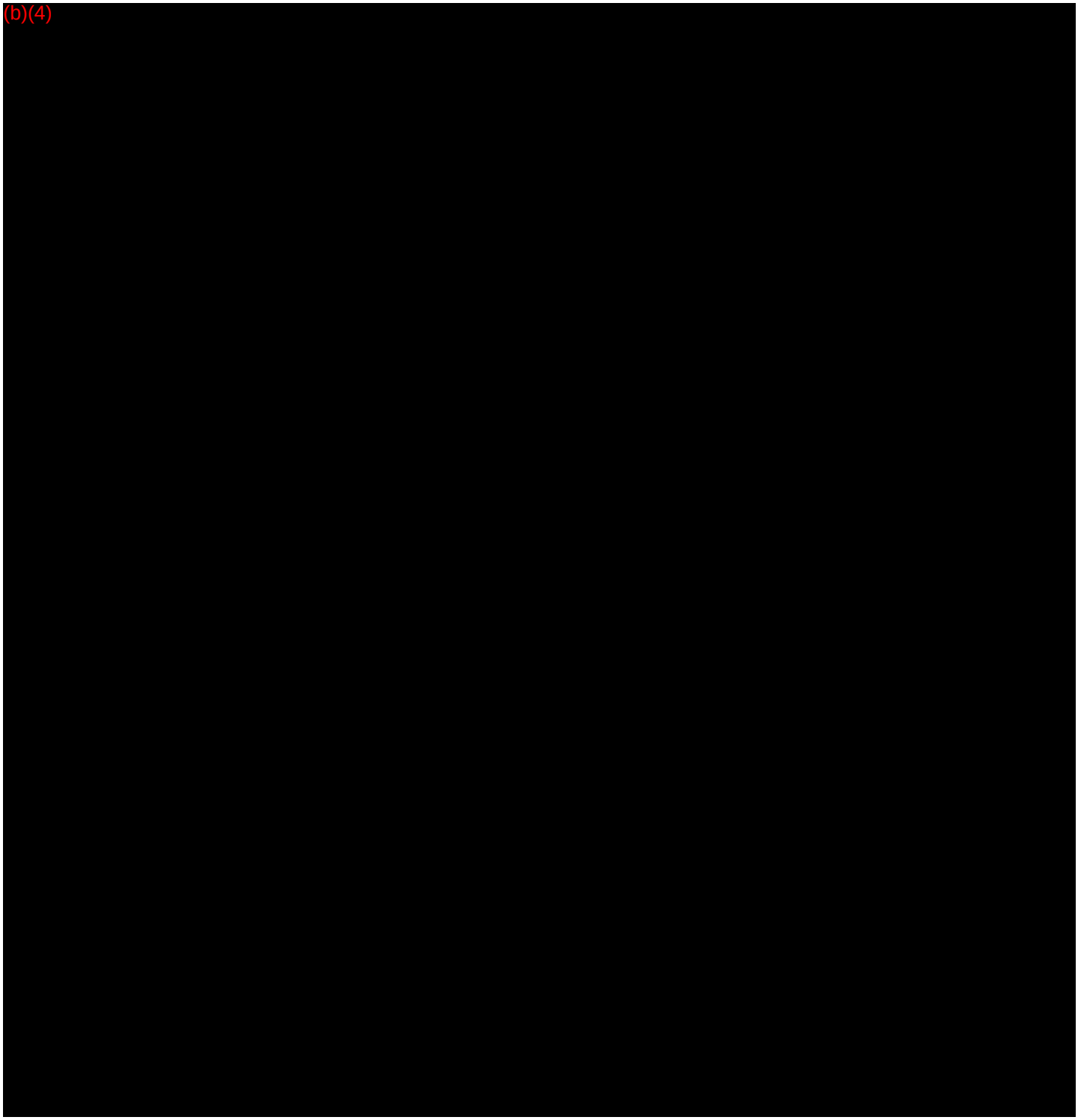

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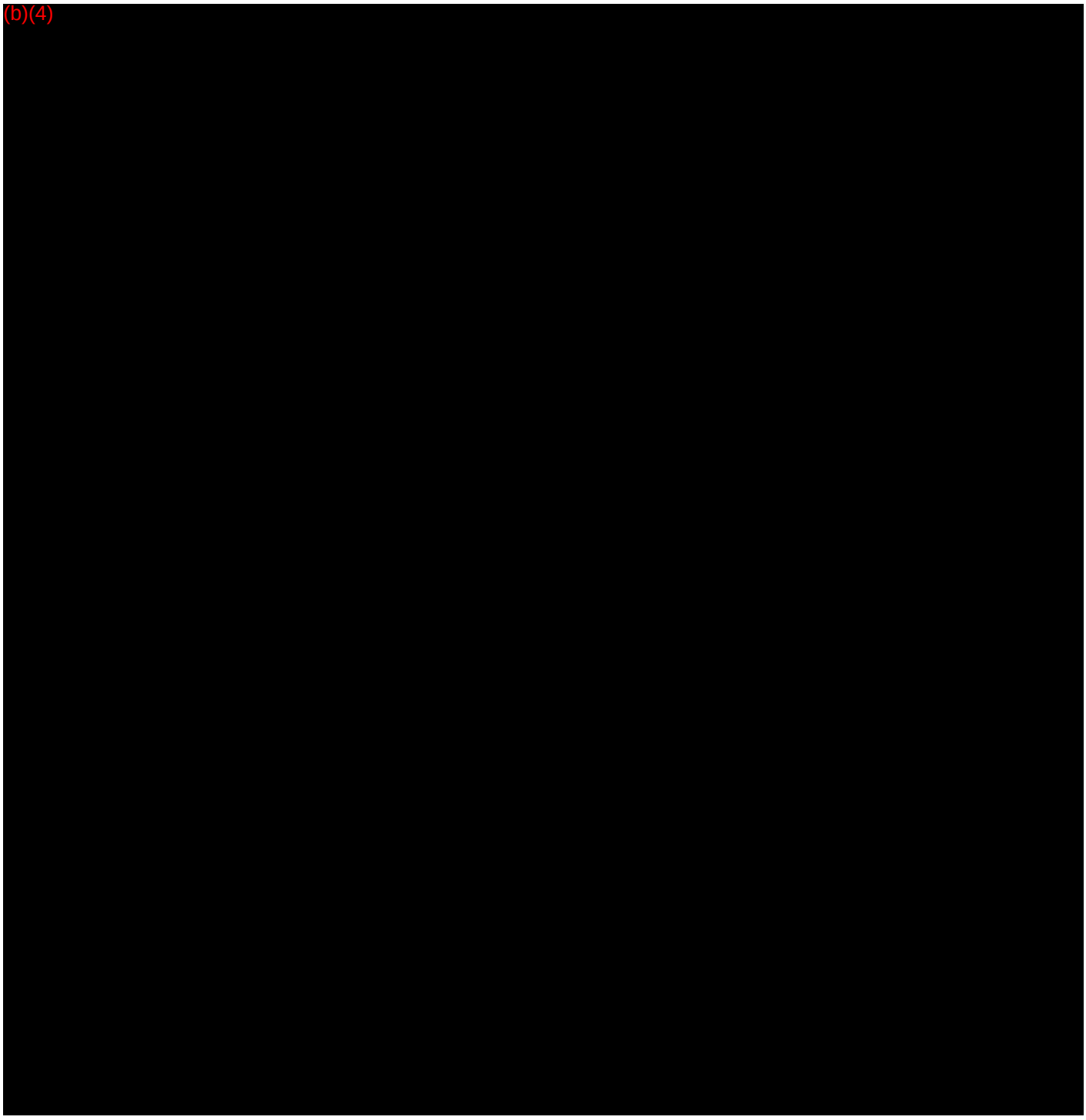

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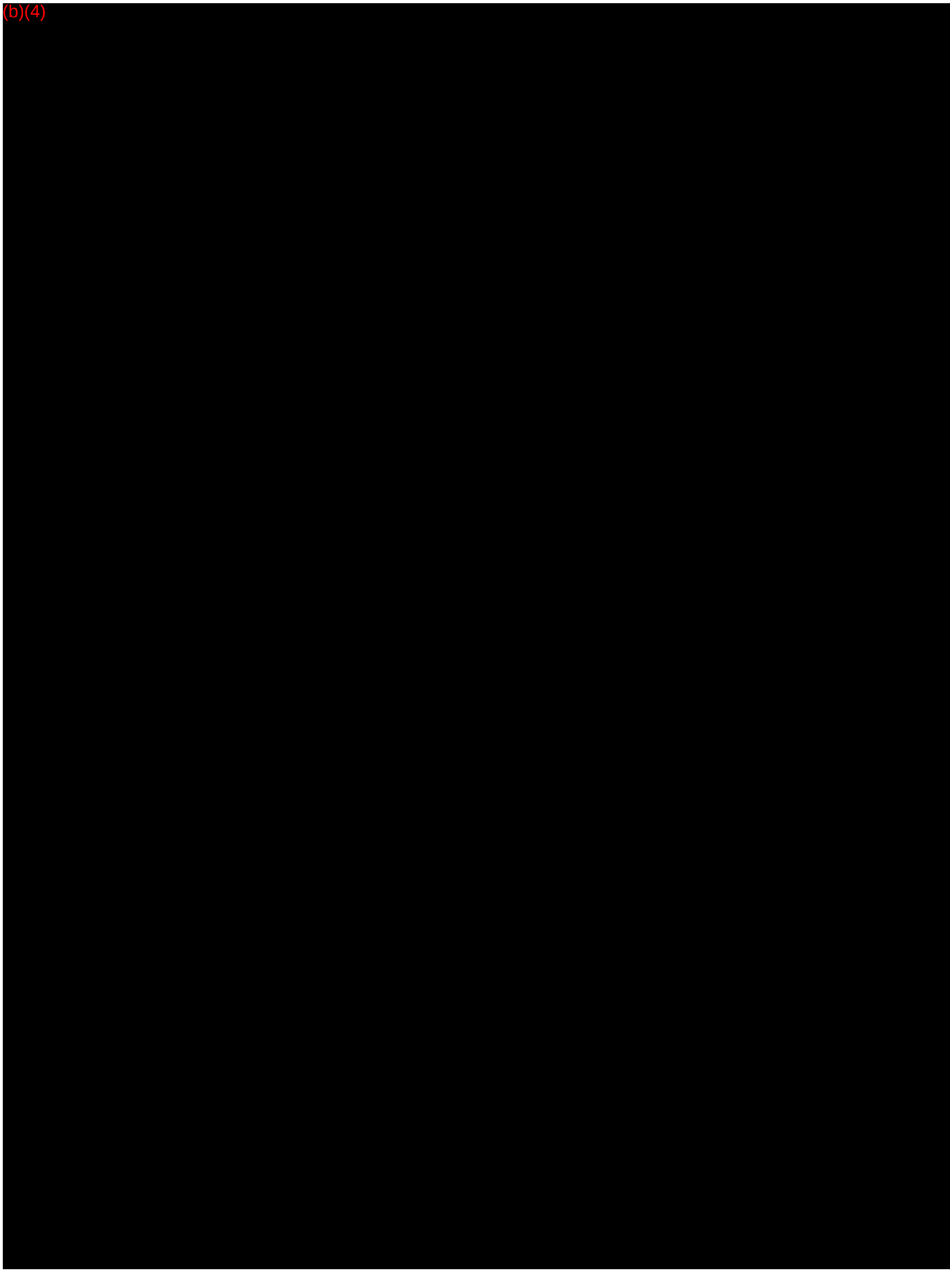

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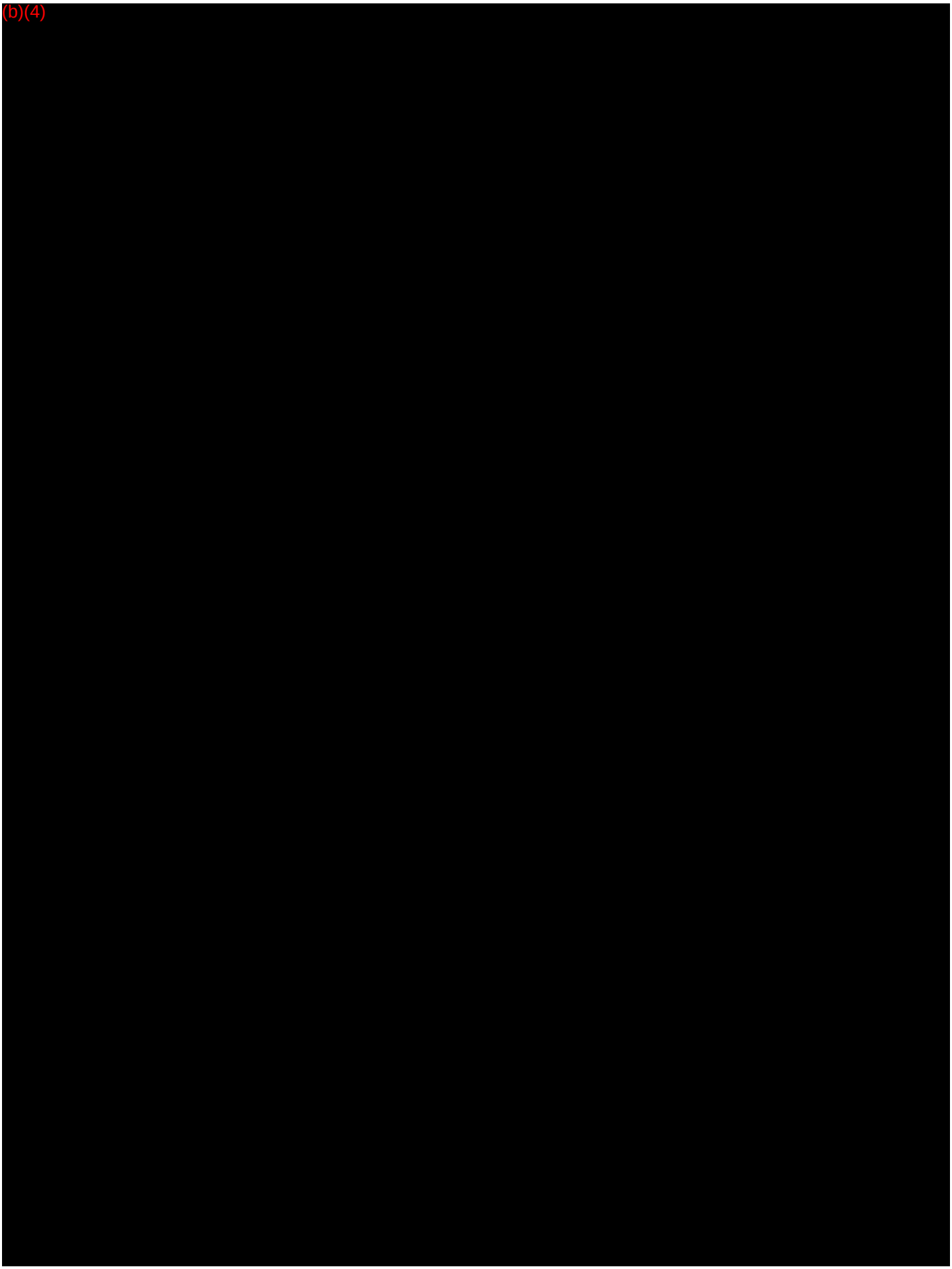

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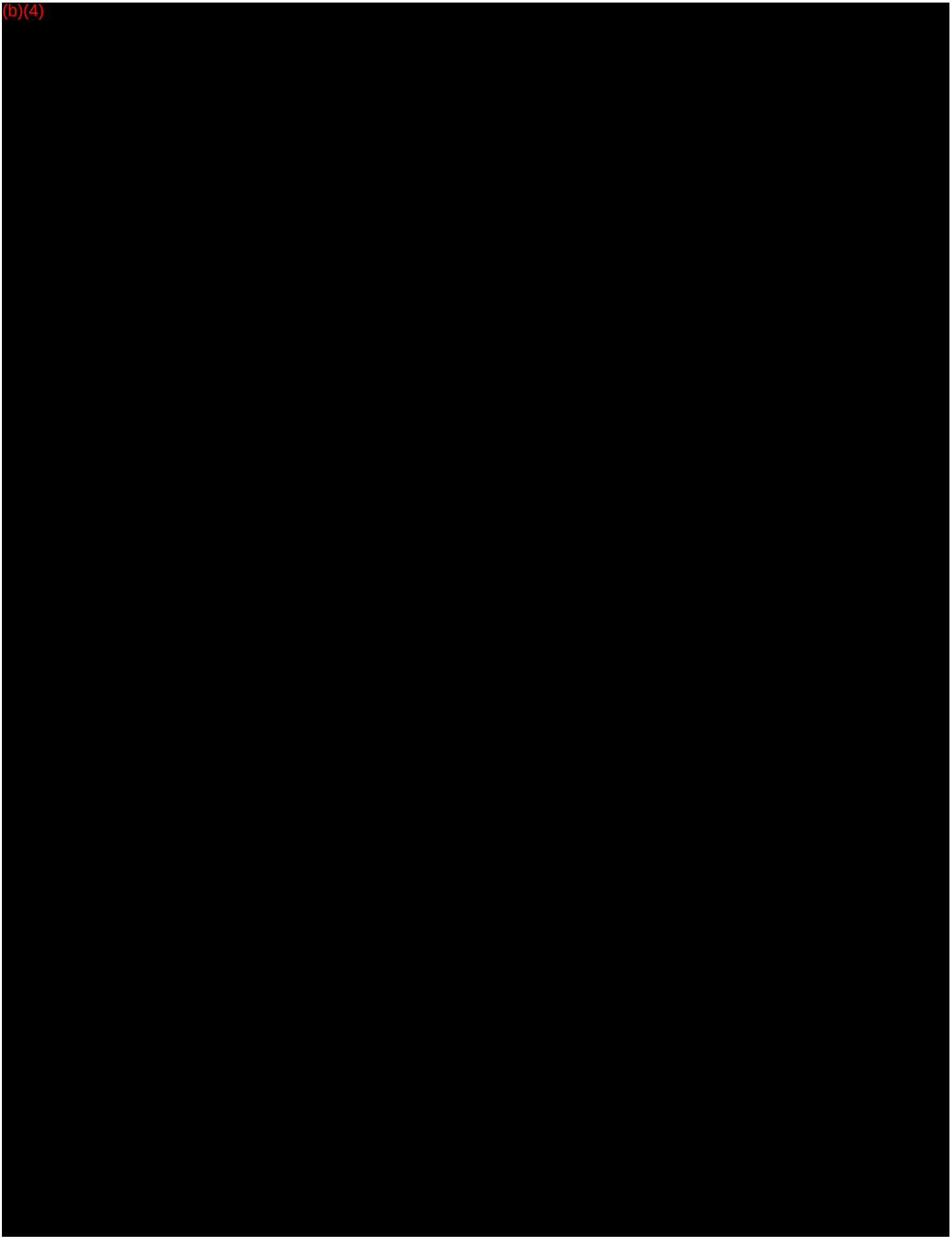

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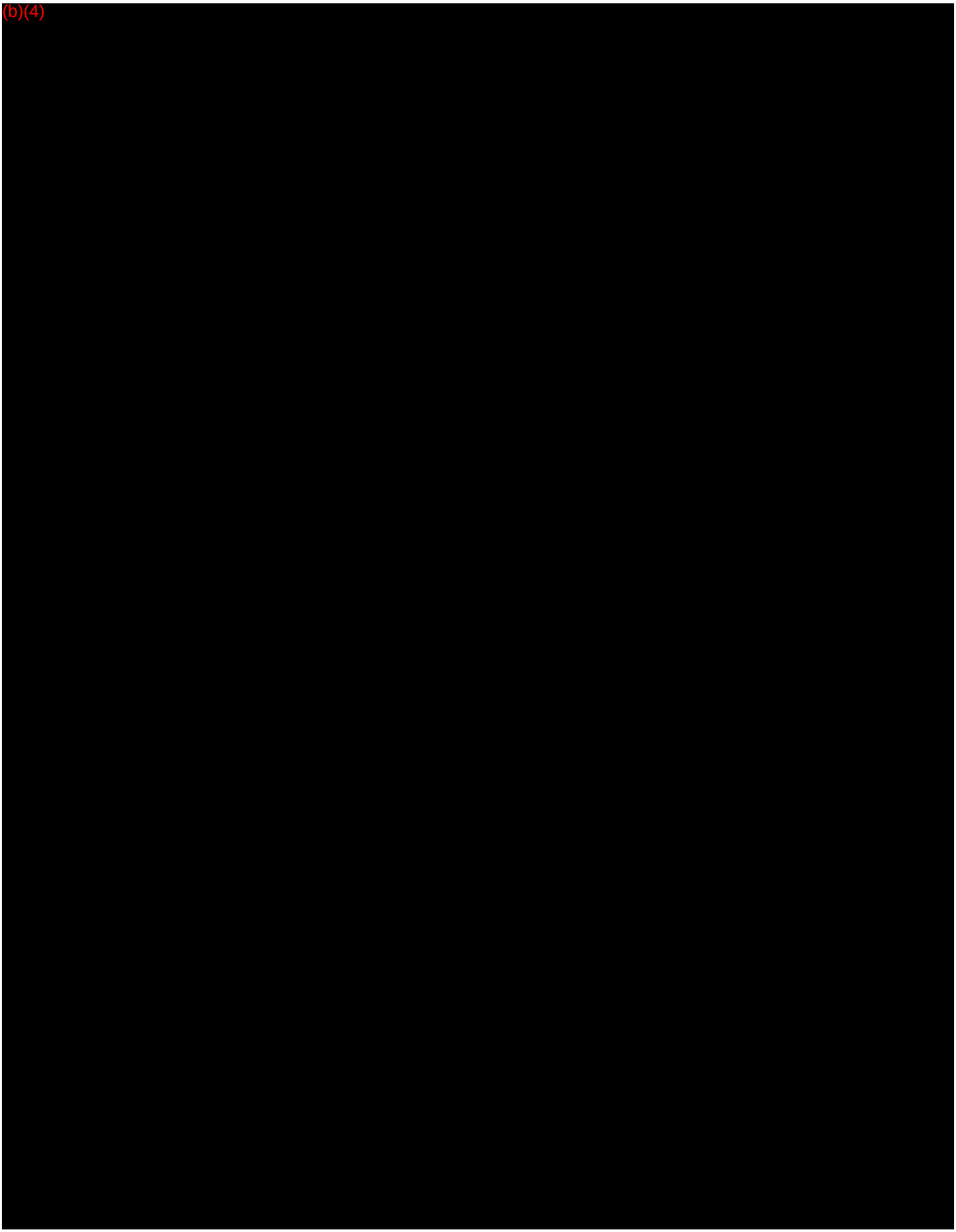

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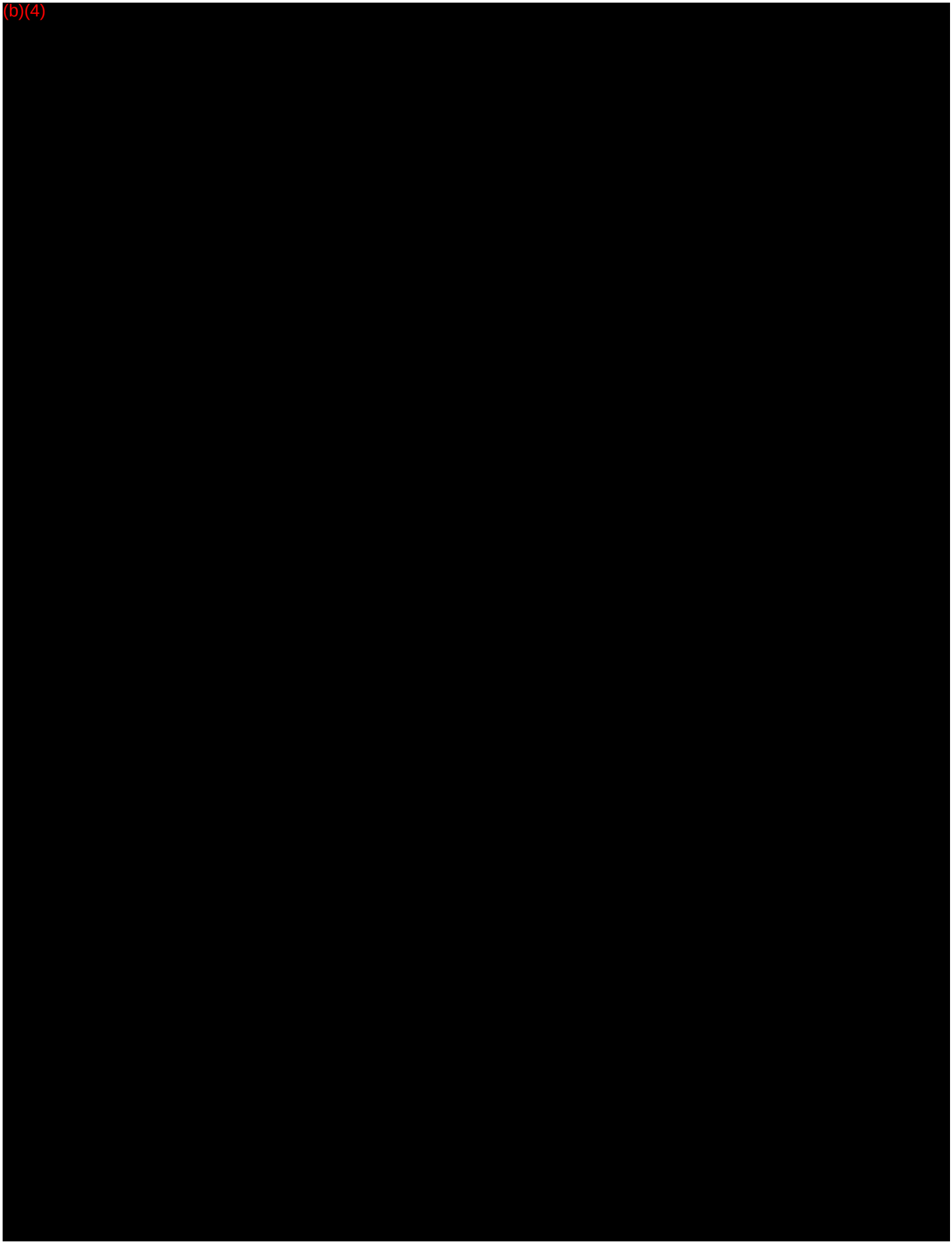

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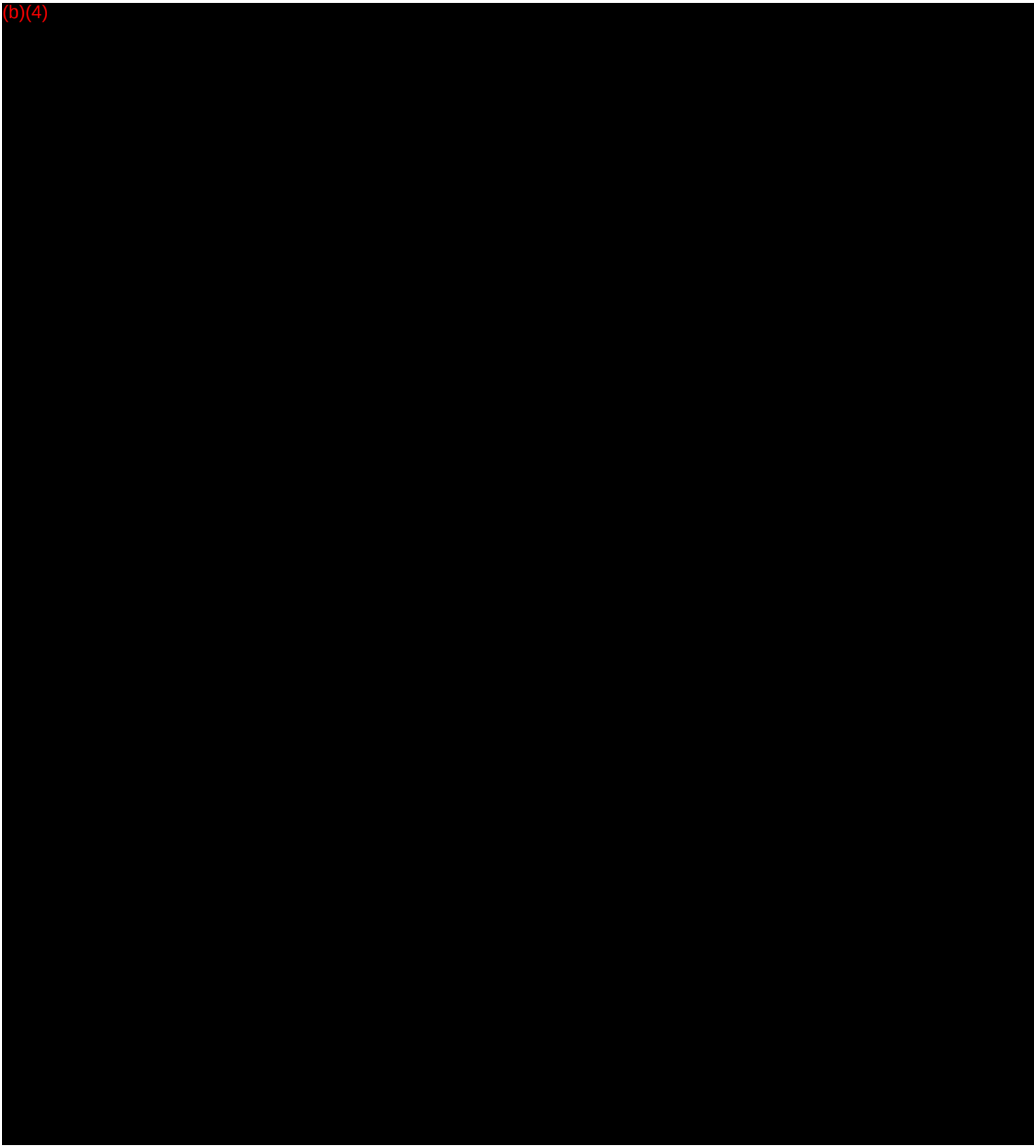

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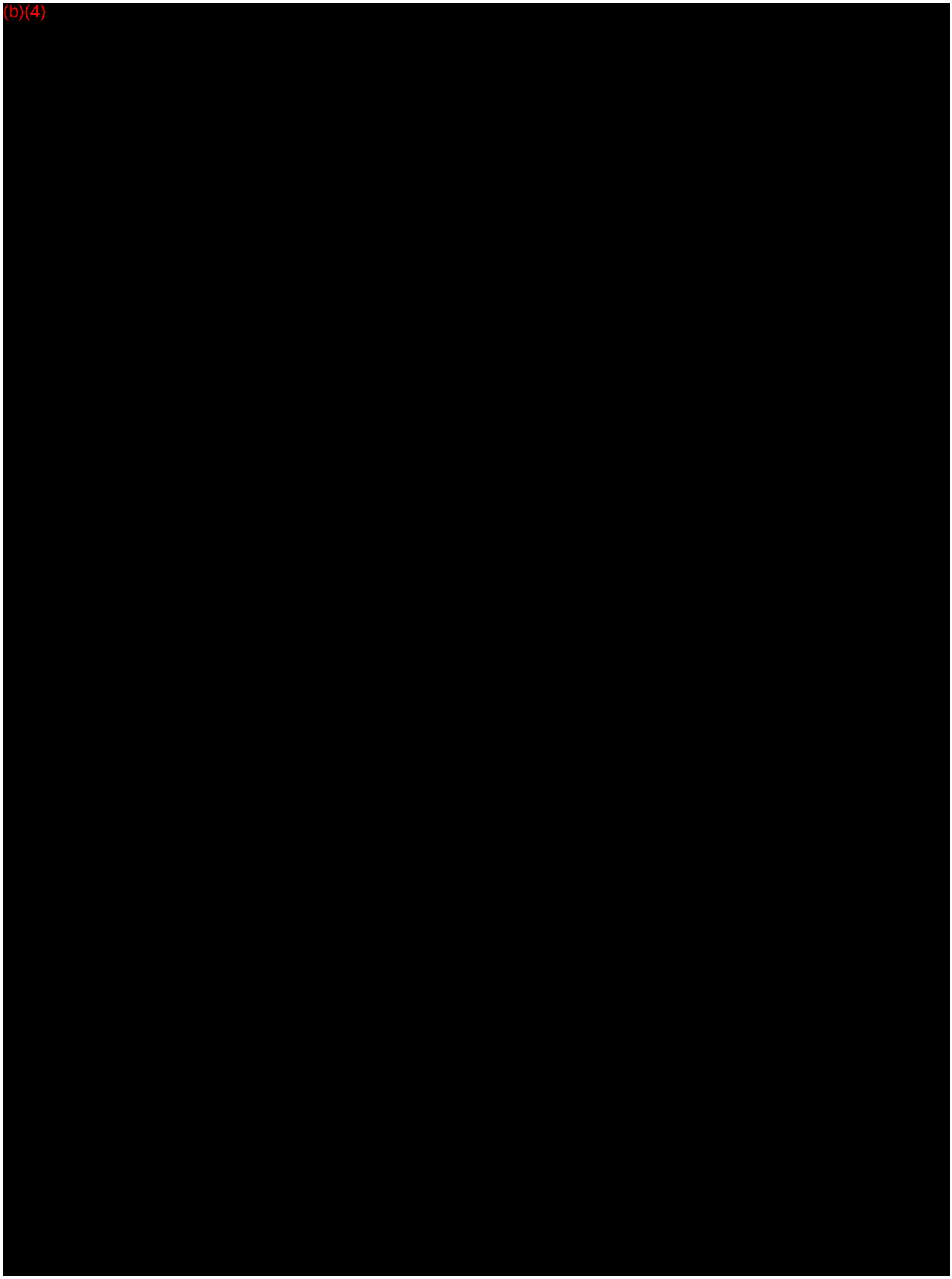

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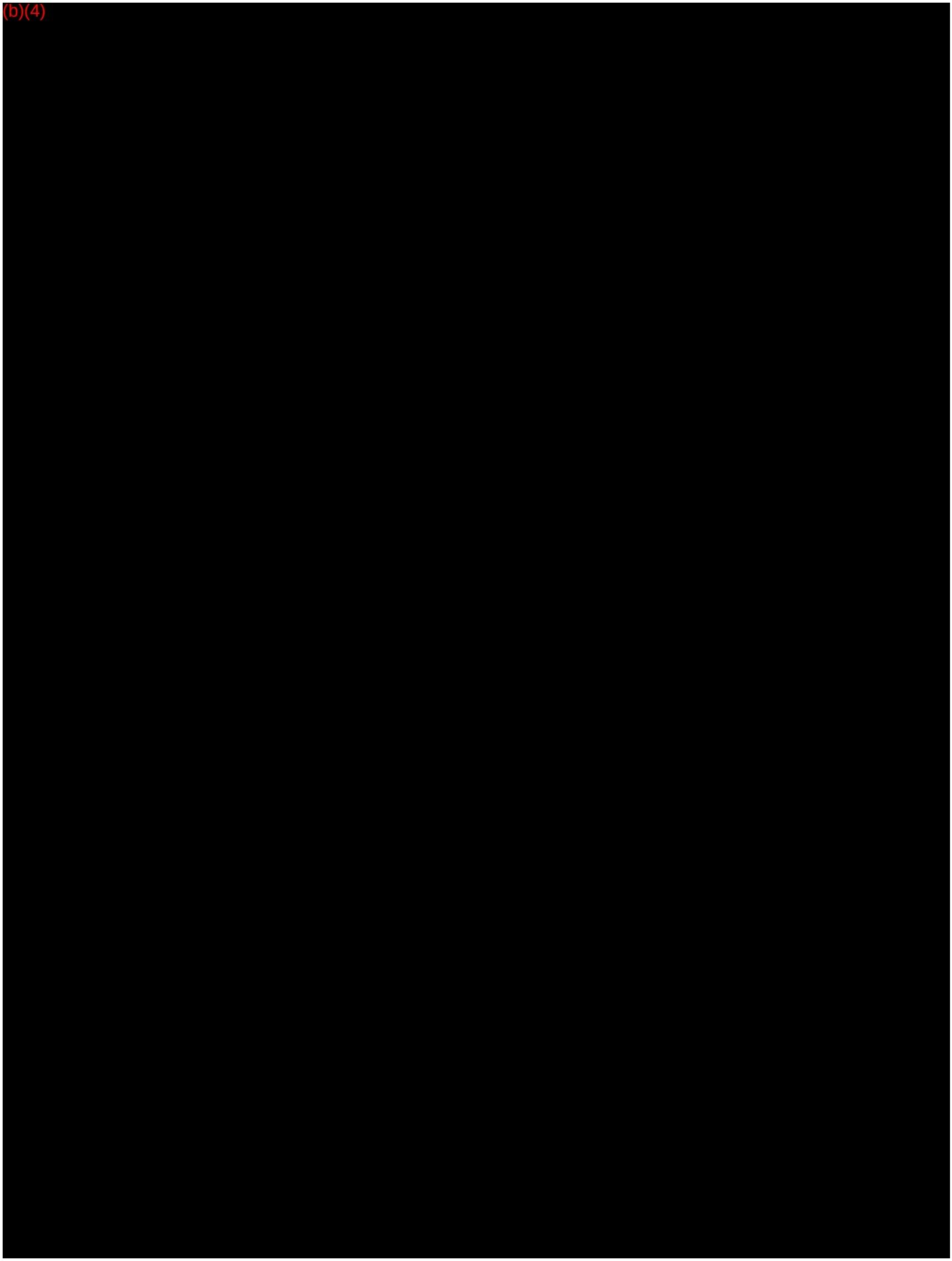

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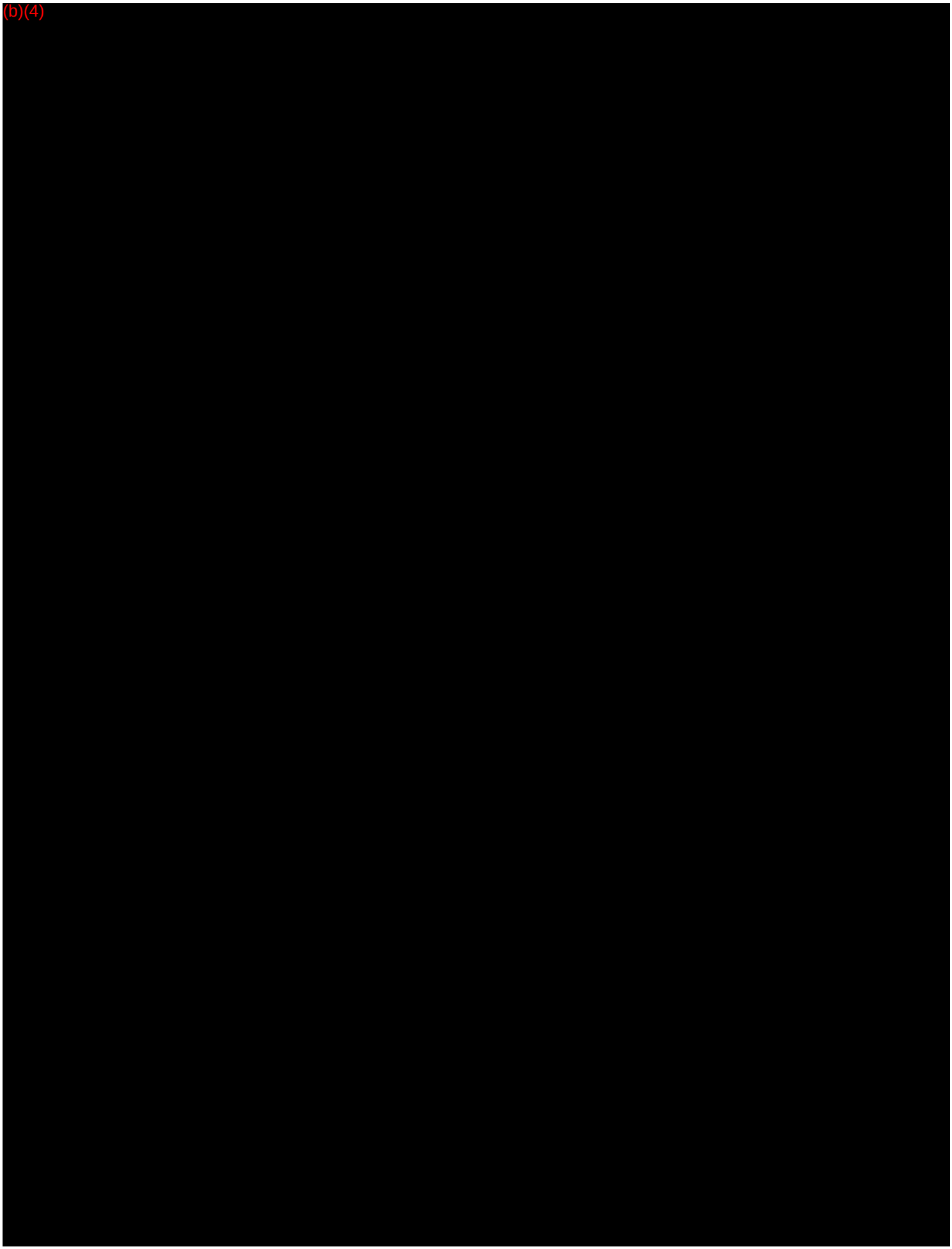

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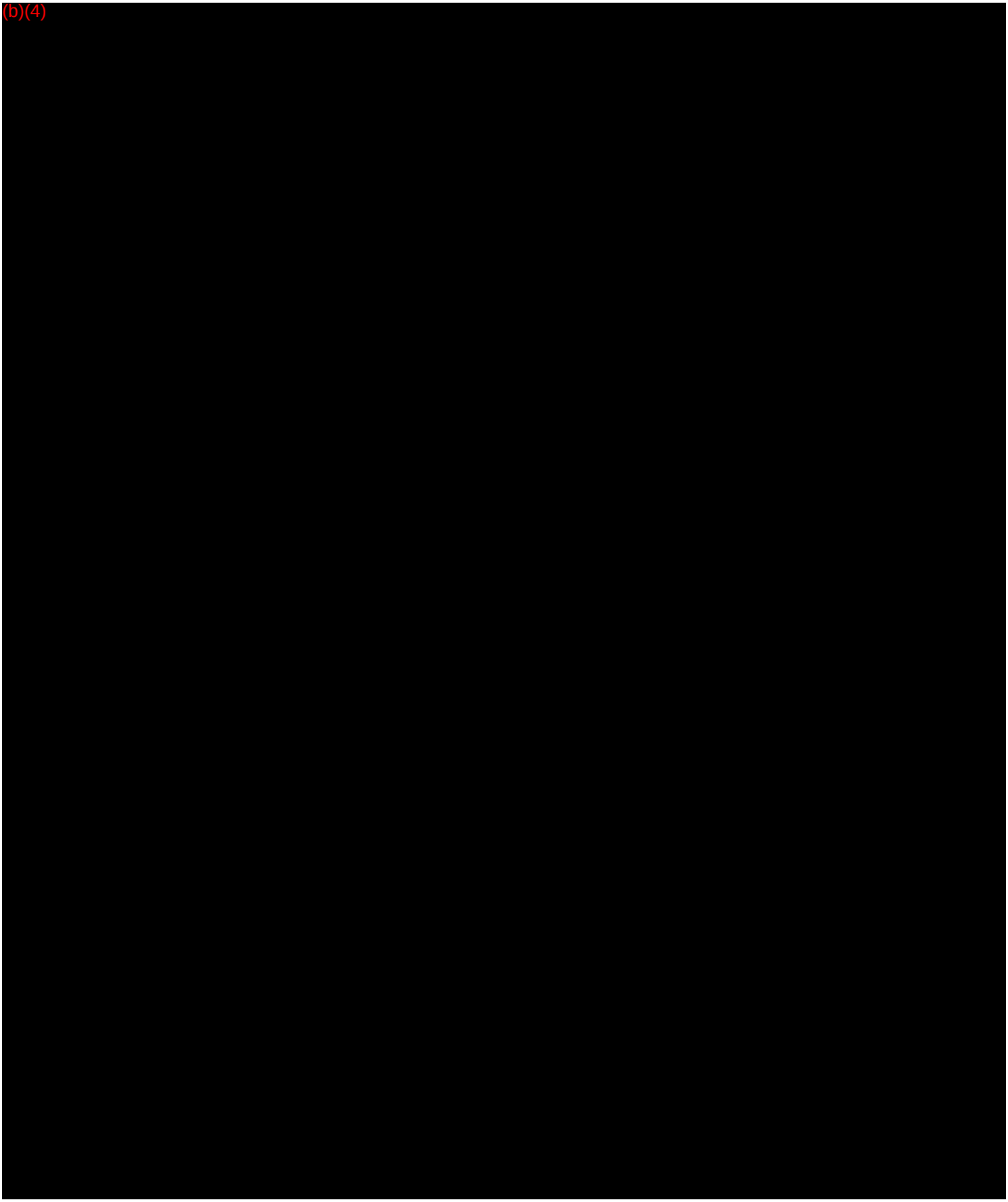

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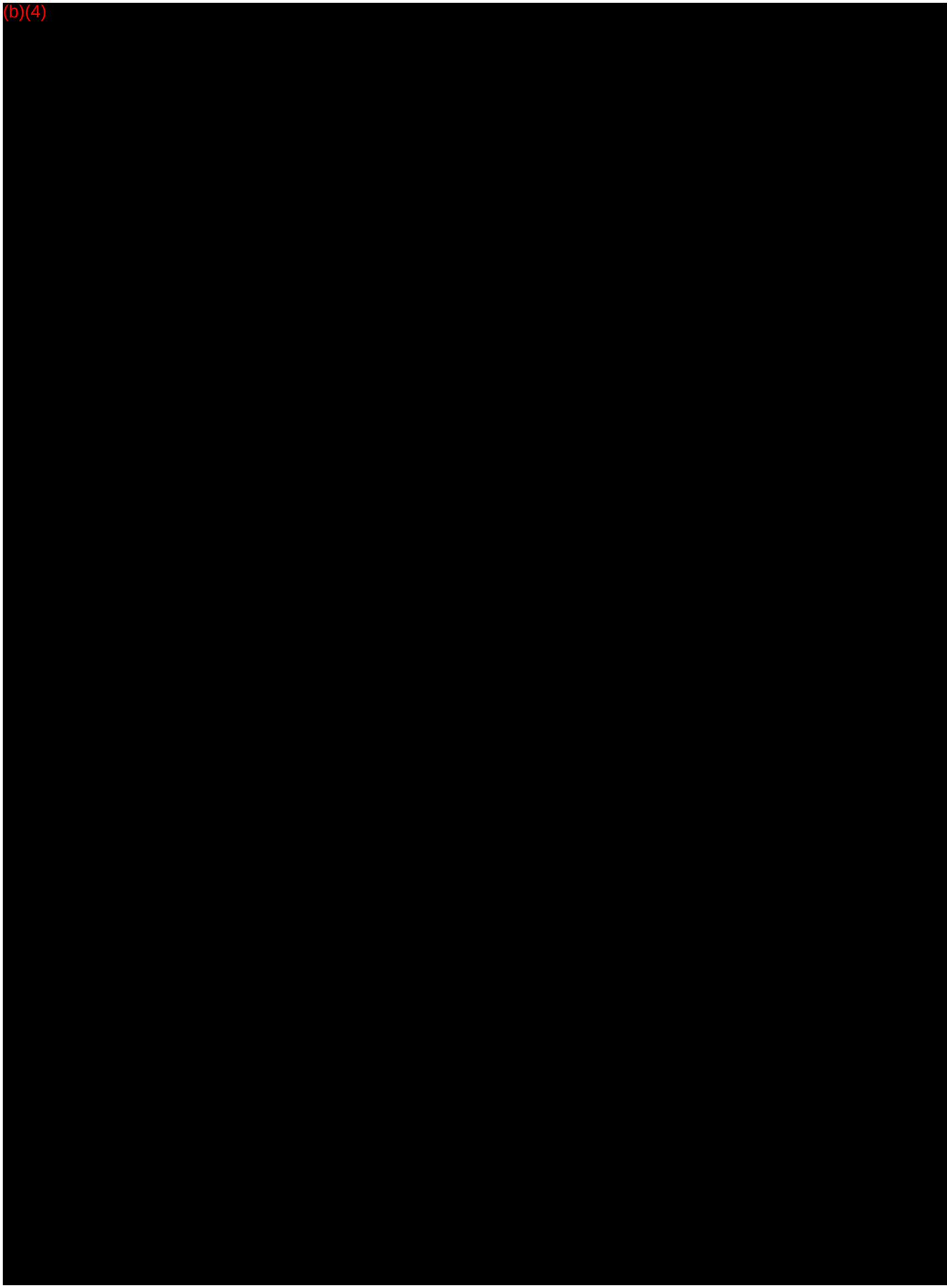

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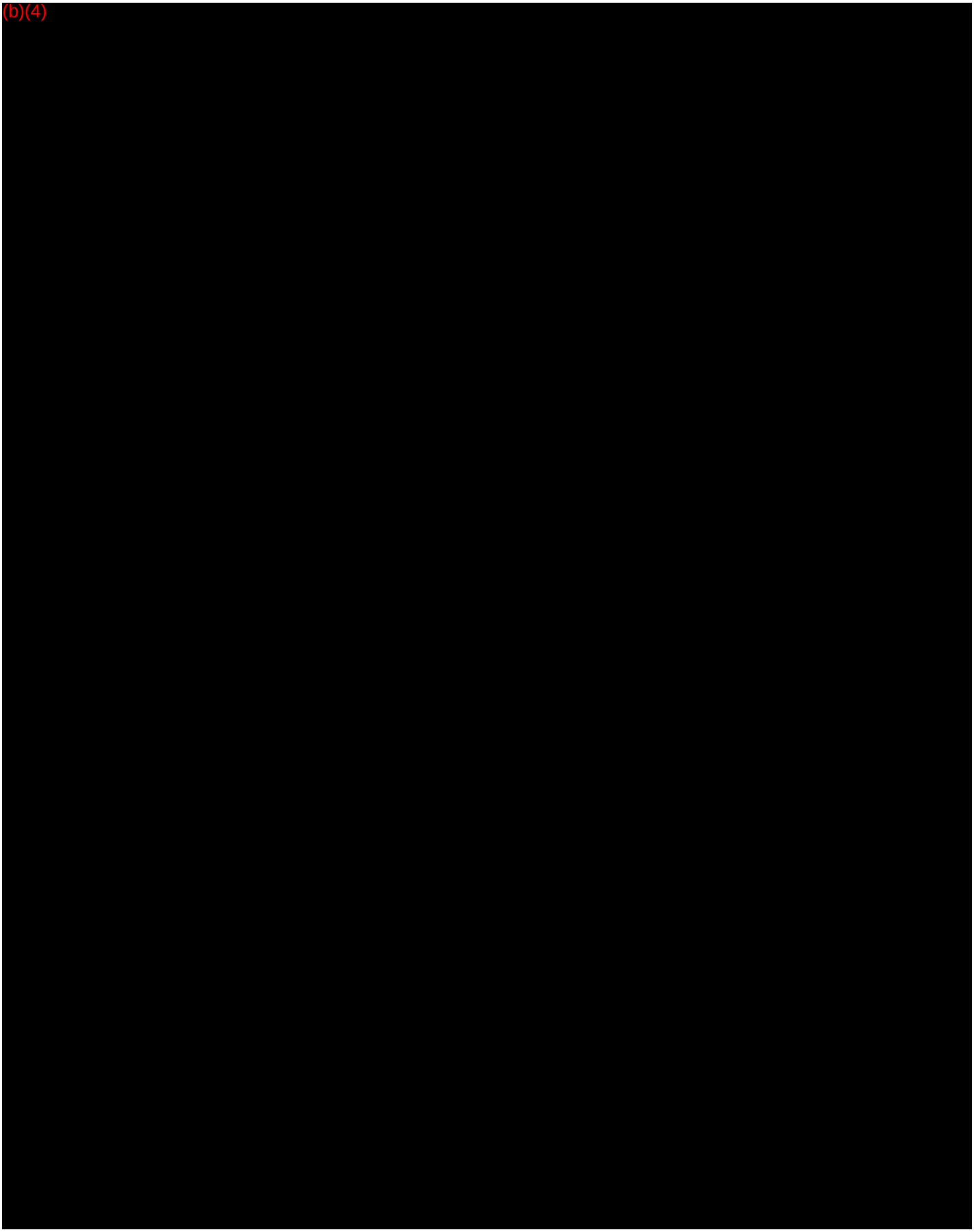

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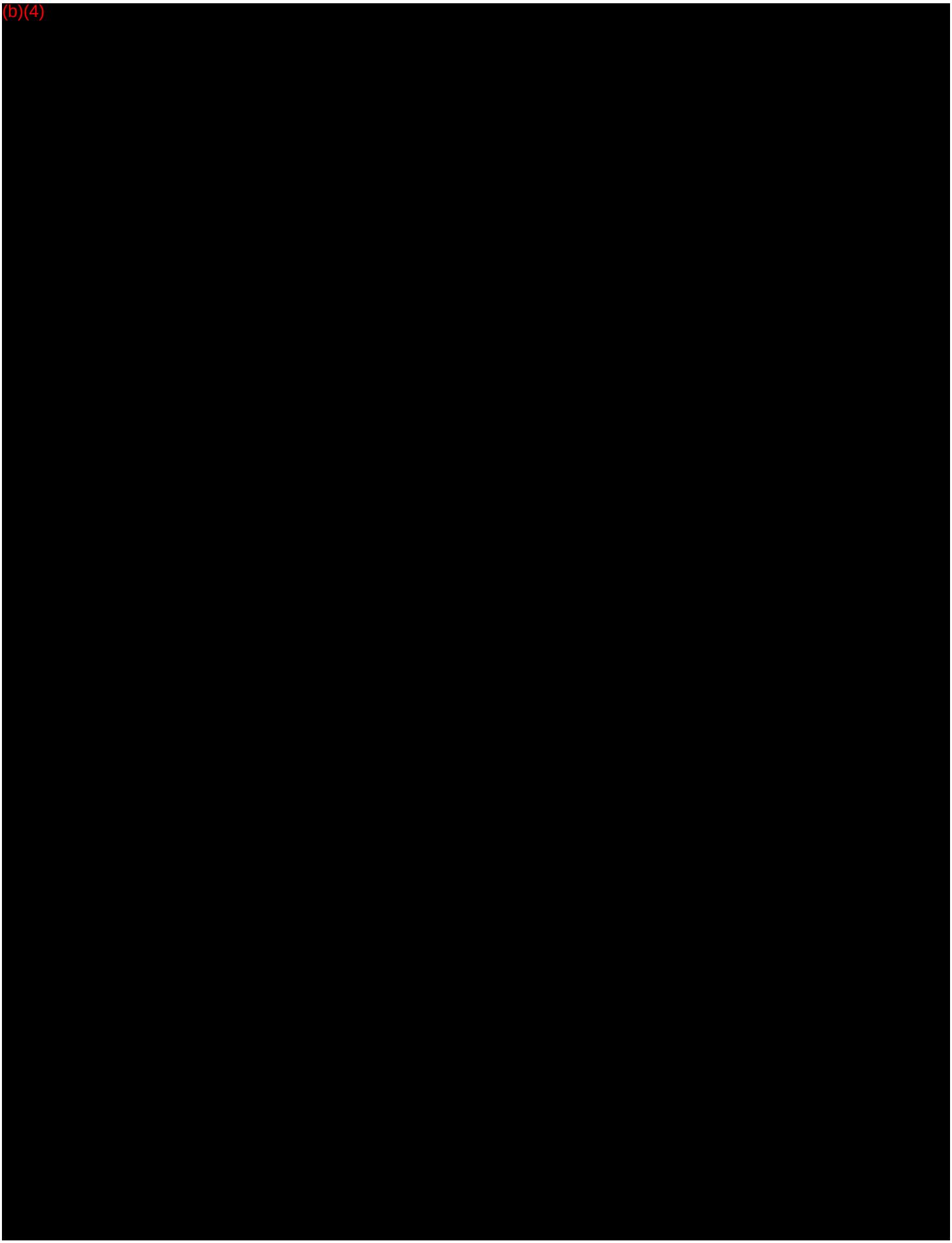

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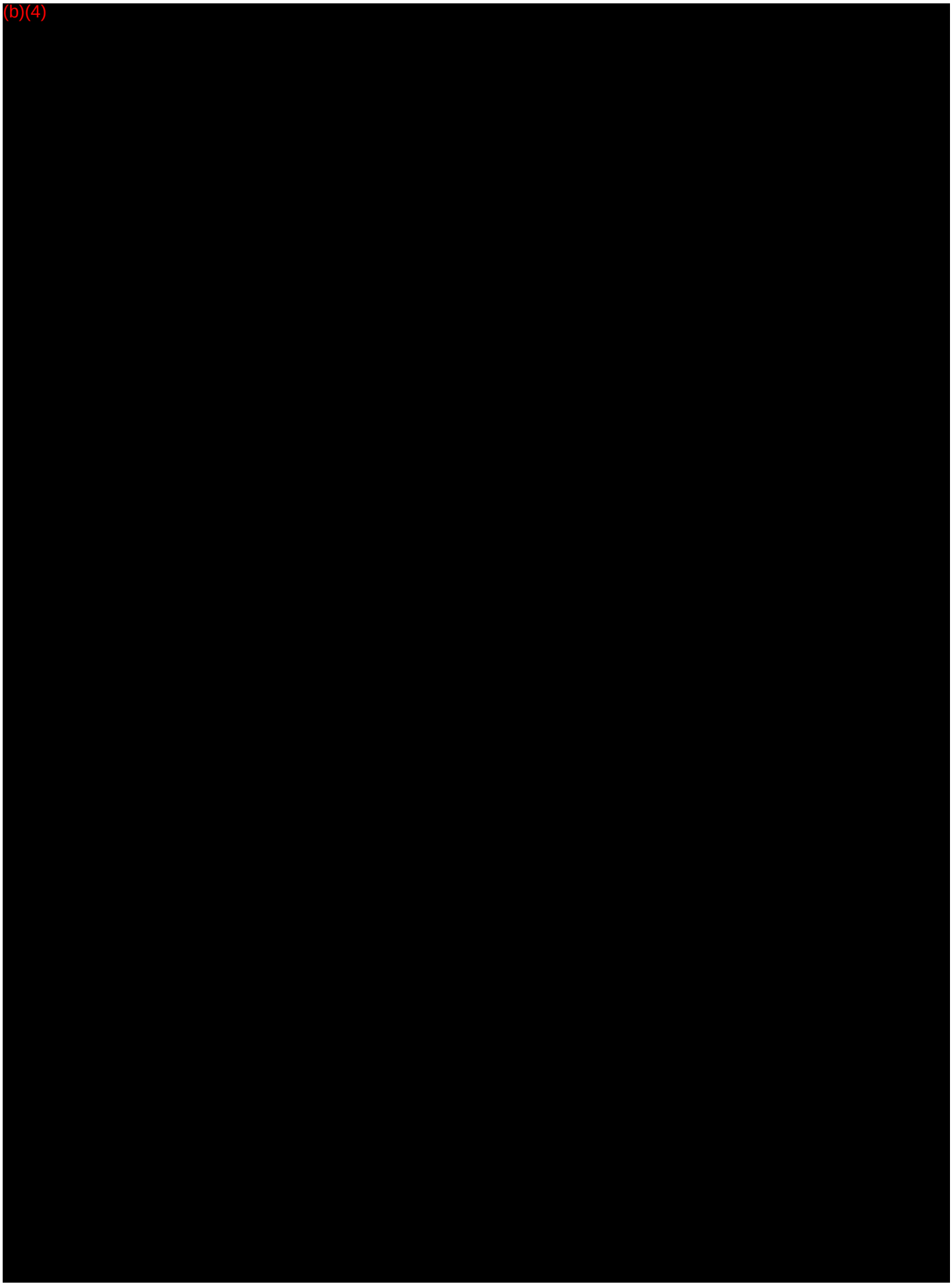

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Software Specification – (b)(4)

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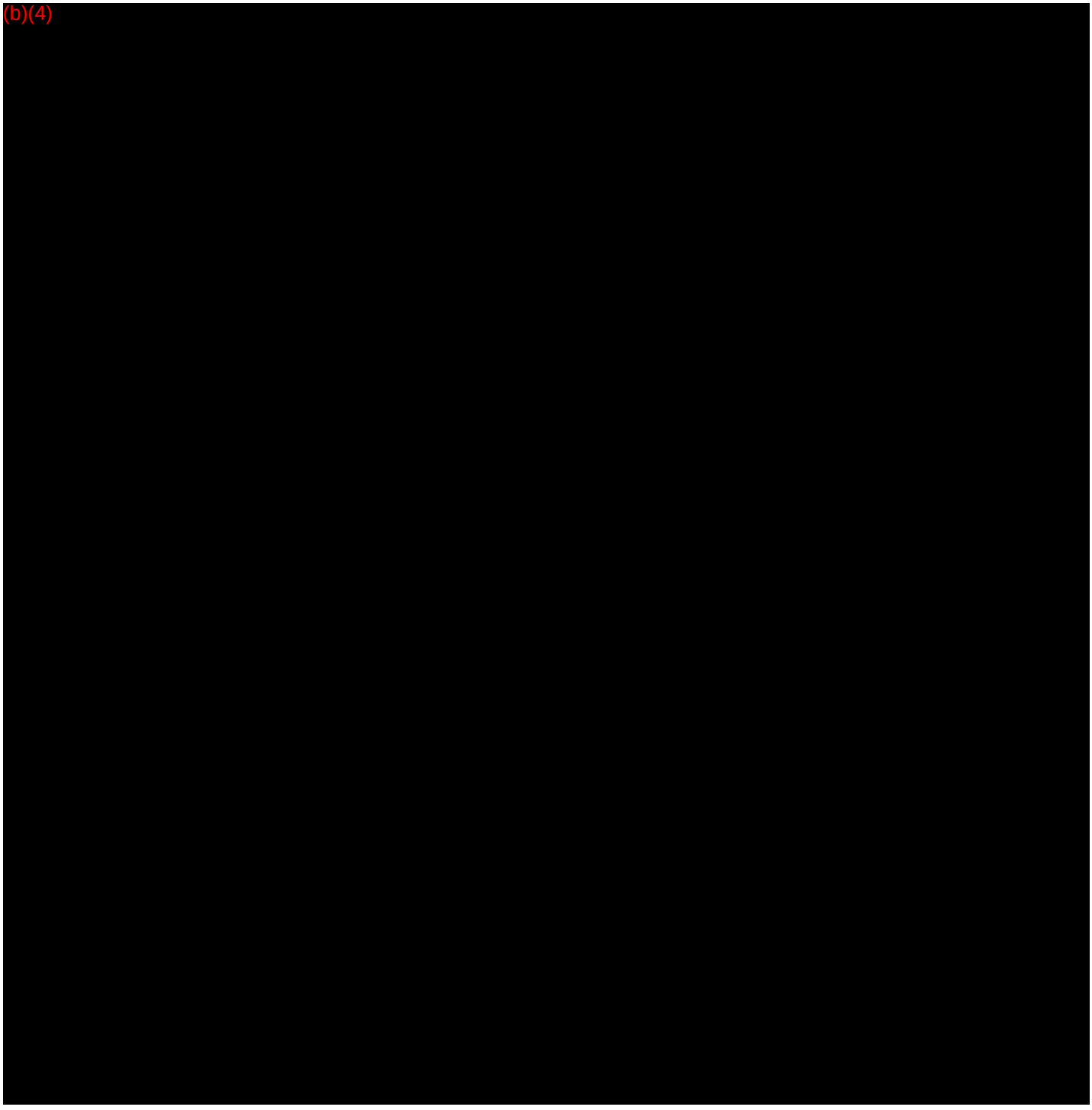

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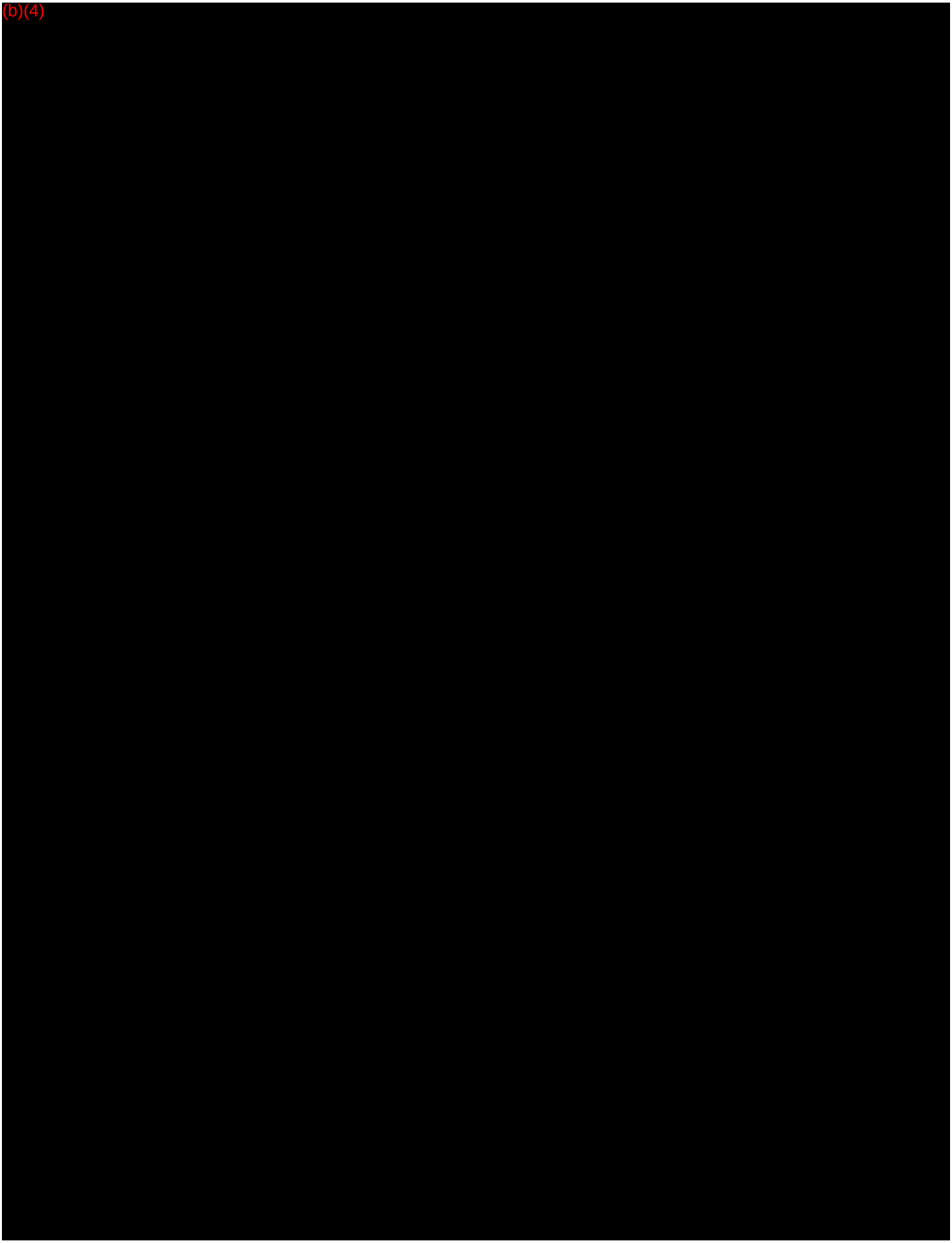

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Traceability Analysis

1. Introduction

The development of the 3Shape Abutment Designer™ Software implements Traceability Analysis by a Trace Matrix (see *Trace Matrix* below).

Note: The 3Shape Abutment Designer™ Software is an add on to the 3Shape Dental System™ Software (classified as 872.3661 Optical Impression Systems for CAD/CAM, Product Code NOF, 510(K) Exempt).

The trace shown is extracted from the Dental System™ Software Trace Matrix and only relates to the Abutment Designer.

The Trace Matrix links Identified Hazards, User Needs, Requirements, Specifications, and Validation and Verification.

Note: 3Shape Software Product Development Documentation is structured into a suite of Requirement Specifications (RS) and a suite of Software Specifications (SS).

Each Requirement Specification and Software Specification contains an embedded test protocol for Validation and Verification respectively.

Therefore, the Validation and Verification testing requirements are implicitly identified by the unique RS and SS document IDs listed in in the Trace Matrix.

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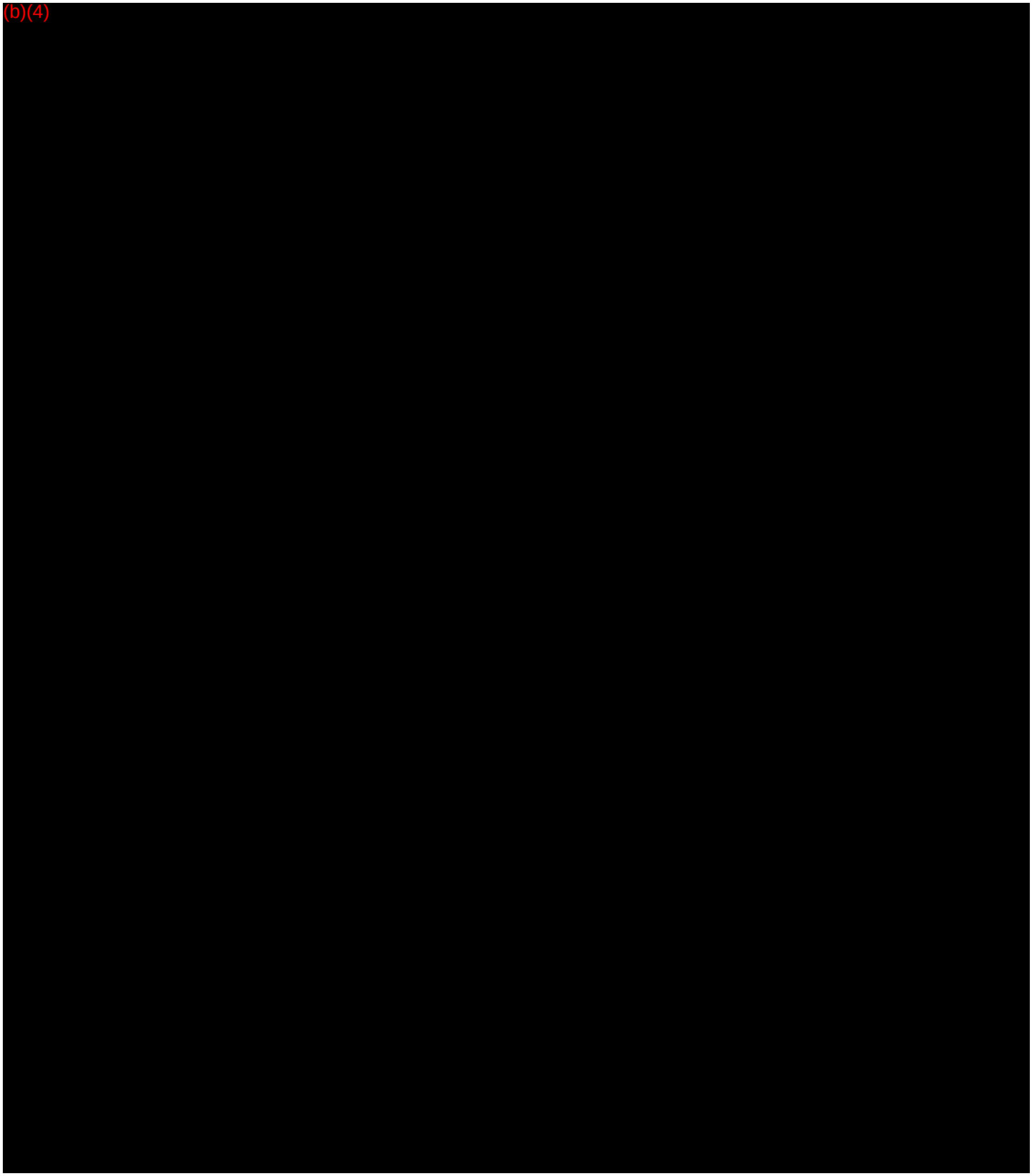
2. Trace Matrix

(b)(4)



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Software Development Environment Description

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Human Factors Engineering Checklist

MANUFACTURER	
Manufacturer's Name and Address:	**3Shape A/S, Holmens Kanal 7, 1060 Copenhagen K, Denmark**
Type and Name(s) of Medical Device(s):	**3Shape Abutment Designer™ Software**

Element	Covered In
1 Introduction 1.1 Use related Hazards 1.2 Use Scenarios Resulting in Hazards	N/A

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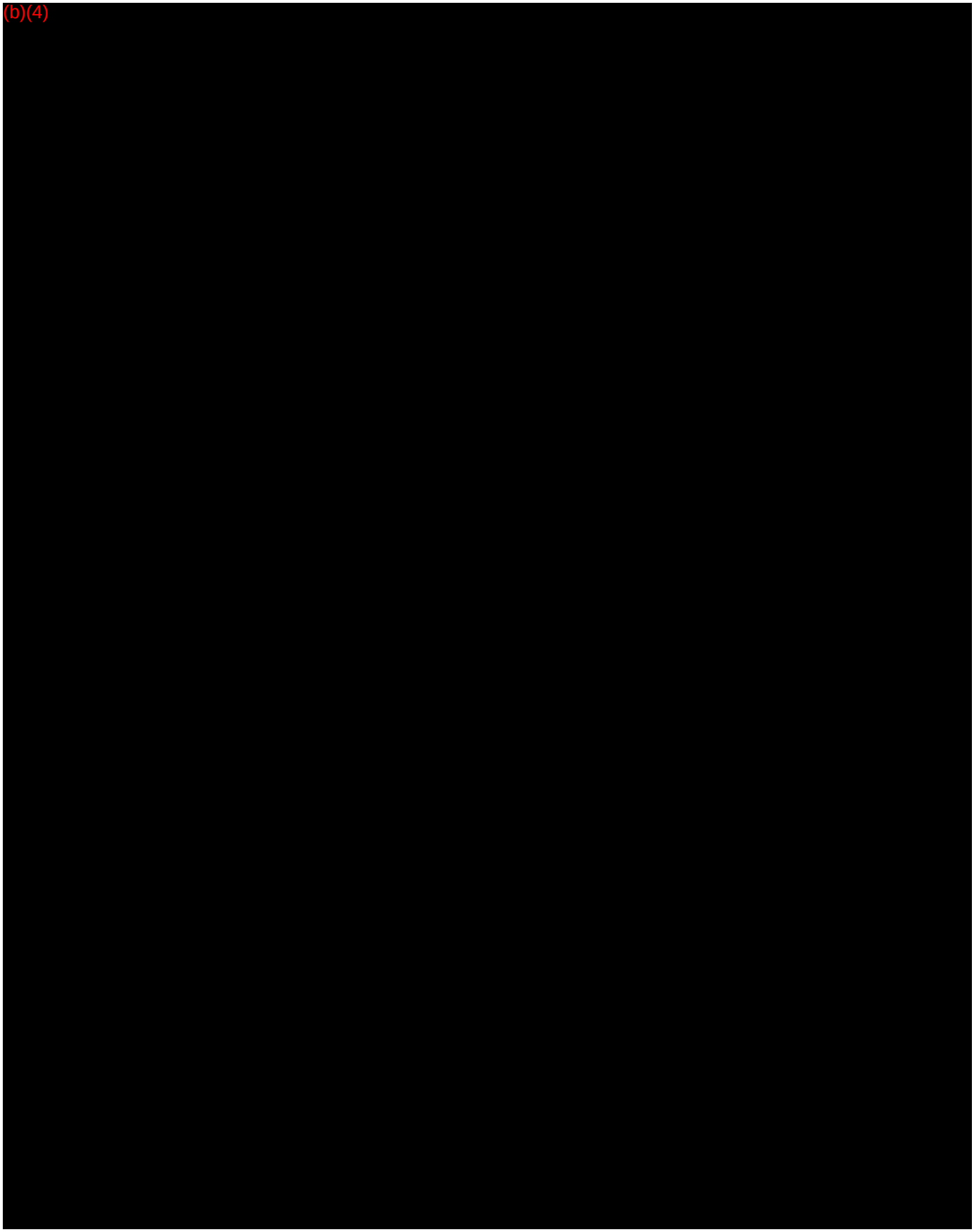

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Records processed under FOIA Request 2016-8070; Released by CDRH on 10/5/2017

3shape

Validation Result – (b)(4)

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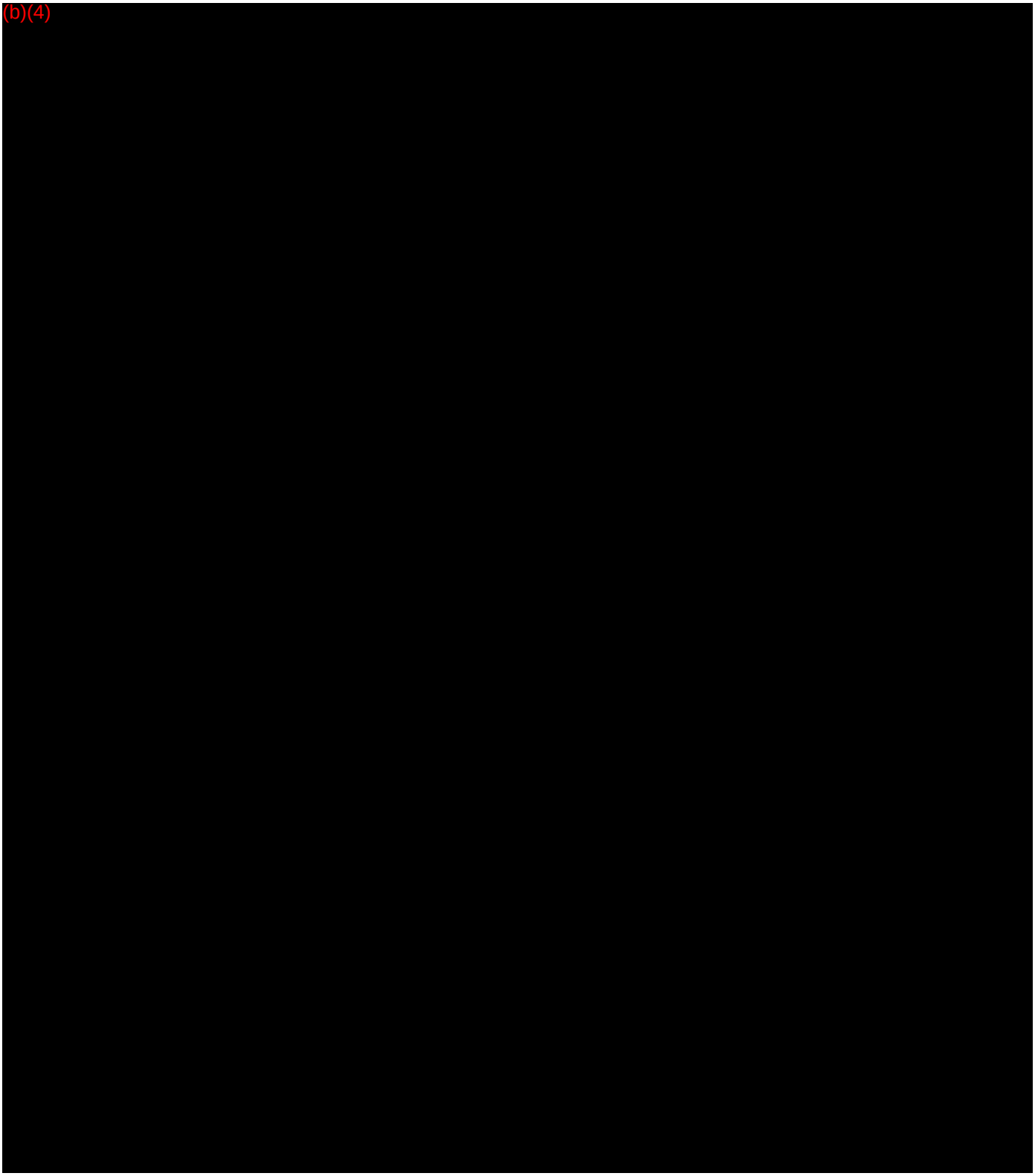

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Requirement Specification – (b)(4)

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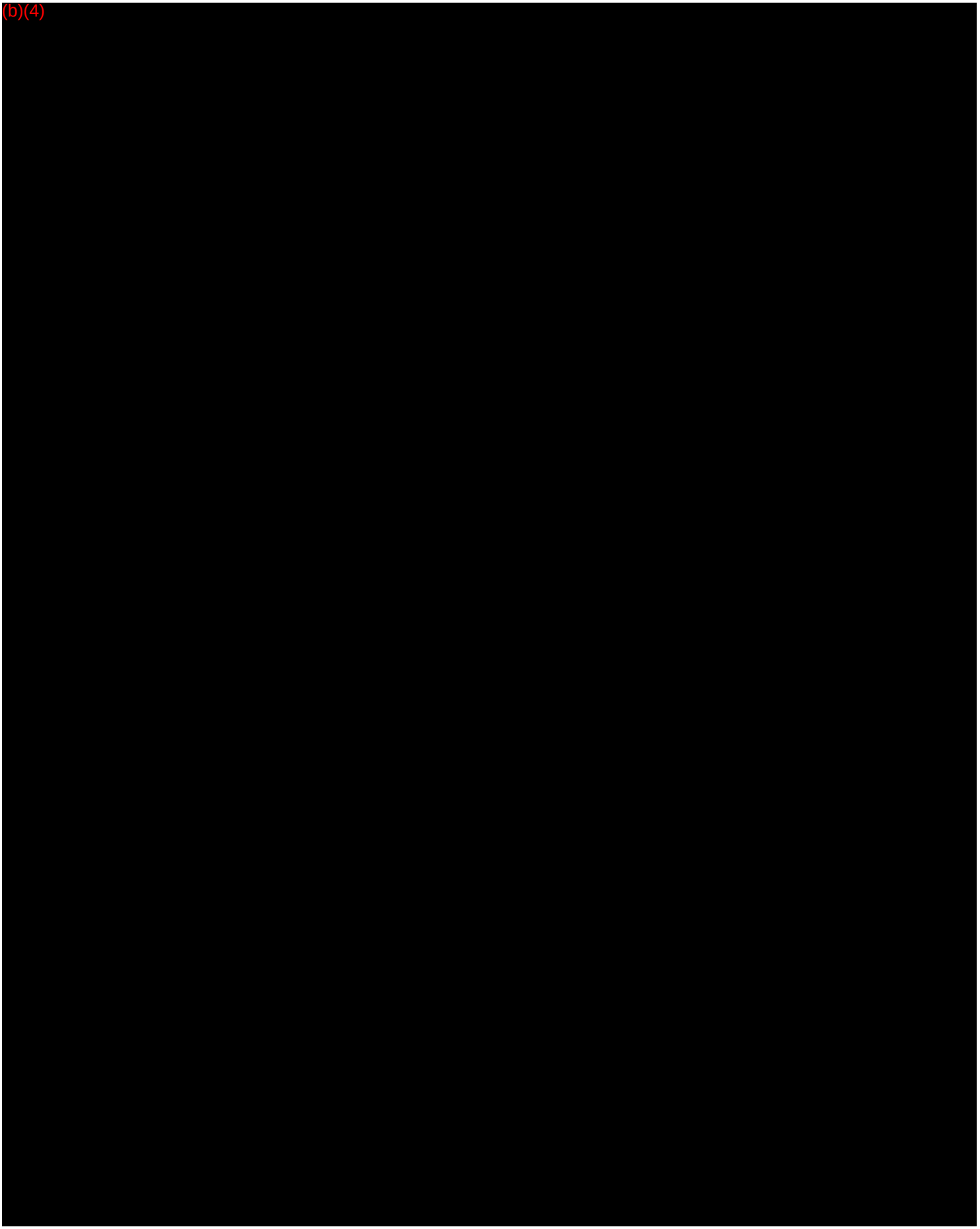

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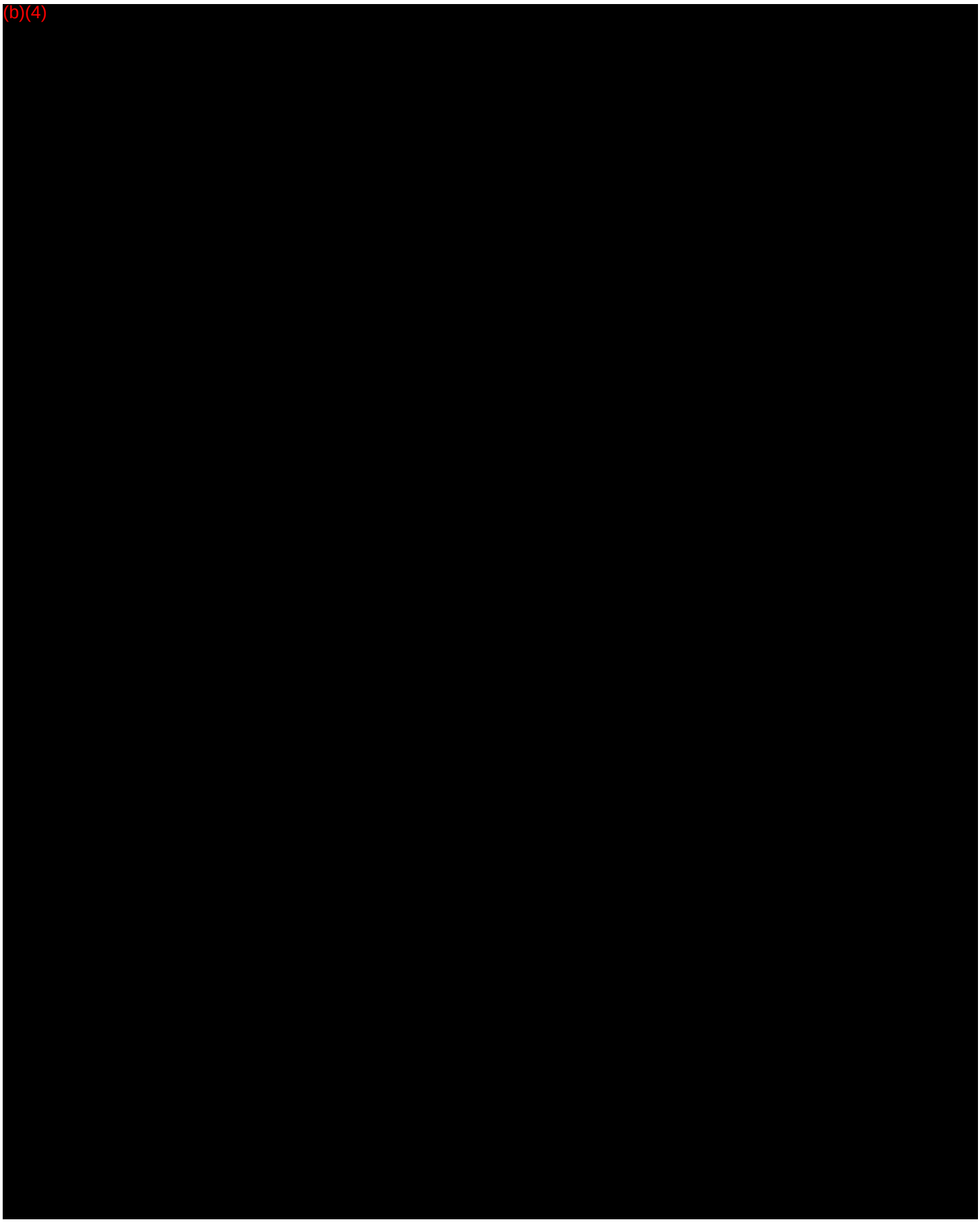

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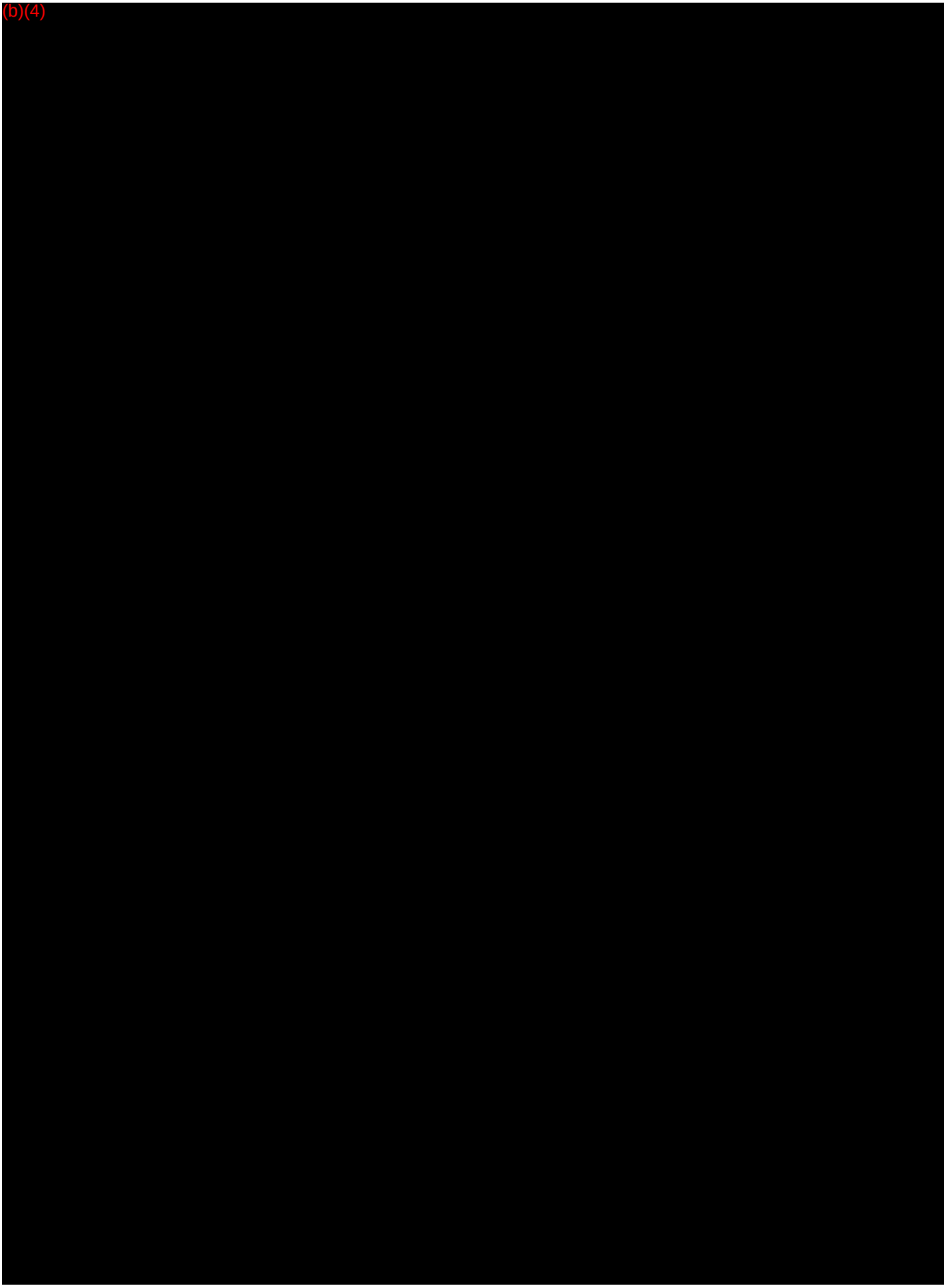

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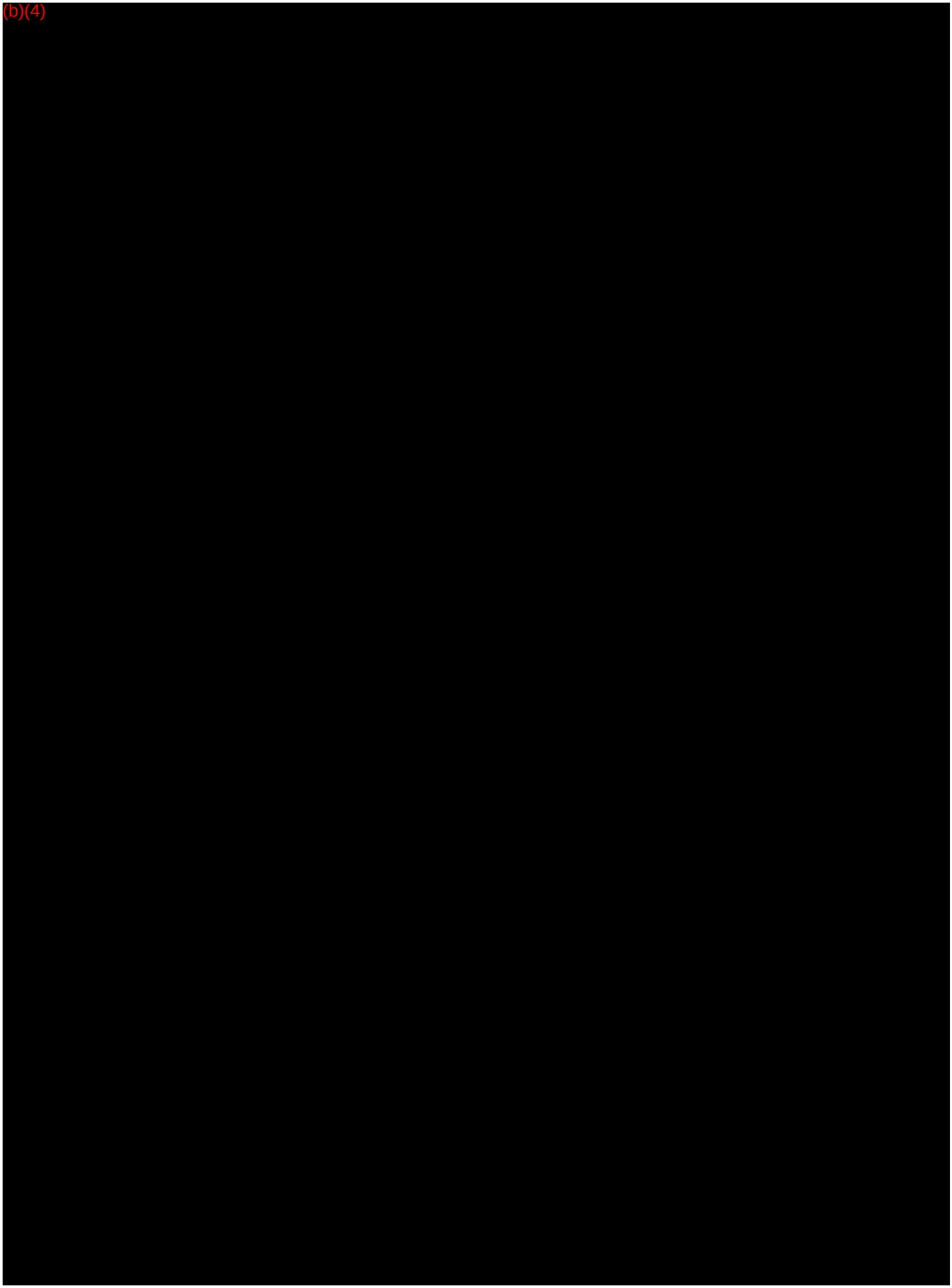

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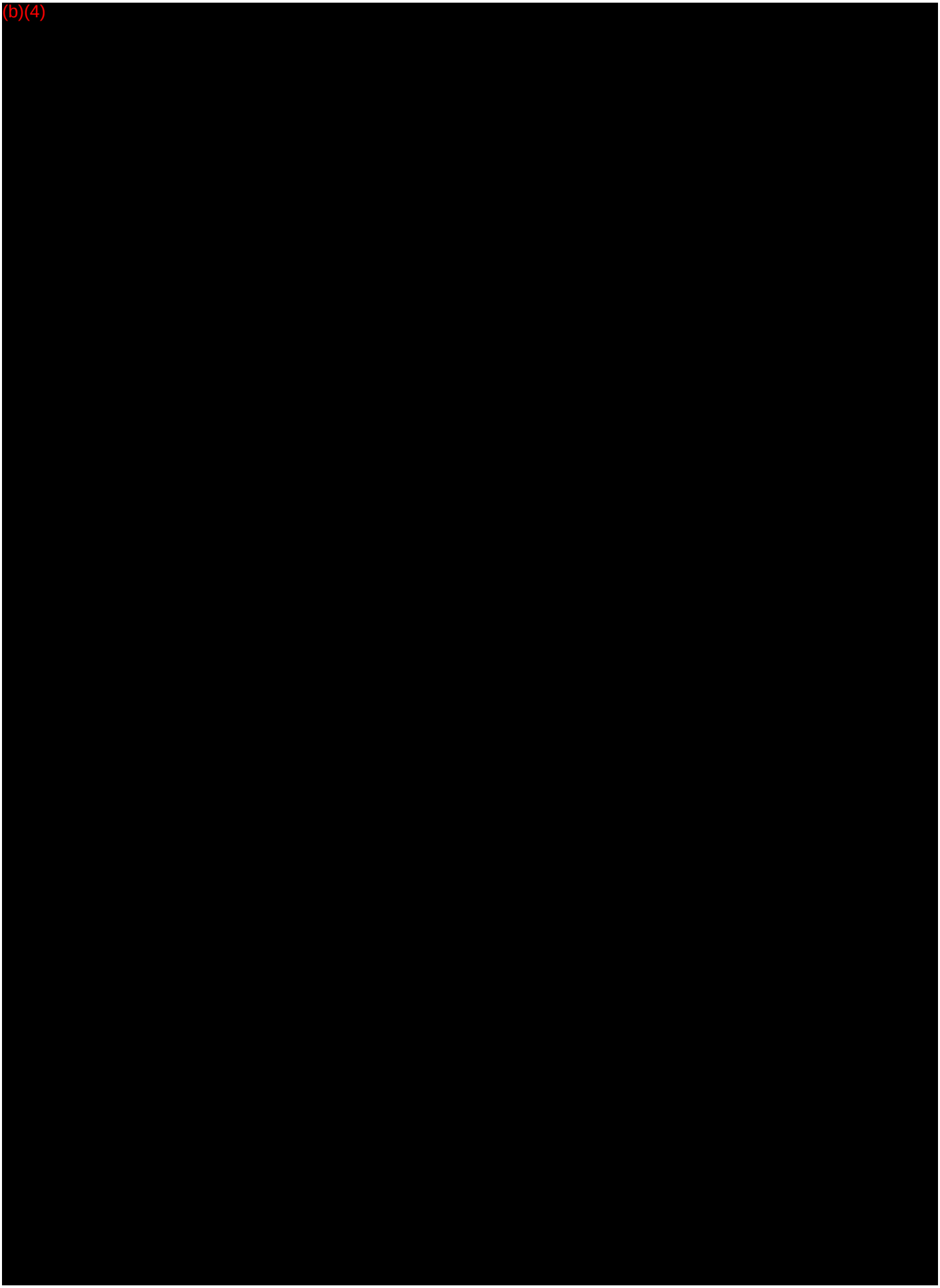

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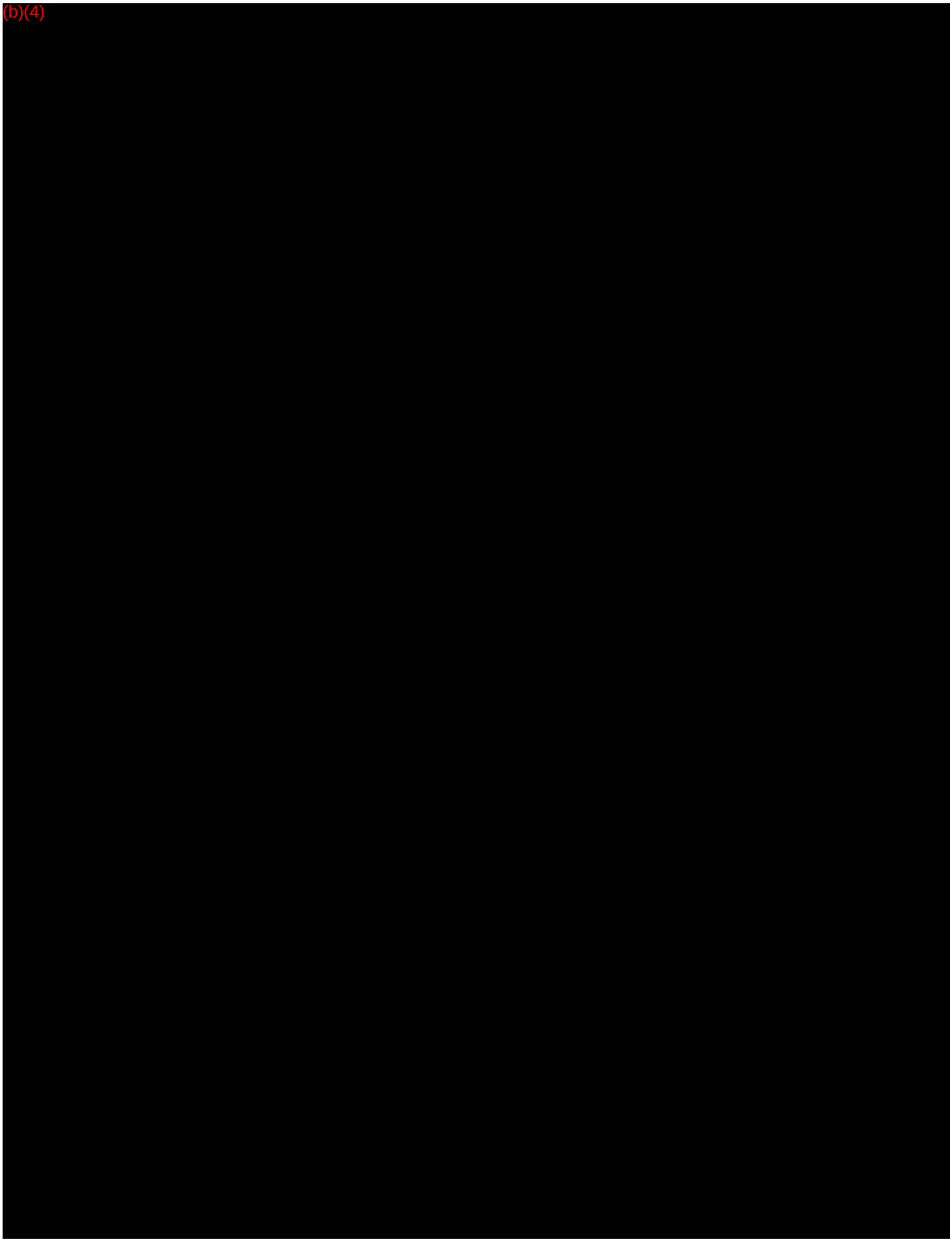

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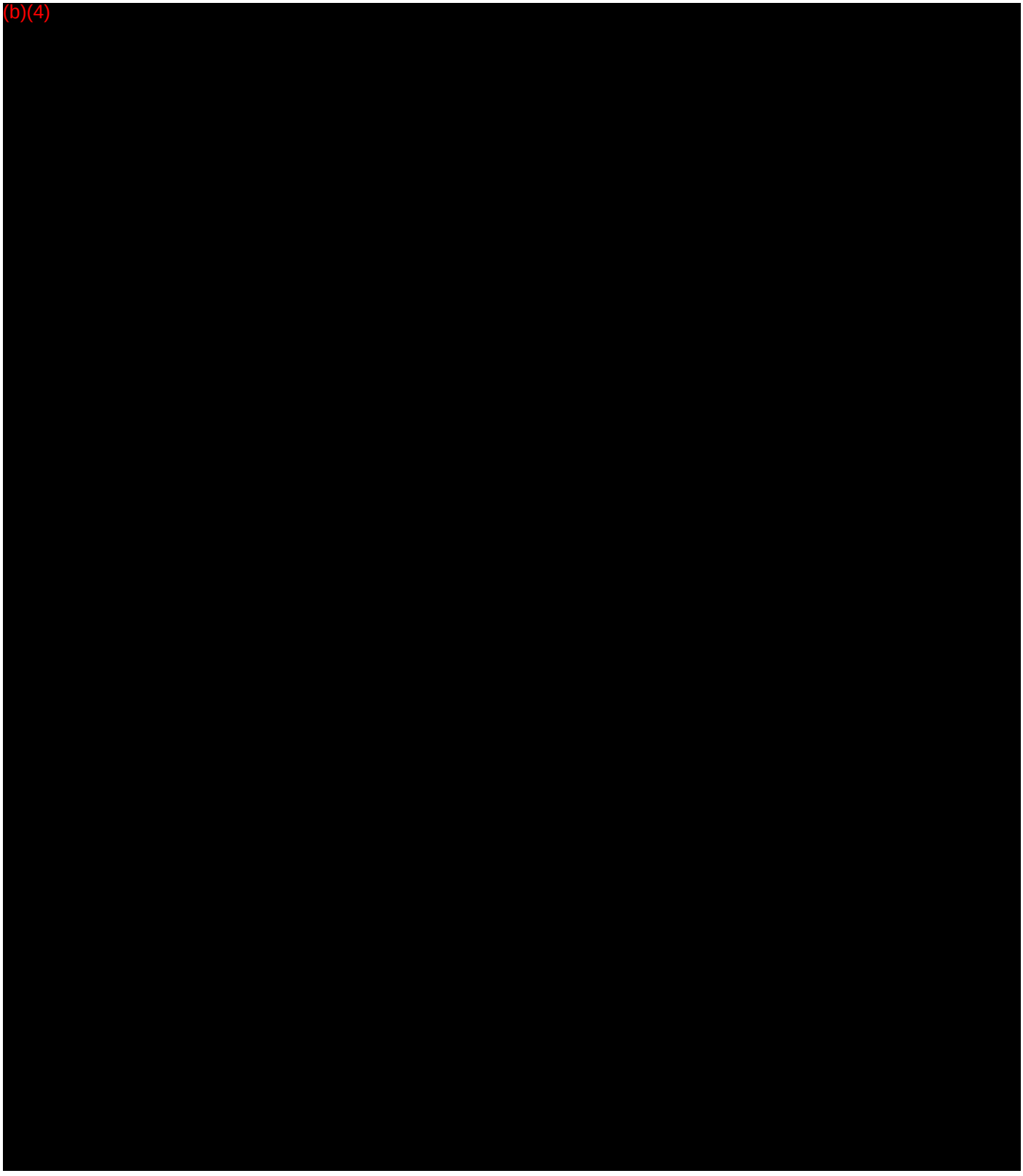

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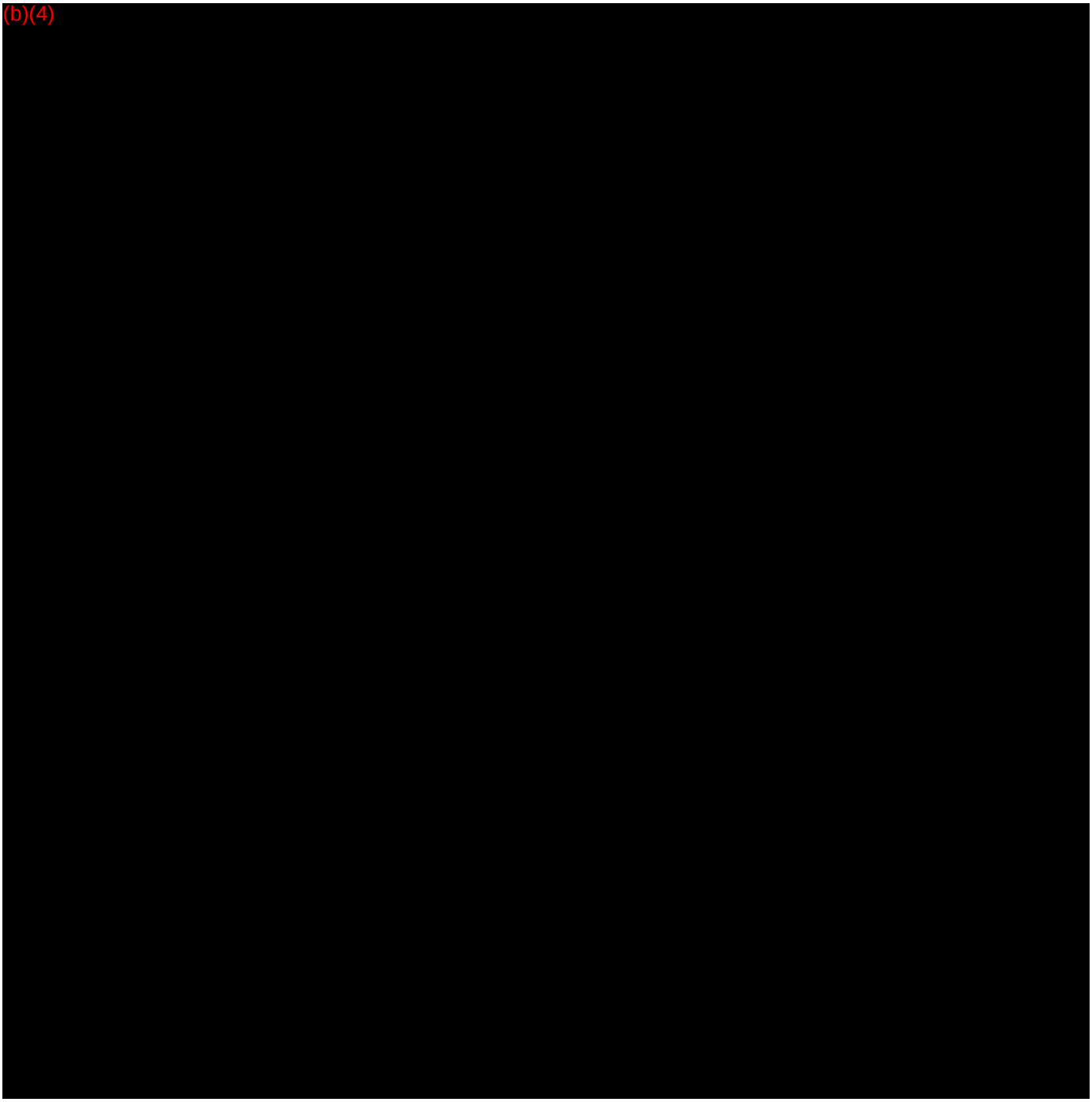

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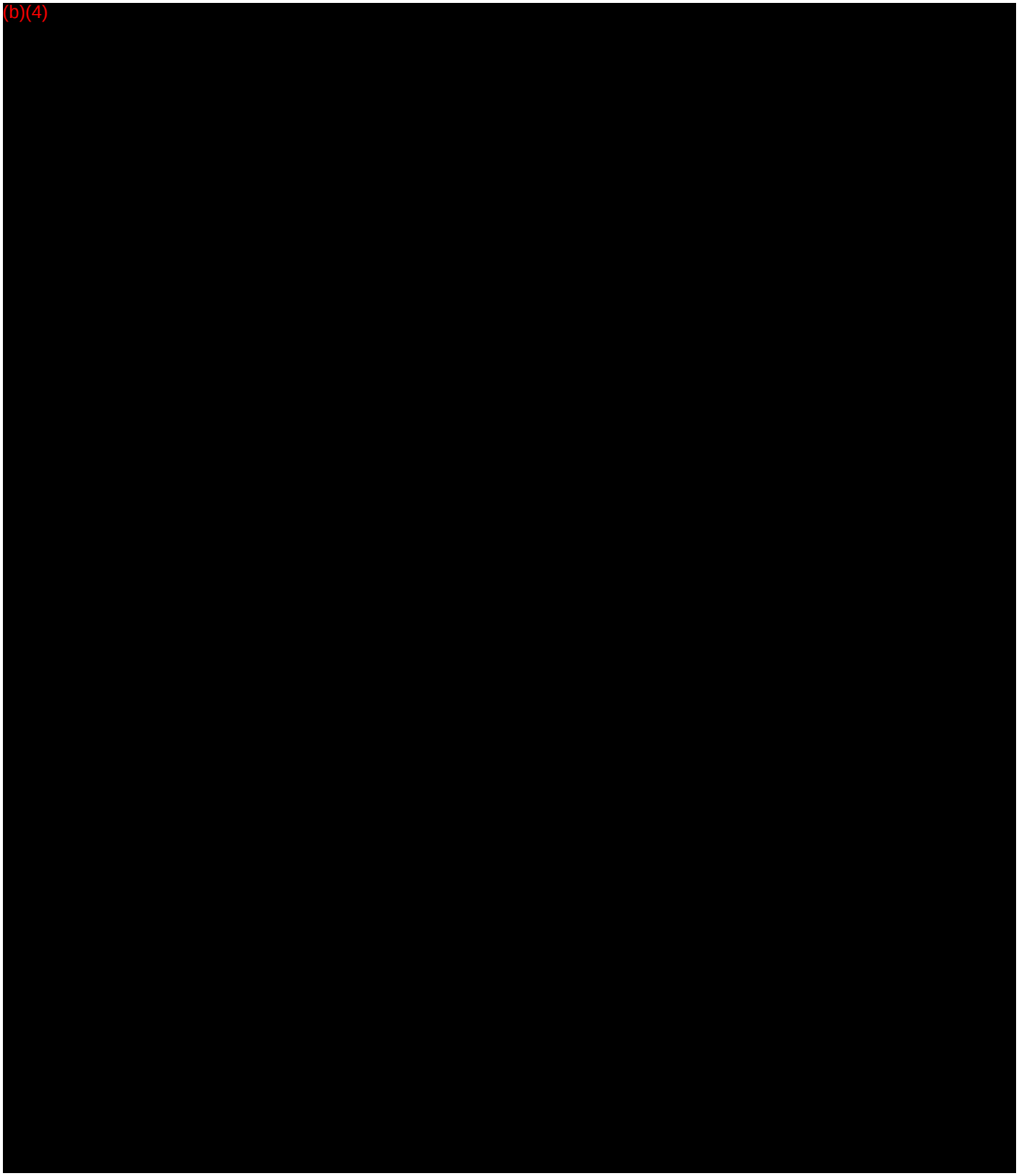

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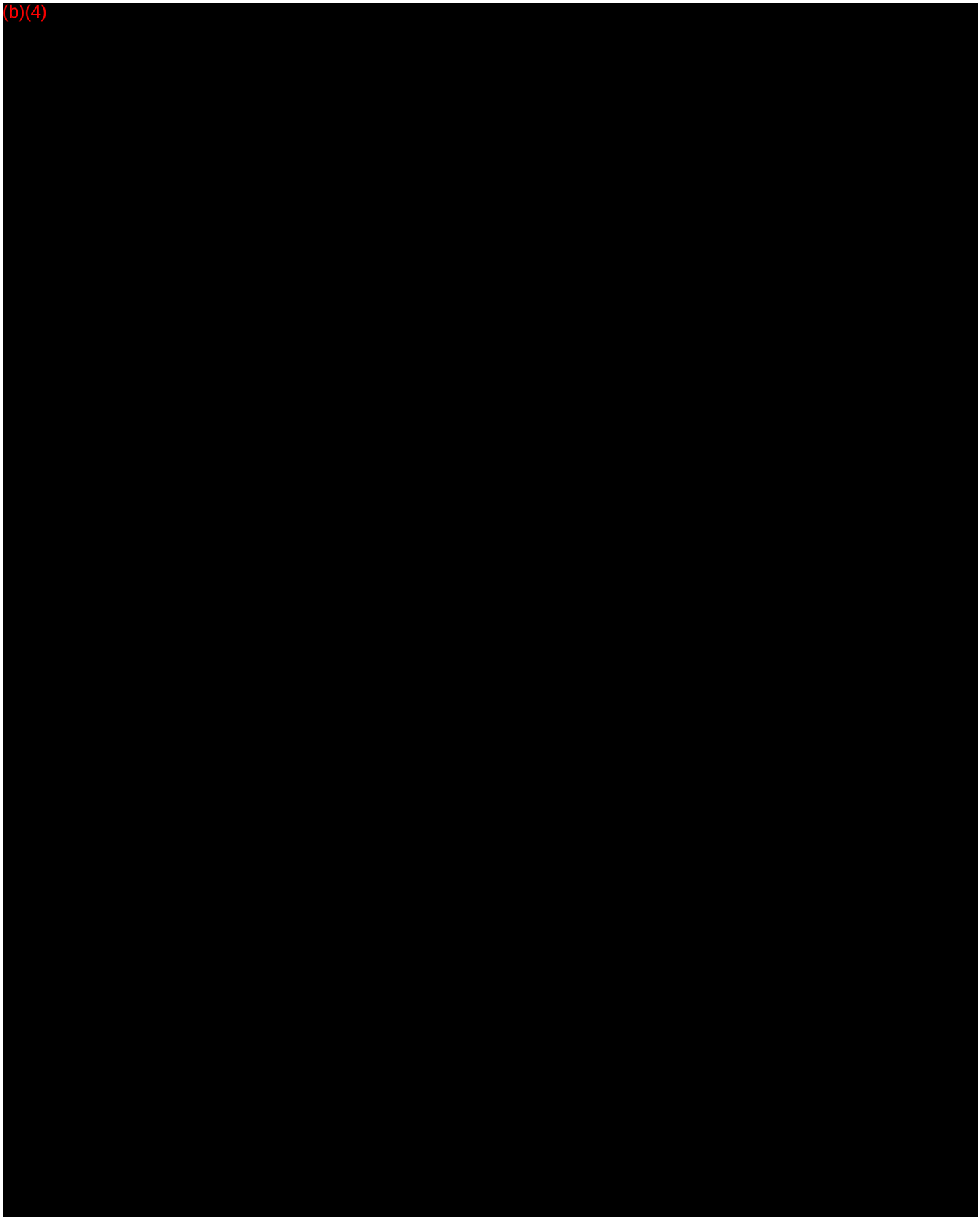

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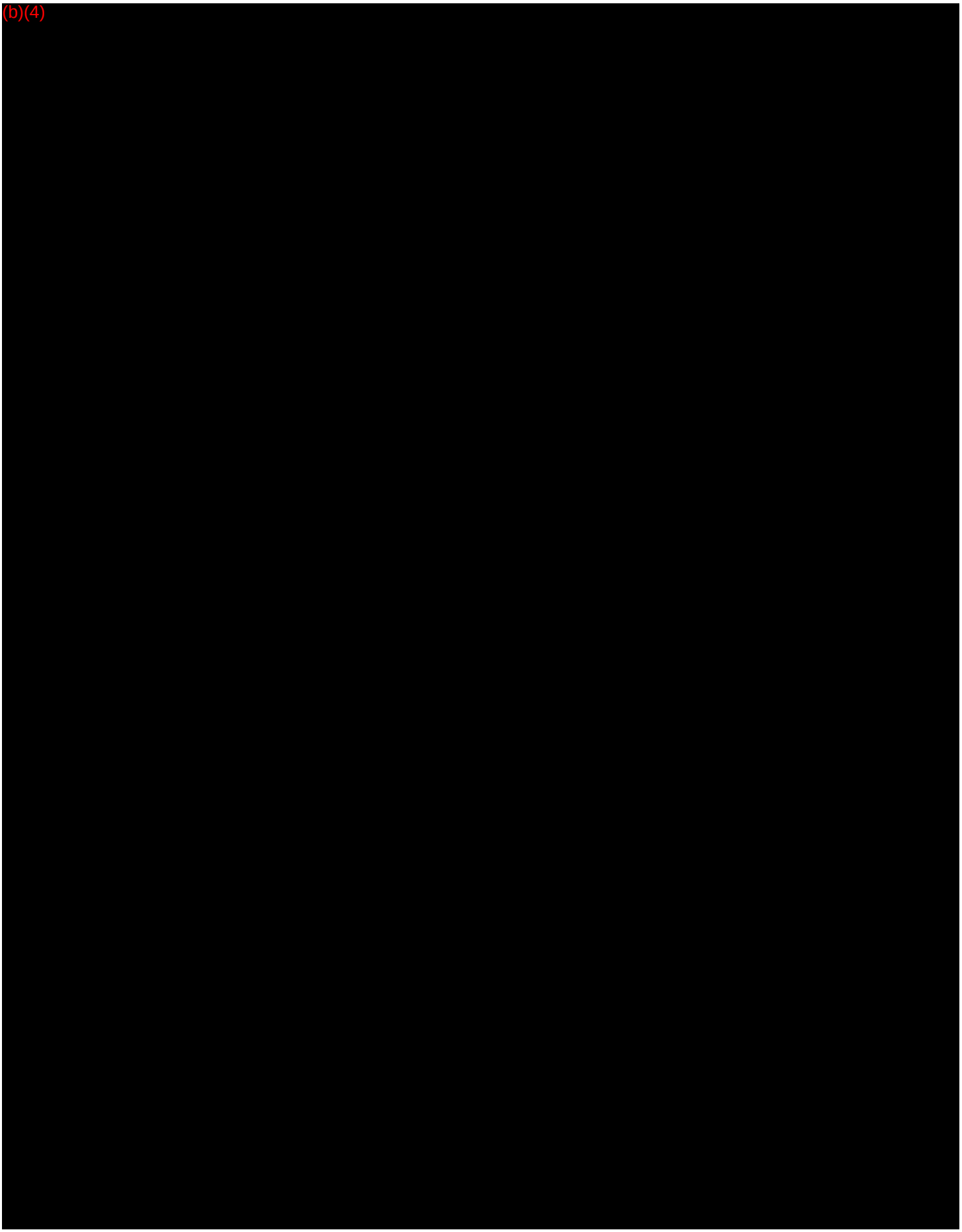
3shape

Validation Result – (b)(4)

(b)(4)



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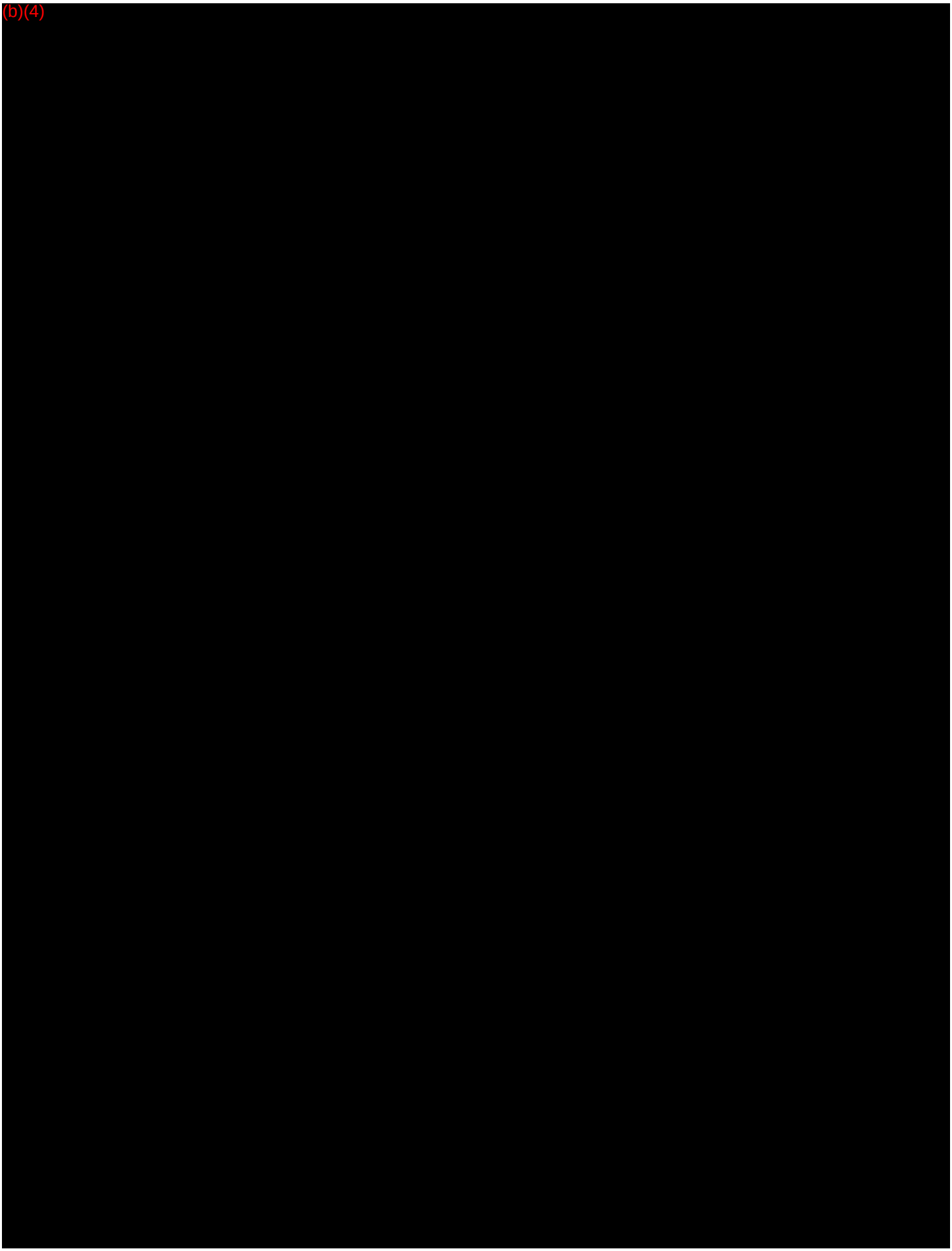

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Requirement Specification – (b)(4)

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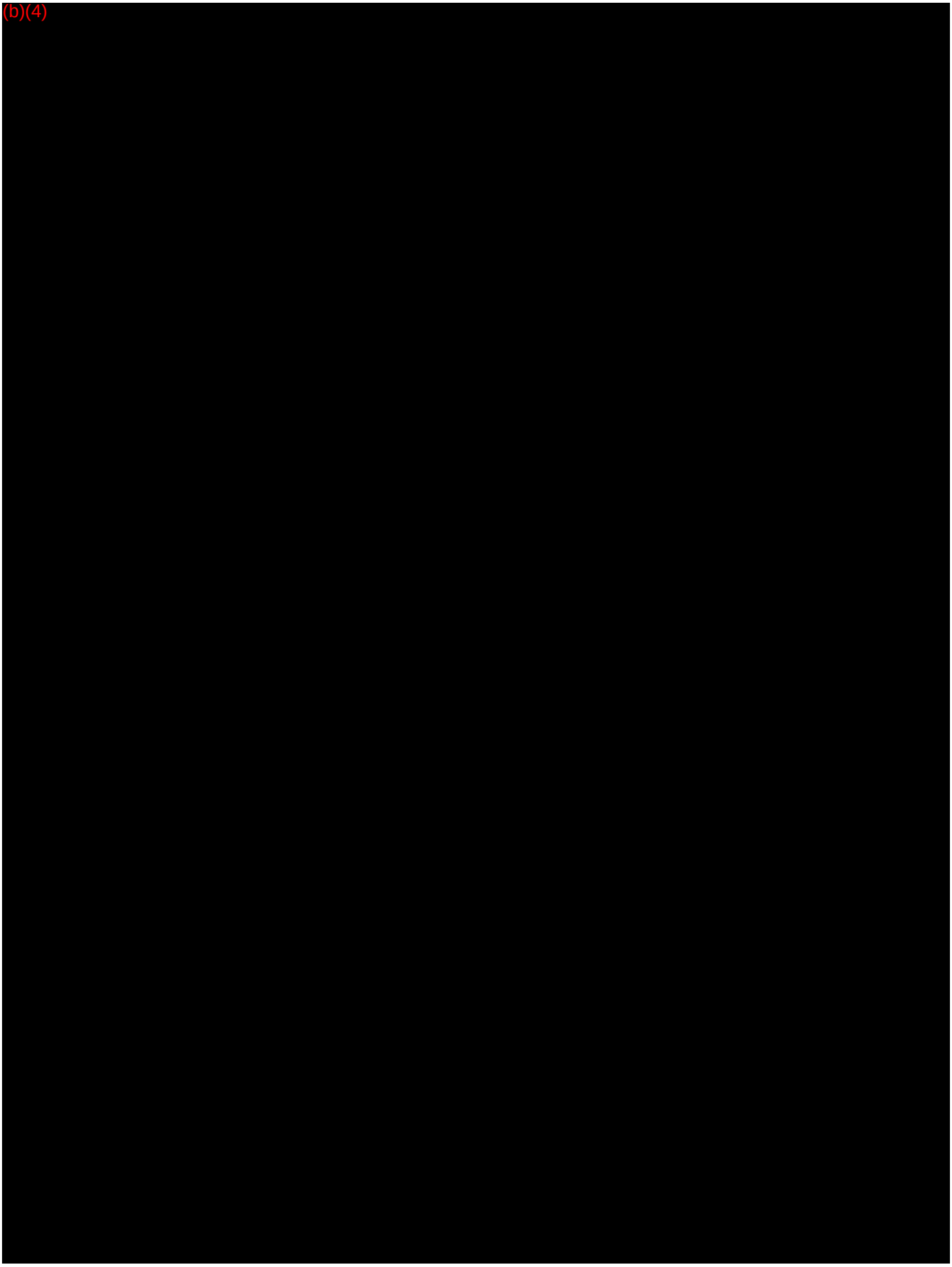

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3shape

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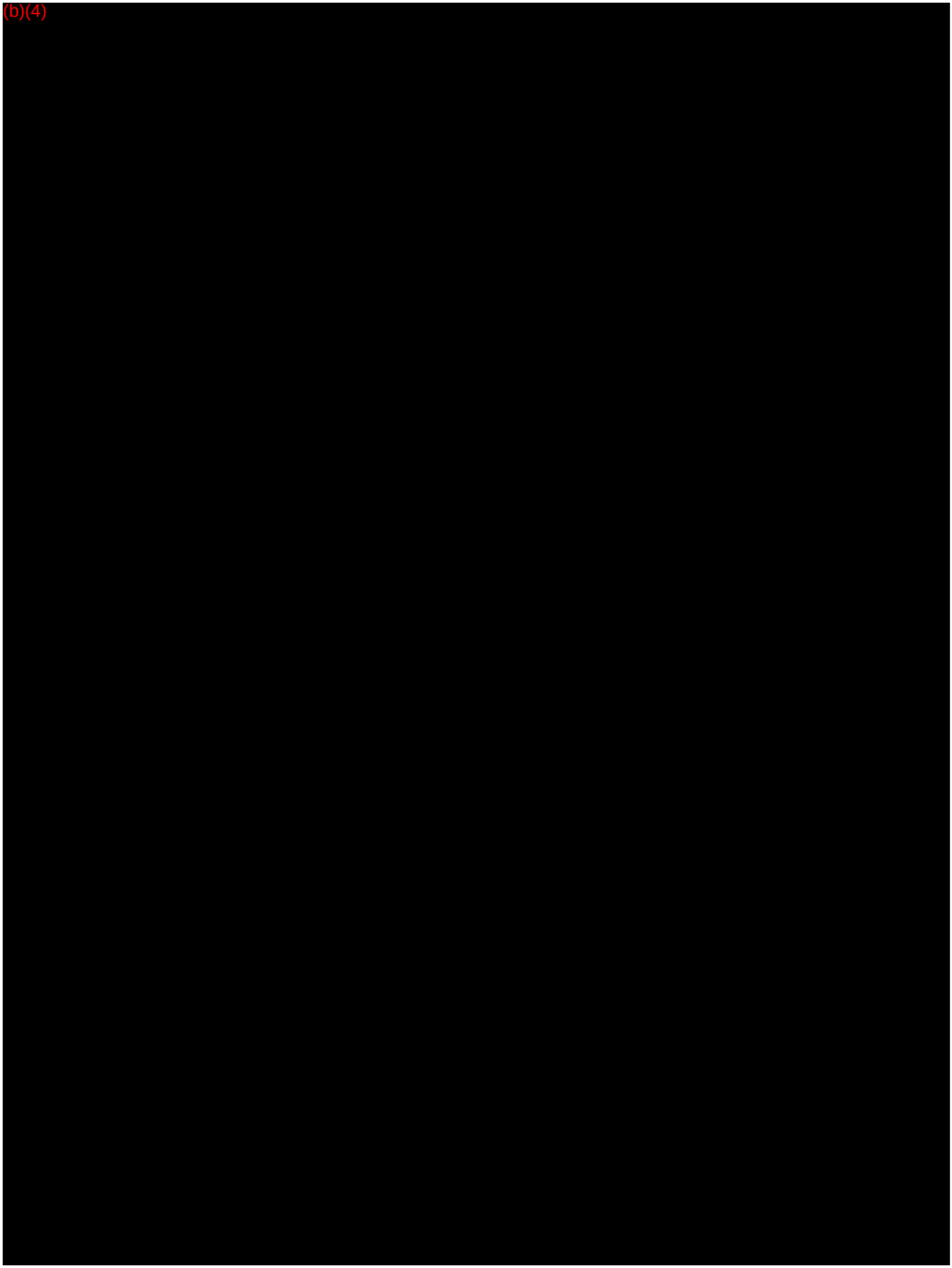

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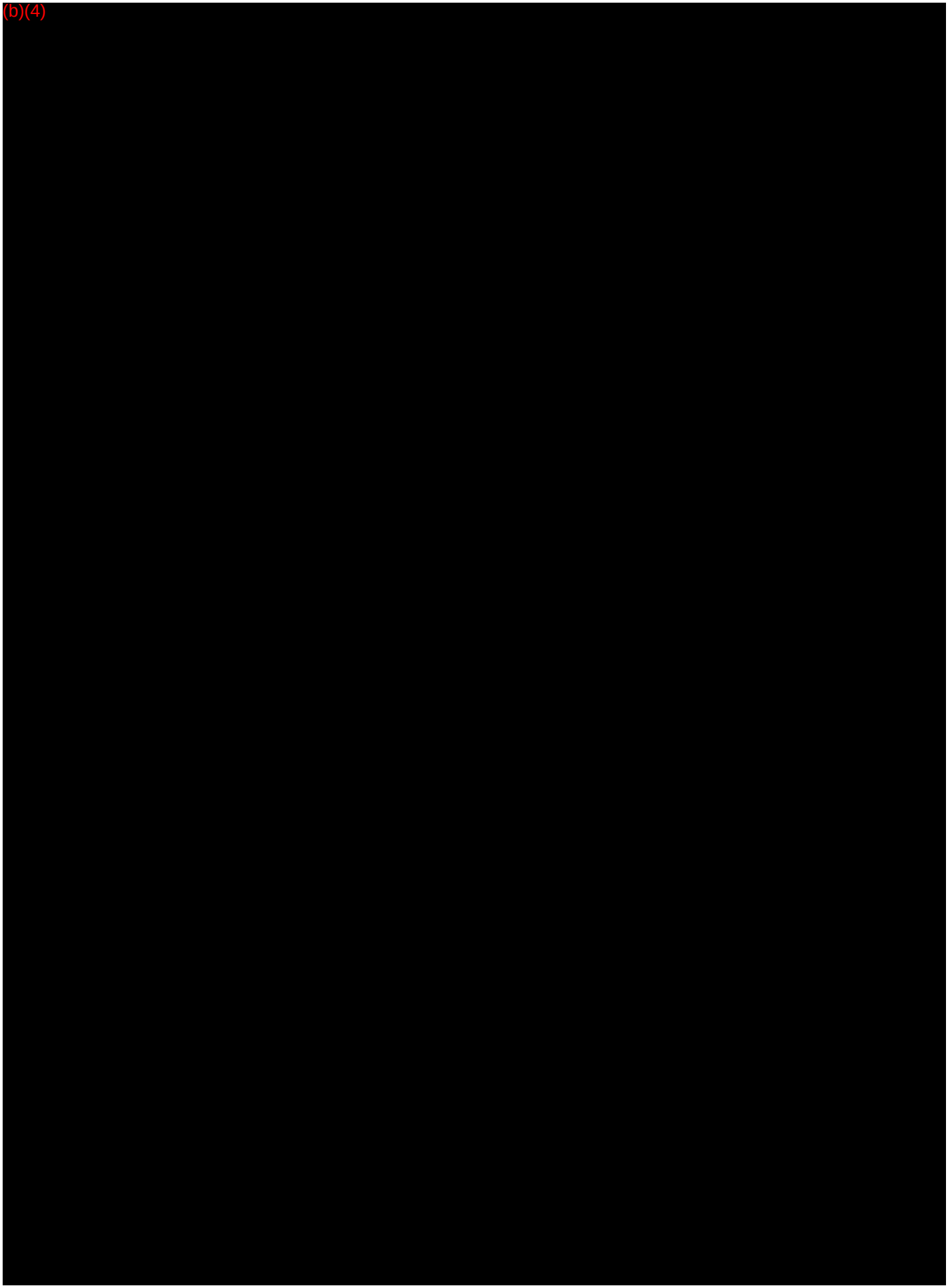

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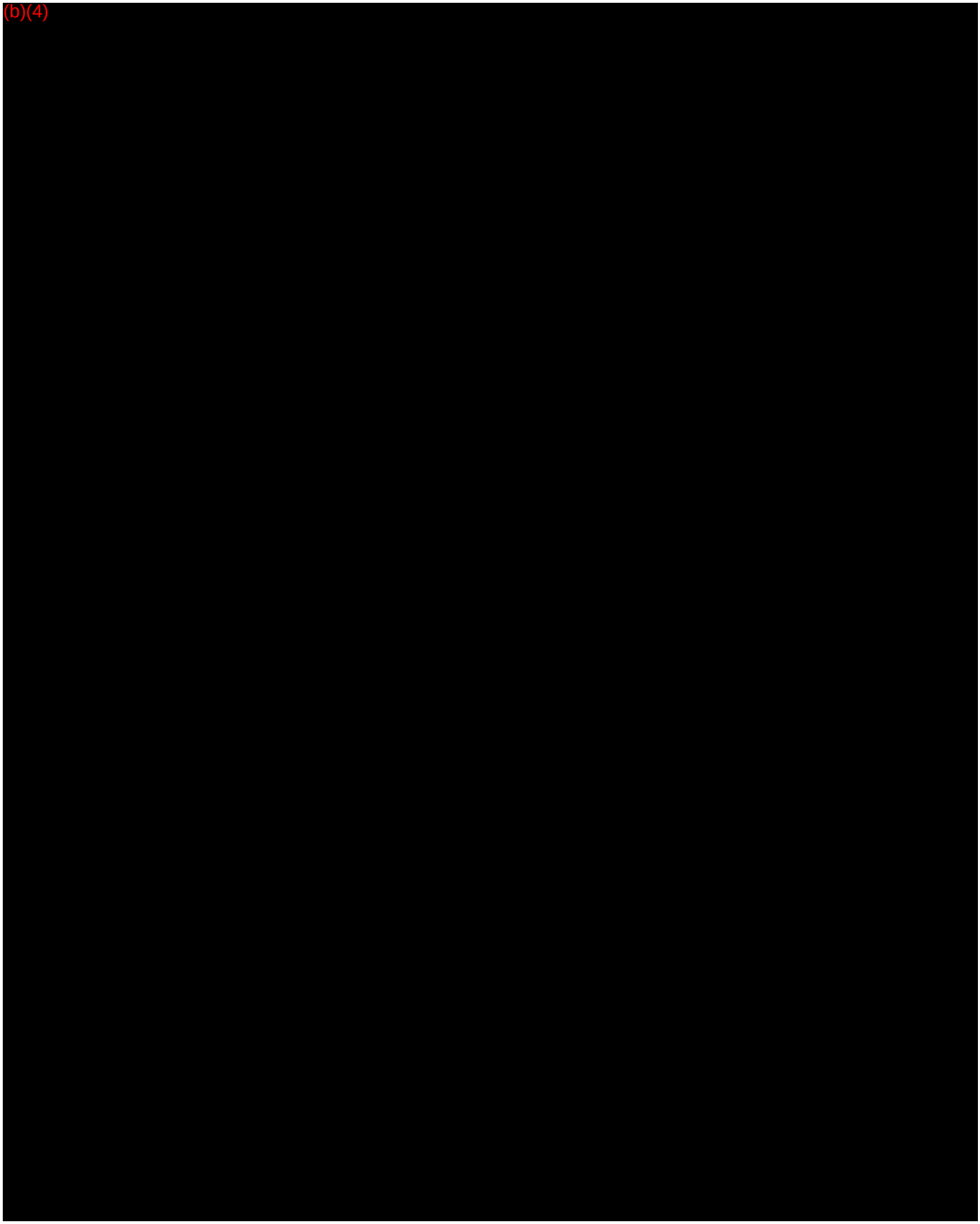

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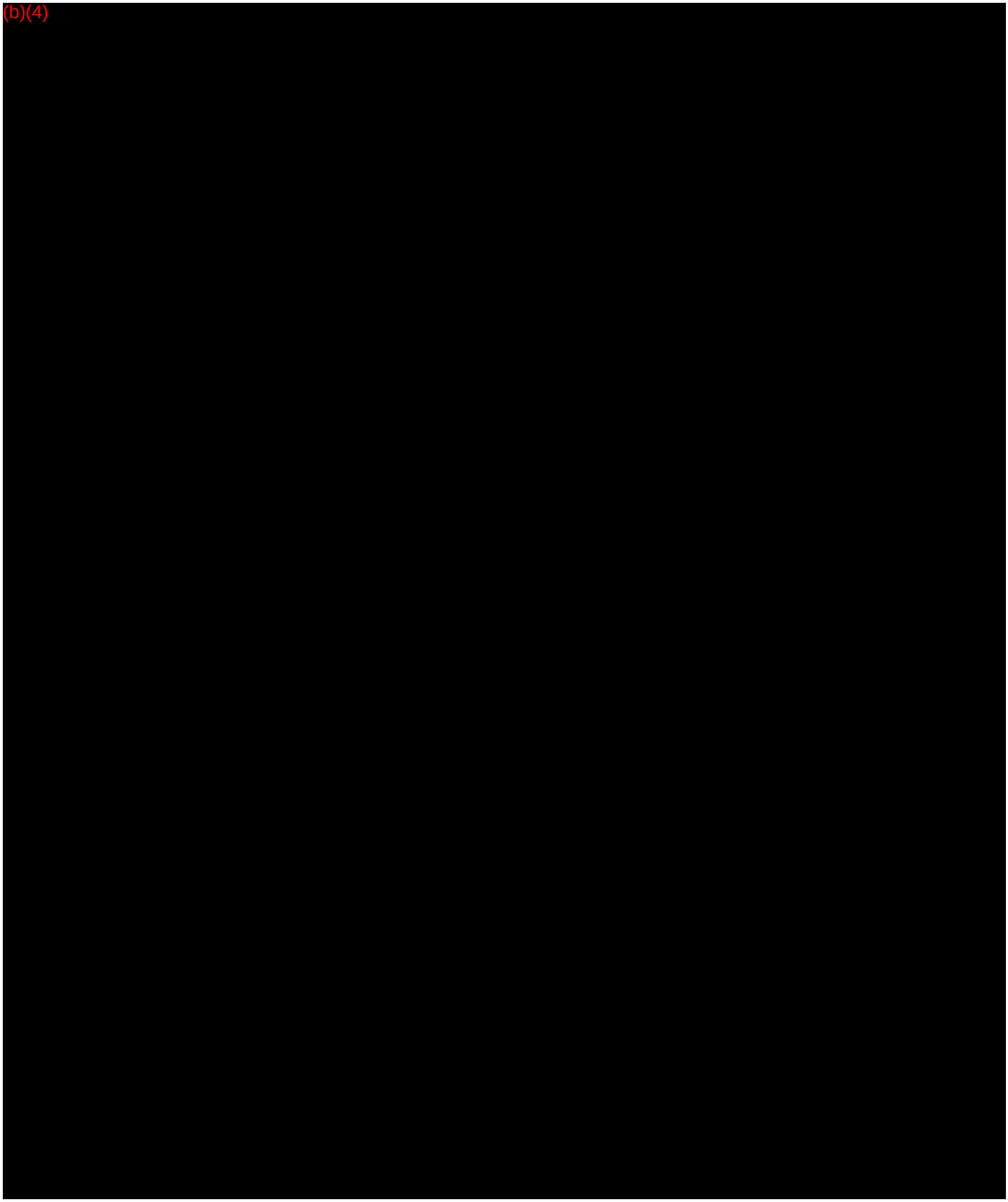

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3shape

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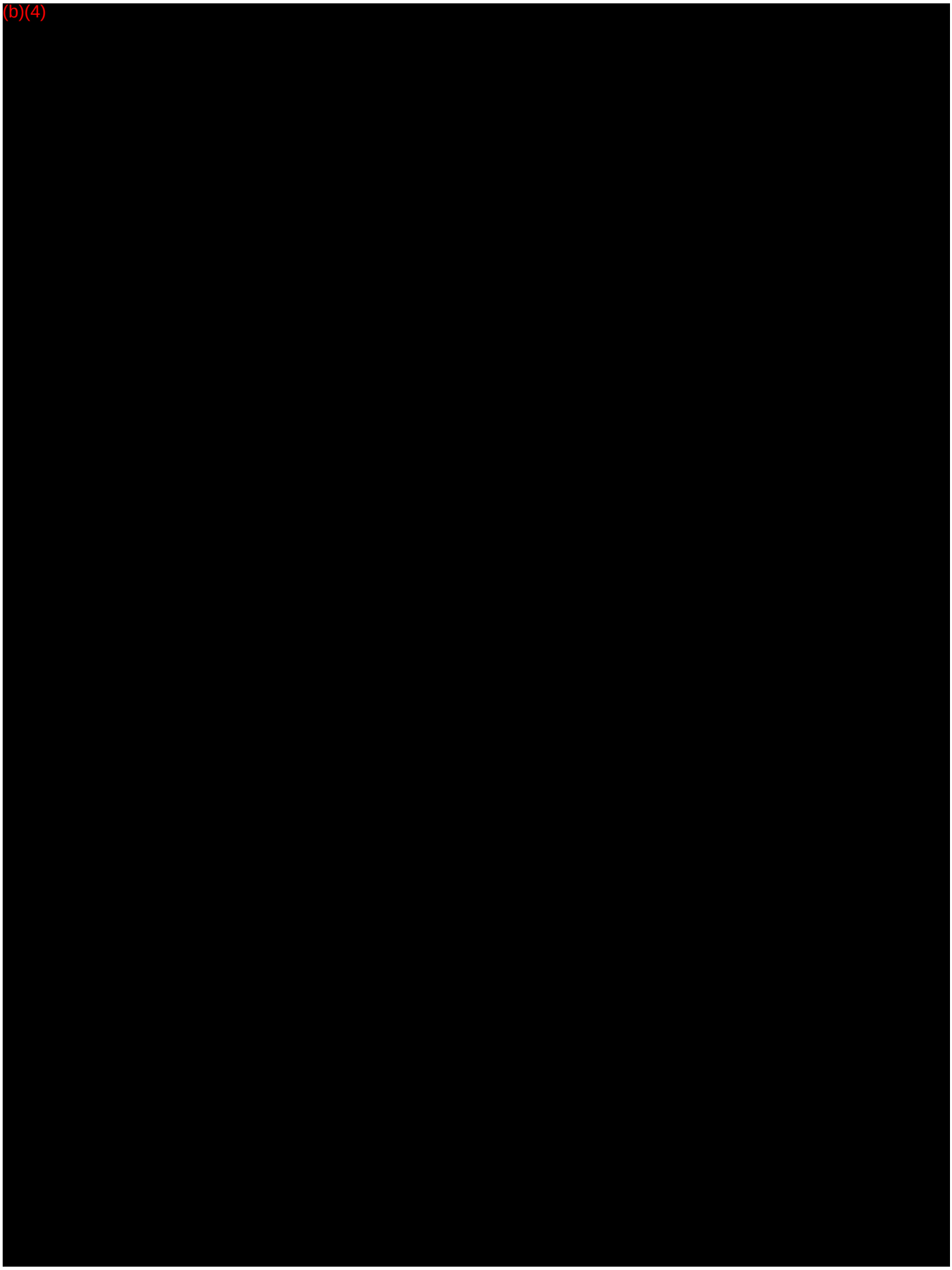

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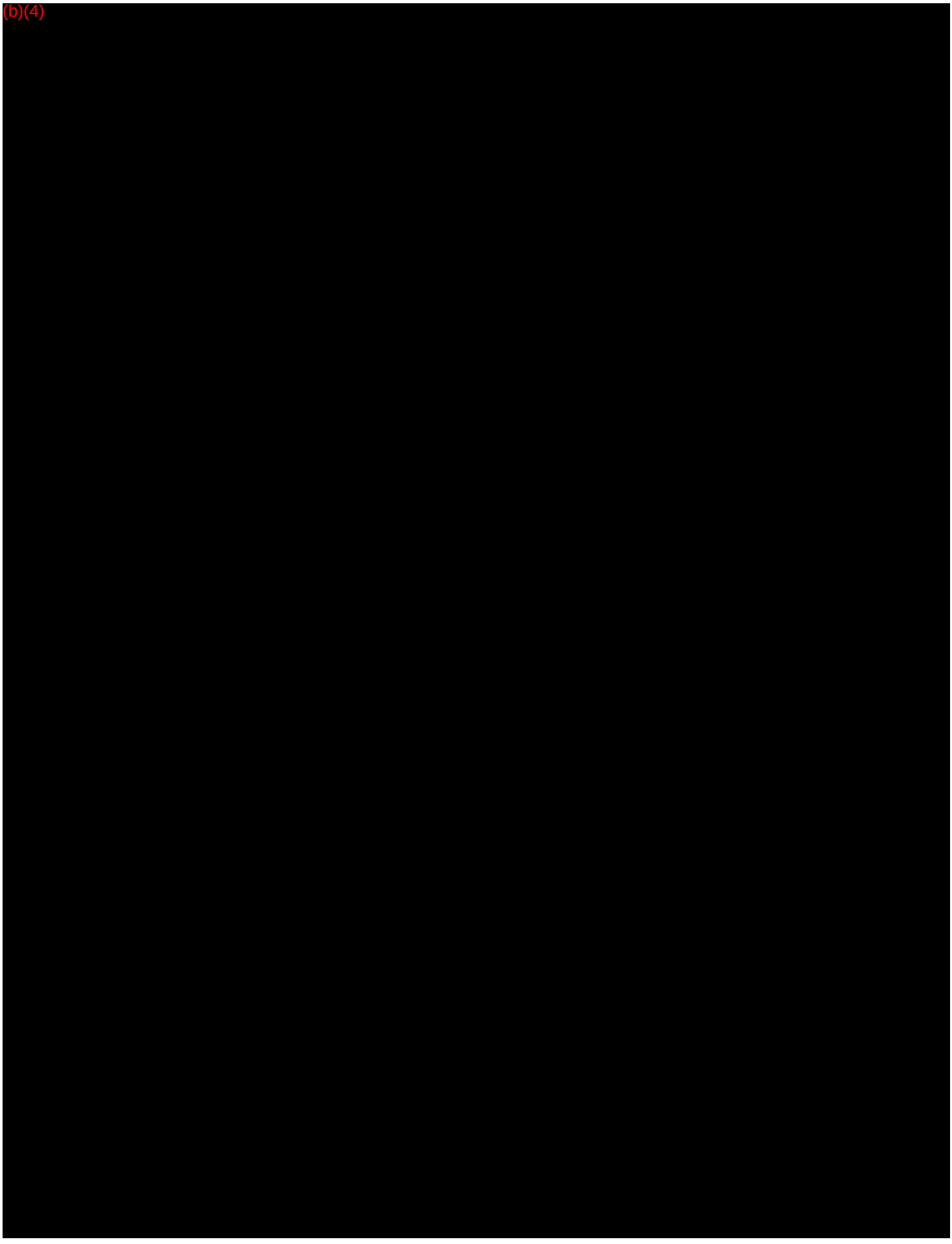

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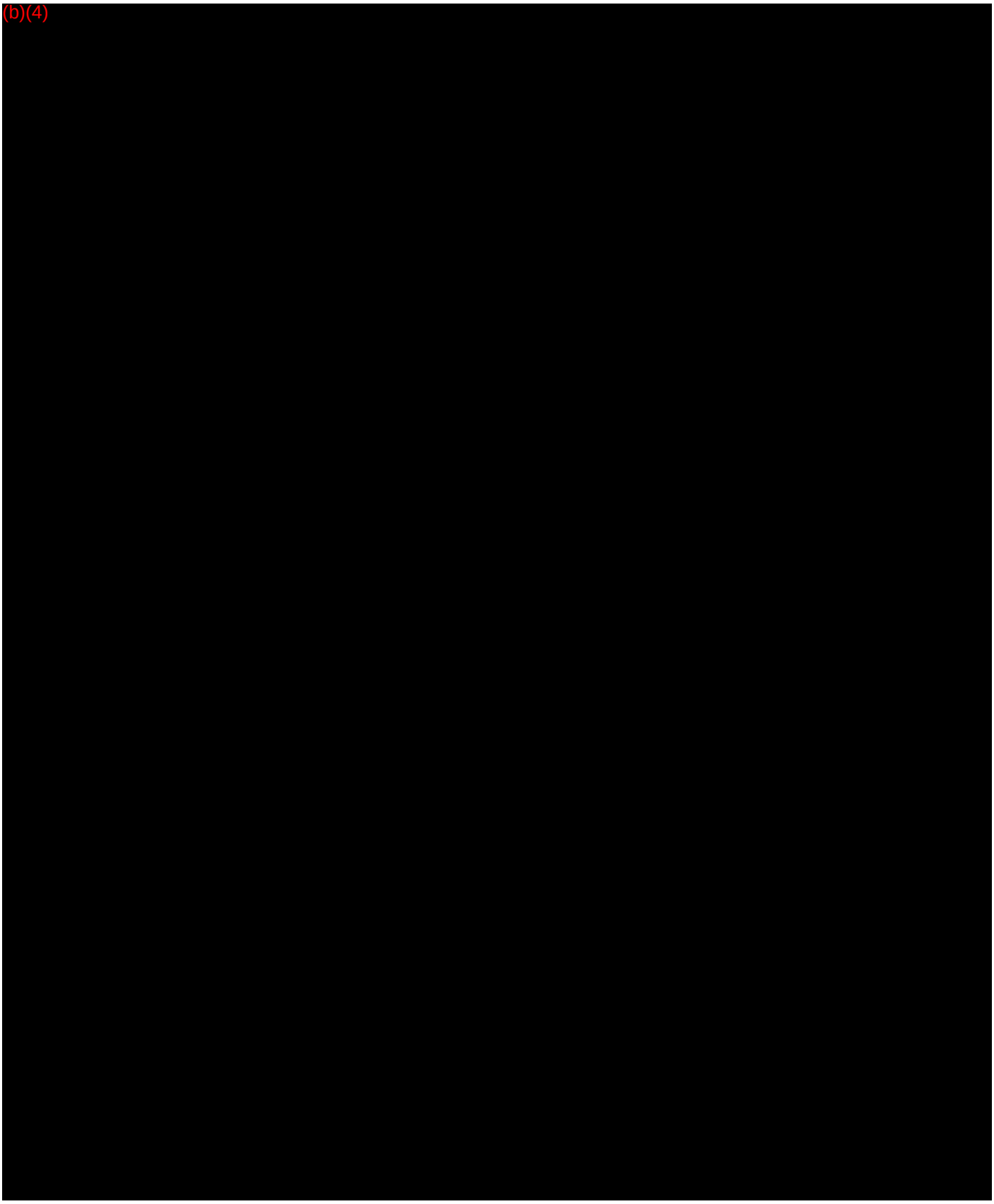

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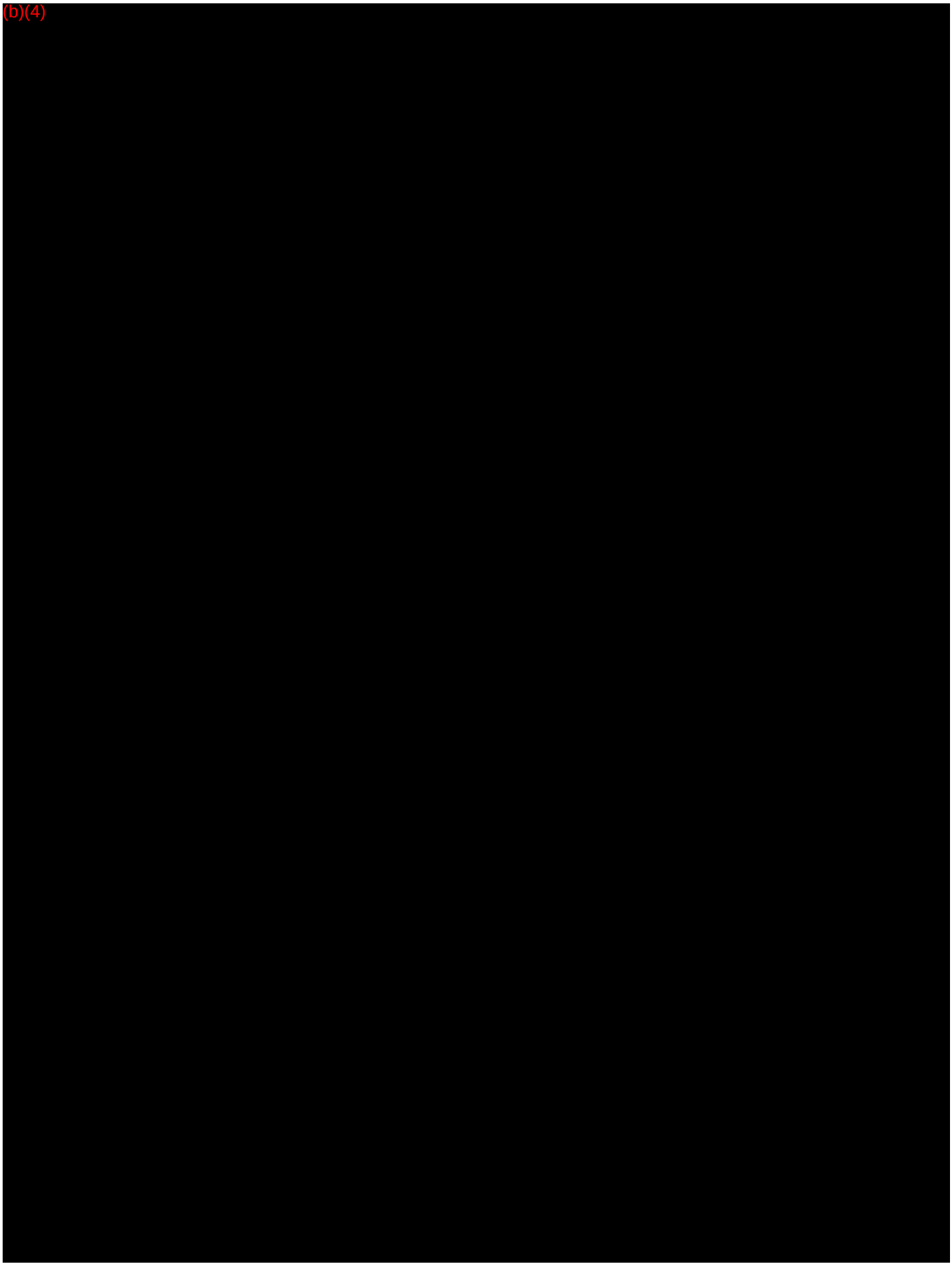

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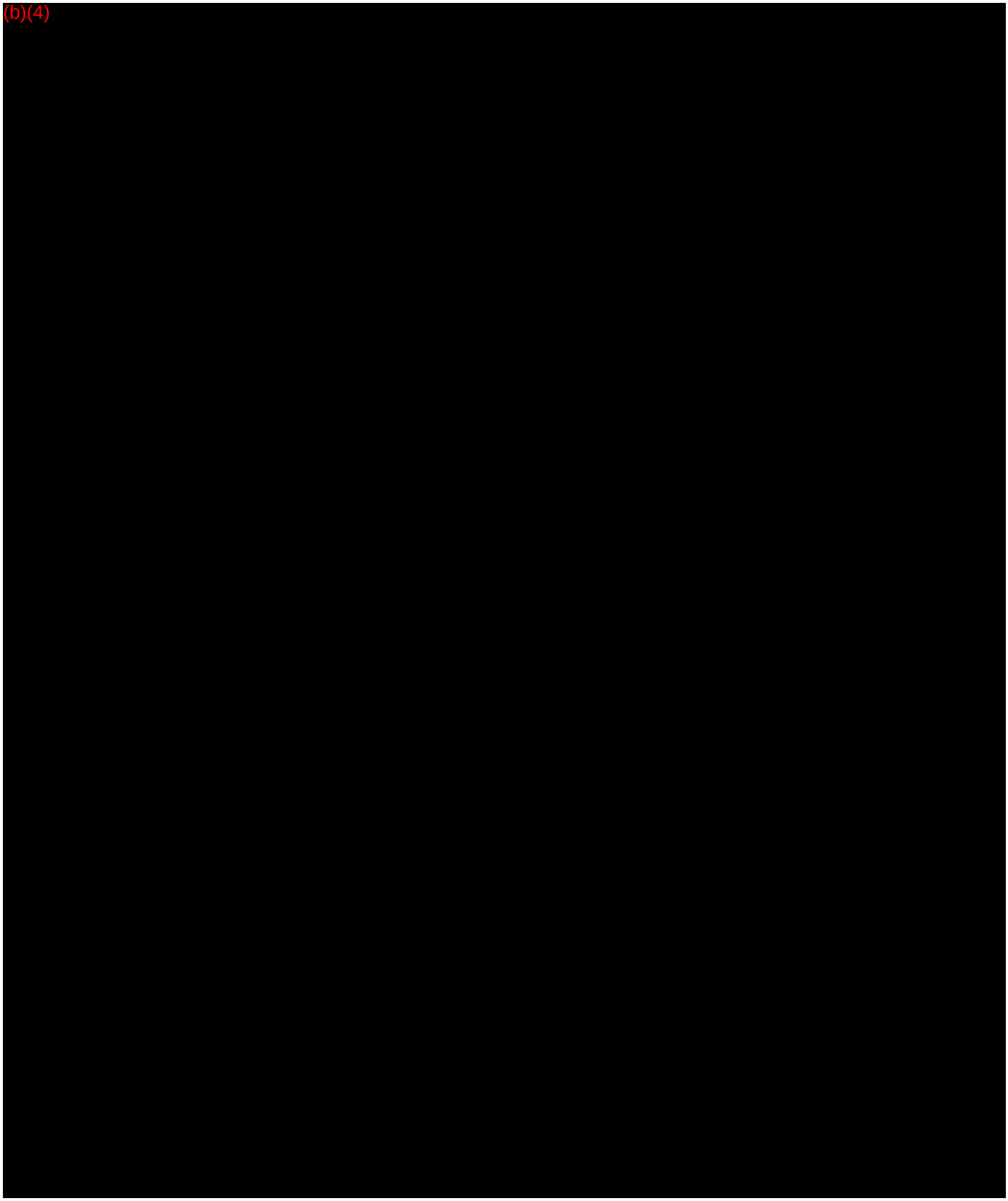

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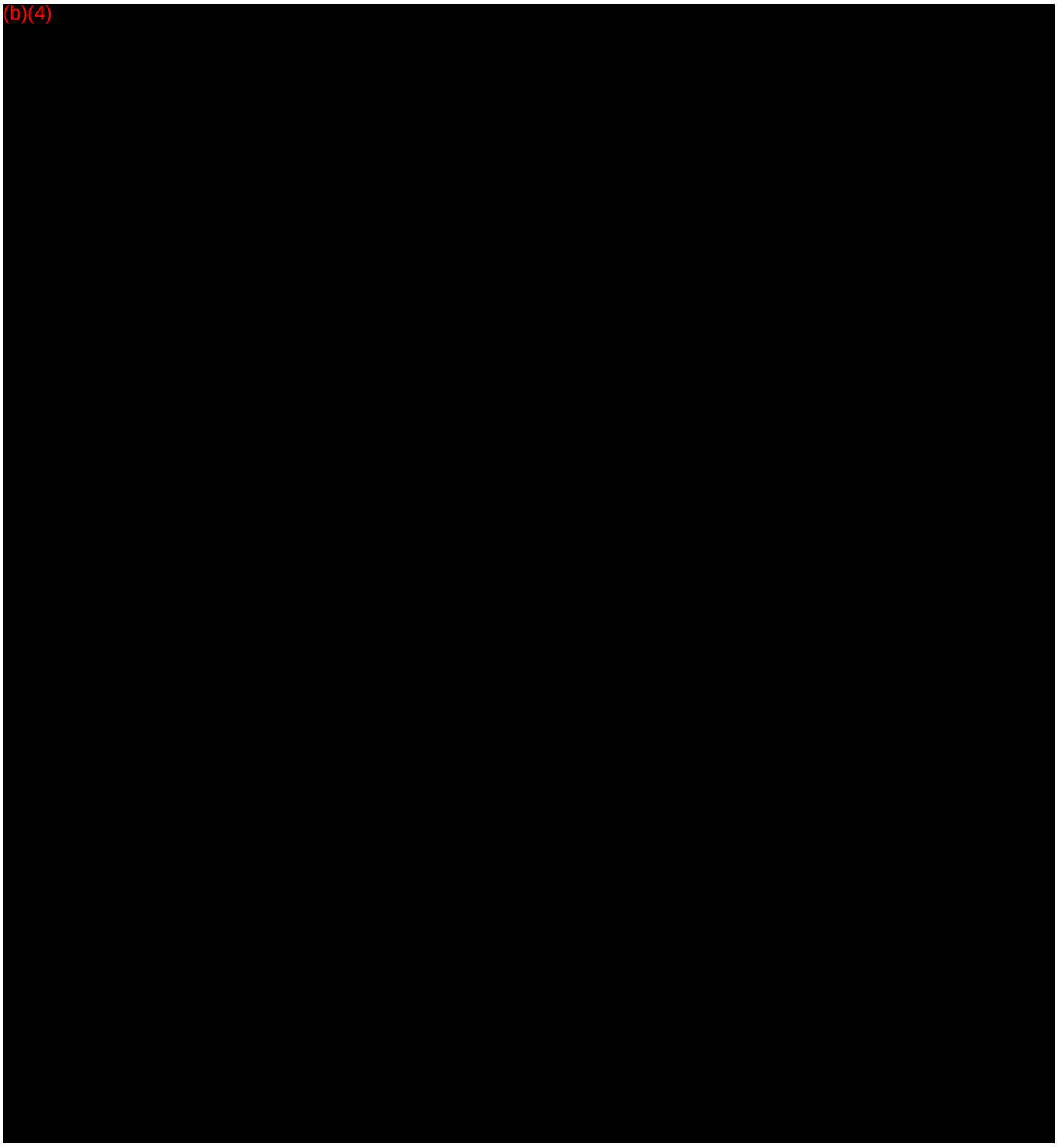

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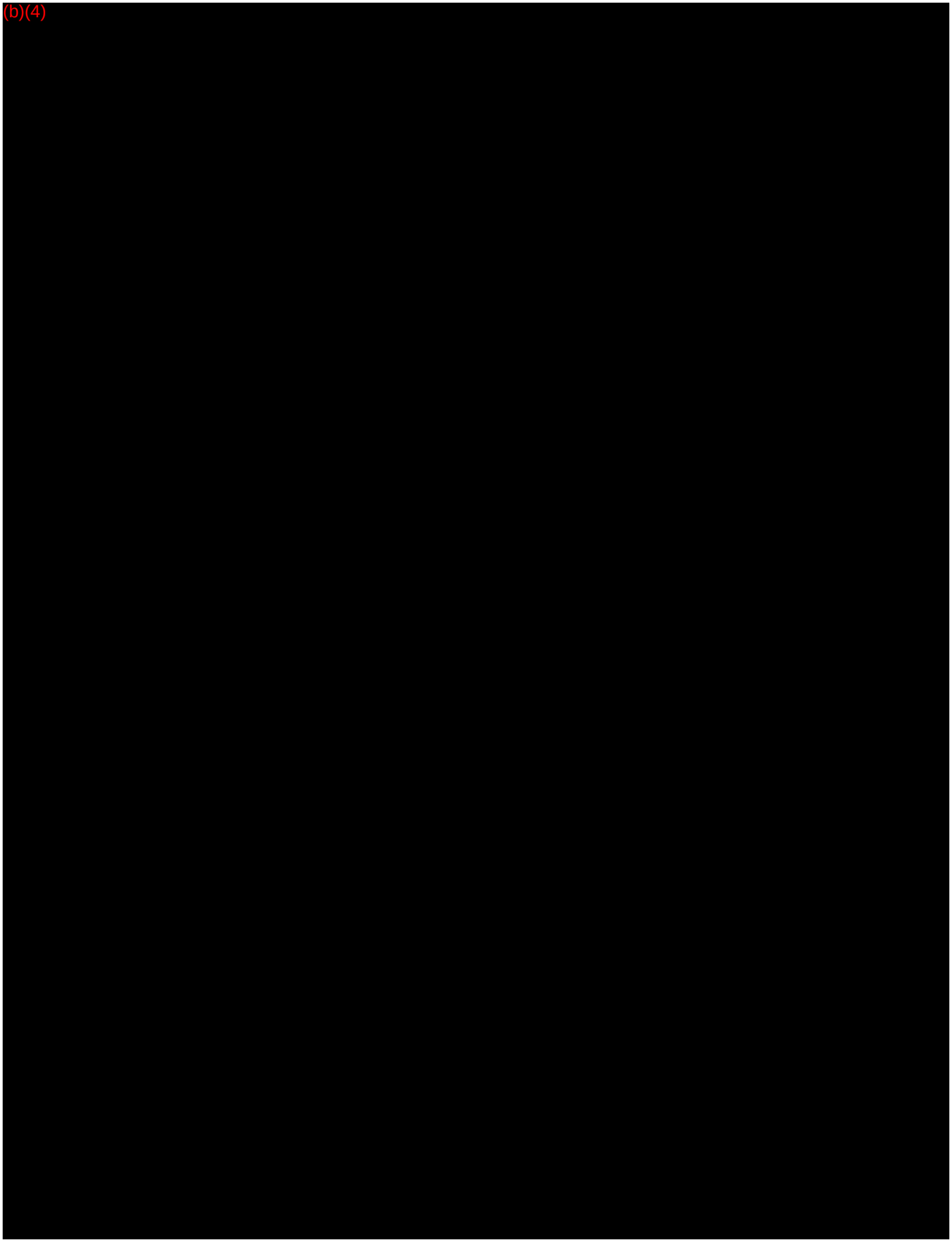

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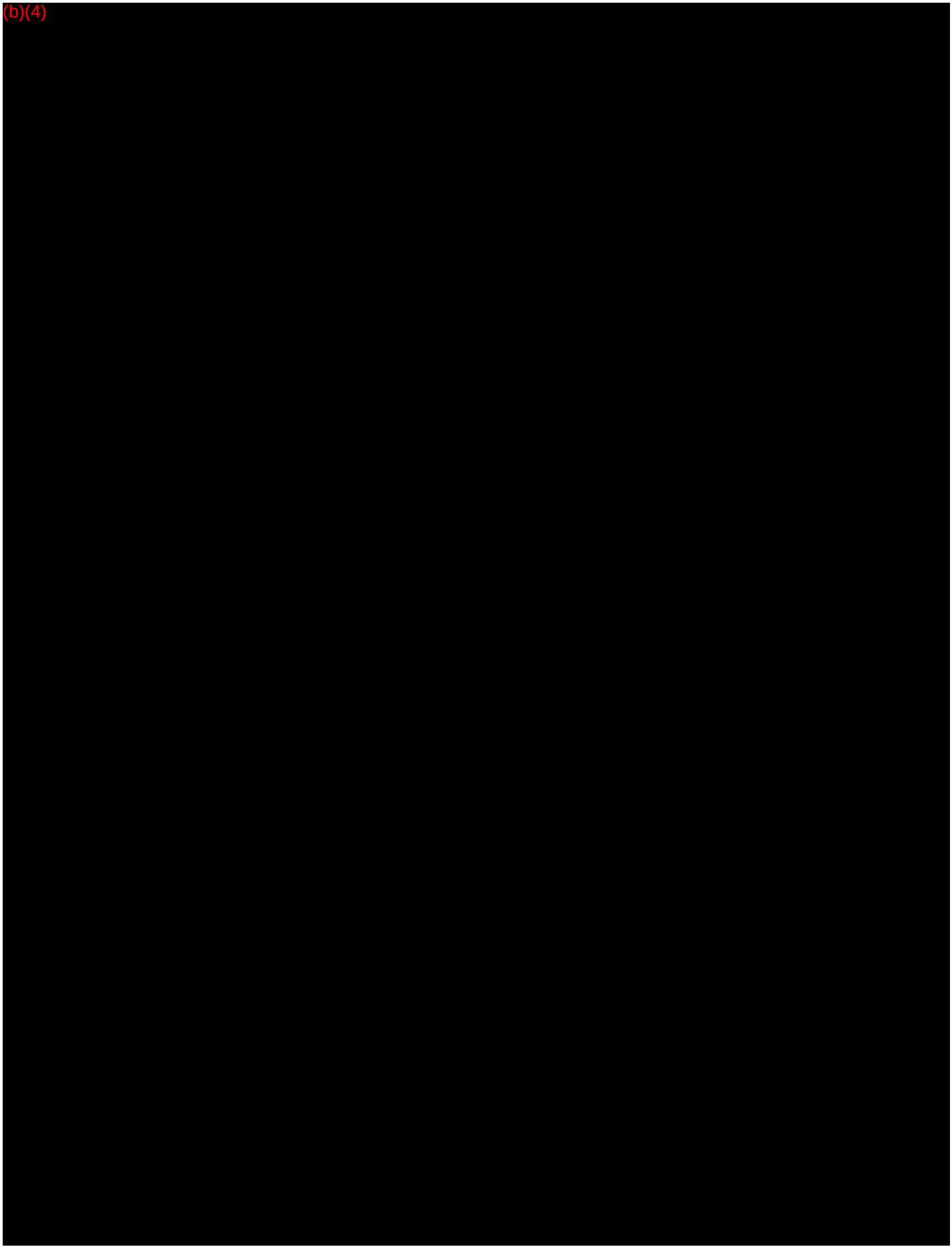

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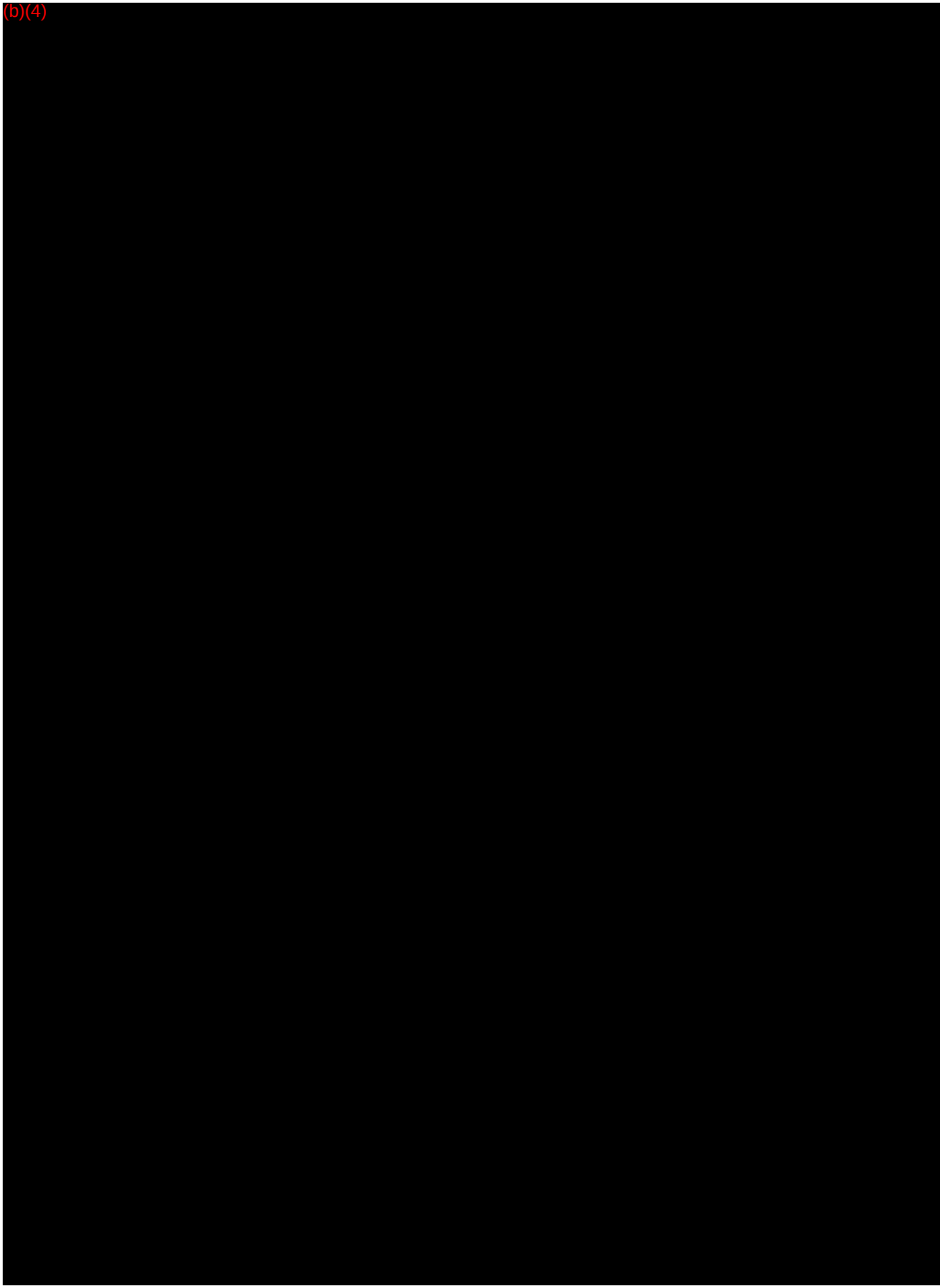

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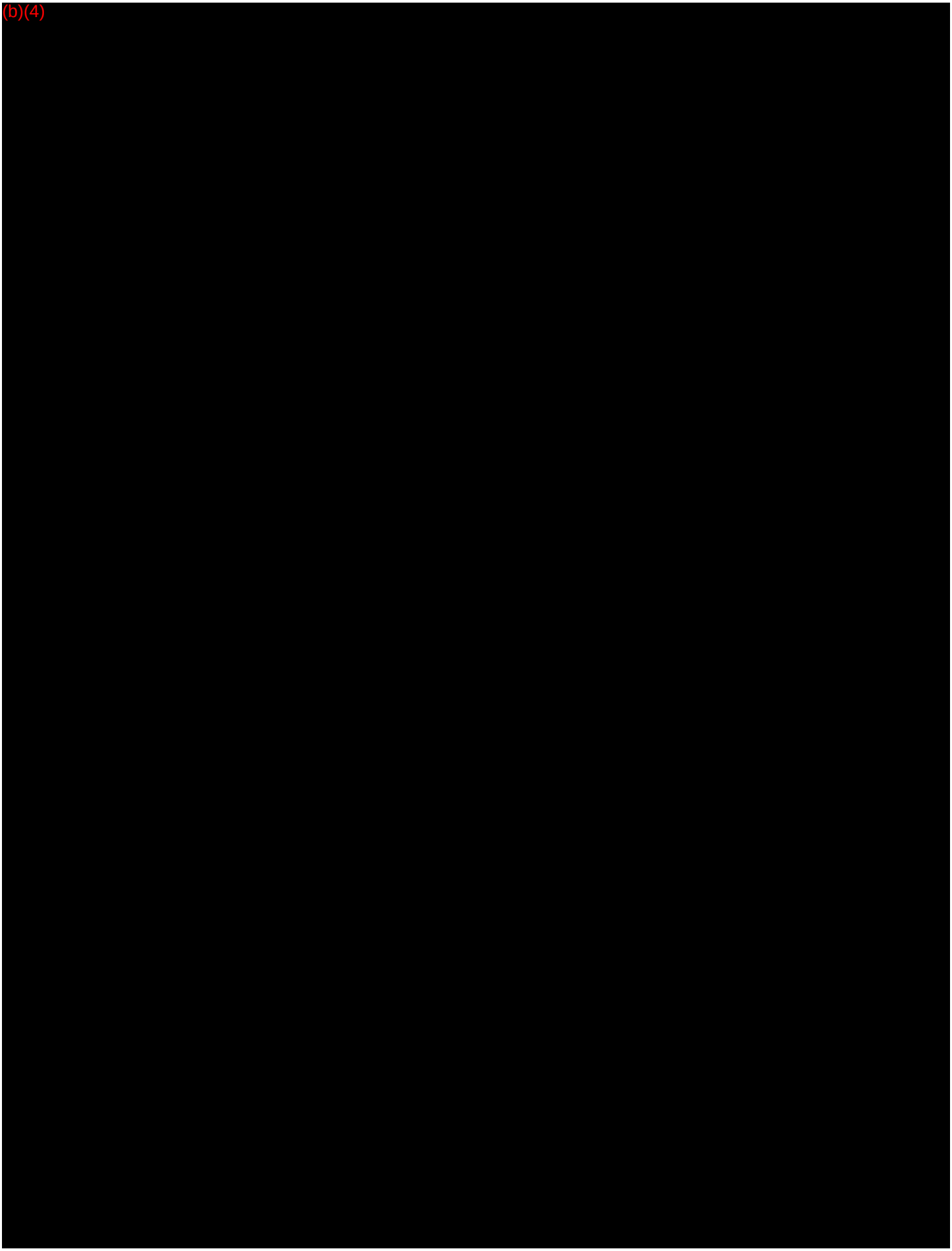

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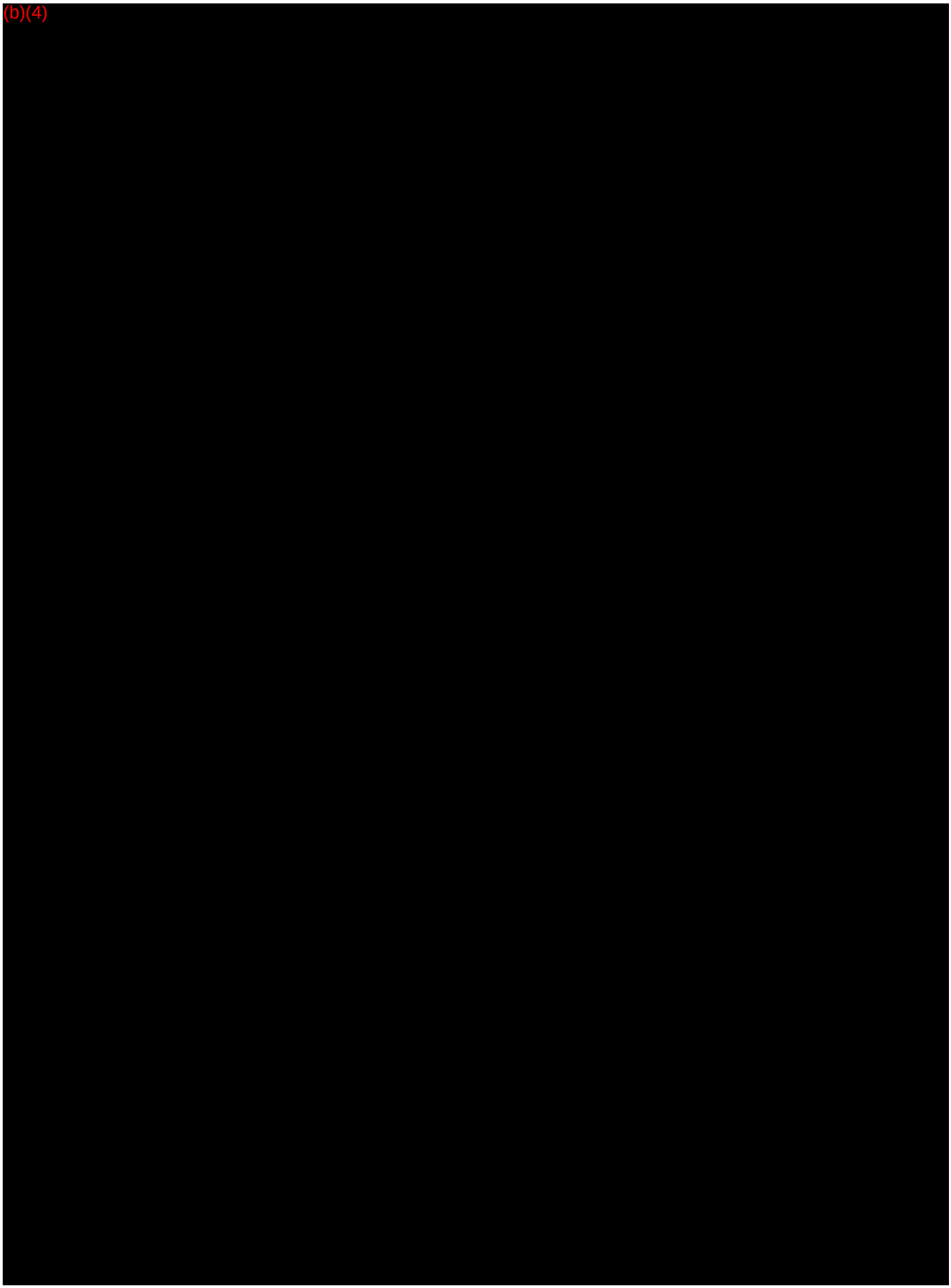

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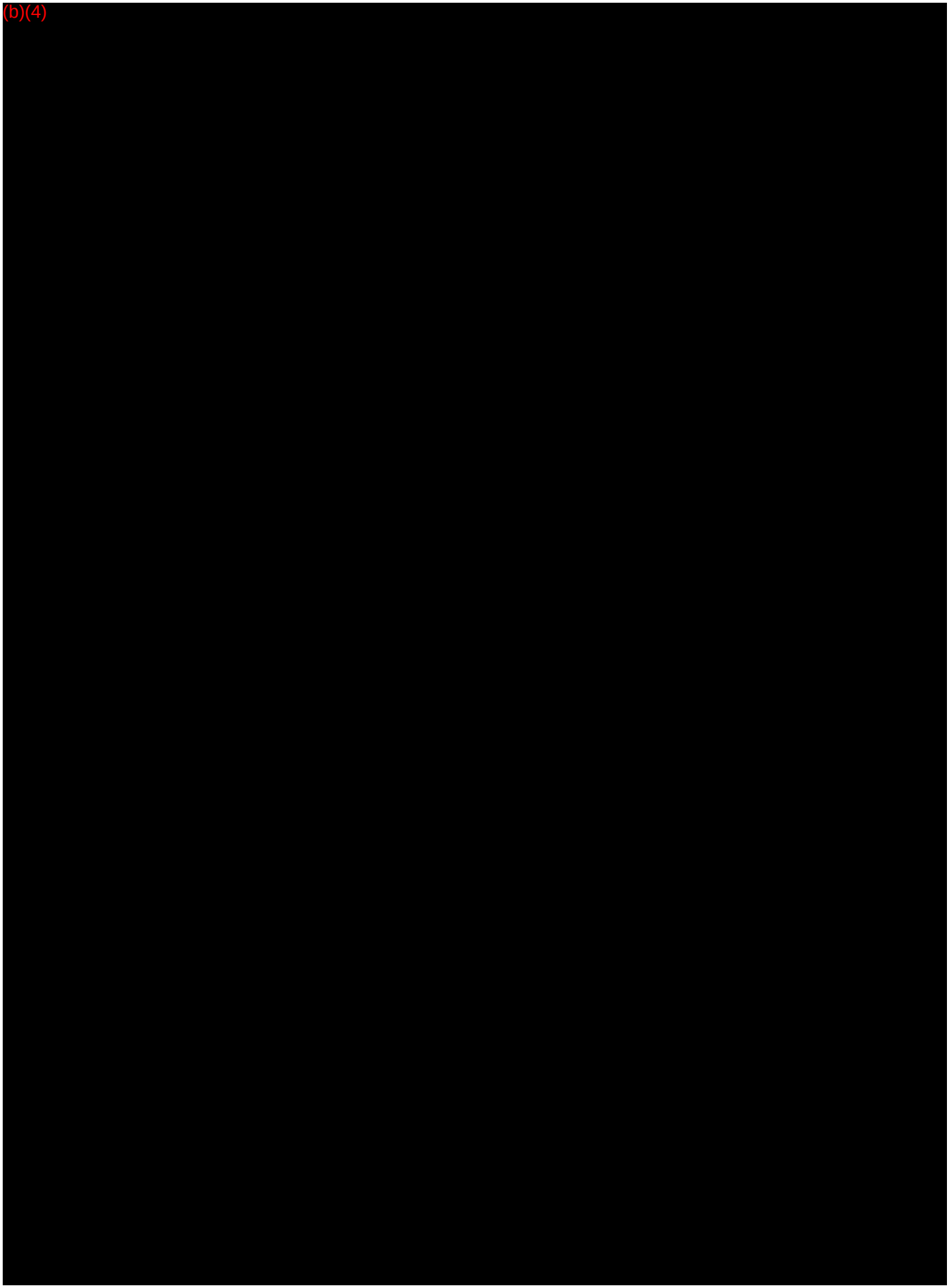

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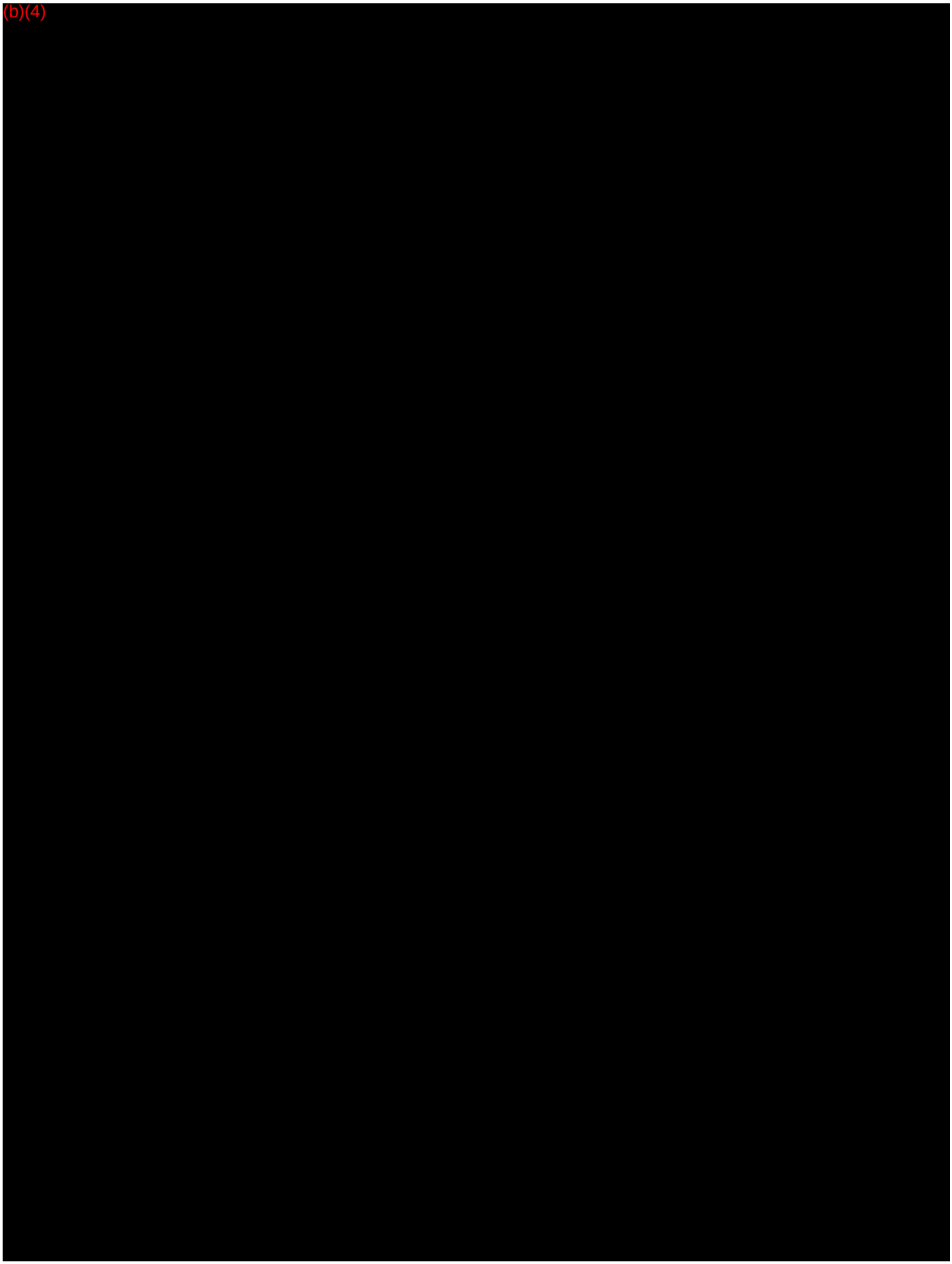

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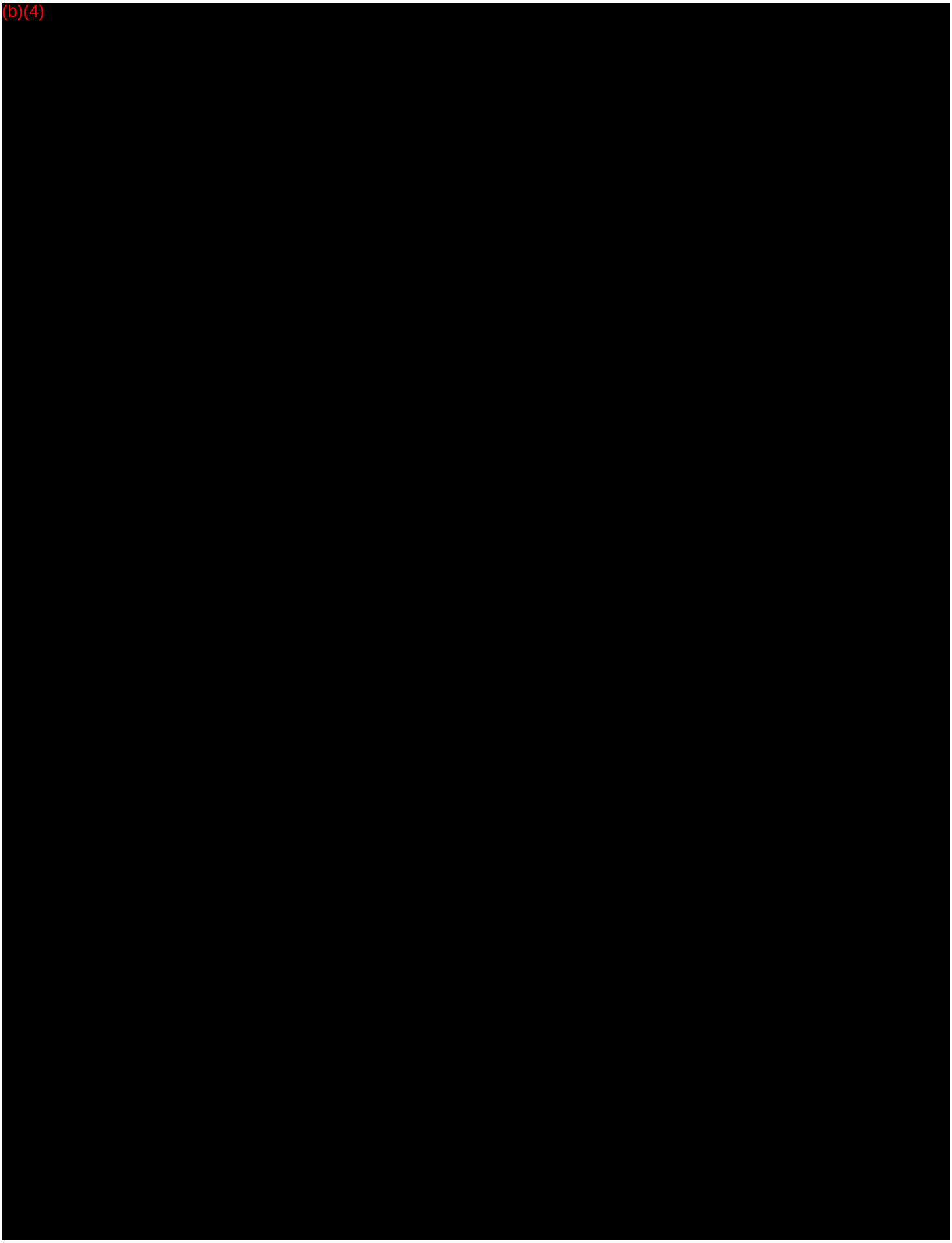

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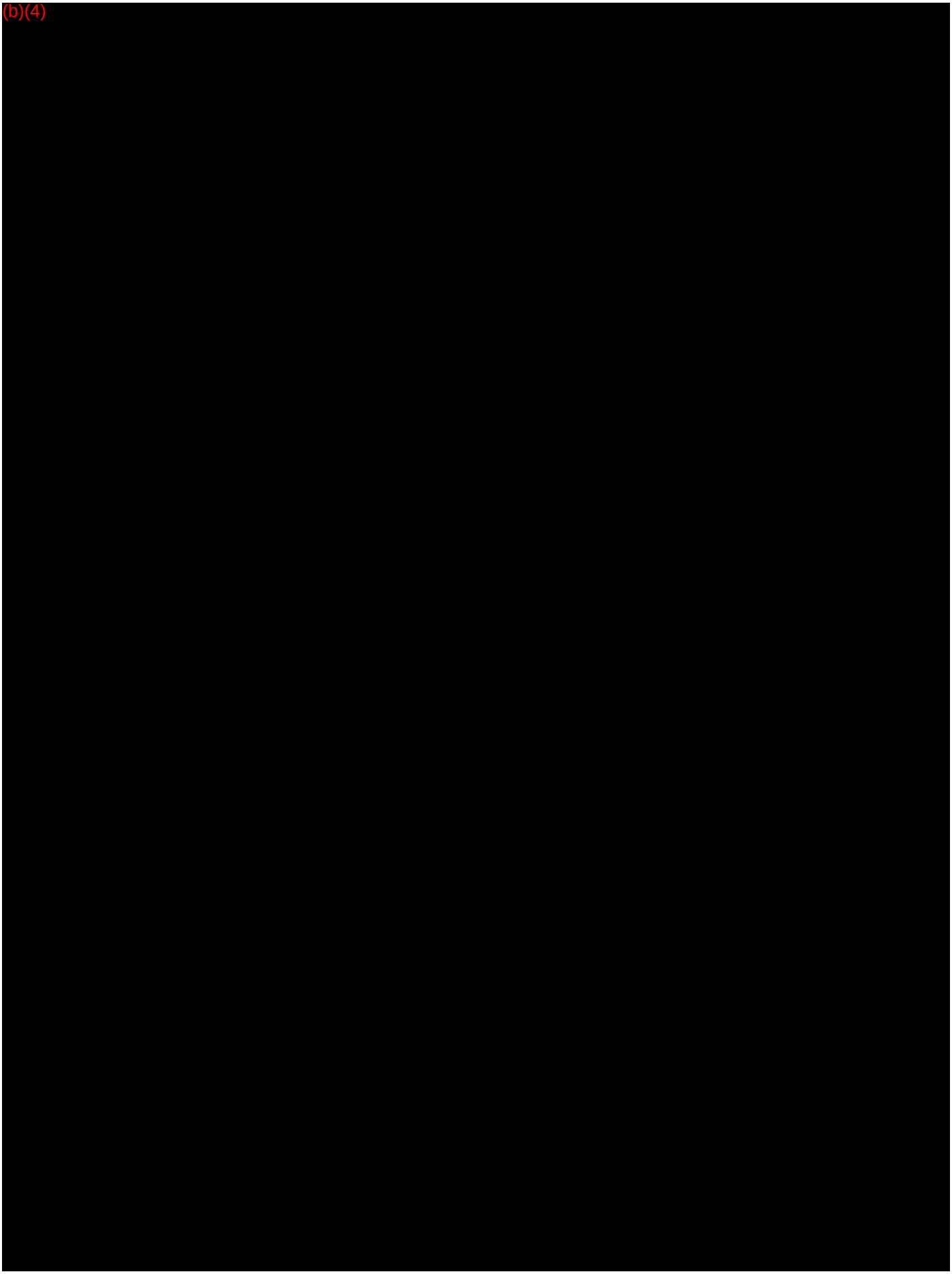

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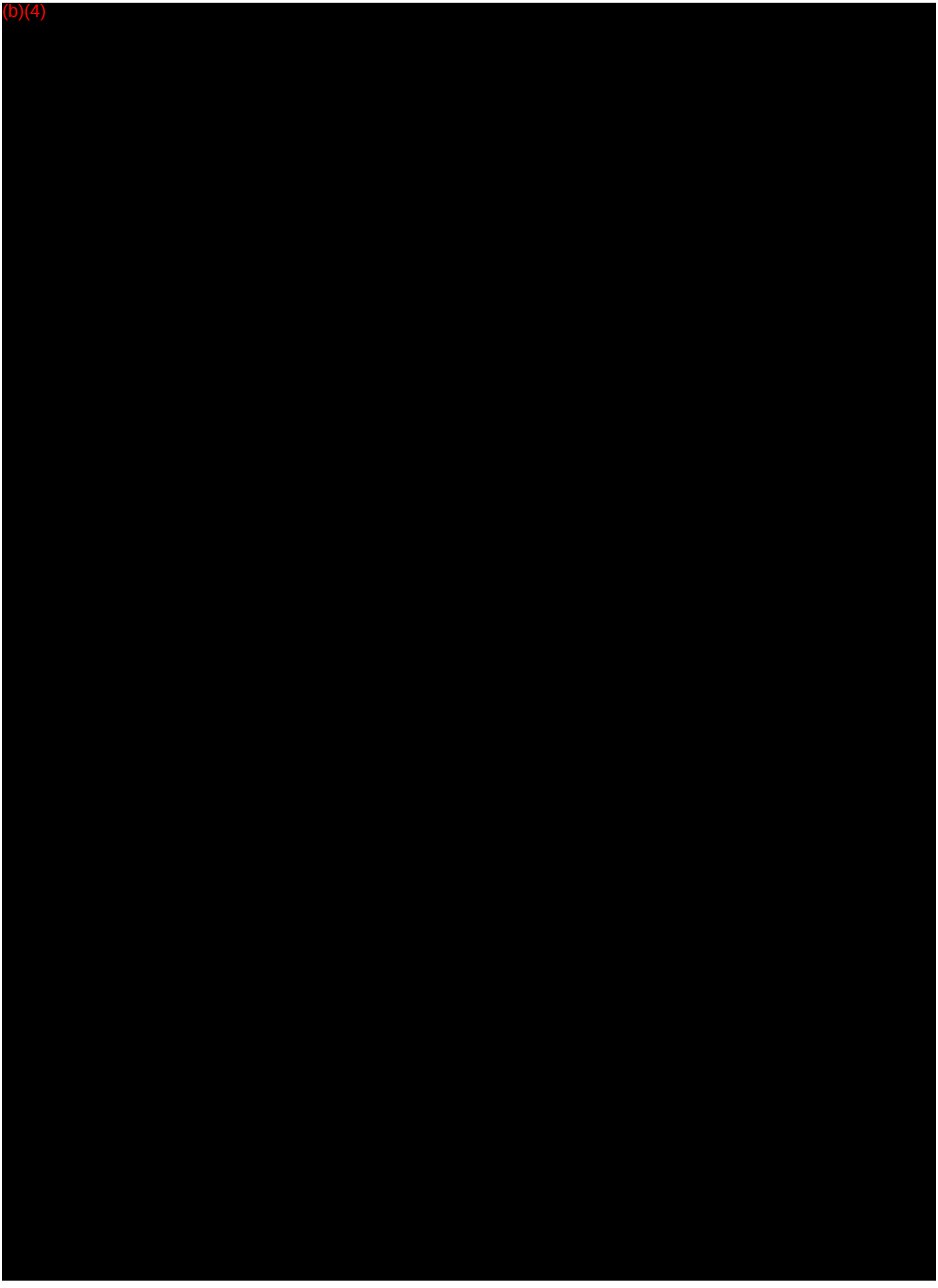

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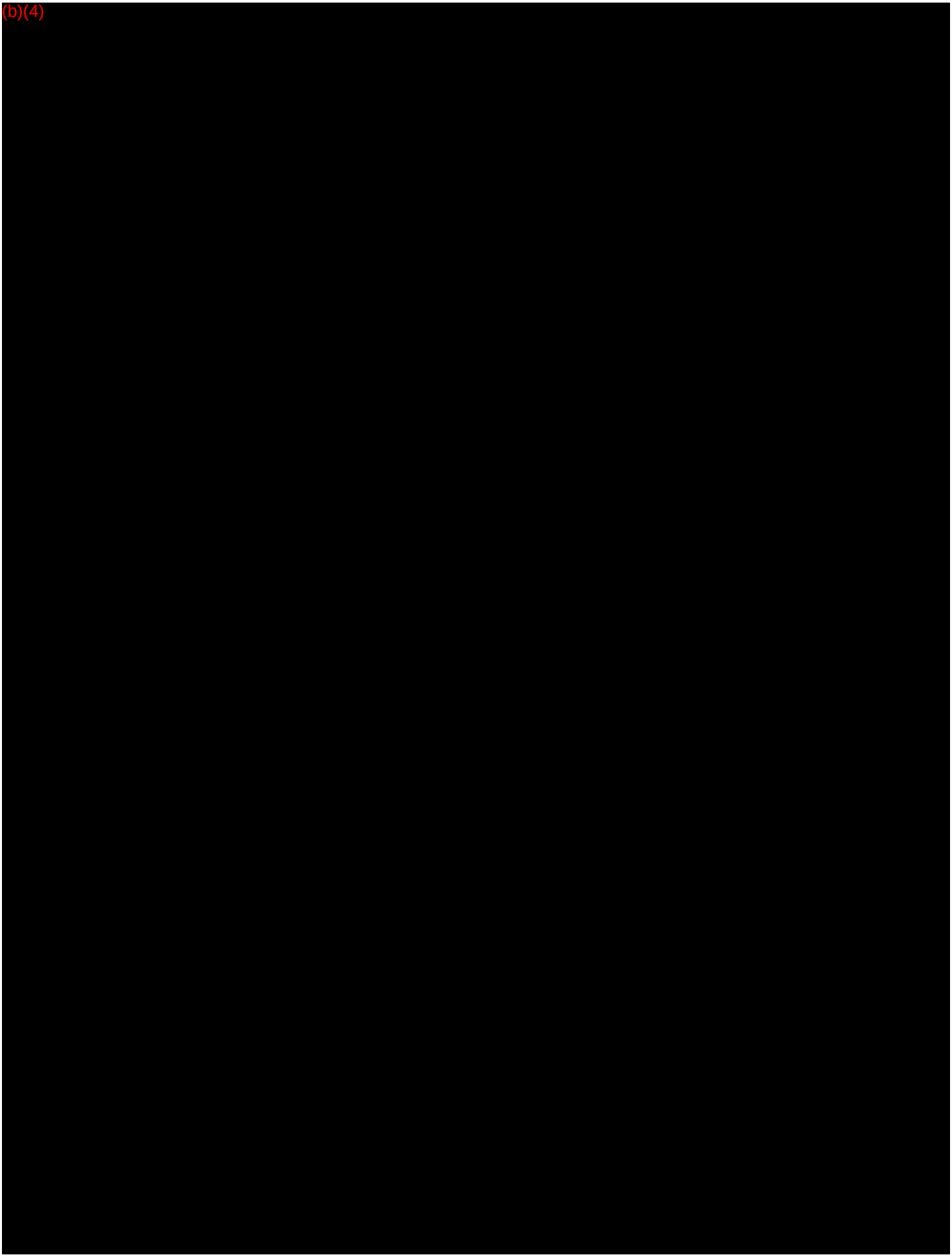

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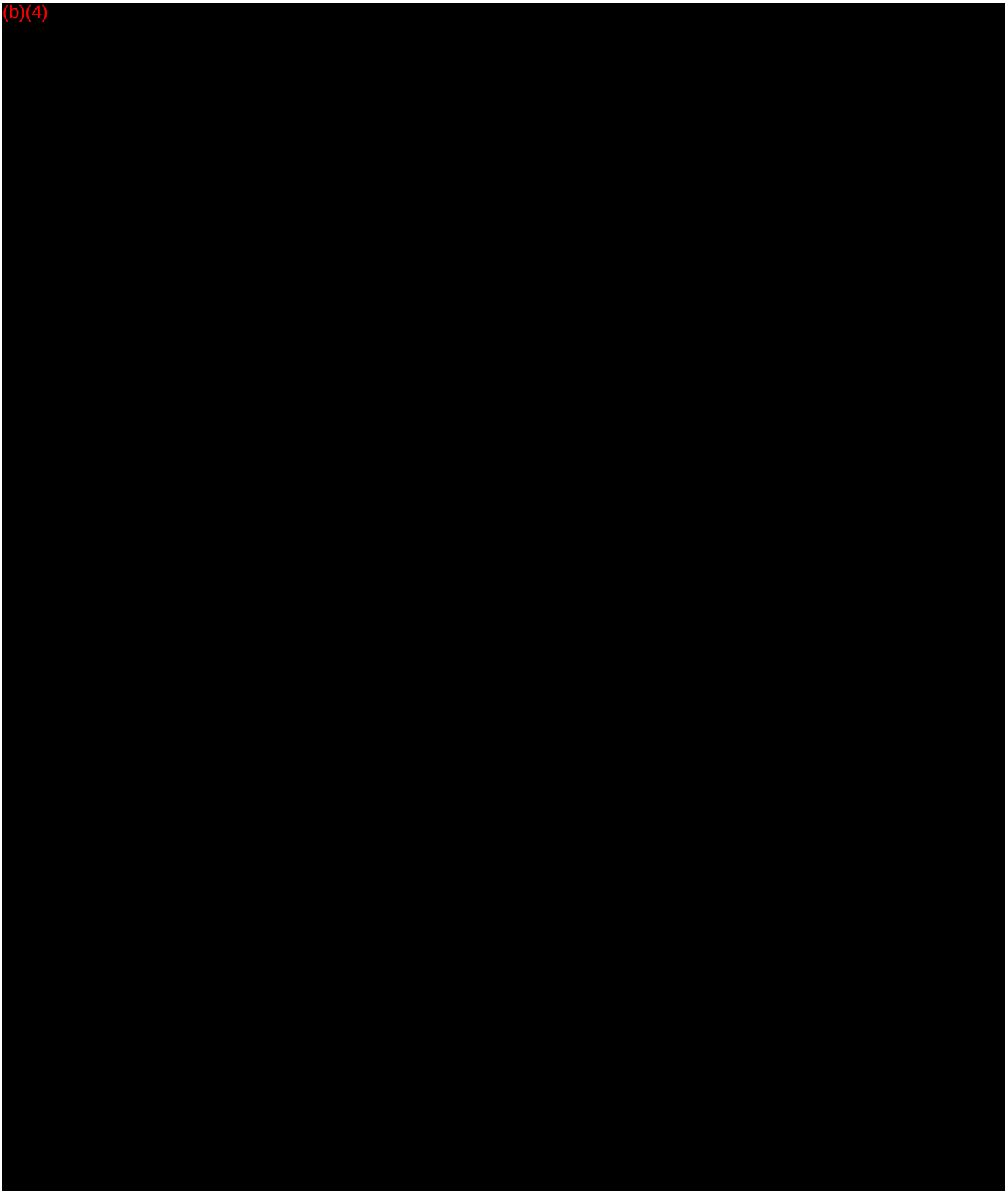

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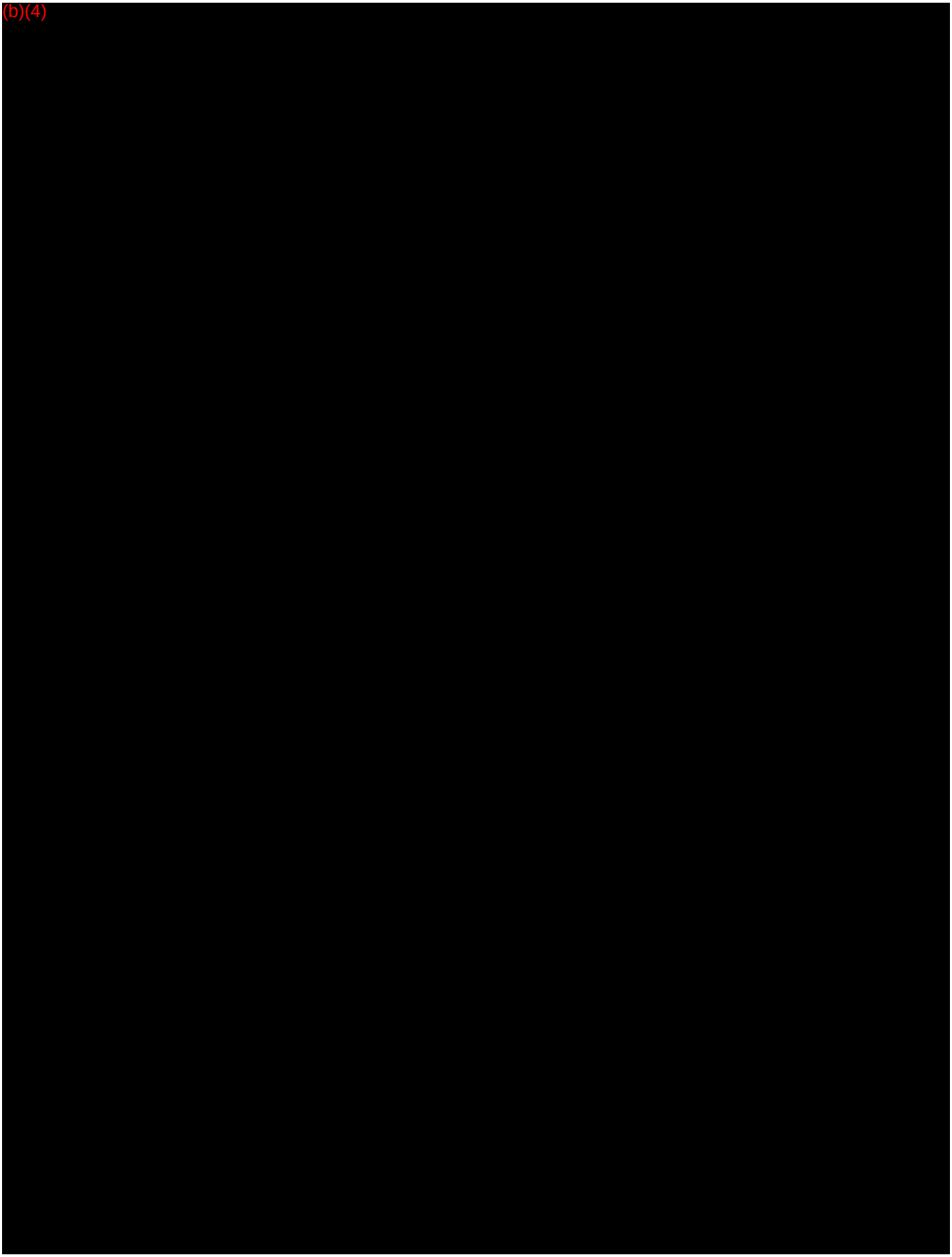

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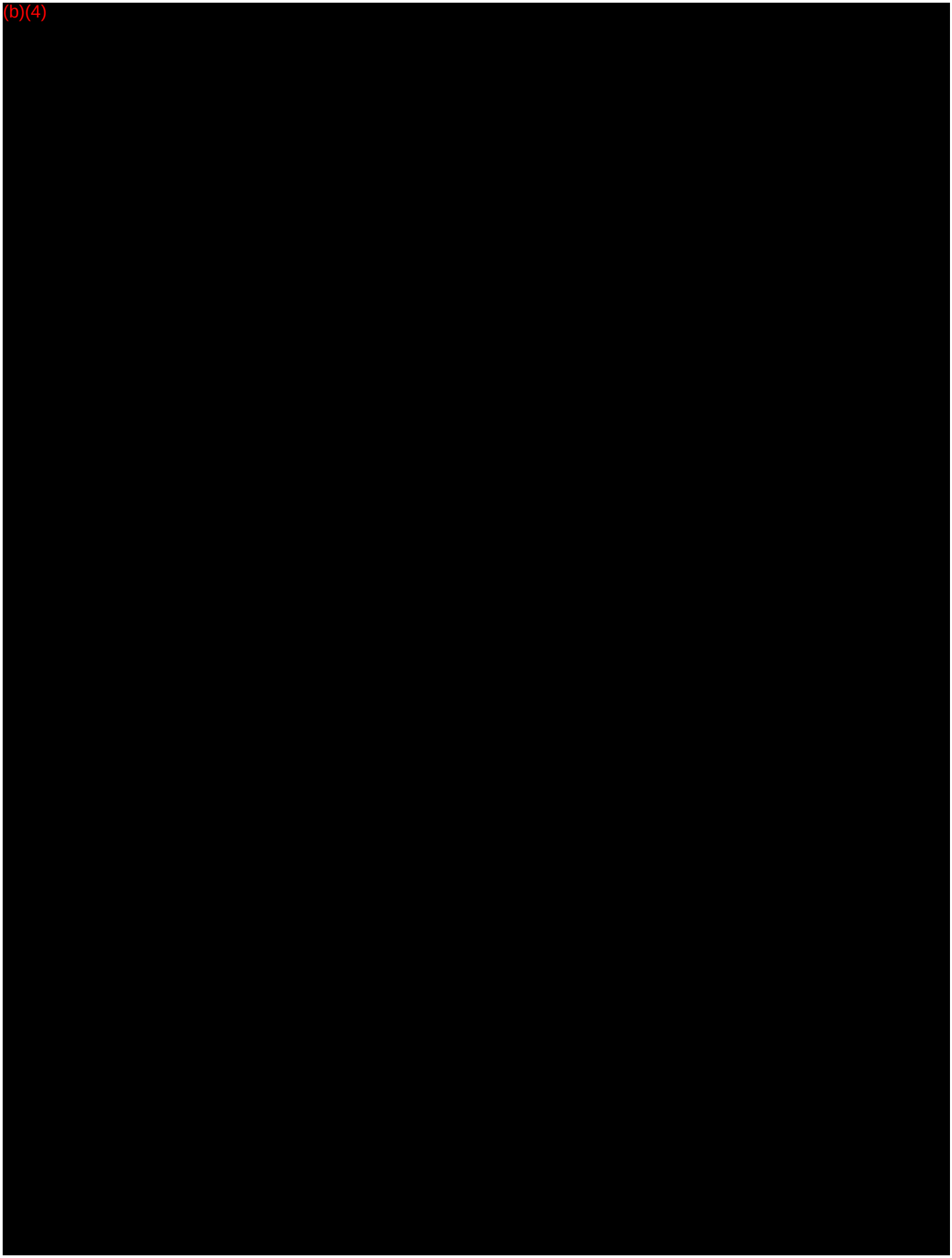

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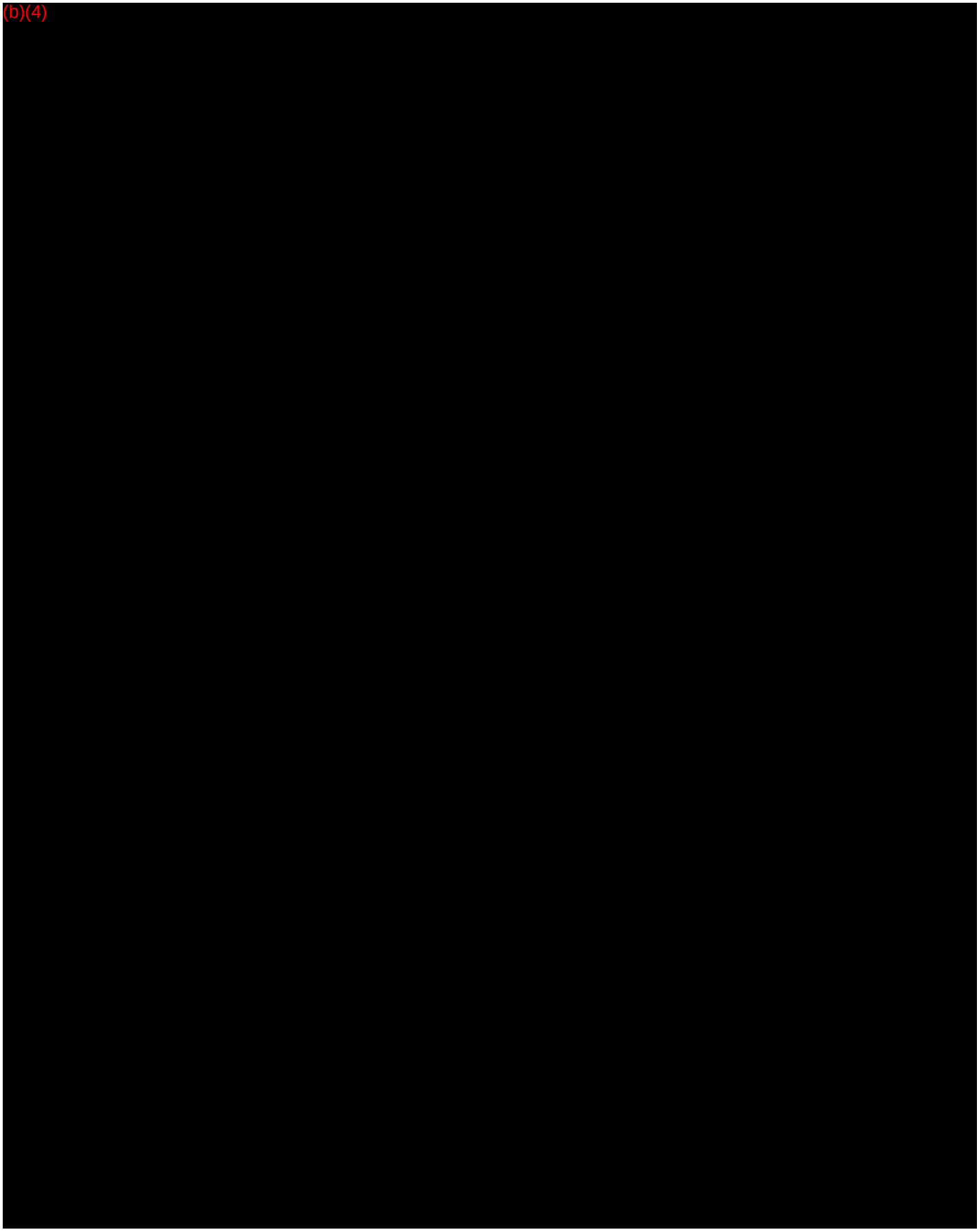

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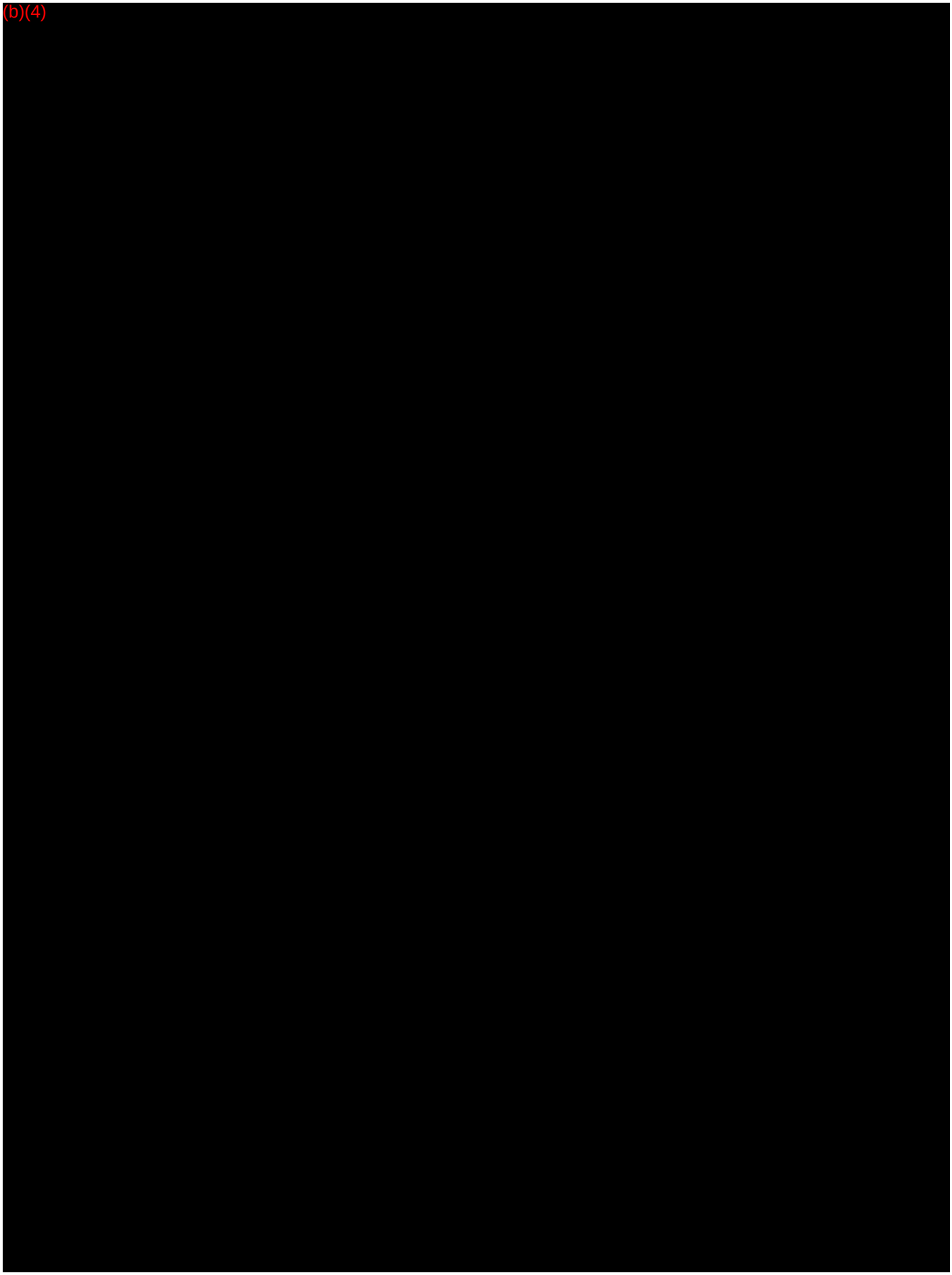

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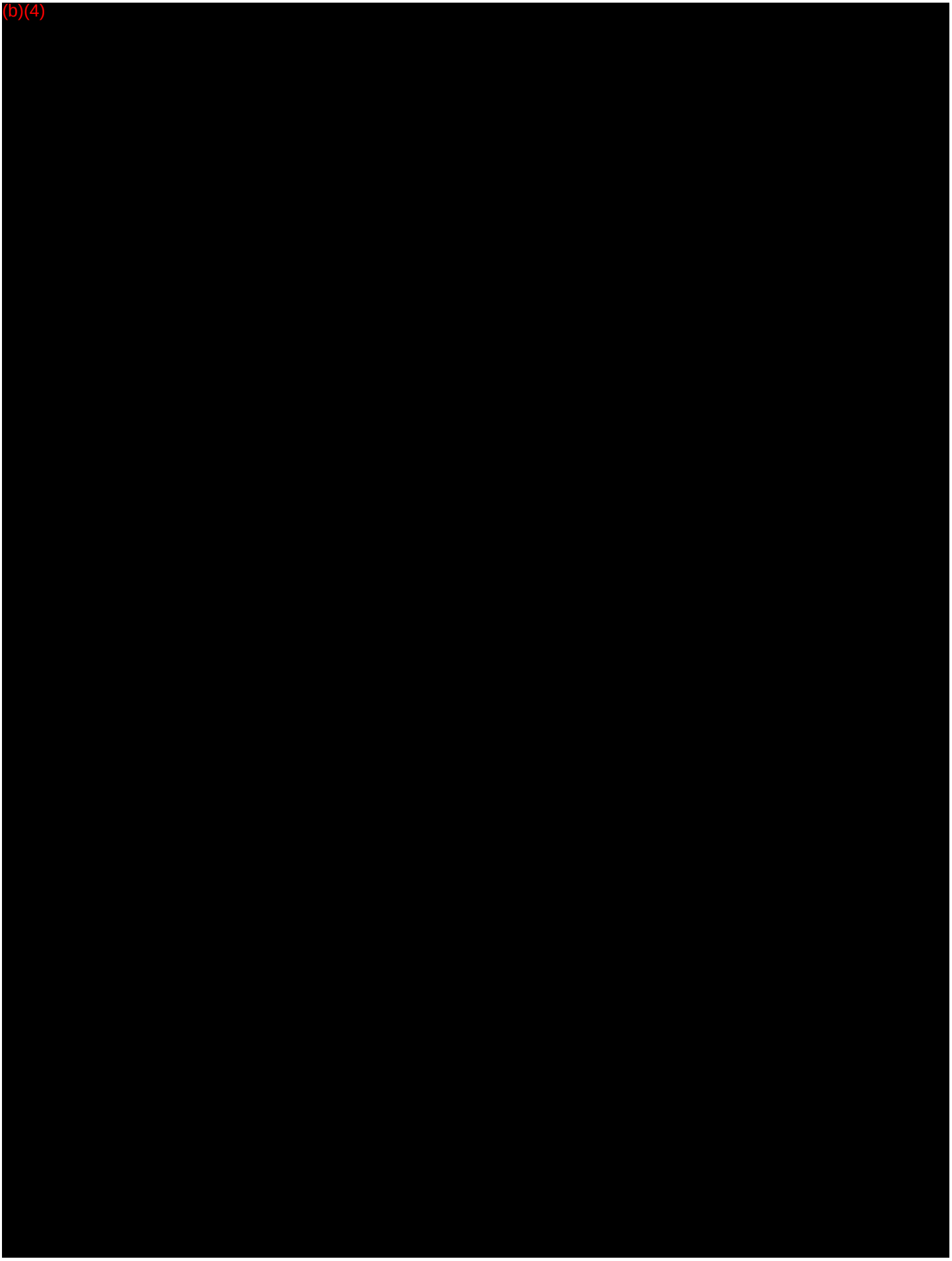

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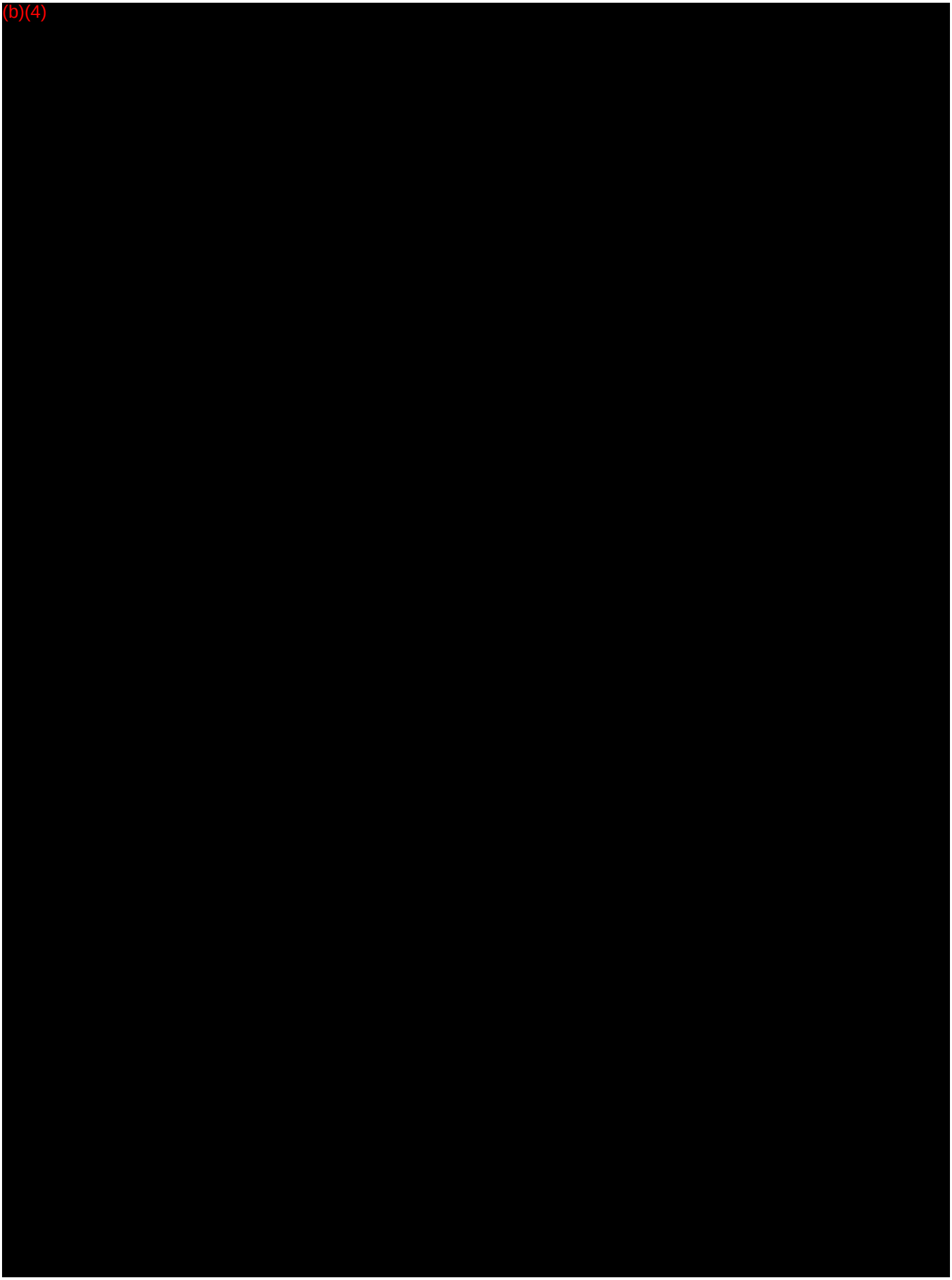

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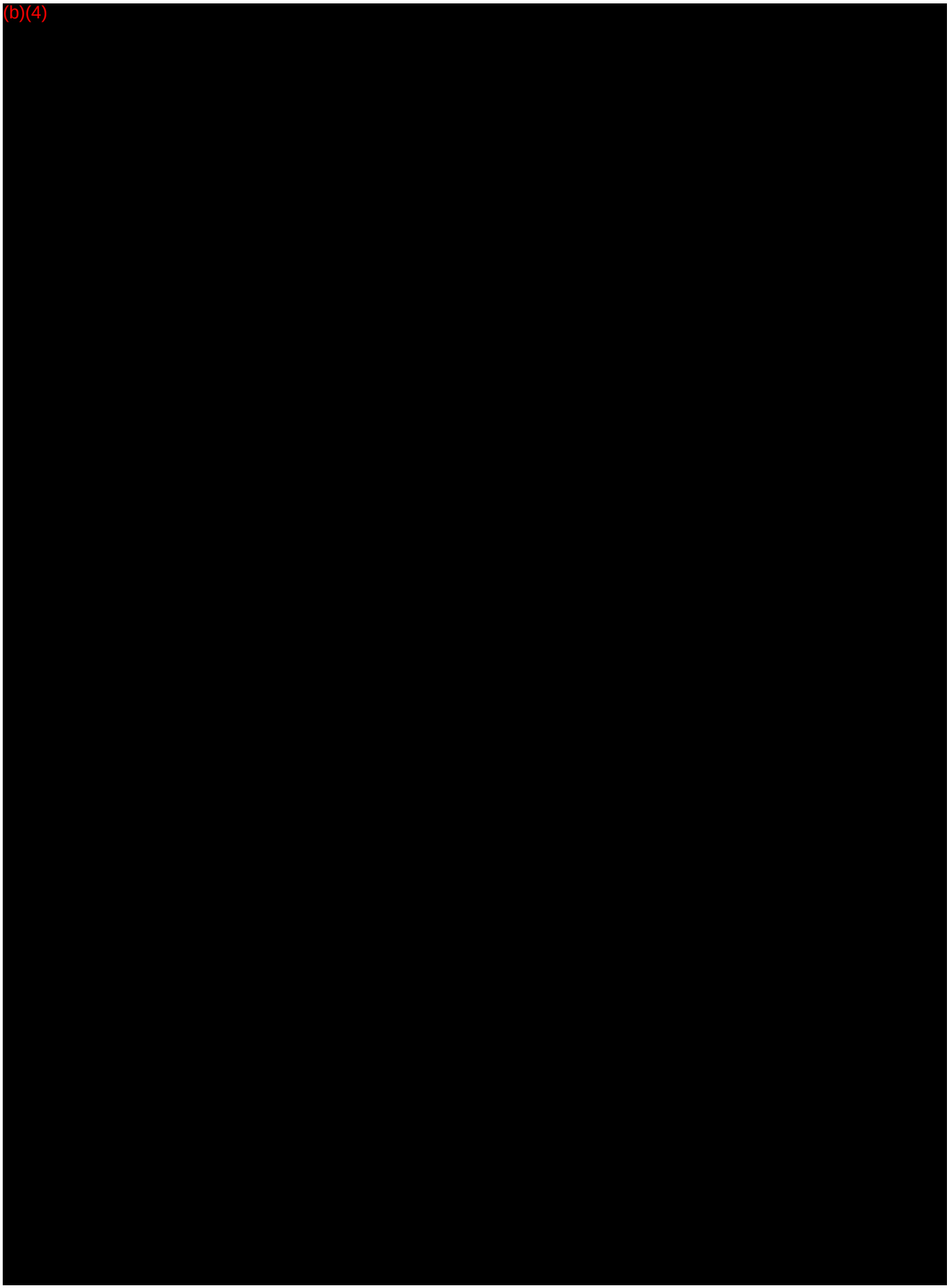

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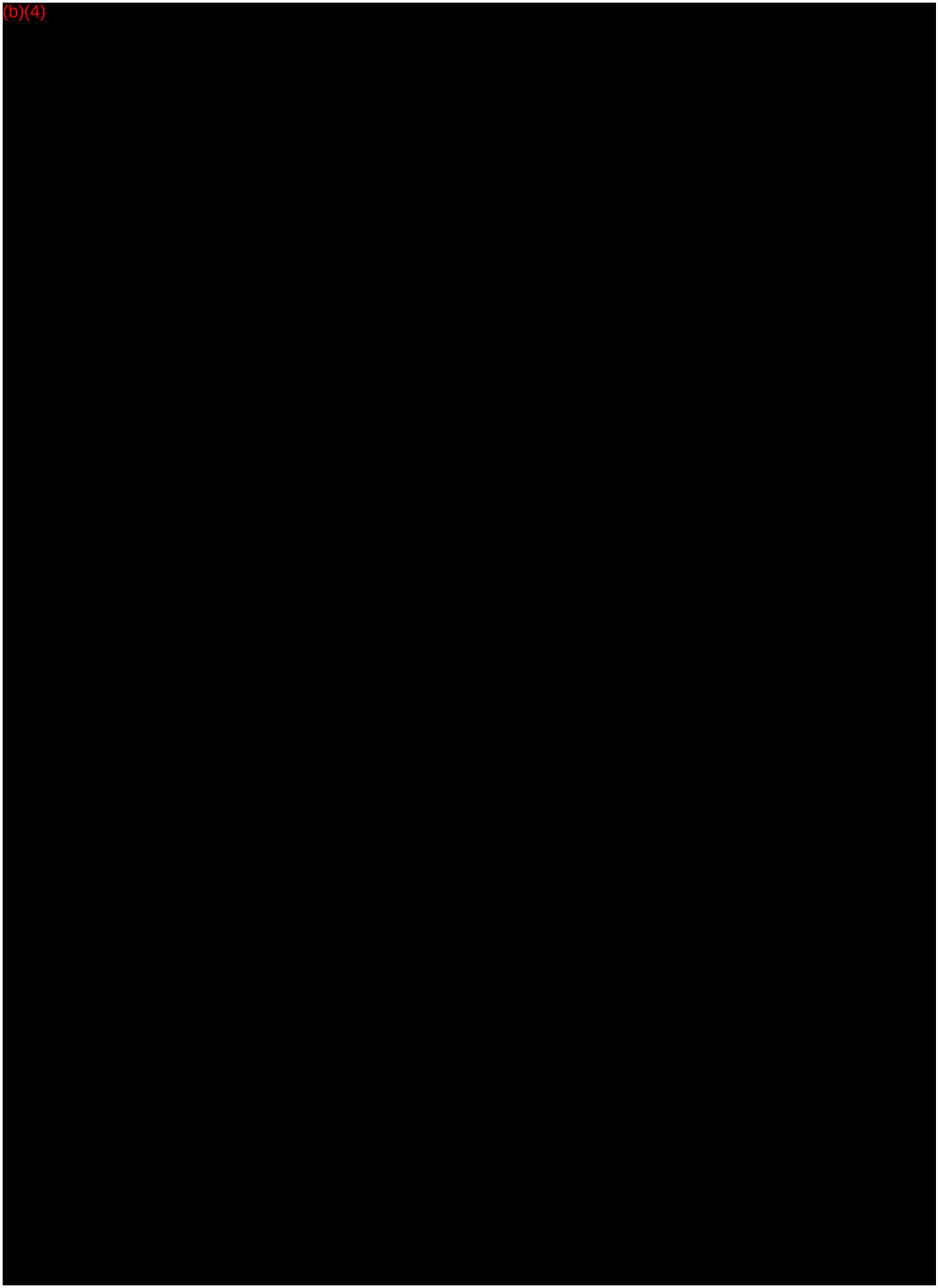

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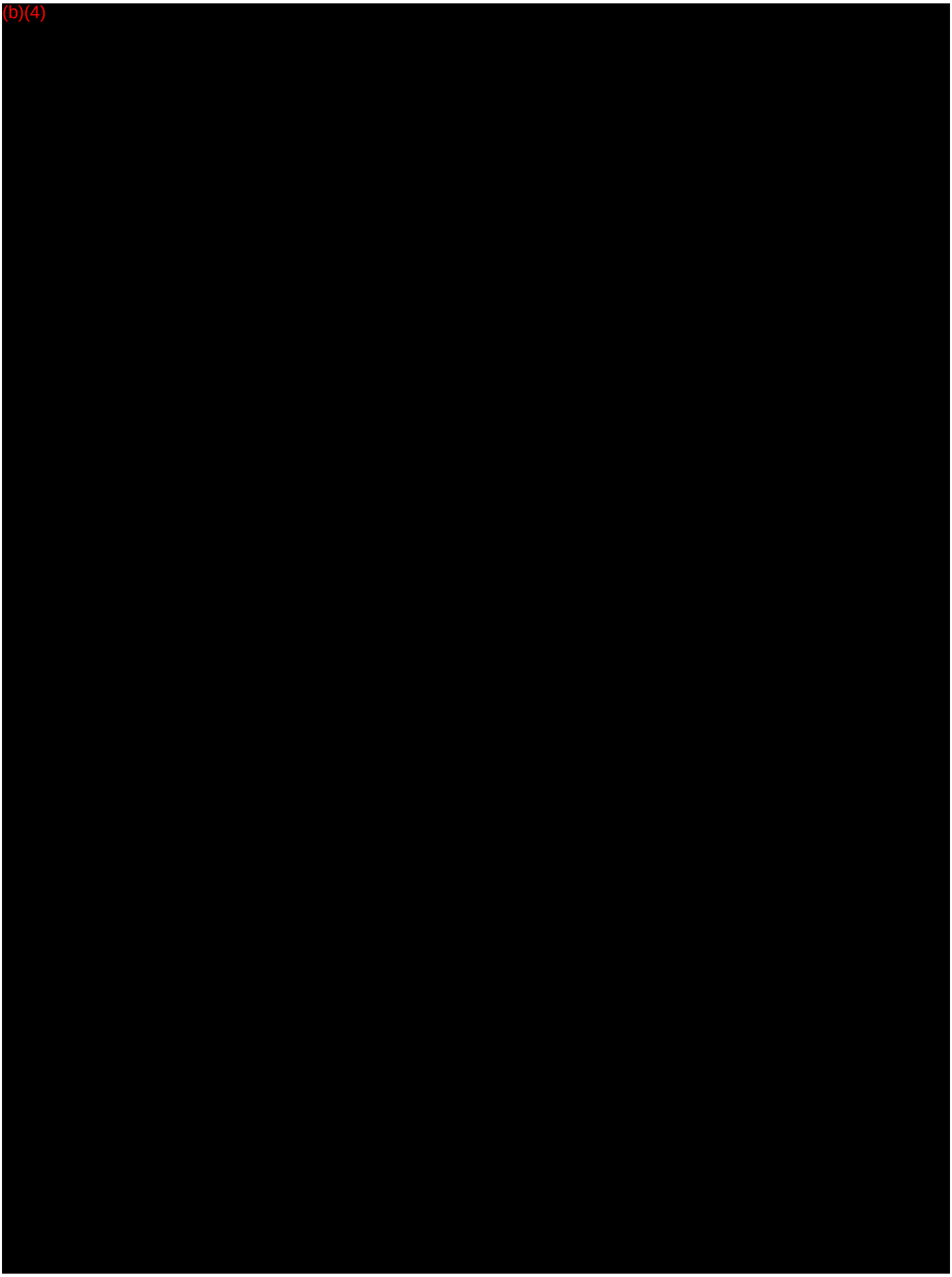

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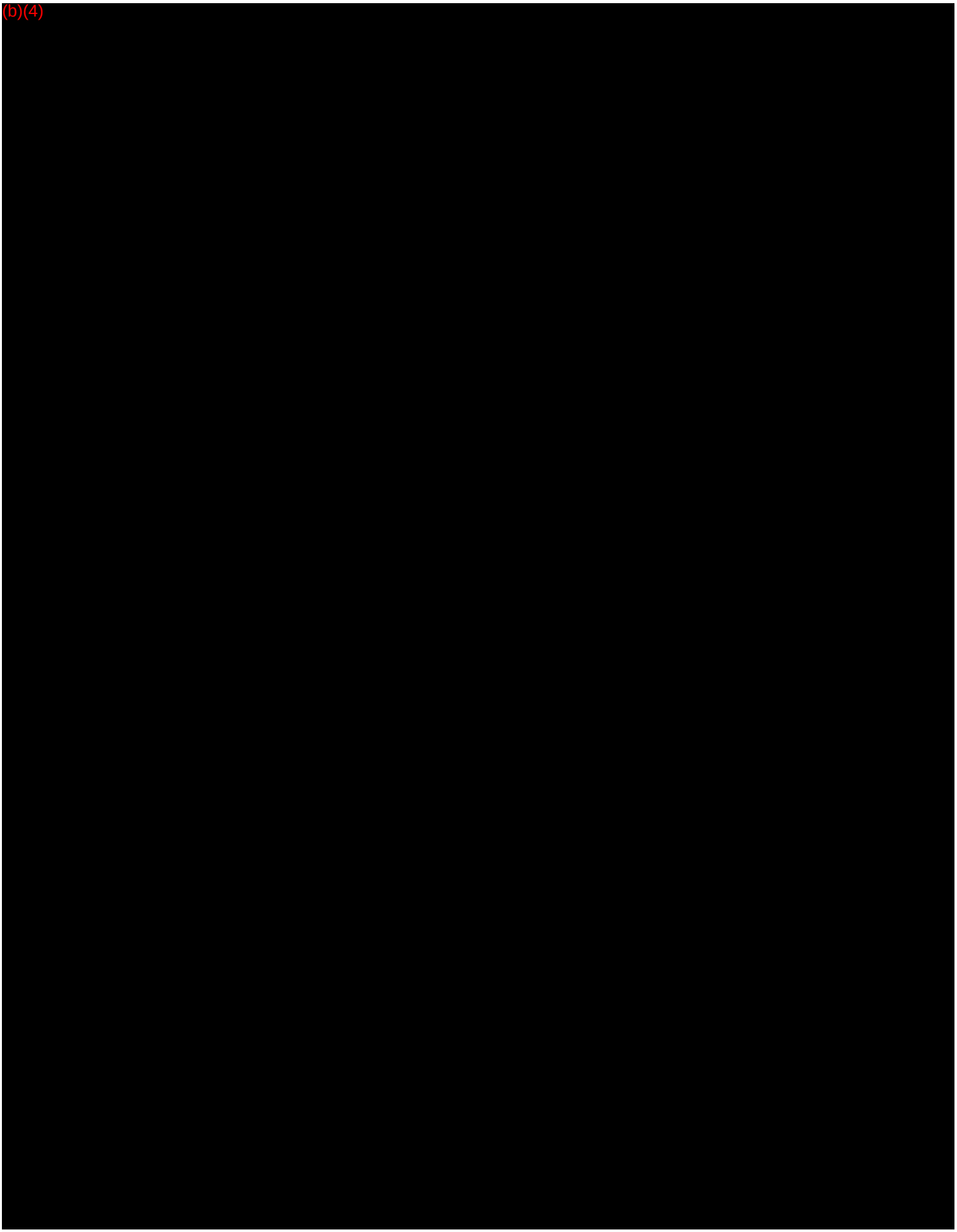

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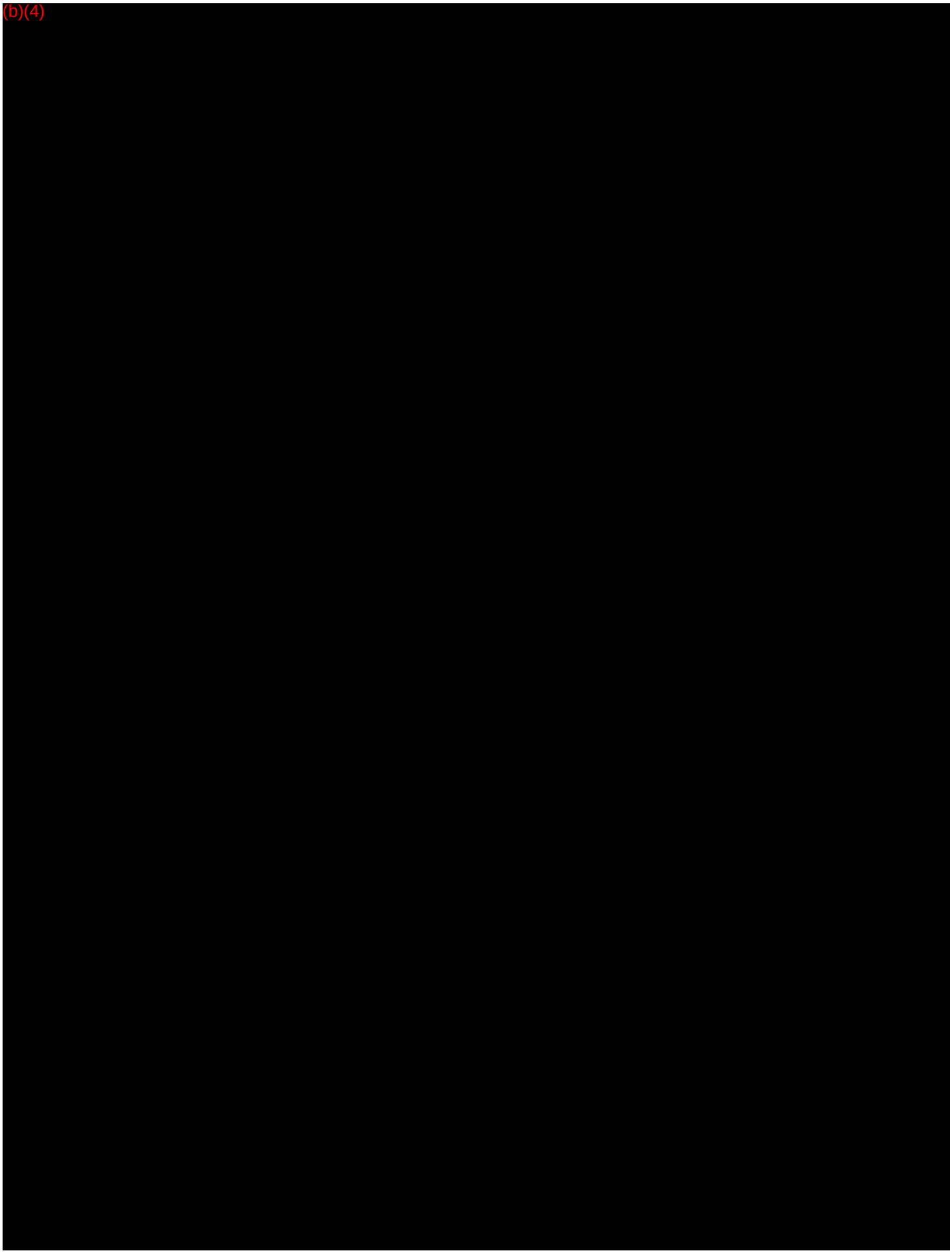

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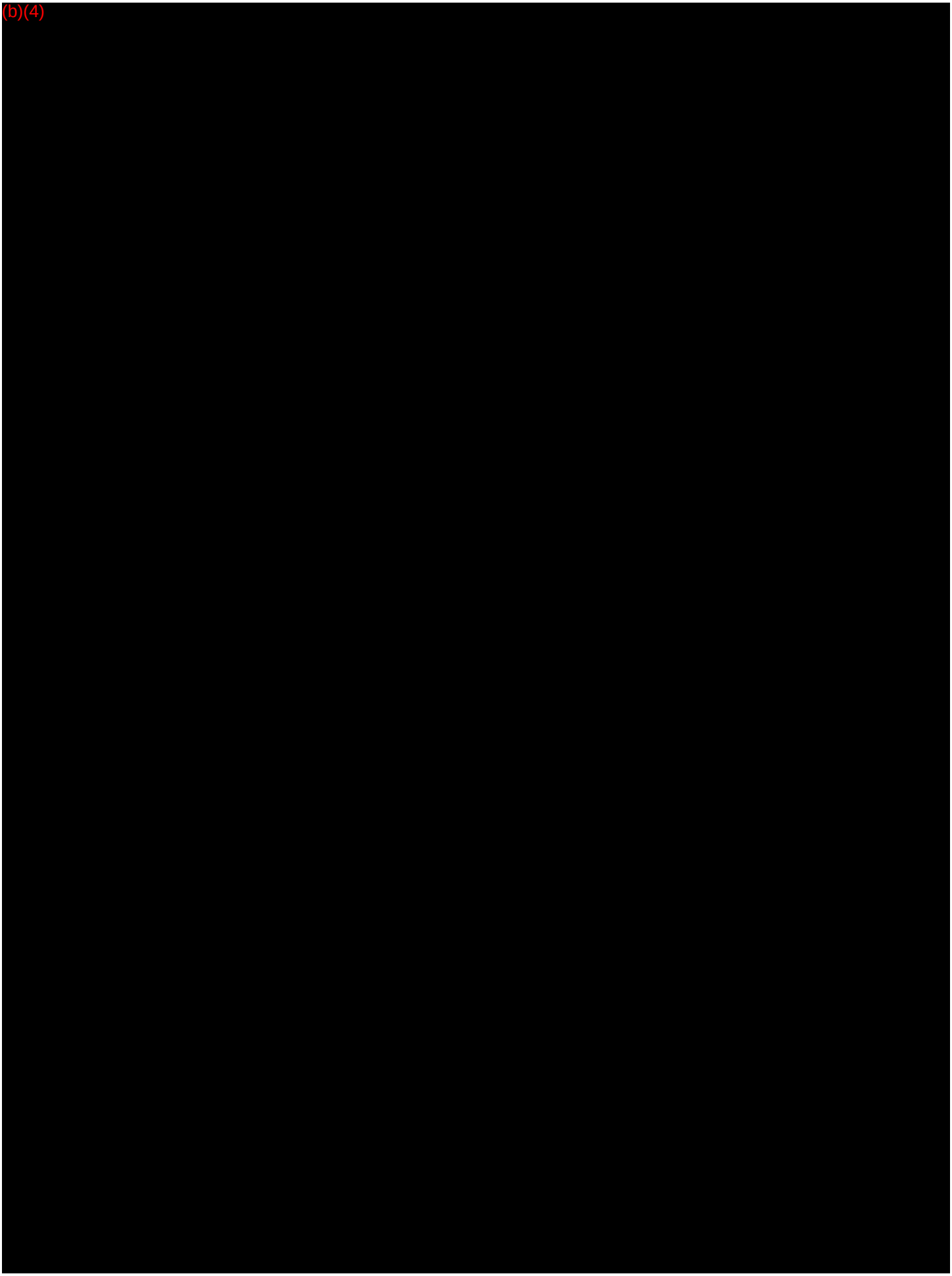

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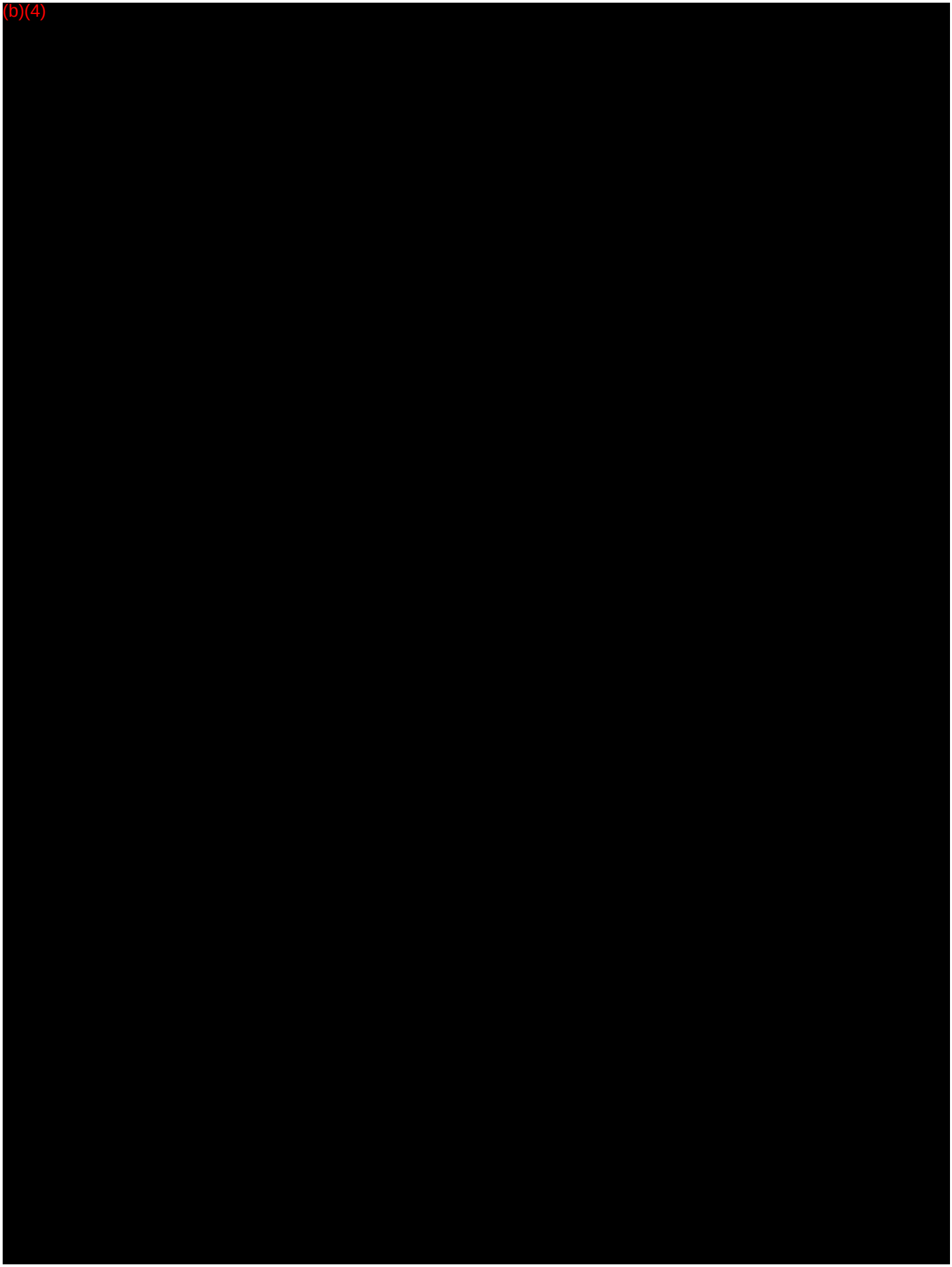

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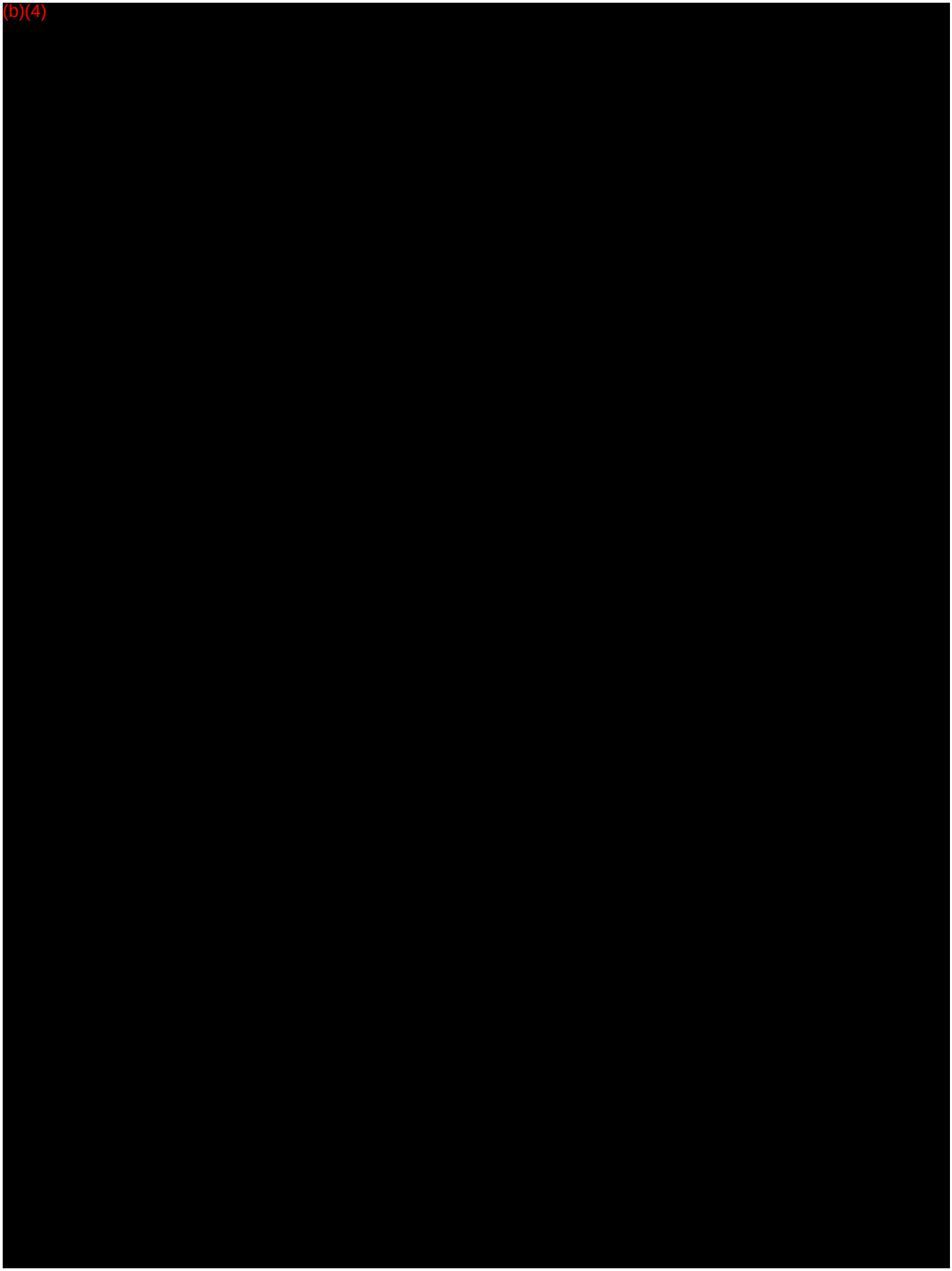

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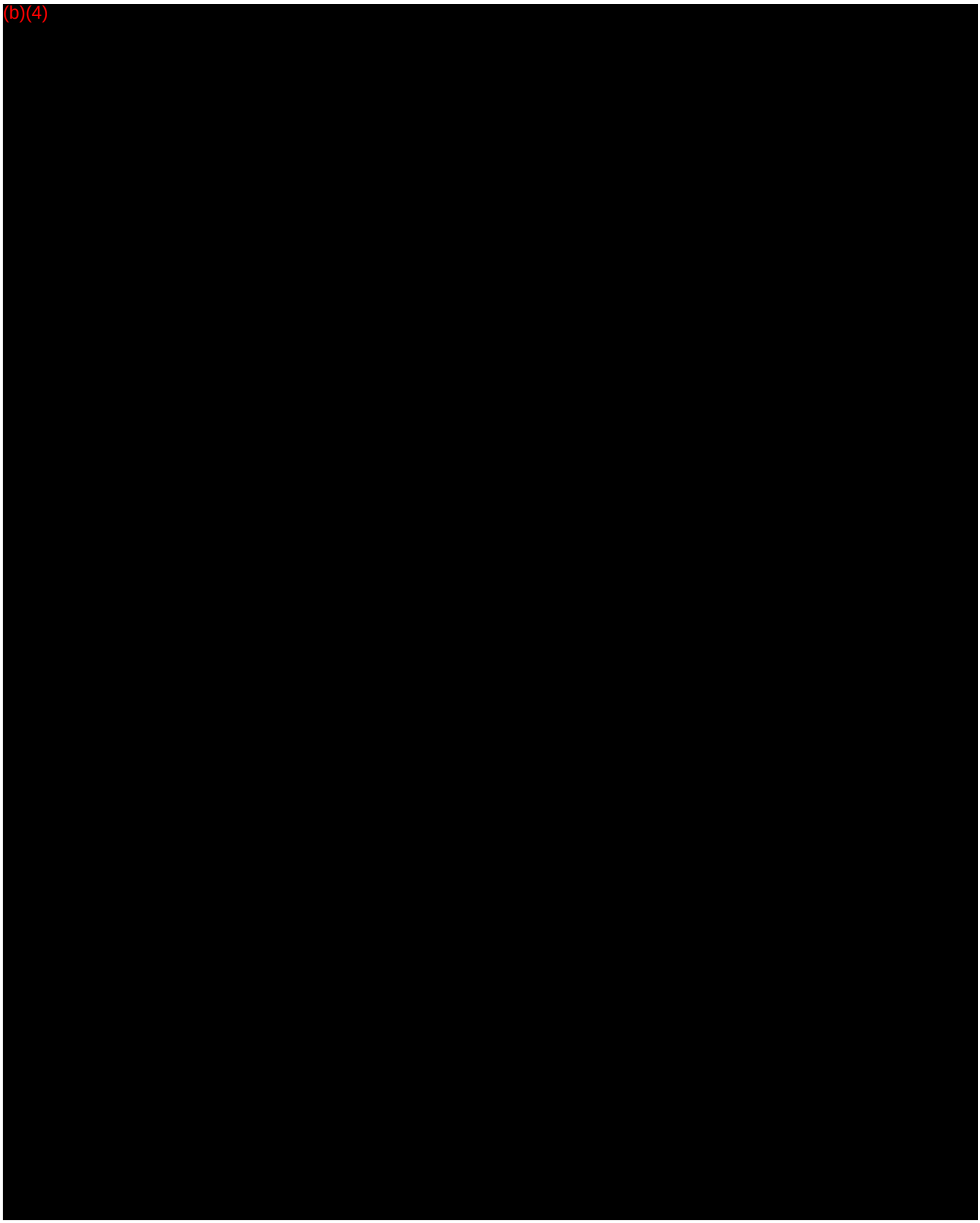

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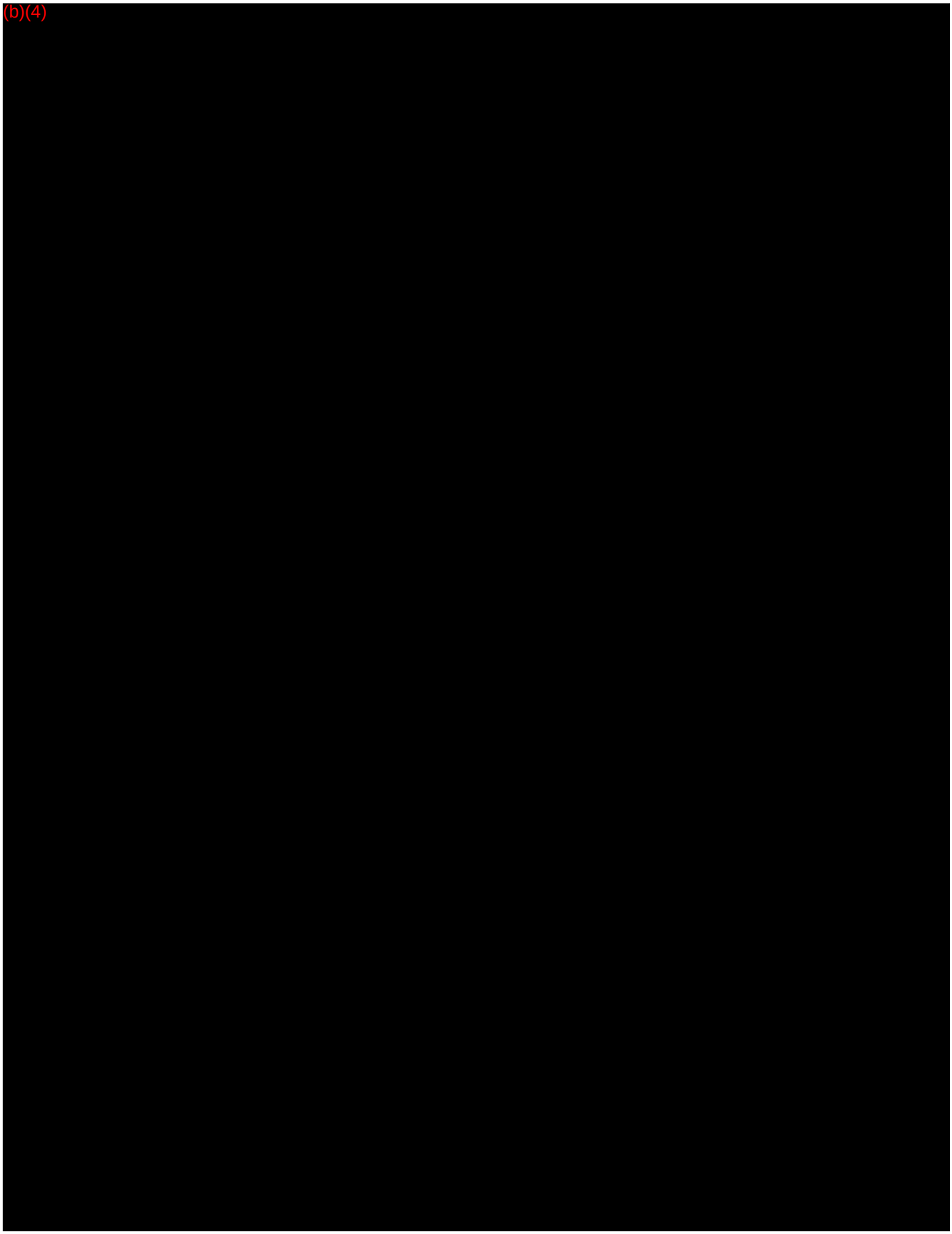

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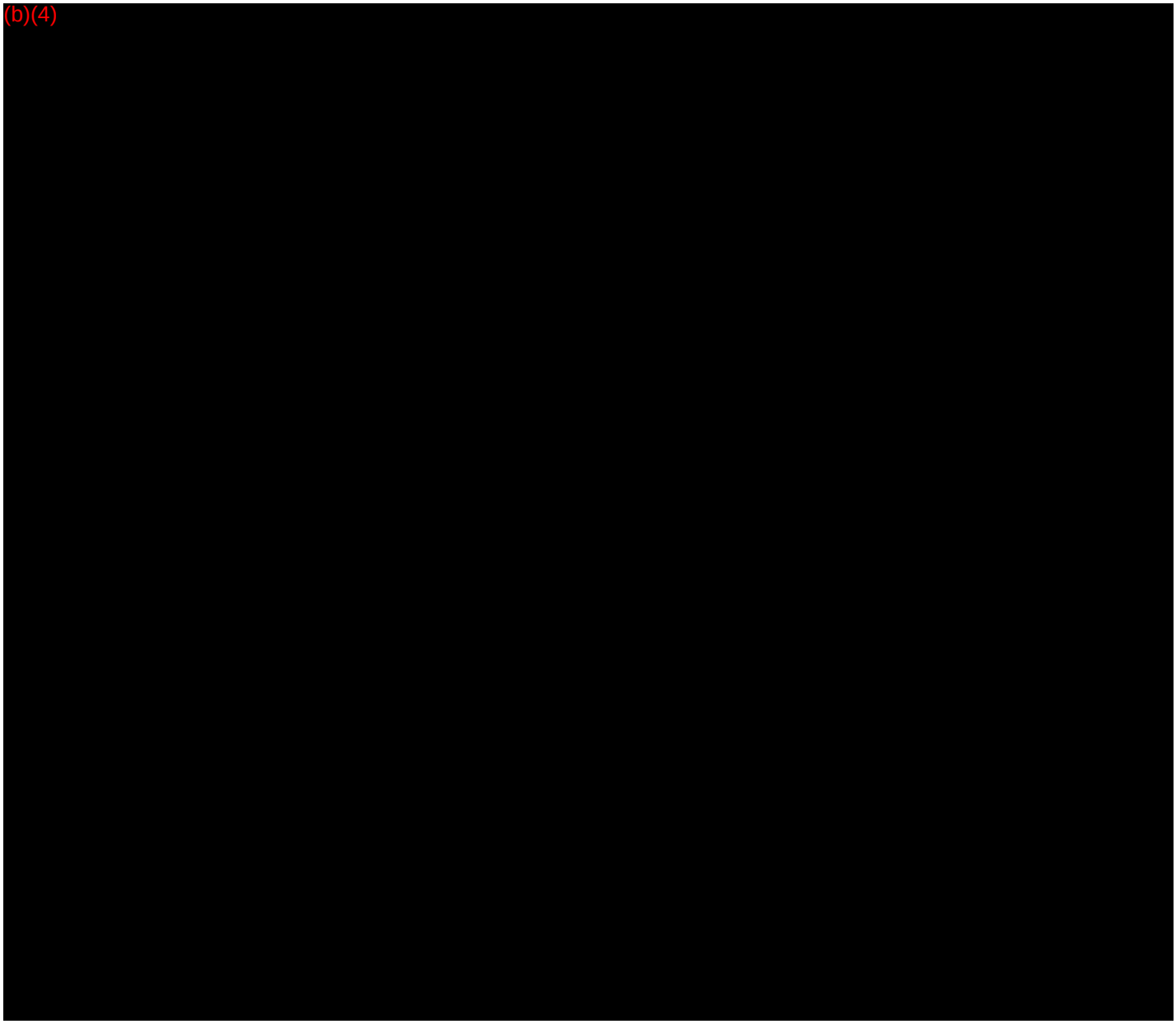

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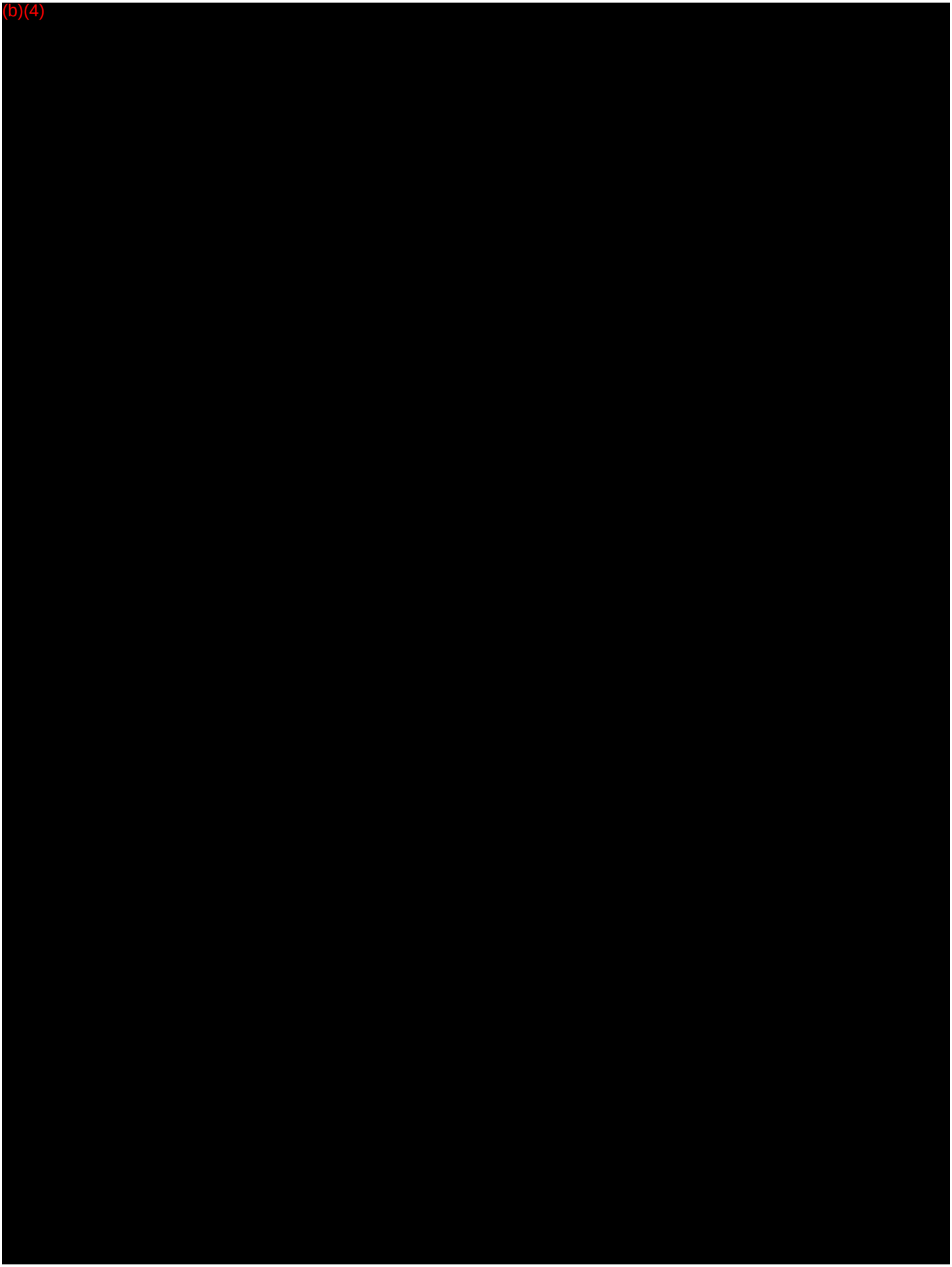

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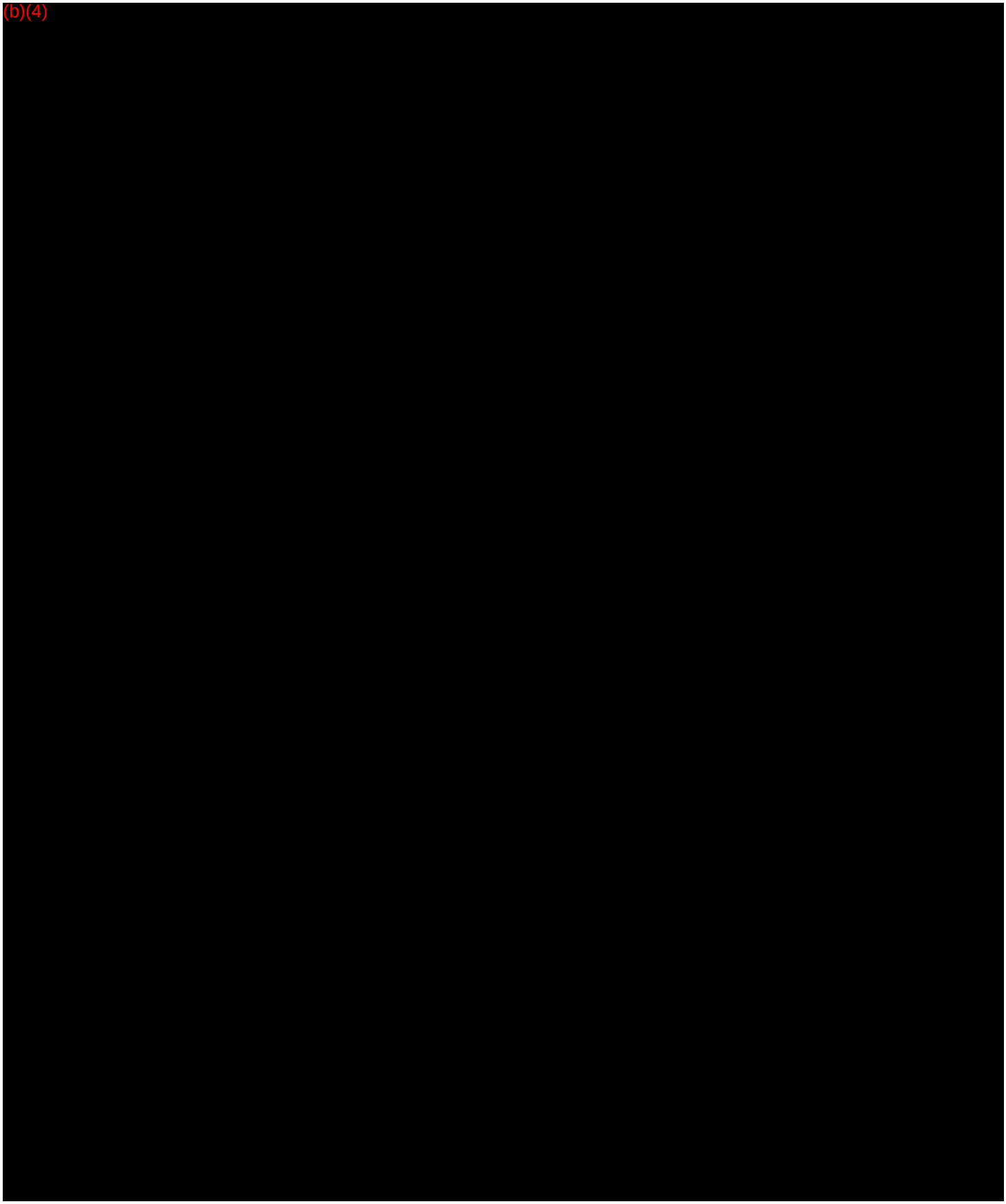

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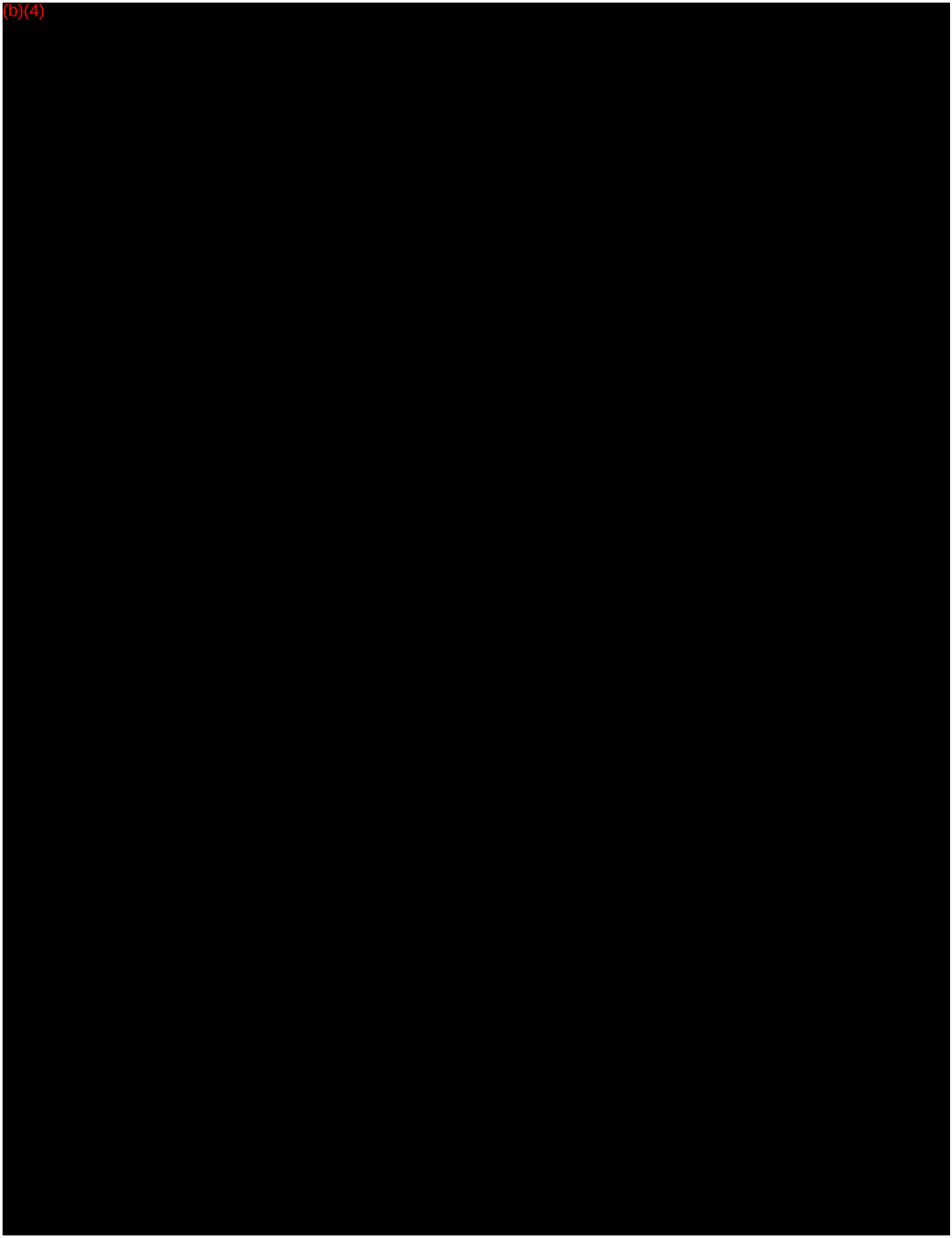

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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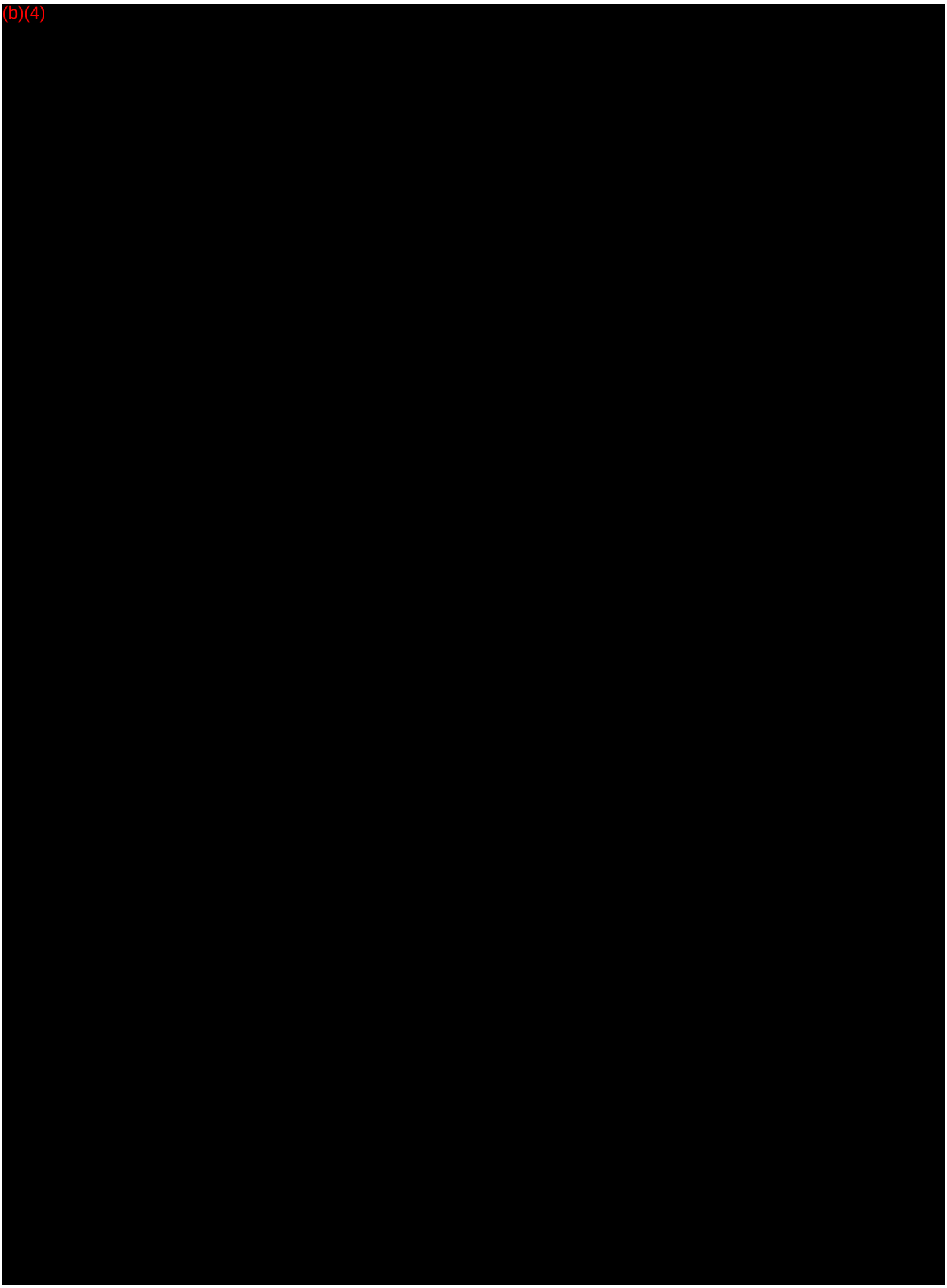

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(b)(4)

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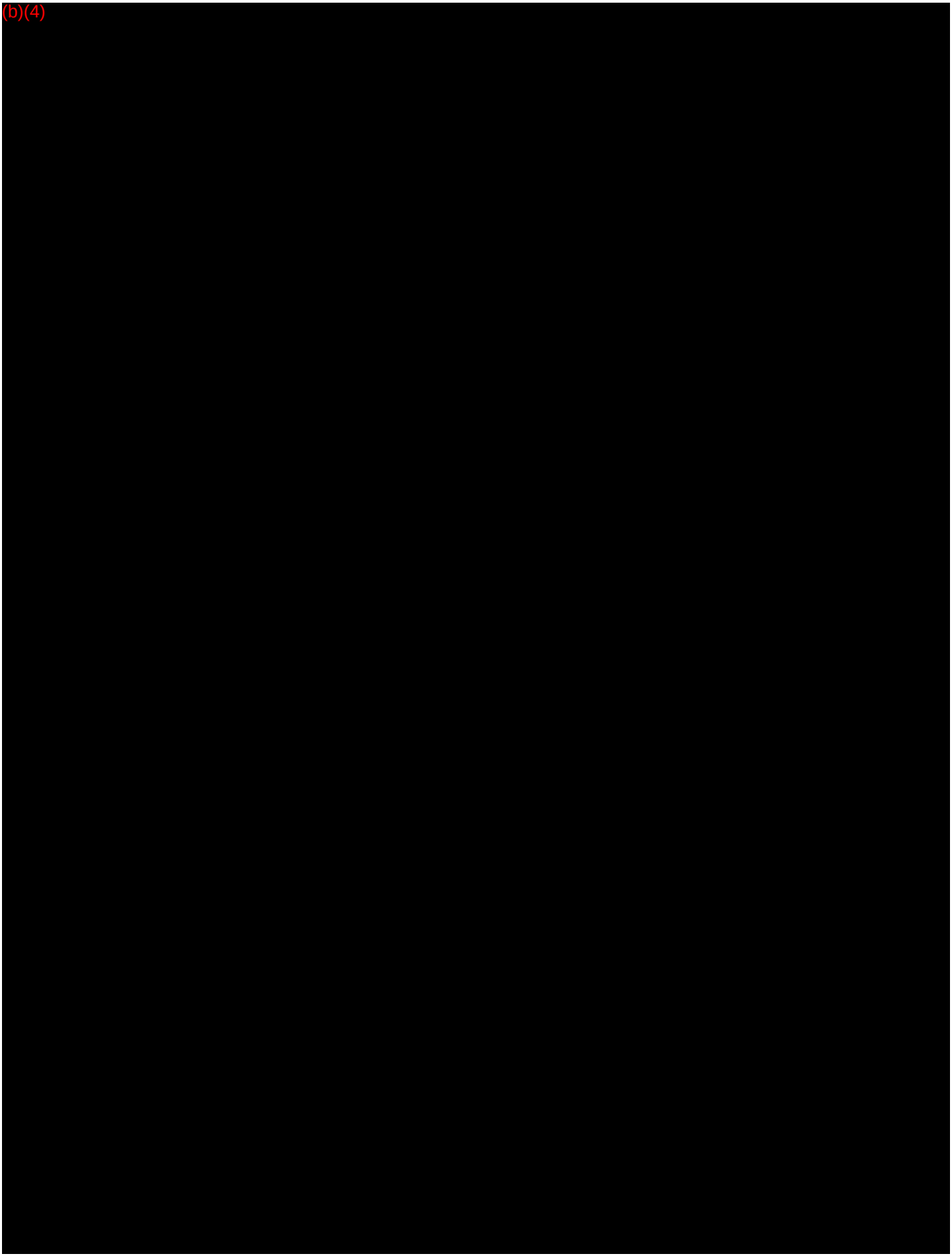
3shape

Verification Result–(b)(4) R

(b)(4)



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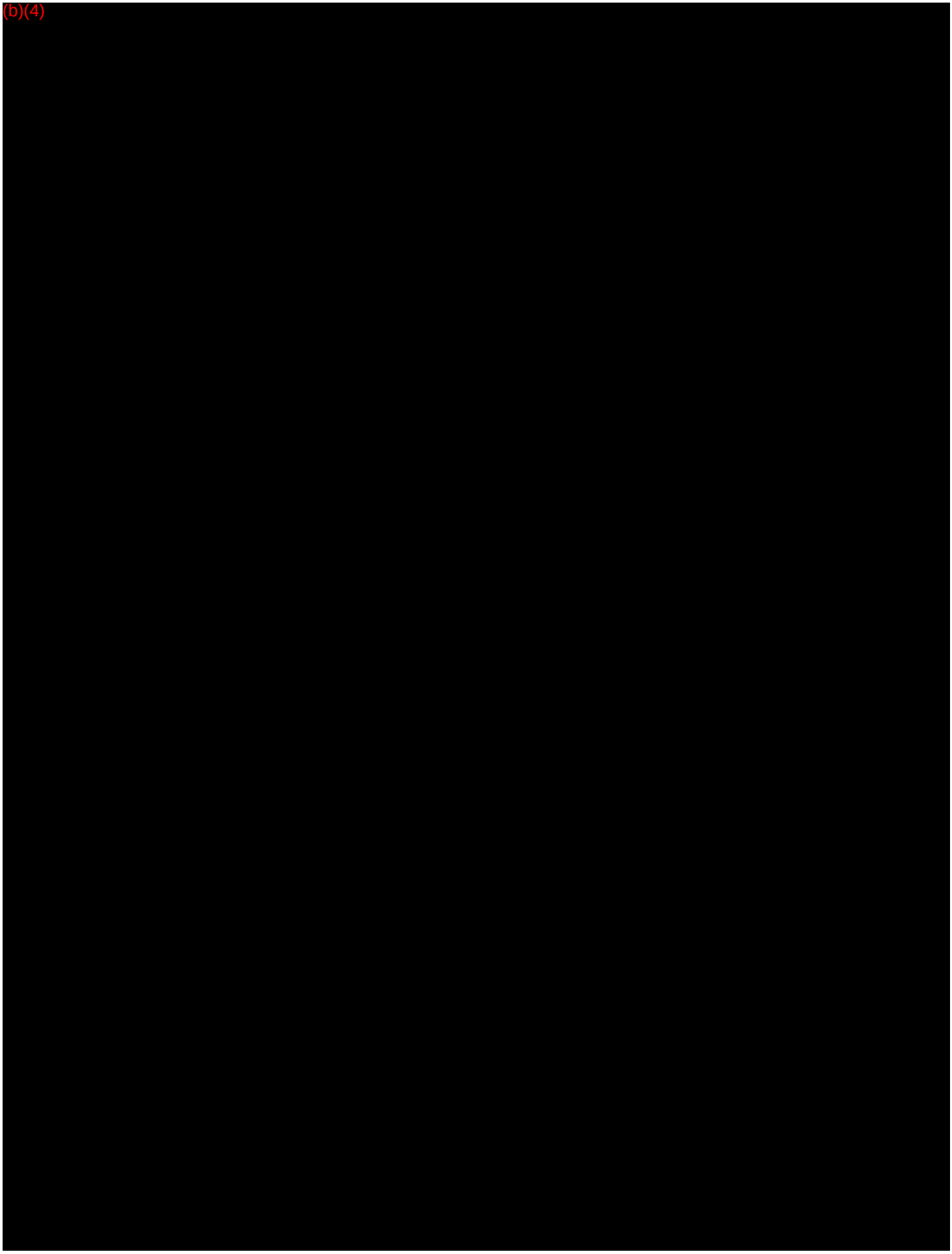
(b)(4)



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(b)(4)

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Revision Level History

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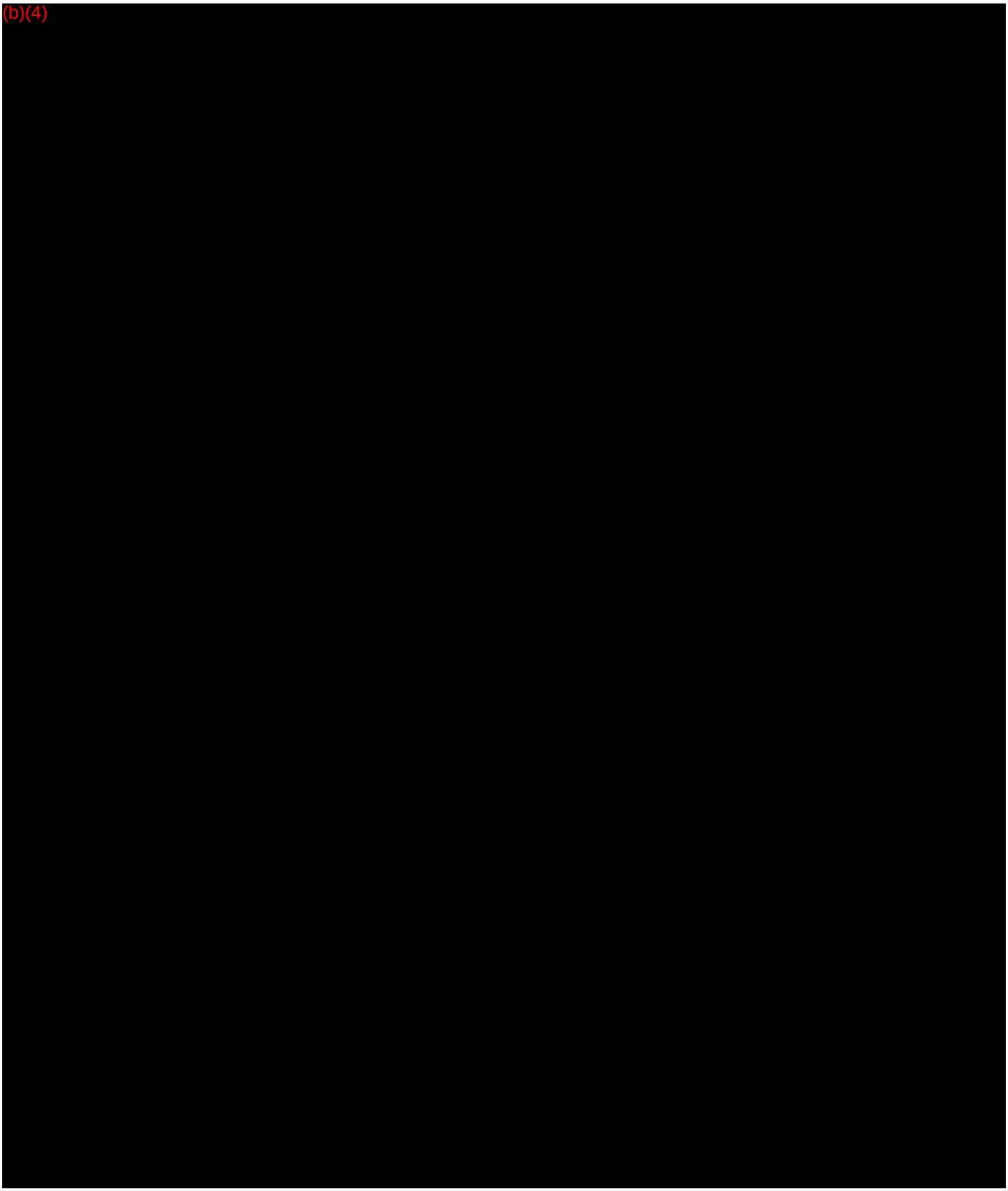
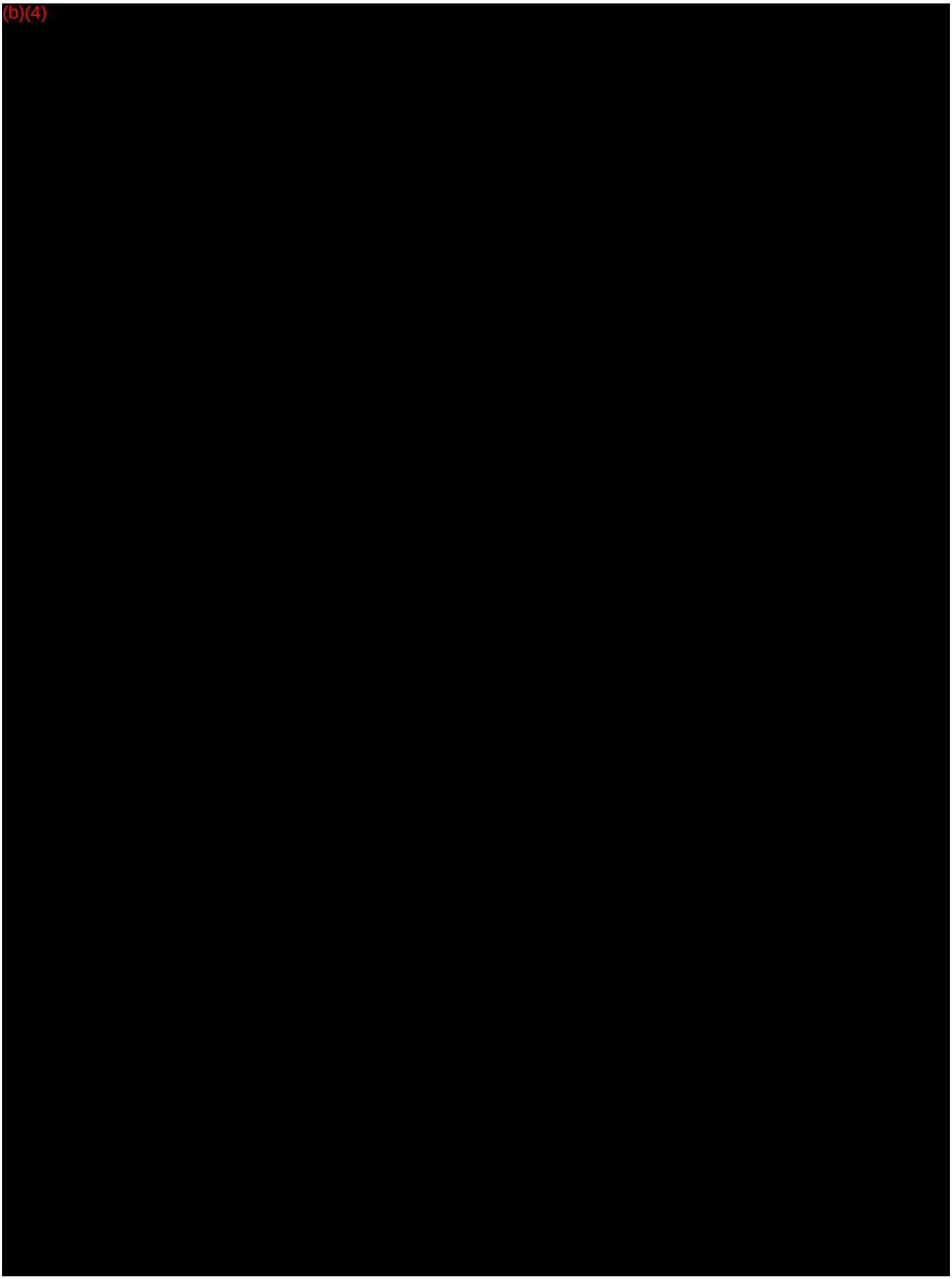


Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2016-8070; Released by CDRH on 10/5/2017

(b)(4)



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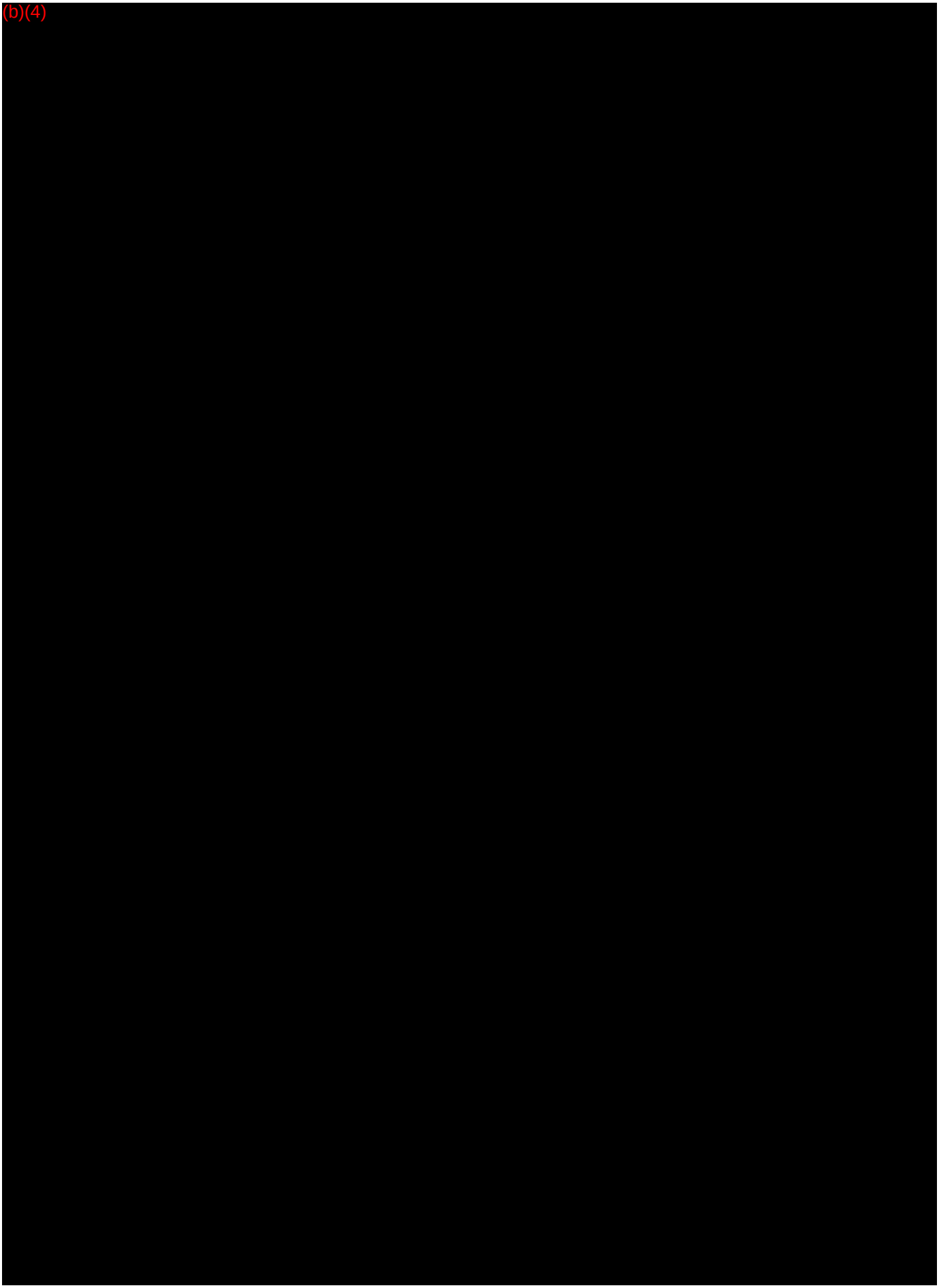
(b)(4)



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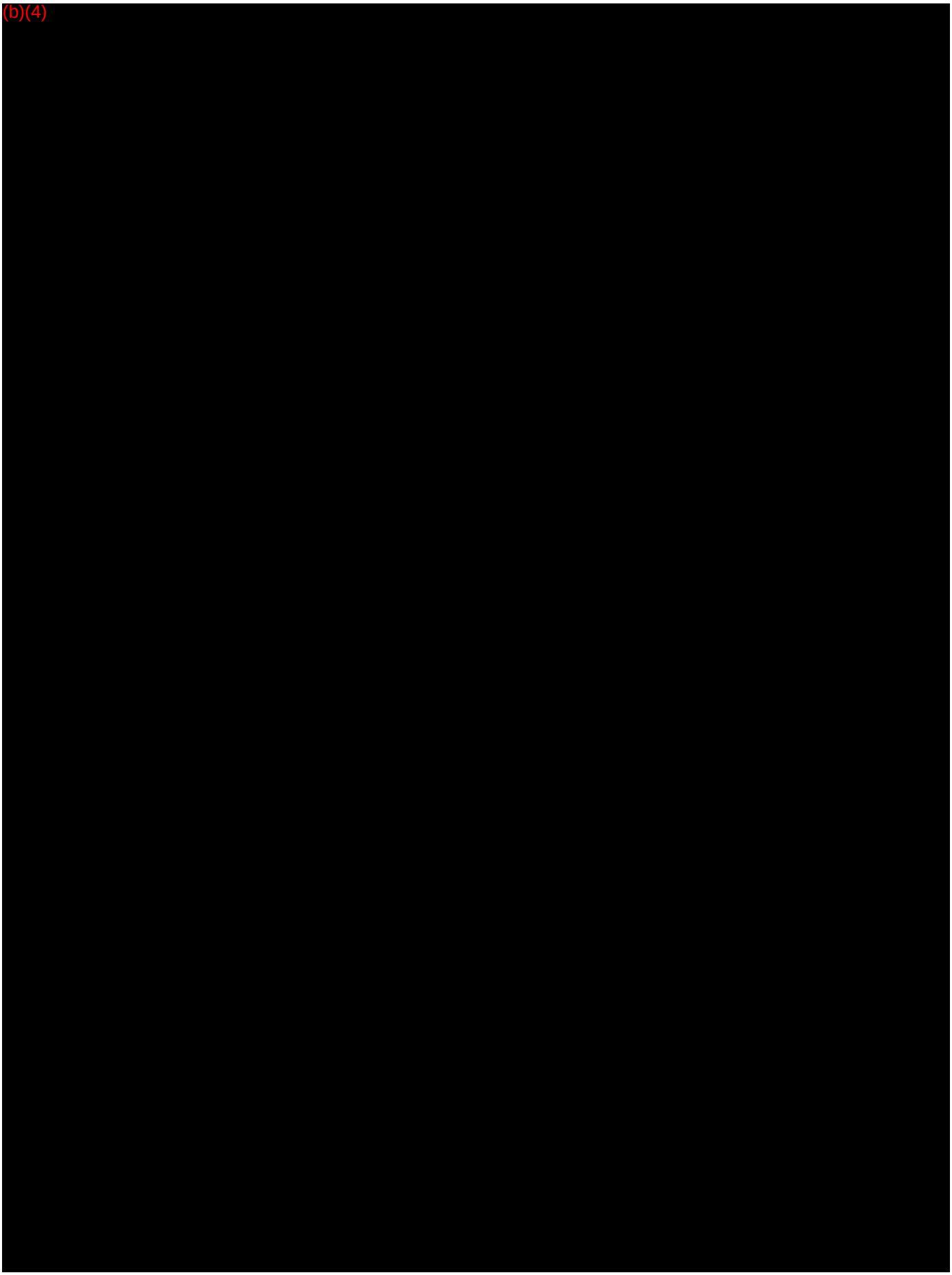
(b)(4)



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(b)(4)

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Unresolved anomalies

The list of the 3 remaining software anomalies in 3Shape Abutment Designer™ Software (b)(4)) can be seen in

Table 1.

(b)(4)

Table 1: List of open bugs in 3Shape Abutment Designer™ Software 2015-1 (version 2.15.2.0)

Bug ID	Description	Safety Impact	Resolution	Justification for Resolution

(b)(4)

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Labeling

3Shape Abutment Designer™ is an add-on module to 3Shape Dental System™ which is classified as 872.3661 Optical Impression Systems for CAD/CAM, Product Code NOF (510(K) Exempt). Throughout this submission there will be references to 3Shape Dental System™, but only the documentation relevant to 3Shape Abutment Designer™ has been included.

This VOL_013 includes the following documents which are excerpts of the 3Shape Dental System™ labeling:

3Shape Dental System Software Brochure	appendix 13-1
Manual DS-2.15.2.0-A-En version	appendix 13-2

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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3shape

Dental System™

Industry-leading scanning and CAD solutions

Excerpt version

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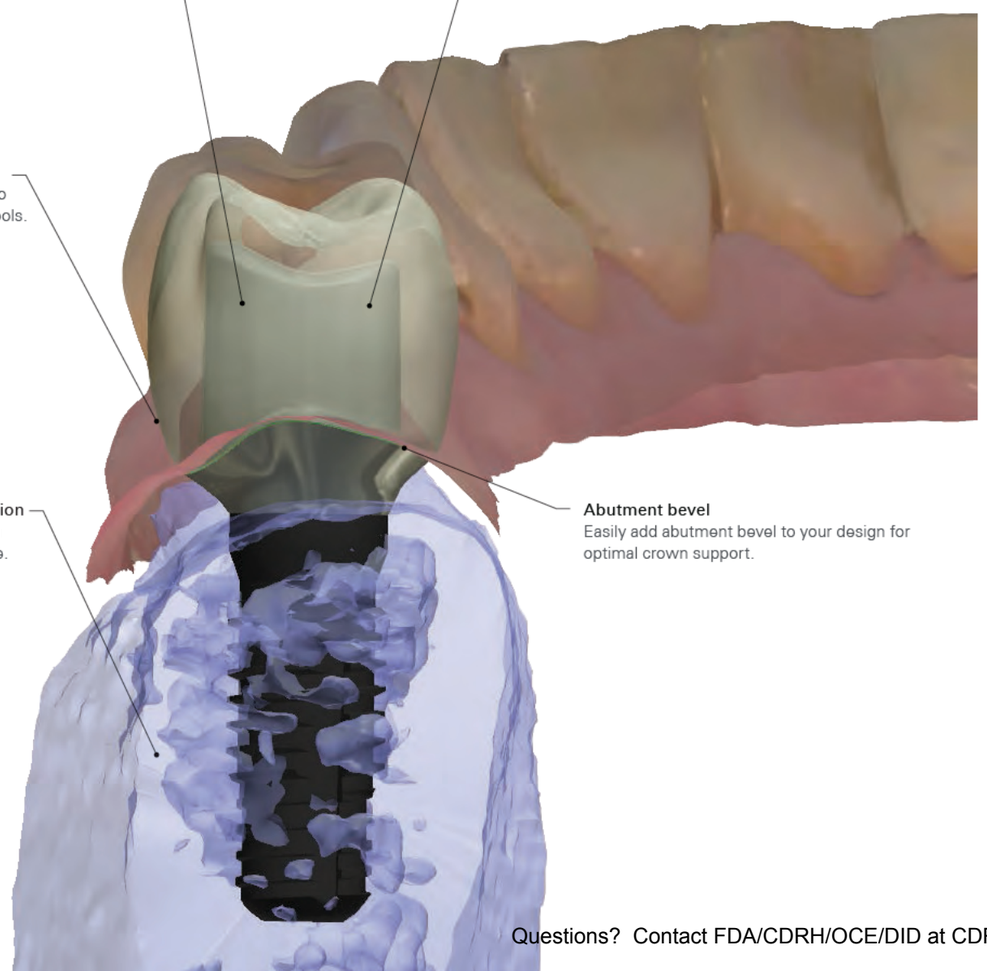
Get better esthetics and save costs with customized abutments

More and more labs are customizing abutments because they get improved clinical results, better esthetics and cost savings. Abutment Designer™ lets you automatically design the customized abutment and emergence profile with smooth transitions and optimal esthetics.

COMING Auto-Abutment
Automatically generate an abutment that optimally fits the crown design.

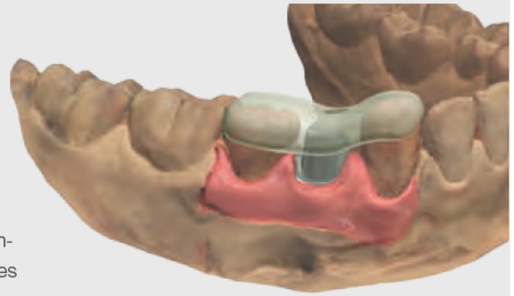
All types of abutments
Create customized abutments, screw-retained crowns and anatomical abutments.



Easily adjust to Gingiva
Snap emergence profile to gingiva or use freeform tools.

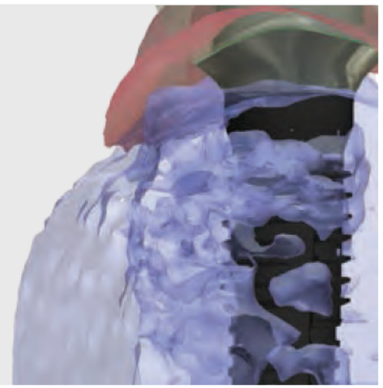
COMING Bone information
Improve abutment design by visualizing the jawbone.

Abutment bevel
Easily add abutment bevel to your design for optimal crown support.



NEW Add abutment position guides
Help your dentist easily and accurately place abutments, temporaries or veneers using custom designed positioning guides created in the same workflow.

More than 50 implant libraries
Get abutments from both original and compatible-with implant manufacturers covering all global and key regional players.
www.3shapedental.com/implant-systems*



COMING Bone information for better clinical results
Include bone data from CBCT scans to create better abutments without collisions and optimally shaped to the thickness of the gingiva.

**Only libraries using FDA-cleared components permitted in the US.*

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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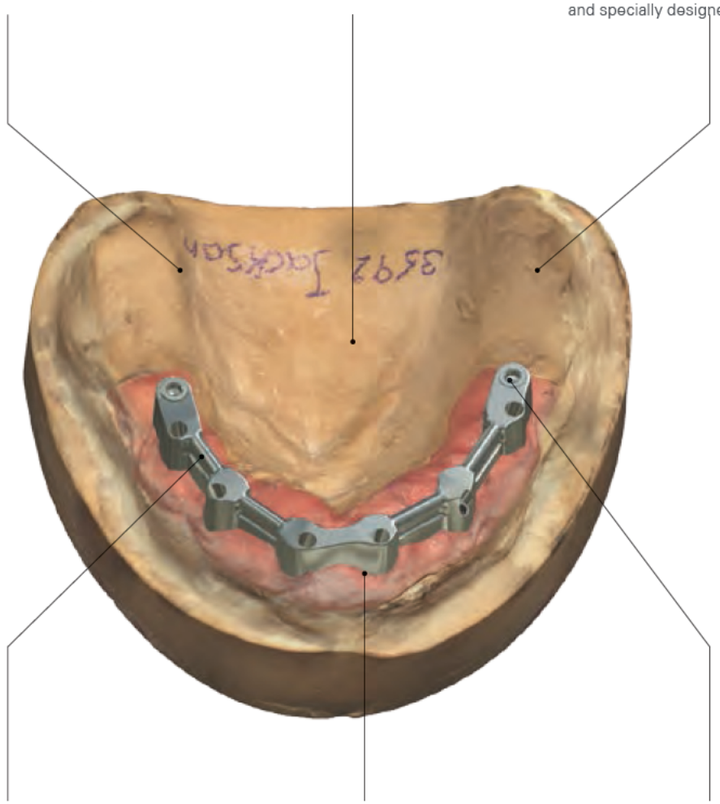
When accuracy and esthetics matter

Expand your lab's business by offering a high value service that is rapidly growing in demand. Design sophisticated implant bars and bridges with the utmost precision using flexible tools and ISO-documented 3Shape scanner accuracy.

Design any type of bar
Support for a wide range of standard bar and bridge types such as Primary, Dolder, Hader, Hybrid, Canada, and Wrap-around.

Extensive range of implant libraries*
Support for direct-seating and multi-unit abutments.

Proven bar accuracy with 3Shape scanners
Accuracy on all 3Shape scanners is verified and documented according to ISO12836 and specially designed implant objects.



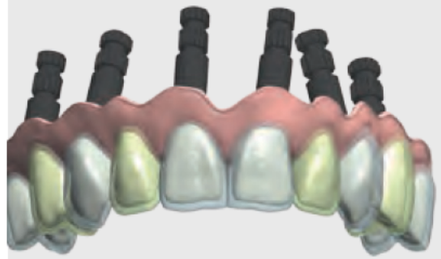
NEW Freely apply different types of bars
Combine multiple types in a single design with the new smooth surface transition that ensures an optimal finish.

NEW Improved finish with new Cut-to-gingiva
Match the bar to the underlying gingiva and achieve high quality with the newly enhanced surface finish.

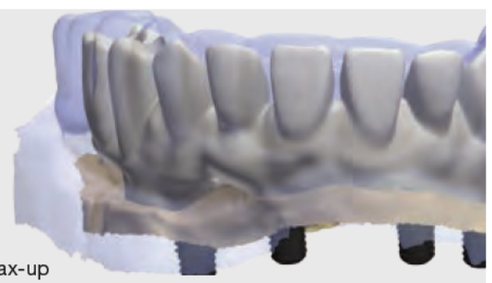
Add any type of attachment
Freely add slide or ball attachments, locators and retention holes. Adjust position and angle if needed.

**Only libraries using FDA-cleared components permitted in the US.*

COMING Perfectly matching secondary structures
Design your bar and then easily and precisely create its matching secondary according to the bar's attachments and form.



Esthetic implant bridges with gingiva
Easily design implant bridges complete with gingiva based on the final anatomy and a gingiva boundary that you define.



COMING Designs obtained directly from the Denture or Wax-up
Scan the denture and virtually cut back to facilitate design of an optimal implant bridge, or scan an original wax-up bridge to create a file for copy milling.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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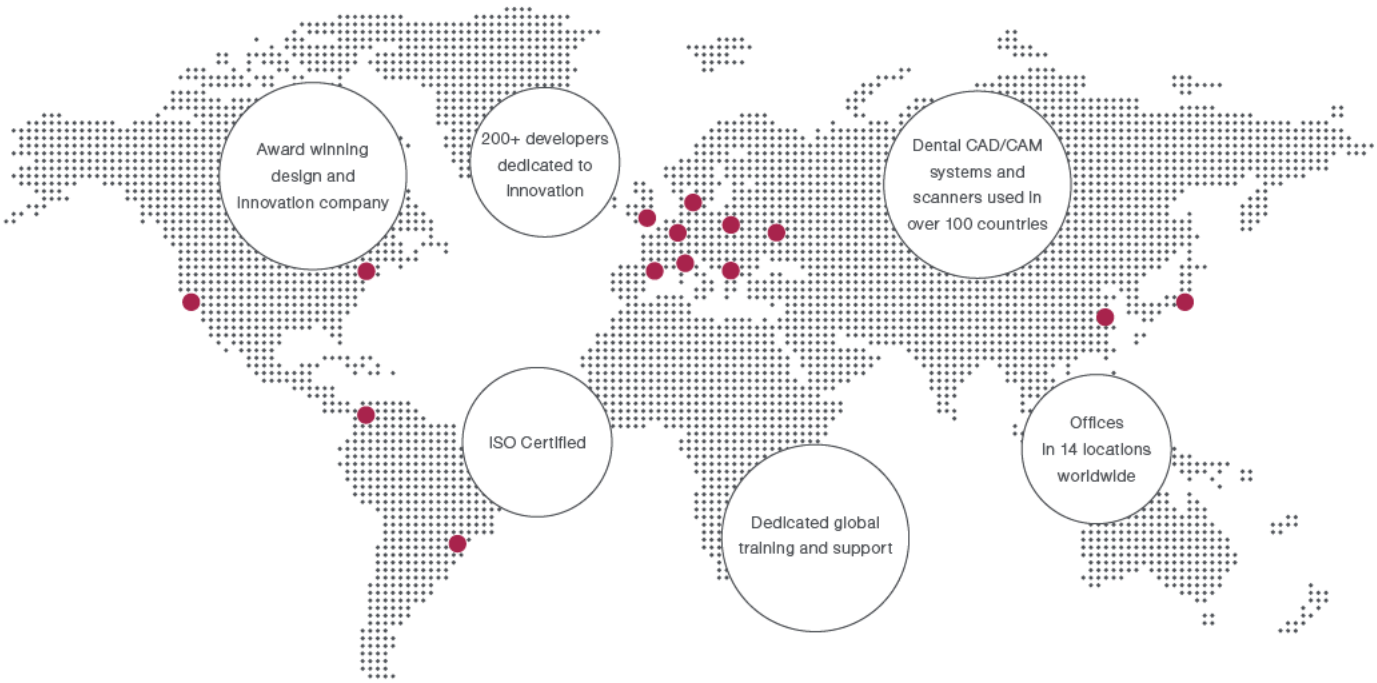
3Shape develops 3D technologies for dental practices and labs



Backing labs with care, technology and expertise

Expert Training

Unlimited Upgrade

Global Support

3Shape LABcare™ is an integral part of your annual 3Shape subscription. It bundles services that are designed to ensure your investment, secure maximum uptime, and help you get the most from your solution year after year.

Find 3Shape online

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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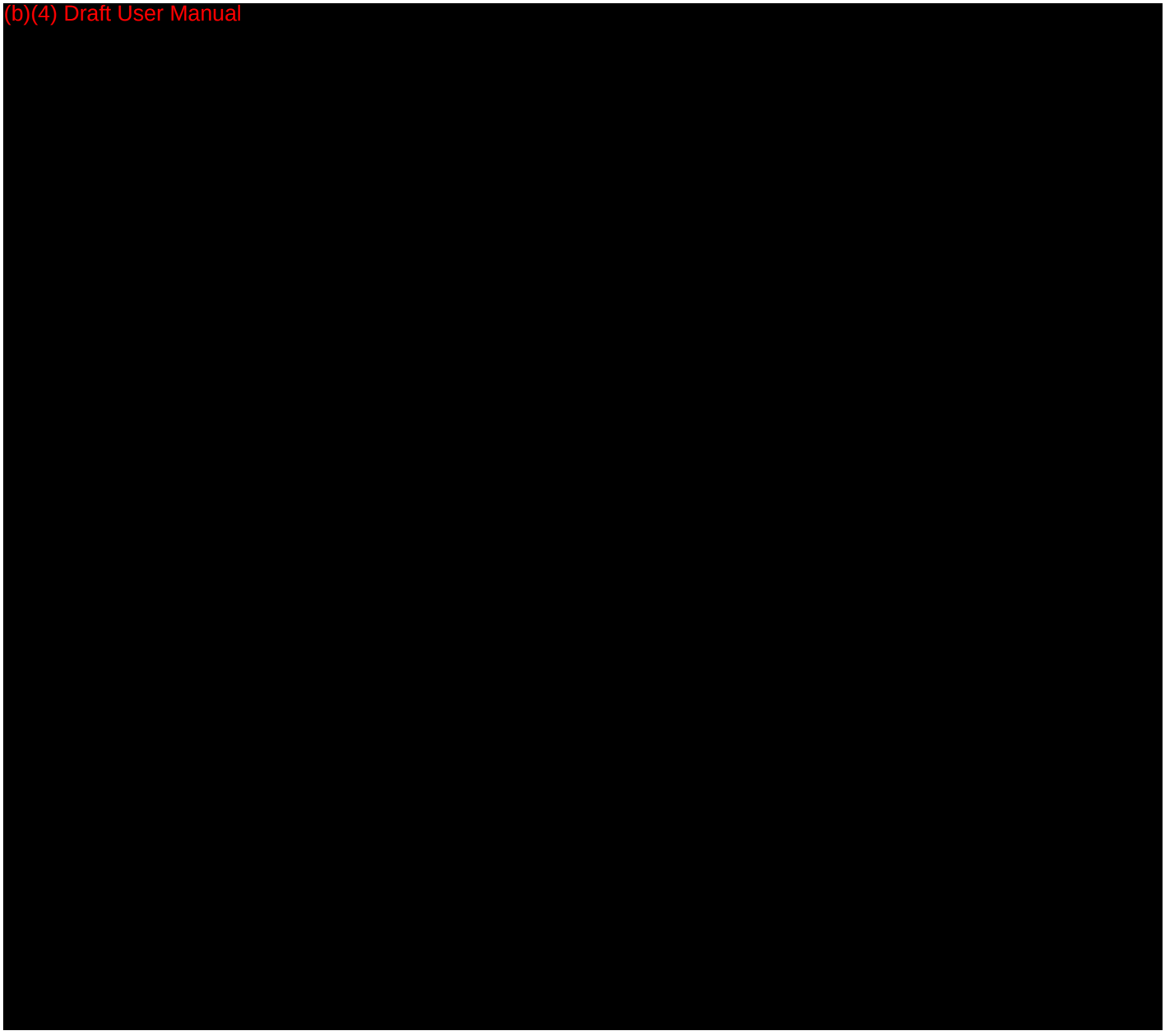
3Shape Dental System 2015

User Manual

(b)(4) Draft User Manual



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b)(4) Draft User Manual

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Appendix A: System Requirements

Item	Minimum Requirements	Recommended
OS	Windows 7 32-bit Professional*	Windows 7 64-bit Professional
RAM	4GB	8GB (16GB**)
Video Card	512MB DirectX 10 (1GB DirectX 10*) NVIDIA GeForce	1GB DirectX 11 (2GB DirectX 11*) NVIDIA GeForce
Available HDD Space	250GB	500GB (1TB***)
CPU	Intel Core i5 or equivalent	Intel Core i7 or equivalent
Monitor resolution	1920 x 1080 pixels	1920 x 1080 pixels
3D Mouse		3DConnexion SpaceMouse™ Pro
Network	Internet connection	
USB ports	USB 2.0 port for 3Shape desktop scanner****	
Mouse	Mouse with wheel button support	

* Minimum requirement for the Implant Studio is Windows 7 64-bit with 1GB DirectX 10 video card. 2GB DirectX 11 video card is recommended.
** For simultaneous scanning and modelling of large cases, we recommend 16GB RAM.
*** We recommend 1TB Hard Drive if used as a stand-alone system or a server with the order folder.
**** D250 scanners require serial port. For D250 scanners, 3Shape supports only PCs purchased from 3Shape as very few PCs are compatible.

Note!

- 3Shape Desktop scanners work only on USB 2.0 ports.
- 3Shape Desktop Scanners do not work on shared USB connections.
- It is recommended to connect keyboard, mouse and dongle to free USB 3.0 ports, when available.

Note! For D250 scanners, we recommend keeping the existing PC delivered with the system for scanning, and installing a new PC (Windows 7, 64-bit, 6-8 GB RAM) as a design station.

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Appendix G: Implant Libraries for 3Shape Dental System™

Providers of Implant Solutions	Implant Systems								Implant Solutions					Manufacturing		Consumables (for local use)				Additional info
	Nobel Biocare	Biomet3i	Straumann	Zimmer Dental	Astra Tech DENTSPLY	Friadent DENTSPLY	CAMLOG	Other systems	1-Piece (Titanium)	1-Piece (Zirconia)	2-Piece (Ti base + ZrAbutm)	Implant Bars & Bridges	Digital implant models	Providers milling center	Local milling by 3rd Party	Blanks with pre-milled interface	Titanium bases	Intraoral Scan bodies	Digital model analogs	Comments
Alpha Bio-Tec. (IL) www.alpha-bio.net								- Alpha Bio Tec	X		X	X	X		X	X	X			
Argen (US) www.argen.com	+	+	+	+	+	+			X		X			X		X	X	X	X	- FDA, CE
ATLANTIS™ (SE) www.dentsplyimplants.com	+	+	+	+	+	+	+	- Keystone Dental - BioHorizons	X	X				X						- FDA, CE
BEGO (DE) www.bego.com	+	+	+	+	+	+	+	- BEGO Implant Systems - and more	X	X	X	X		X			X	X		- FDA, CE - CE-labelled prosthetic screws
BioComp (NL) www.biocomp.eu								- BioComp	X		X				X	X	X	X	X	- CE, ISO
Biodenta (CH) www.biodenta.com	+	+	+	+	+		+	- Biodenta	X		X	X	X	X				X	X	- FDA, CE pending
BioHorizons (US) www.biohorizons.com	+		+	+				- BioHorizon	X		X				X	X	X	X		- FDA, CE
Biomet (US) www.biomet.com	+	+	+						X	X	X			X				X		- FDA, CE - Encode® healing abutments
Biotech International (FR) www.biotech-dental.com								- Biotech			X		X		X		X	X	X	- CE
Bredent (DE) www.bredent.com								- Sky			X				X		X	X	X	- FDA, CE

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CADBLU (US) www.cadbludental.com	+	+	+	+	+			- Bio Horizons - MIS Implants	X		X	X	X	X				X	X	- FDA
CAMLOG (CH) www.camlog.com							+	- CONELOG - iSy	X		X	X		X	X		X	X		
CAP (US) www.cap-us.com	+	+	+	+	+	+			X		X	X	X	X	X	X	X		X	
CMC (US) www.custom-milling.com	+	+	+	+	+	+	+	- Bio Horizons - Osstem - LifeCore - Ultra-Lock - Neoss	X	X	X	X		X				X		- FDA, CE
Core3D International (NL) www.core3dcenters.com	+	+	+	+	+	+	+	- Avinent - BioComp - BioHorizons - MIS Implants - and many more	X		X	X	X	X	X	X	X	X	X	- FDA, CE, Health Canadà, TGA (AUS), Taiwan regulatory - MHLW:Ministry of Health, Labour and Welfare (JP)
C-Tech Implant (IT) www.c-tech-implant.com								- C-Tech Implant	X		X	X			X		X			- CE
Degudent (DE) www.degudent.com	+	+	+	+	+	+	+	- Medentika	X	X	X			X	X		X			
Dental Consulting (DE) www.gadau-consulting.com	+		+	+	+	+	+	- ICX-Medentis - Osstem	X		X	X	X	X	X	X	X	X	X	- FDA pending, CE
Dentaurum Implants (DE) www.dentaurum-implants.de								- Dentaurum Implants			X				X		X	X		- CE, PAL
Dentegris Deutschland (DE) www.dentegris.de								- Dentegris Implants			X	X			X		X			
Dentsply-Friadent (DE) www.dentsply-friadent.com						+		- Xive - Ankylos	X	X	X			X						- CE
DESS (ES) www.dess-abutments.com	+	+	+	+	+	+		- BioHorizon	X		X			X	X		X	X		- CE - ISO 13485 - ISO 9001
Digital Dental Group-DDG (ISR) www.ddg-scanlab.com	+	+	+	+	+	+	+	- Microdent - BioHorizons - MIS-Implants - and more	X	X	X	X			X	X	X	X	X	- FDA pending, CE
DIO-Implants (KR) www.dioimplant.com	+							- DIO Implants	X	X	X	X		X	X					- FDA,CE, KFDA, SFDA

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Elos Medtech Pinol (DK) www.elosmedtech.com	+	+	+	+	+	+	+	- Neoss	X		X	X	X	X	X	X		X	X	- FDA, CE
EuroTeknika (FR) www.euroteknika.com	+	+	+	+	+			- Anthogyr - Biotech - Easy Implant - MIS Implants - and more	X		X	X	X	X		X	X	X	X	- FDA, CE
GC Advanced Technologies (US) www.gc-at.com	+	+	+	+	+			- BioHorizons - Sybron	X	X	X			X						
Glidewell (US) www.glidewelldental.com	+	+	+	+	+	+	+	- Prismatik DentalCraft - Keystone Dental - Neoss	X	X	X	X	X	X			X	X	X	- FDA, CE pending
Heraeus Kulzer (DE) www.heraeus.com	+	+	+	+	+	+	+	- Thommen	X	X	X		X	X						
Ivocar Wieland (DE)	+	+	+	+	+	+		- Dentaurum Implants	X		X	X		X	X		X		X	
LaStruttura (IT) www.lastruttura.it	+	+	+	+	+	+		- Sweden&Martina - Megagen - Prodent - and many more	X	X		X	X	X				X	X	- CE 93/42
Medentika (DE) www.medentika.de	+	+	+	+	+	+	+	- Medentika M-Implant	X		X	X		X	X	X	X	X		- CE
Medentis Medical (DE) www.medentis.de	+		+		+	+		- ICX Templant	X		X	X	X	X			X	X		- CE
Medical Production (FR) www.medical-production.eu					+			- Euroteknika	X		X	X	X		X	X	X	X		- CEO 499 - ISO 9001 - ISO 13485
MIS Implants Technology (IL) www.mis-implants.com								- MIS Implants			X				X		X			- FDA, CE
Neodent (BR) www.neodent.com.br	+		+					- Neodent Implant Systems	X	X	X	X			X			X		
Neoss (UK) www.neoss.com	+	+	+	+	+			- Neoss	X		X	X	X	X	X	X	X		X	- FDA, CE
Nobel Biocare (CH) www.nobelbiocare.com	+	+	+	+	+				X	X	X			X						- FDA, CE
NT Trading (DE) www.nt-trading.com	+	+	+	+	+	+	+	- Thommen - Sweden&Martina	X		X	X		X	X	X	X	X	X	- FDA, CE, CMDCAS, GOST R, TGC - Mexico

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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								- BEGO											Certification
Phibo (ES) www.phibo.com	+	+	+	+	+	+	+	- PHIBO - BTI - Sweden&Martina - MIS Implants - and many more	x	x	x	x	x	x				x	x	- FDA, CE - ISO 13485 - ISO 9001
Prowital (DE) www.prowital.de								- Prowital			x				x		x	x	x	- CE - EN-ISO 9001-V472008 - EN ISO-13485-2003AC2009 - Certificate Directive-93-42 EWG
Ritter Implants (DE) www.ritterimplants.com			+	+				- Alpha-BioTec. - MIS Implants	x		x		x		x		x	x	x	x	- FDA, CE
Straumann (CH) www.straumann.com			+						x	x	x			x	x		x	x		- CE
Sweden&Martina S.p.A (IT) www.sweden-martina.com								- Sweden&Martina	x	x	x	x	x	x			x	x	x	
Target3D (USA) www.target3d.com	+	+	+	+	+	+	+	- Osstem - Bio Horizons - MIS-Implants - and more	x	x	x	x	x		x	x	x	x	x	- FDA, CE
Thommen Medical (CH) www.thommenmedical.com								- Thommen			x	x					x	x		- FDA, CE
TRI Implants (CH) www.tri-implants.com								- TRI Implants			x						x	x	x	
3dental (ES) www.3dental.es	+	+	+	+	+	+		- BioComp - Sweden&Martina - DYNA	x	x		x	x	x					x	

+ -Available for Dental System™ x -Available from the manufacturer

Note! All information is given without guarantee and based exclusively on information made available by the implant system providers. Please contact your local 3Shape re-seller to obtain the most current list.

Note! Only Implant Libraries based on Dental Implants with 510(k) clearance can be used in Abutment Designer™ in the United States. Cleared libraries must be activated by 3Shape. Please ask your Implant Library Provider to contact 3Shape if you wish to use a cleared library that has not already been activated. The software will block any attempt to use a non-cleared library.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Appendix H: Terms and Abbreviations

The following table explains file type abbreviations used in 3Shape Dental System.

File Format	Description
3ML	Zipped, compressed XML file typically used for setup and customization. 3Shape proprietary format.
3SE	3Shape and Sirona proprietary format for exported orders. Orders from Sirona system, can be imported into 3Shape system.
3OX	3Shape Communicate Order Exchange format used by partners and customers to retrieve and send orders. 3Shape proprietary format.
3OXZ	Zipped archive containing 3OX file and references to DCM models. 3Shape proprietary format.
3SI	3Shape and Sirona proprietary format for imported orders. Orders exported from 3Shape system, can be imported into Sirona system.
DCM	Dental Compressed Model file. Contains compressed 3D model data, attached objects (splines, annotations, etc.), marks and additional string properties. 3Shape proprietary format used for scans and CAD designs.
DLL	Dynamic-link library, Microsoft shared library concept.
DME	Dental System Material Export file. Contains materials, references to materials and external files. The file can be imported into another 3Shape Dental System. 3Shape proprietary format.
STL	Describes surface geometry of three-dimensional objects. Used for scans and CAD designs. Industry standard.
ULDC	3M Lava proprietary format. Order files from 3M scanners can be imported into 3Shape System.
XML	Extensible Markup Language, used for configuration files, etc.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Appendix I: Contact Information

3Shape Headquarters

Europe, Middle East & Africa Sales
Holmens Kanal 7
1060 Copenhagen K
Denmark

P: +45 70 27 26 20

3Shape North America

North American Sales
Somerset Hills Corporate Center
10 Independence Boulevard,
Suite 150
Warren, New Jersey
07059, USA

P: +1 908 867 0144

3Shape (Shanghai) Co., Ltd

Asian Sales
Room 906, Tower A of Eton Place
No. 69, Dongfang Road
200120 Shanghai,
China

P: +86 21 5835 2281

3Shape South America

Latin American and Caribbean Sales
Carrera 13 # 82-91
Oficina 401
110221 Bogotá,
Colombia

P: +57 1 691 95 08

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2016-8070; Released by CDRH on 05/25/2017

K151455/S001

3shape

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center - WO66-G609
10903 New Hampshire Avenue
Silver Spring, Maryland 20993-0002
USA

FDA/CDRH/DCC
JAN 11 2016
RECEIVED

January 8, 2016

Re: 510(k) # K151455/S001 Additional Information (AI) Request – Replacement eCopy

Att.: Document Mail Clerk

Enclosed please find our reply to the Additional Information request received by email July 31, 2015. The following documentation has been included:

Document ID	Title	Starting Page Number
001	AI1 Reply – Cover Letter	1
002	AI1 Reply	3
003	510(k) Summary	19
004	Substantial Equivalence Comparison	23
005	Software Description	26
006	Vertical Offset Description	34
007	Device Hazard Analysis	35
008	Cyber Security Analysis	36
009	Architecture Design Chart	37

14

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2016-8070; Released by CDRH on 10/5/2017

Document ID	Title	Starting Page Number
010	Software Design Specification	43
011	Traceability Analysis	44
012	Unresolved Anomalies	49
013	Proposed Labeling	51
014	Indications for Use Statement	52
015	SW Requirement Specifications	53
016	Verification and Validation	54
017	Product Risk Assessment	57
018	SW-SOP-0011 – Handling of FDA Cleared Implant Libraries in 3Shape Software	60
019	Appendix 1 – Library Confirmation Letters	61
020	Appendix 2 - User Manual / Labeling	63

Submission copies: 2 (eCopy and paper). The eCopy is an exact duplicate of the paper copy.

Best regards,
3Shape A/S

Hanne Nielsen
Regulatory Affairs Manager

3Shape A/S, CVR-no.: 2555 3489 Holmens Kanal 7, 1060 Copenhagen, Denmark, Tel: +45 7027 2620 www.3Shape.com

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2016-8070; Released by CDRH on 10/5/2017

K151455/S001

FDA CDRH DMC

DEC 09 2015

Received

3shape

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center - WO66-G609
10903 New Hampshire Avenue
Silver Spring, Maryland 20993-0002
USA

December 7, 2015

Re: 510(k) # K151455/S001

Att.: Document Mail Clerk

Enclosed please find revised electronic copy of Appendix 1 of the above mentioned submission. No changes have been made to the paper version of the documentation submitted October 14th. The following documentation has been included:

Document ID	Title	Starting Page Number
001	AI1 Reply – Cover Letter	1
019	Appendix 1 – Library Confirmation Letters	61

Submission copies: 2 (eCopy and paper). The eCopy is an exact duplicate of the paper copy.

Best regards,
3Shape A/S

Hanne Nielsen
Regulatory Affairs Manager

3Shape A/S, CVR-no.: 2555 3489 Holmens Kanal 7, 1060 Copenhagen, Denmark, Tel: +45 7027 2620 www.3Shape.com

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2016-8070; Released by CDRH on 10/5/2017

Received
OCT 19 2015
FDA CDRH DMC

3shape

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center - WO66-G609
10903 New Hampshire Avenue
Silver Spring, Maryland 20993-0002
USA

FDA CDRH DMC
OCT 19 2015
Received

October 15, 2015

K151455/S001

Re: 510(k) # K151455 Additional Information (AI) Request

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3Shape A/S, CVR-no.: 2555 3489 Holmens Kanal 7, 1060 Copenhagen, Denmark, Tel: +45 7027 2620 www.3Shape.com

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2016-8070; Released by CDRH on 10/5/2017

Document ID	Title	Starting Page Number
011	Traceability Analysis	44
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013	Proposed Labeling	51
014	Indications for Use Statement	52
015	SW Requirement Specifications	53
016	Verification and Validation	54
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Best regards,
3Shape A/S

Hanne Nielsen
Regulatory Affairs Manager

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3shape

Food and Drug Administration
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January 8, 2016

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510(k) # K151455

Reply to Additional Information #1 request dated July 31, 2015

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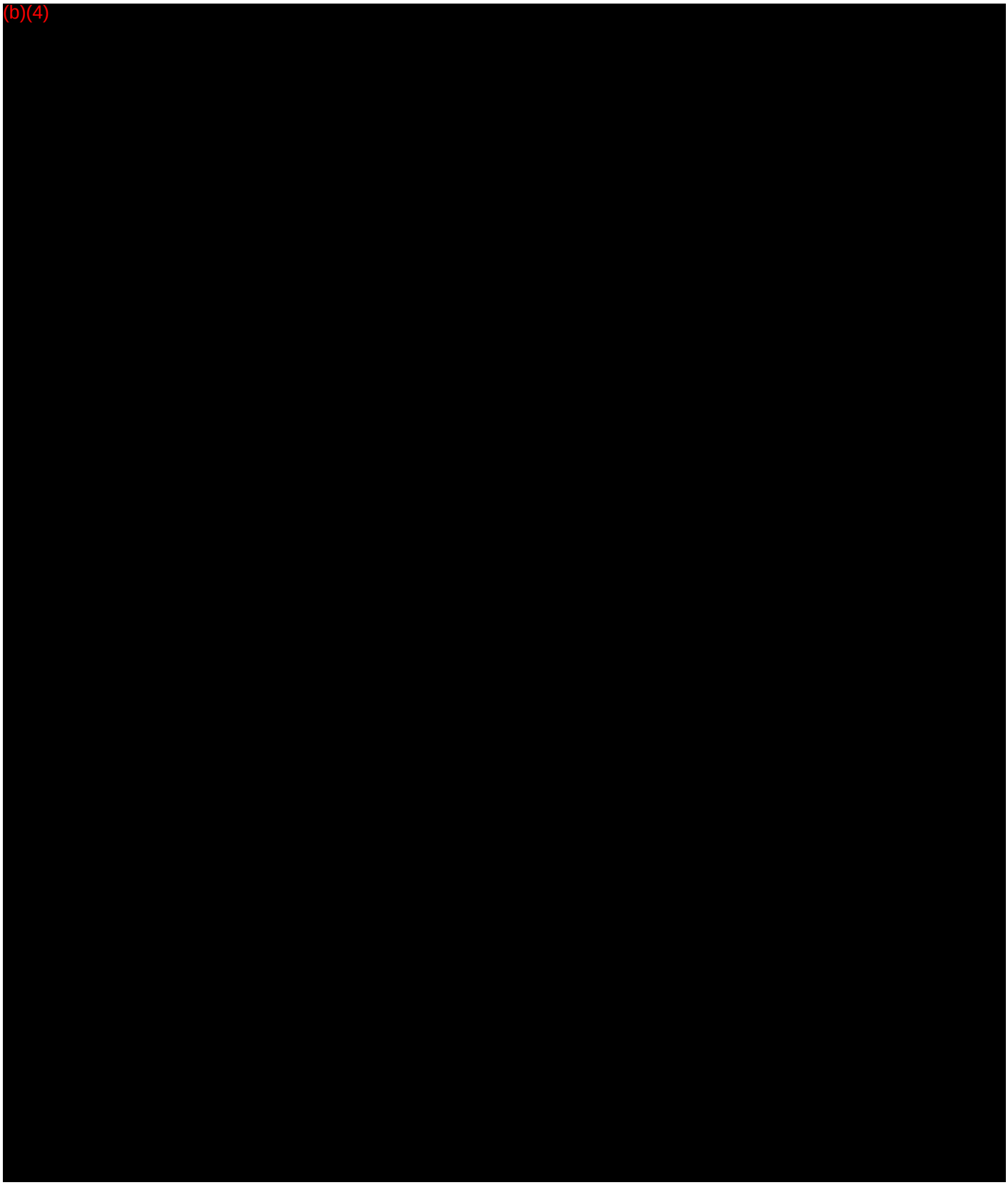

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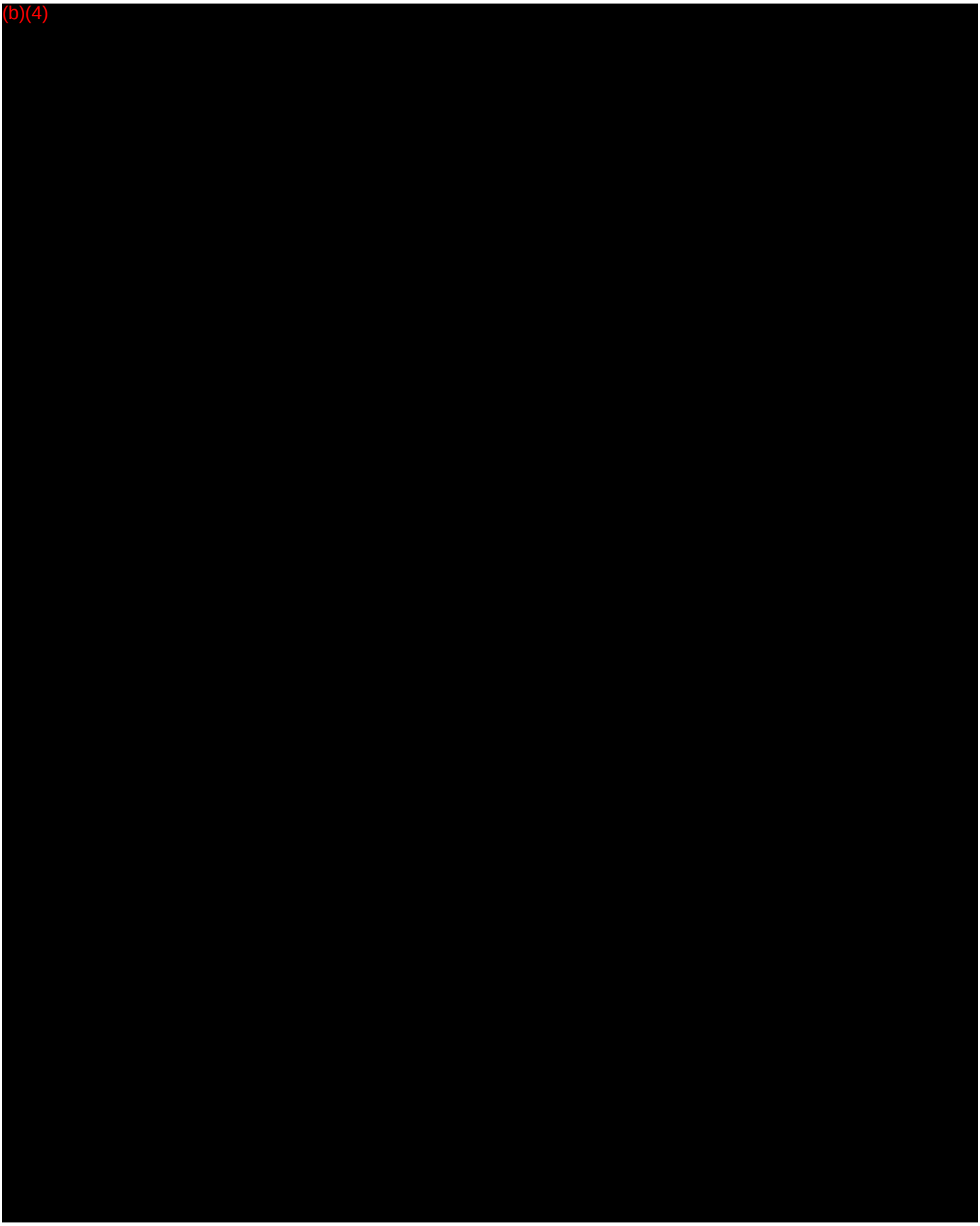

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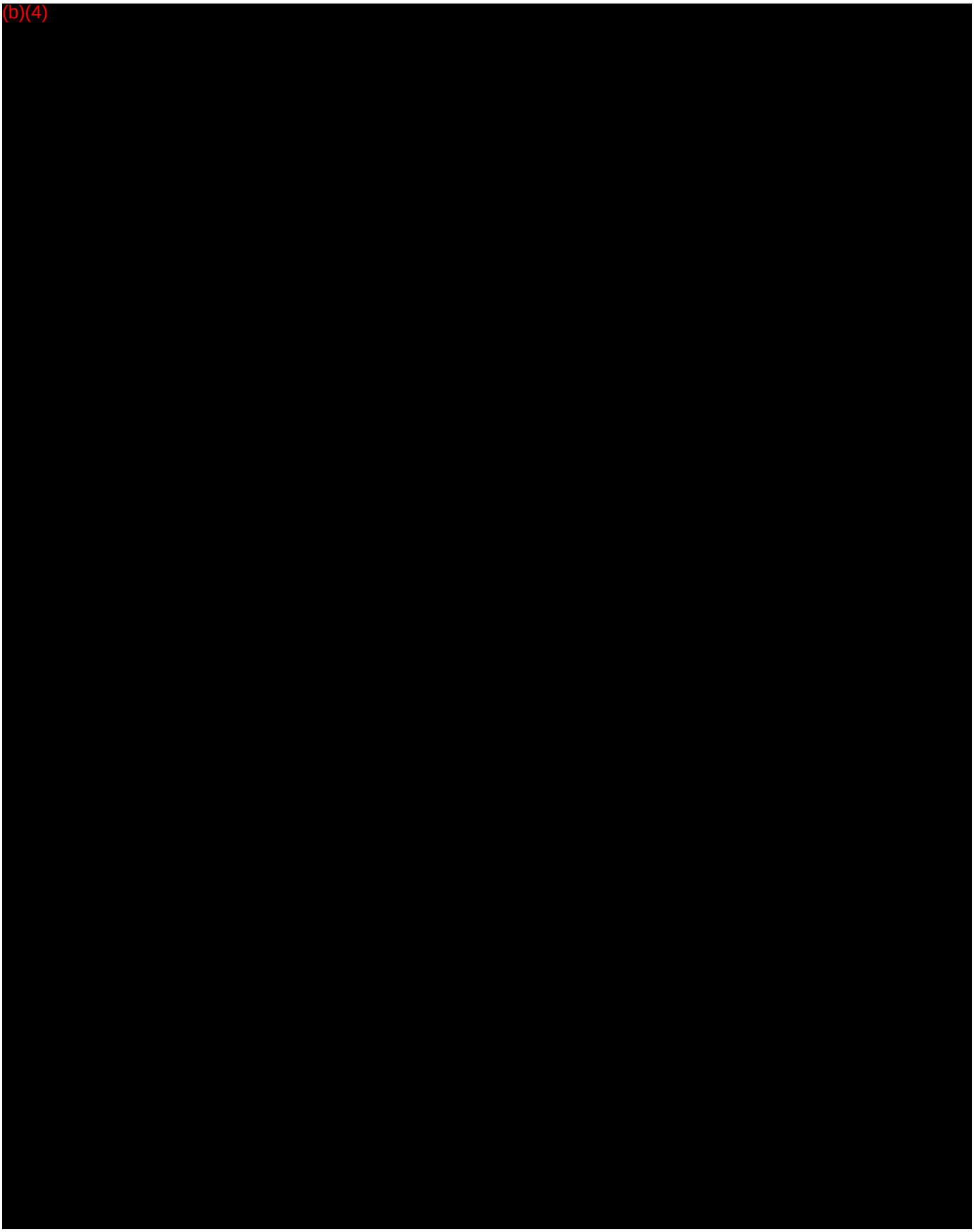

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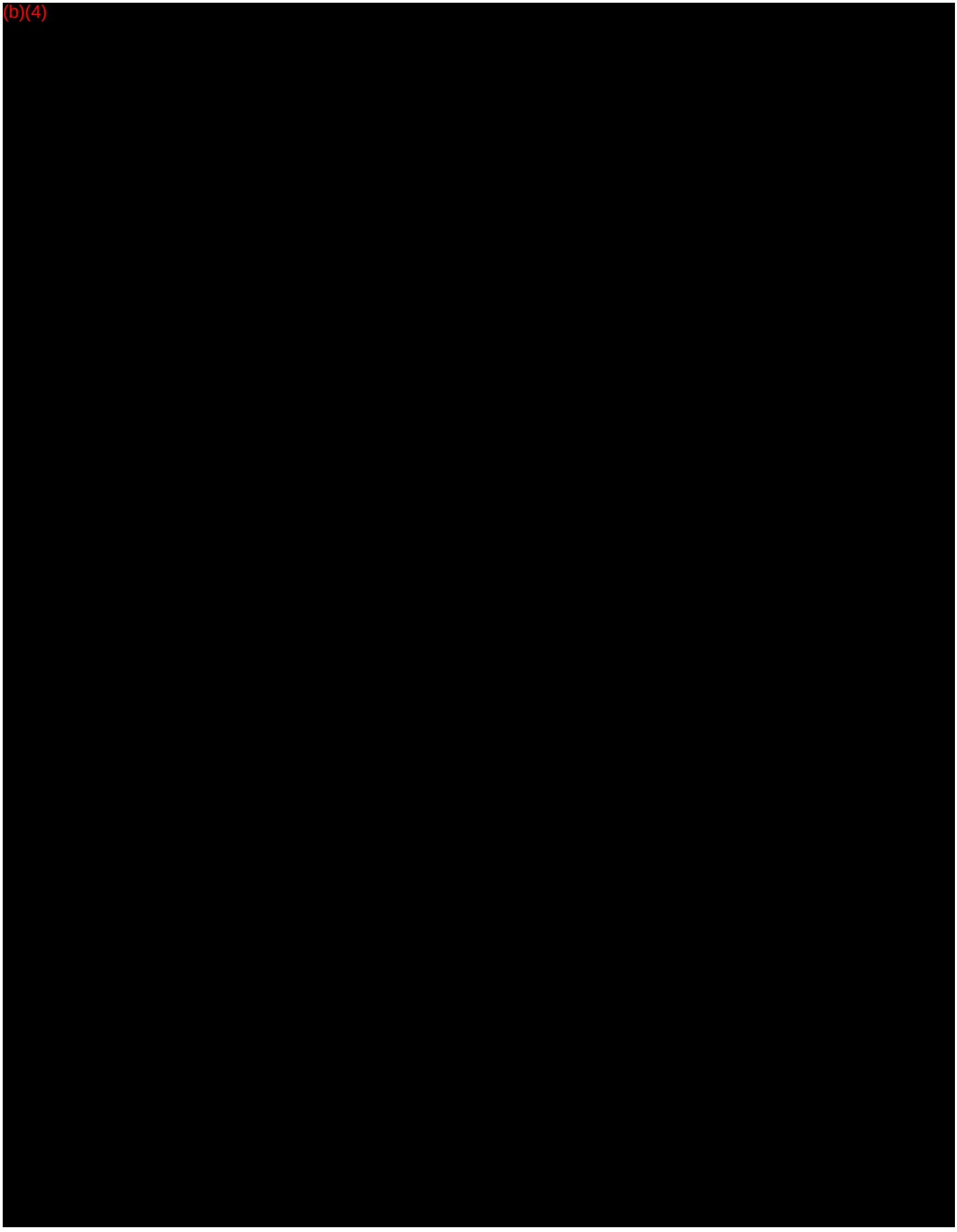

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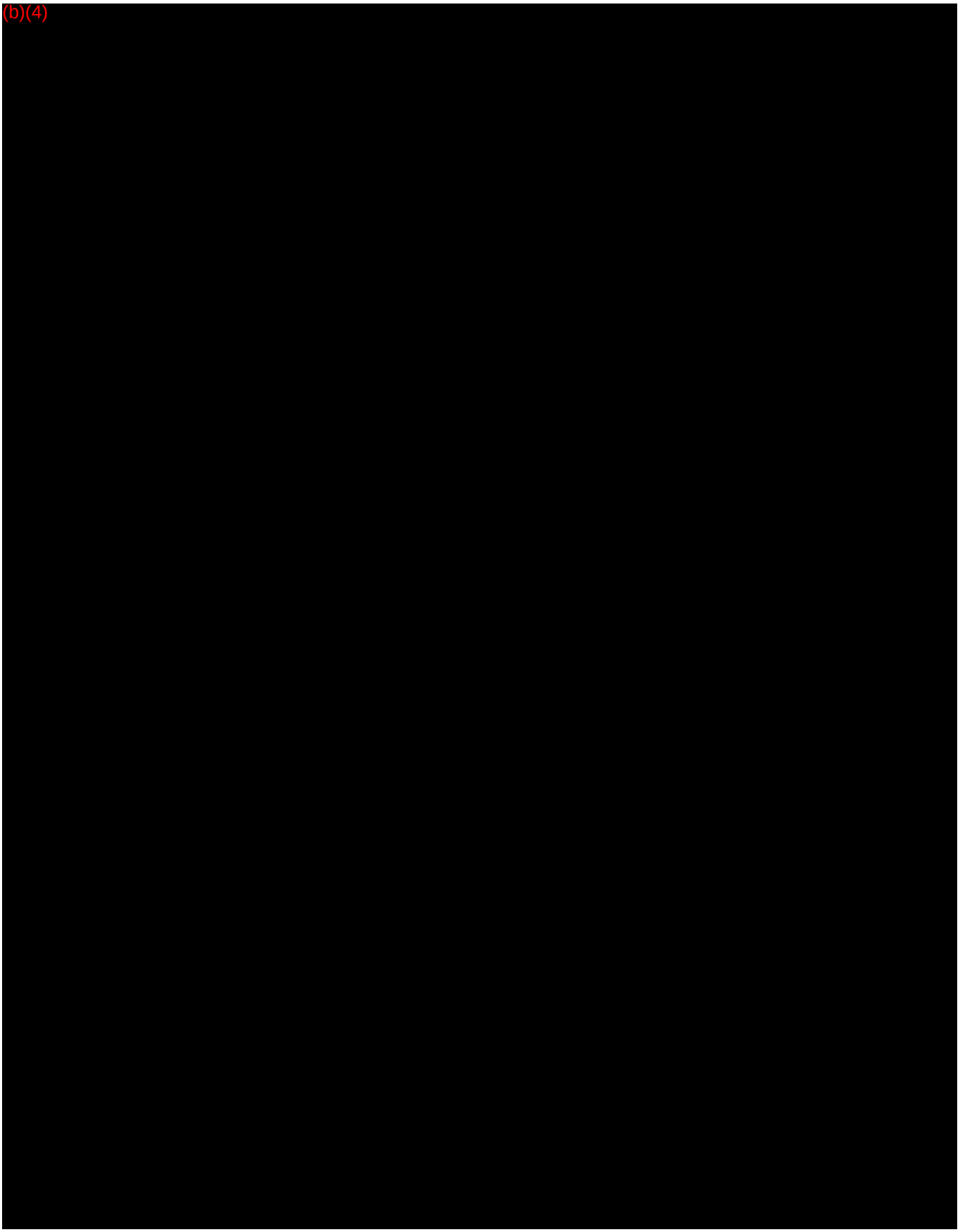

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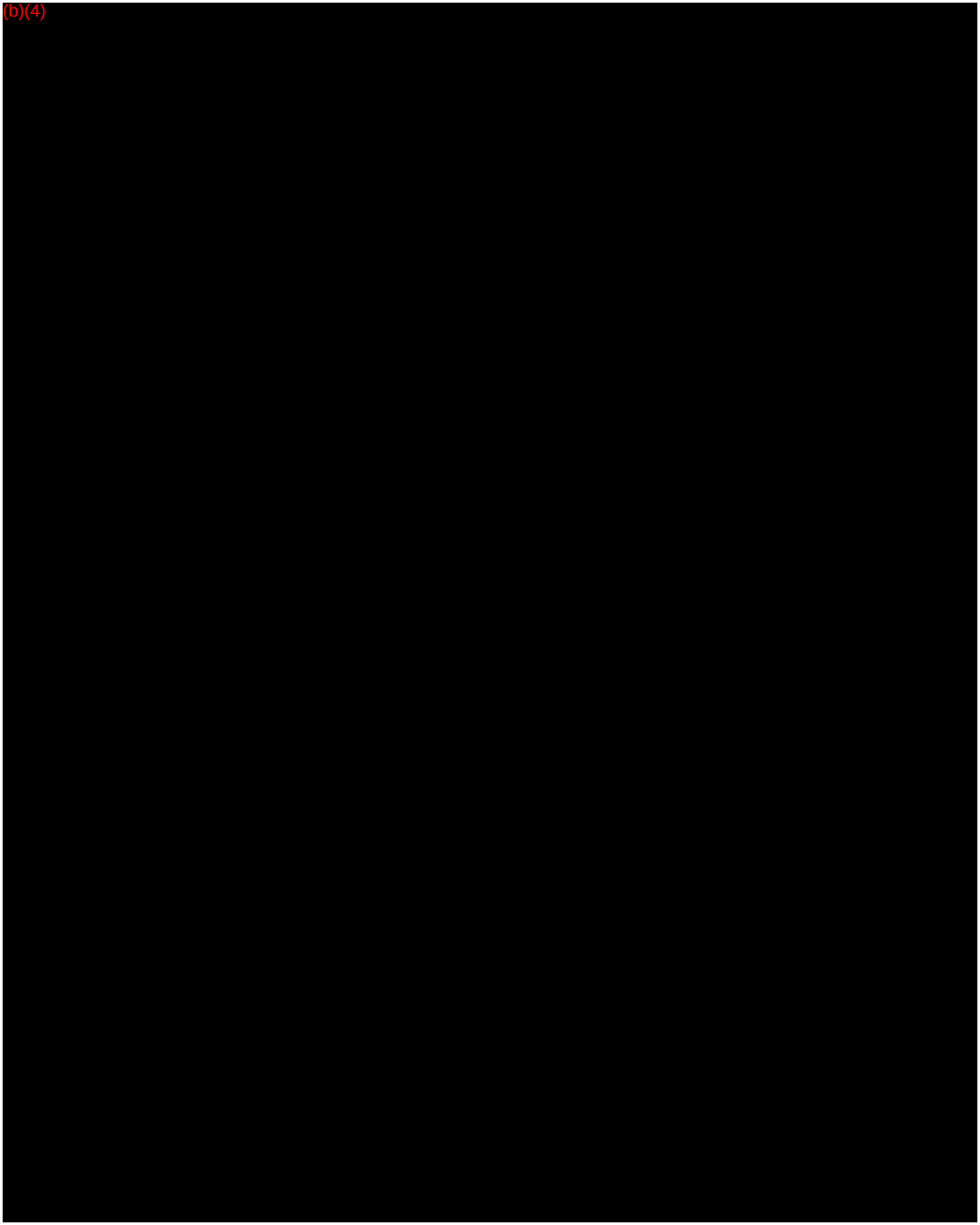

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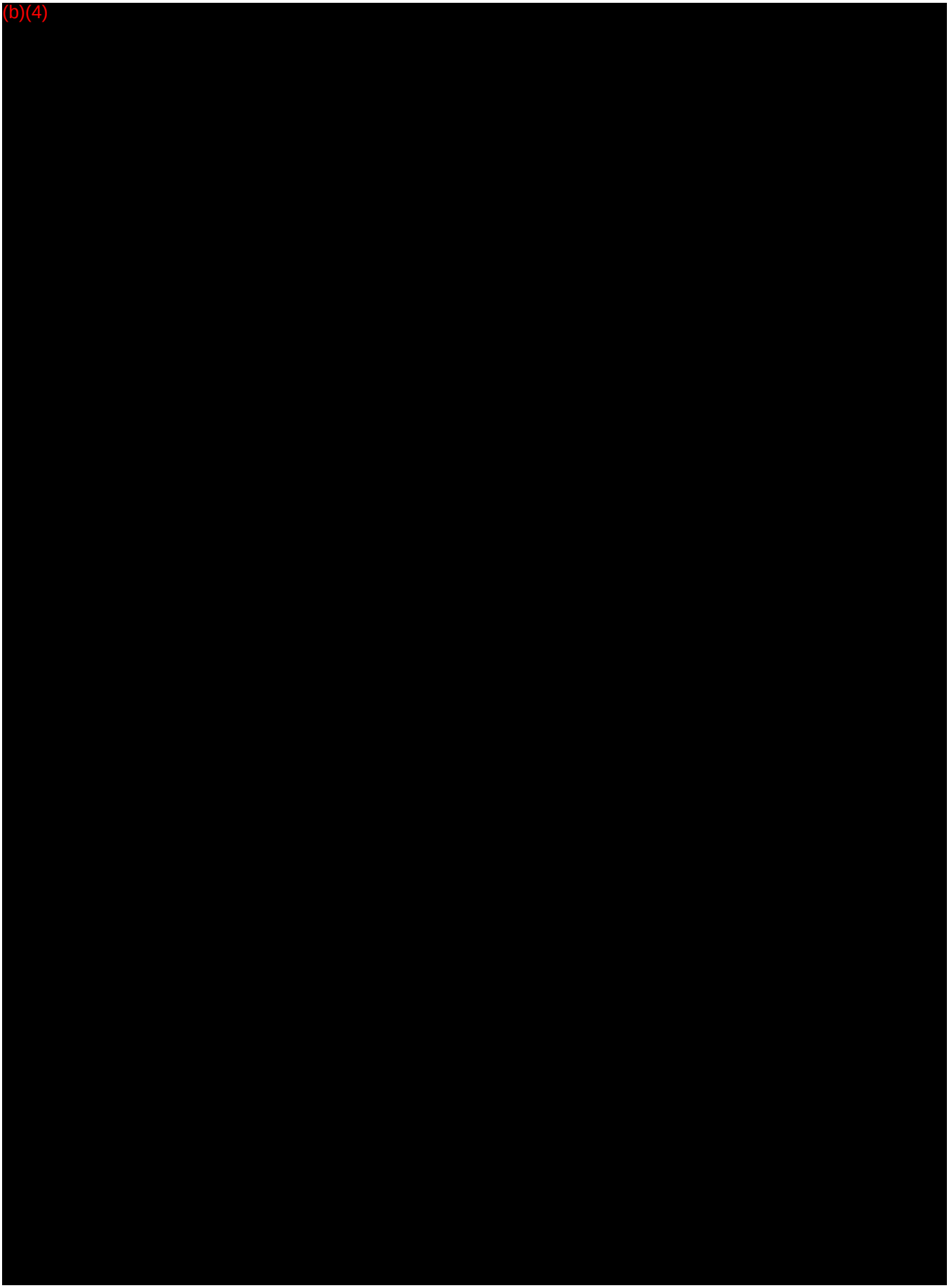

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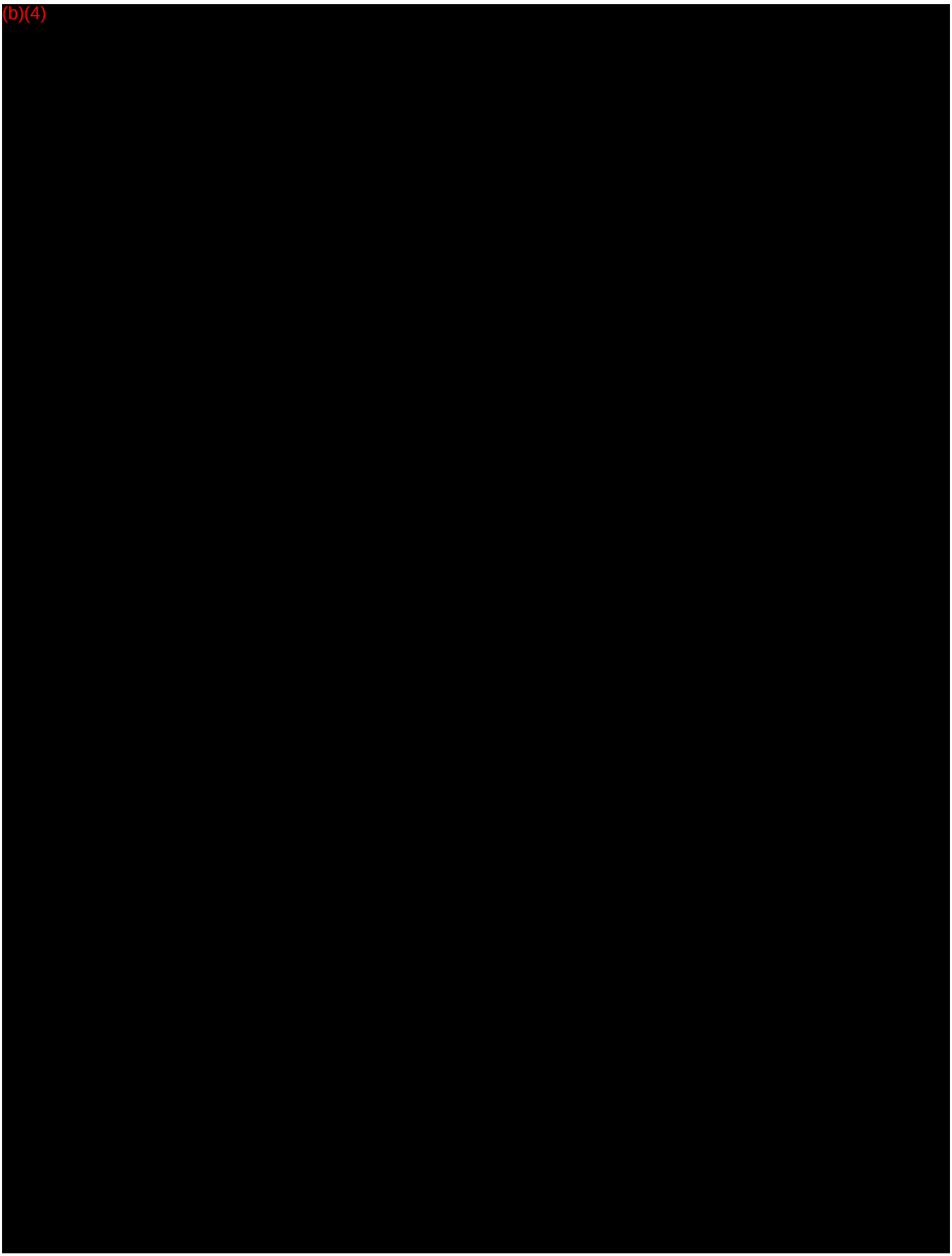

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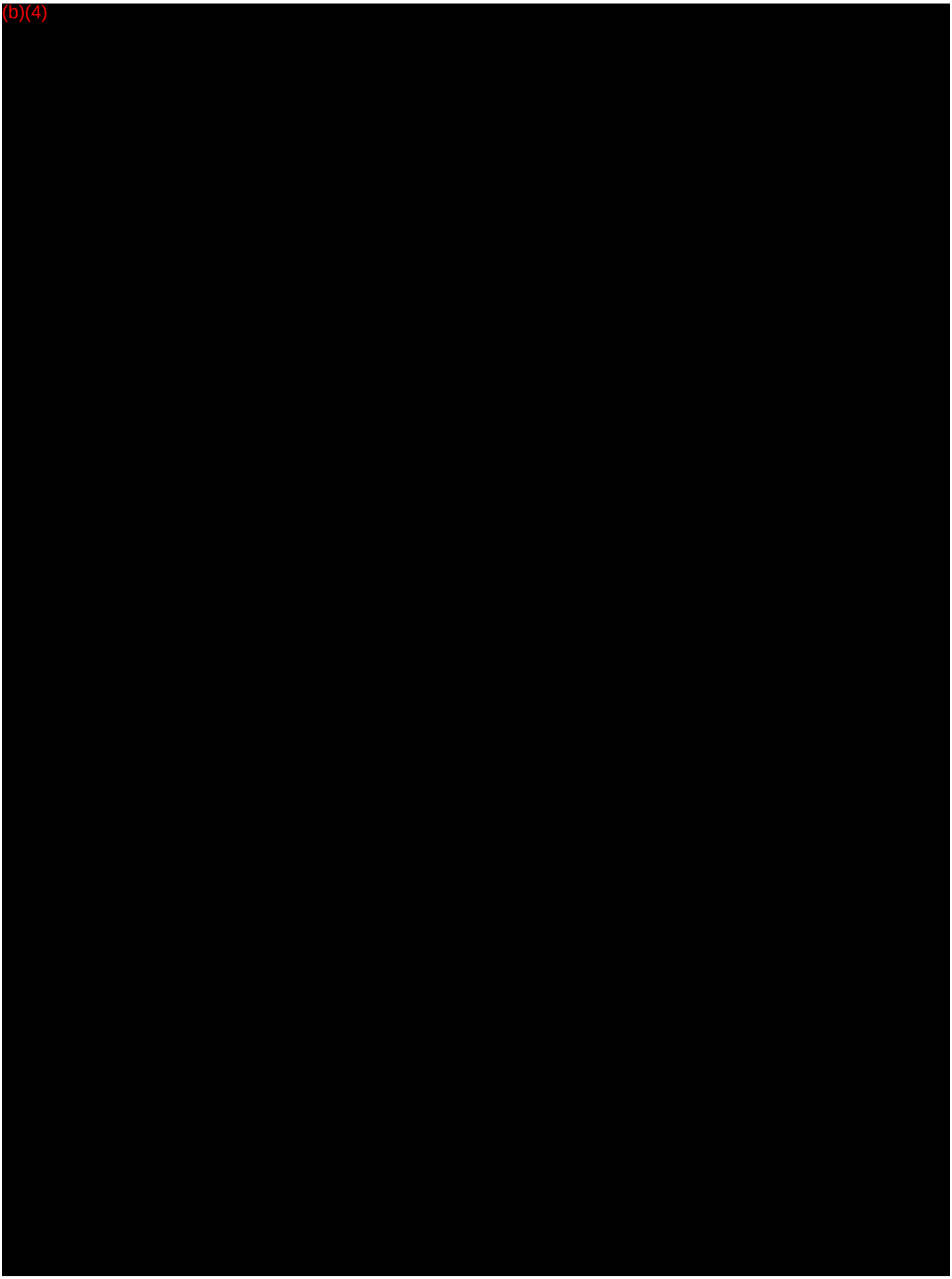

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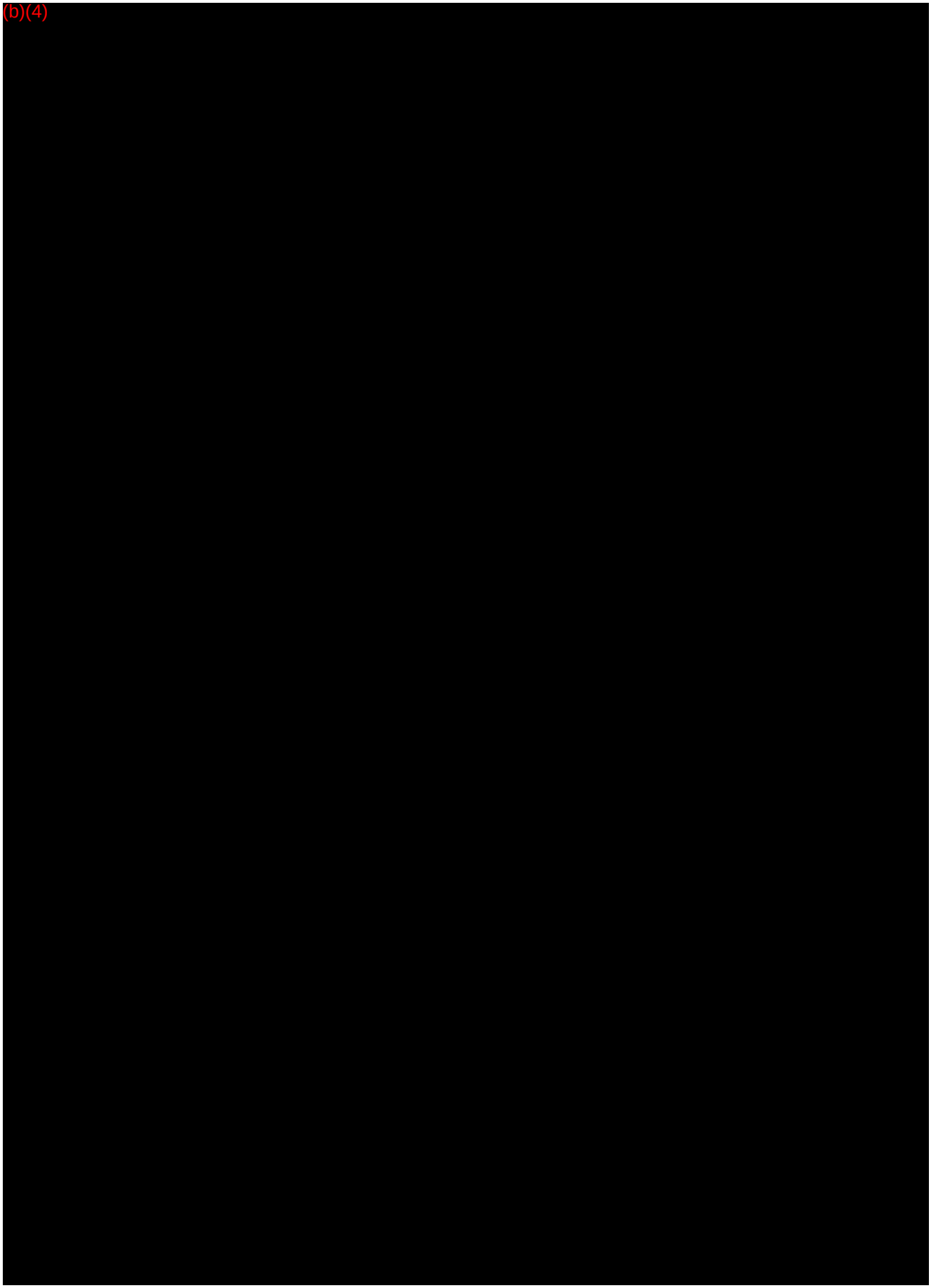

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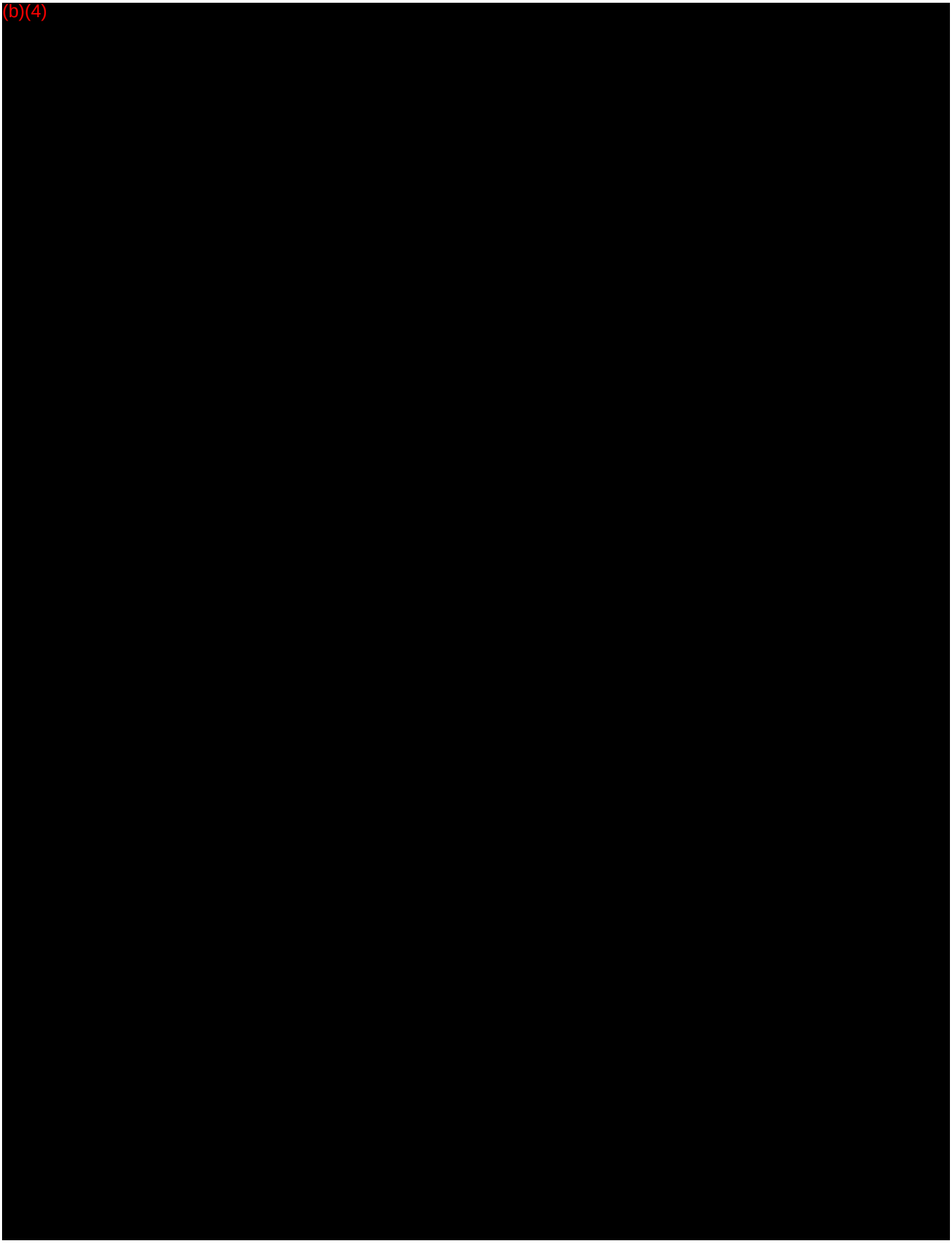

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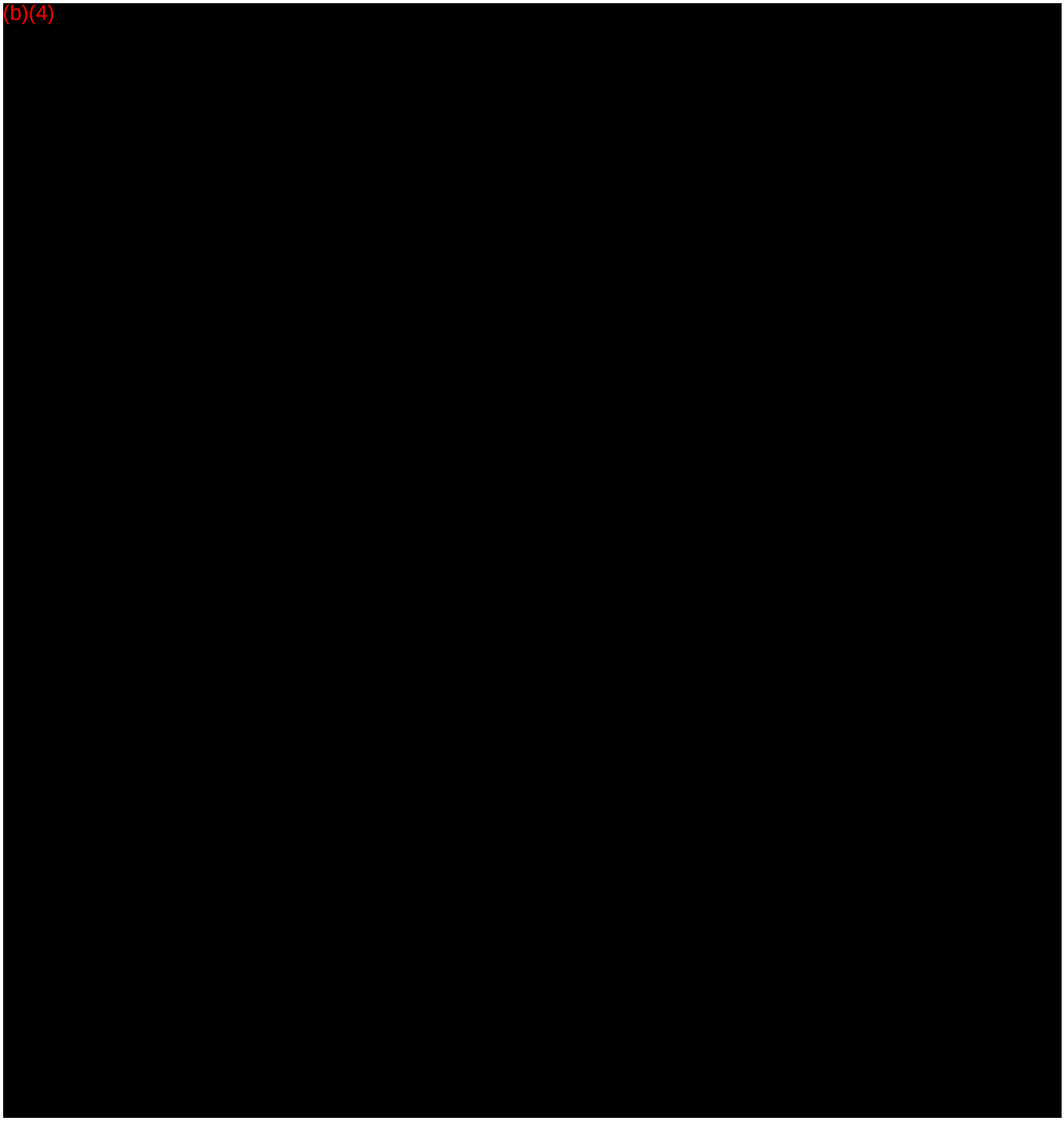

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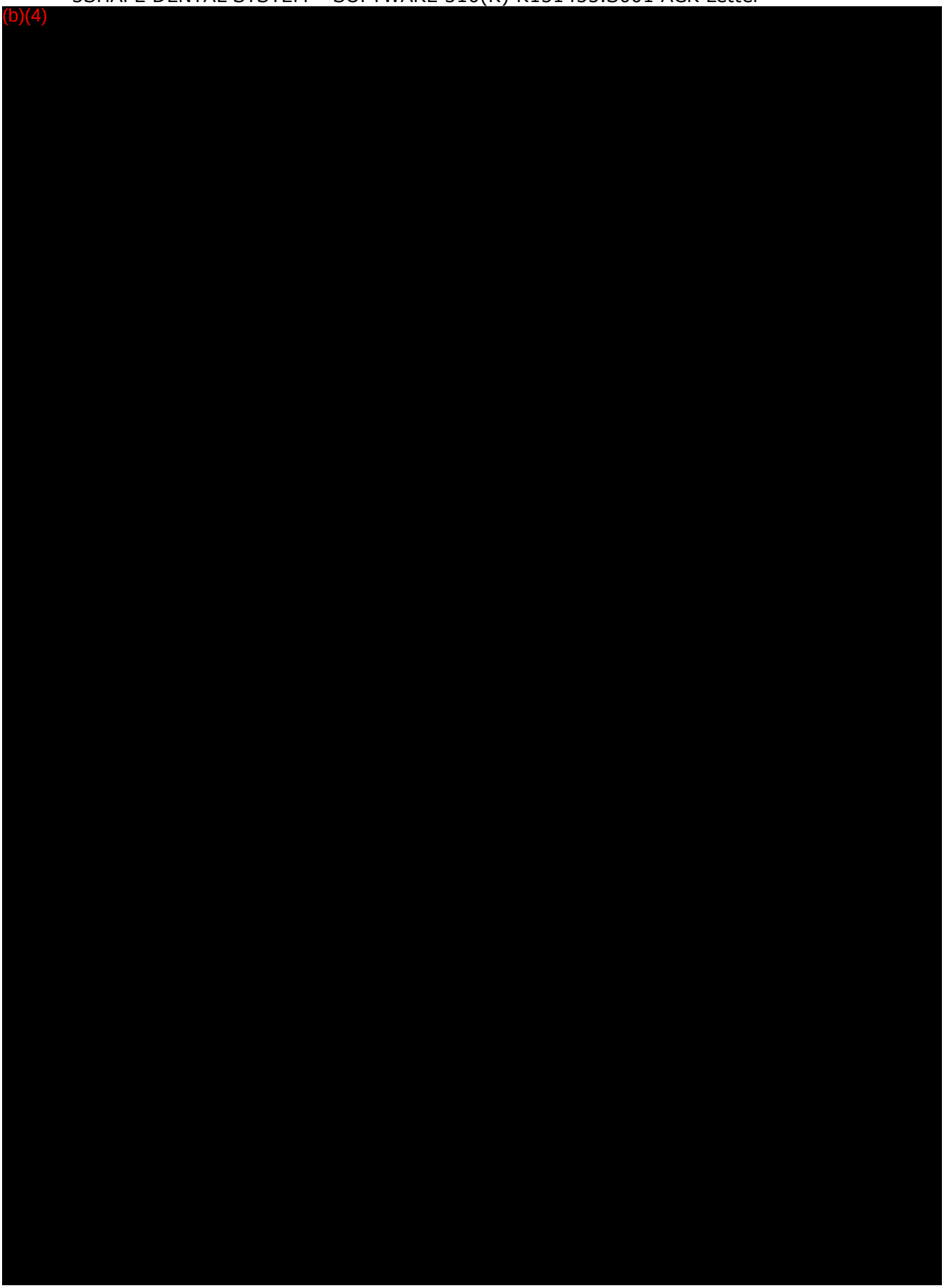

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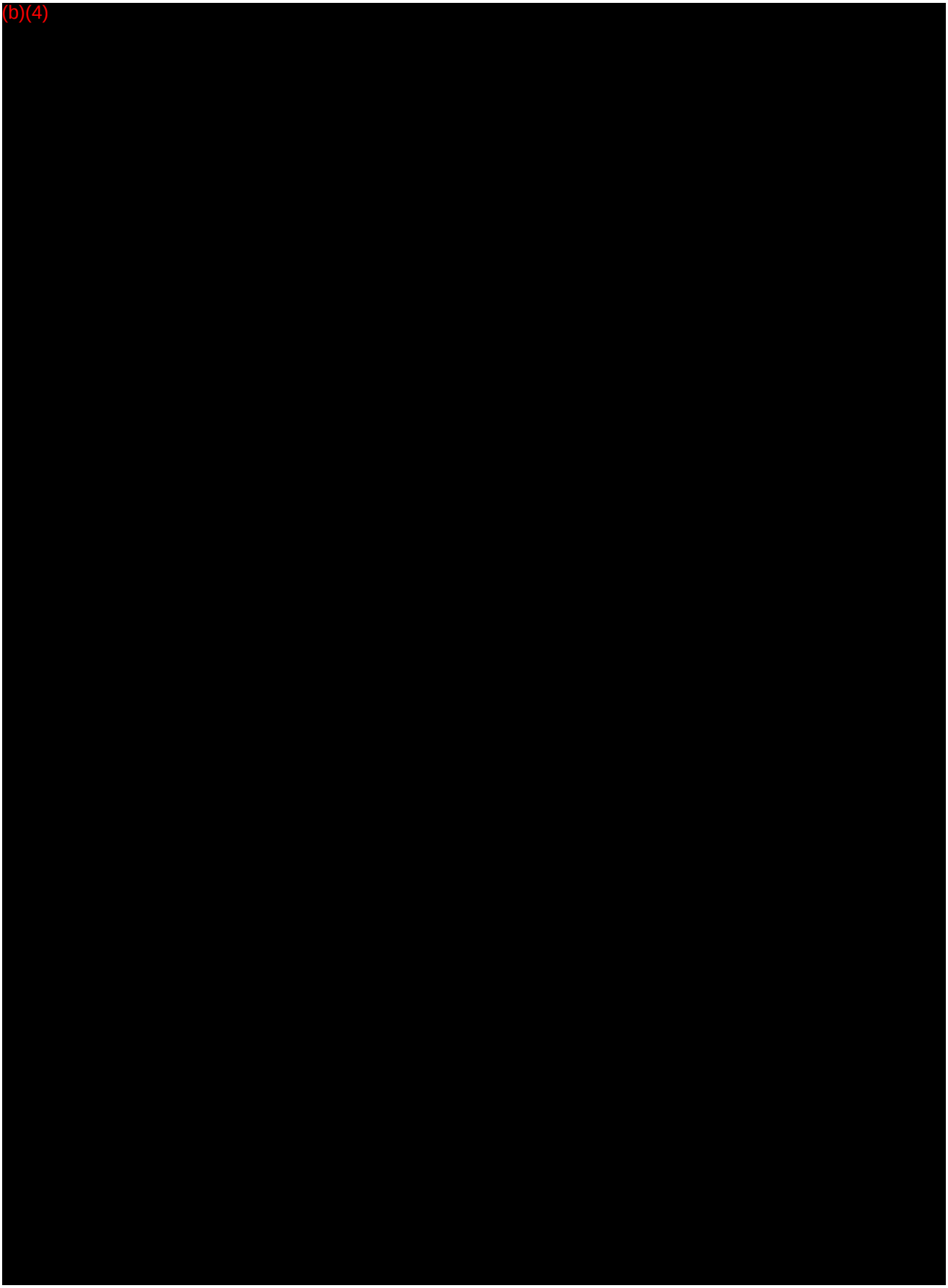

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Records processed under FOIA Request 2016-8070; Released by CDRH on 10/5/2017

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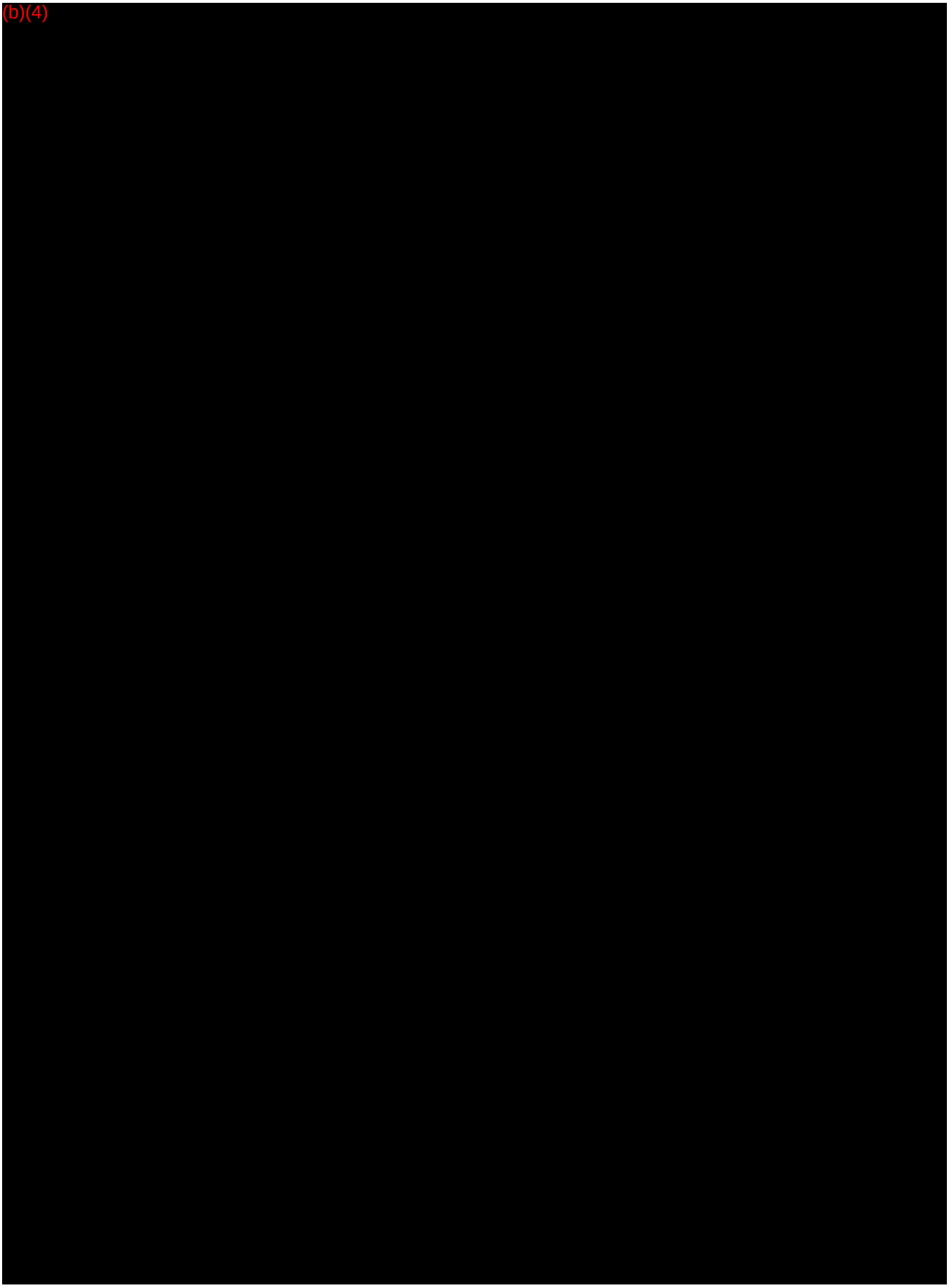

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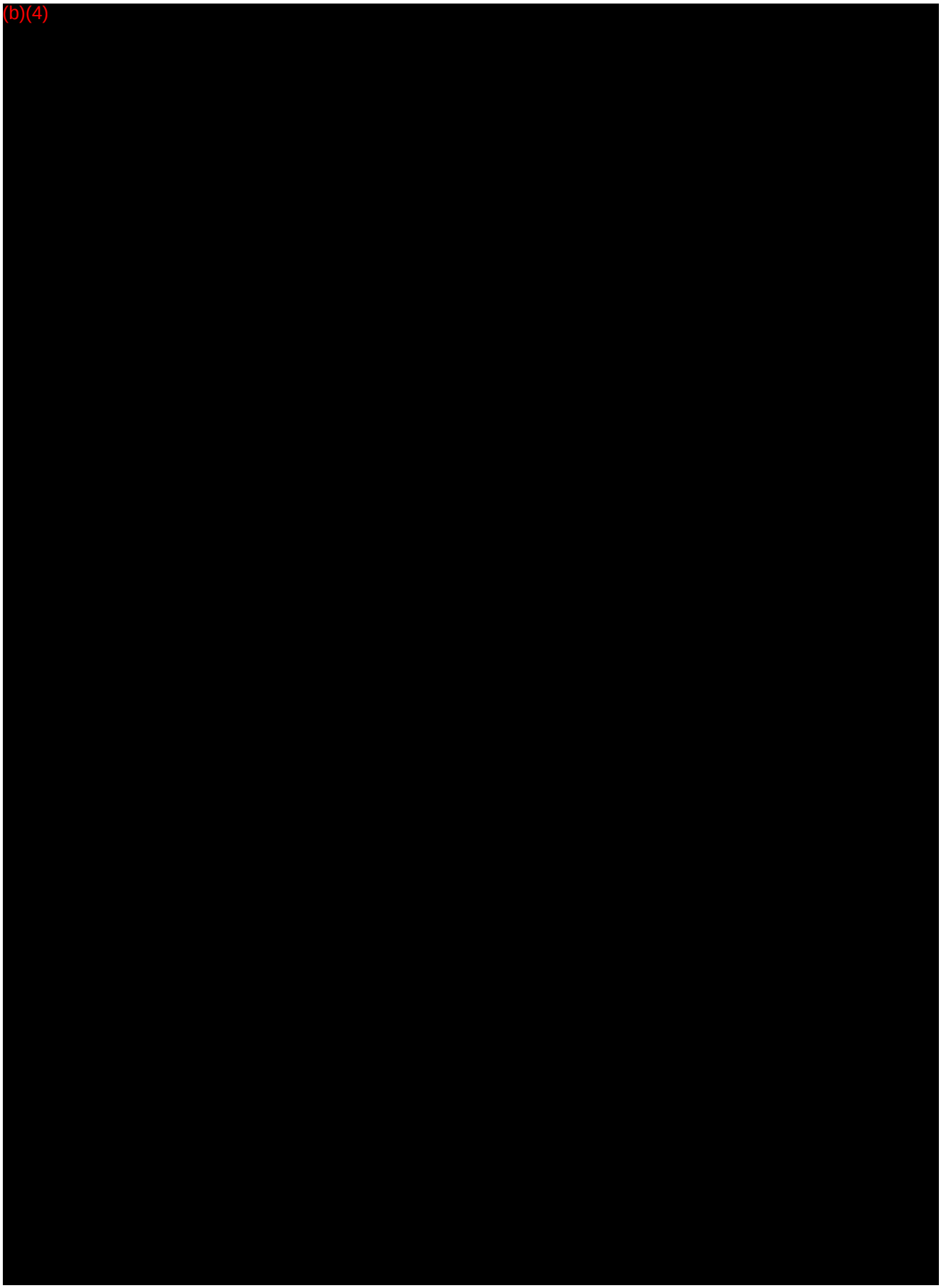

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Records processed under FOIA Request 2016-8070; Released by CDRH on 10/5/2017

510(K) SUMMARY – Traditional 510(K)

Submitter Information

A Company Name:	3Shape A/S
B Company Address:	Holmens Kanal 7 DK-1060 Copenhagen K
C Company Phone: Company Fax:	+45 7027 2620 +45 7027 2621
D Contact Person:	Hanne Nielsen Regulatory Affairs Manager
E Date Summary Prepared:	October 12, 2015

Device Identification

A Trade/proprietary Name:	3Shape Abutment Designer™ Software
B Common Name:	Abutment Designer
C Device Classification Name:	Endosseous Dental Implant Abutment
C Regulation Number:	872.3630
C Classification:	Class II
D Product Code:	NHA

Predicate Device

The 3Shape Abutment Designer™ Software has equivalent intended use and technical characteristics as the Sirona Dental CAD/CAM System (K100152).

3Shape Abutment Designer™ Software does not provide any physical parts that can come into contact with the patient.

The software output is restricted in the U.S. to be manufactured by a holder of an implant abutment 510(k) or milled per the specific instructions provided by the holder of a 510(k) marketing clearance for a patient specific implant abutment.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2016-8070; Released by CDRH on 10/5/2017

This is indicated in the device labelling.

Therefore, the differences between the Device and the predicates do not raise additional concerns concerning the Device's safety and effectiveness.

Intended Use

The 3Shape Abutment Designer™ Software is intended for designing endosseous dental implant abutments based on digital scans of 3D models.

Device Description

The 3Shape Abutment Designer™ Software receives scan data containing topographical characteristics of real teeth, dental impressions, or stone models. The software provides the user with the ability to create matching endosseous dental implant abutments using computer aided design.

The output of the device is a computer file containing the abutment(s) in digital form which can be used by manufacturers that hold an implant abutment 510(k) or are milling per the specific instructions provided by the holder of a 510(k) marketing clearance for a patient specific implant abutment.

The 3Shape Abutment Designer™ Software can be run on properly configured "off-the-shelf" PC hardware running Microsoft® Windows and using a standard keyboard and mouse.

Scientific Concept

The underlying scientific concept is the use of CAD/CAM technology for the optical acquisition of the topographical characteristics of dental impressions, and models and the design of individual mesostructures using recorded data (CAD).

Summary of the technological characteristics

The 3Shape Abutment Designer™ is a software only device programmed in the Delphi programming language and has the following PC/laptop requirements:

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Item	Minimum Requirements	Recommended	Predicate Device
OS	Windows 7 32-bit Professional*	Windows 7 64-bit Professional	Windows Vista 32-bit
RAM	4GB	8GB (16GB)	6GB
Video Card	512MB DirectX 10 (1GB DirectX 10) NVIDIA GeForce	1GB DirectX 11 (2GB DirectX 11) NVIDIA GeForce	512 MB DirectX 10 NVIDIA Quadro
Available HDD Space	250GB	500GB (1TB)	500GB
CPU	Intel Core i5 or equivalent	Intel Core i7 or equivalent	Intel Core i7
Monitor resolution	1440 x 900 pixels	1920 x 1080 pixels	Unknown
3D Mouse	None	3DConnexion SpaceMouse™ Pro	Unknown
Network	Internet connection		Unknown
Ports	USB 2.0 port for 3Shape desktop scanner		Serial Port PCI card for inEOS scanner
Mouse	Mouse with wheel button support		Unknown

Nonclinical Testing

Software, hardware, and integration verification and validation testing was performed in accordance with the FDA Guidance Document "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" (Issued on May 11, 2005).

Prior to release, verification and validation testing of the 3Shape Abutment Designer™ Software has been completed using the approved acceptance criteria: Each user need has its own validation acceptance criteria; each specification has its own verification acceptance criteria; bug verification consists in ensuring issue is not reproducible; issues reported by beta partners must be reviewed and handled appropriately; beta partners must report functionality to be an improvement over previous version.

The validation suite includes validation of implemented mitigations related to device hazards identified in the risk management procedures.

All test results have been reviewed and approved, showing the 3Shape Abutment Designer™ Software to be safe and effective.

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Clinical Testing

Clinical testing is not a requirement and has not been performed.

Conclusion

Based on a comparison of intended use, indications, construction materials, principle of operations, features and technical data, and the test results, the 3Shape Abutment Designer™ Software is found to be substantial equivalent with the Predicate Devices.

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Substantial Equivalence Comparison

1. Predicates

The 3Shape Abutment Designer™ Software has the same intended uses and technical characteristics as the Sirona Dental CAD/CAM System (K100152) as listed in "Table 1: Predicate"

Table 1: Predicate

Predicate	Manufacturer	510(k) number	Product code
Dental CAD/CAM System	Sirona	K100152	NHA*

* Endosseous dental implant abutments, 21CFR872.3630

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2. Intended Use Comparison

2.1. 3Shape Abutment Designer™ Software

The Device's Intended Use, Intended users, and Intended Operational is stated in the "VOL_001_Administrative Documents" volume of this submission and reproduced here:

> *The 3Shape Abutment Designer Software is intended as an aid the restoration of chewing function in partially or fully edentulous mandibles and maxillae. The 3Shape Abutment Designer Software is intended for use by a dental practitioner or dental laboratory staff for designing the patient specific component of a two-piece, one-piece, or hybrid dental implant abutment. The single or multi-unit abutment design is intended to be used by the manufacturer of an endosseous dental implant abutment to create the final device.*
>
> *Intended users are Dental Practitioners and Dental Laboratory staff.*
>
> *Intended Operational Environment is Dental Laboratories."*

In the following sections, the similarities with the predicate are discussed.

2.2. Dental CAD/CAM System

The predicate's Intended Use can be extracted from the FDA 510(k) Premarket Notification Database:

> *"The Sirona Dental CAD/CAM System is intended for use in partially or fully edentulous mandibles and maxillae in support of single or multiple-unit cement retained restorations. The system consists of three major parts: TiBase, InCoris mesostructure, and CAD/CAM software. Specifically, the InCoris mesostructure and TiBase components make up a two-piece abutment which is used in conjunction with endosseous dental implants to restore the function and aesthetics in the oral cavity.*
>
> *The InCoris mesostructure may also be used in conjunction with the Camlog Titanium base CAD/CAM (types K2244.xxxx) (K083496) in the Canmlog Implant System. The CAD/CAM software is intended to design and fabricate the InCoris mesostructure. The InCoris mesostructure and TiBase two-piece abutment is compatible with the following implants systems:*
>
> *[List of compatible implant systems omitted for brevity]*

Underlined segments indicate similarity with 3Shape Abutment Designer™ Software.

Note, the predicate is a CAD/CAM System bundled with physical two-piece abutments; the 3Shape Abutment Designer™ Software is CAD/CAM only.

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3. Characteristics Comparison

A Characteristics Comparison can be seen in "Table 2: Substantial Equivalence Chart".

Table 2: Substantial Equivalence Chart

Feature name	3Shape Abutment Designer ™ Software	Sirona Dental CAD/CAM System (K100152)
Graphical UI	Yes	Yes
Windows OS platform	Yes	Yes
Uses standard PC hardware	Yes	Yes
Digitally imports topography of teeth by 3D Scan	Yes	Yes
Uses 3D CAD design tools	Yes	Yes
Custom abutment design	Yes	Yes
Screw retained design	Yes	Yes
Implant Bar design	Yes	Yes
Export to remote milling machine by internet	Yes	Yes
Network Protocol	Internet/TCP-IP	Internet/TCP-IP
Intended users	Dental practitioners and dental labs	Dental practitioners and dental labs
Output type	Computer file	Computer file
Device submission includes pre-manufactured prosthetics*	No	Yes

* Endosseous dental implant abutments as per 21CFR872.3630

4. Conclusion

The 3Shape Abutment Designer™ Software and the predicate only deviate significantly in the cases where the predicate is bundled with a physical dental implant abutment. 3Shape Abutment Designer™ Software does not provide any physical parts that can come into contact with the patient.

The software output is restricted in the U.S. to be manufactured by a holder of an implant abutment 510(k) or milled per the specific instructions provided by the holder of a 510(k) marketing clearance for a patient specific implant abutment.

This is indicated in the device labelling.

The differences between the 3Shape Abutment Designer™ Software and the predicate do not raise additional concerns with respect to the safety and effectiveness of the 3Shape Abutment Designer™ Software.

Based on the information presented, we conclude Substantial Equivalence between the predicate and the 3Shape Abutment Designer™ Software.

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Software Description

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2. Intended Use and Operational Environment

The 3Shape Abutment Designer Software is intended as an aid the restoration of chewing function in partially or fully edentulous mandibles and maxillae. The 3Shape Abutment Designer Software is intended for use by a dental practitioner or dental laboratory staff for designing the patient specific component of a two-piece, one-piece, or hybrid dental implant abutment. The single or multi-unit abutment design is intended to be used by the manufacturer of an endosseous dental implant abutment to create the final device.

Intended users are Dental Practitioners and Dental Laboratory staff.

Intended Operational Environment is Dental Laboratories.

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3. Definitions

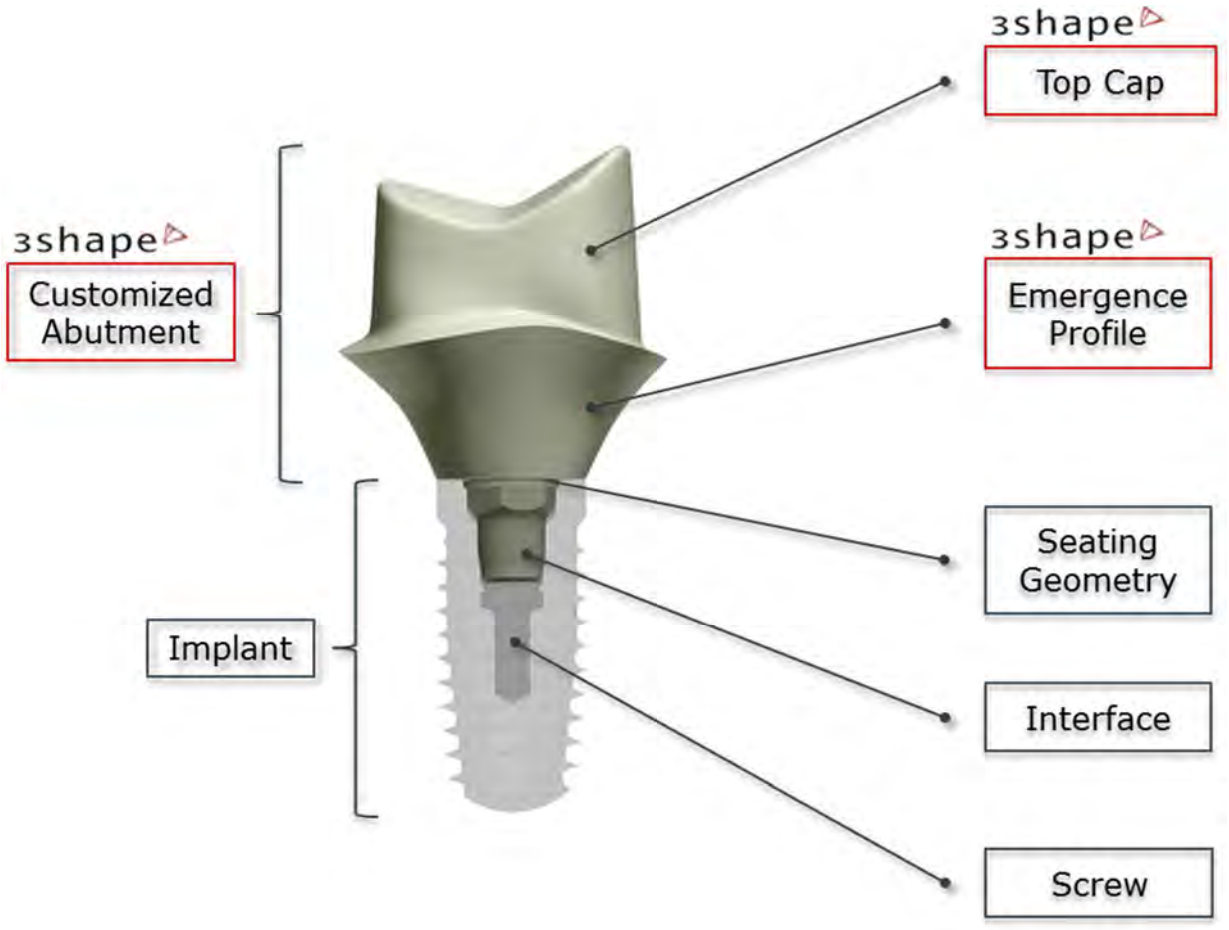
There are four types of Abutments supported by the 3Shape Dental System: Customized, Anatomical, Screw Retained Crown, and Wax-up.

3Shape uses the term "Abutment" to denote all four types. Digitally created abutments are classified as an Endosseous dental implant abutment.

The 3Shape Abutment Designer™ only supports modification of the Abutment itself as exemplified on *Figure 1: Customized Abutment parts*.

A digital representation of the Implant is required for the software to work, but only to ensure the Abutment will fit on the Seating Geometry / Interface of the Implant. The 3Shape Abutment Designer™ does not provide any means to design, alter, or manufacture any part of the Implant including, but not limited to, the abutment-to-implant interface.

Figure 1: Customized Abutment parts



Terms used

The 3Shape Abutment Designer™ Software supports four types of Abutments – however this only has impact on the initial guess of abutment shape as well as slight differences in the User Interface for designing the Abutment.

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There is no difference between the four types on abutment function, manufacturing requirements, output types, etc.

The output of any abutment designed is a computer file of the surface model.

Please find a detailed description in *Table 2: Abutment Types*

Table 2: Abutment Types

Type	**Description**
Customized Abutment	The Customized Abutment comes in 3 subtypes: Custom, Robotic, and Bar Interface. All provide the user with the ability to free-hand modify the Top Cap and Emergence Profile as depicted on *Figure 1: Customized Abutment parts*. The Custom Abutment initial shape guess is based on an anatomic heuristic  The Robotic initial shape guess is based on a classic standard abutment.  The Bar Interface initial shape guess is based on a cylinder.

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Anatomical Abutment	This type of abutment comes with an initial shape guess that matches a crown. 
Screw Retained Crown	This type of abutment comes with an initial shape guess that can be used as a crown and has a screw-hole in the centre. 
Wax-up abutment	This type of abutment comes with an initial shape guess based on a scan of a wax-model. Otherwise, it is equivalent to Anatomical abutment.

Also, throughout the submission the following terms are applicable.

Table 1: Terms

Term	**Definition**
Provider	Any creator of an Implant Library.
Implant Library	A digital representation of an Implant System
Implant System	A physical Dental Implant compatible with one of more abutments
Abutment	Endosseous dental implant abutment as regulated under 872.3630

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Milling Center	An industry term for a large scale provider of Milling. I.e. manufacturer that hold an implant abutment 510(k) or are milling per the specific instructions provided by the holder of a 510(k) marketing clearance for a patient specific implant abutment. Typically, the actual manufacturing is geographically centralized, which makes digital transfer of CAD designed surface files convenient. 3Shape does not own or operate any milling centers.
Local Milling	When the Dental Lab and milling machinery is co-located. 510(k) restrictions also apply as described under "Milling Center". 3Shape does not manufacture or market milling machinery.

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4. Ensuring Regulatory Compliance of Abutments

Abutments are designed to interface with Dental Implants and 3Shape Abutment Designer™ requires a digital representation of the Dental Implant in order to create a functional Abutment.

The digital representations of Dental Implants (called Implant Systems) is collected in files called Implant Libraries.

In the U.S. only Abutments designed against Dental Implants with a 510(k) clearance are allowed in the 3Shape Abutment Designer™ (see *Design stops in the software* below). All settings on the Implant systems will be locked for editing.

Providers of Implant Libraries to be used in the U.S. must supply 3Shape with written documentation in order to have their Libraries activated in the software.

It is the responsibility of the Provider to ensure that the digital representation correctly represent the cleared physical parts.

Design stops in the software

The software provides a "wizard"-type functionality that enable Implant System Providers to create Implant Libraries to be used in the 3Shape Abutment Designer™ Software.

The Provider can subsequently export the library to a computer file for distribution.

It is the Provider's responsibility to ensure to lock the Implant Library. This will prevent anyone but the Provider to modify it. In the U.S., the Provider is the 510(k) holder of the Implant System.

Additionally, Providers of Implant Libraries to be used in the U.S. must supply 3Shape with written documentation in order to have their Libraries activated in the software.

Design stops in the software are implemented according to the following four steps:

i. Libraries are locked to prevent anyone but the Provider to modify it.

ii. The software prevents the end-user from modifying the Implant Library after it has been imported to his or her system.

iii. The software will block any attempt to use a non-cleared Implant System in the U.S.

iv. The software provides design stops for: Abutment Gingival Margin Diameter, Abutment Gingival Margin Height, Abutment Total Height, Abutment Angulation, and Abutment Blank Limitation.

The following table shows the trace of Requirements, Specifications, Validation, and Verification tests relevant.

Items	Requirements	Specifications	Validation	Verification
(b)(4)	[redacted]			

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(b)(4)

5. Manufacturing of Abutments

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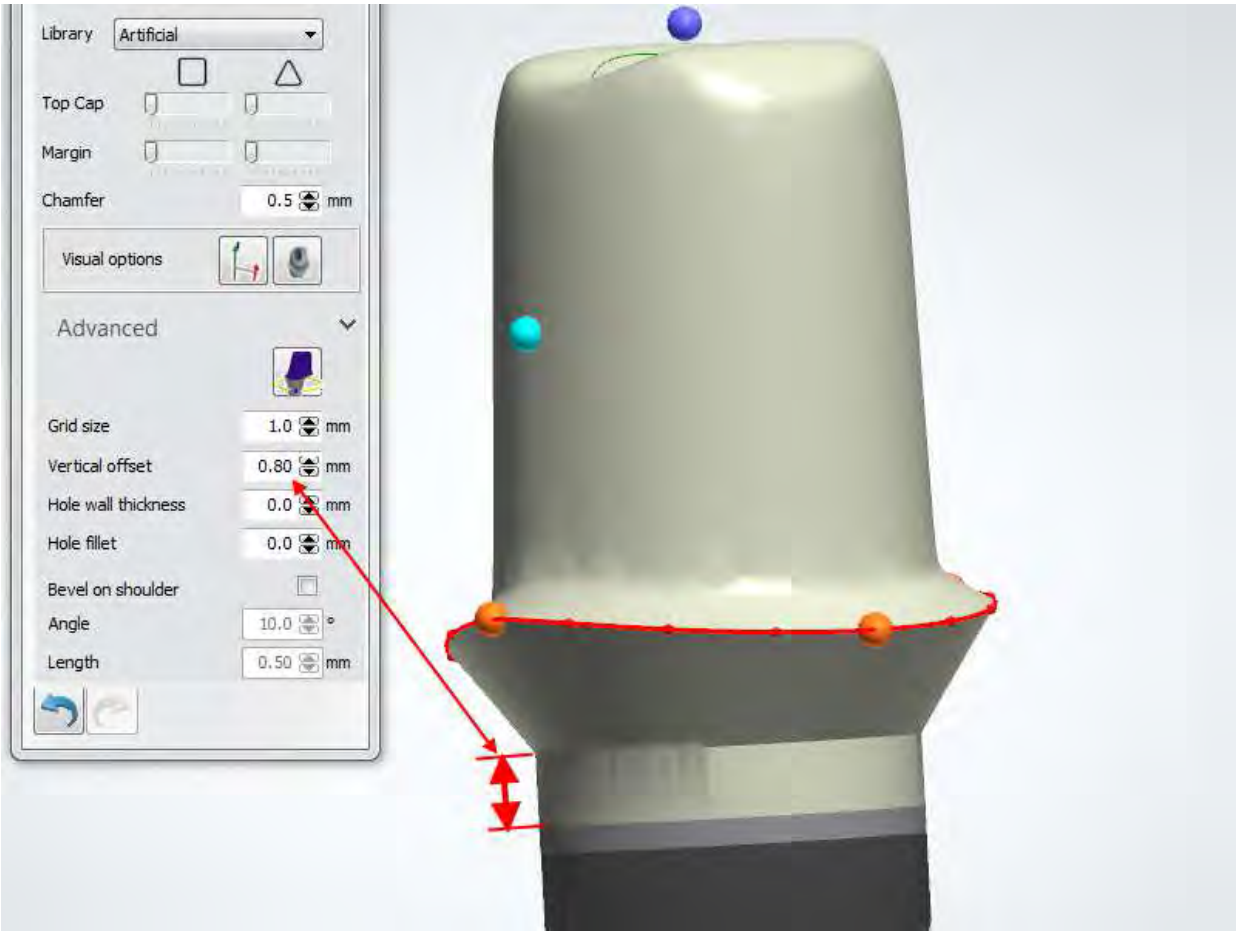
Vertical Offset Description

Vertical offset does not influence on the distance between abutment and implant.

Vertical offset is length of additional vertical cylinder surface before emergence profile to modify the emergence exit profile.



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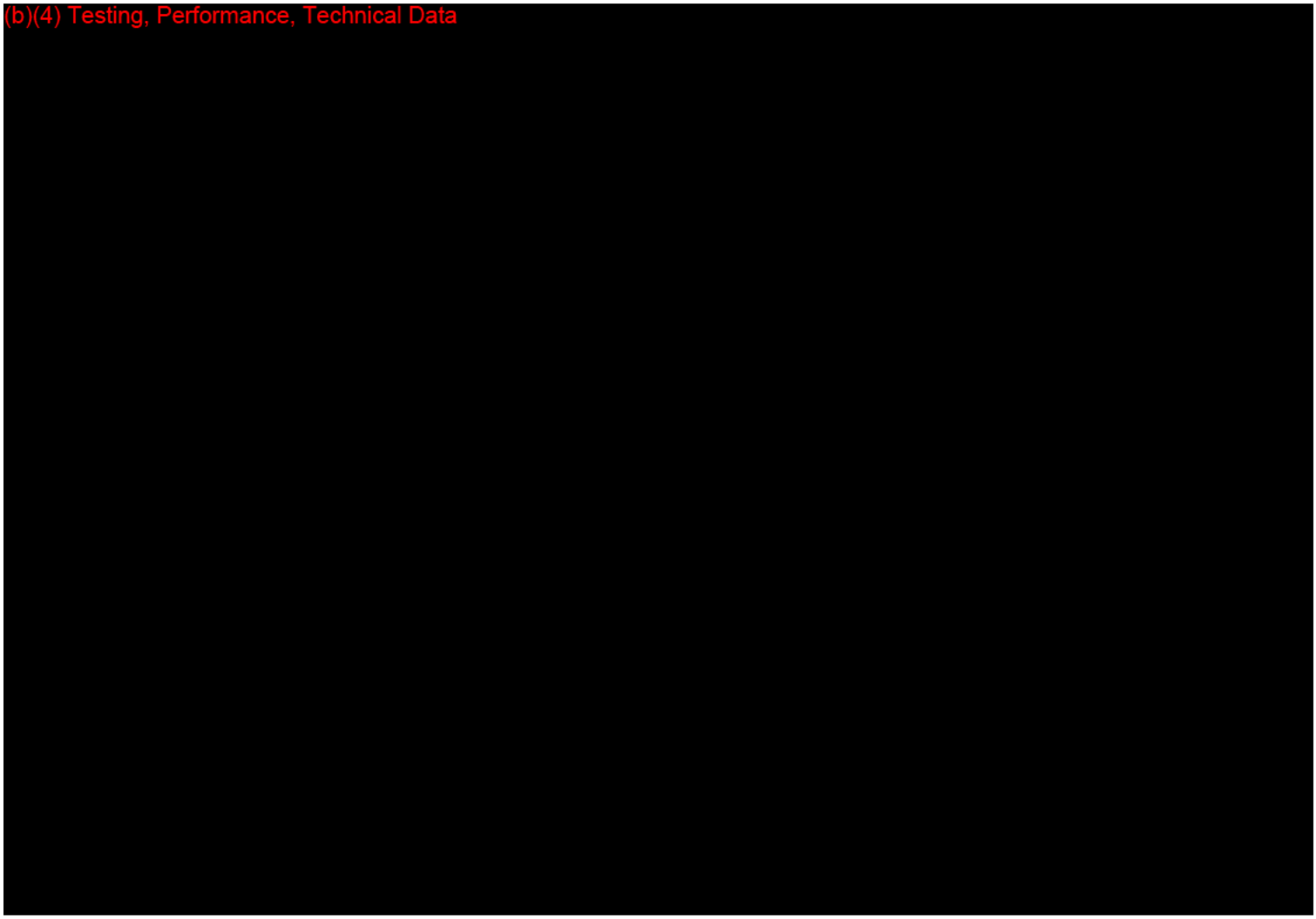
Device Hazard Analysis

(b)(4) Testing, Performance, Technical Data



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Cyber Security Analysis

1. Introduction

Please refer to the Cyber Security Analysis enclosed in this volume.

2. Table of Contents

(b)(4) Cyber Security Analysis

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3shape

Cybersecurity analysis report –

TITLE (b)(4) Cybersecurity Analysis Report

(b)(4)

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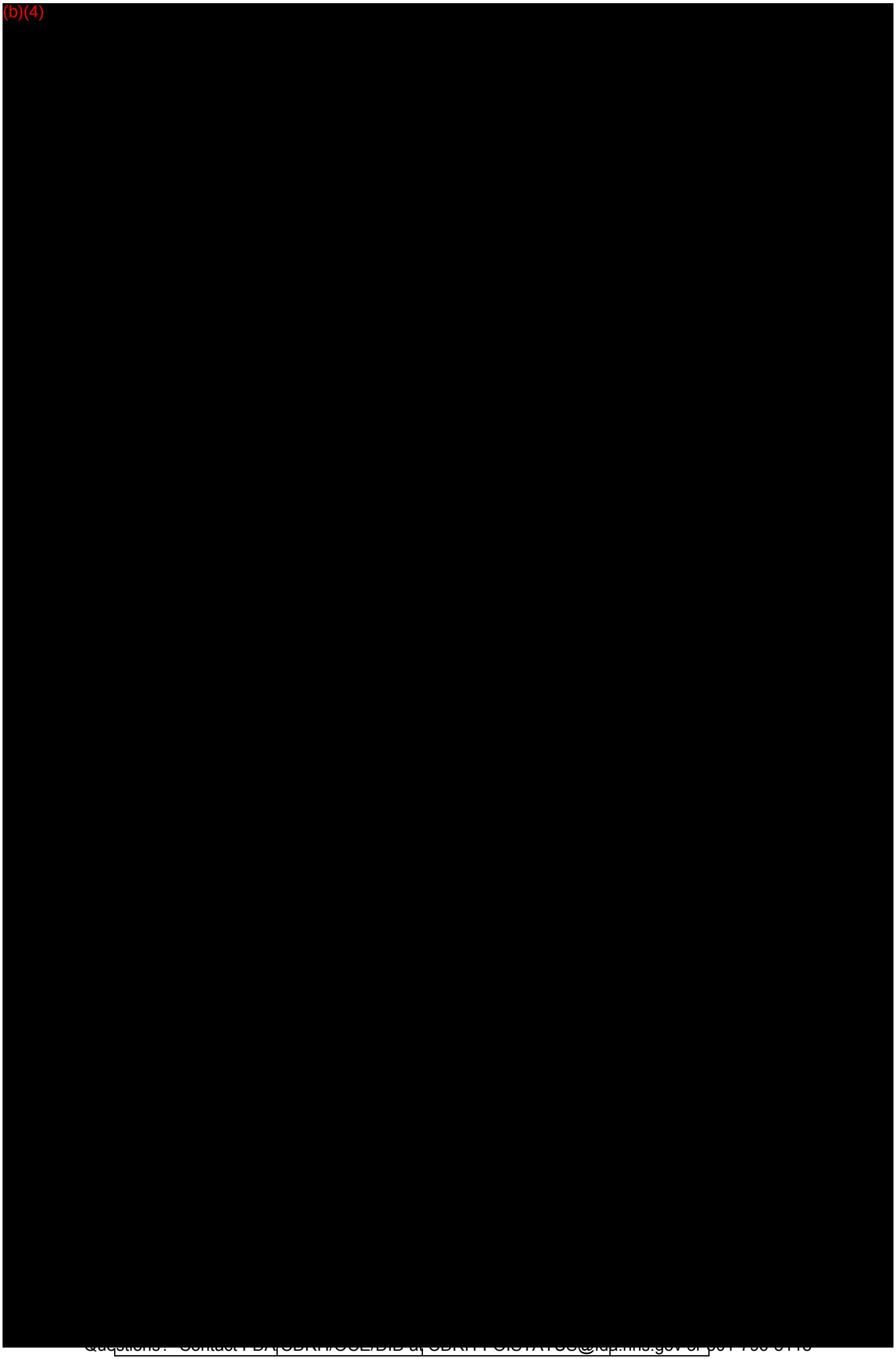

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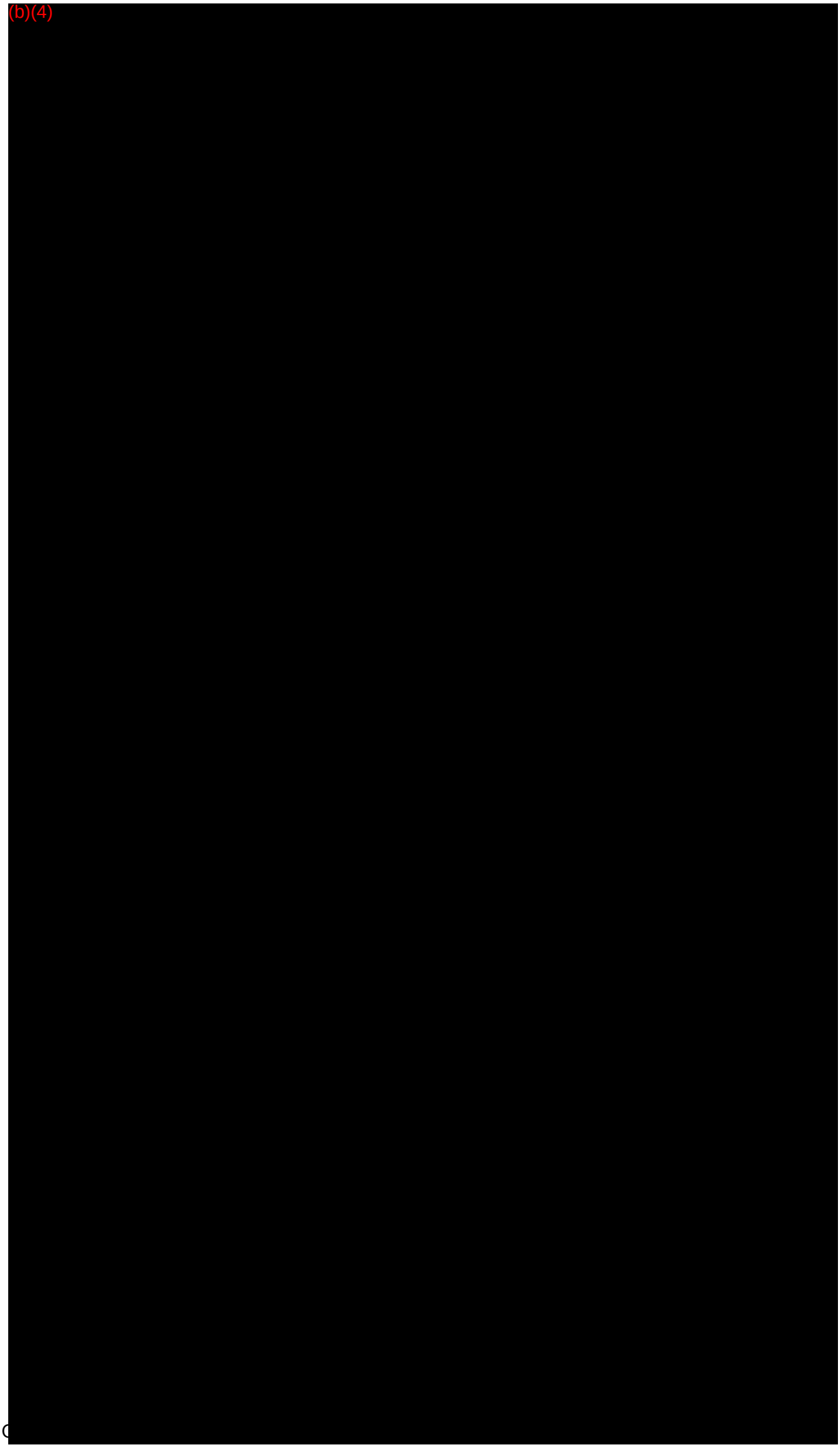

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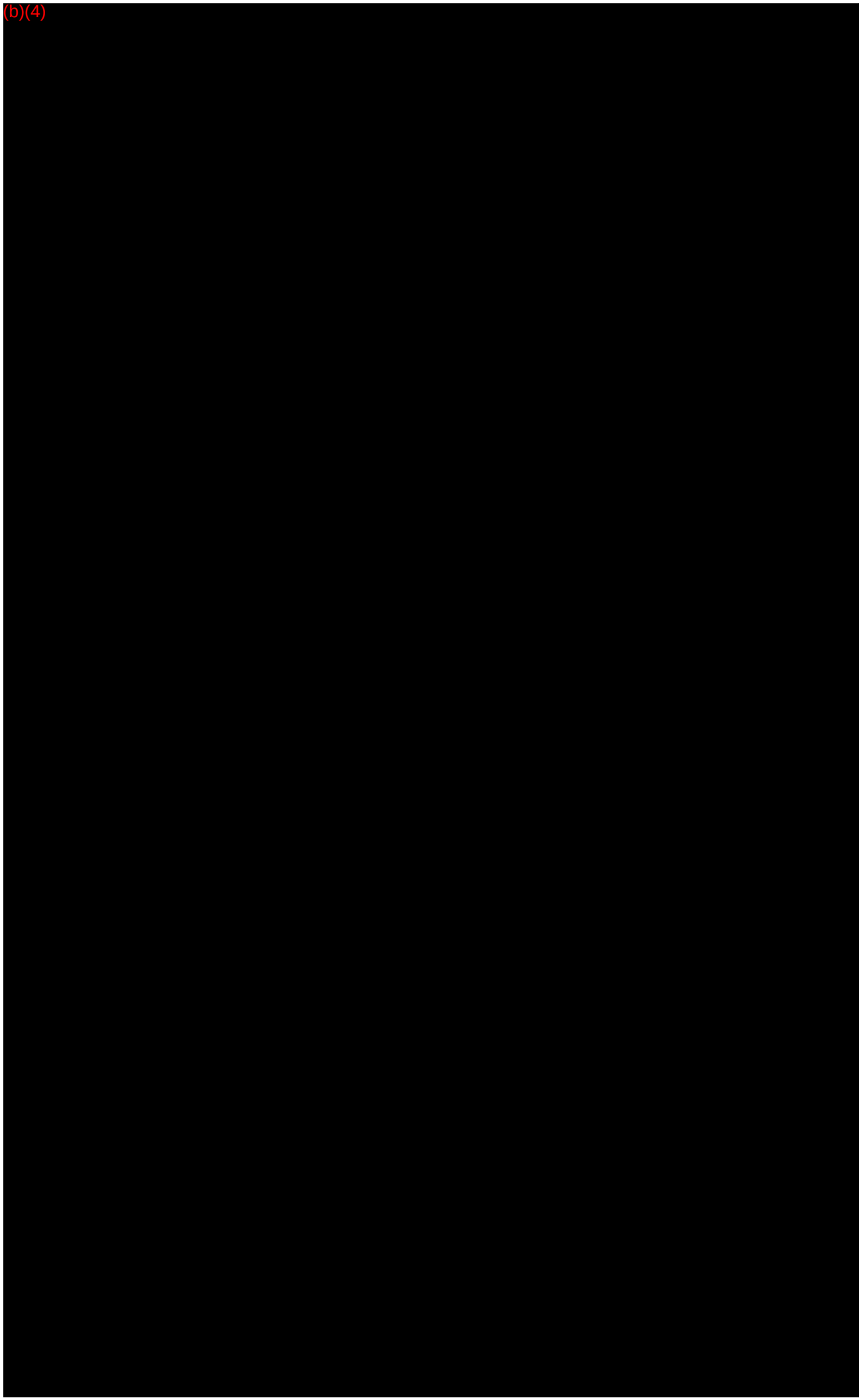

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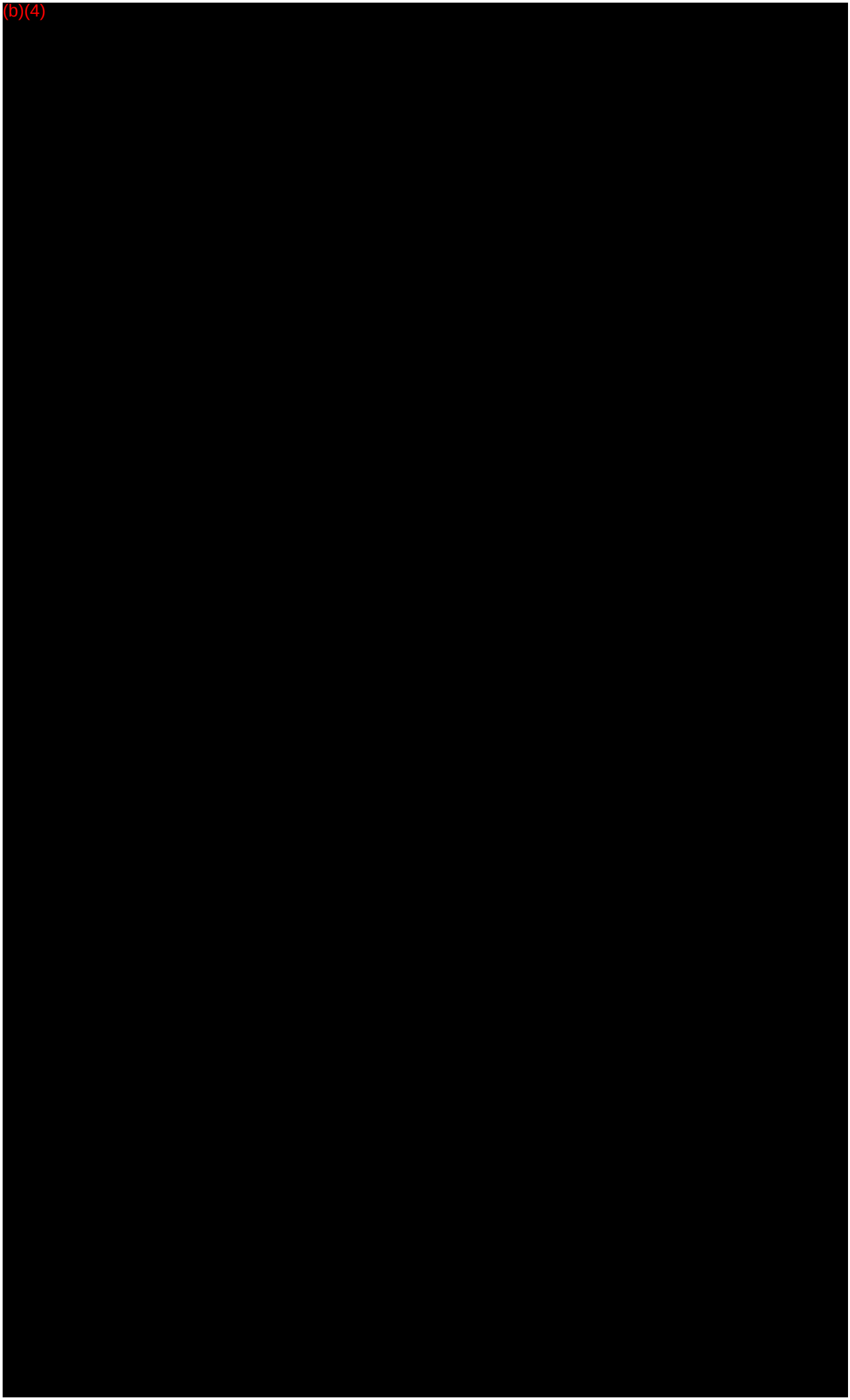

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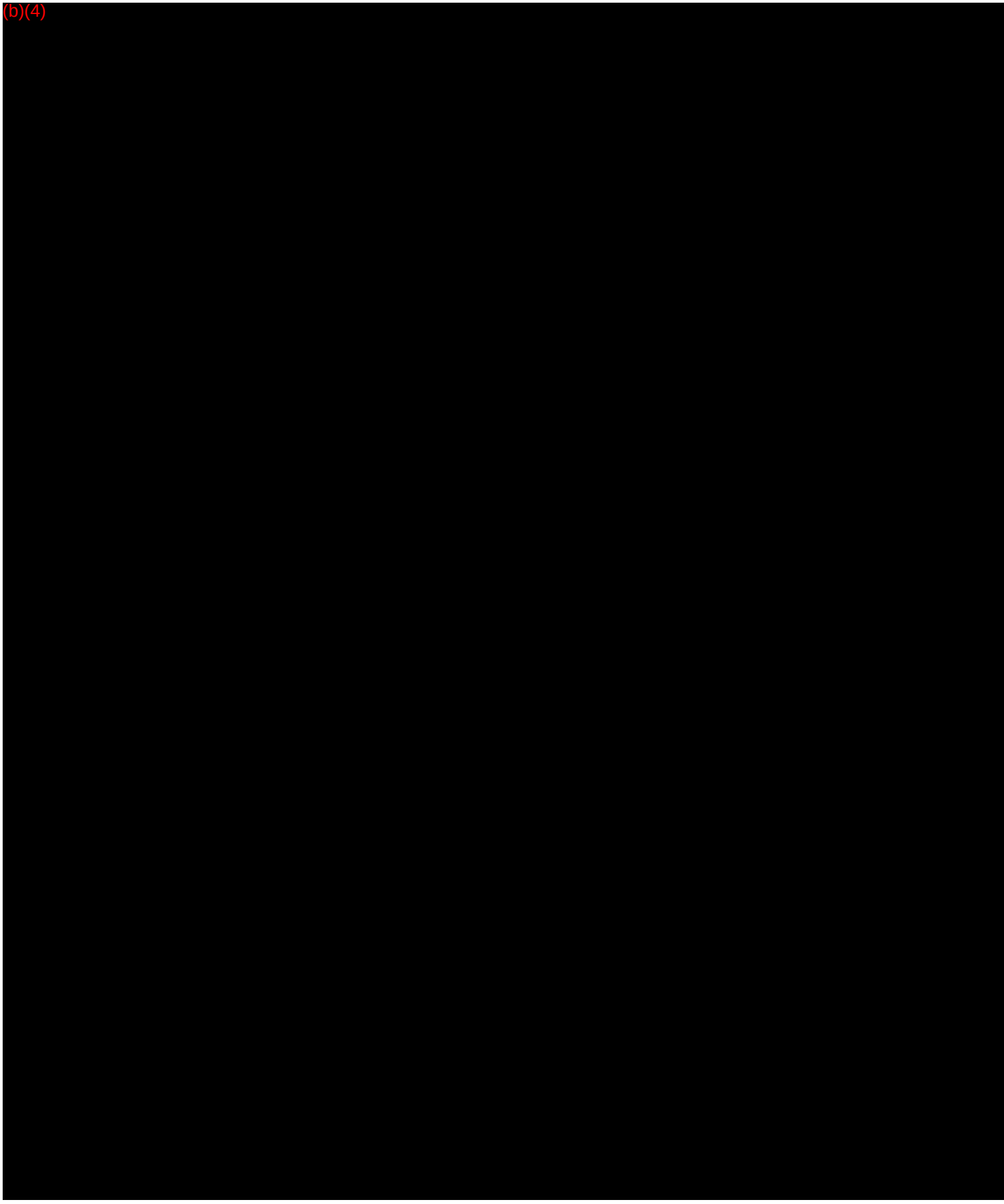

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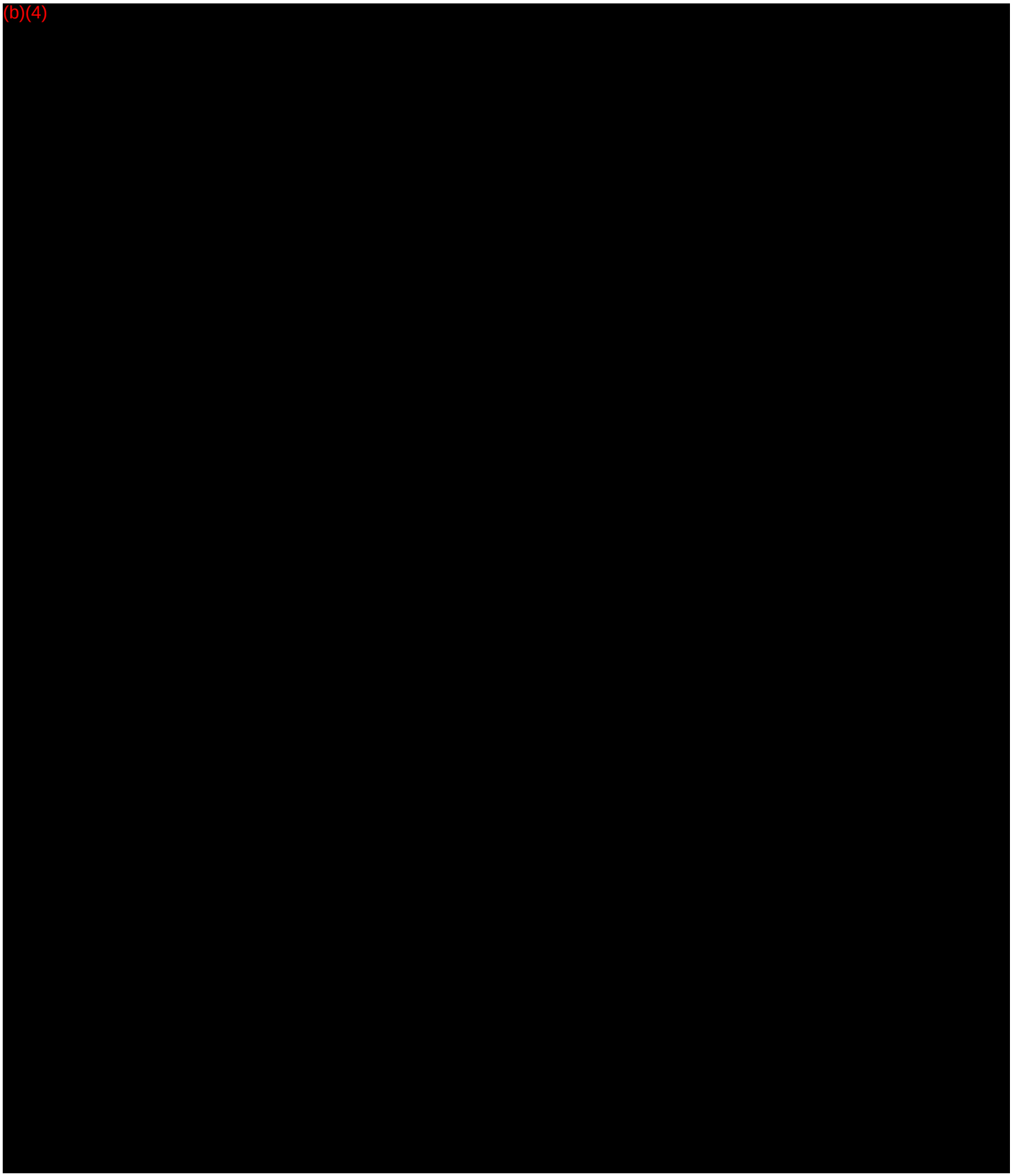
Architecture Design Chart

(b)(4)



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TITLE: ARCHITECTURE DESIGN CHART

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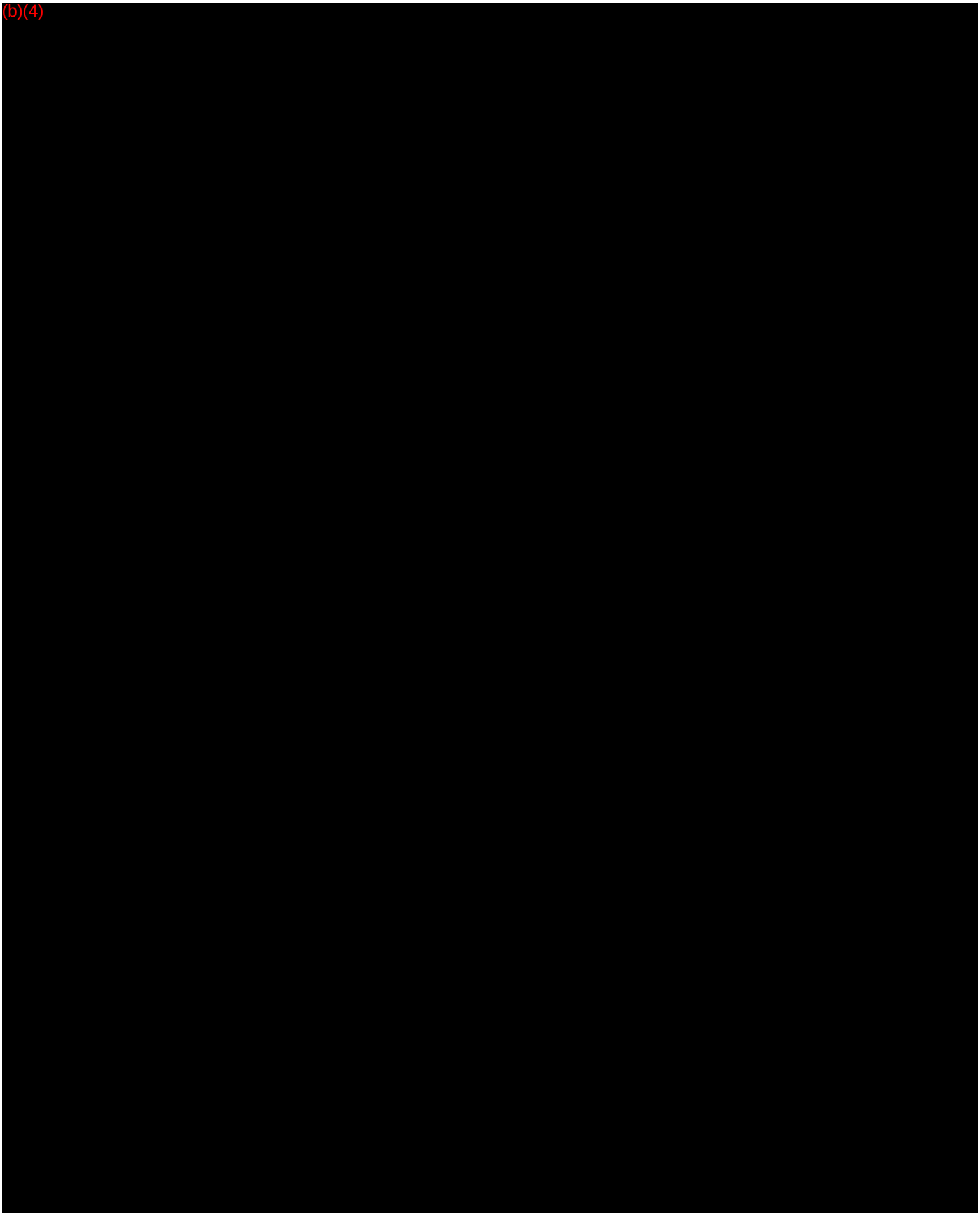

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Software Design Specification

1. Introduction

Please refer to the Software Design Specification enclosed in this volume.

Please note that the Verification Protocol templates are included in the Software Specifications.

For links between the Requirements Specifications and the Software Specifications, please see "VOL_008_Traceability Analysis" enclosed in this submission.

2. Software Design Specification, Table of Contents

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Software Specification – (b)(4)

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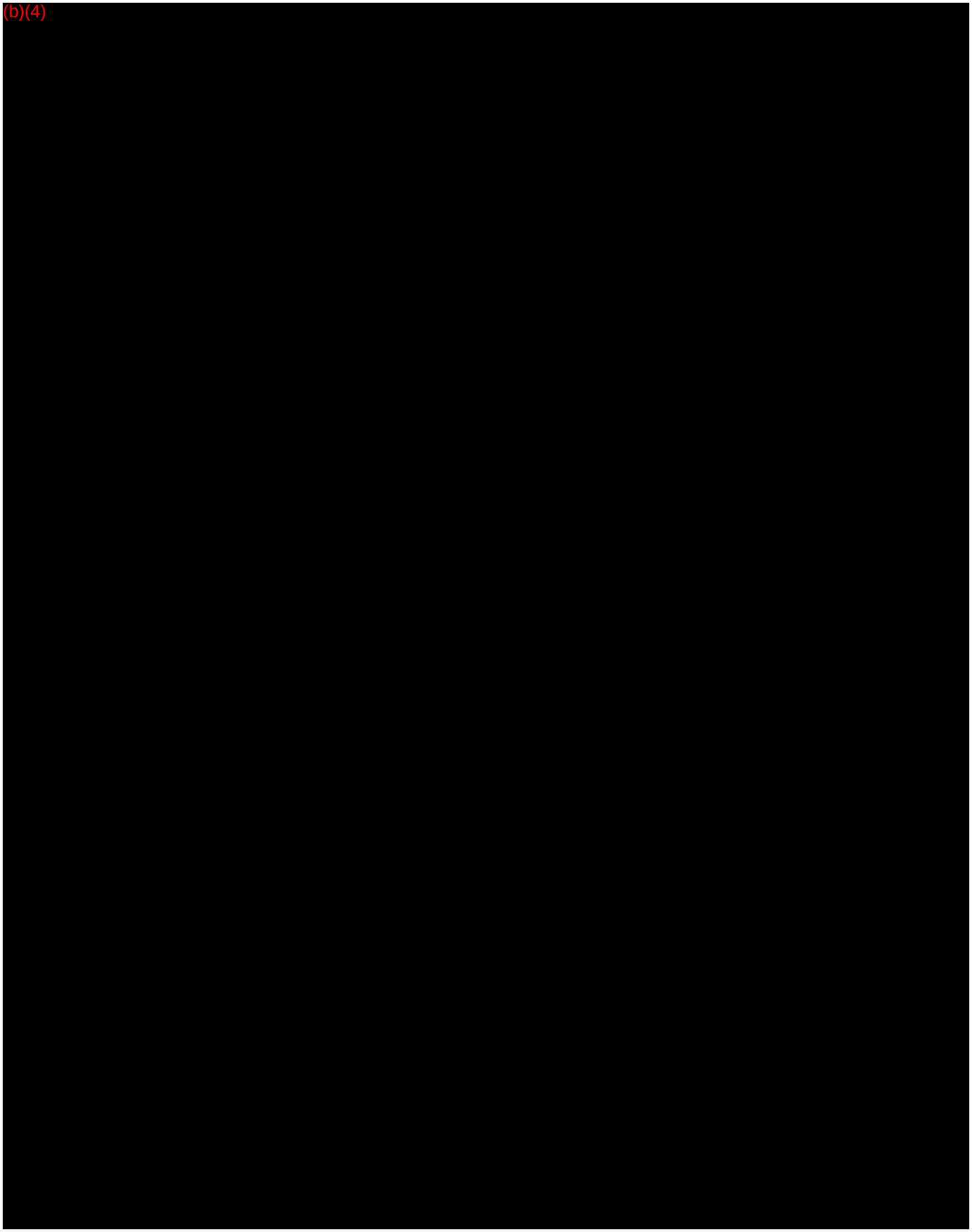

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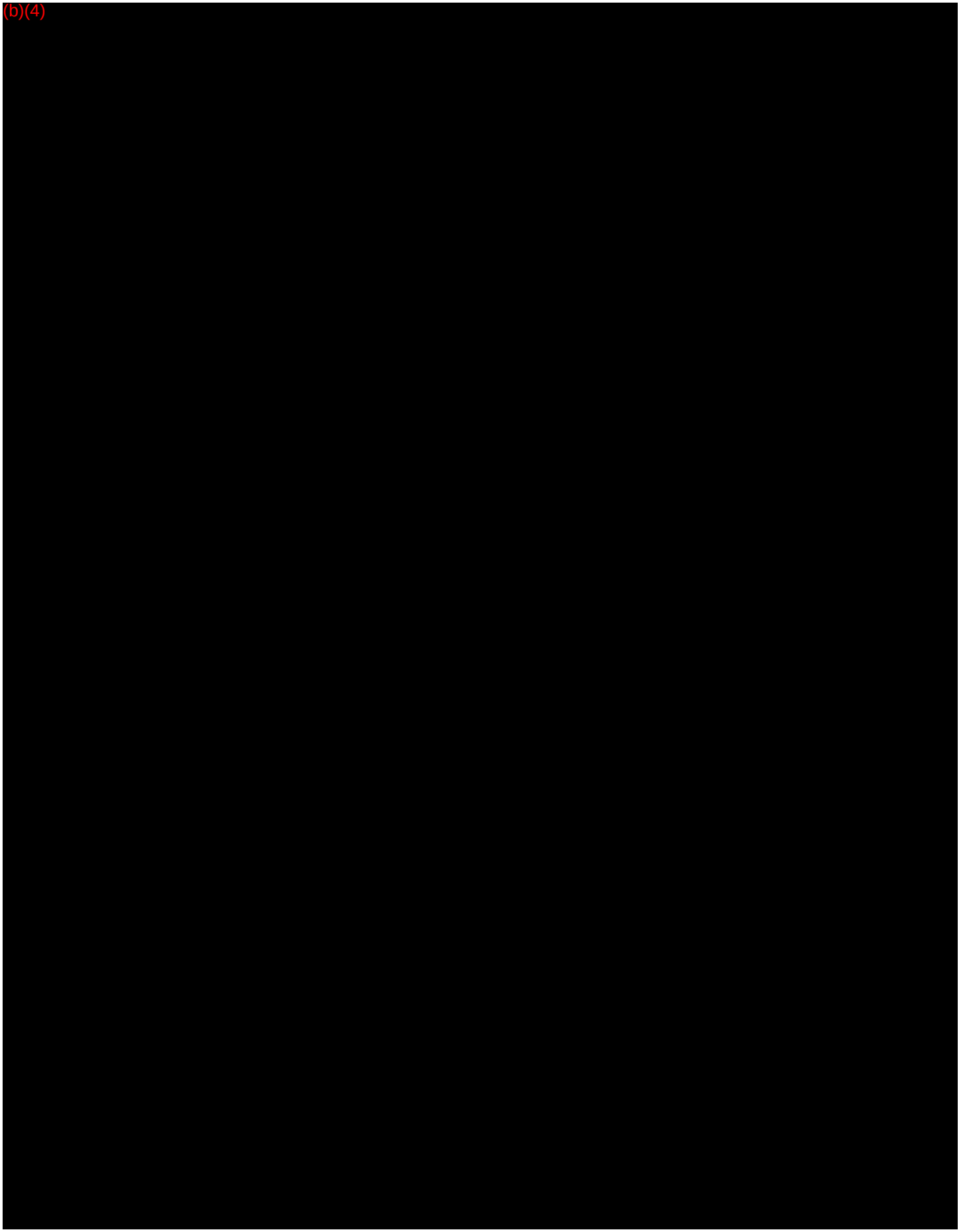

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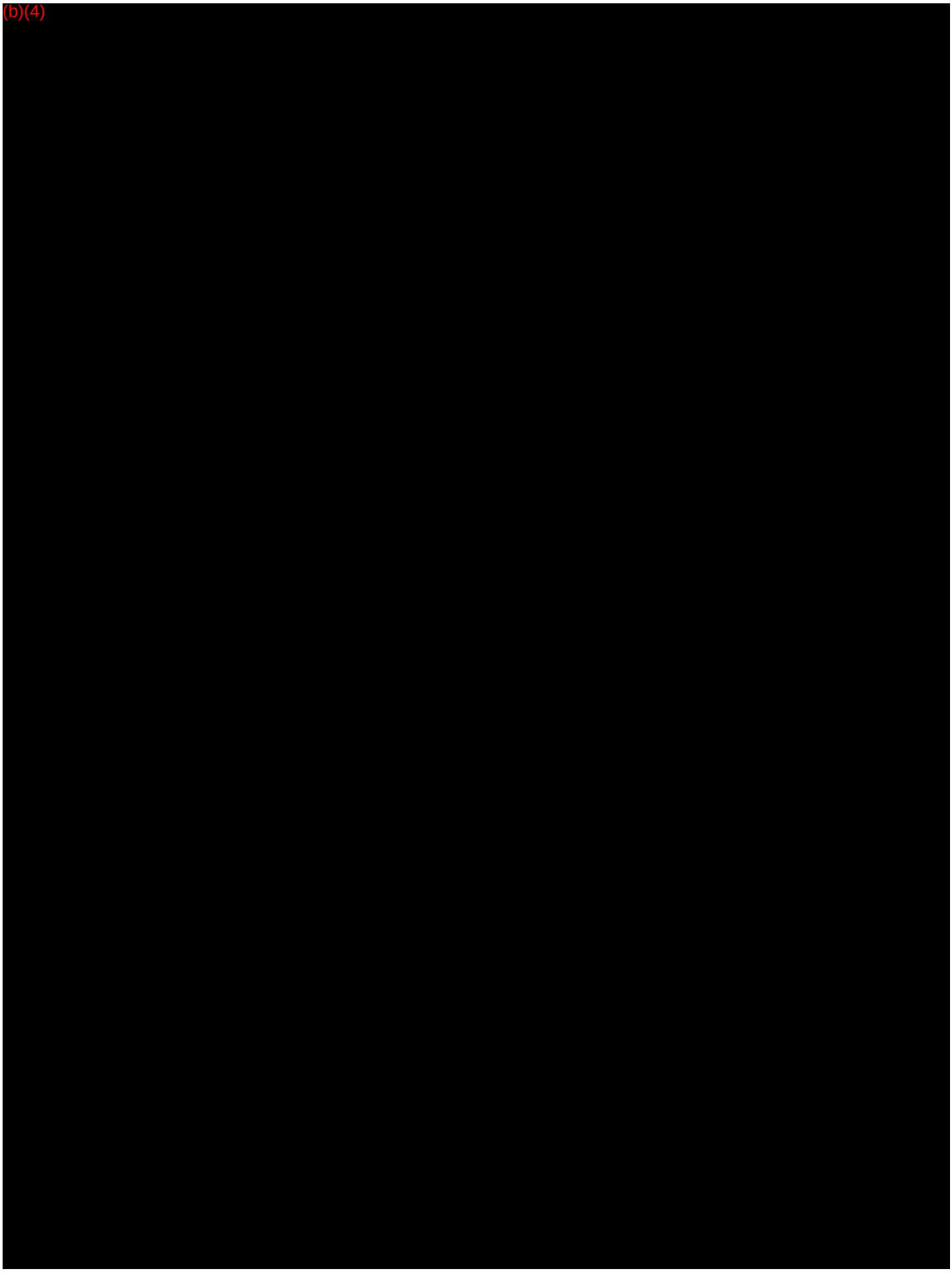

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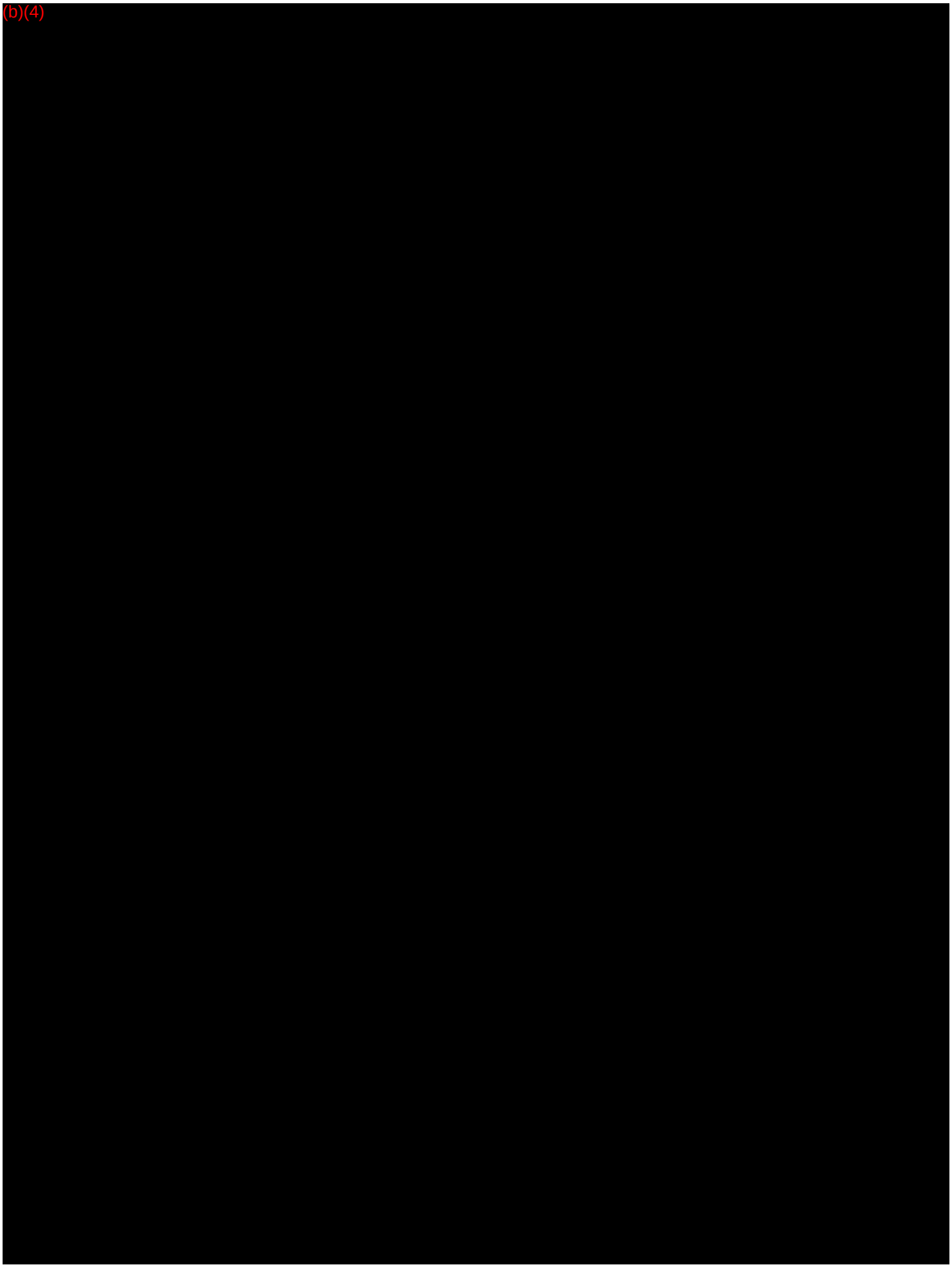

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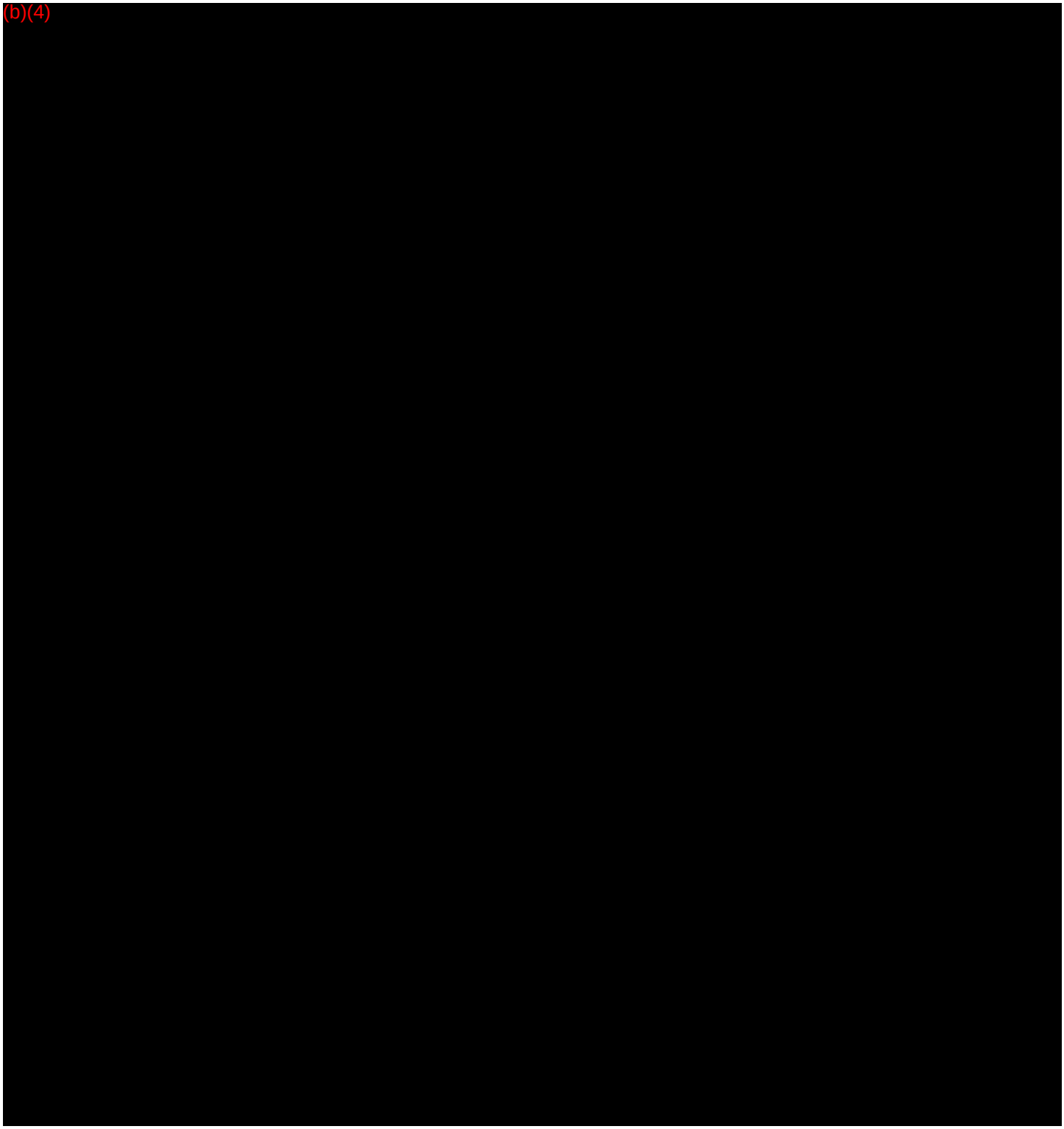

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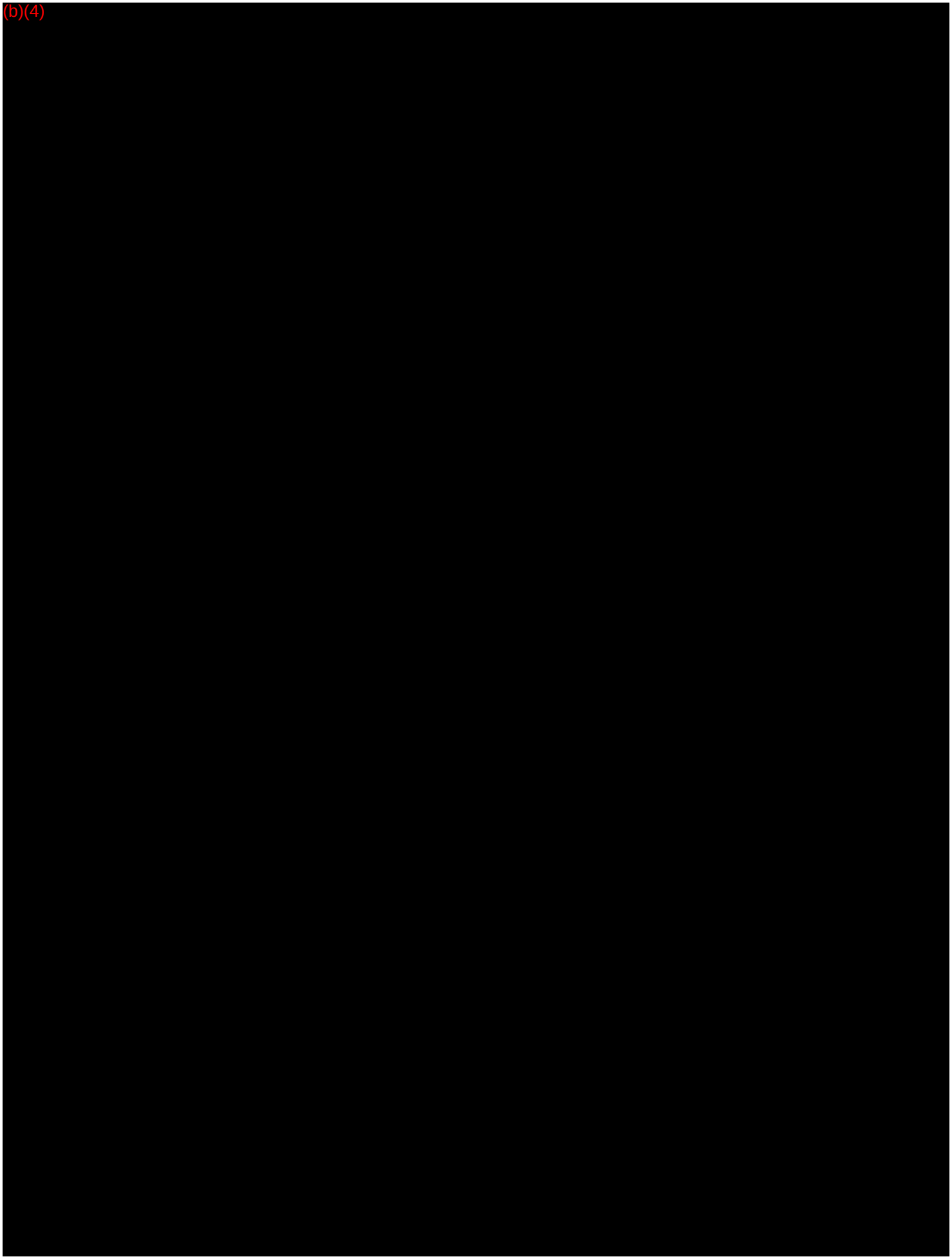

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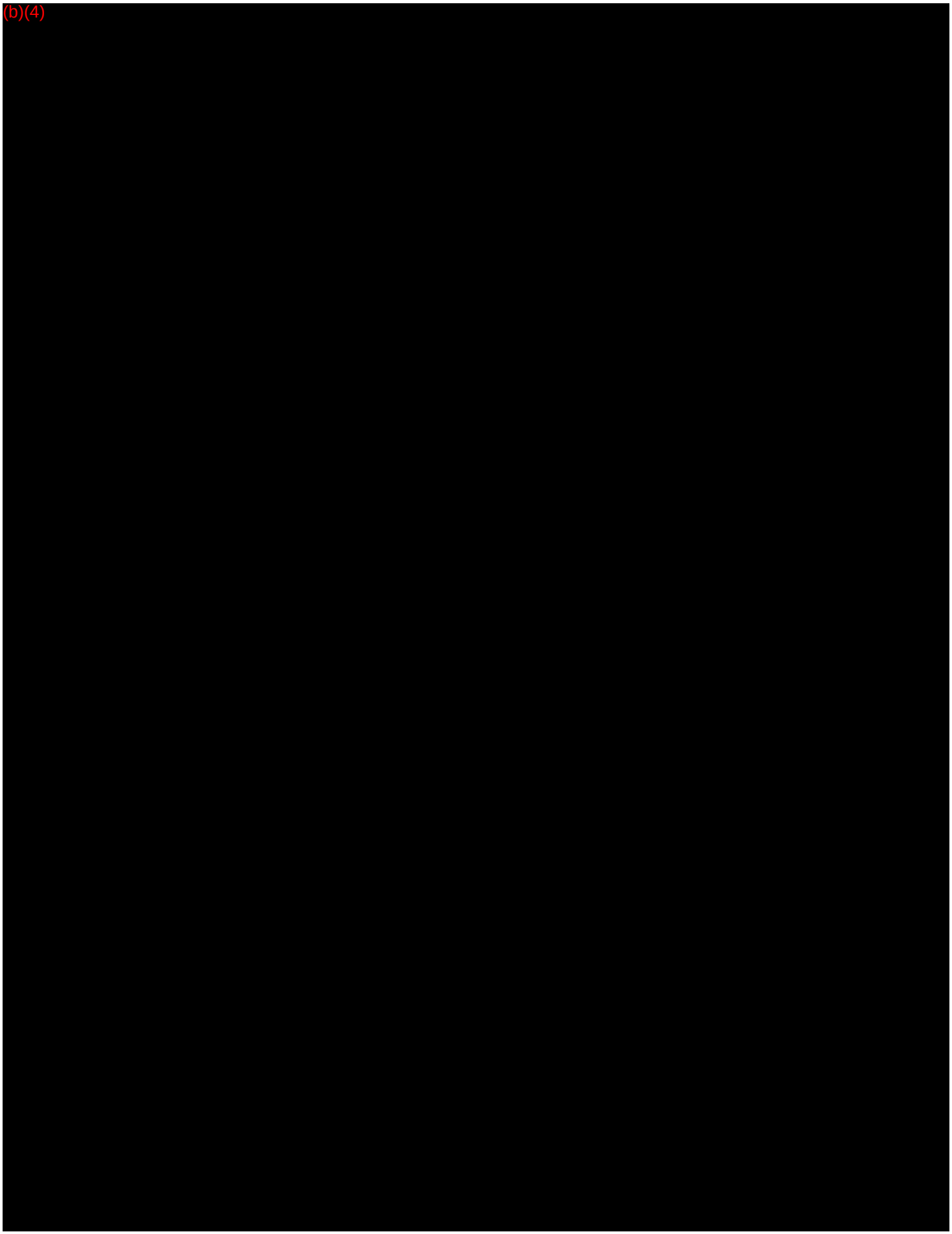

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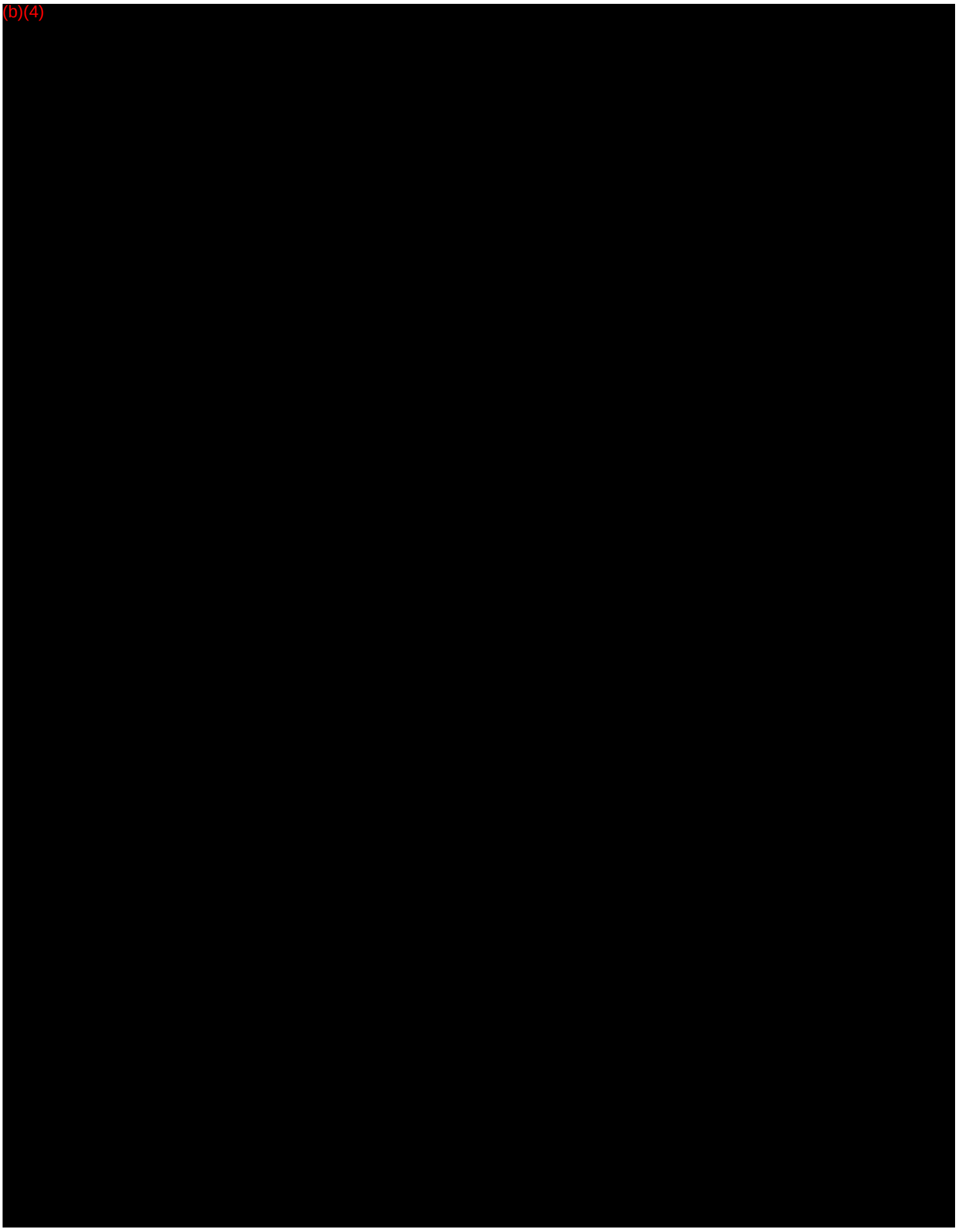

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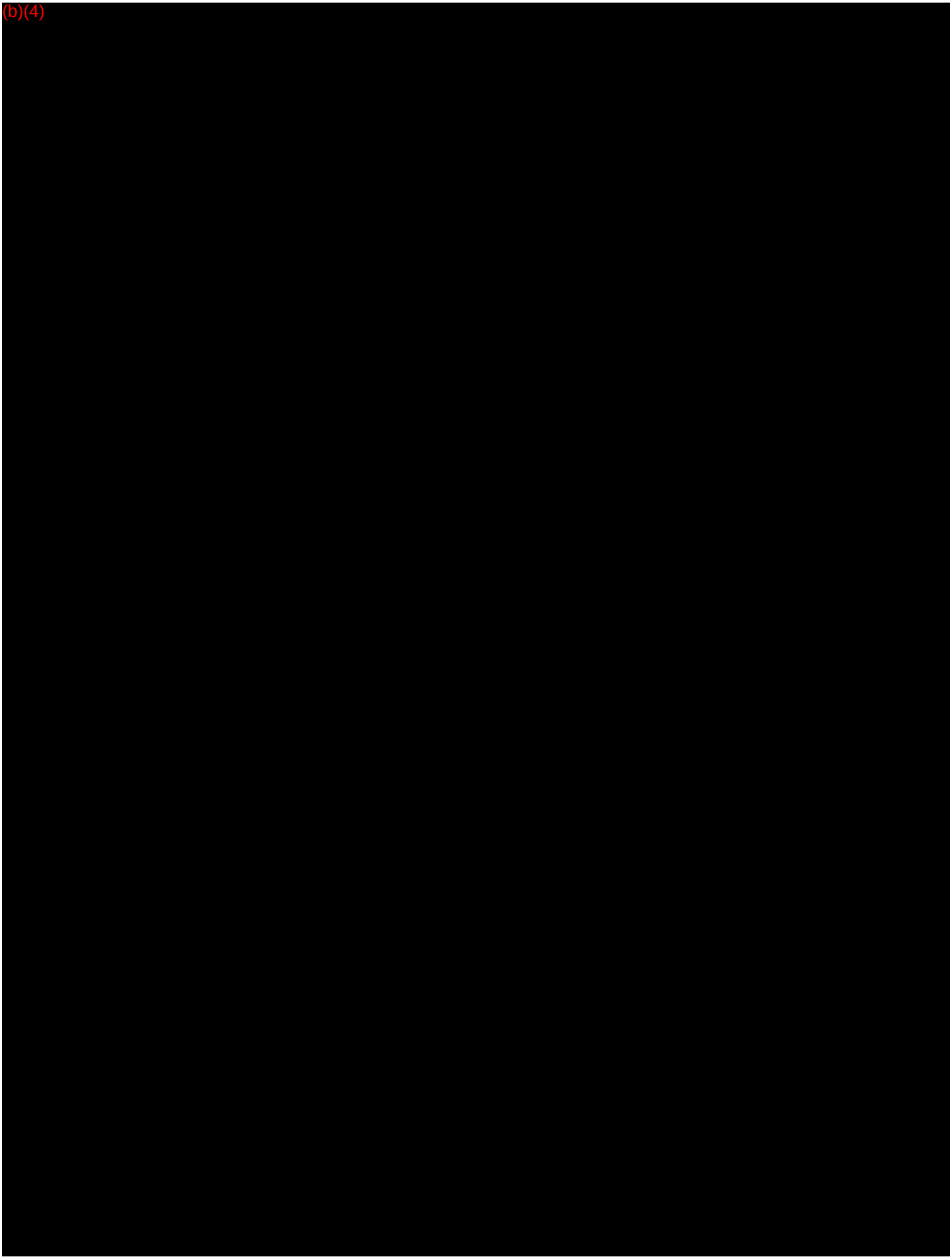

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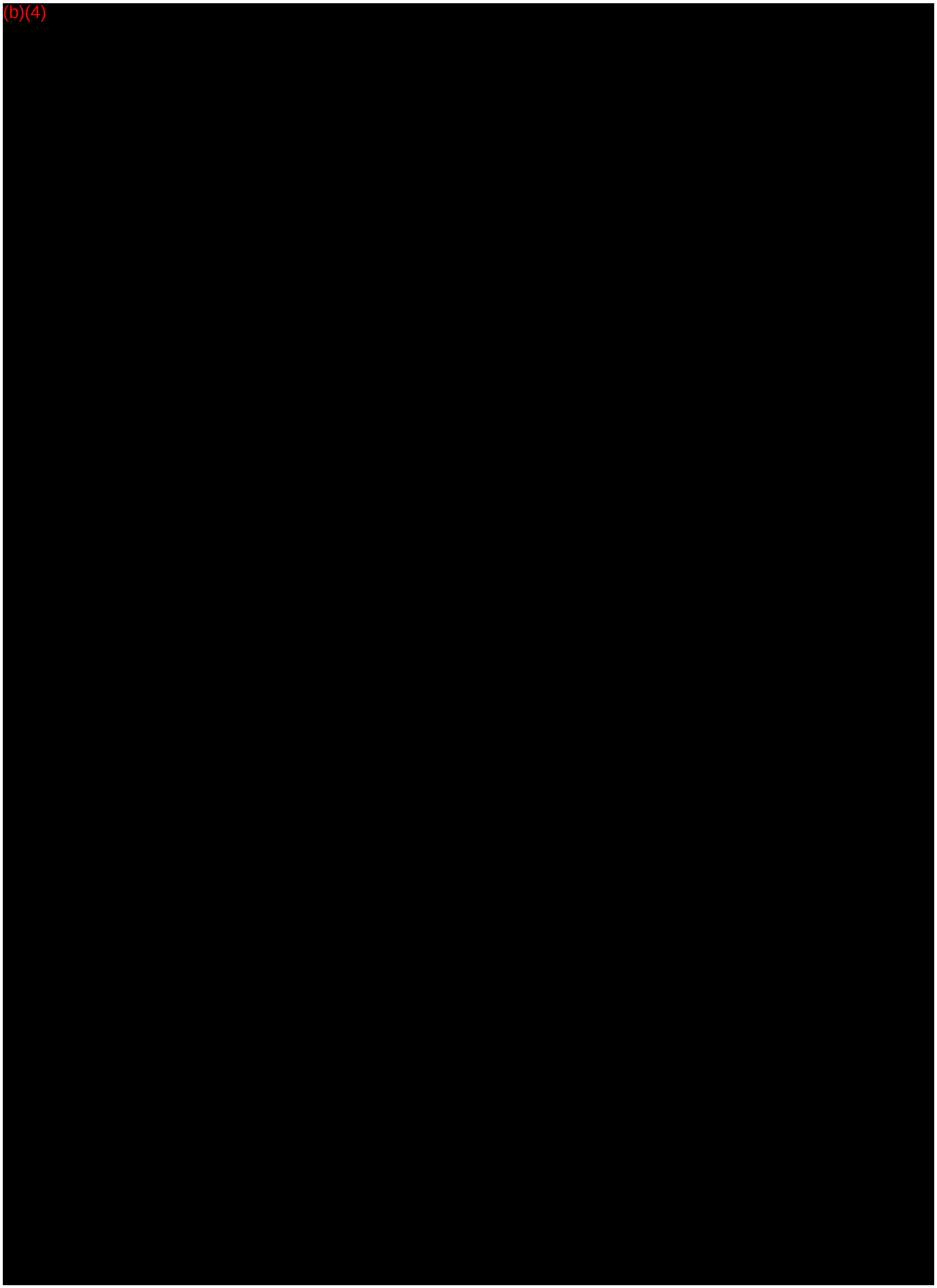

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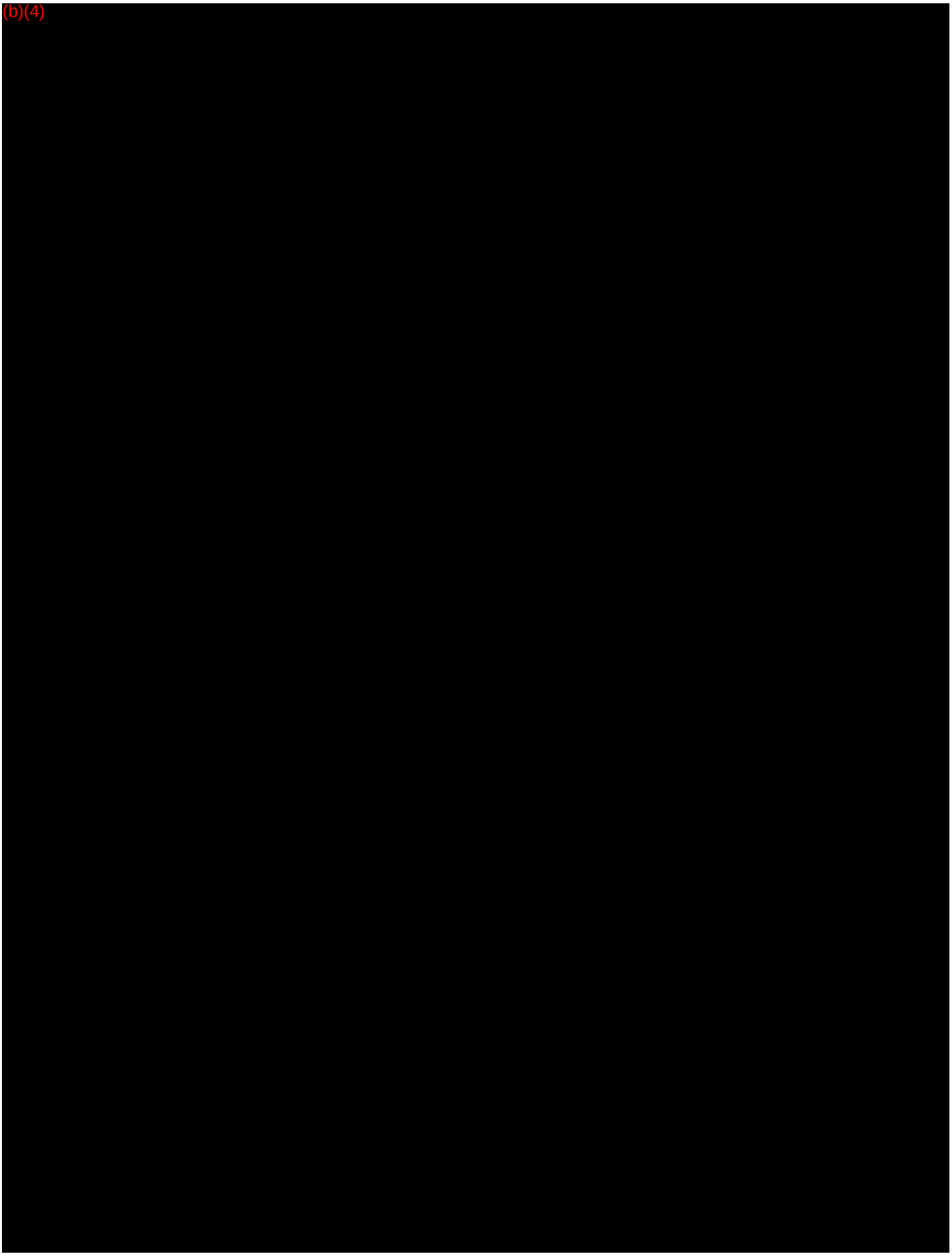

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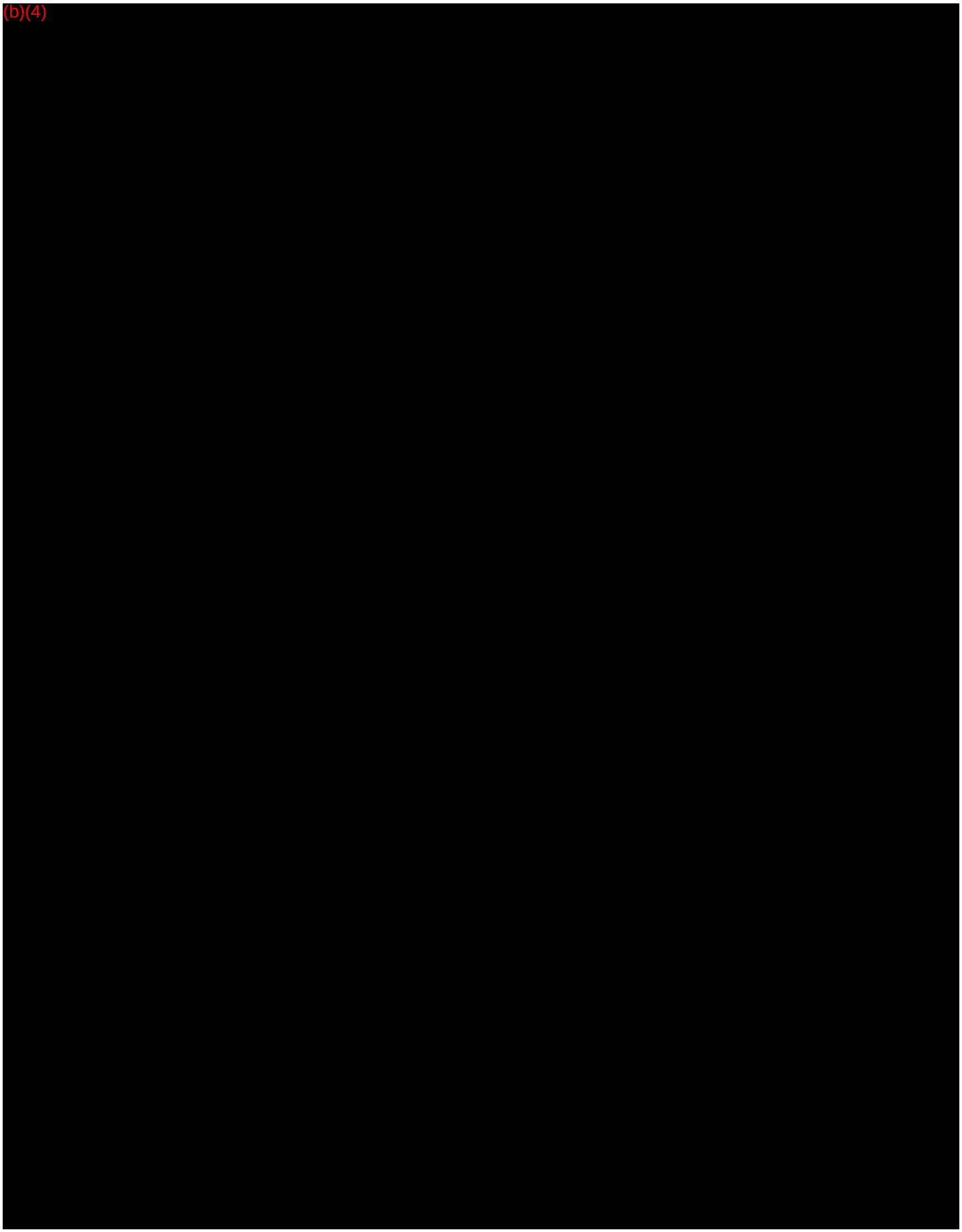

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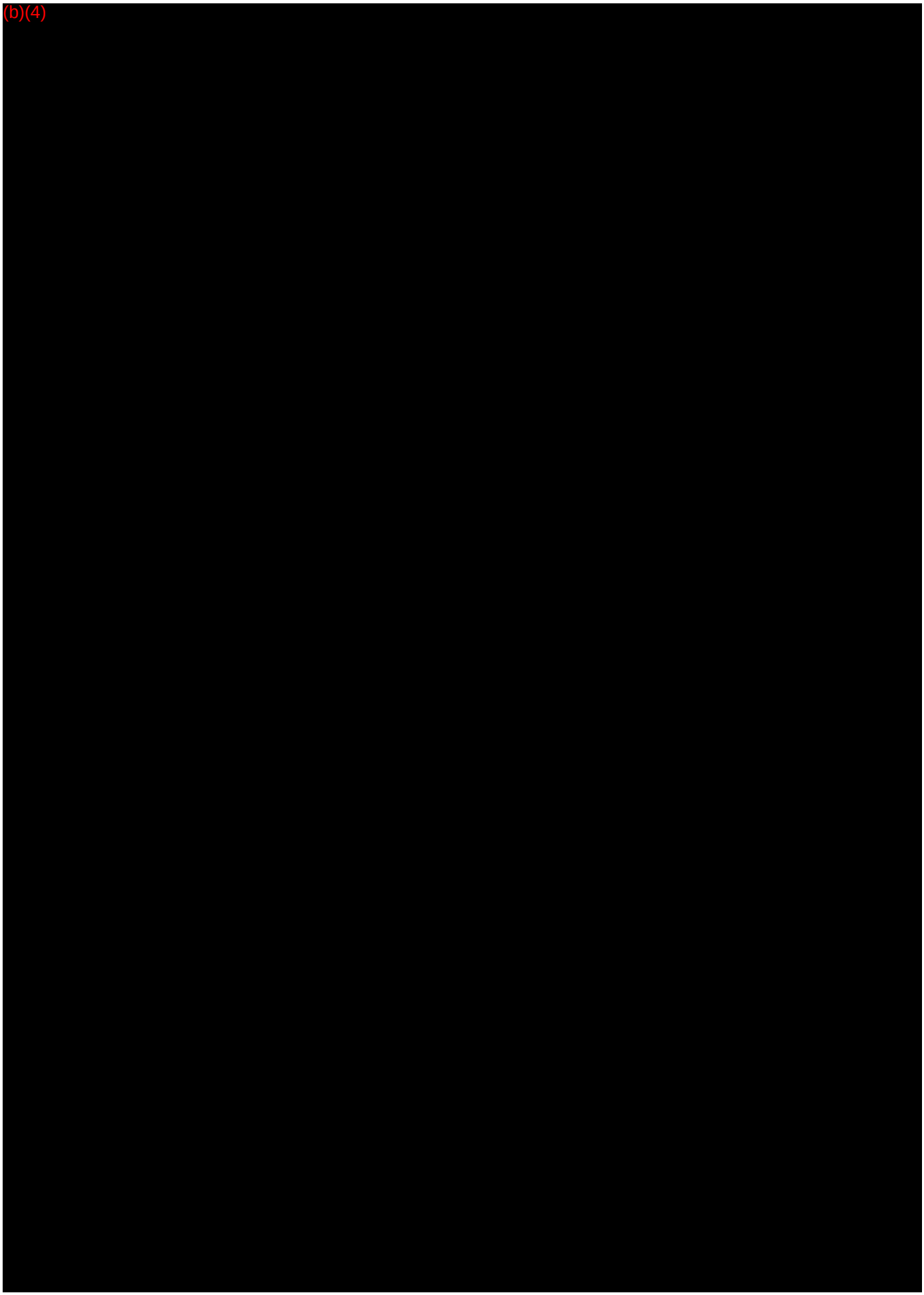

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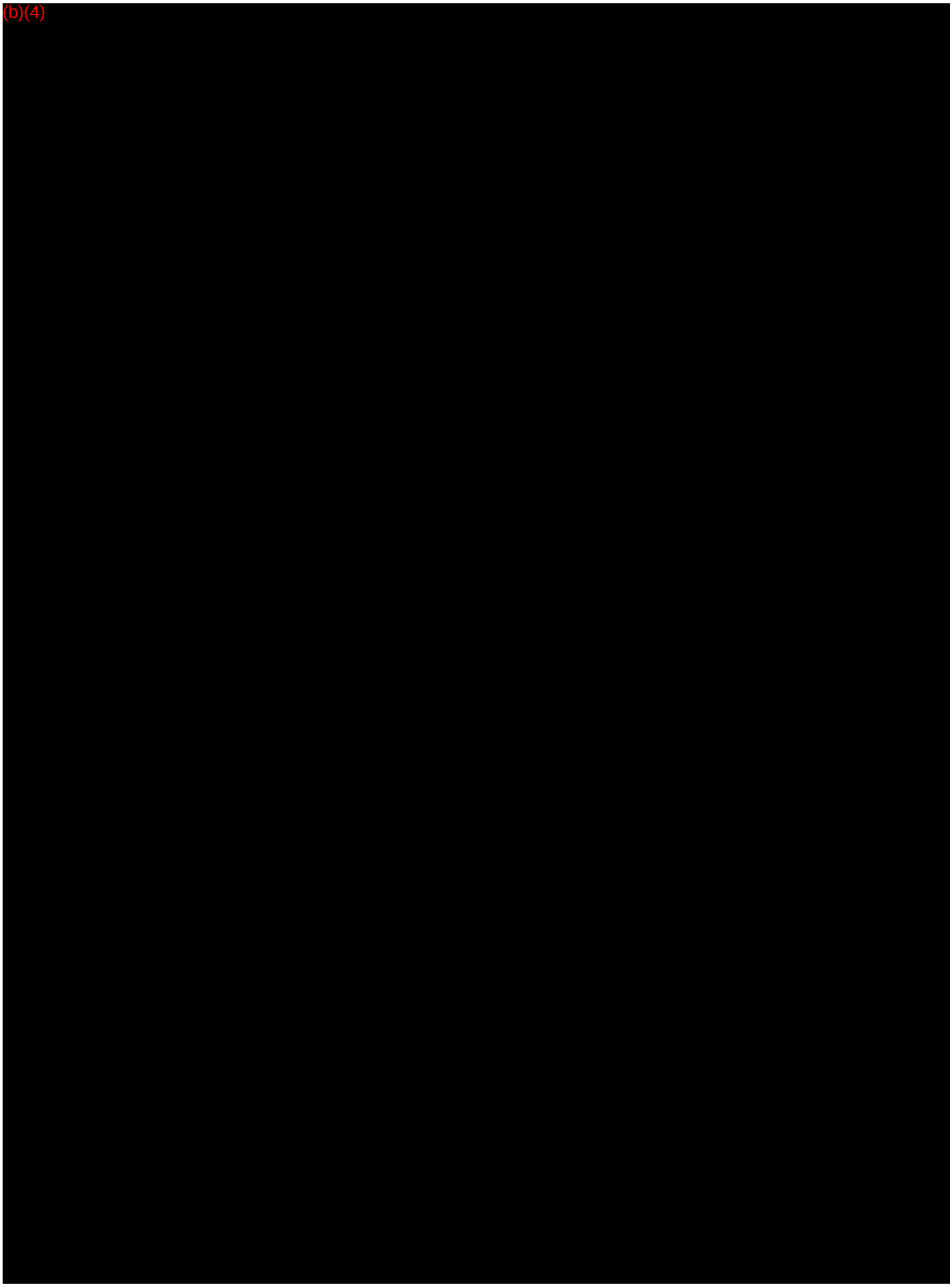

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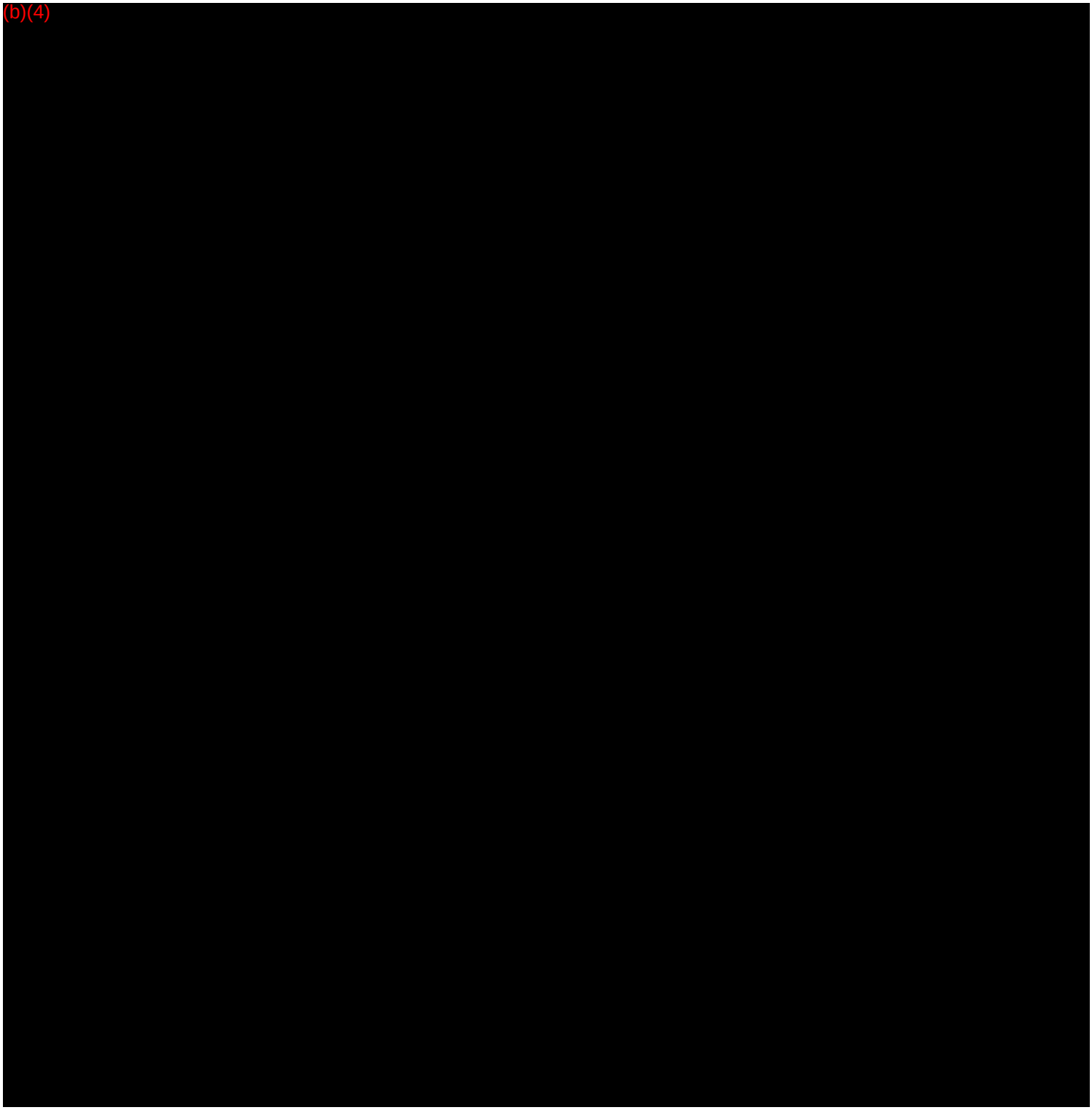

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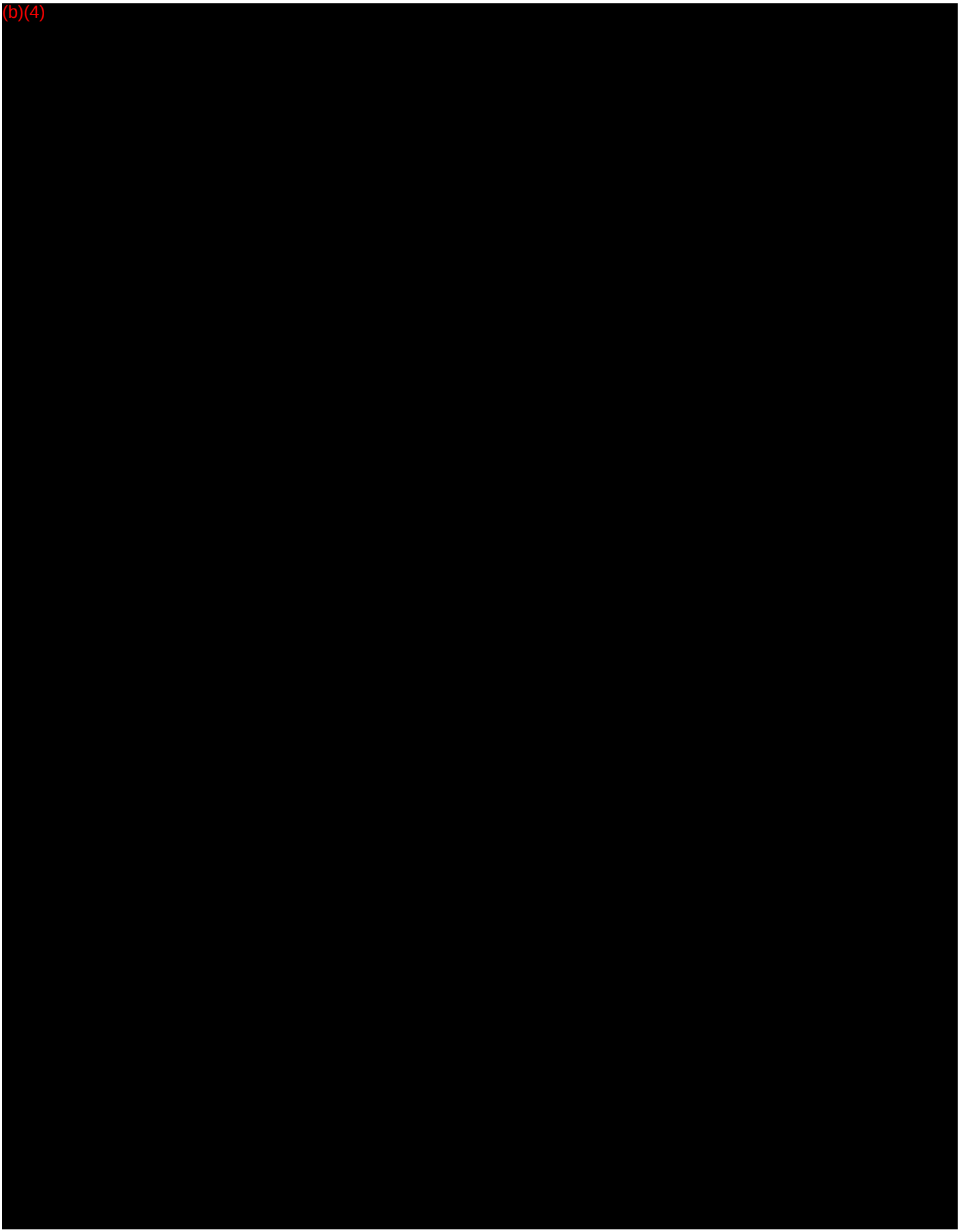

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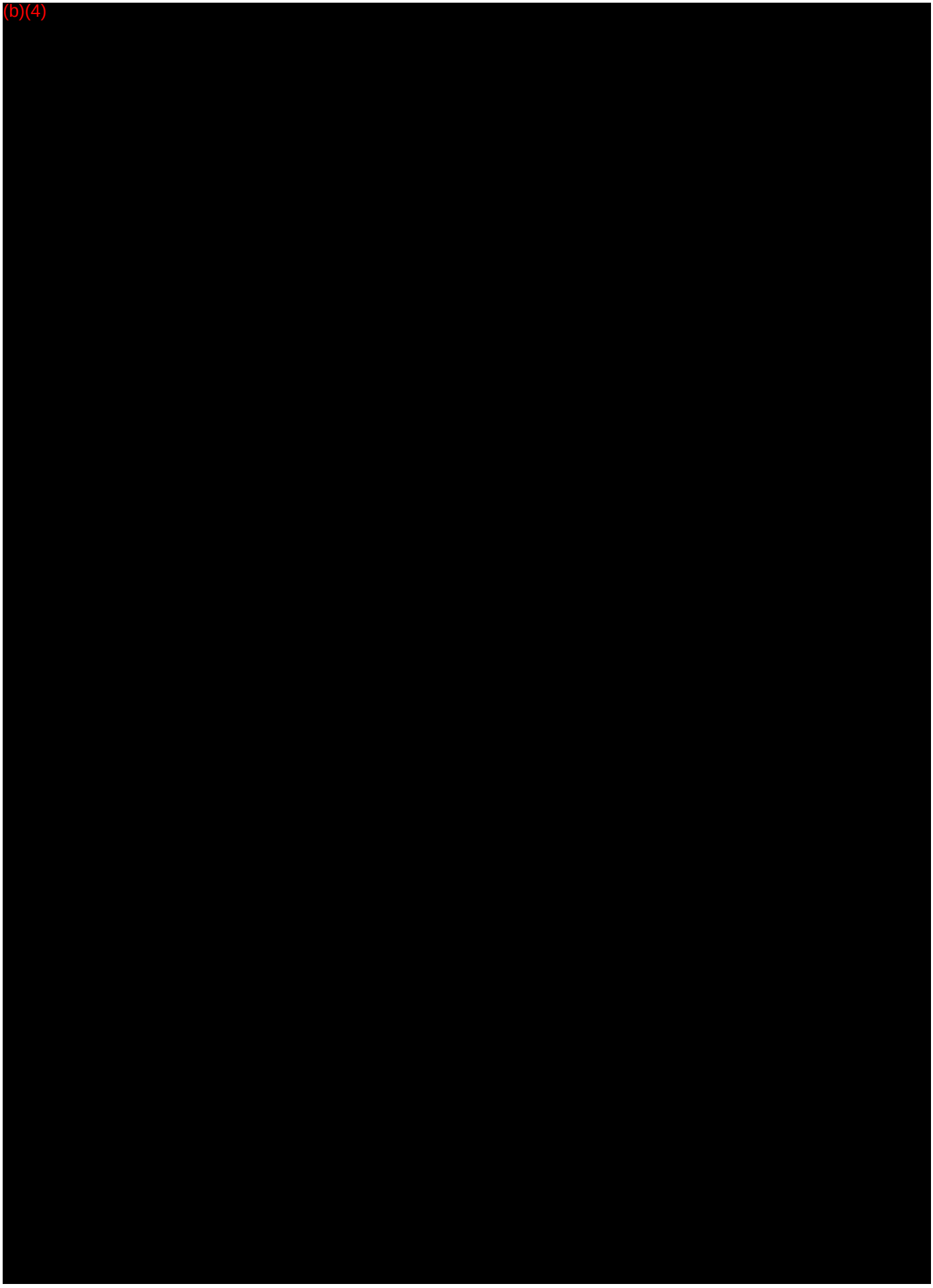

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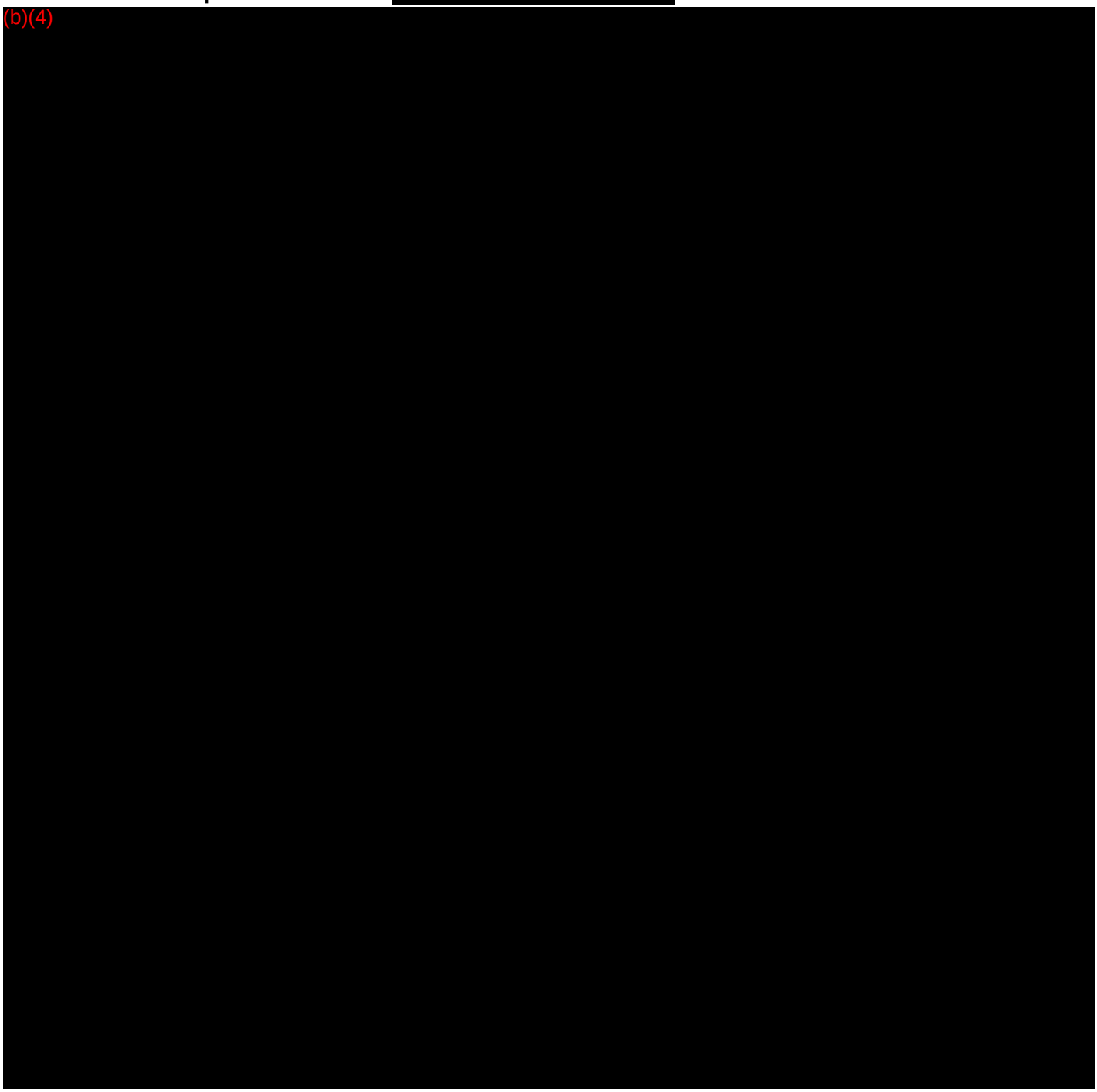

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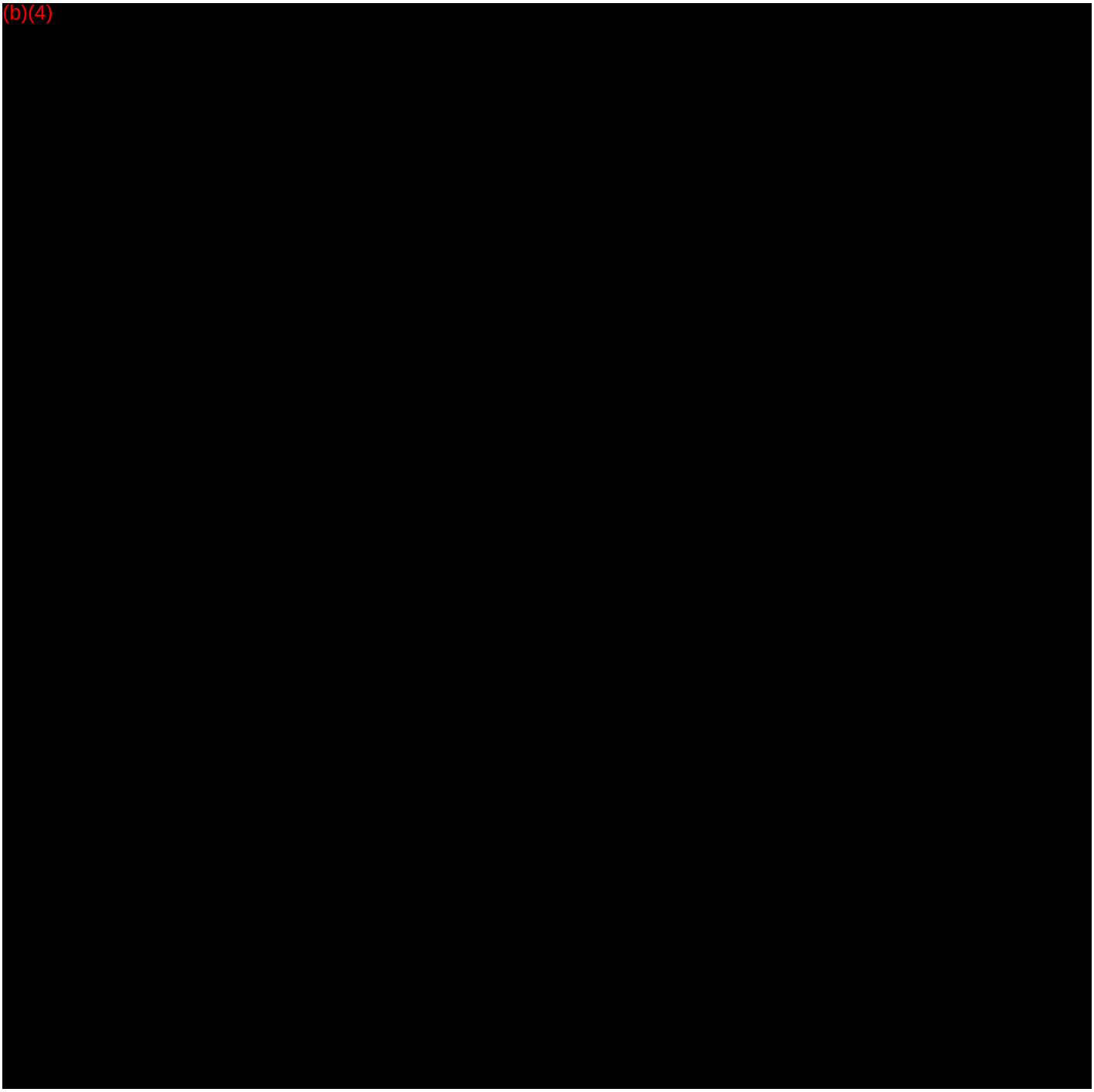

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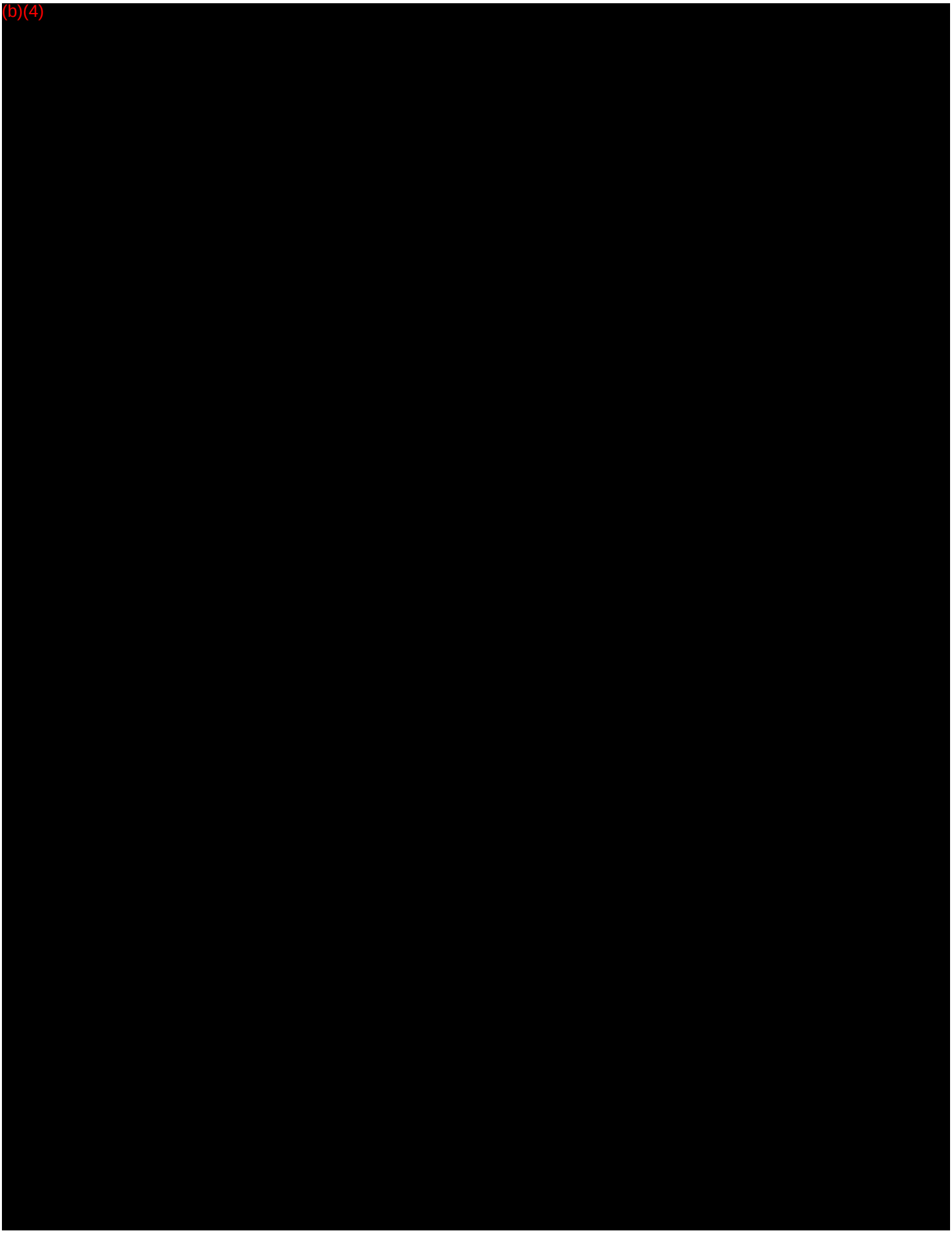

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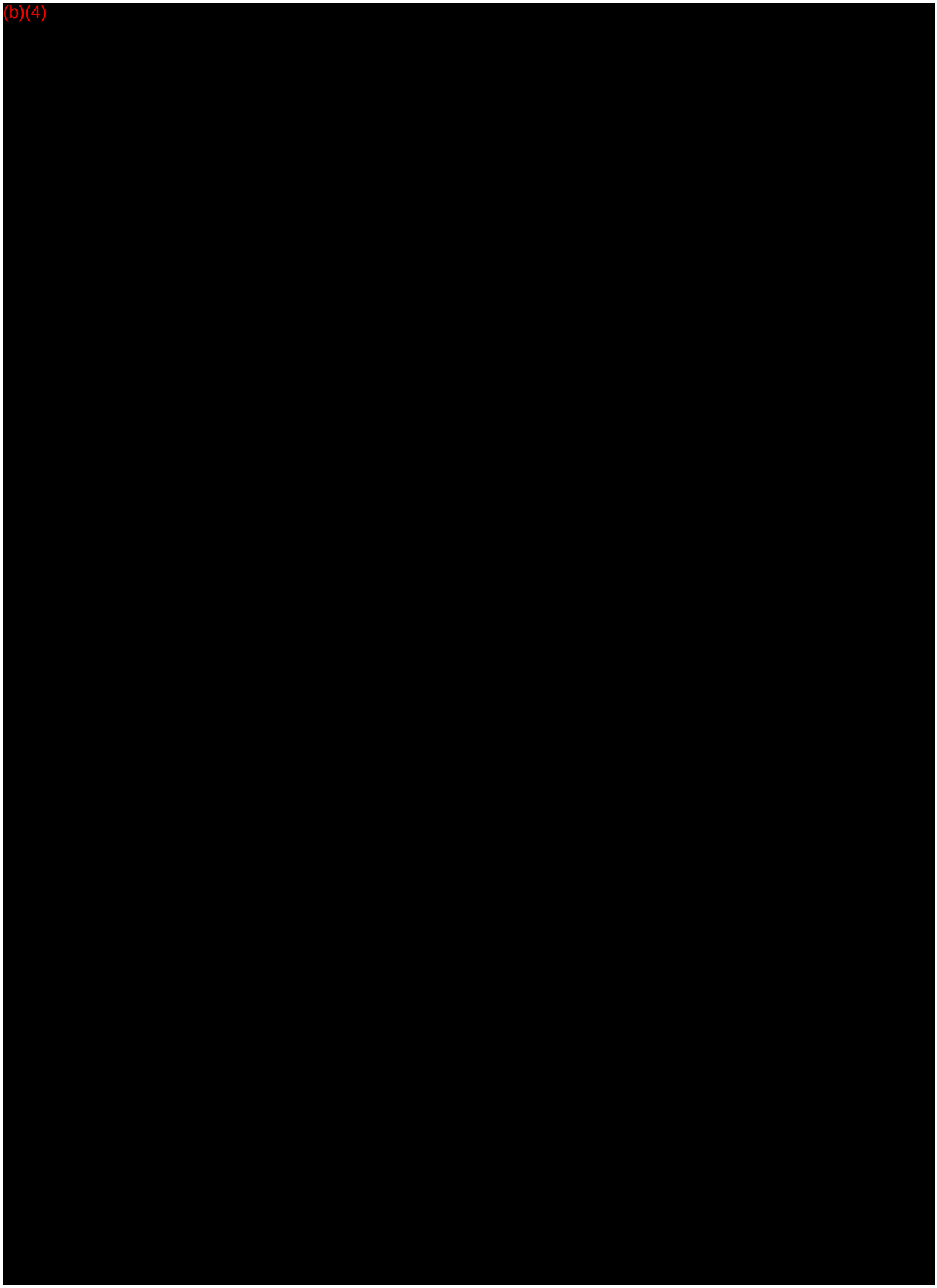

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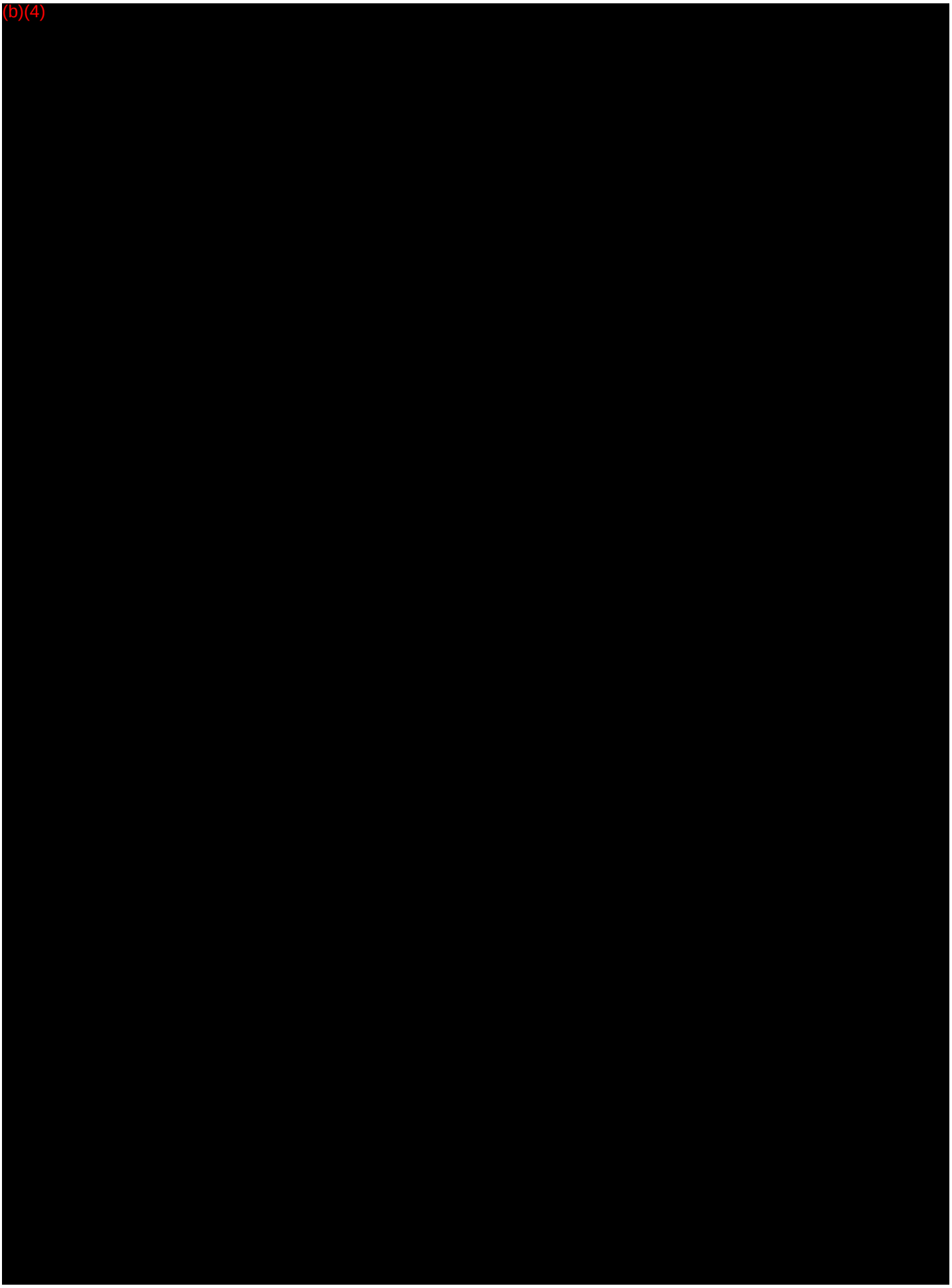

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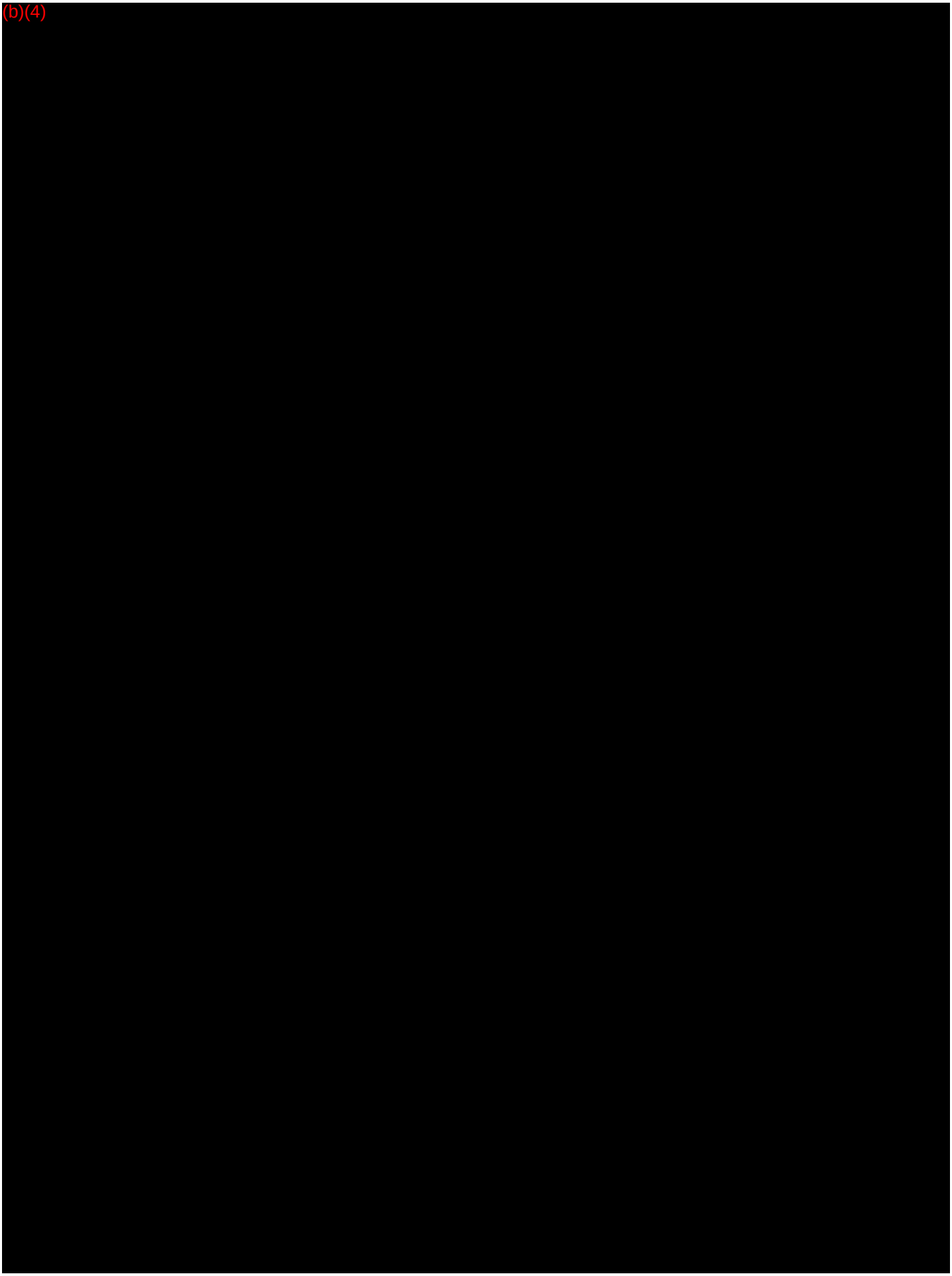

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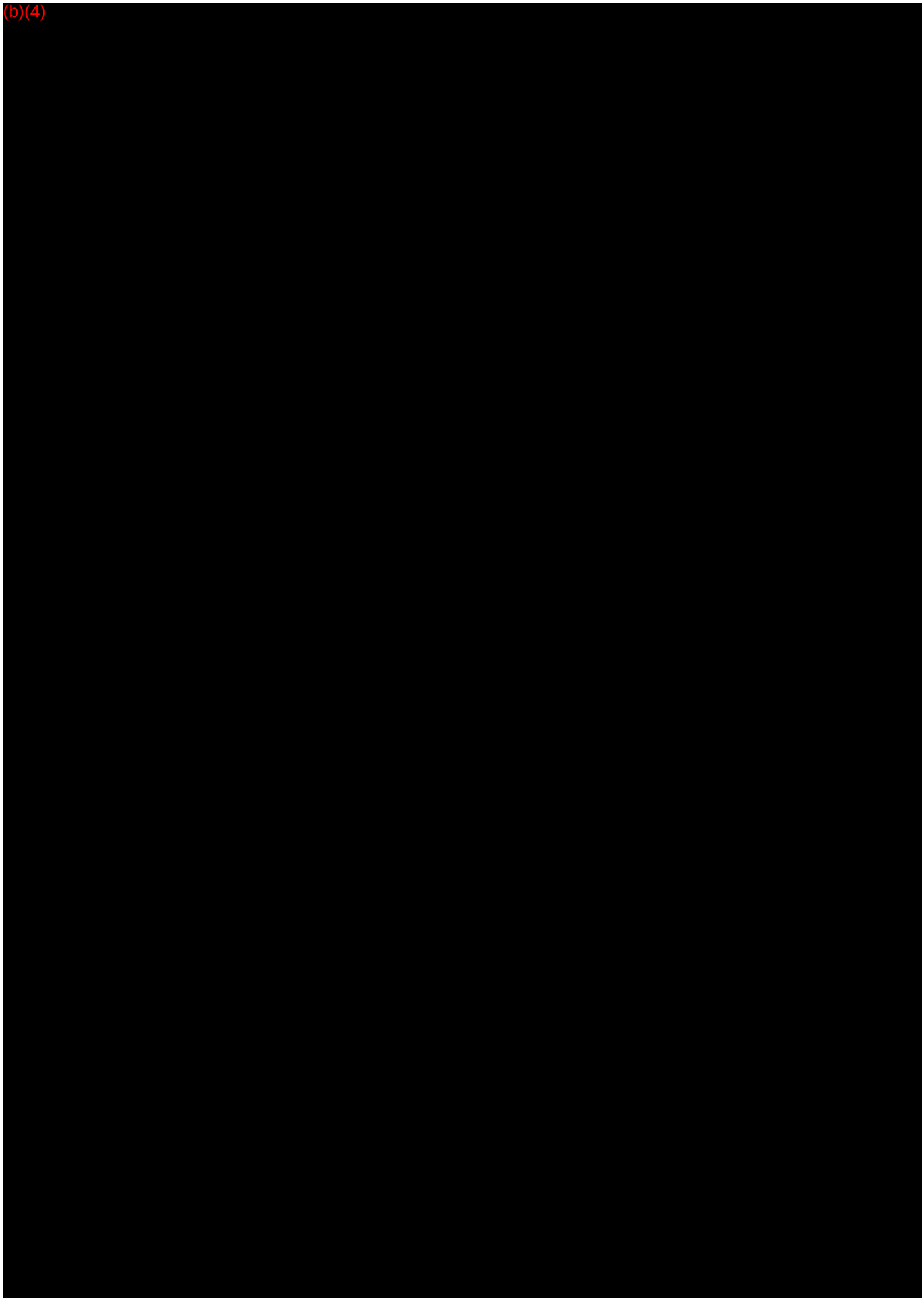

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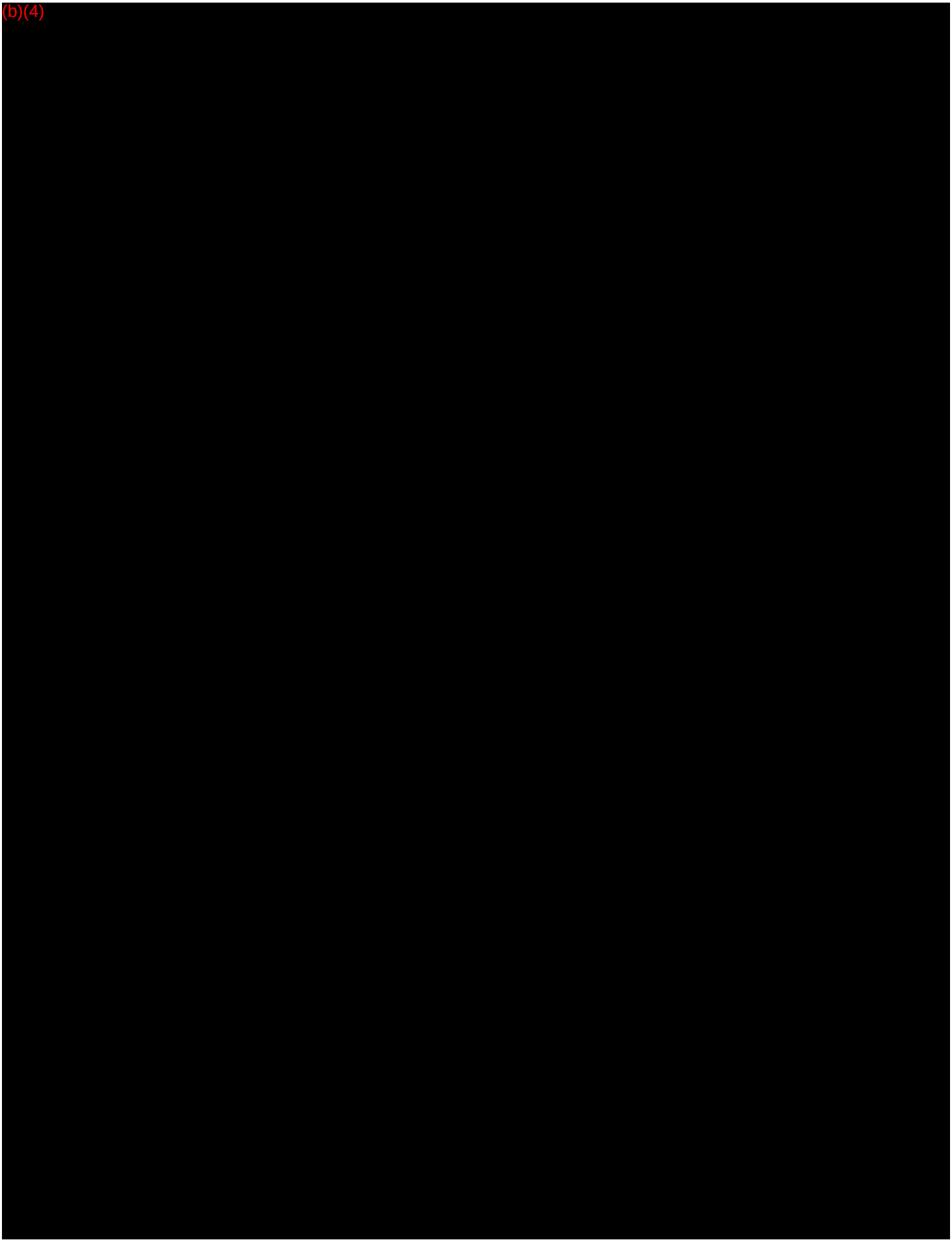

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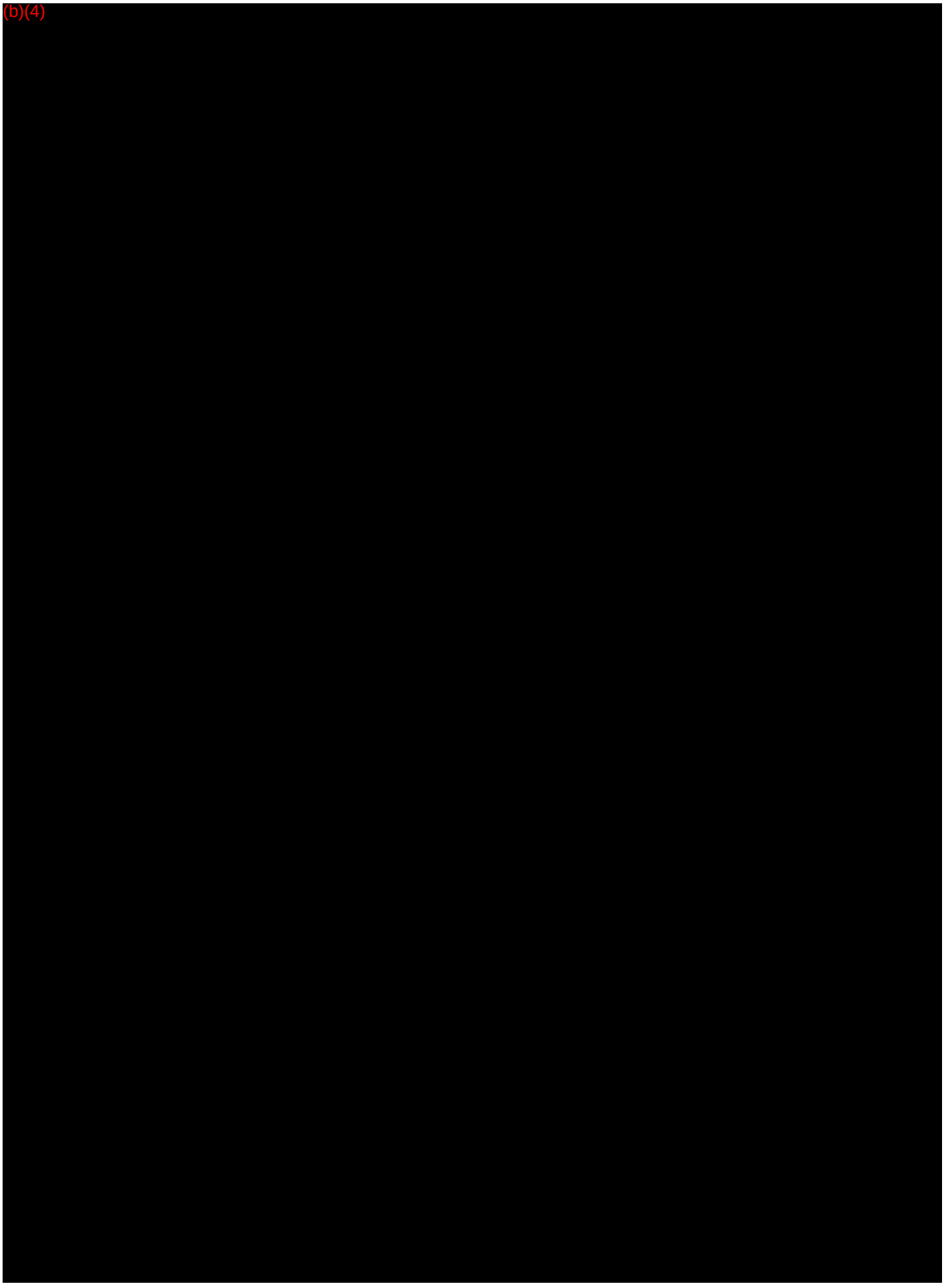

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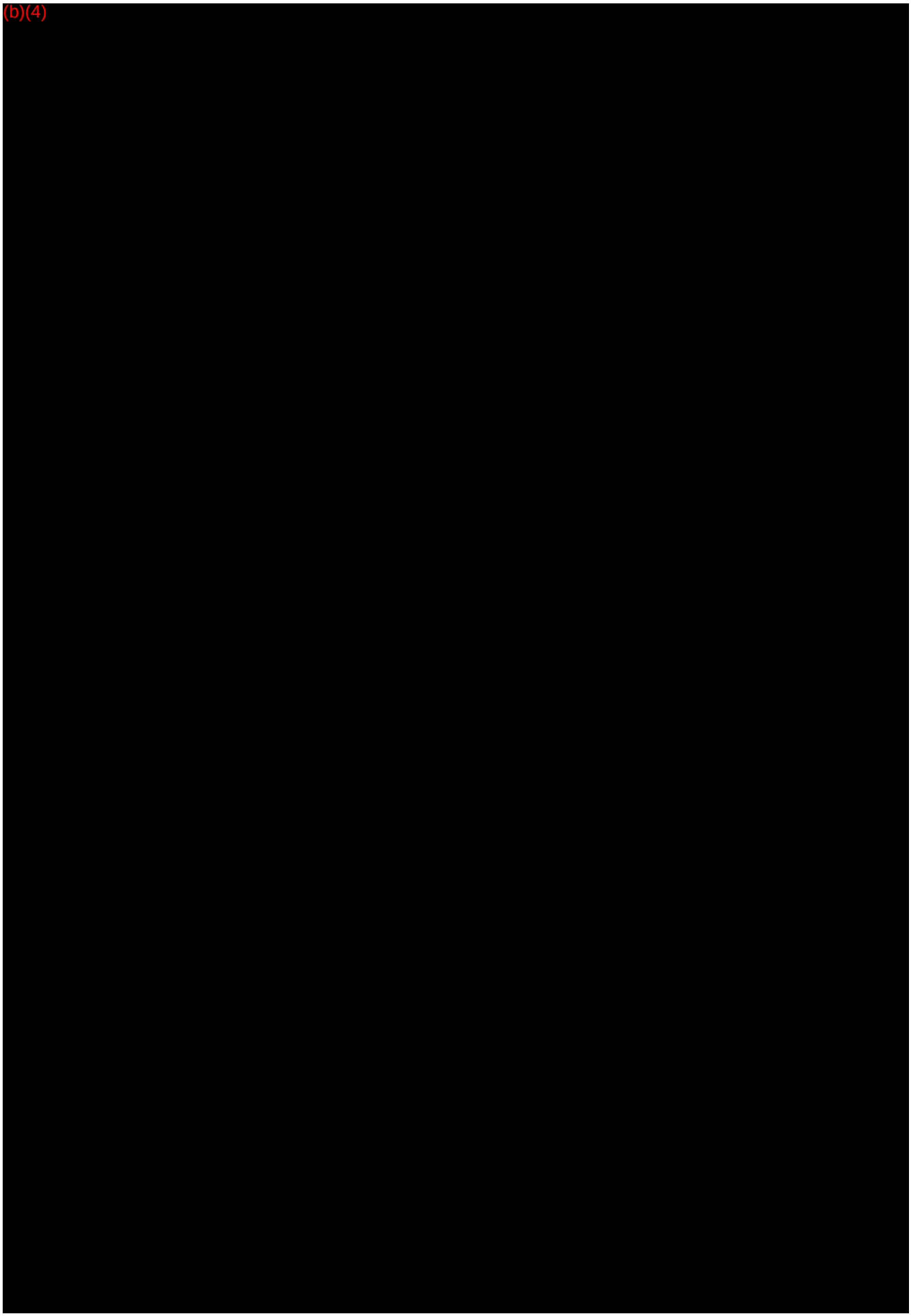

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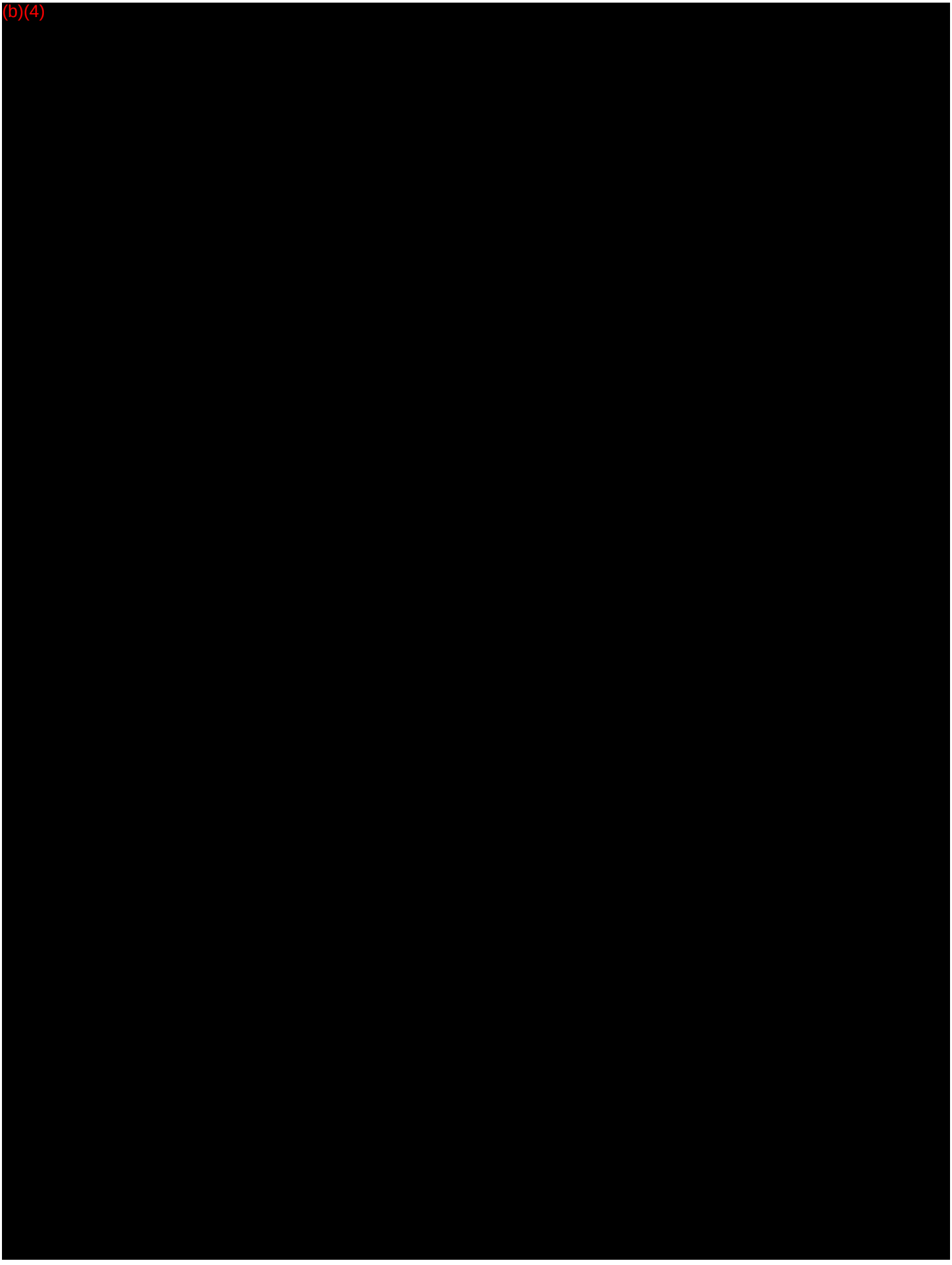

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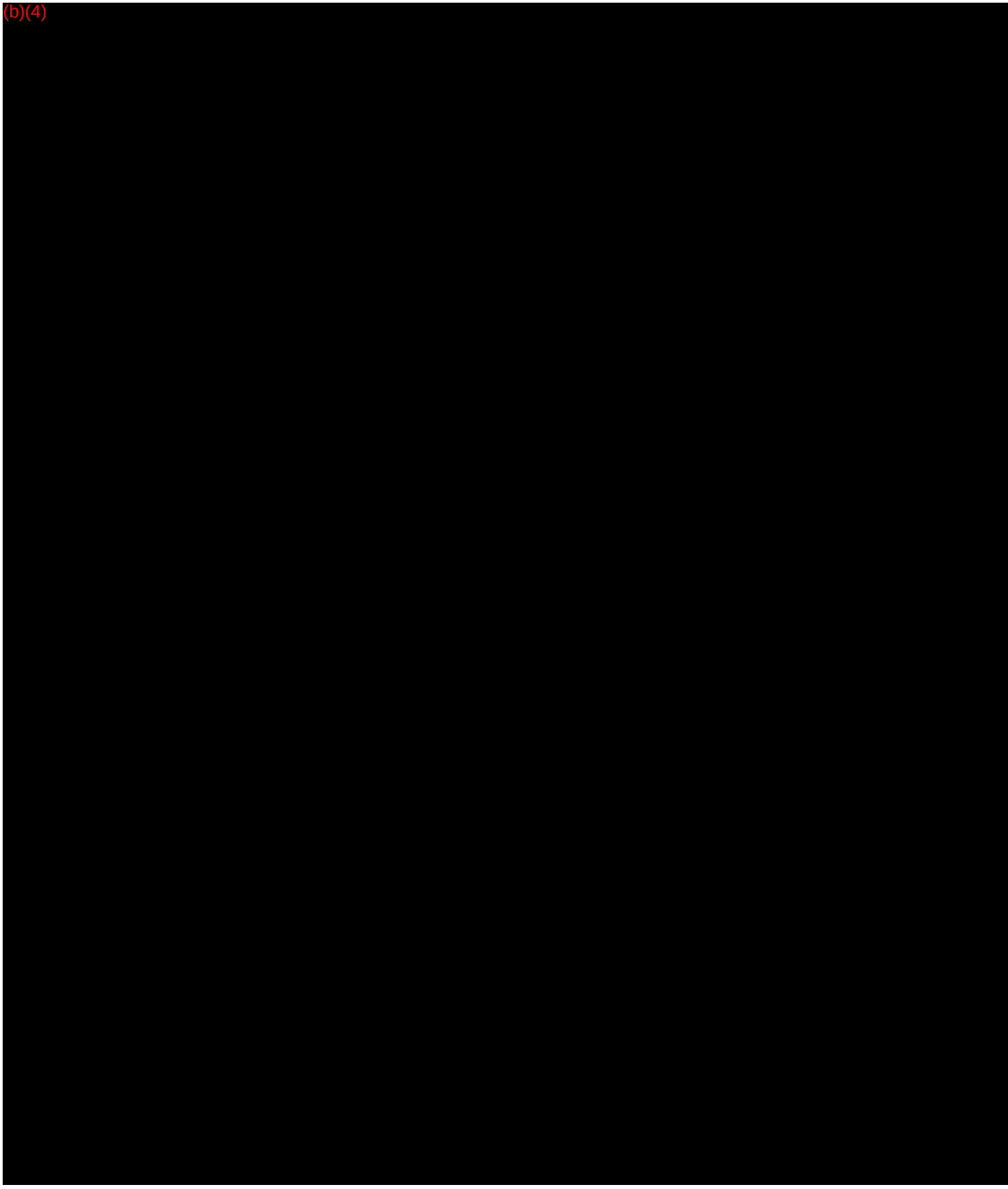

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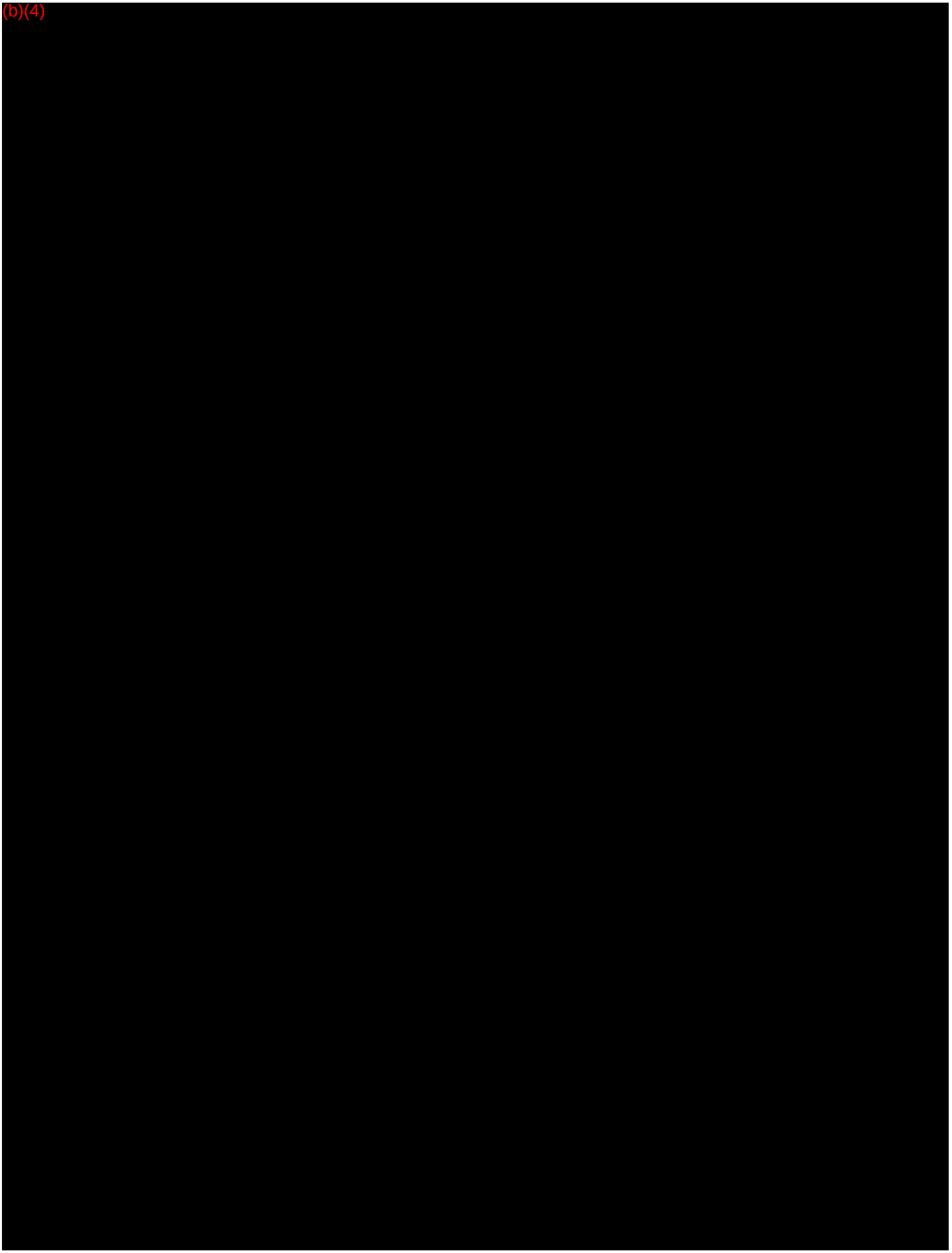

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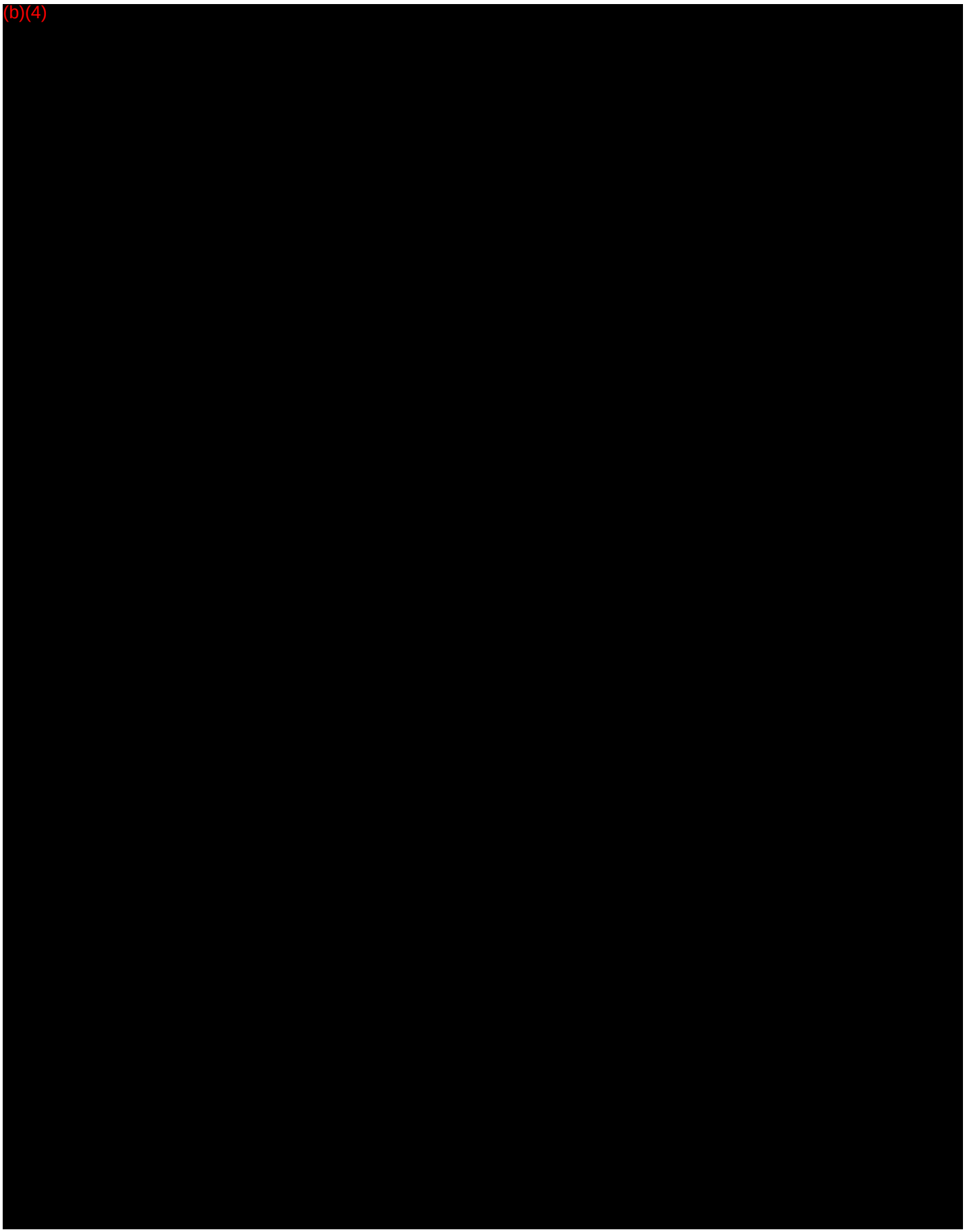

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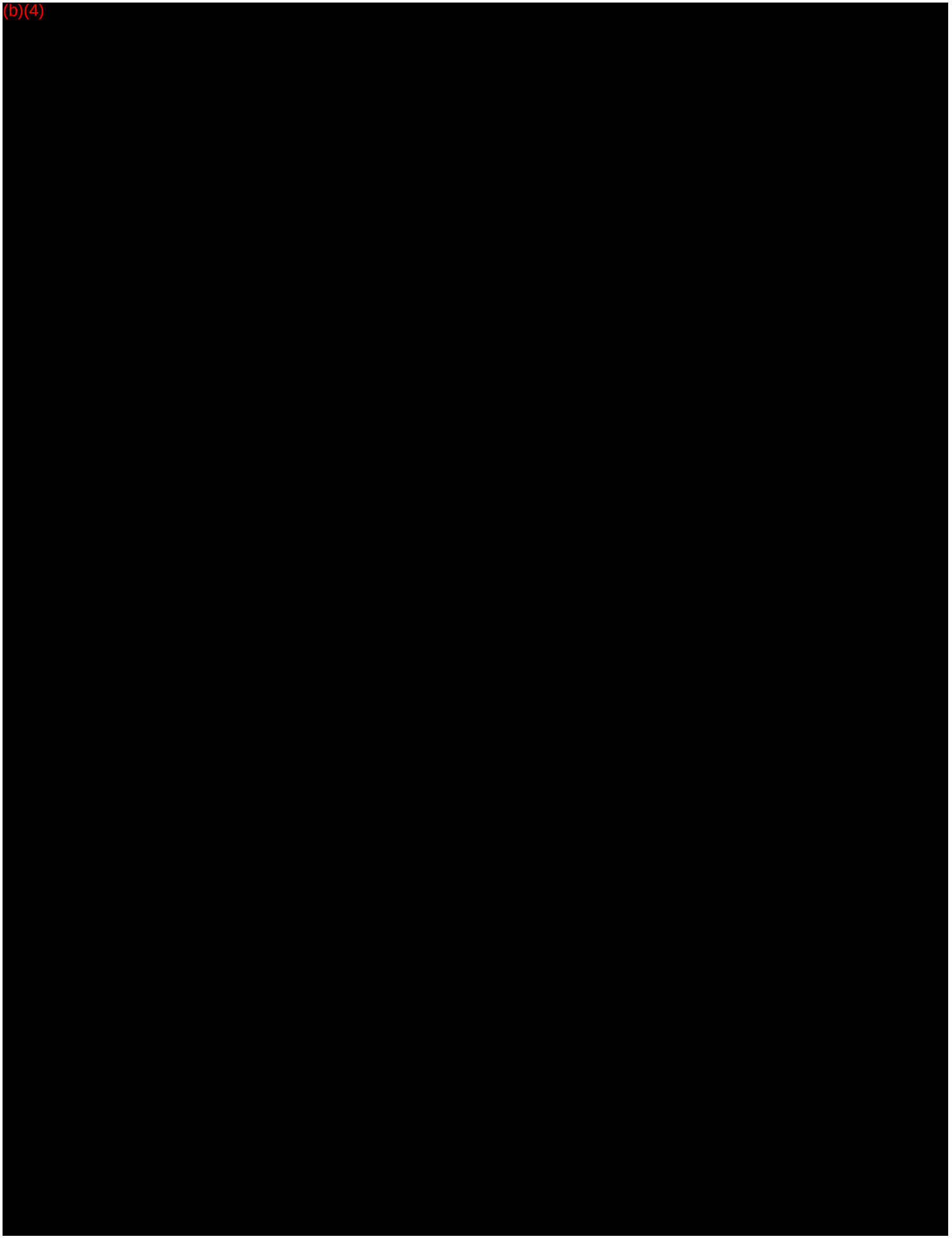

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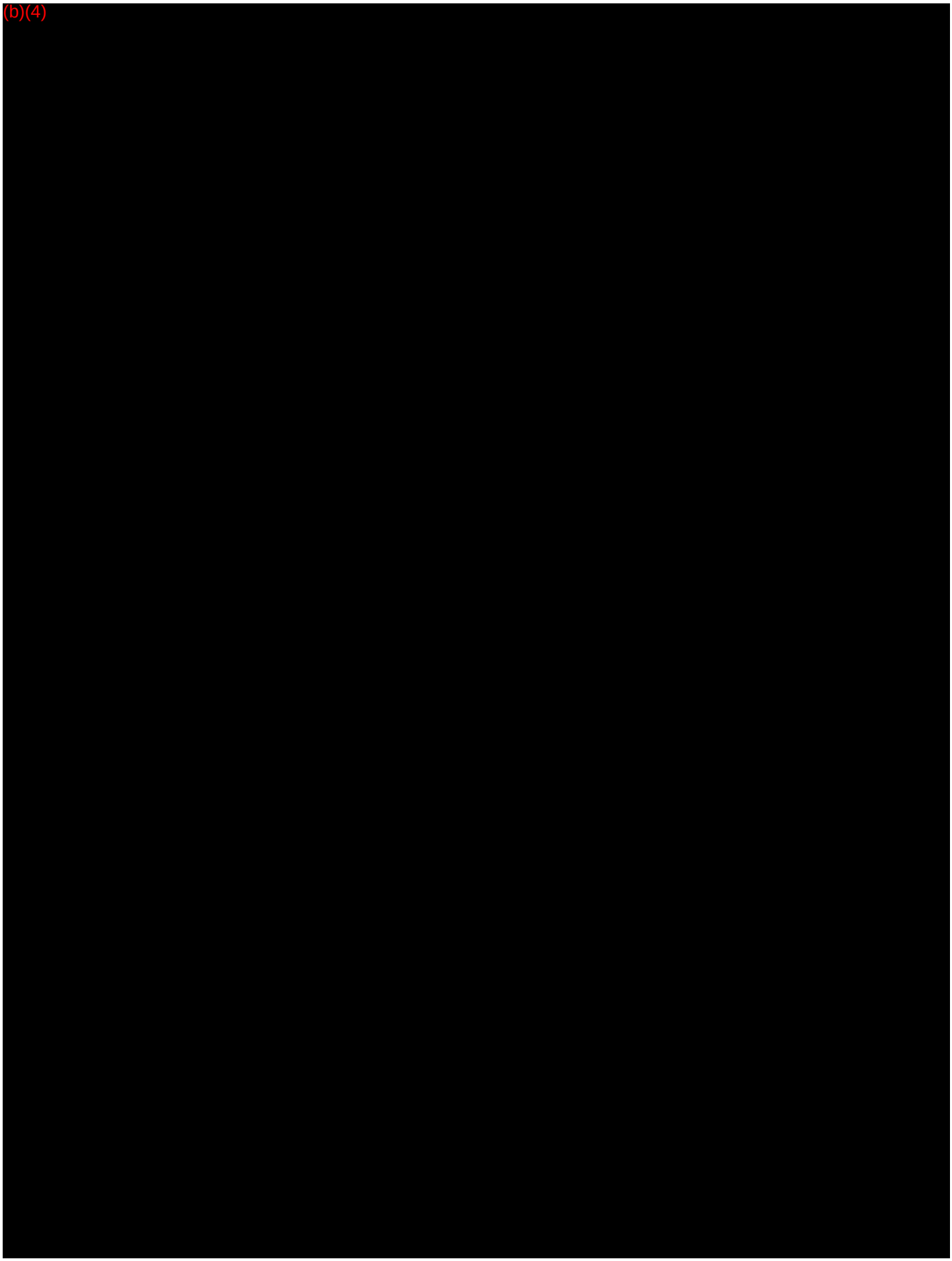

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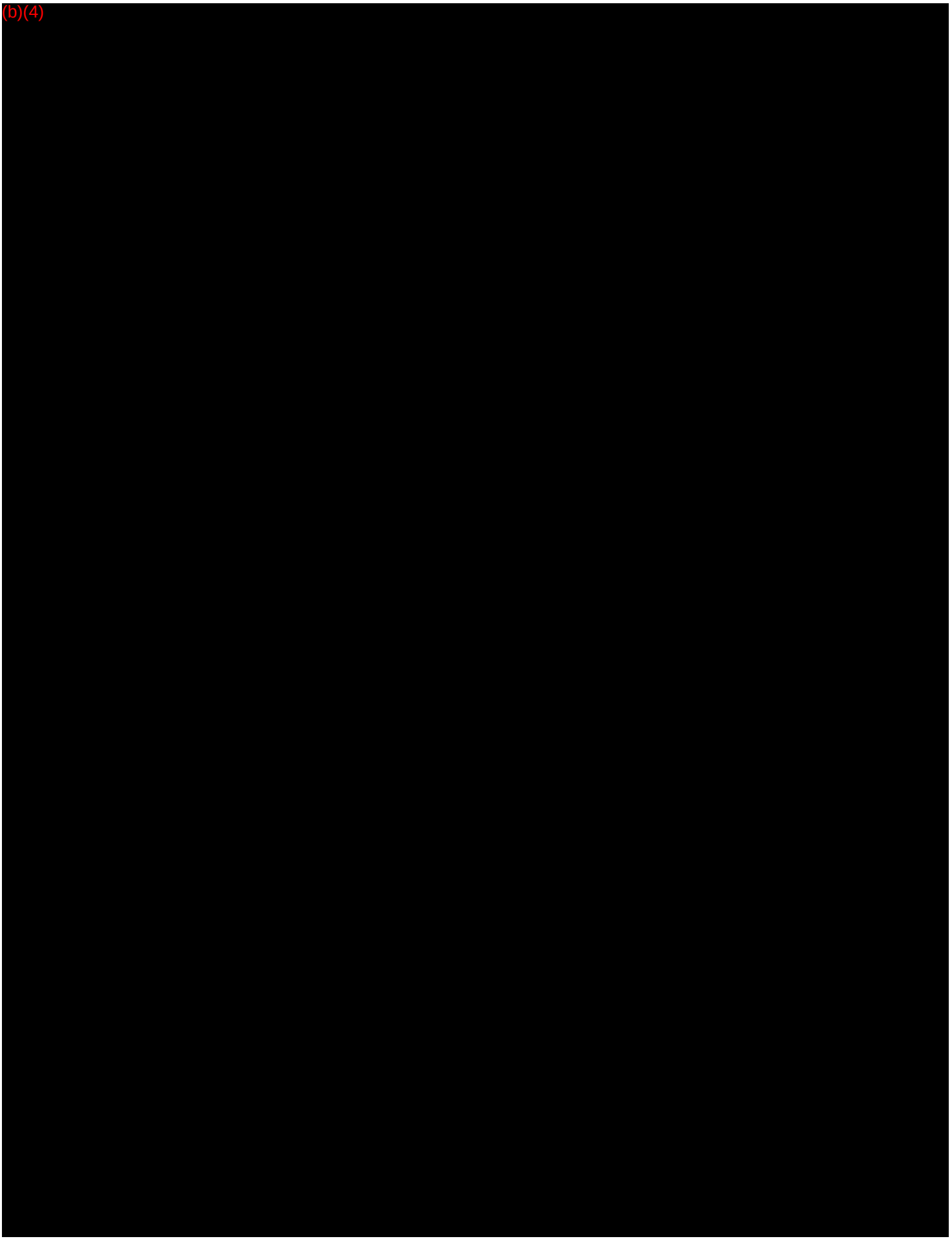

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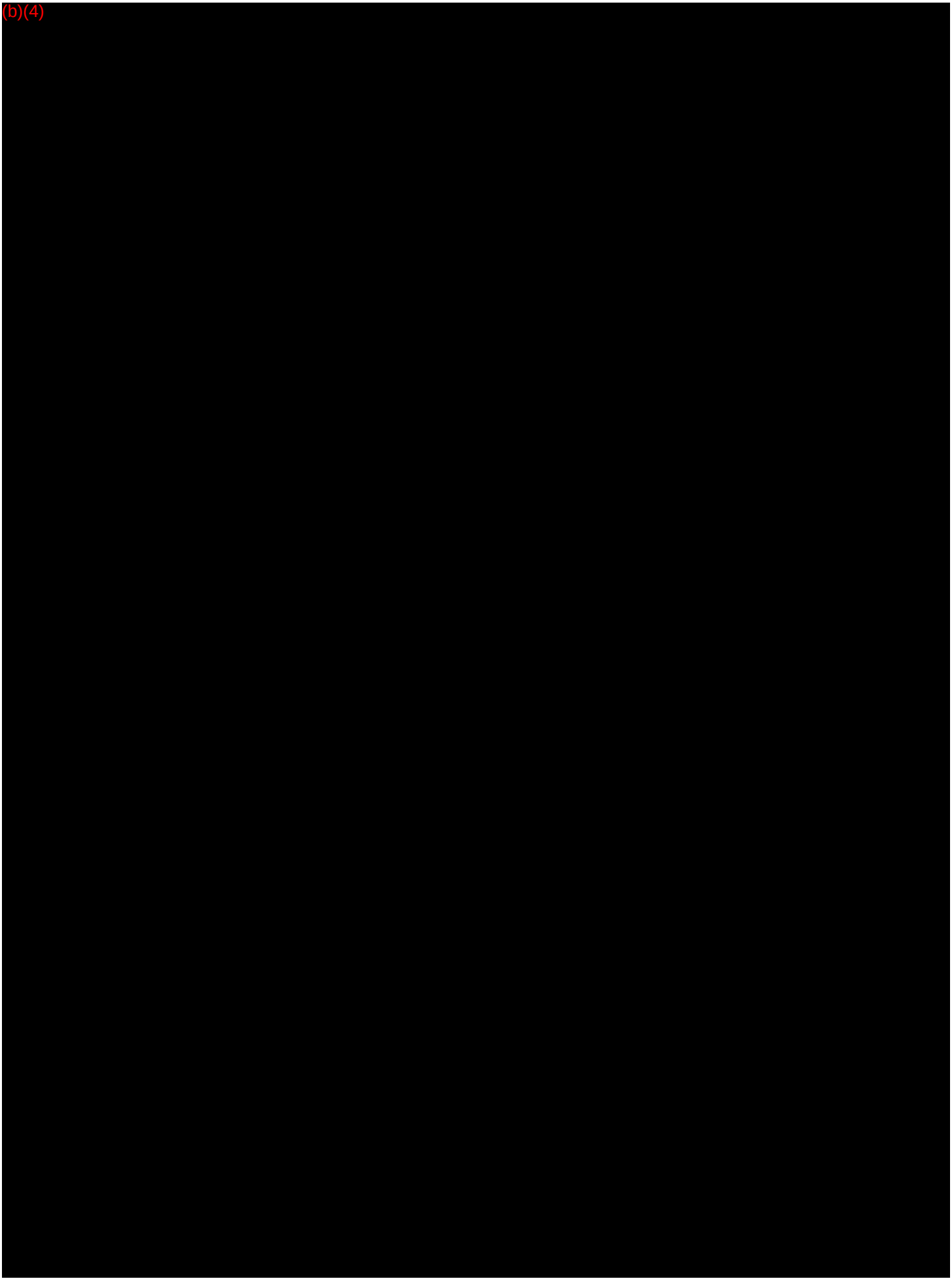

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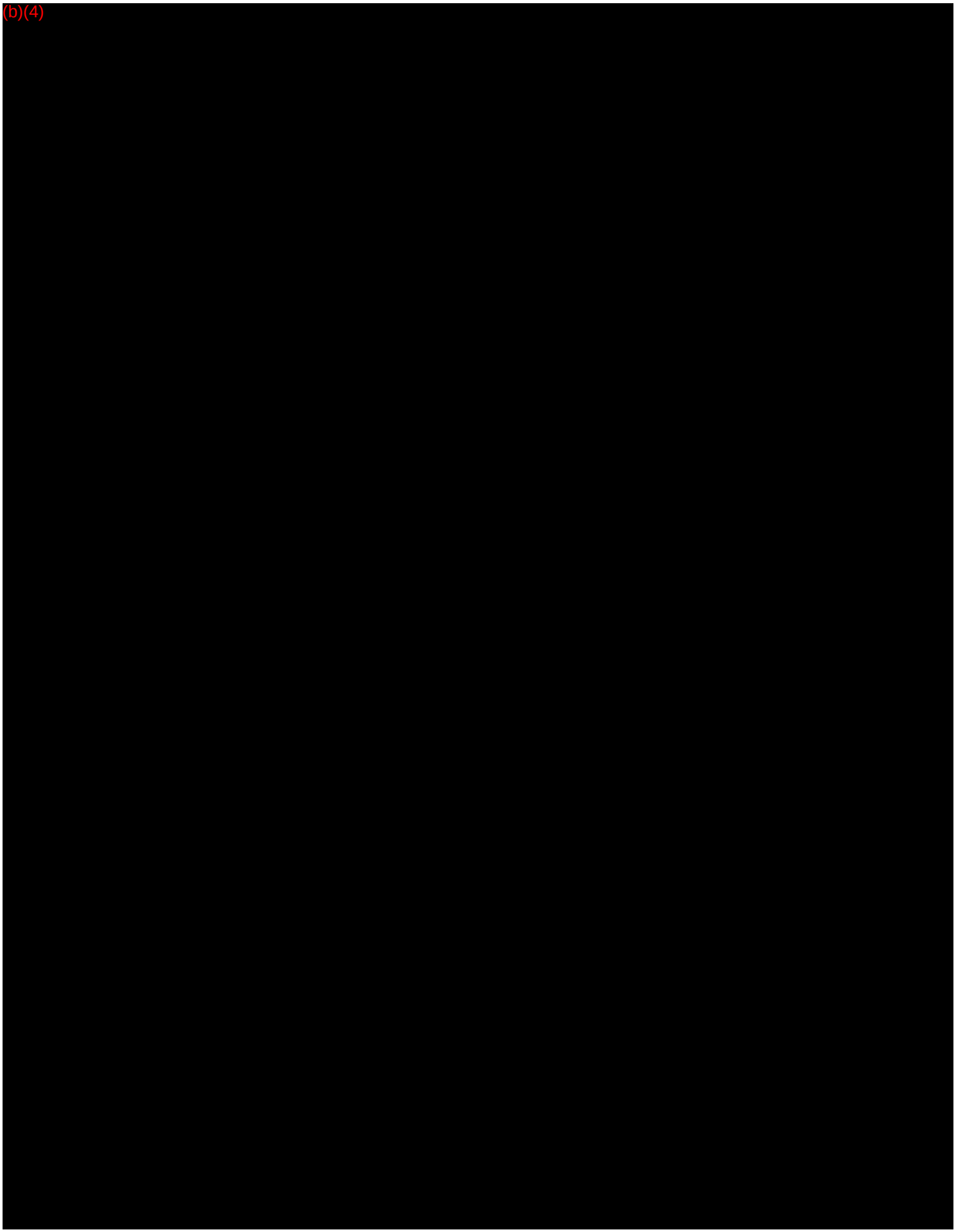

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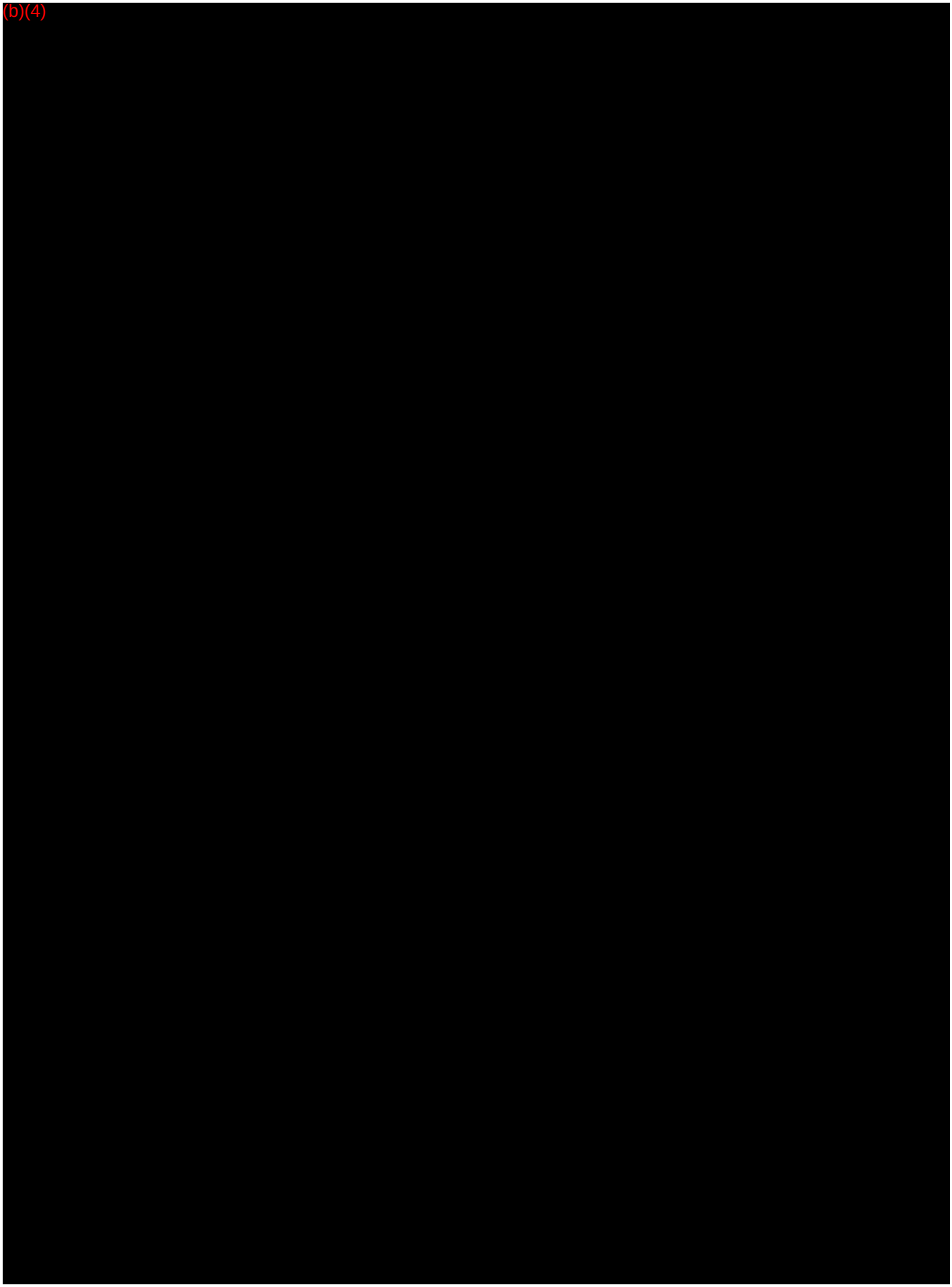

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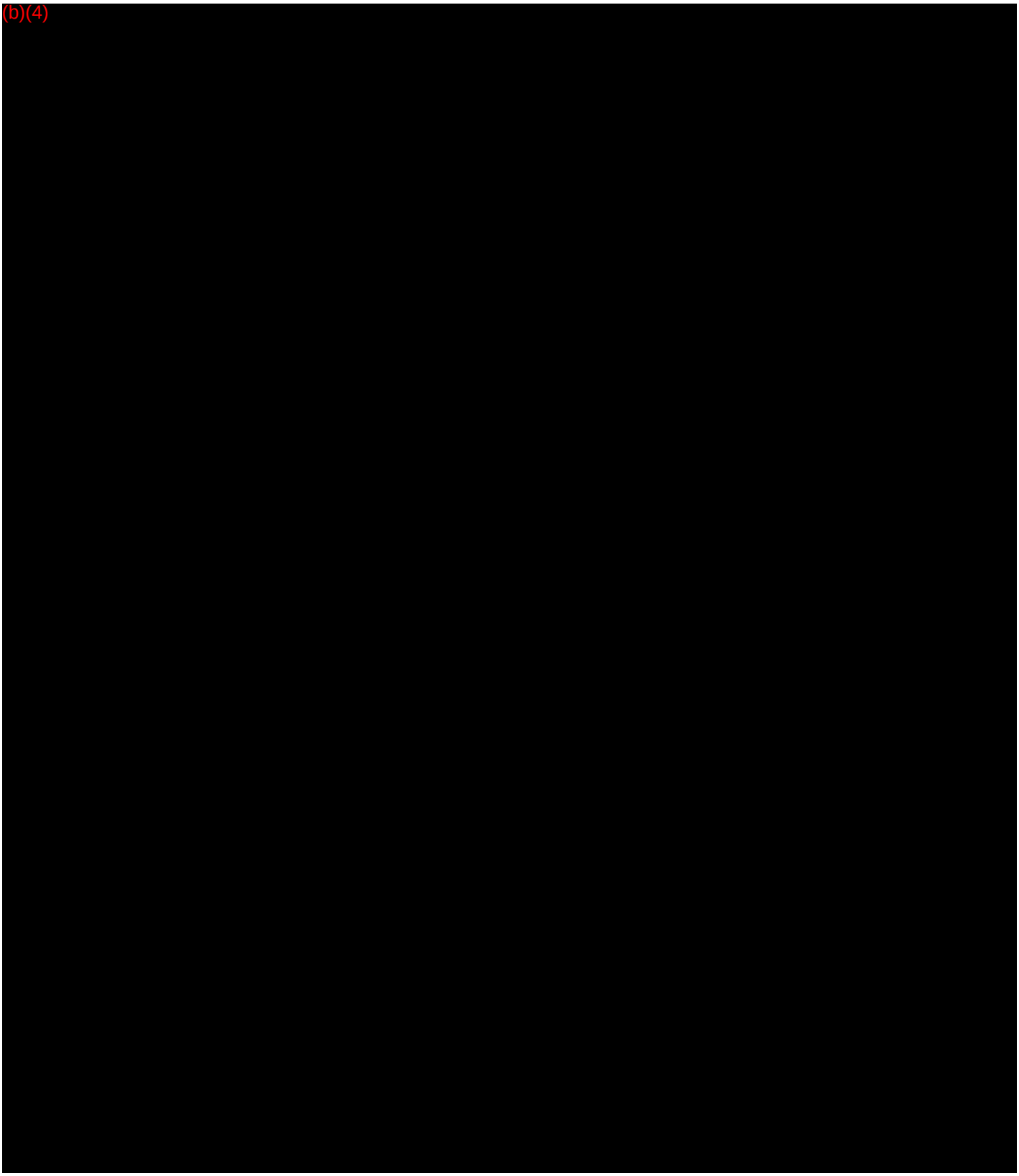

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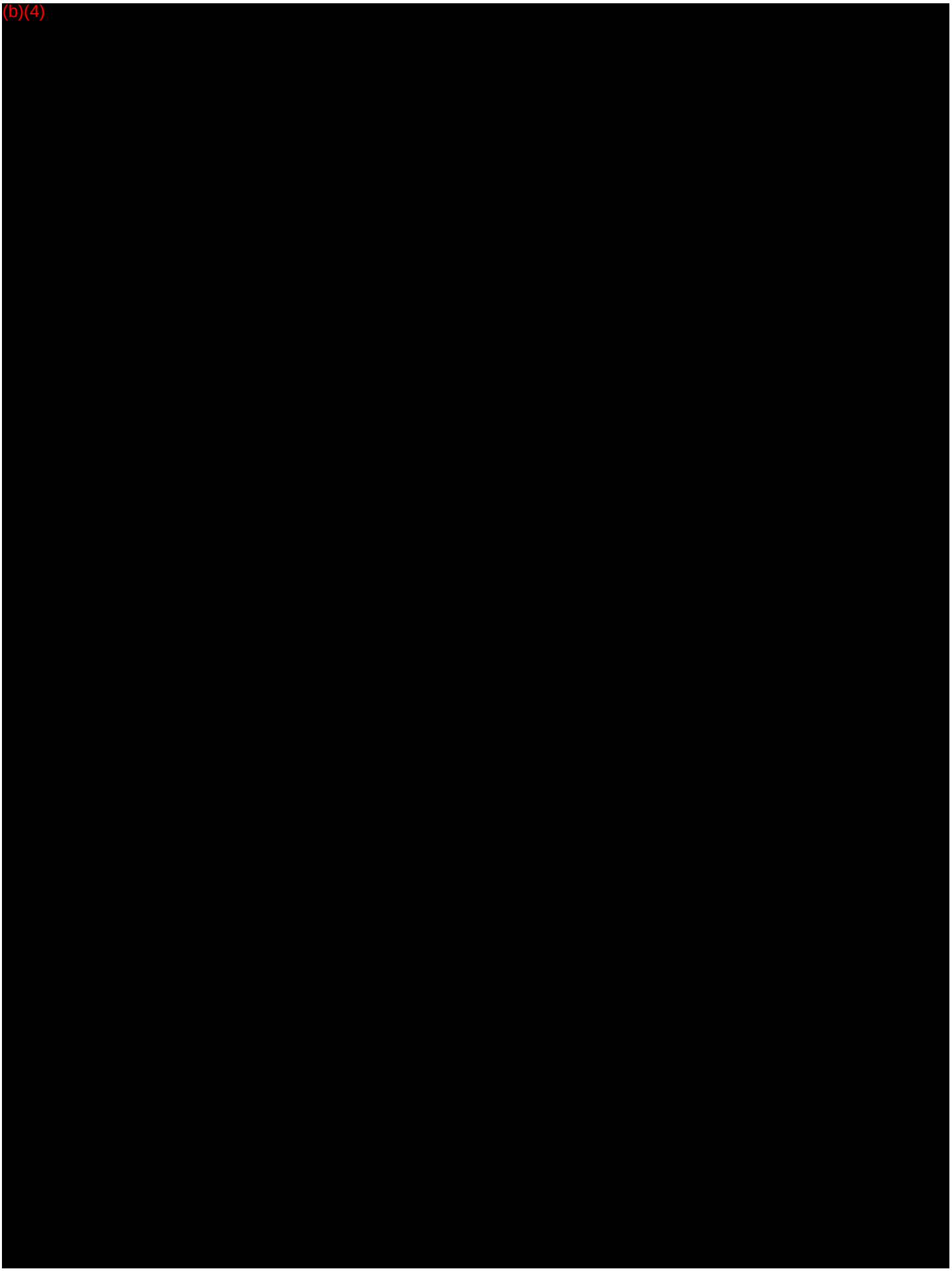

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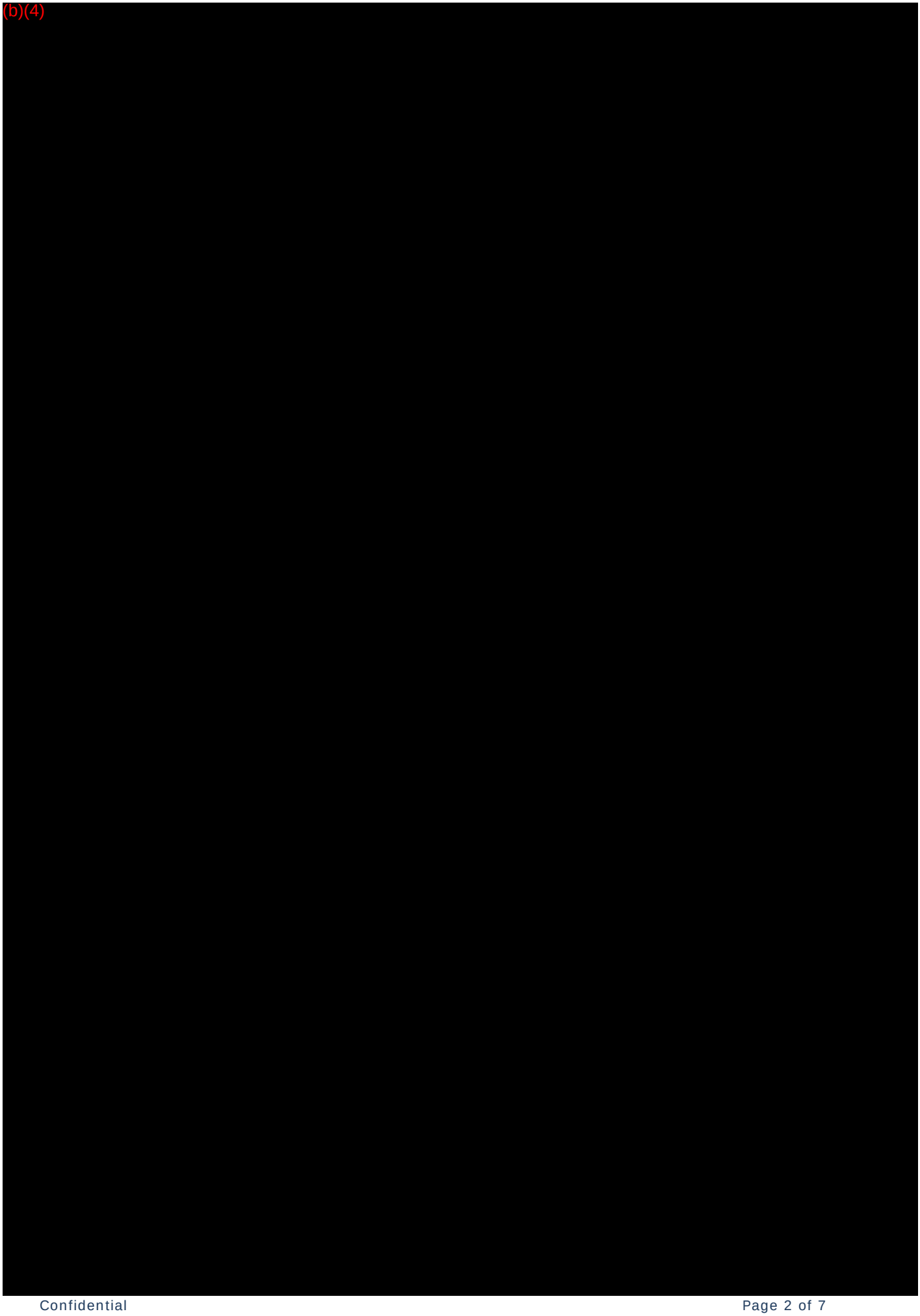

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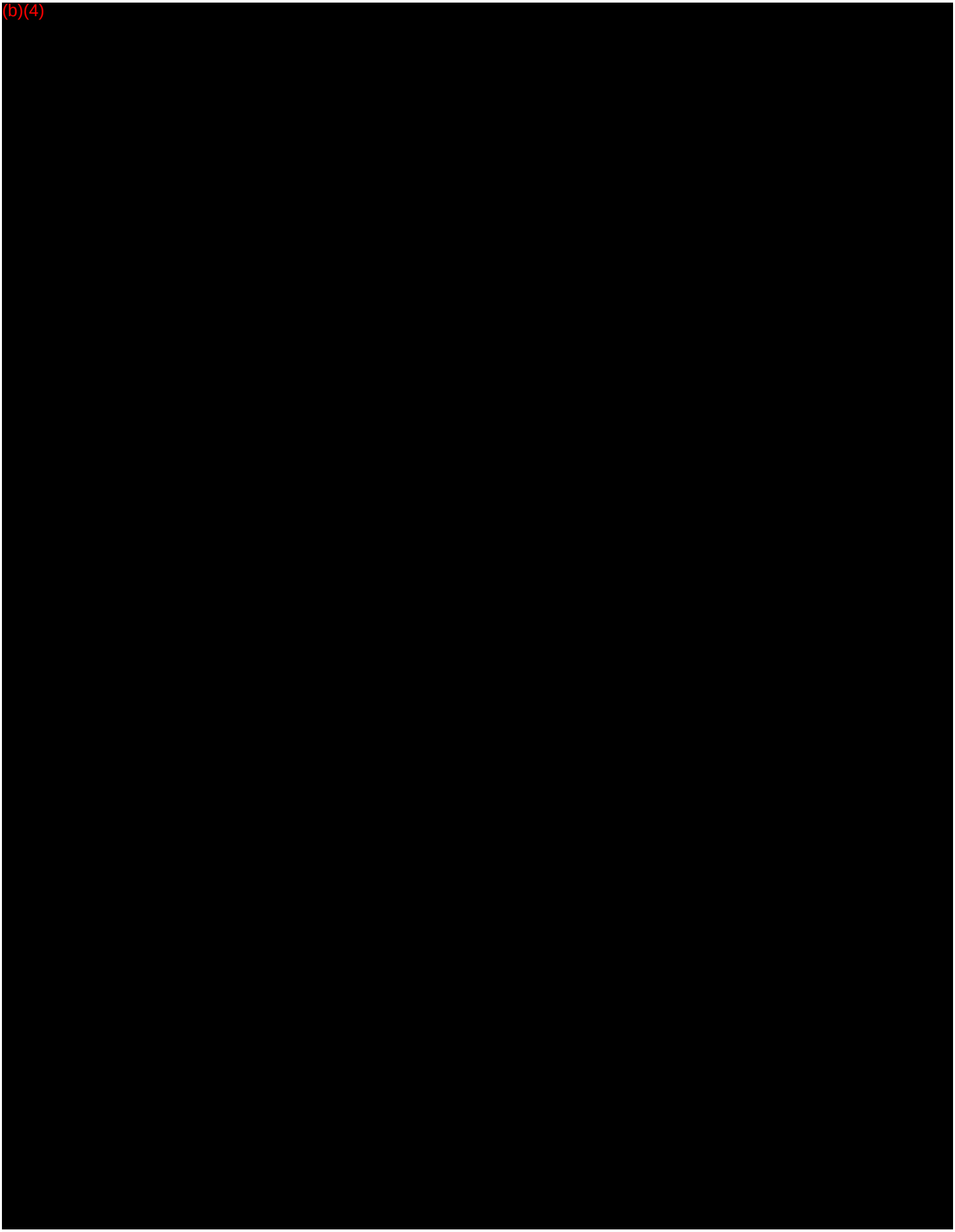

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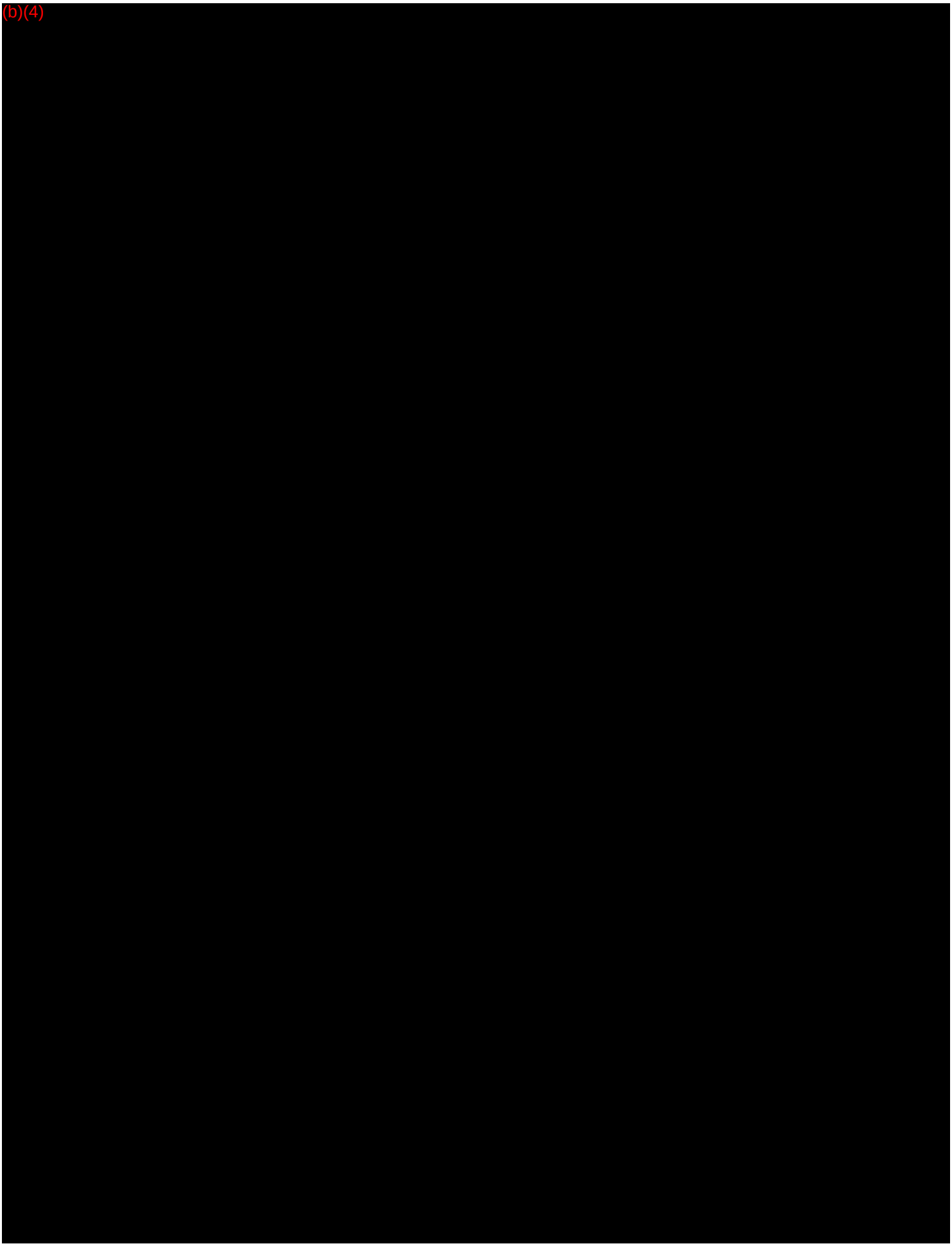

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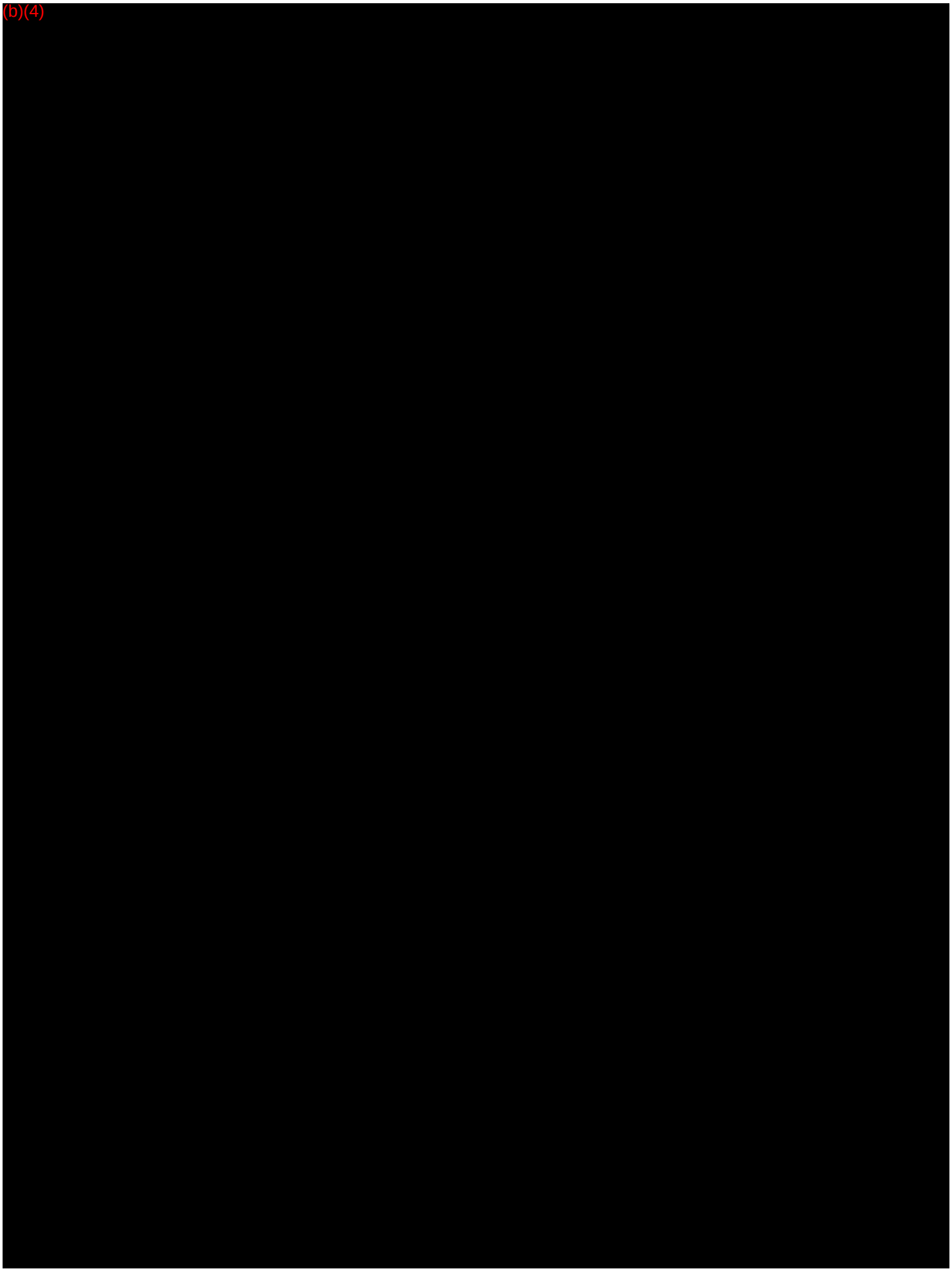

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Traceability Analysis

1. Introduction

The development of the 3Shape Abutment Designer™ Software implements Traceability Analysis by a Trace Matrix (see *Trace Matrix* below).

> **Note:** The 3Shape Abutment Designer™ Software is an add-on to the 3Shape Dental System™ Software (classified as 872.3661 Optical Impression Systems for CAD/CAM, Product Code NOF, 510(K) Exempt).
>
> The trace shown is extracted from the Dental System™ Software Trace Matrix and only relates to the Abutment Designer.

The Trace Matrix links Identified Hazards, User Needs, Requirements, Specifications, and Validation and Verification.

> **Note:** 3Shape Software Product Development Documentation is structured into a suite of Requirement Specifications (RS) and a suite of Software Specifications (SS).
>
> Each Requirement Specification and Software Specification contains an embedded test protocol for Validation and Verification respectively.
>
> Therefore, the Validation and Verification testing requirements are implicitly identified by the unique RS and SS document IDs listed in in the Trace Matrix.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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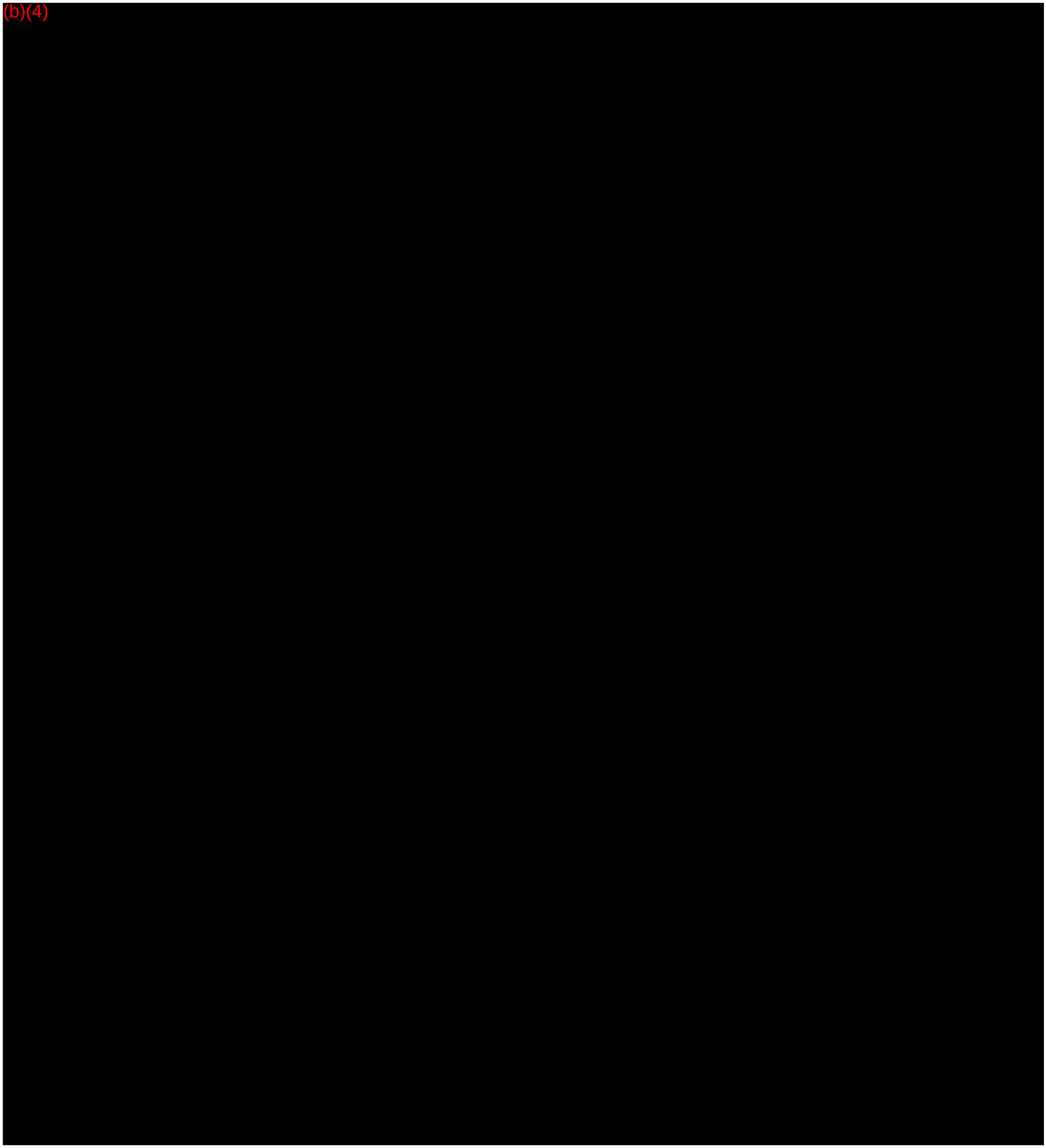
2. Trace Matrix

(b)(4)



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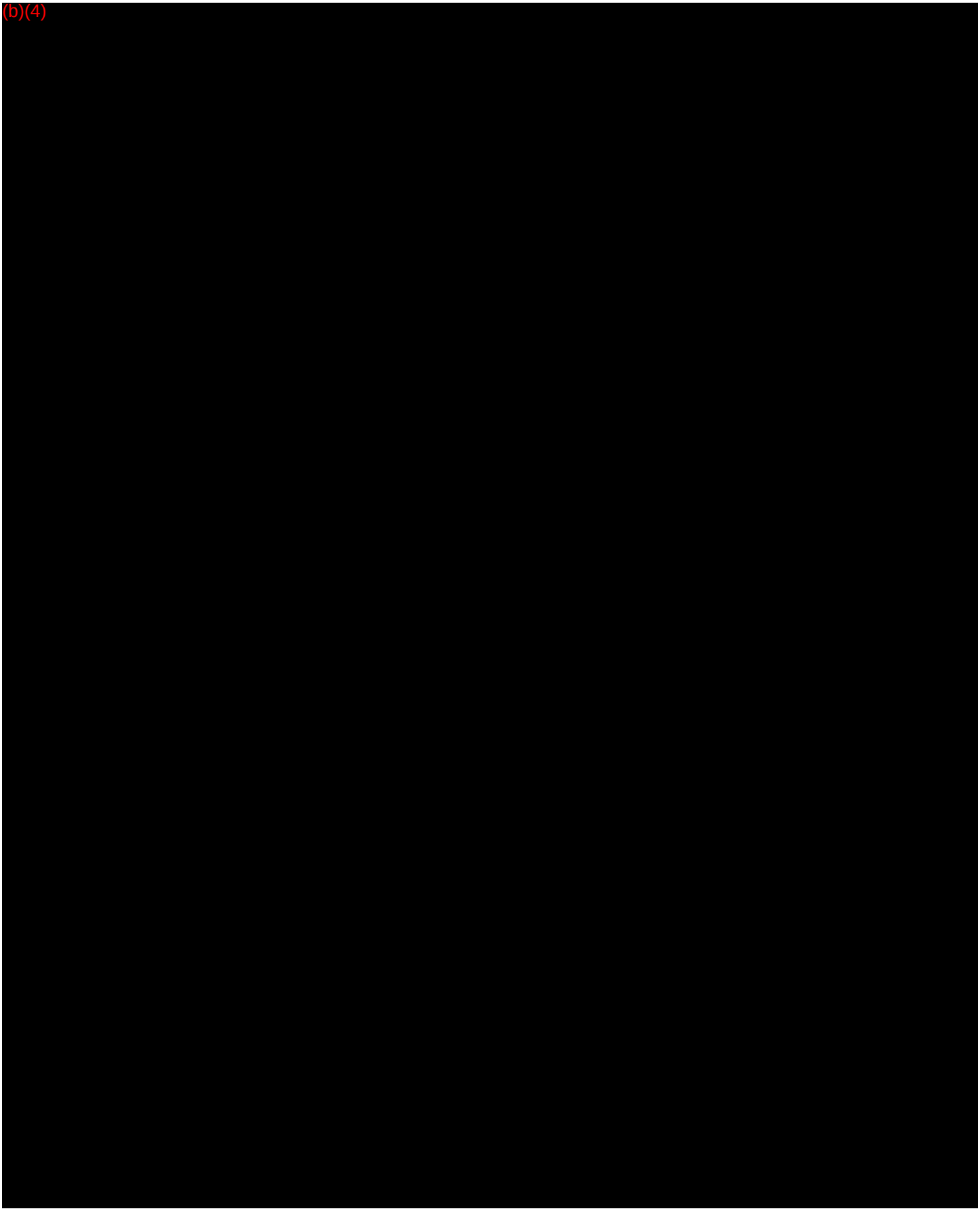

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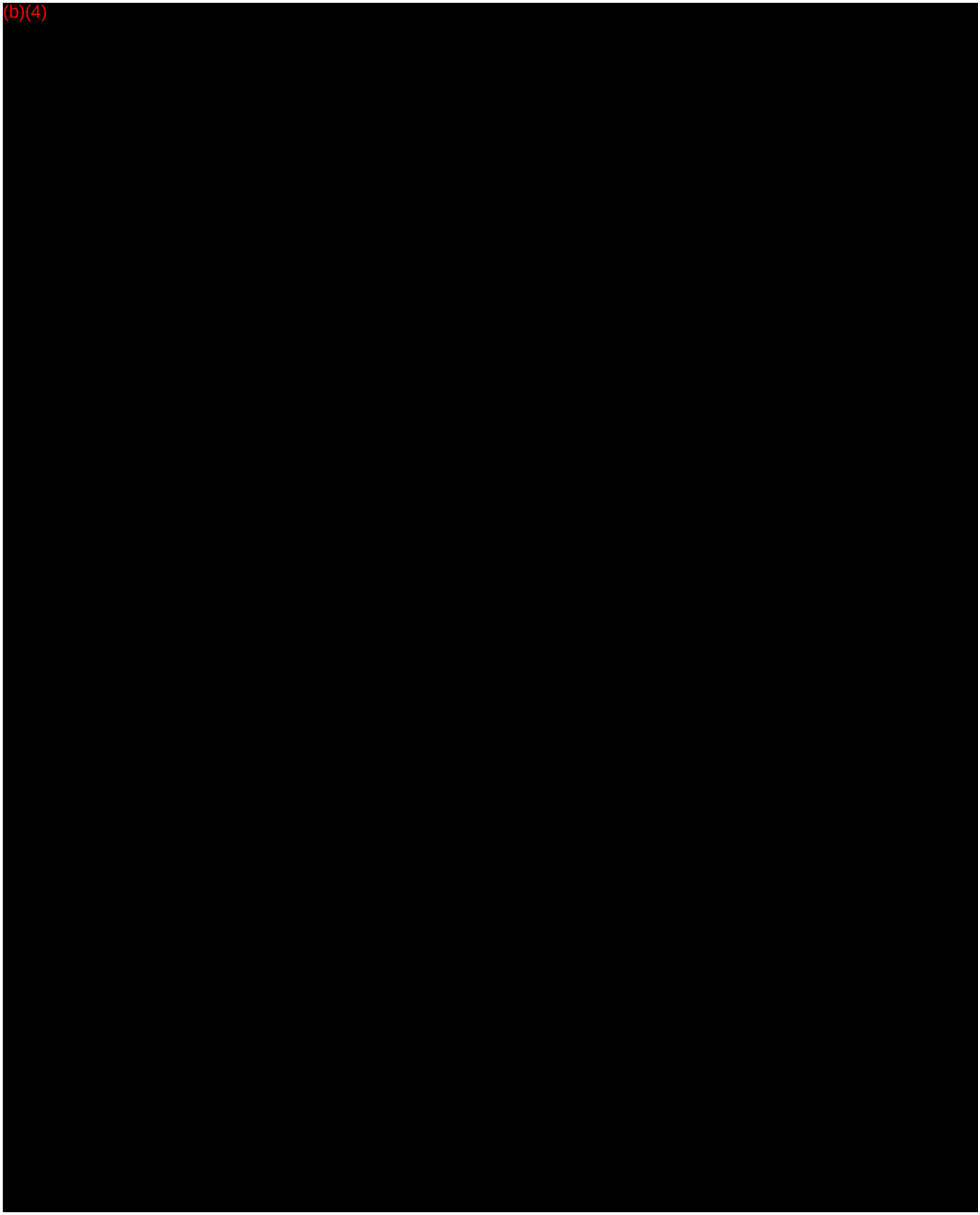

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Unresolved anomalies

The list of the 3 remaining software anomalies in 3Shape Abutment Designer™ Software (b)(4)) can be seen in

Table 1.

(b)(4)

Table 1: List of open bugs in 3Shape Abutment Designer™ Software (b)(4)

Bug ID	Description	Safety Impact	Resolution	Justification for Resolution
(b)(4)				

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Proposed Labelling

The 3Shape Abutment Designer™ Software is a prescription device and is exempt from needing adequate directions for lay use.

The following labelling is included (please see "VOL_013 Labelling" of this submission):

- PDF copy of User Manual DS-2.15.2.0-A-EN
- Dental System™ Brochure

The application is for download only, and hence there is no CD label.

Device Specific Requirements

There are no applicable requirements in a device-specific regulation.

Special Controls Document

The 3Shape Abutment Designer™ Software falls into the following product group:

NHA

The guidance document entitled "Class II Special Controls Guidance Document: Root-Form Endosseous Dental Implants and Endosseous Dental Implant Abutments" serve as the special control.

The Guidance Document lists the below labelling requirements.

Requirement	**Referenced in**
Labelling in sufficient detail to satisfy the requirements of 21 CFR 807.87(e)	DS-2.15.2.0-A-EN Safety and Setup Guide
Provide users with a surgical manual along with the instructions for use	N/A - The 3Shape Abutment Designer ™ Software is not used in surgery
Provide all relevant precautions and warnings in the professional labelling	DS-2.15.2.0-A-EN Safety and Setup Guide
Precautions or warnings that relate to unpackaging or sterility	N/A - The 3Shape Abutment Designer ™ Software is a software device and not supplied sterile.
If any parts are provided non-sterile we recommend that you provide sterilization instructions	N/A - The 3Shape Abutment Designer ™ Software is a software device and not supplied sterile.
If patient labelling is appropriate, we recommend that you follow Guidance on Medical Device Patient Labelling; Final Guidance for Industry and FDA Reviewers	N/A - 3Shape Abutment Designer ™ Software is a prescription device and patient labeling is not required.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Dental System™

Industry-leading scanning and CAD solutions

Excerpt version

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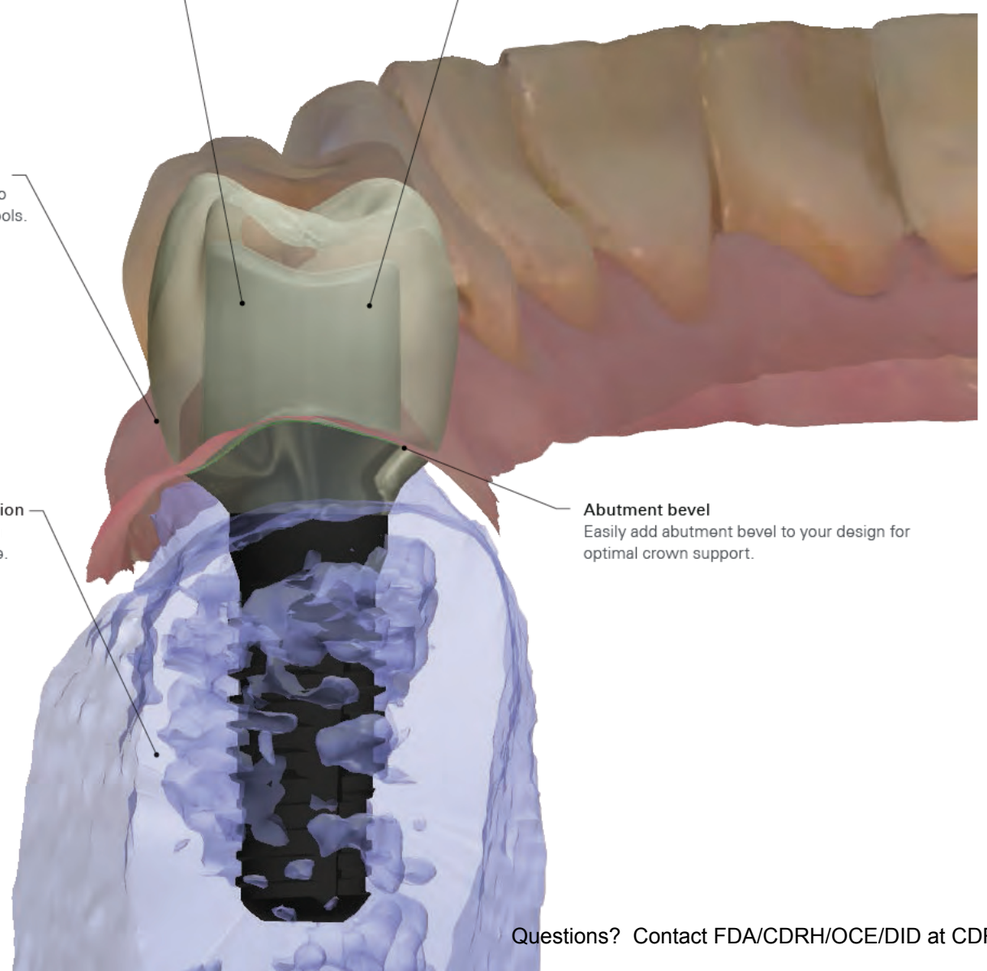
Get better esthetics and save costs with customized abutments

More and more labs are customizing abutments because they get improved clinical results, better esthetics and cost savings. Abutment Designer™ lets you automatically design the customized abutment and emergence profile with smooth transitions and optimal esthetics.

COMING Auto-Abutment
Automatically generate an abutment that optimally fits the crown design.

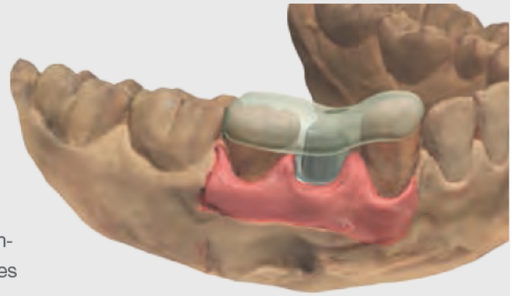
All types of abutments
Create customized abutments, screw-retained crowns and anatomical abutments.



Easily adjust to Gingiva
Snap emergence profile to gingiva or use freeform tools.

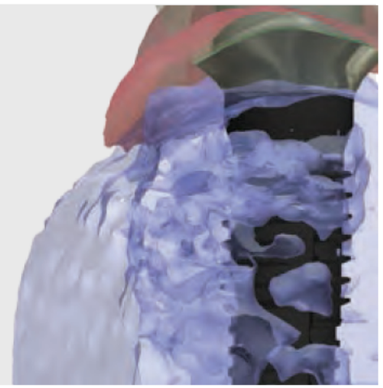
COMING Bone information
Improve abutment design by visualizing the jawbone.

Abutment bevel
Easily add abutment bevel to your design for optimal crown support.



NEW Add abutment position guides
Help your dentist easily and accurately place abutments, temporaries or veneers using custom designed positioning guides created in the same workflow.

More than 50 implant libraries
Get abutments from both original and compatible-with implant manufacturers covering all global and key regional players.
www.3shapedental.com/implant-systems*



COMING Bone information for better clinical results
Include bone data from CBCT scans to create better abutments without collisions and optimally shaped to the thickness of the gingiva.

**Only libraries using FDA-cleared components permitted in the US.*

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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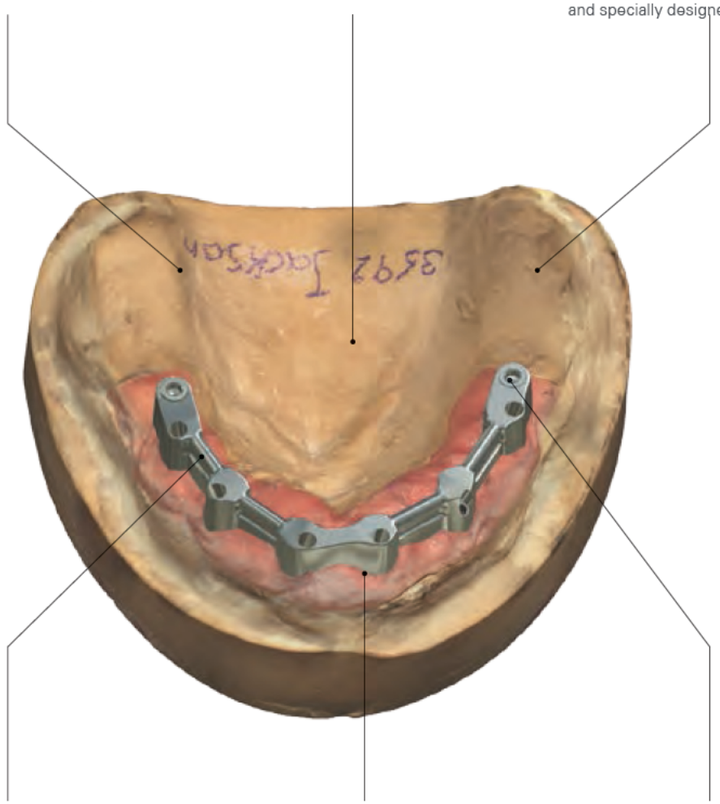
When accuracy and esthetics matter

Expand your lab's business by offering a high value service that is rapidly growing in demand. Design sophisticated implant bars and bridges with the utmost precision using flexible tools and ISO-documented 3Shape scanner accuracy.

Design any type of bar
Support for a wide range of standard bar and bridge types such as Primary, Dolder, Hader, Hybrid, Canada, and Wrap-around.

Extensive range of implant libraries*
Support for direct-seating and multi-unit abutments.

Proven bar accuracy with 3Shape scanners
Accuracy on all 3Shape scanners is verified and documented according to ISO12836 and specially designed implant objects.



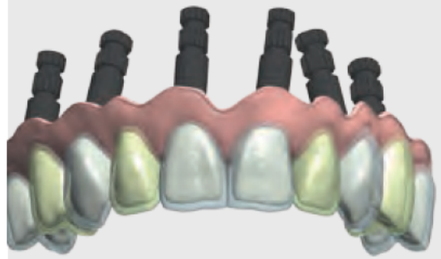
NEW Freely apply different types of bars
Combine multiple types in a single design with the new smooth surface transition that ensures an optimal finish.

NEW Improved finish with new Cut-to-gingiva
Match the bar to the underlying gingiva and achieve high quality with the newly enhanced surface finish.

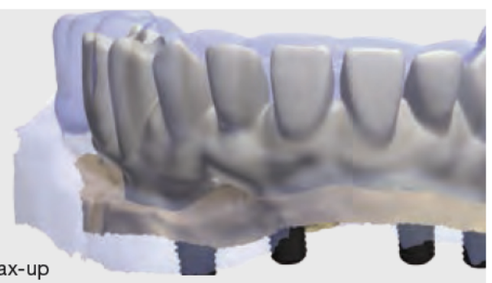
Add any type of attachment
Freely add slide or ball attachments, locators and retention holes. Adjust position and angle if needed.

**Only libraries using FDA-cleared components permitted in the US.*

COMING Perfectly matching secondary structures
Design your bar and then easily and precisely create its matching secondary according to the bar's attachments and form.



Esthetic implant bridges with gingiva
Easily design implant bridges complete with gingiva based on the final anatomy and a gingiva boundary that you define.



COMING Designs obtained directly from the Denture or Wax-up
Scan the denture and virtually cut back to facilitate design of an optimal implant bridge, or scan an original wax-up bridge to create a file for copy milling.

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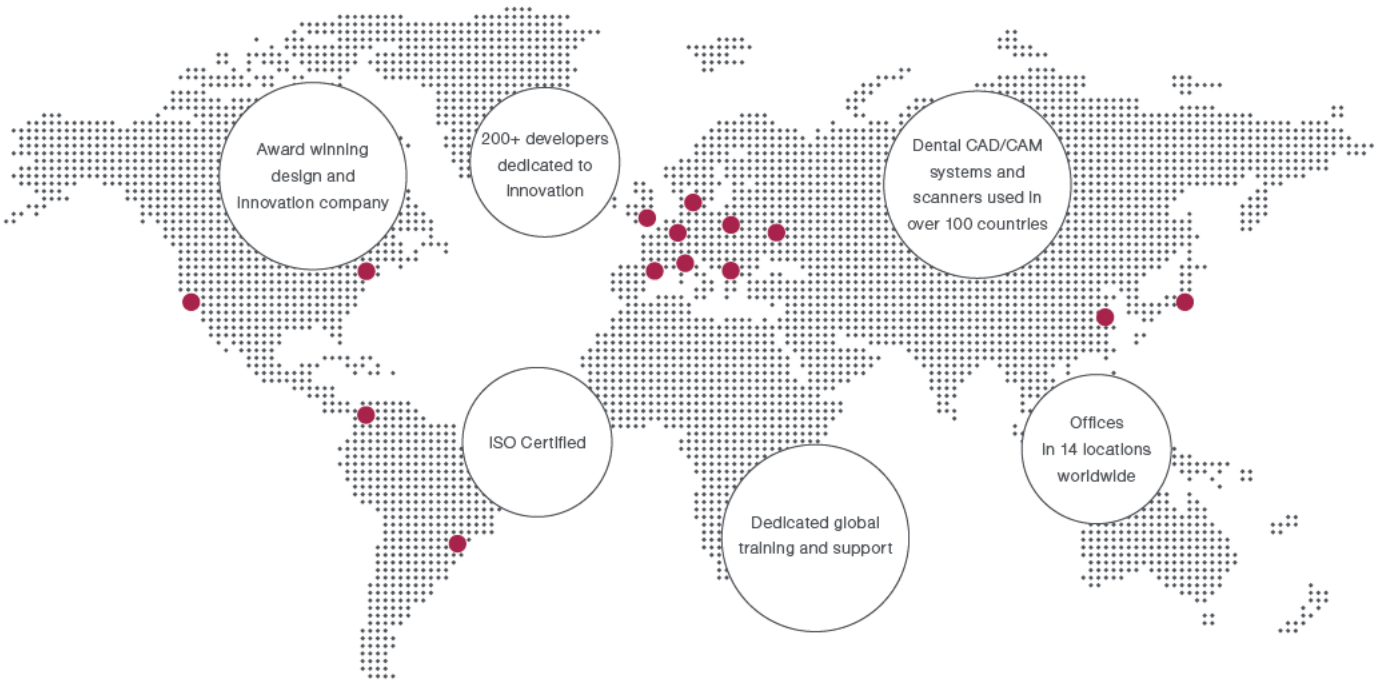
3Shape develops 3D technologies for dental practices and labs



Backing labs with care, technology and expertise

Expert Training

Unlimited Upgrade

Global Support

3Shape LABcare™ is an integral part of your annual 3Shape subscription. It bundles services that are designed to ensure your investment, secure maximum uptime, and help you get the most from your solution year after year.

Find 3Shape online

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K151455

Device Name
3Shape Abutment Designer™ Software

Indications for Use *(Describe)*
The 3Shape Abutment Designer Software is intended as an aid the restoration of chewing function in partially or fully edentulous mandibles and maxillae. The 3Shape Abutment Designer Software is intended for use by a dental practitioner or dental laboratory staff for designing the patient specific component of a two-piece, one-piece, or hybrid dental implant abutment. The single or multi-unit abutment design is intended to be used by the manufacturer of an endosseous dental implant abutment to create the final device.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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Software Requirement Specification

1. Introduction

Please refer to the Software Requirement Specifications enclosed in this volume.

Please note that the Validation Protocol templates are included in the Requirement Specifications.

For links between the Requirements Specifications and the Software Specifications, please see "VOL_008_Traceability Analysis" enclosed in this submission.

Note: Some of these documents may have requirements referring to other areas than 3Shape Abutment Designer™. See the Trace matrix for reference to which requirements are relevant for 3Shape Abutment Designer™.

2. Table of Contents

(b)(4)

Order Management (added document)
Configuration
Sending and receiving
Manufacturing Interfaces
Order Import and Export (added document)
User Manual
Material import export
User Interface (newly created document)
Parametric Abutment Design (updated version)
Parametric Abutment Design. Version from 2.15.3.0 patch
Wax-up Design
Implant Bars (updated version)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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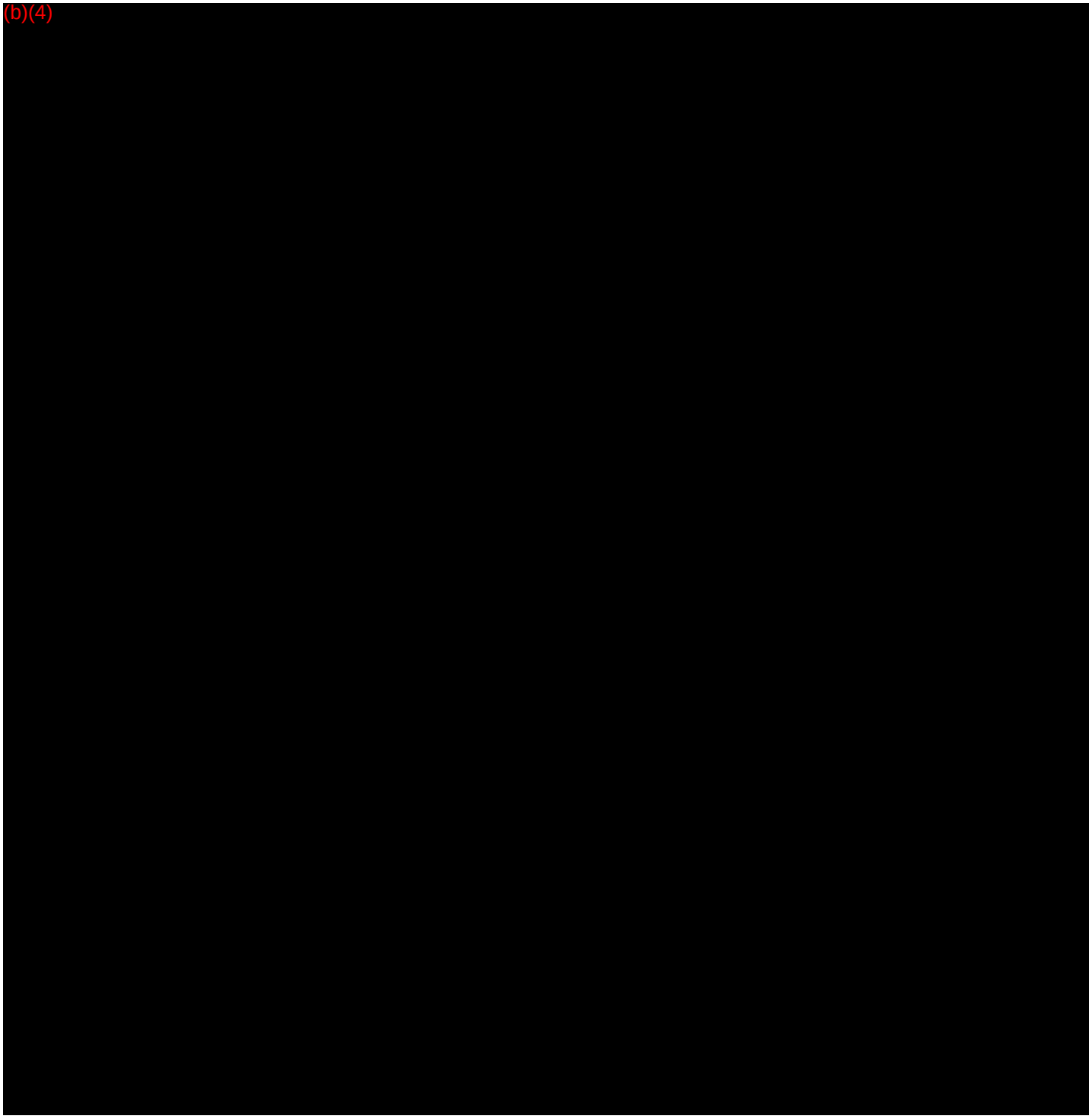

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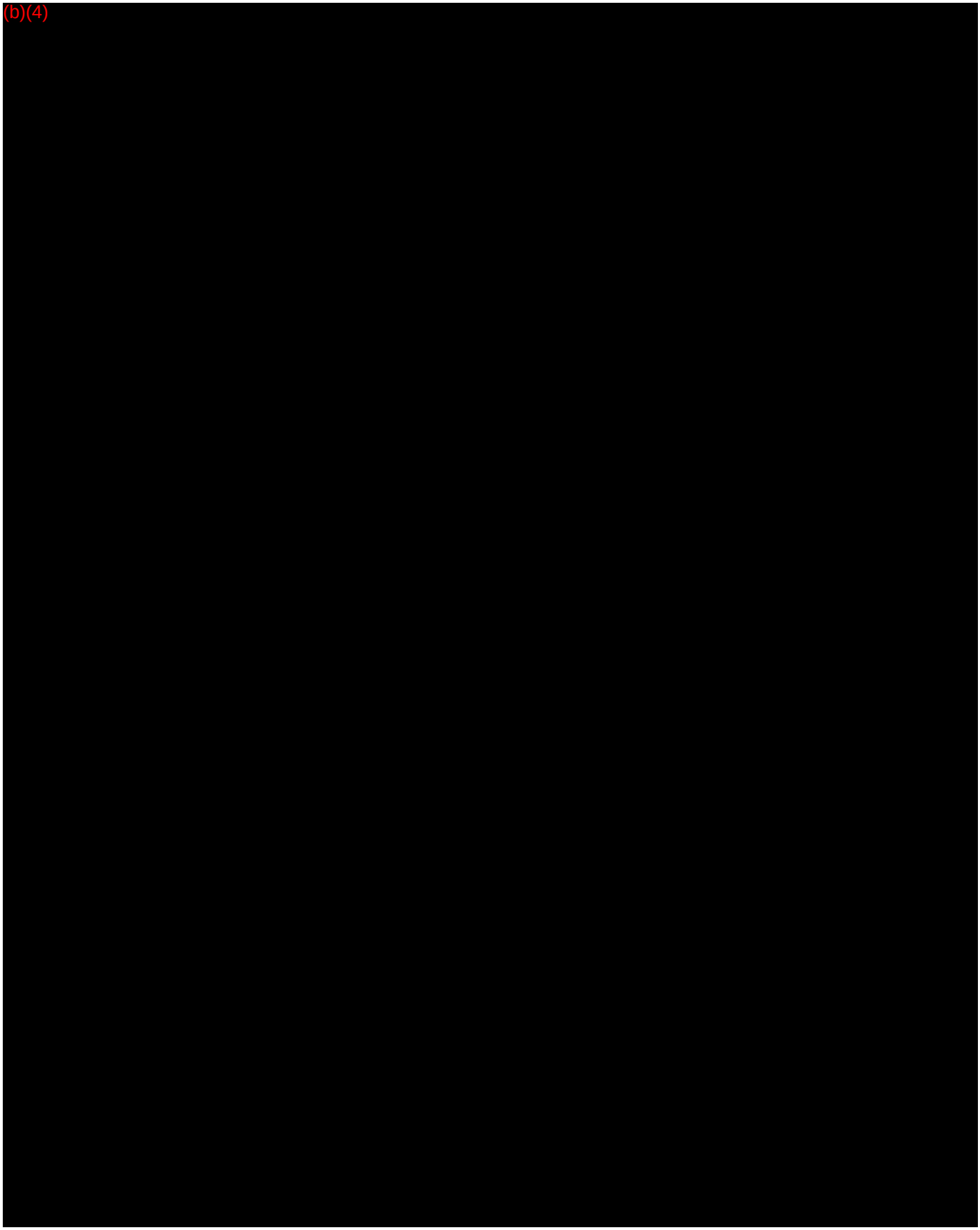

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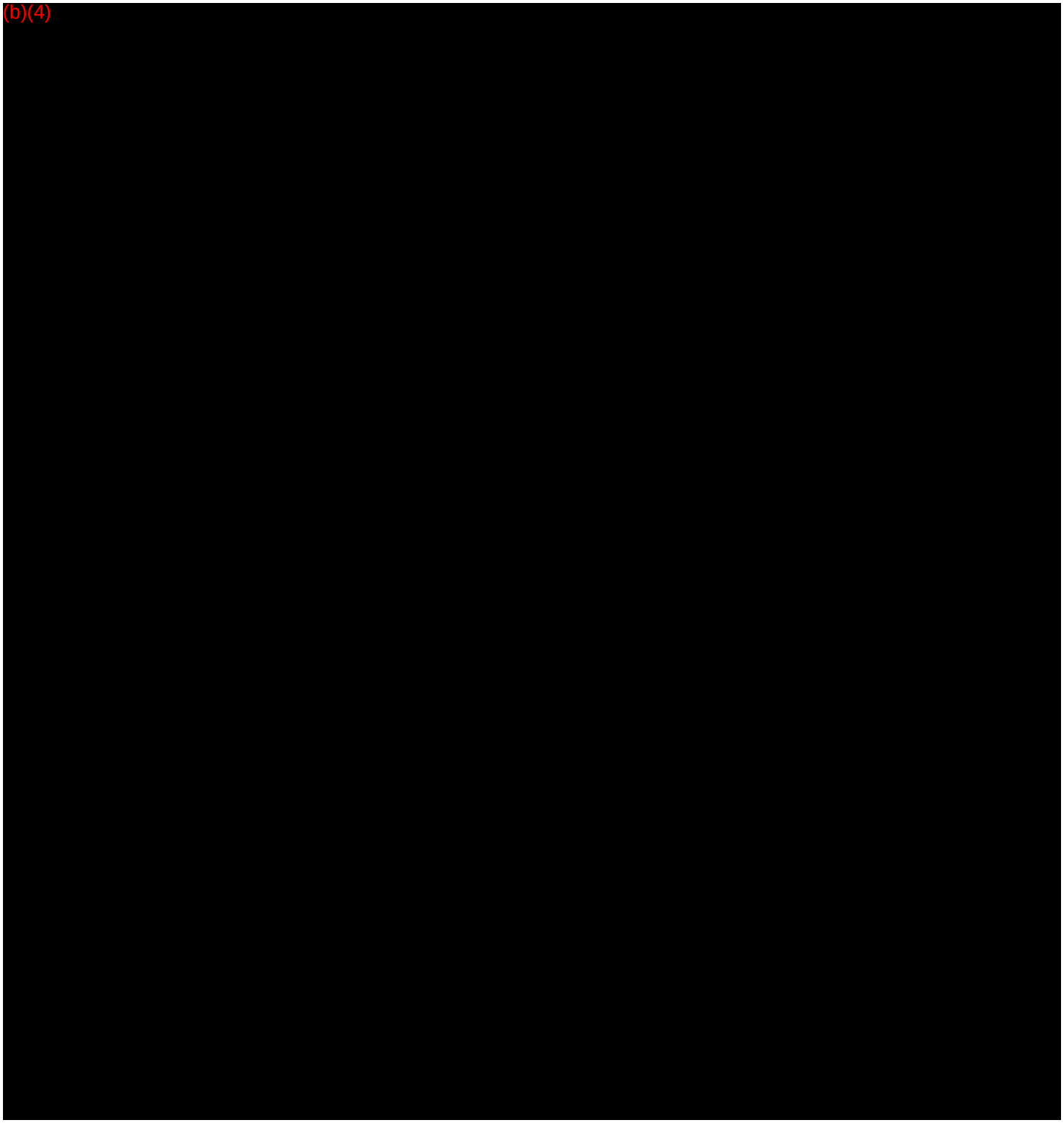

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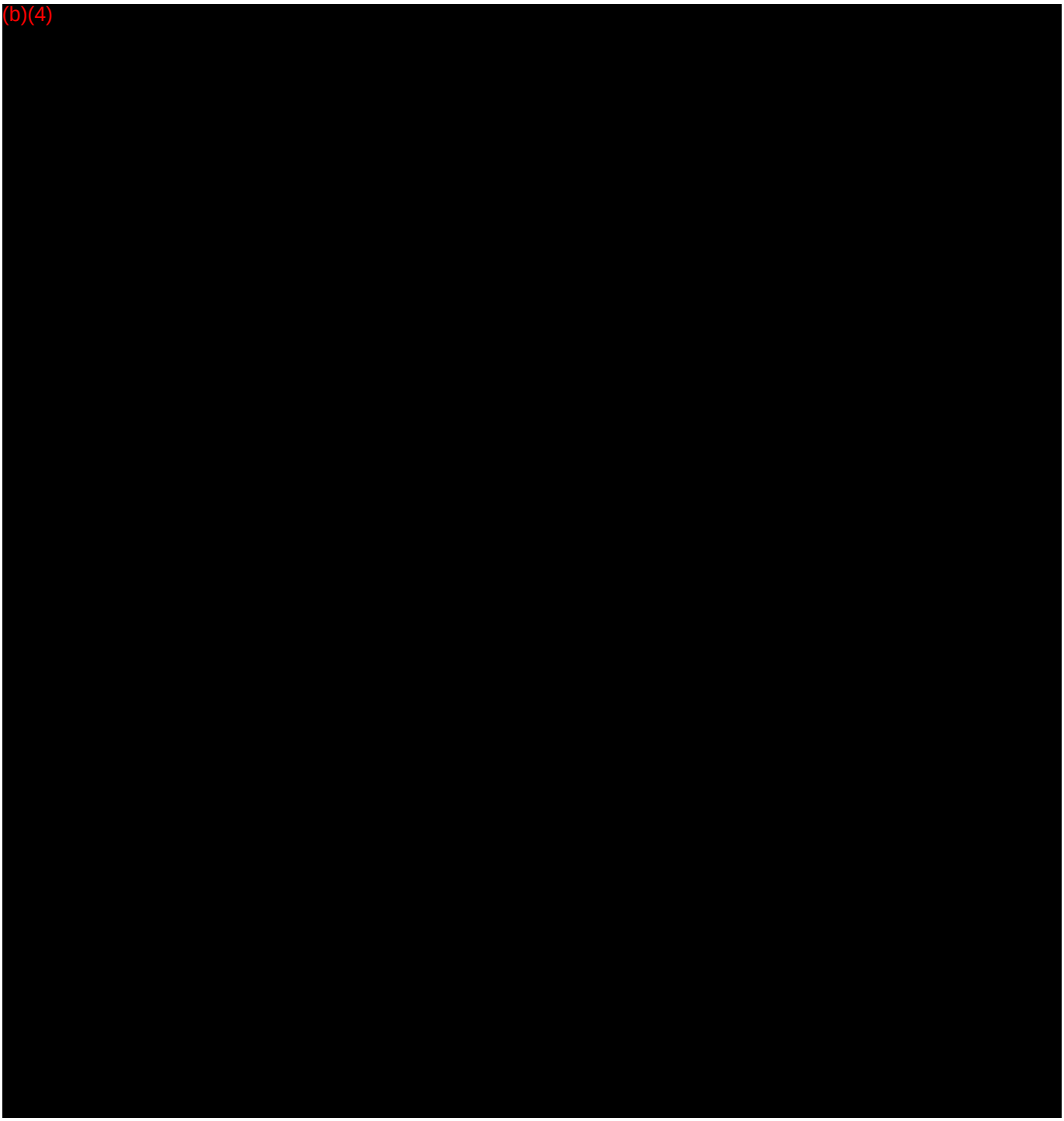

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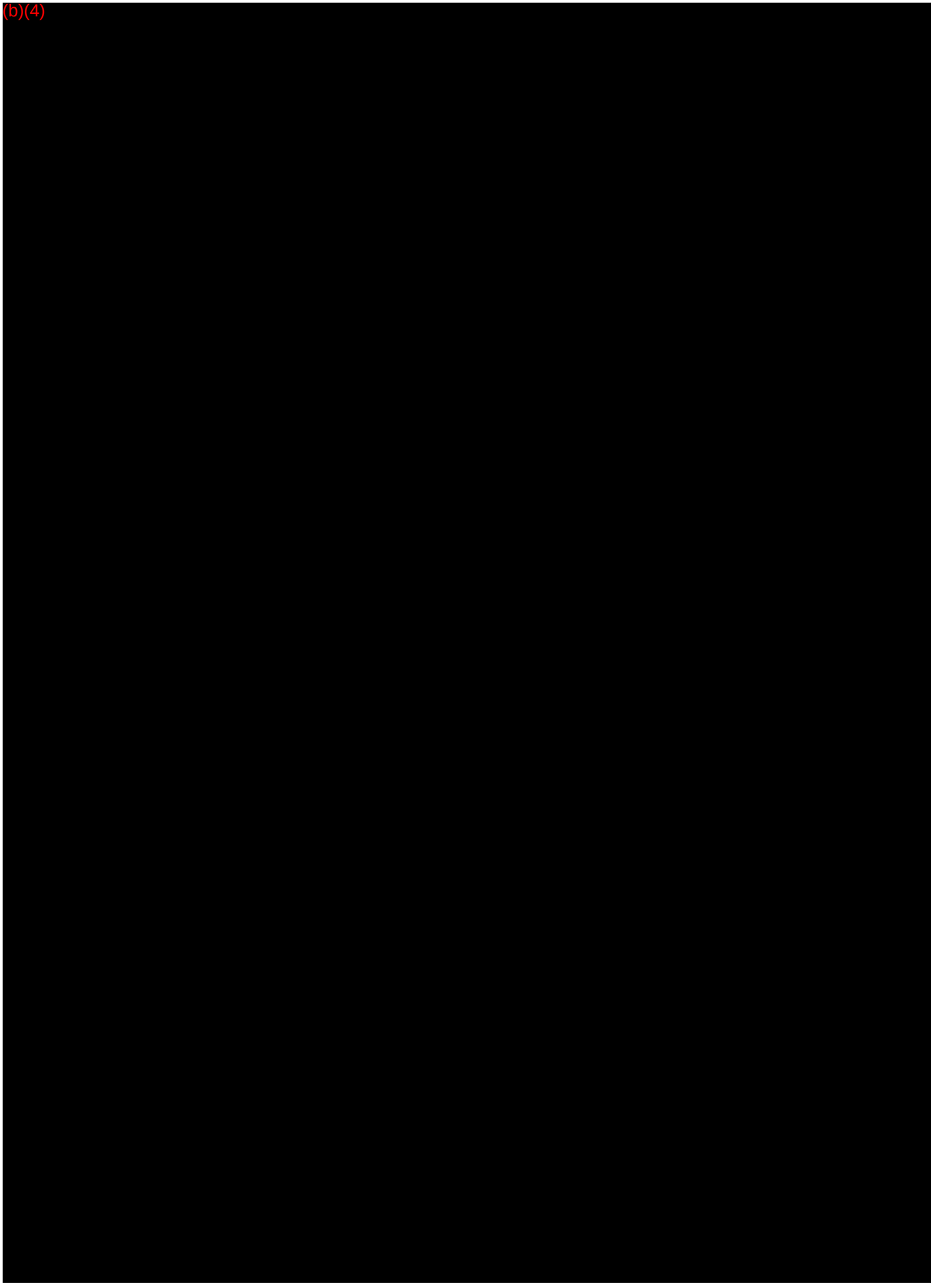

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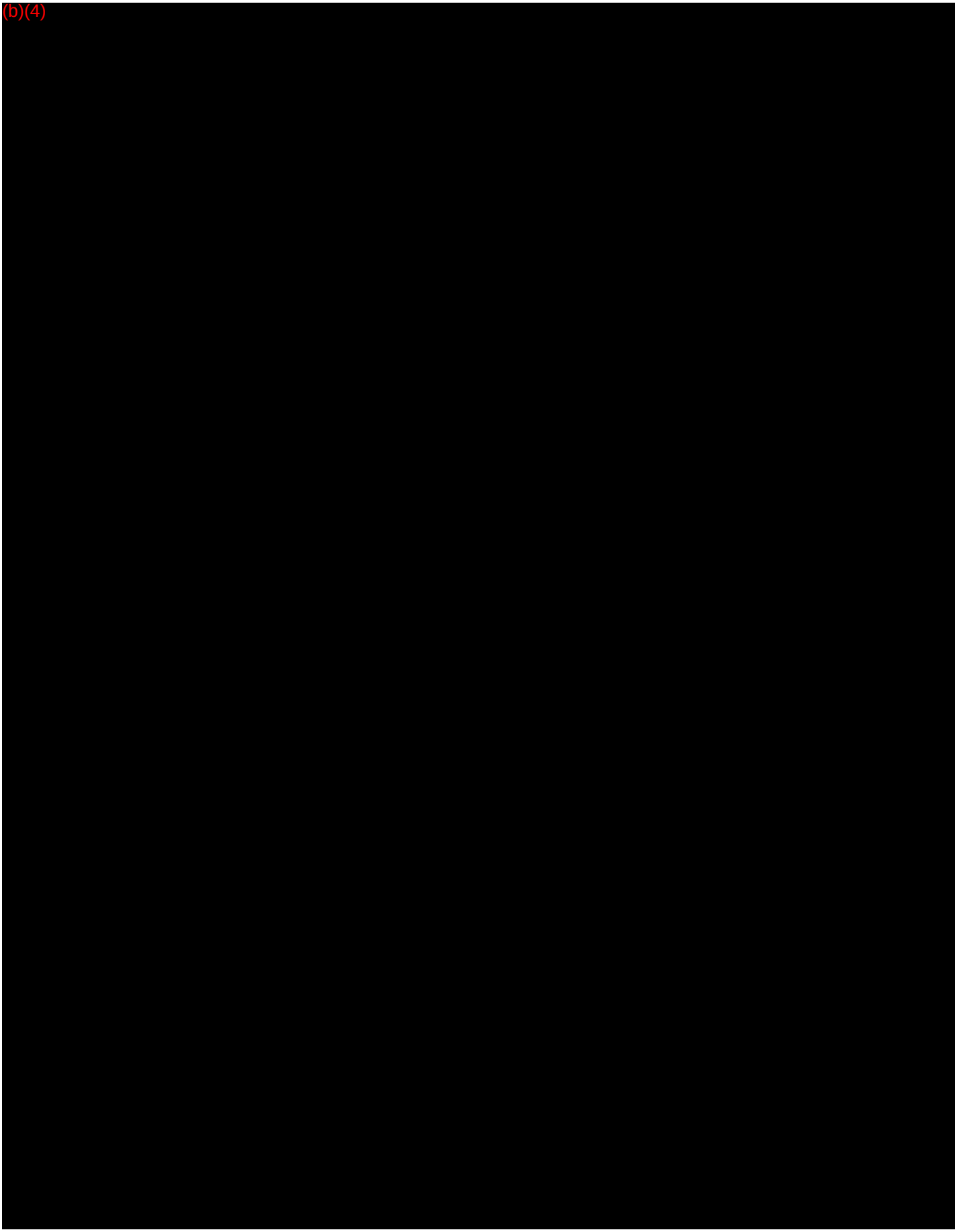

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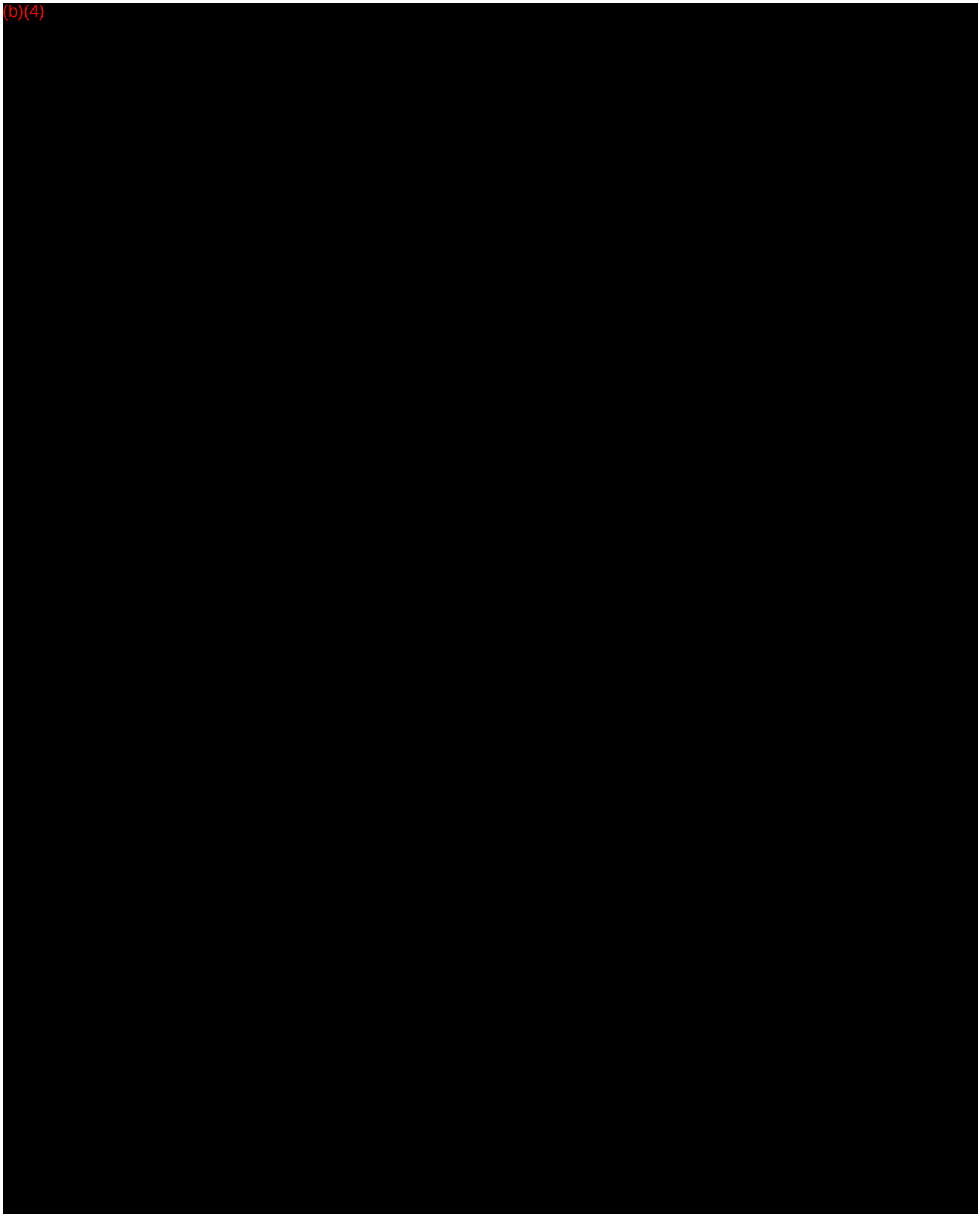

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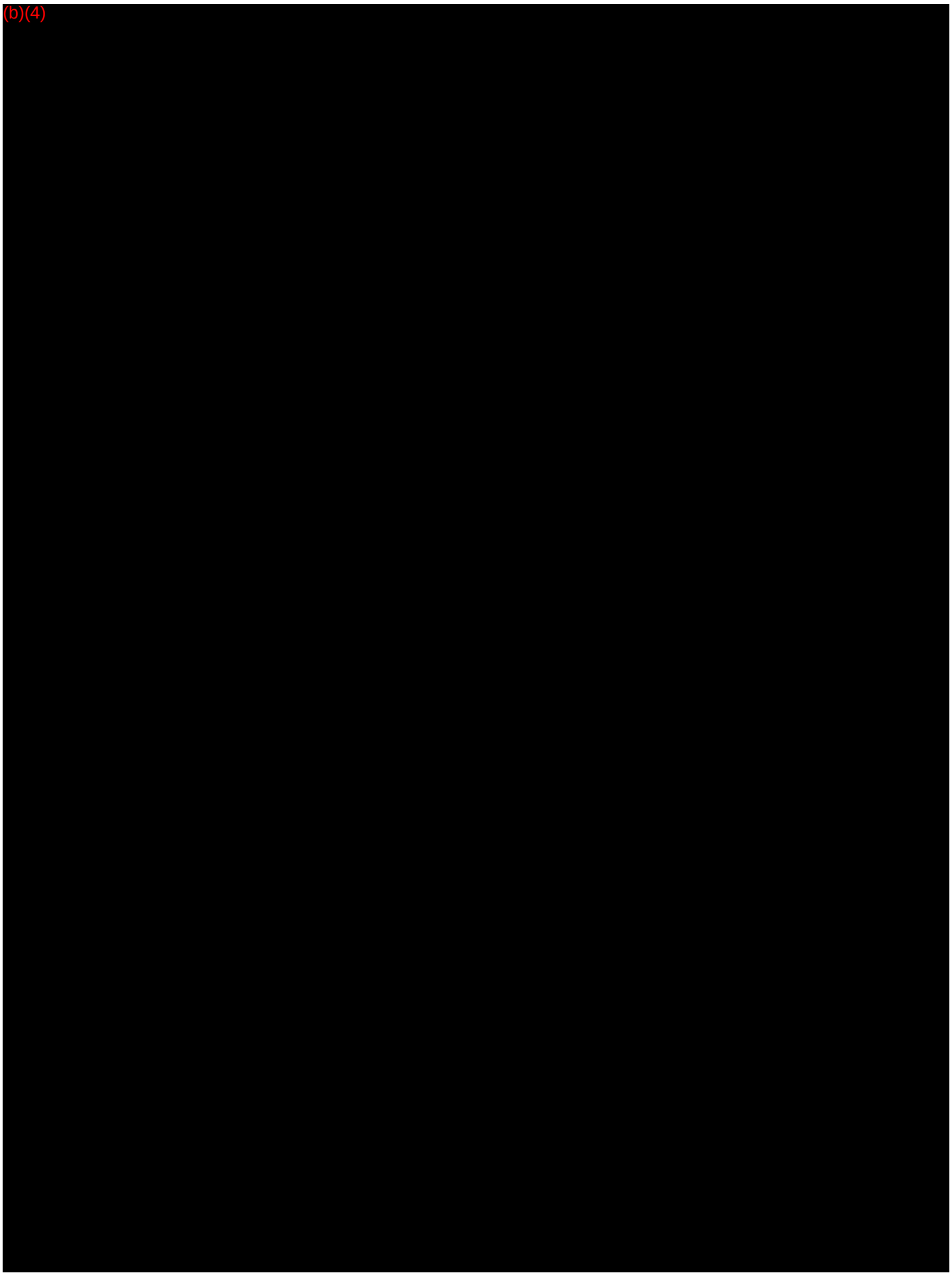

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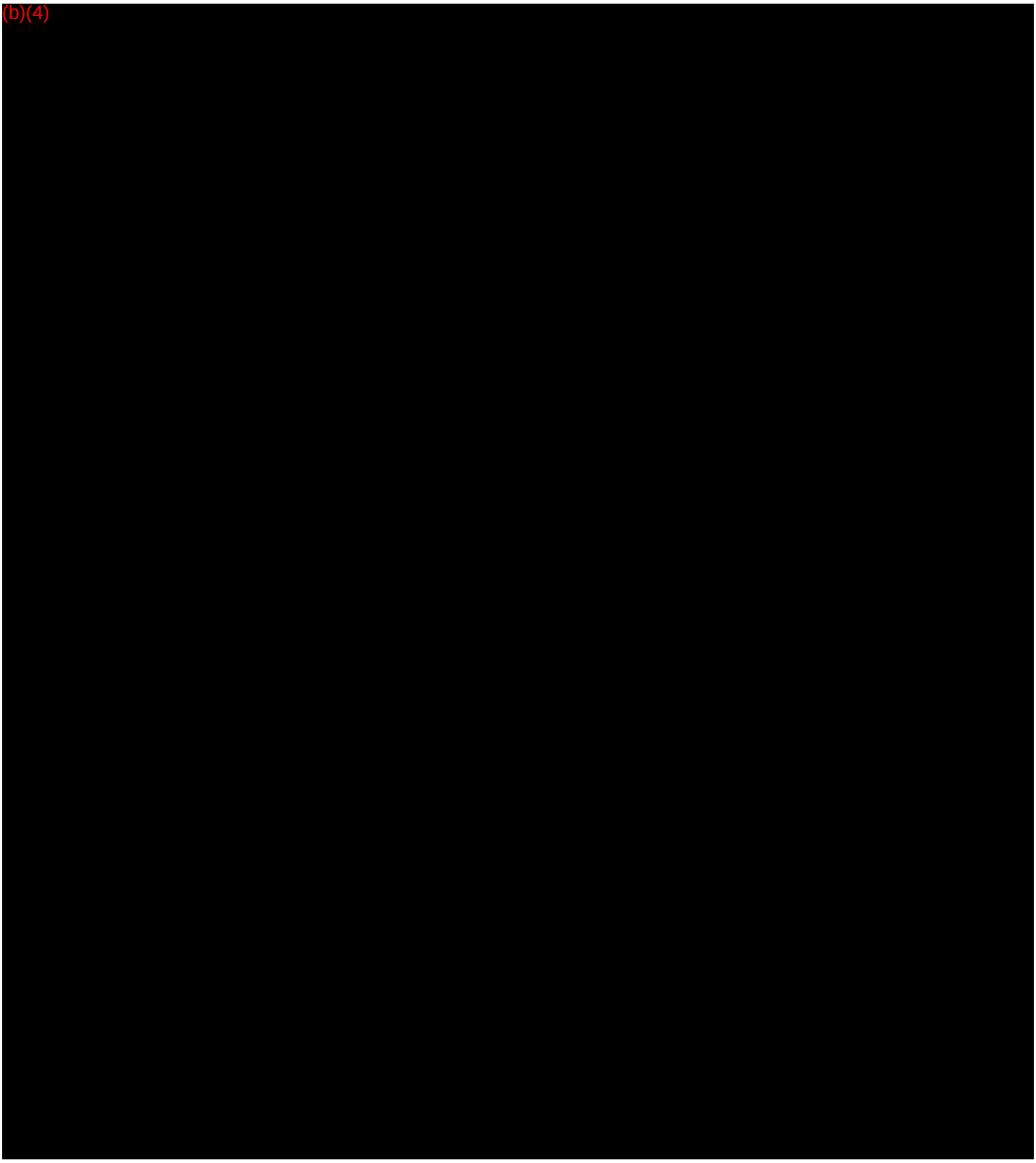

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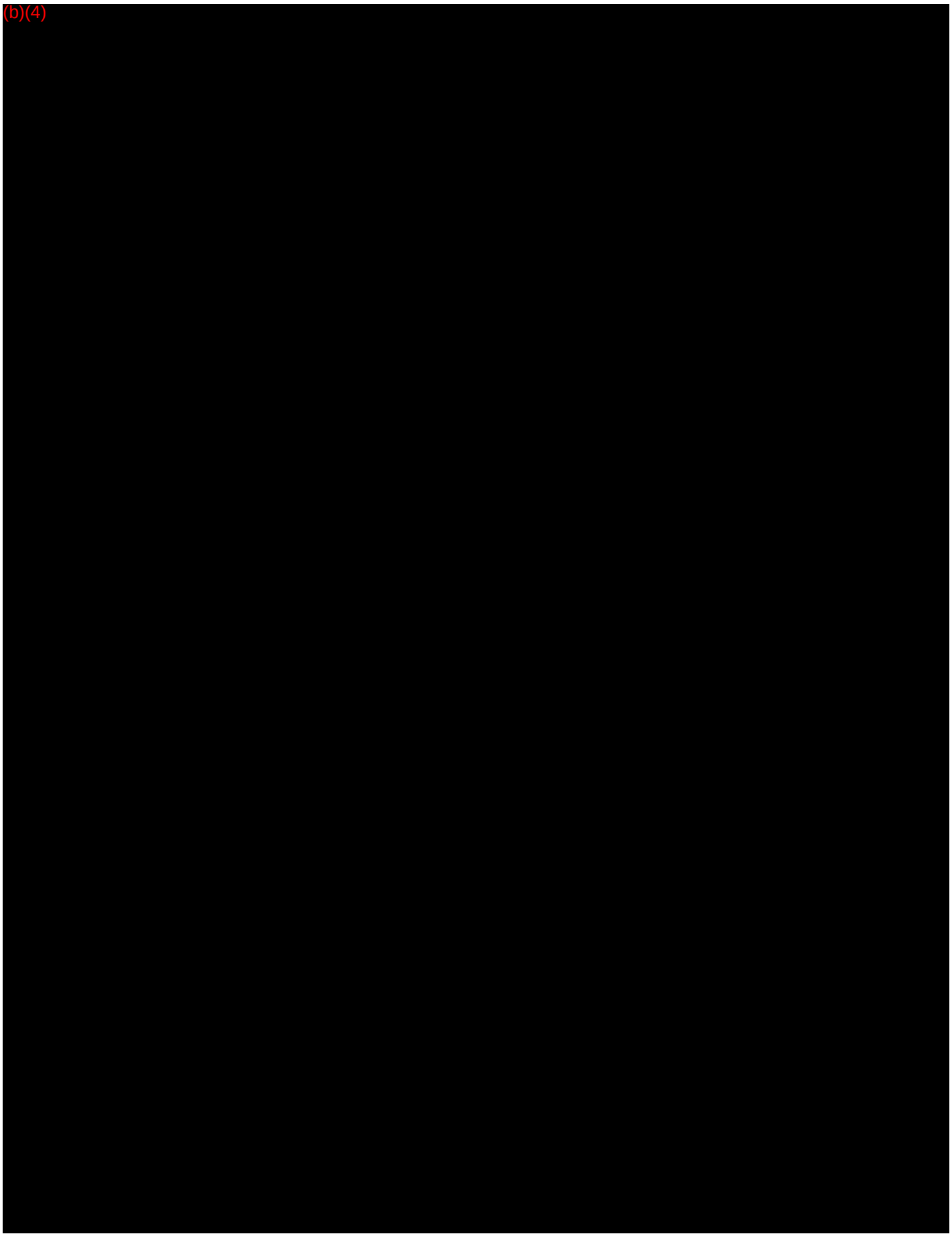

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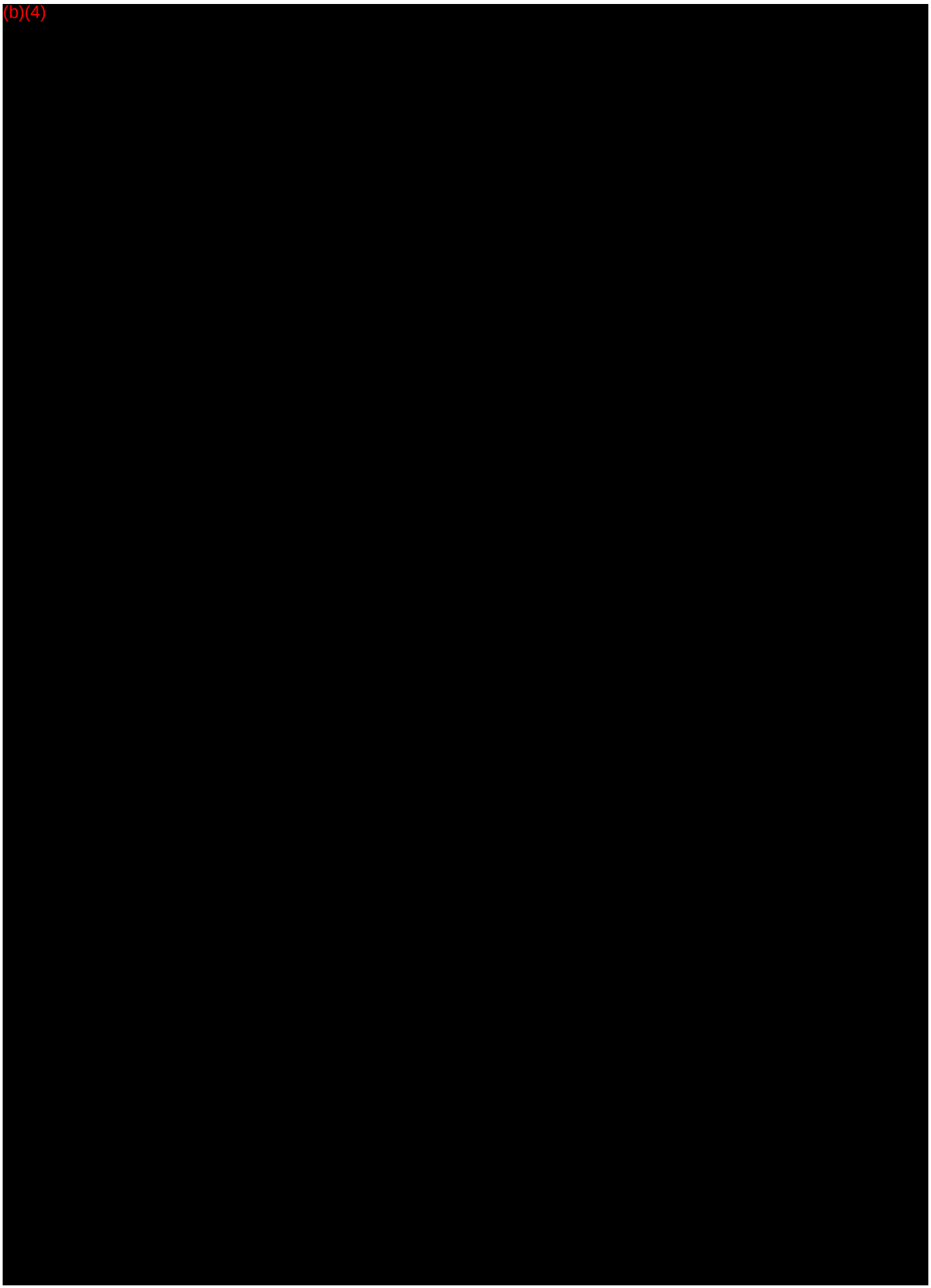

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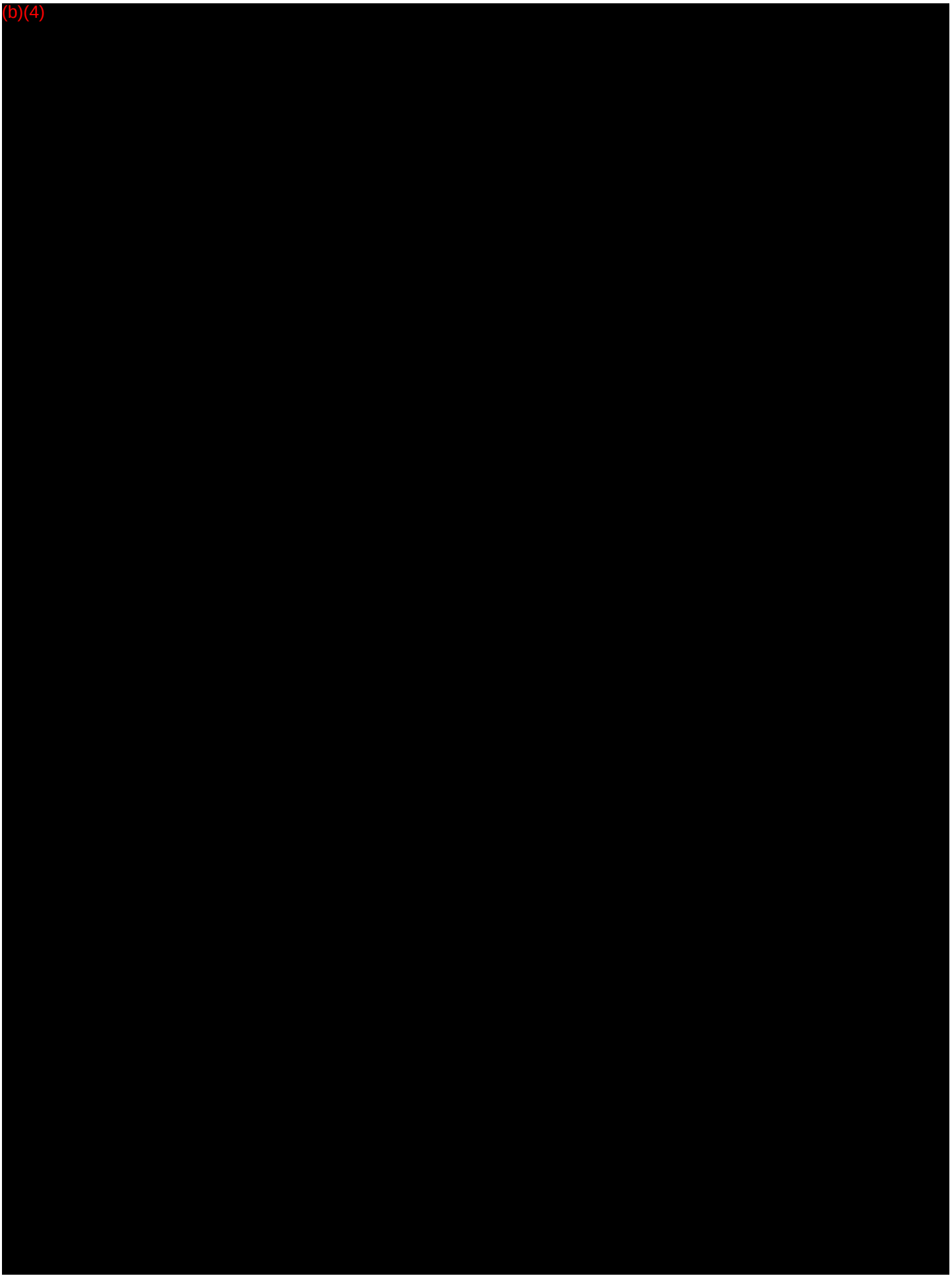

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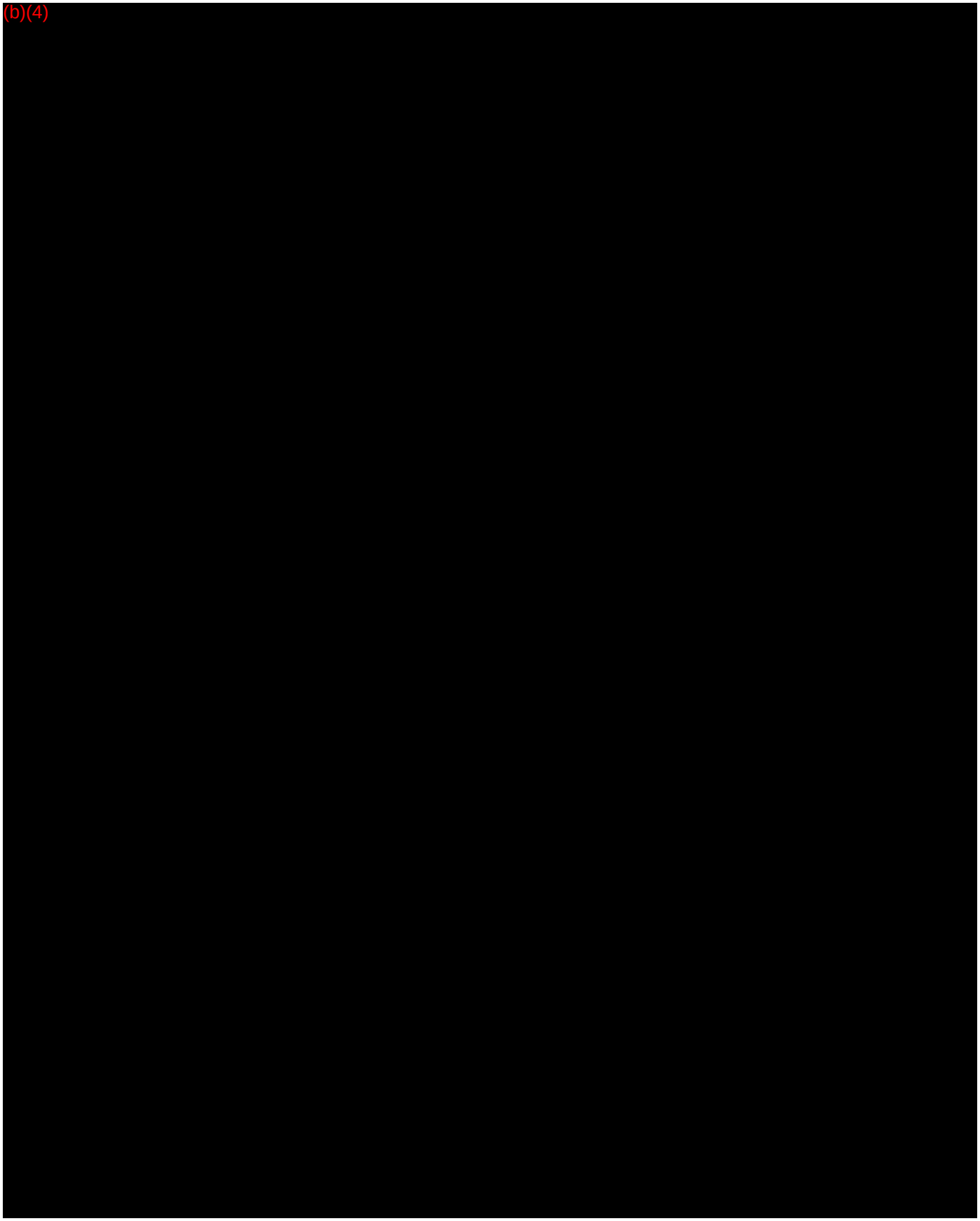

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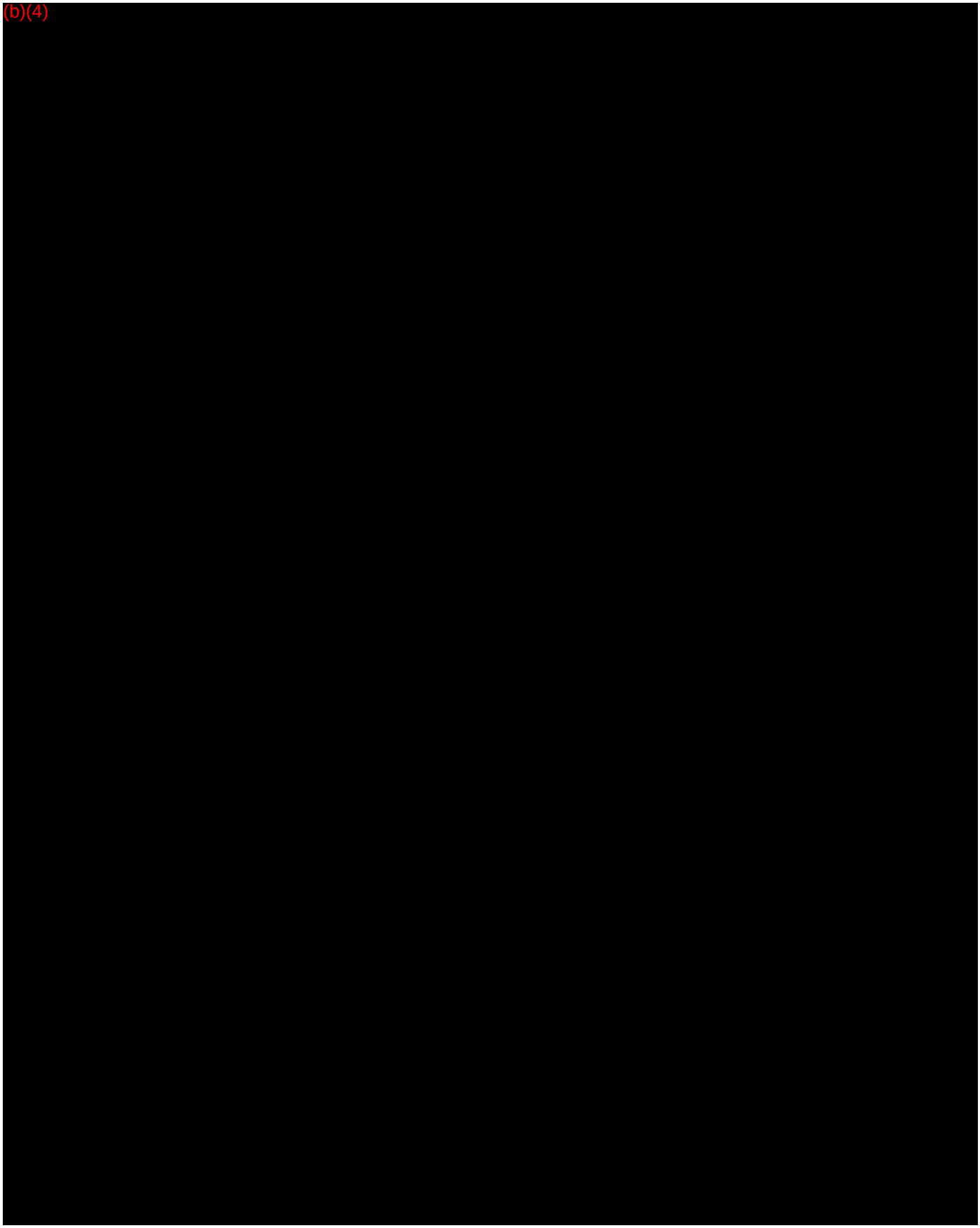

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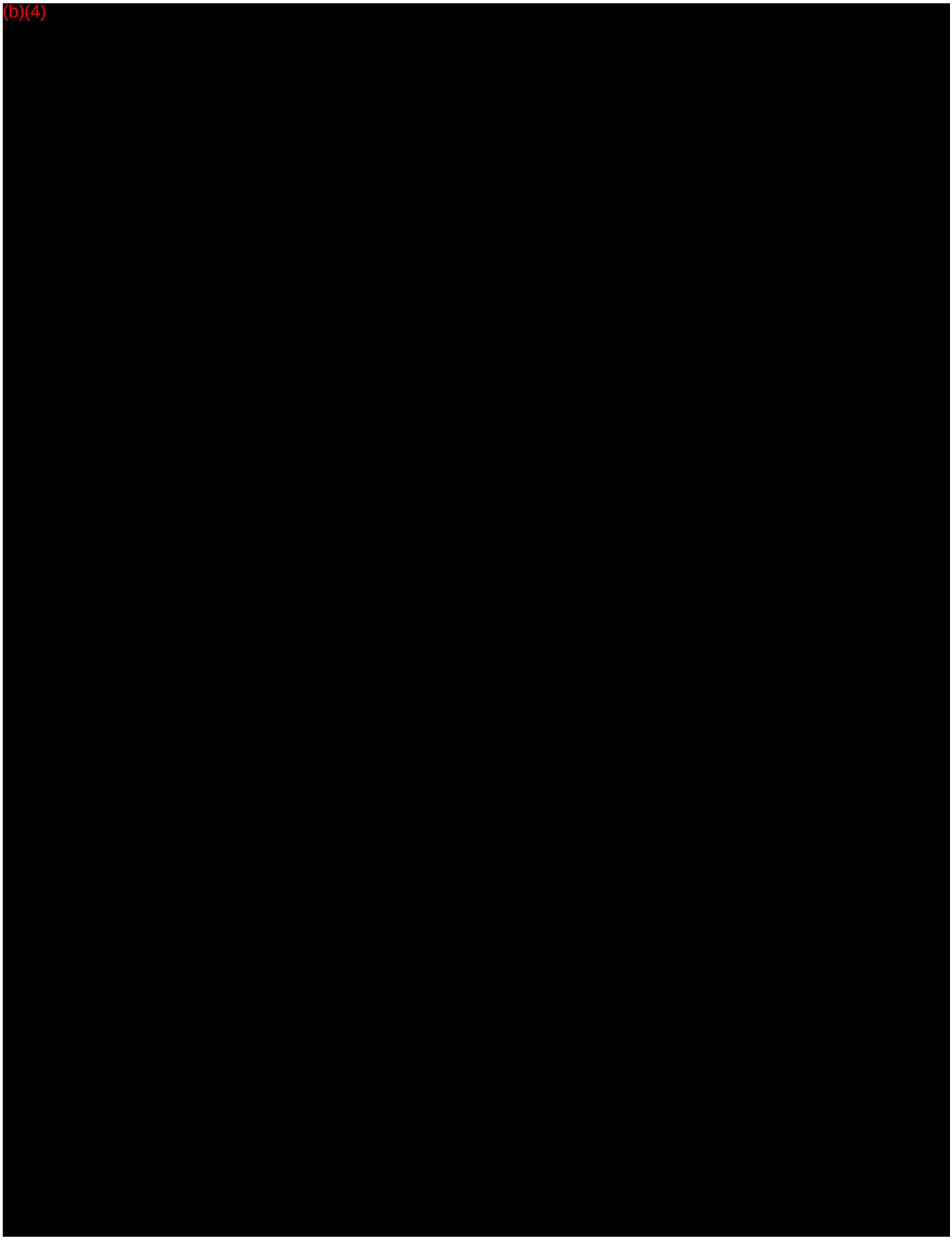

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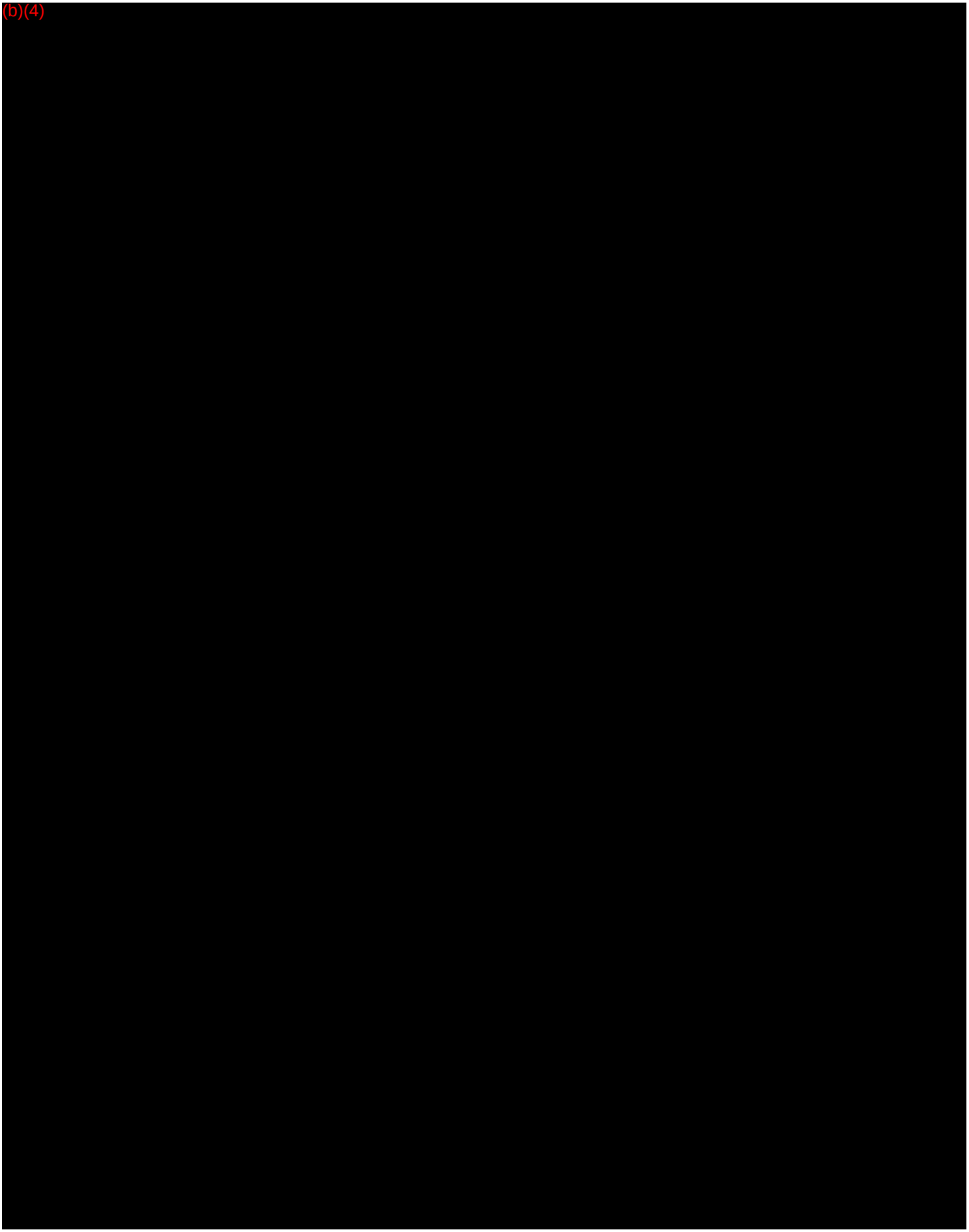

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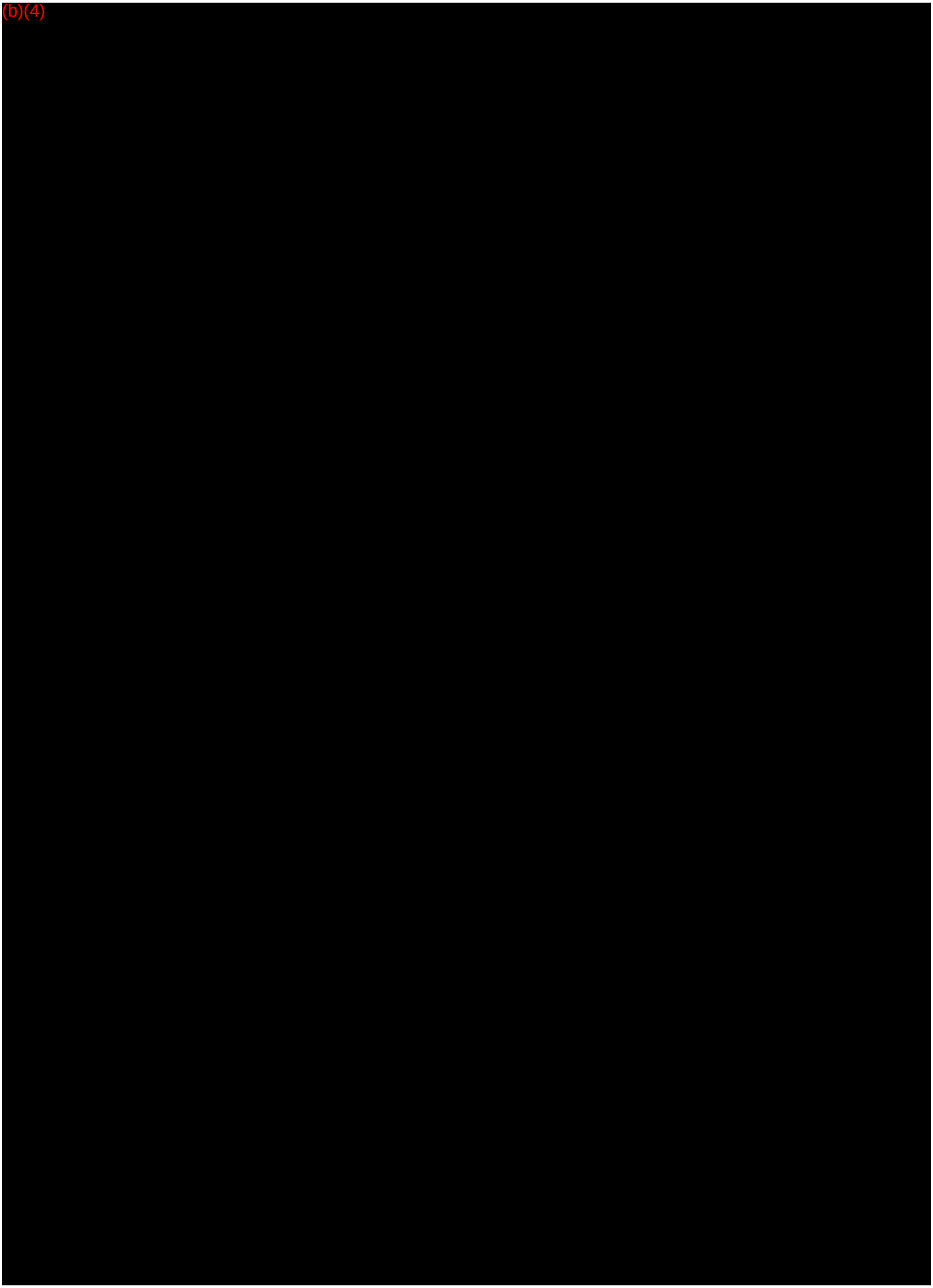

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Verification and Validation Documentation

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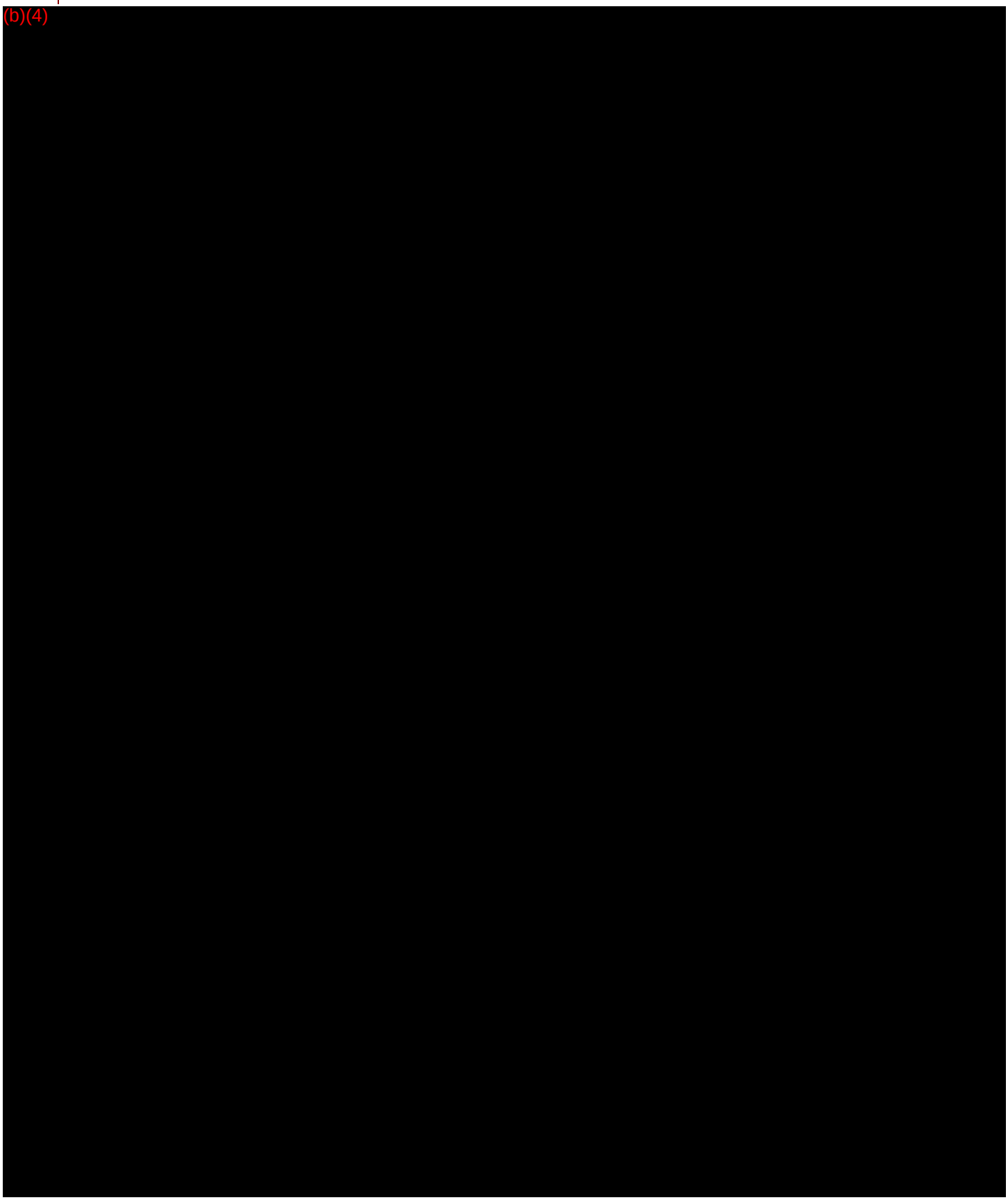

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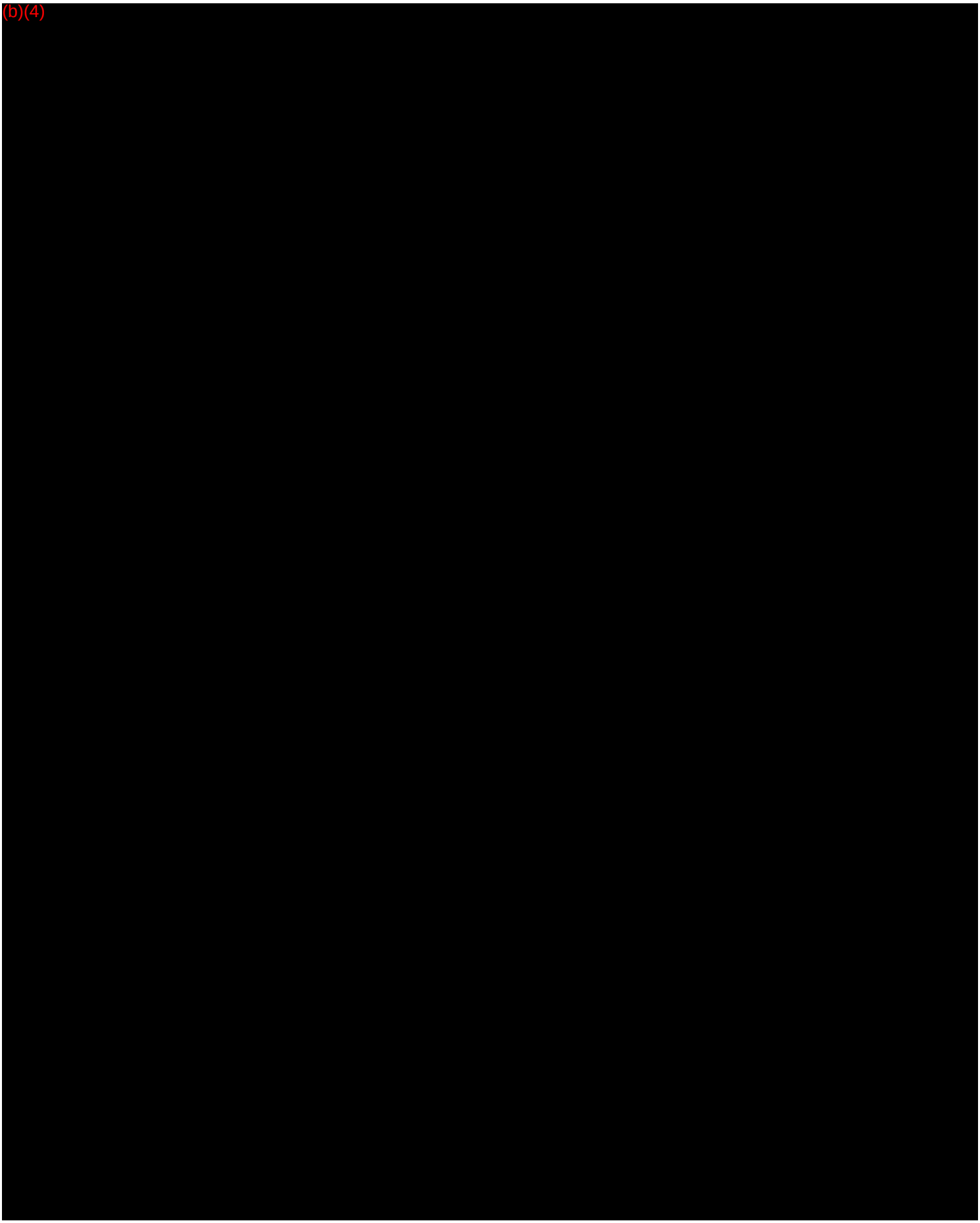

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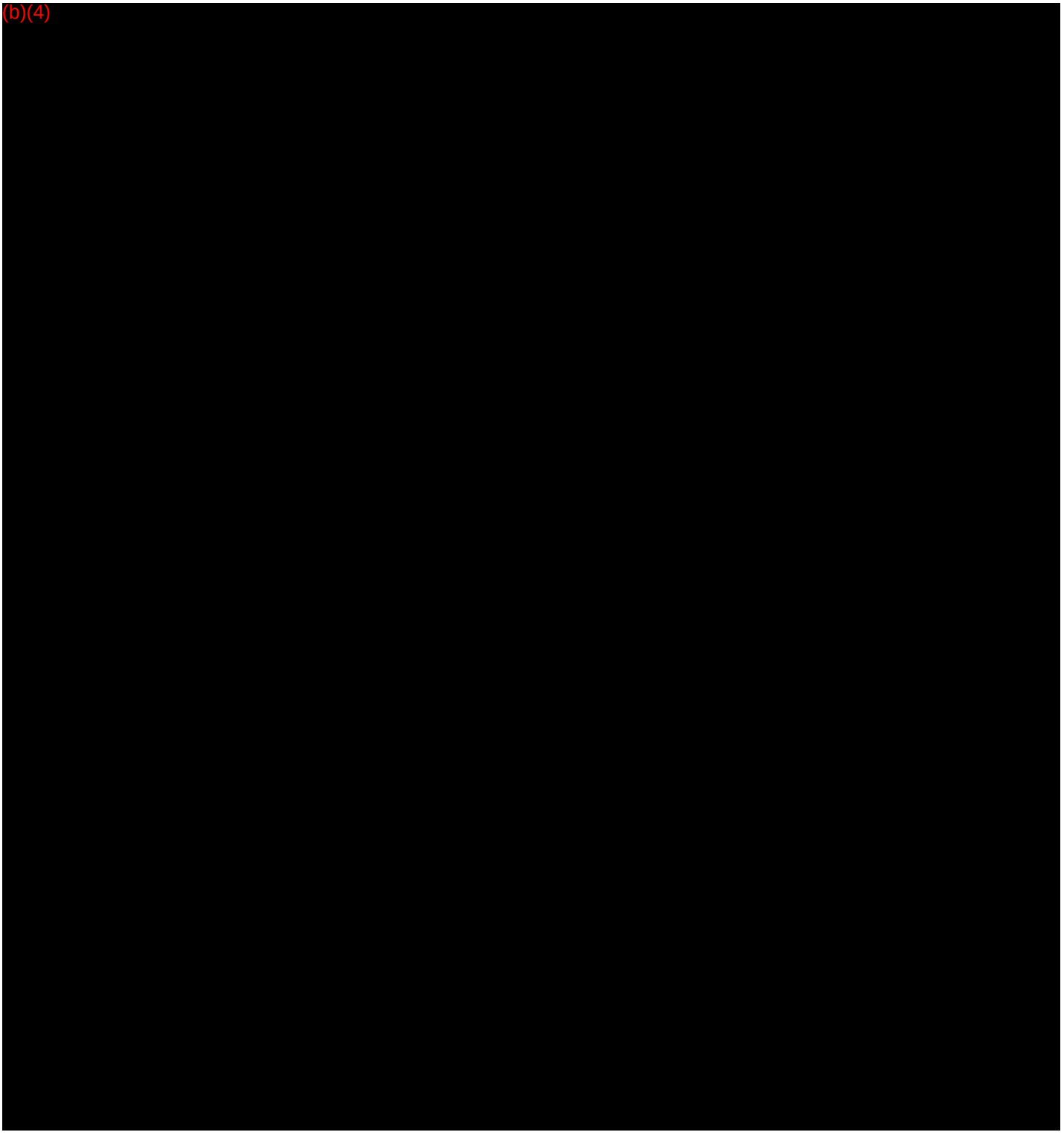

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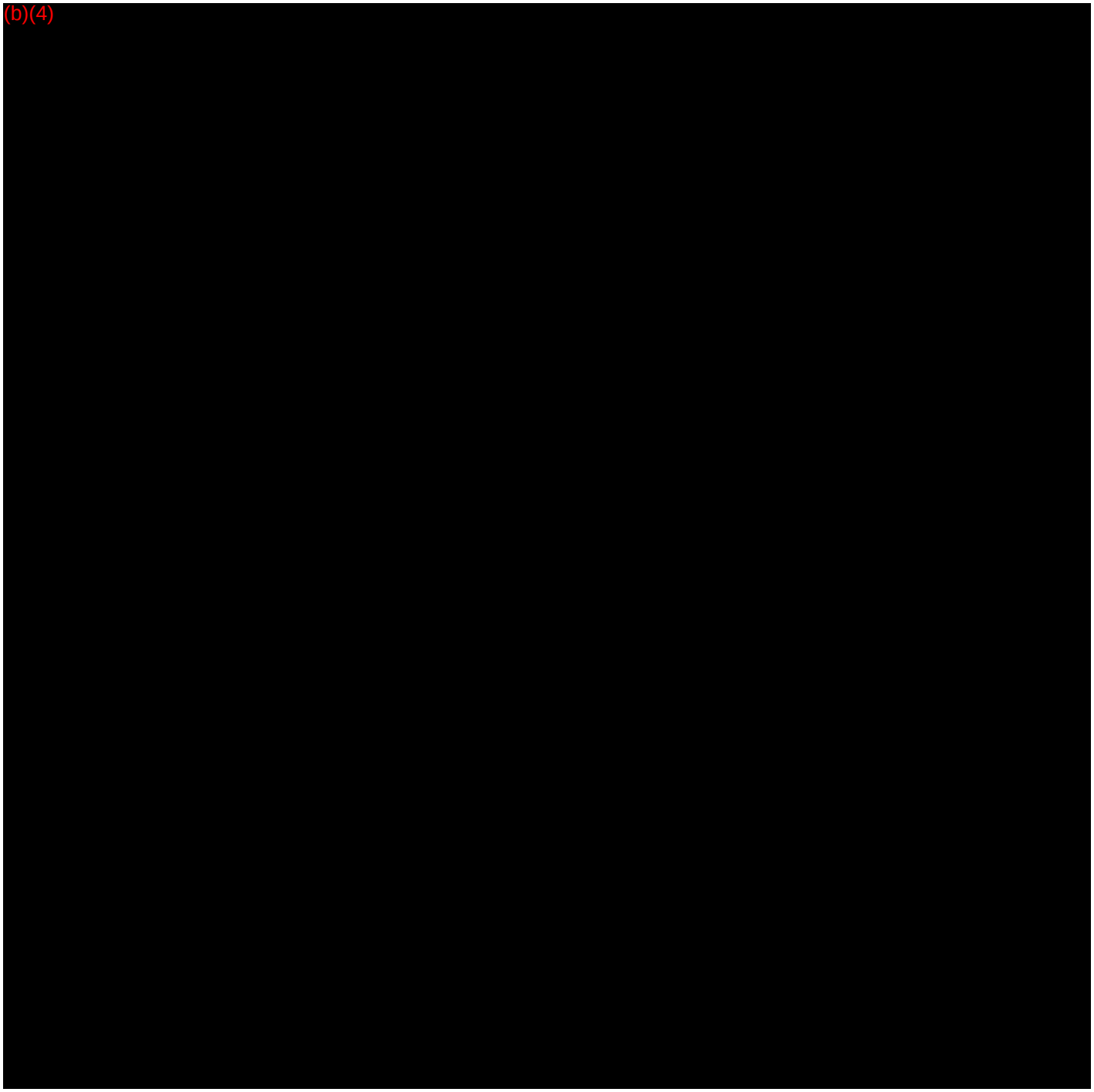

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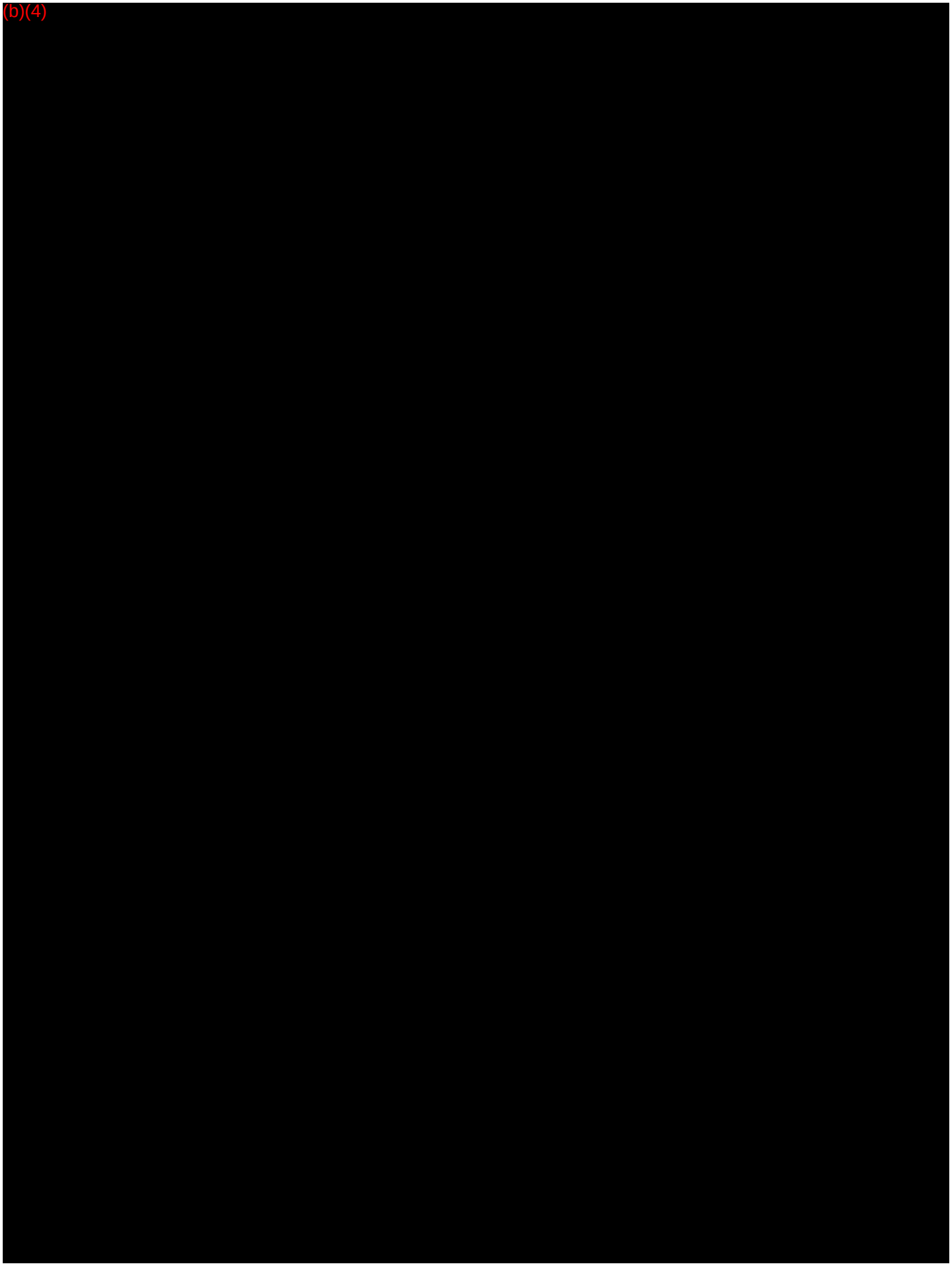

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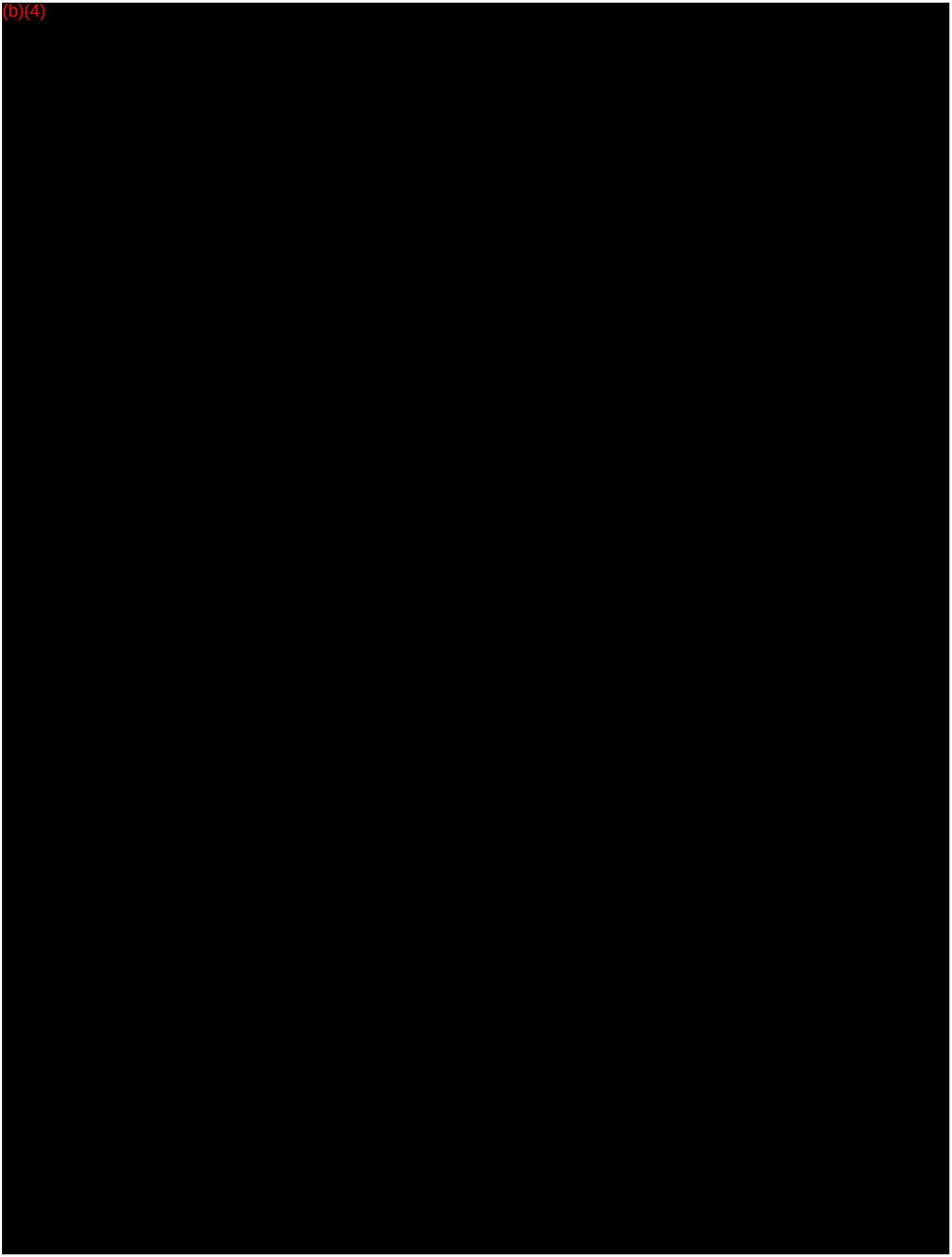

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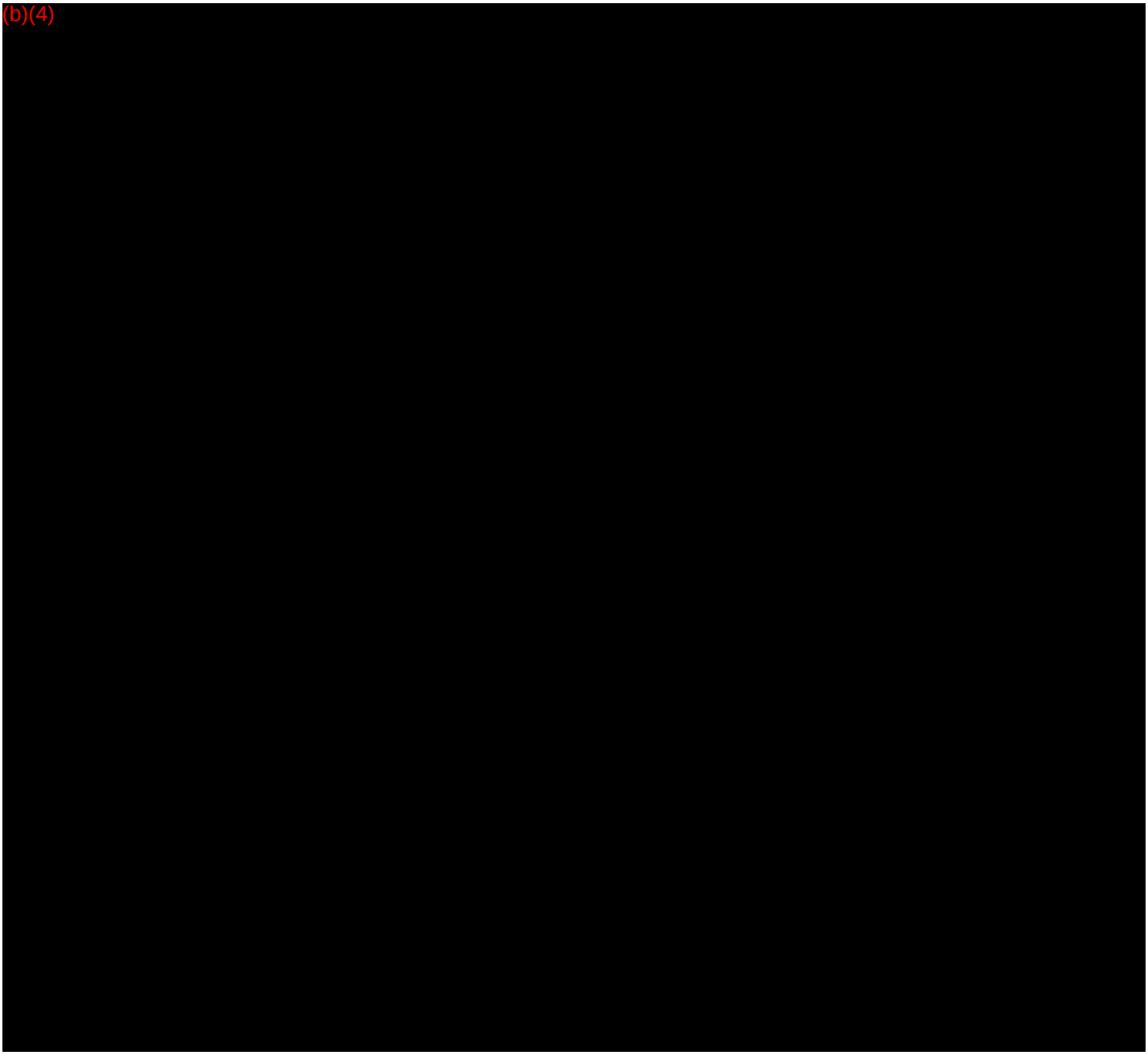

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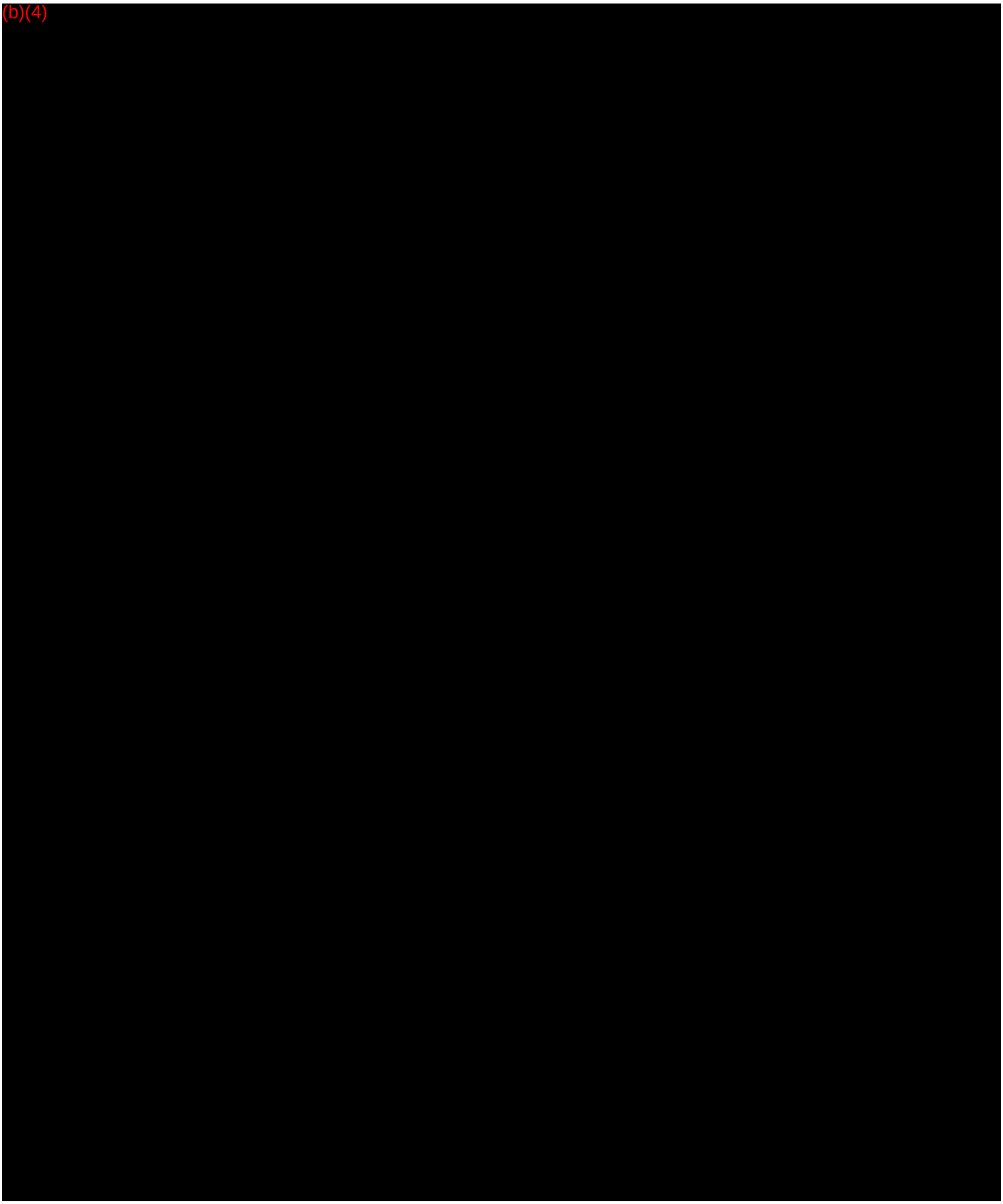

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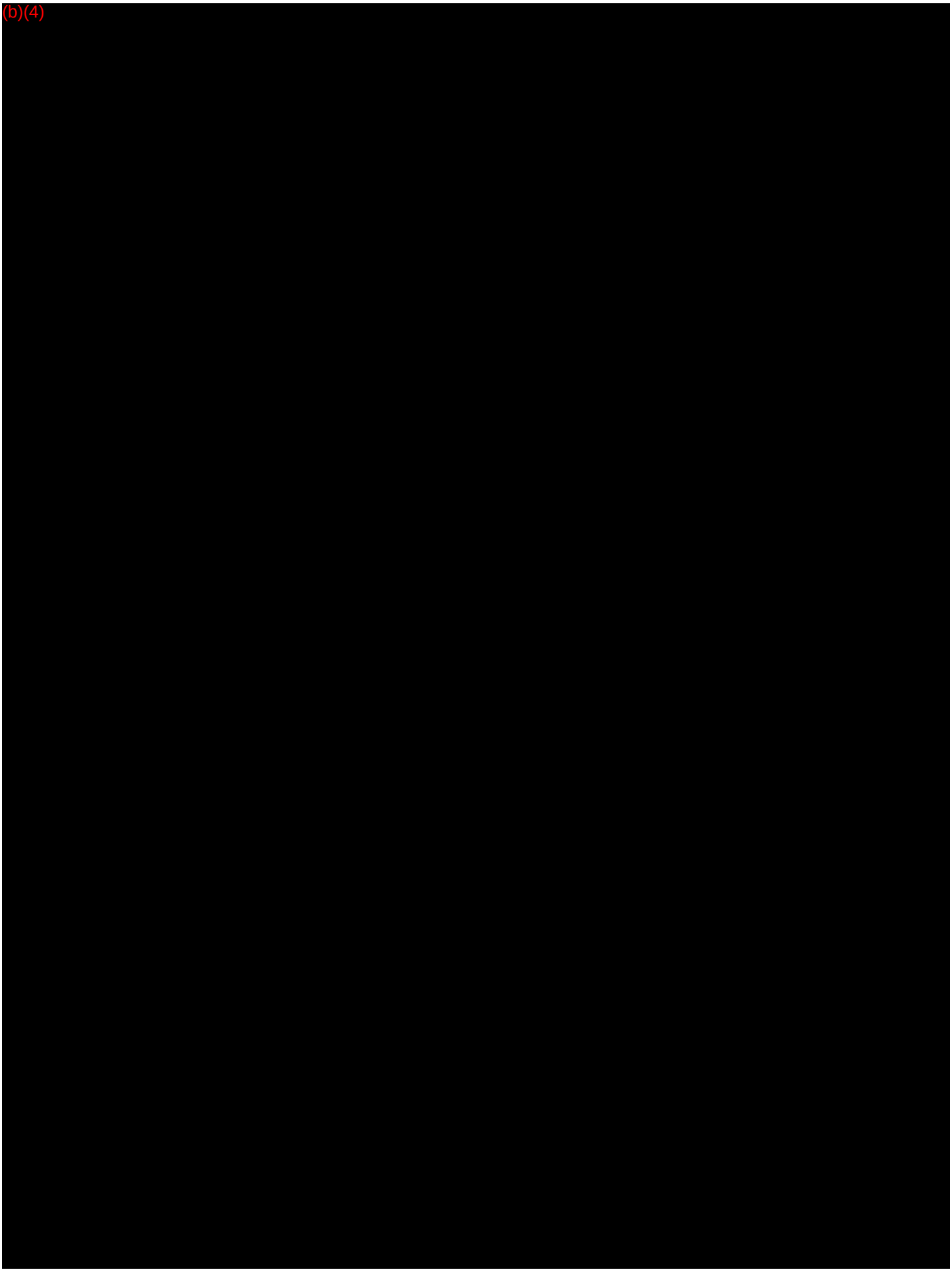

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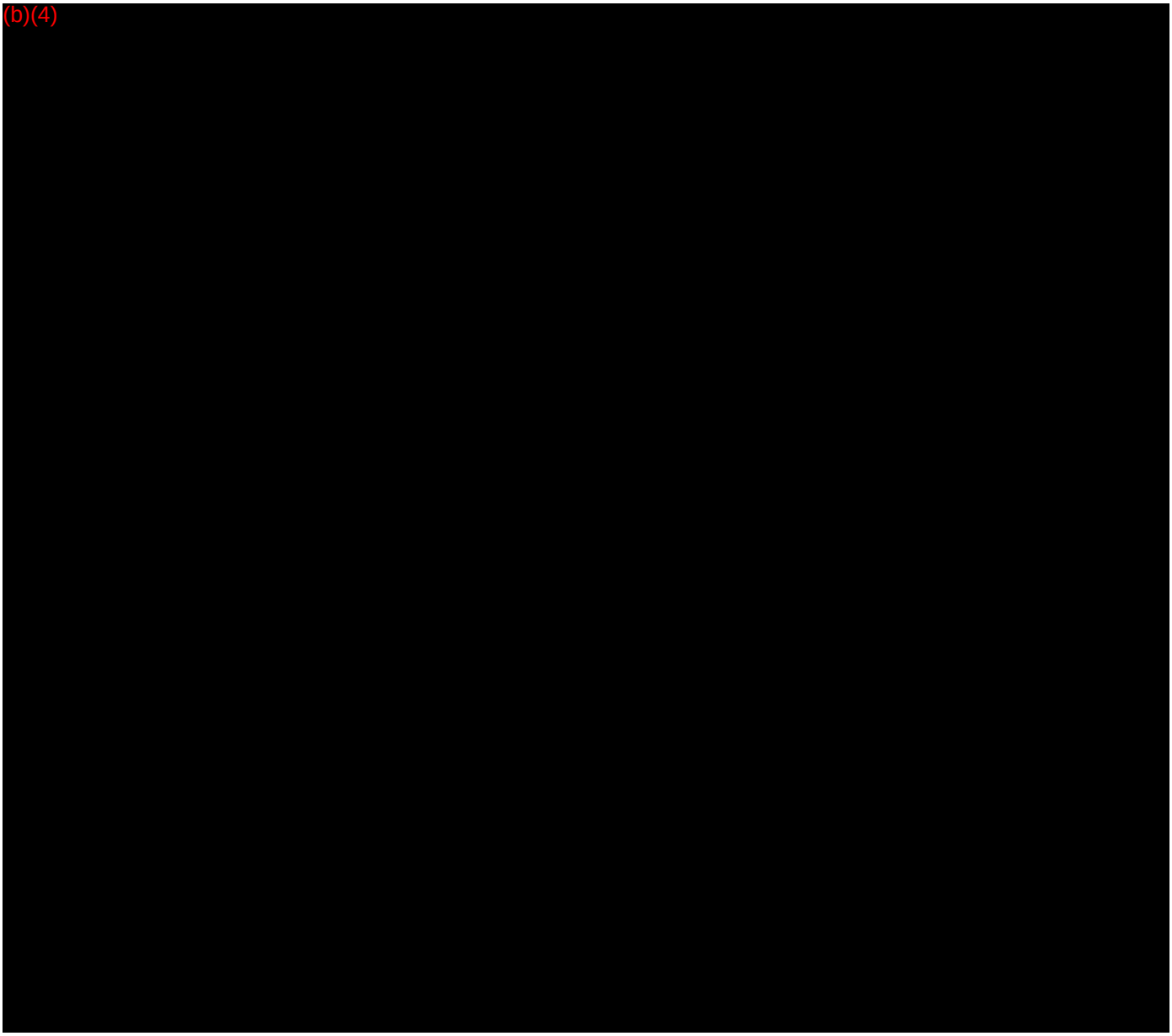

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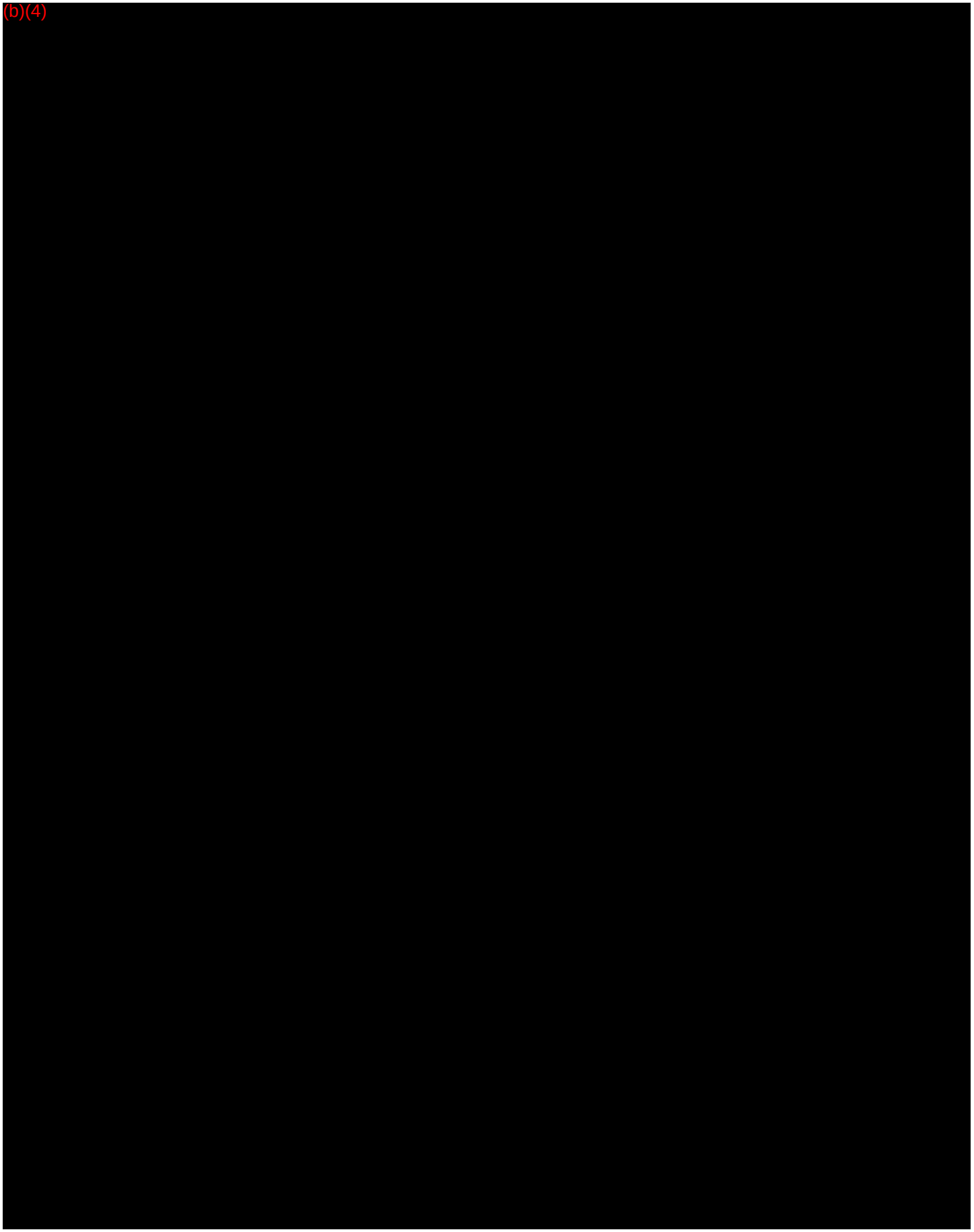

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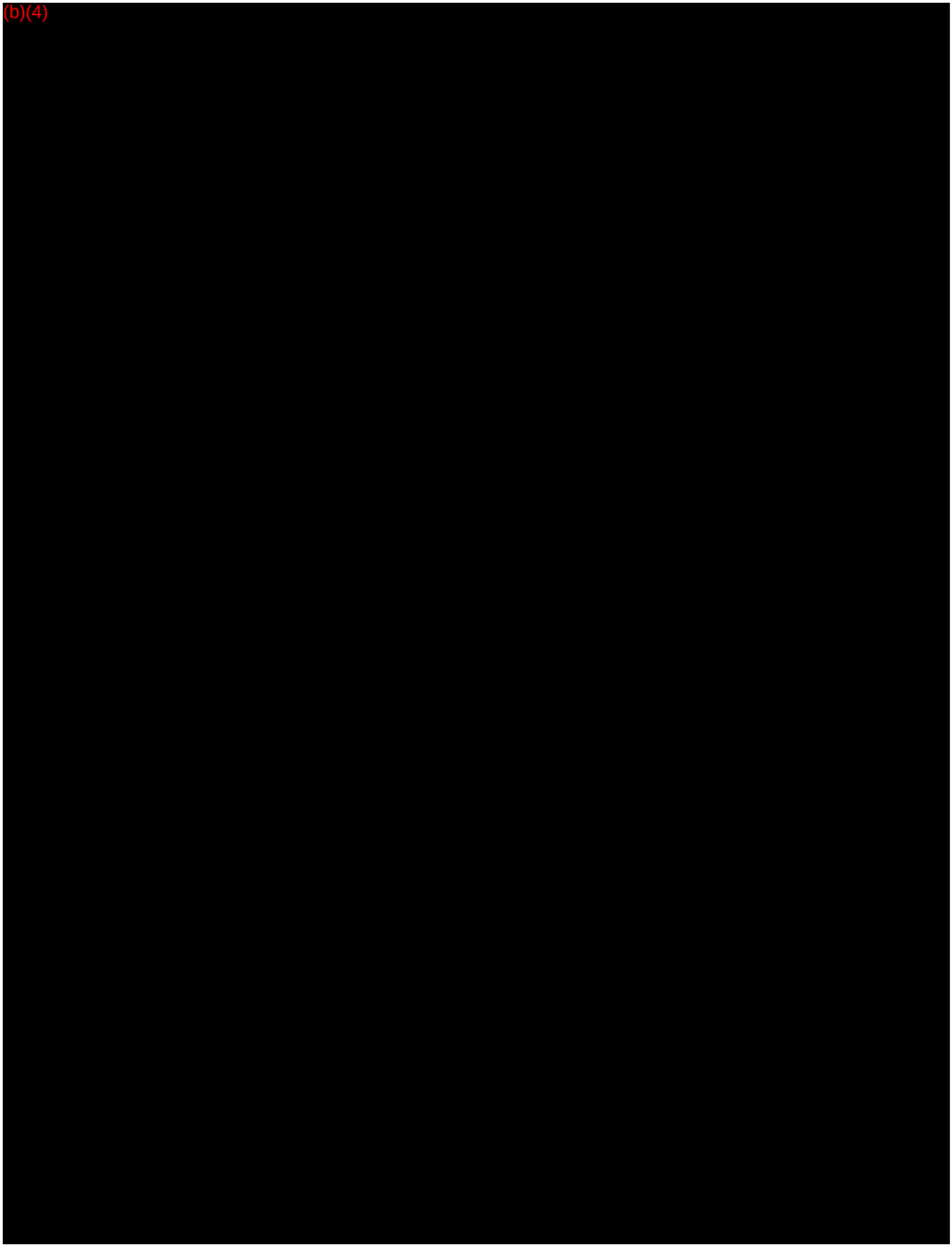

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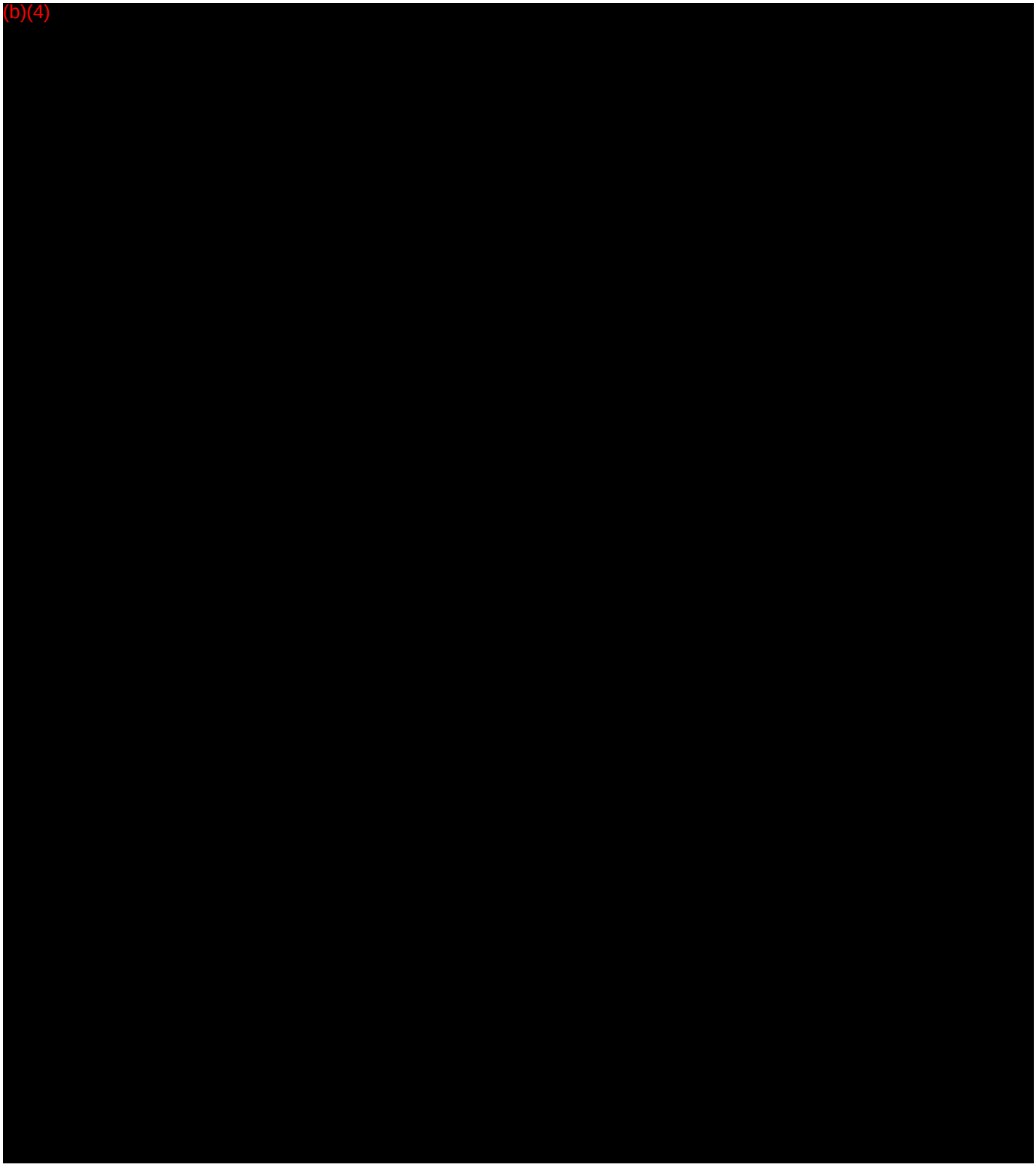

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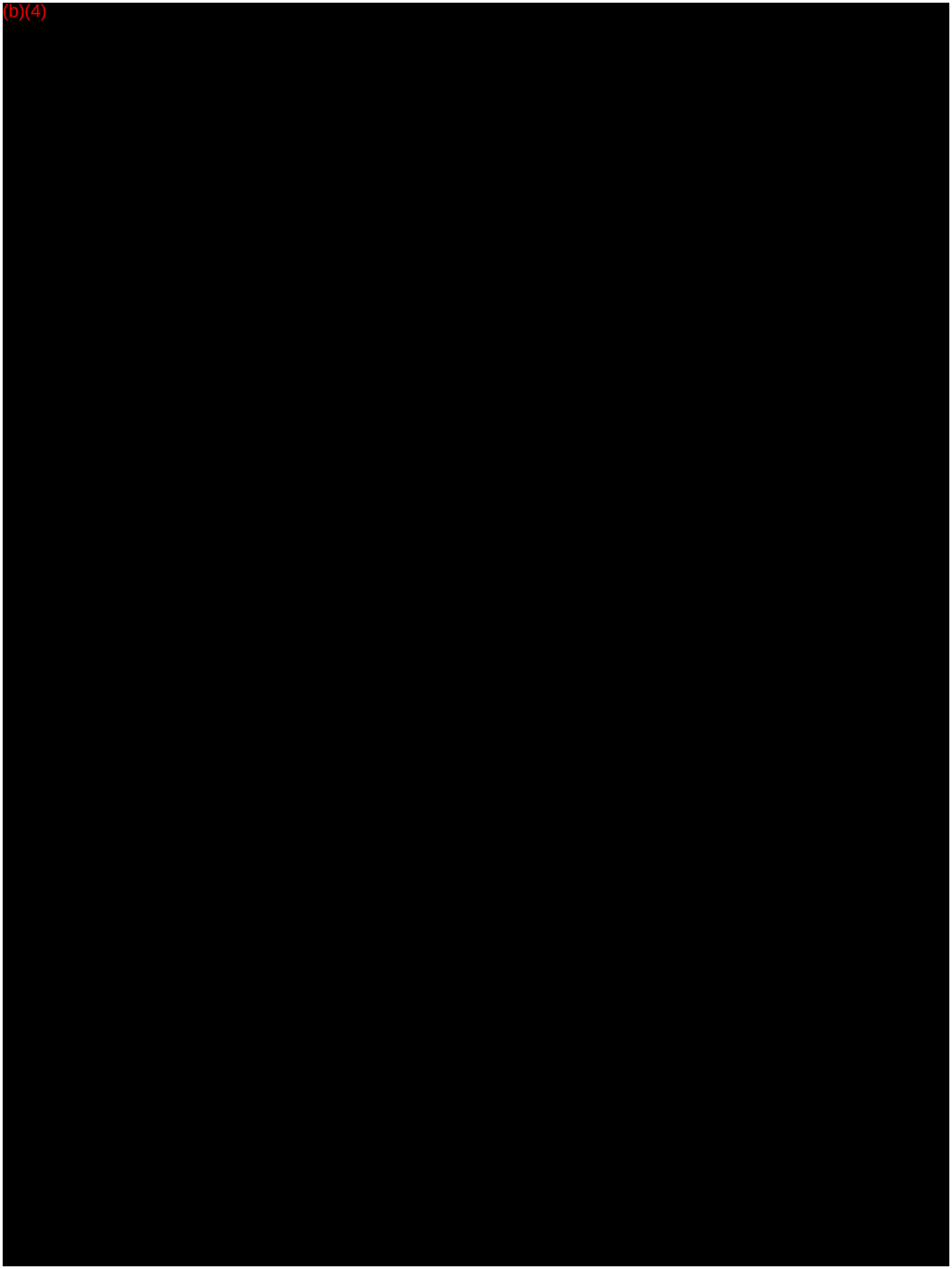

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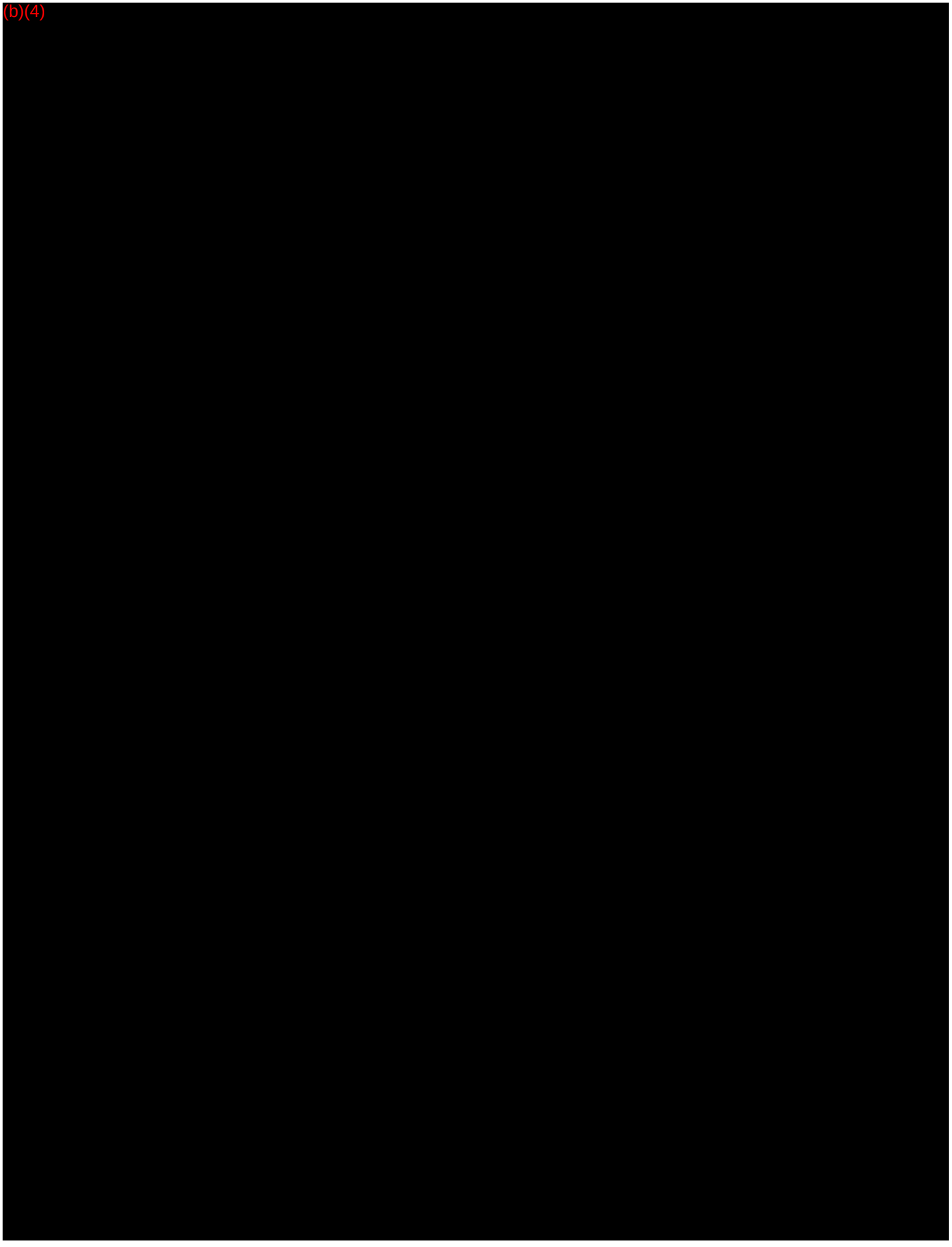

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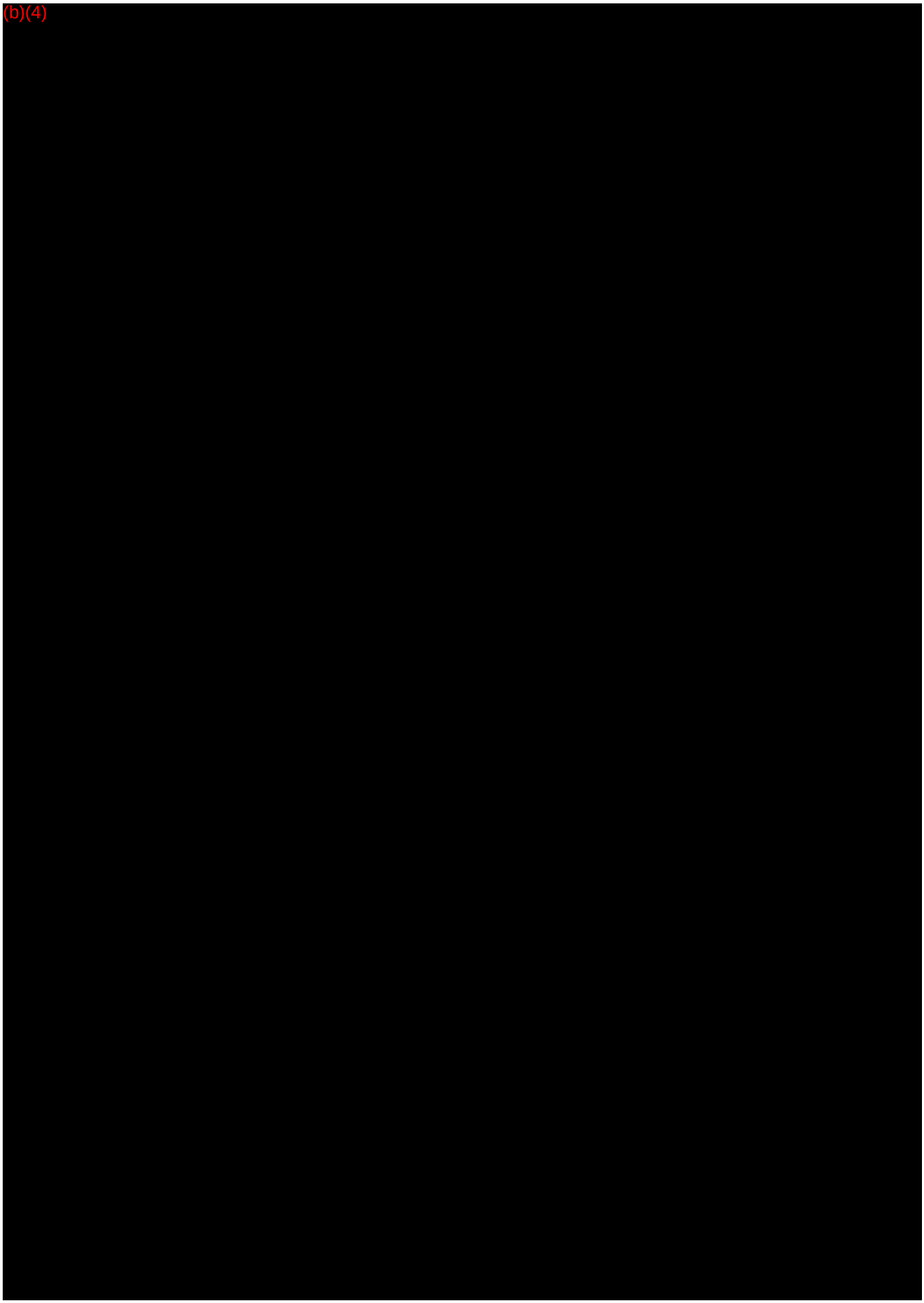

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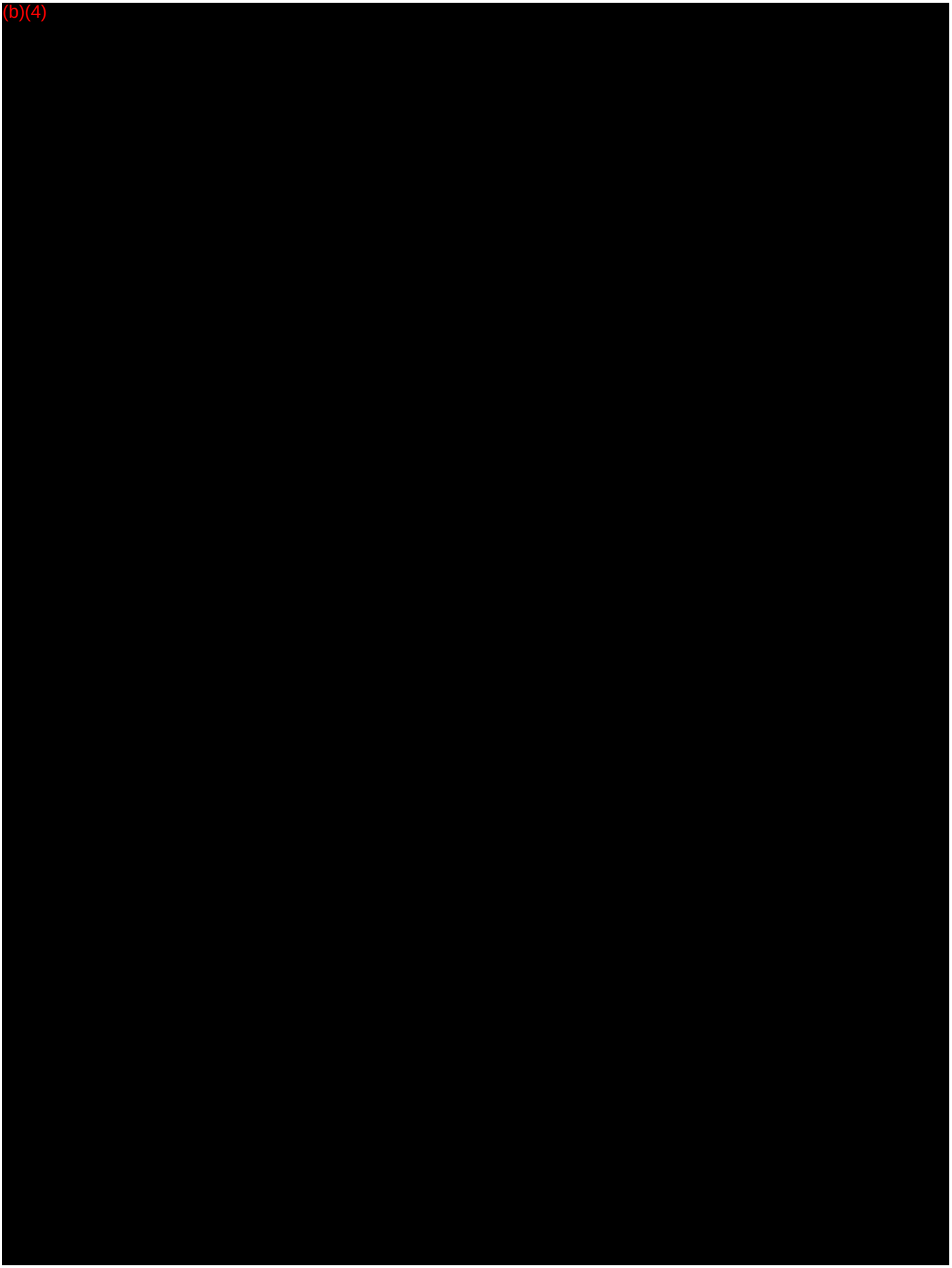

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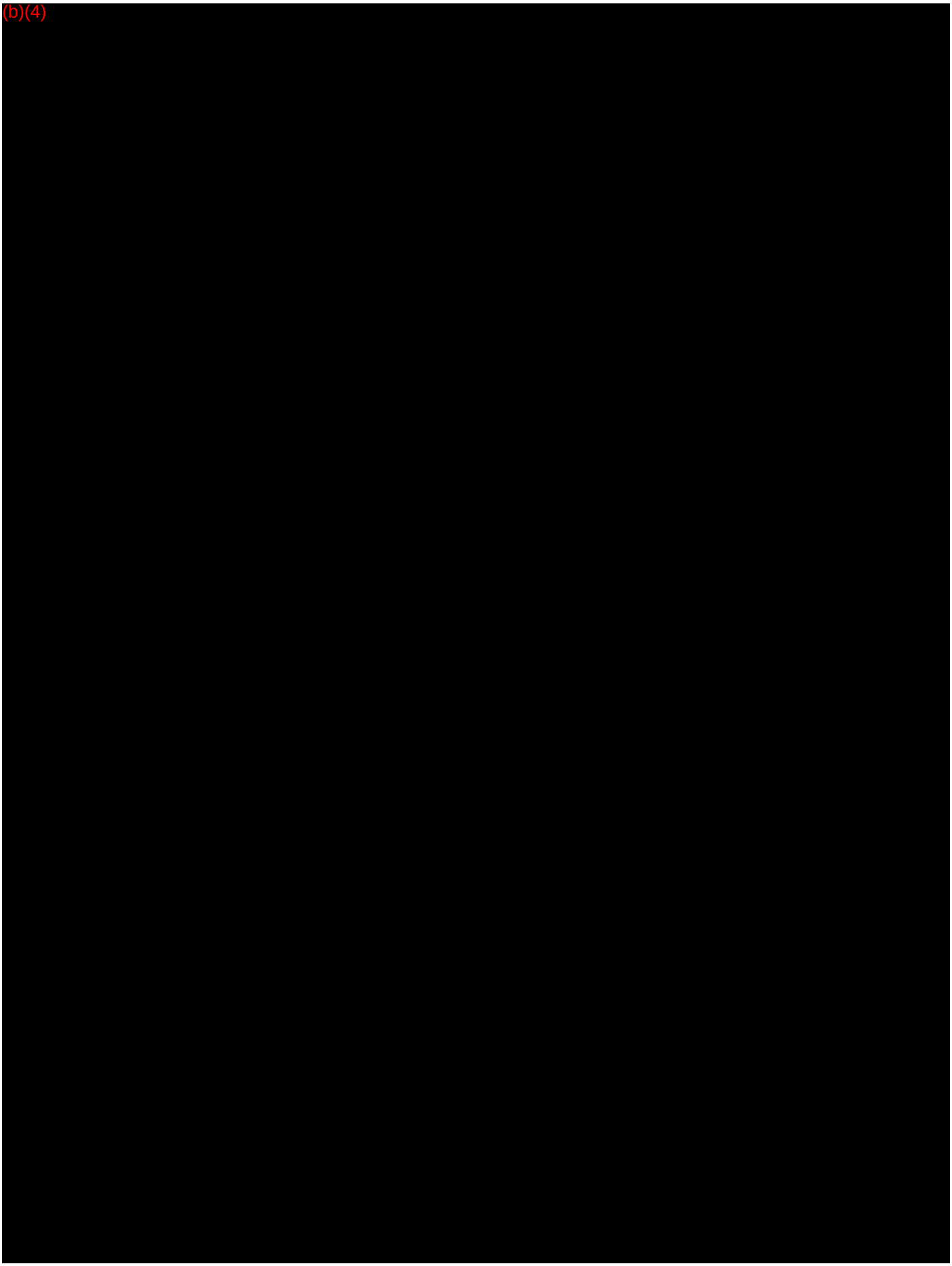

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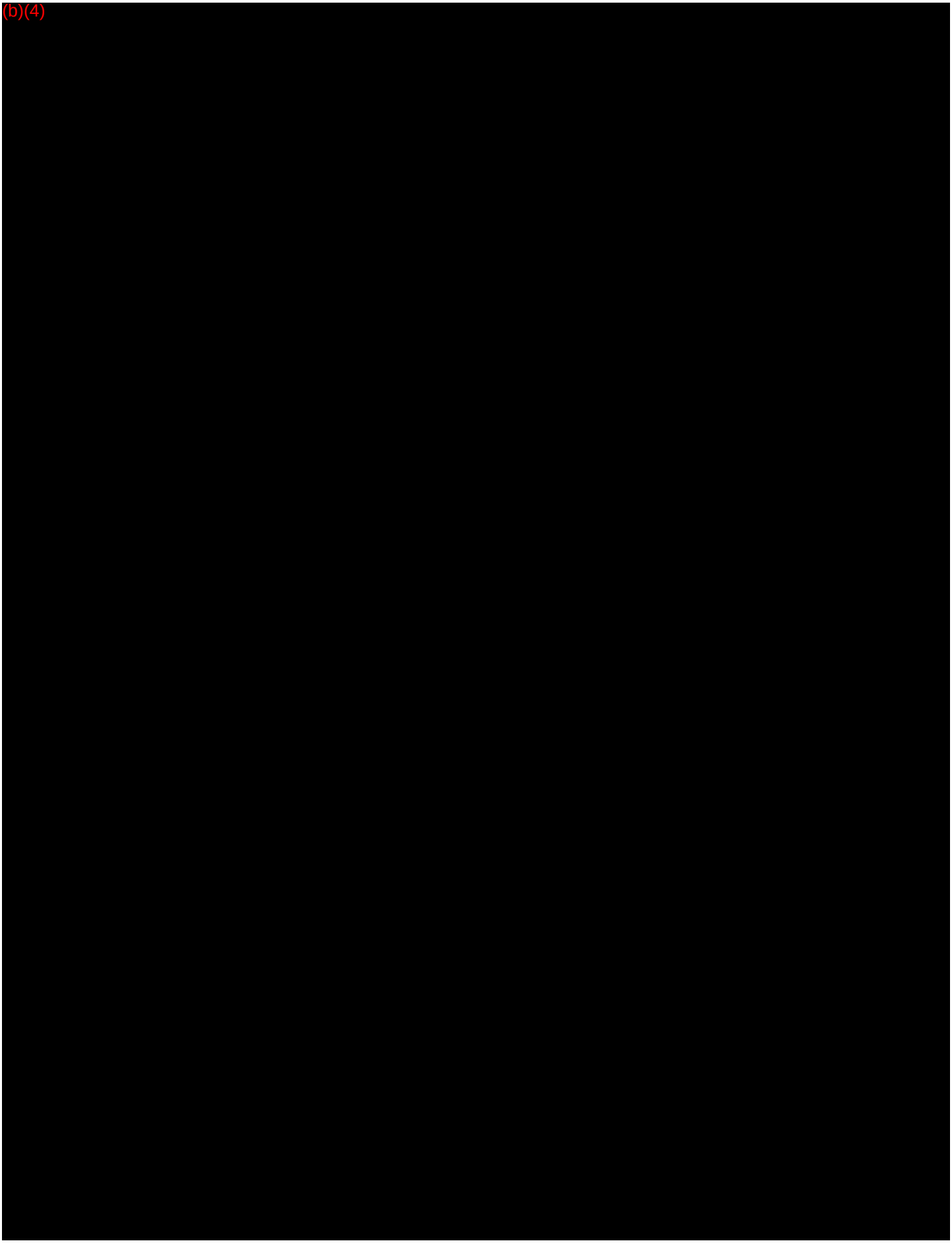

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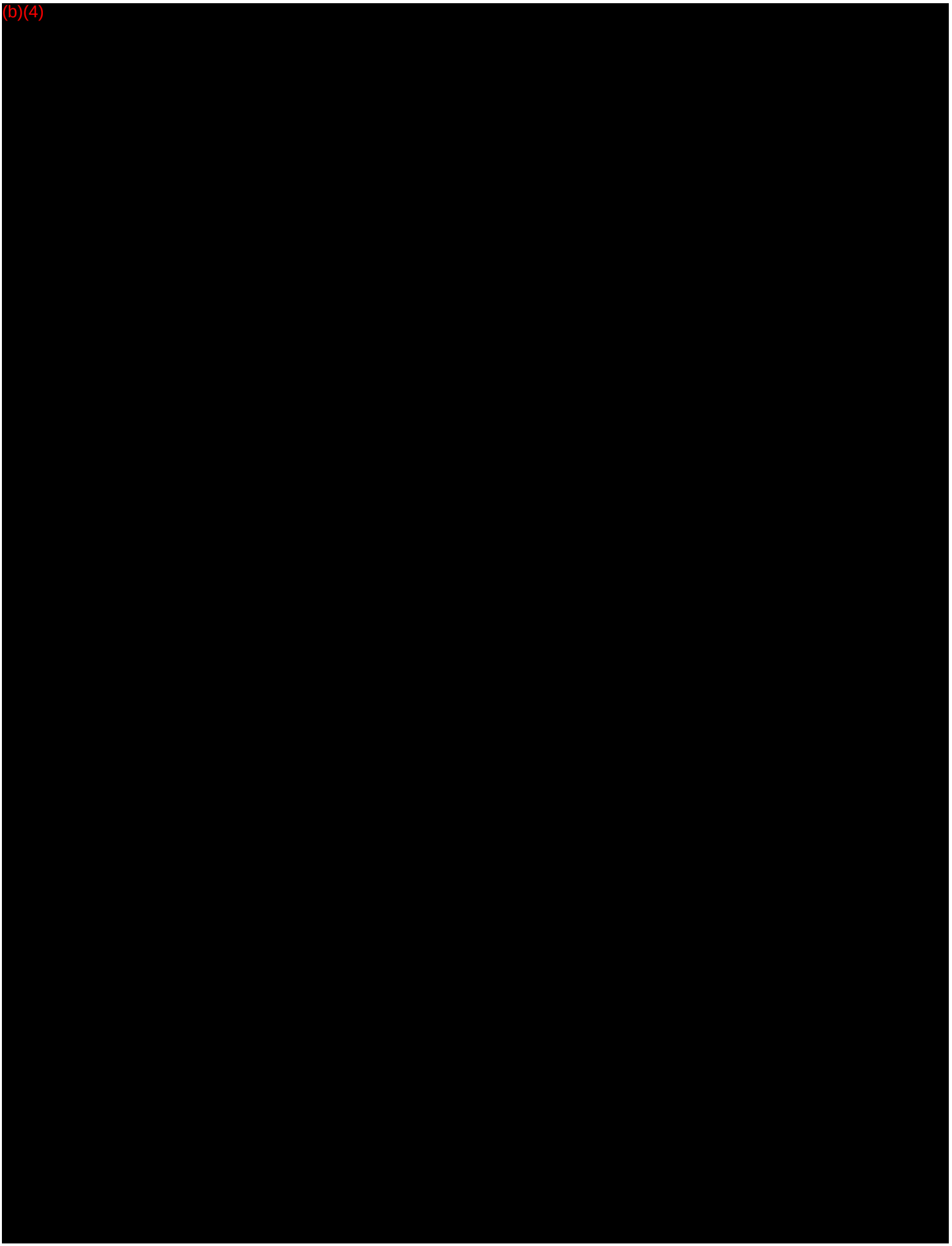

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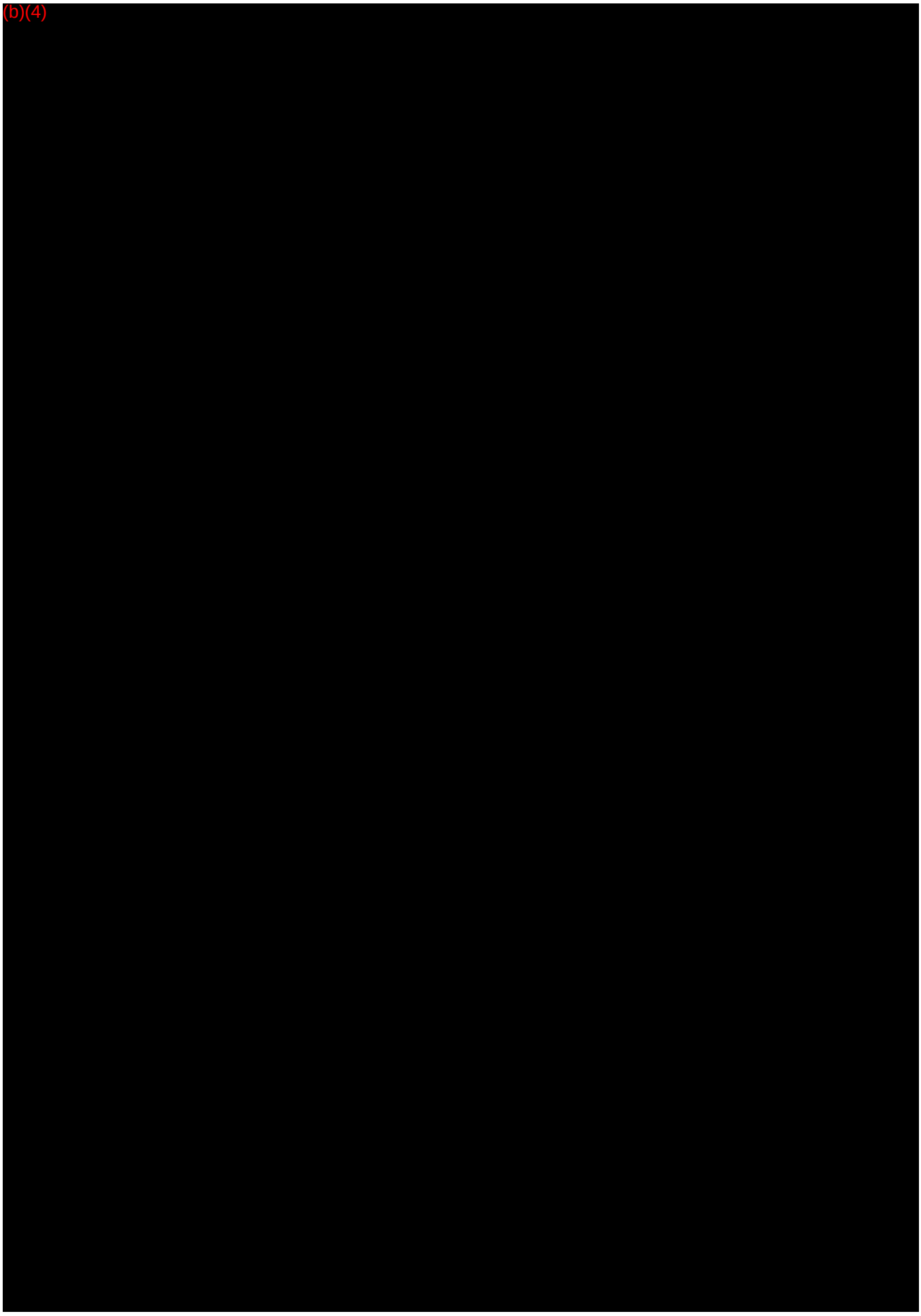

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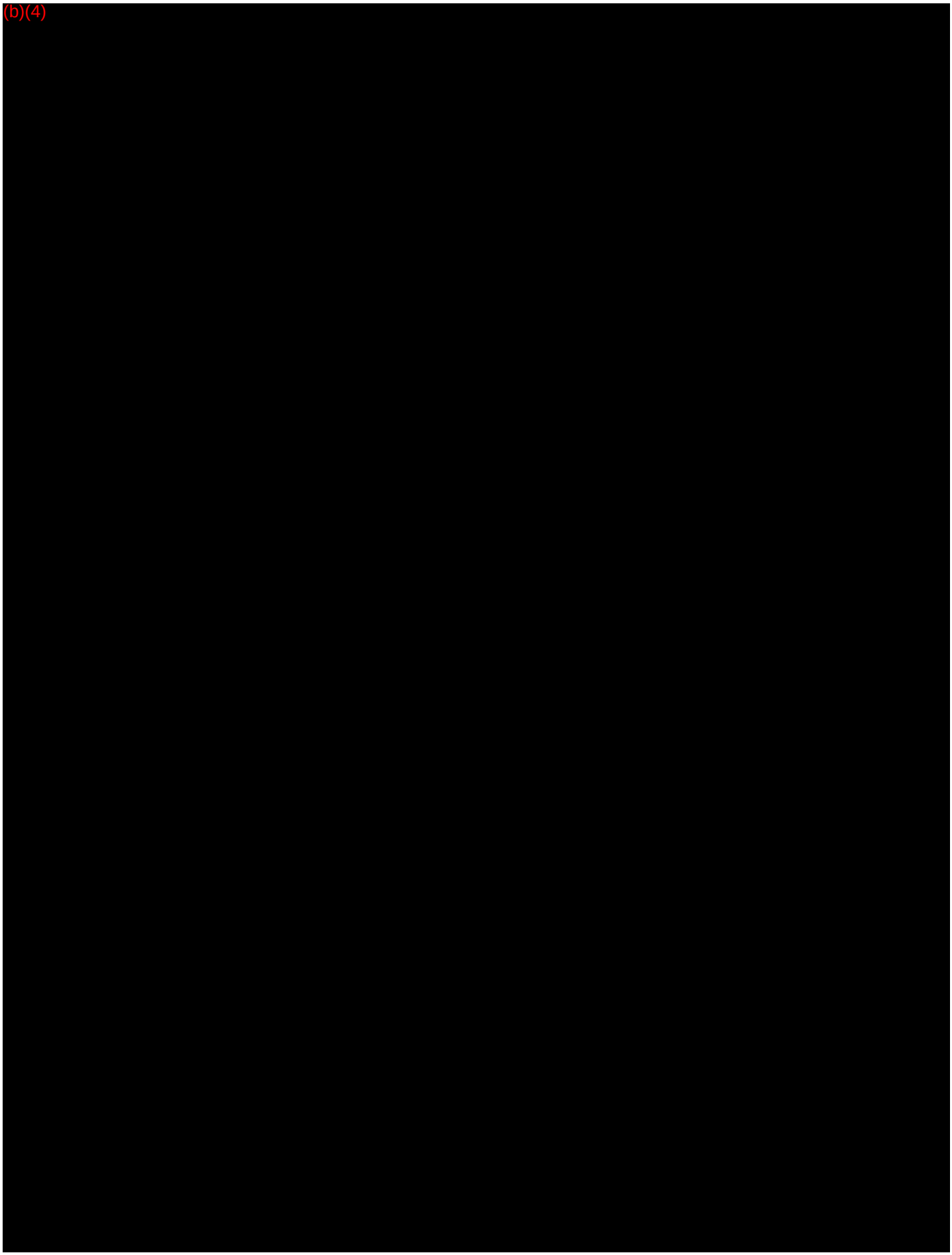

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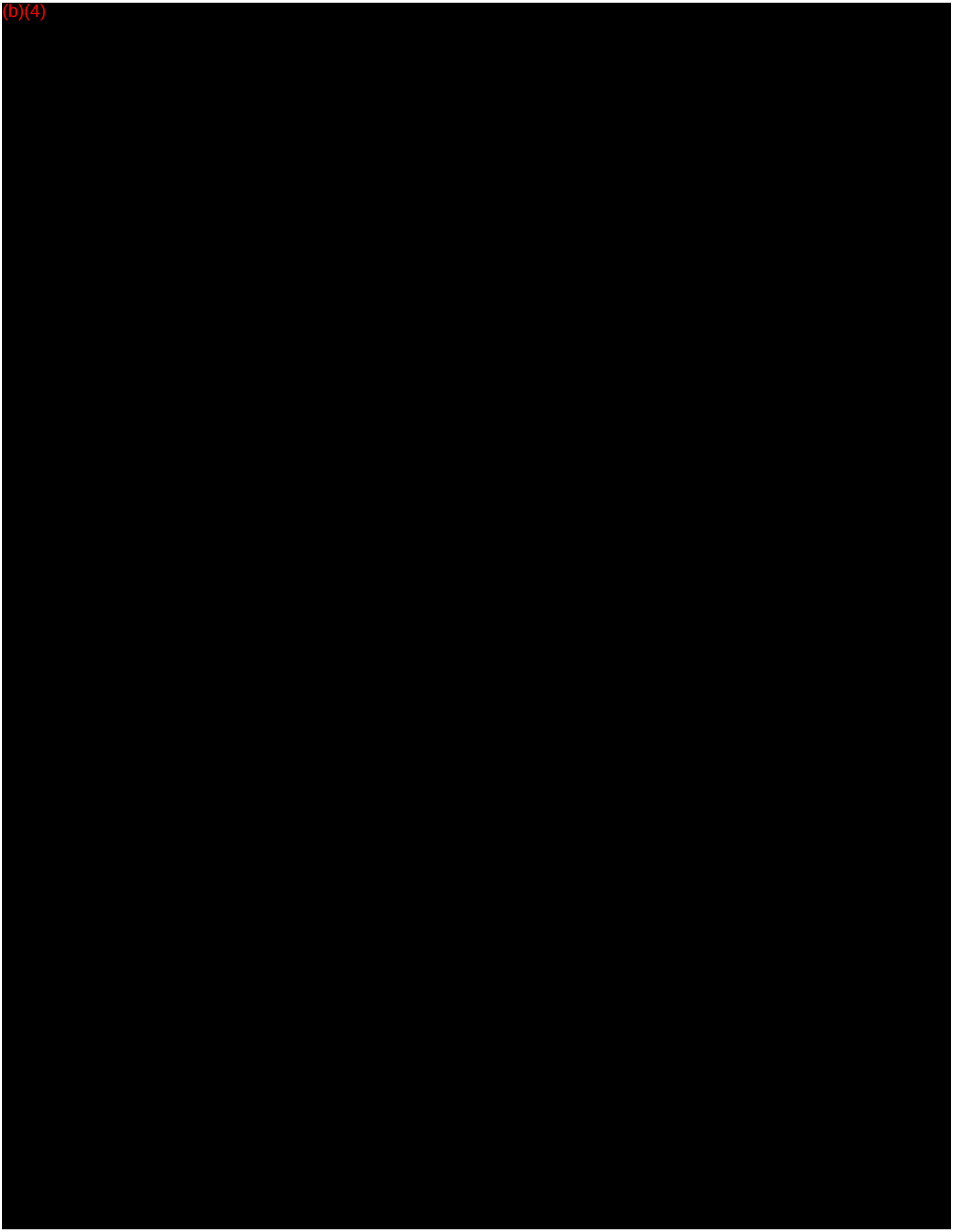

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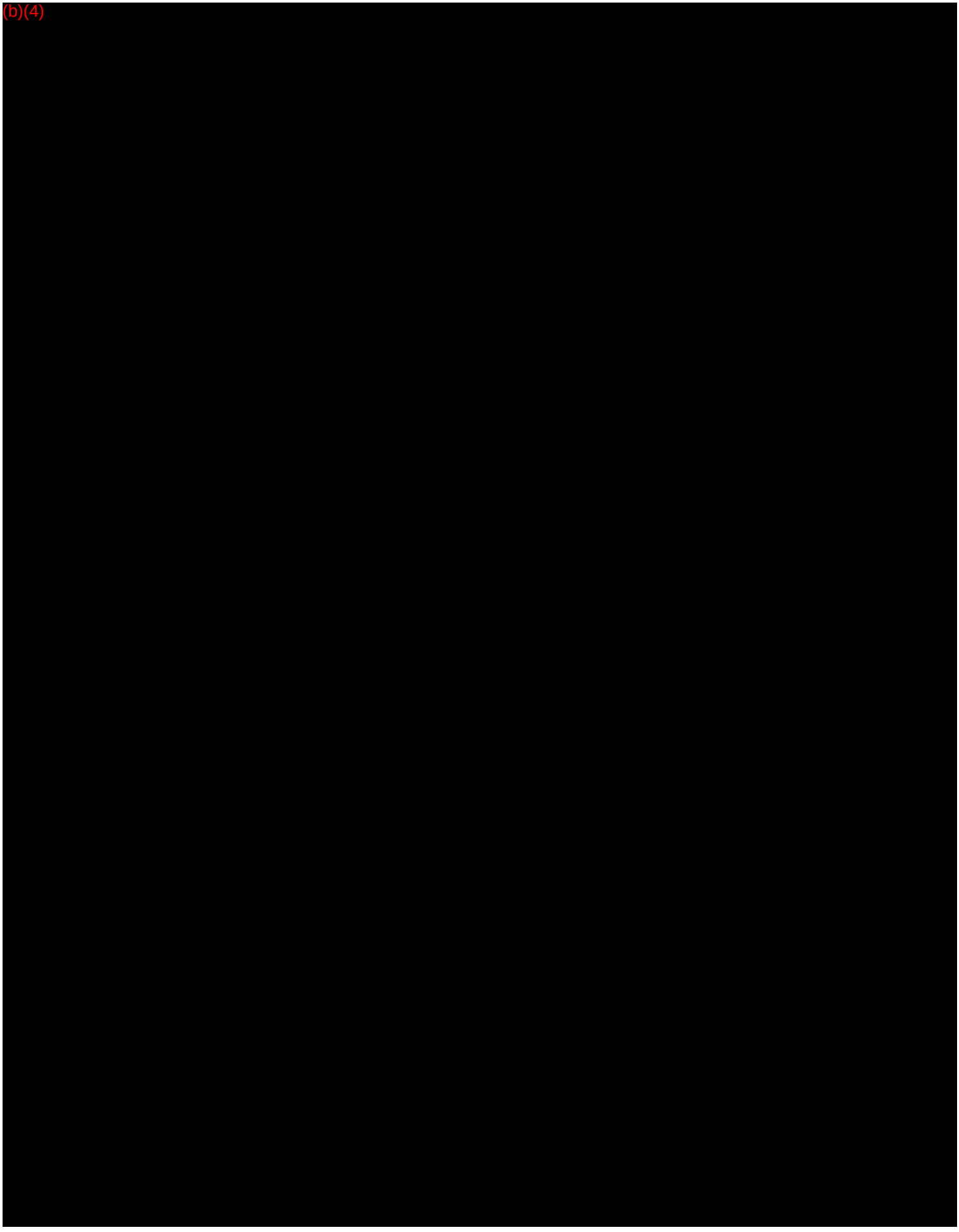

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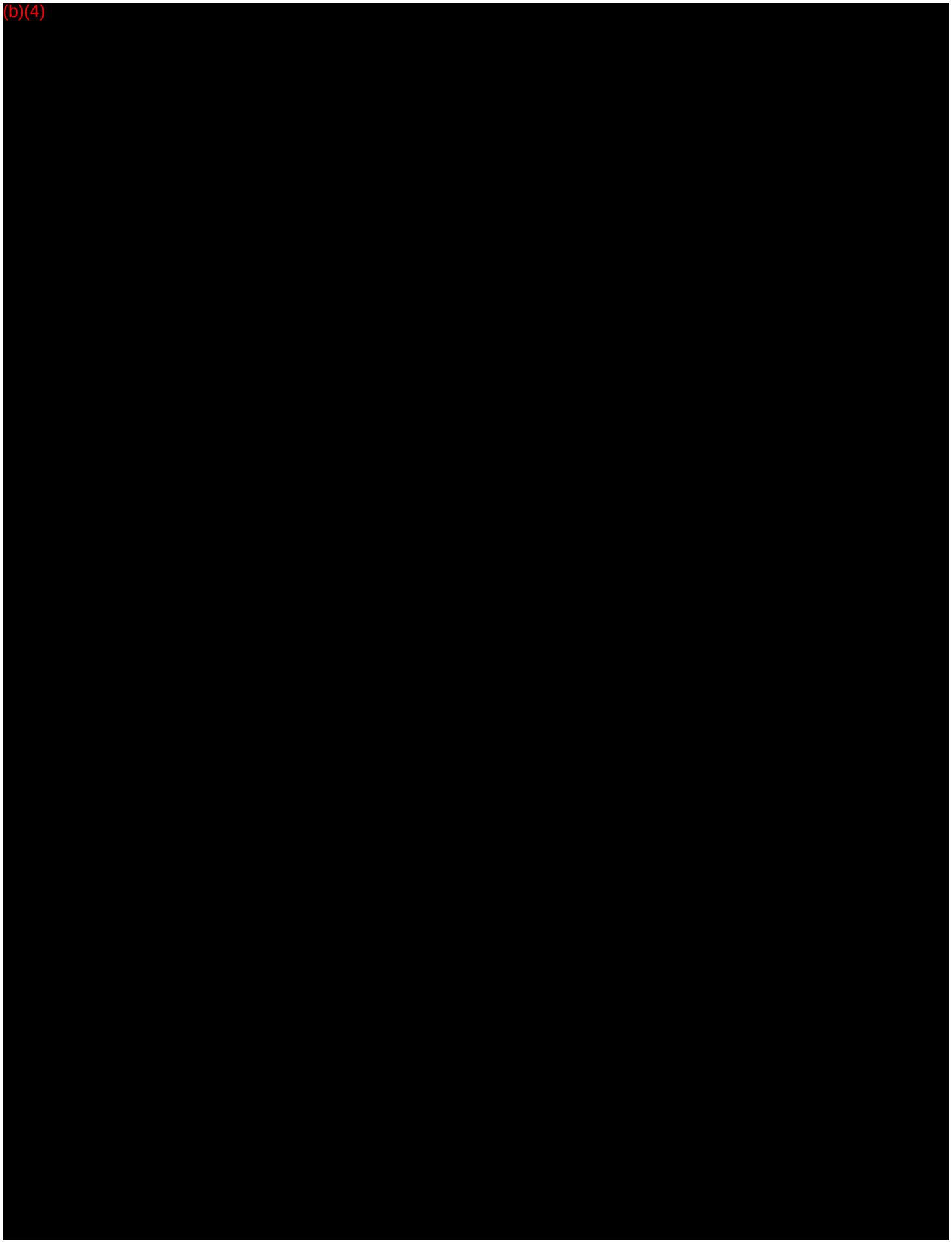

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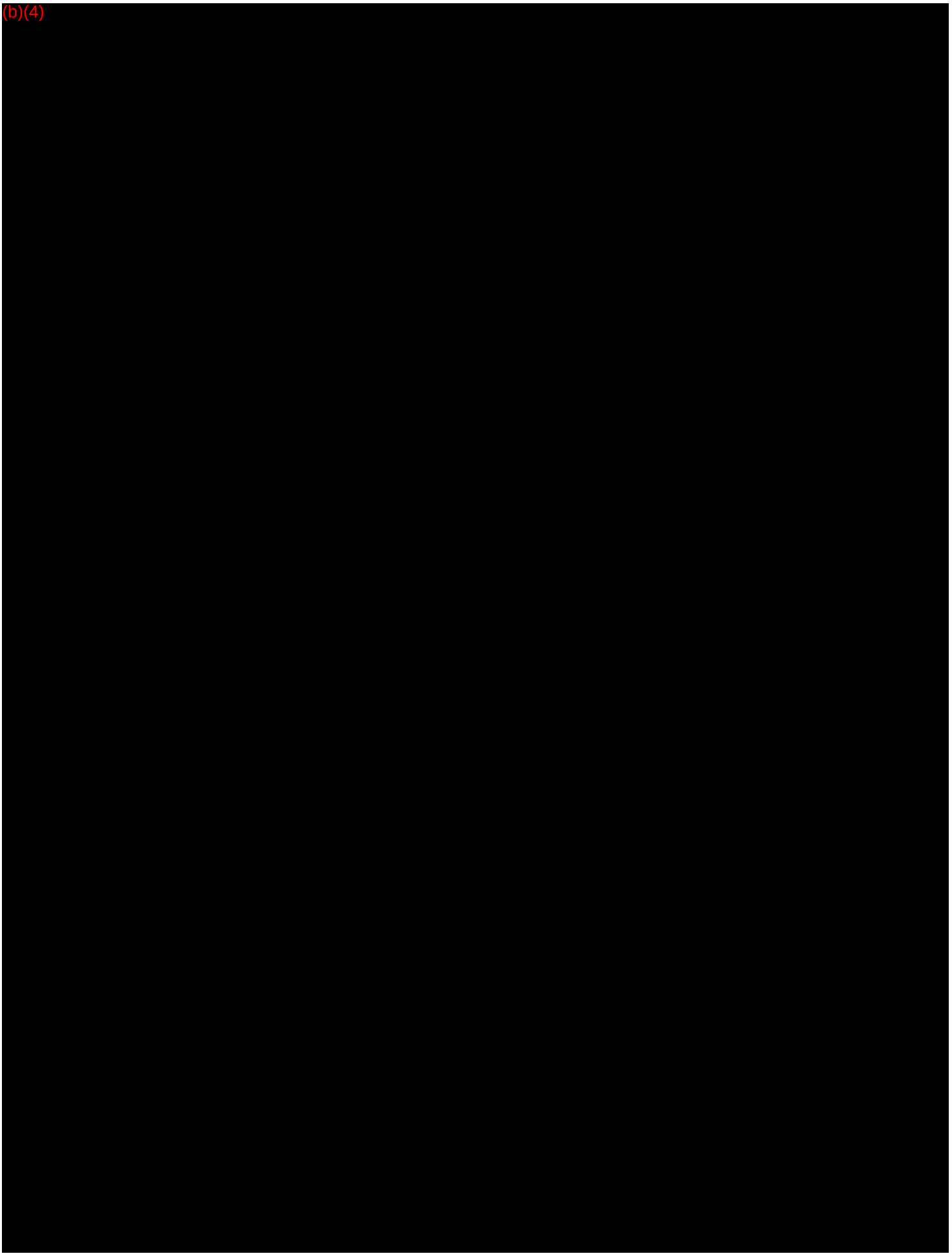

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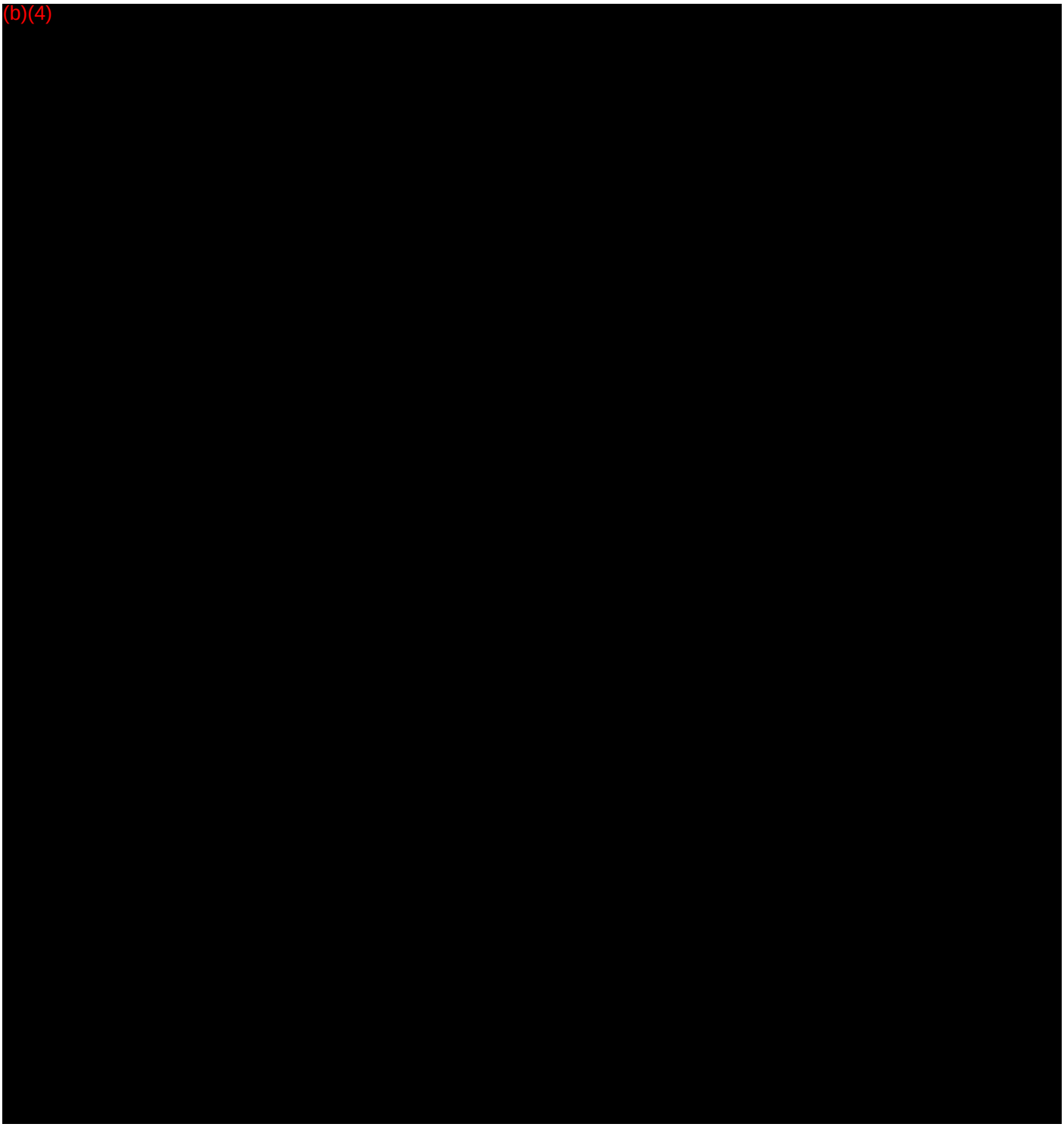

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Validation Result – (b)(4)

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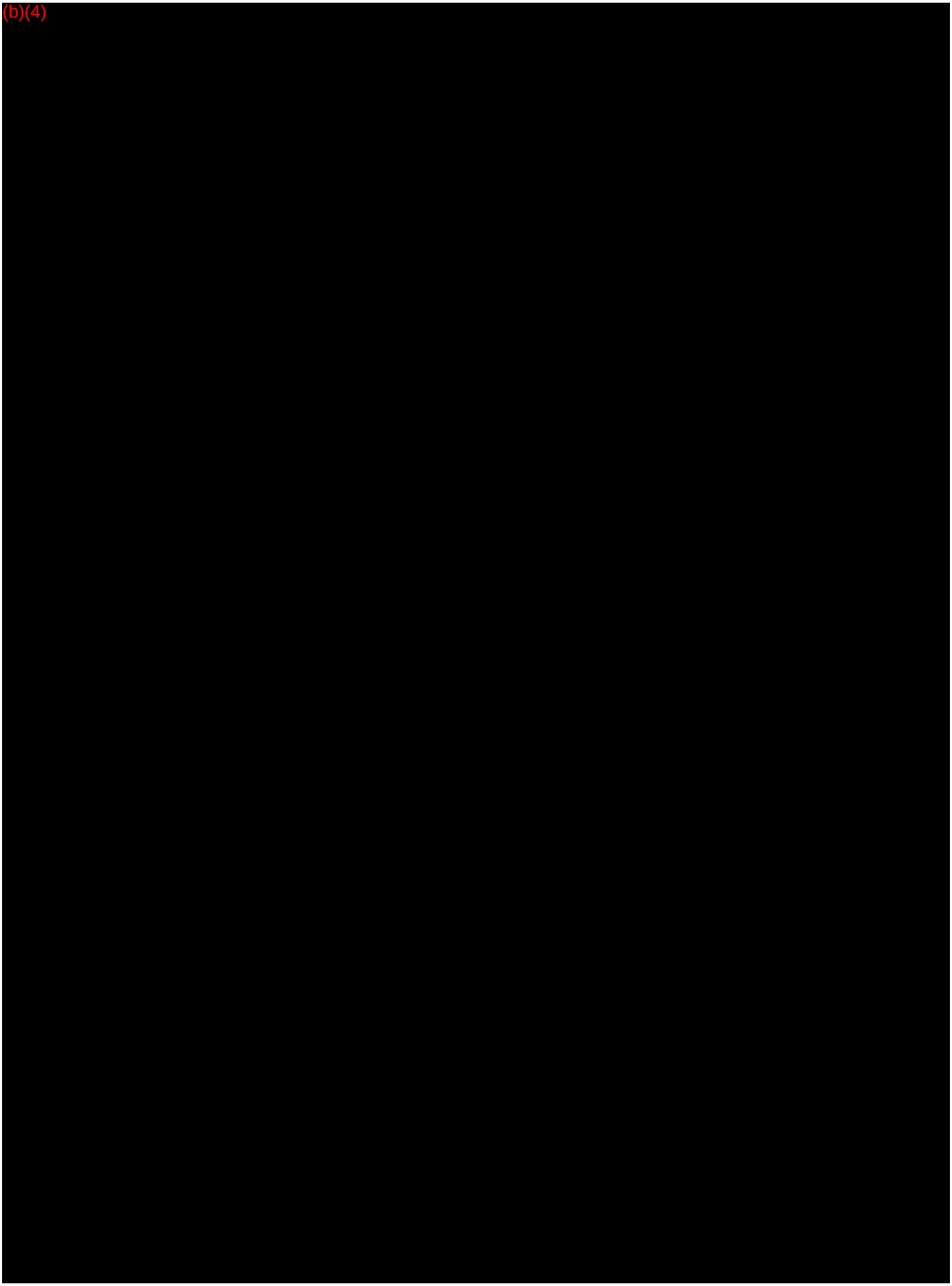

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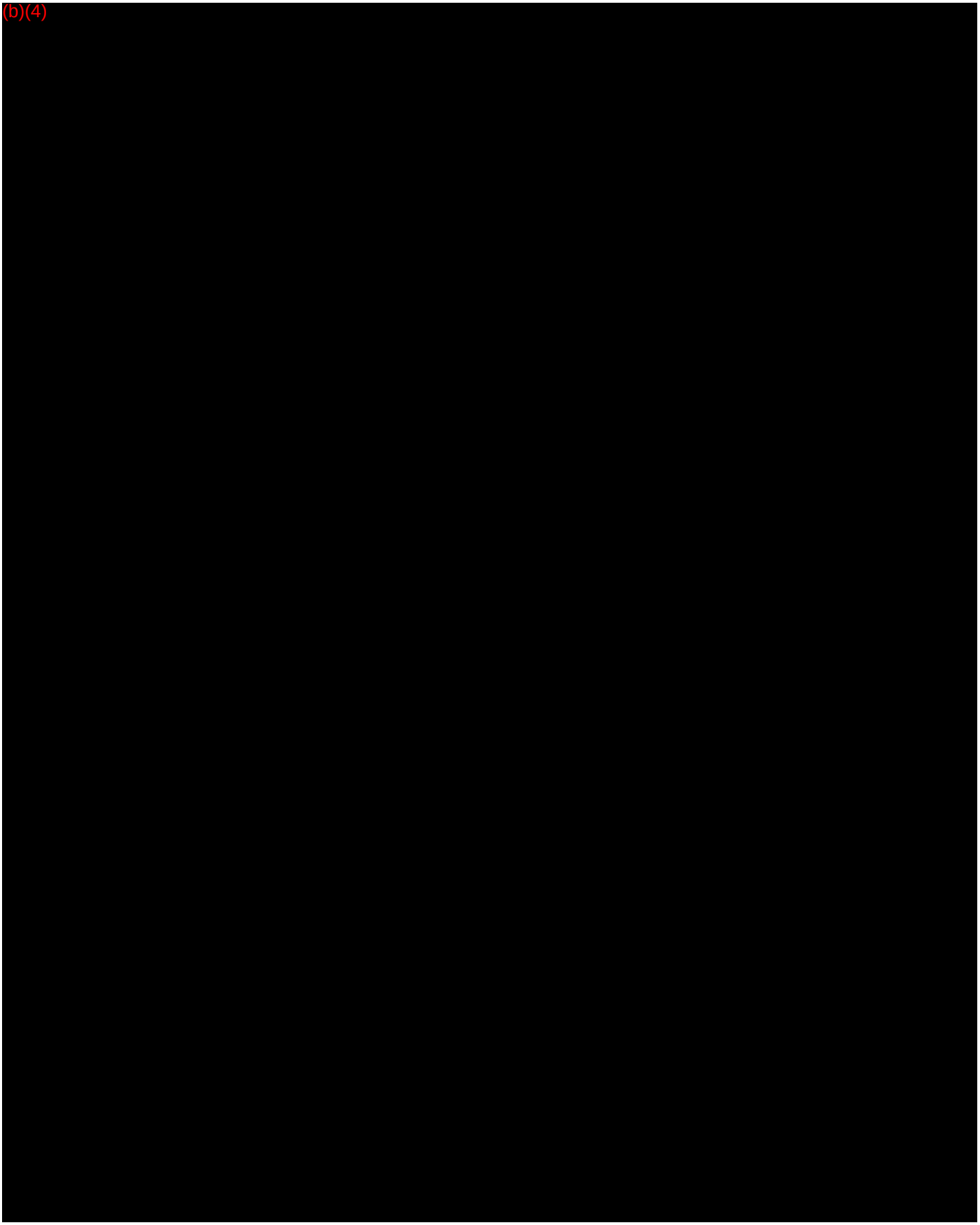

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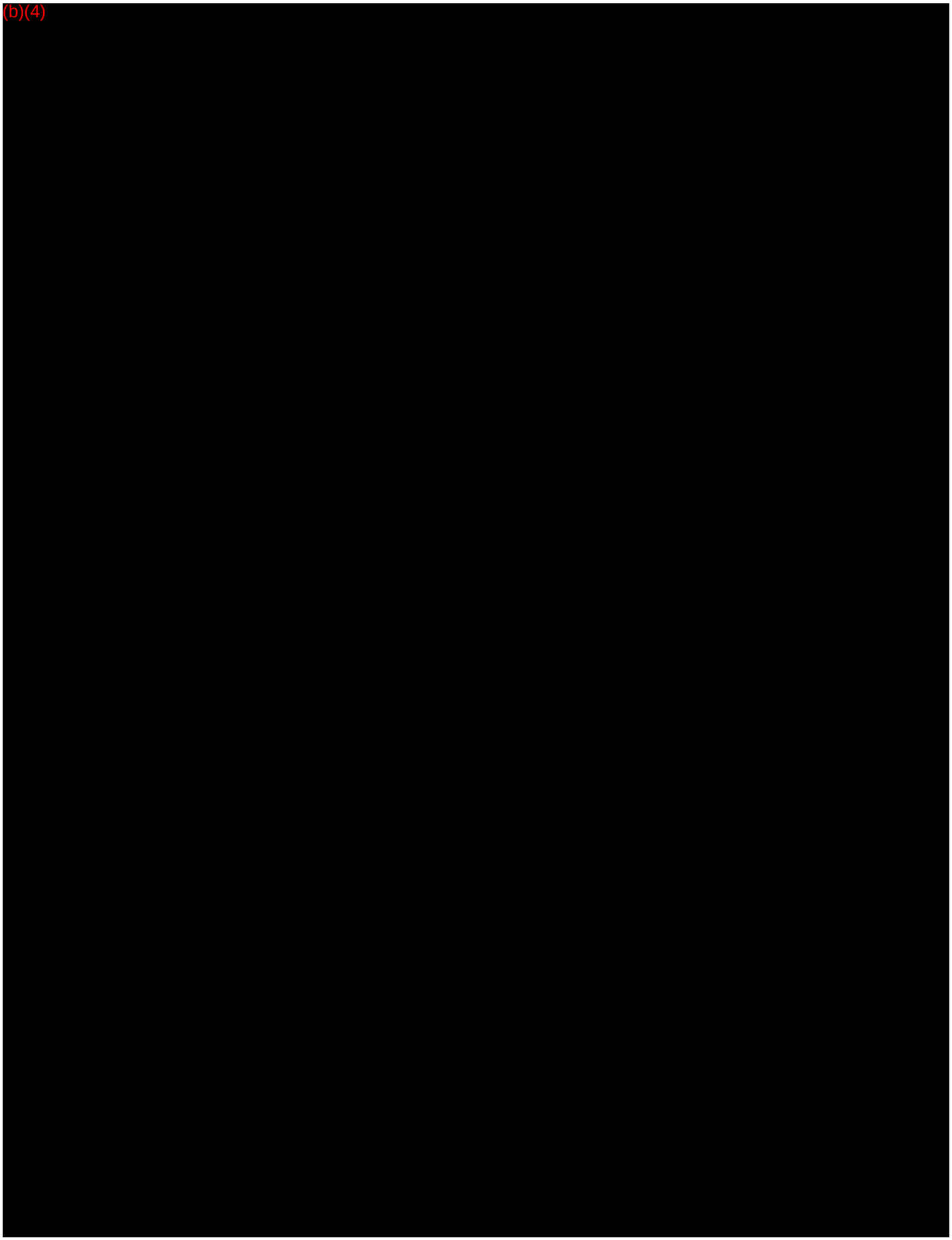

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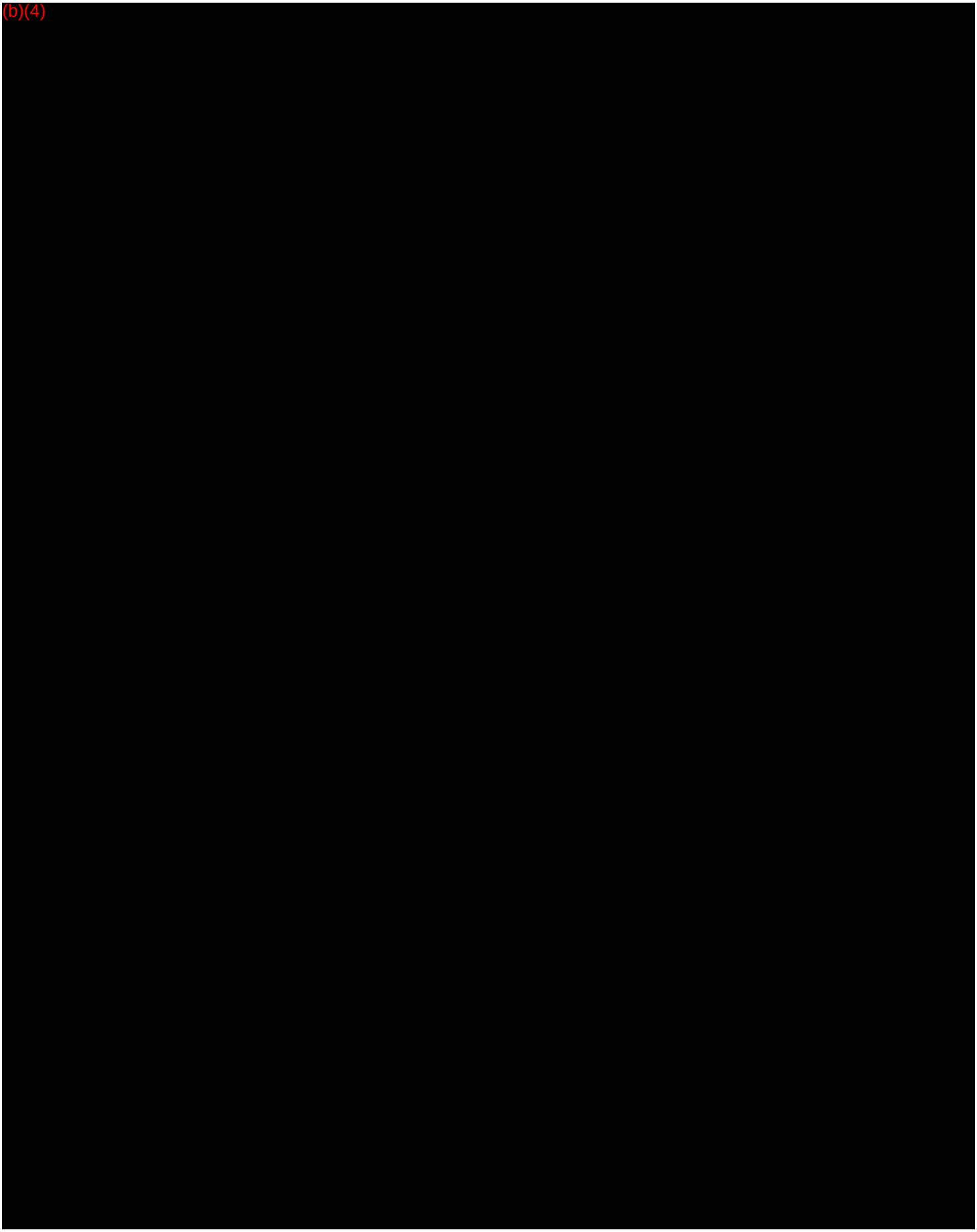

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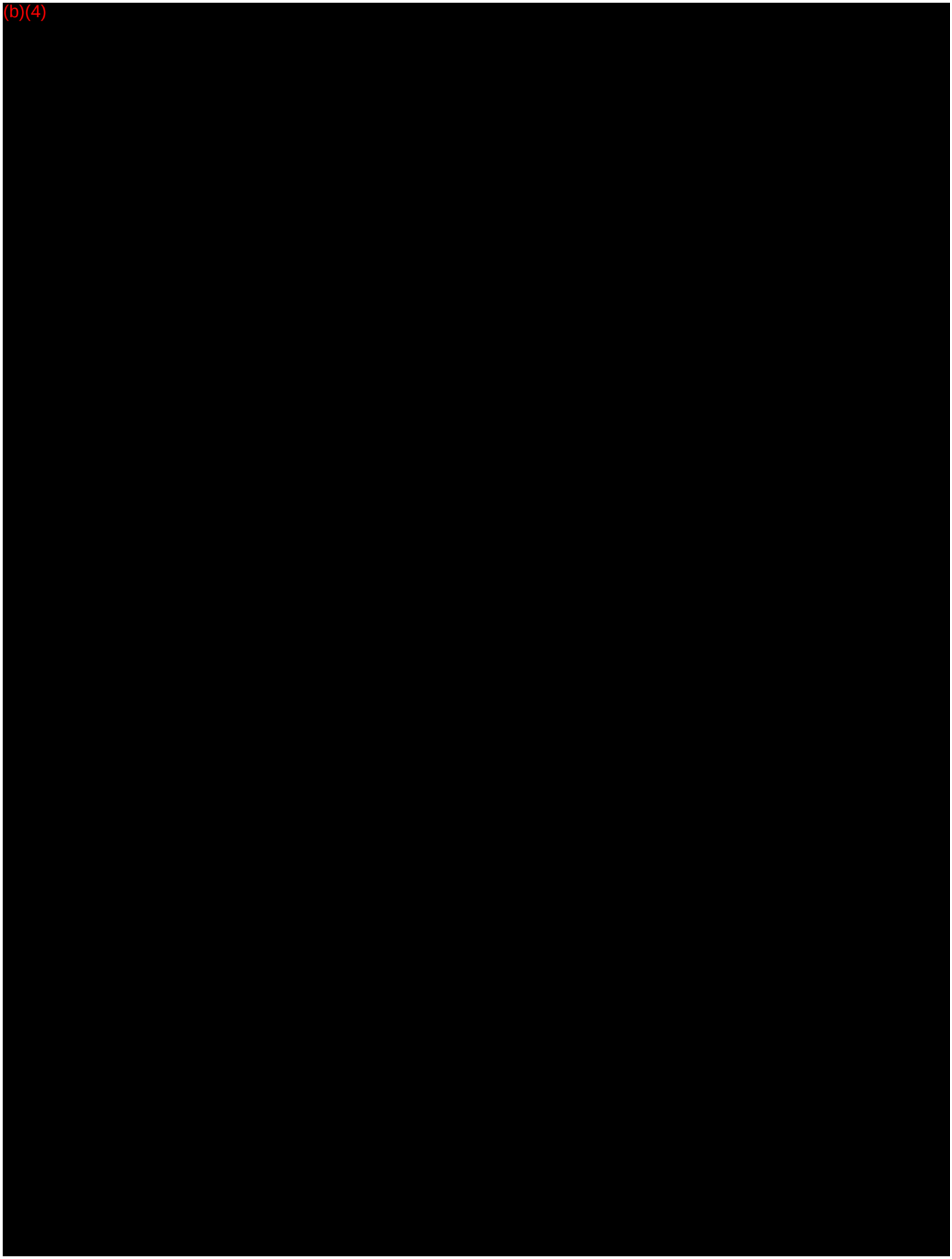

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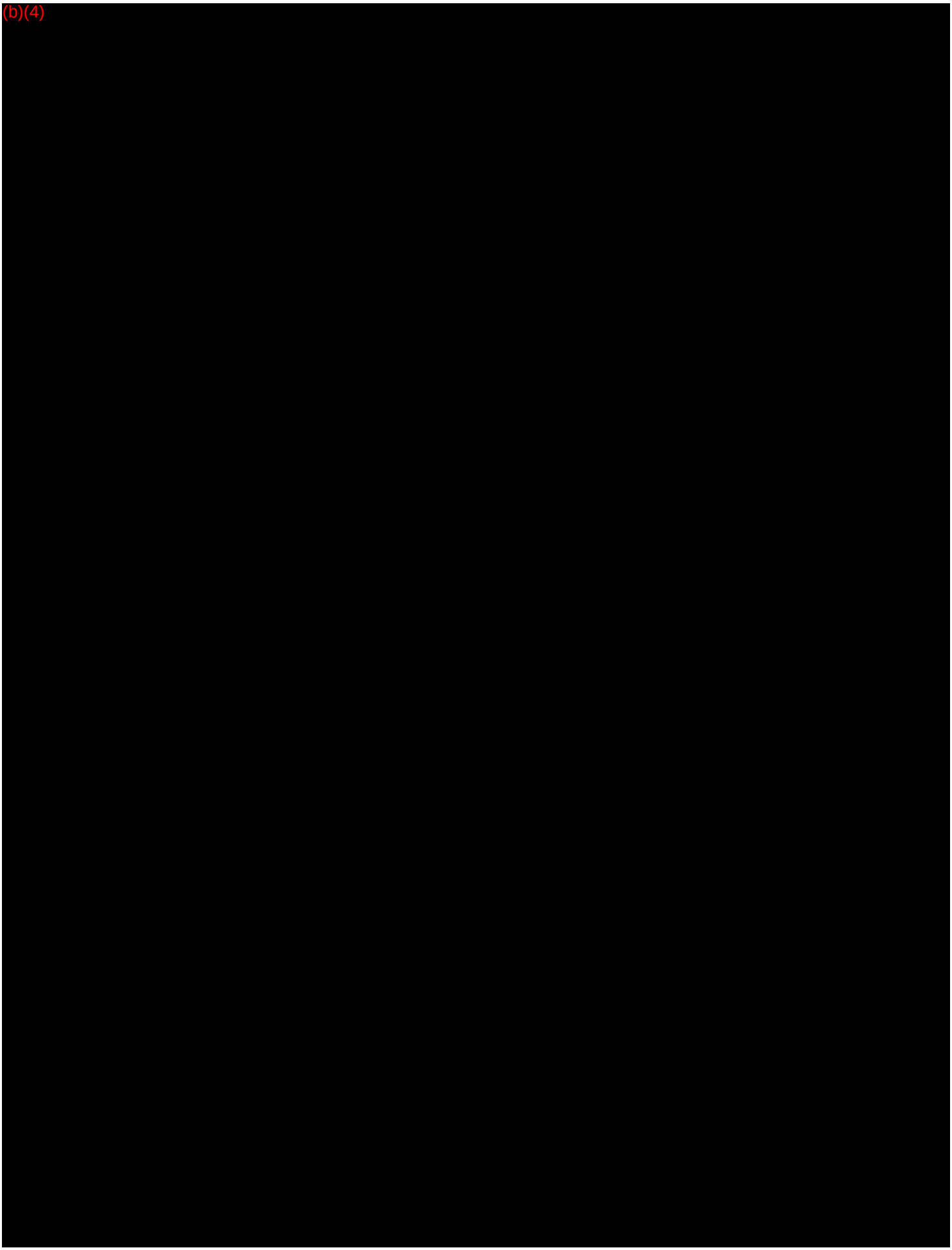

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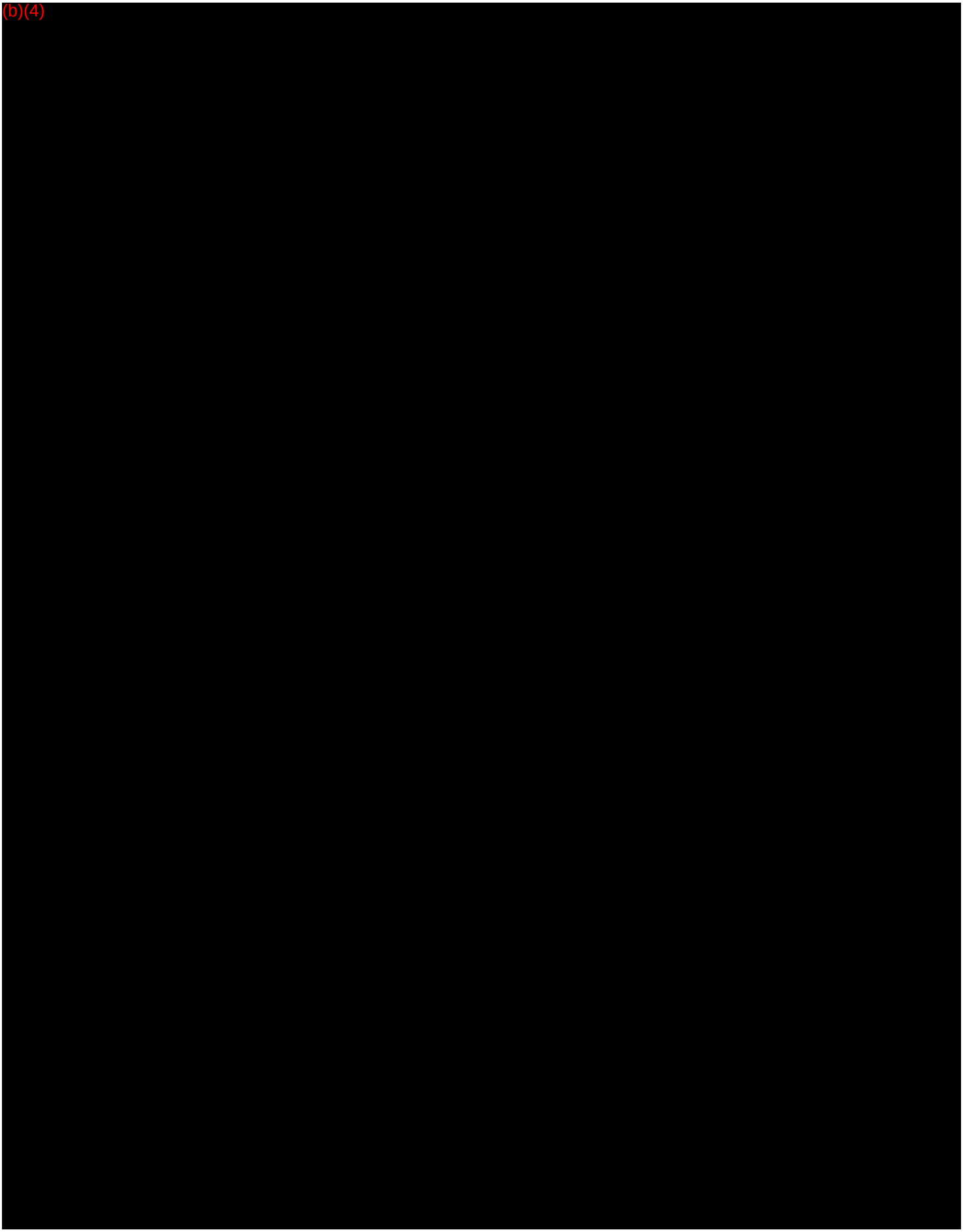

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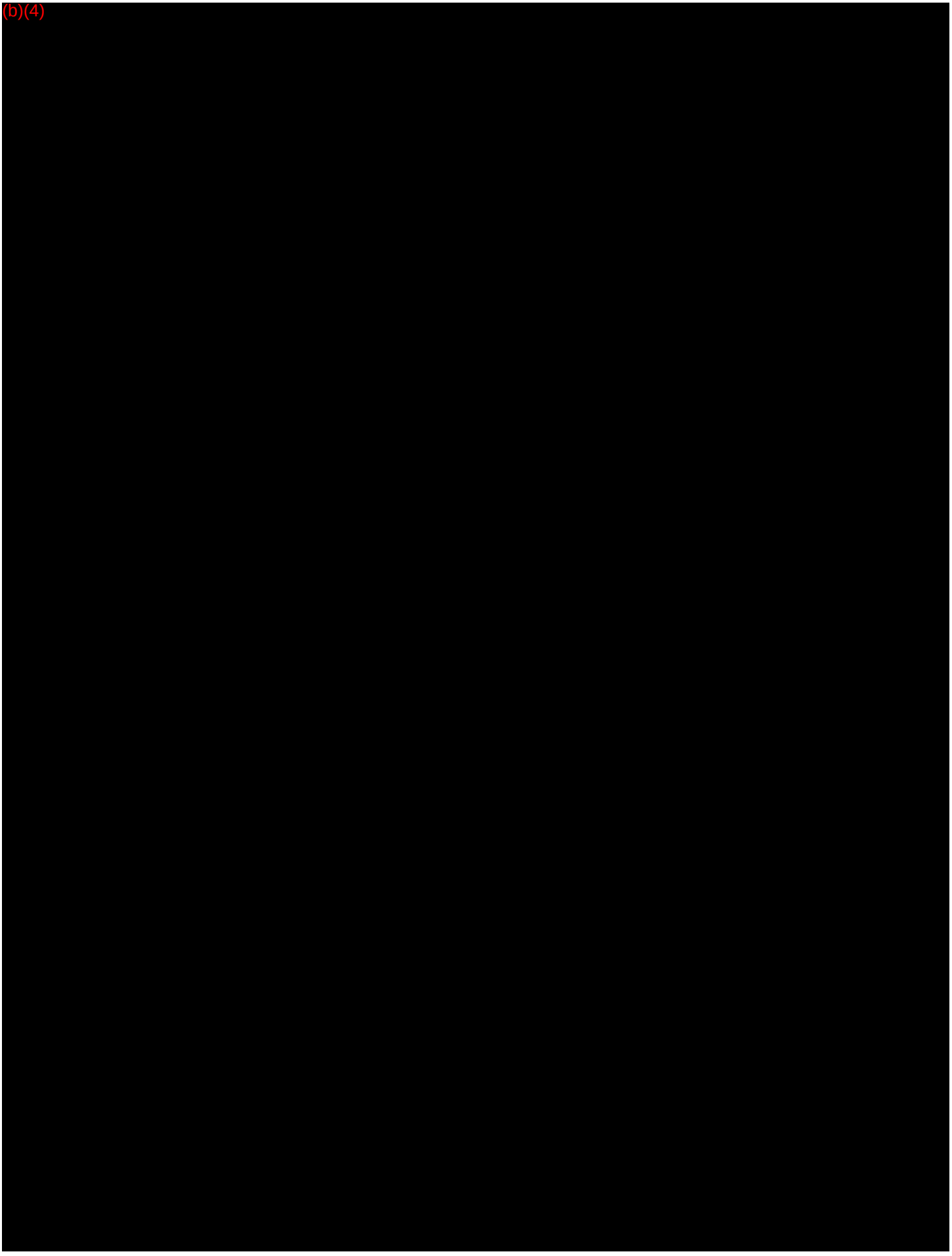

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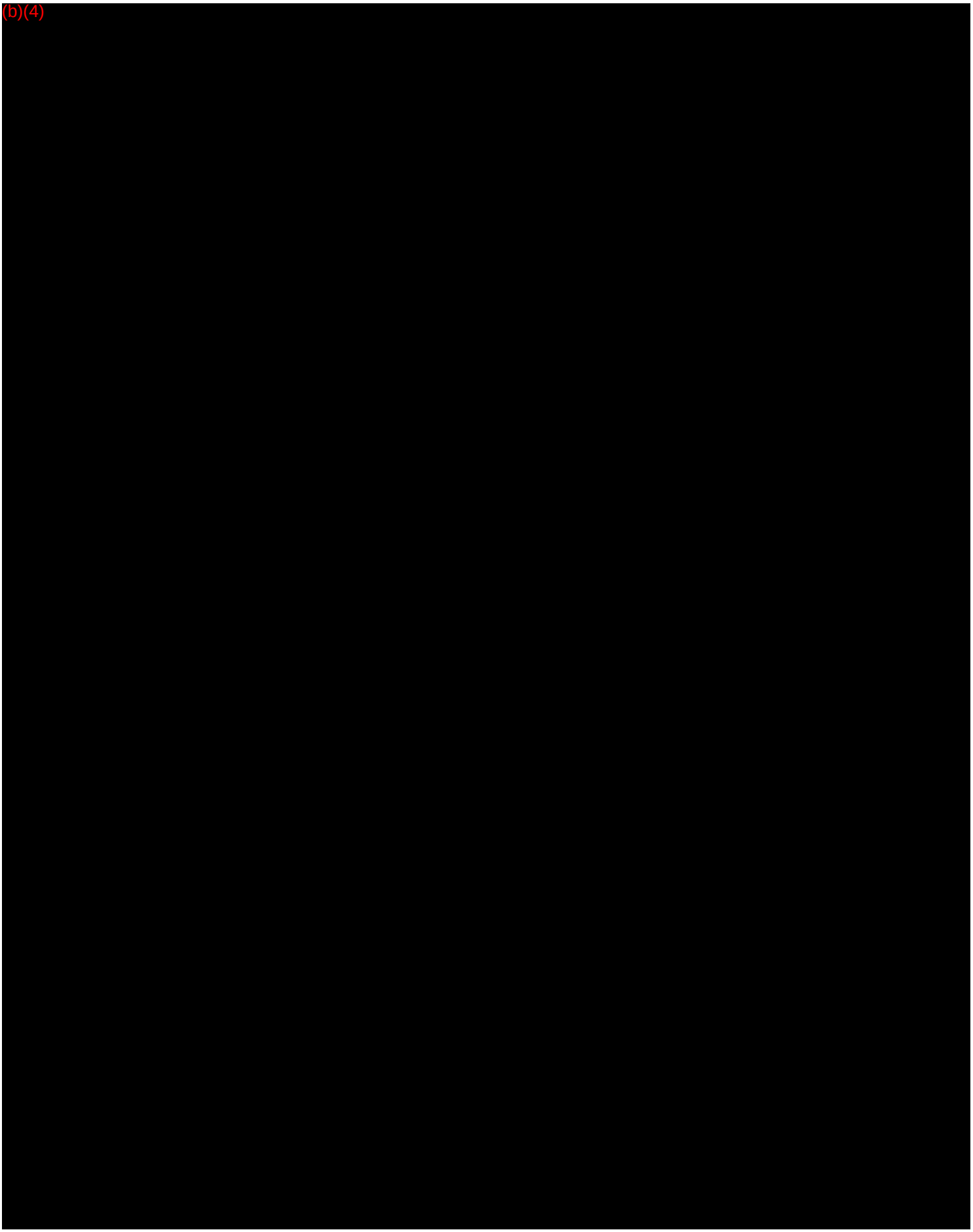

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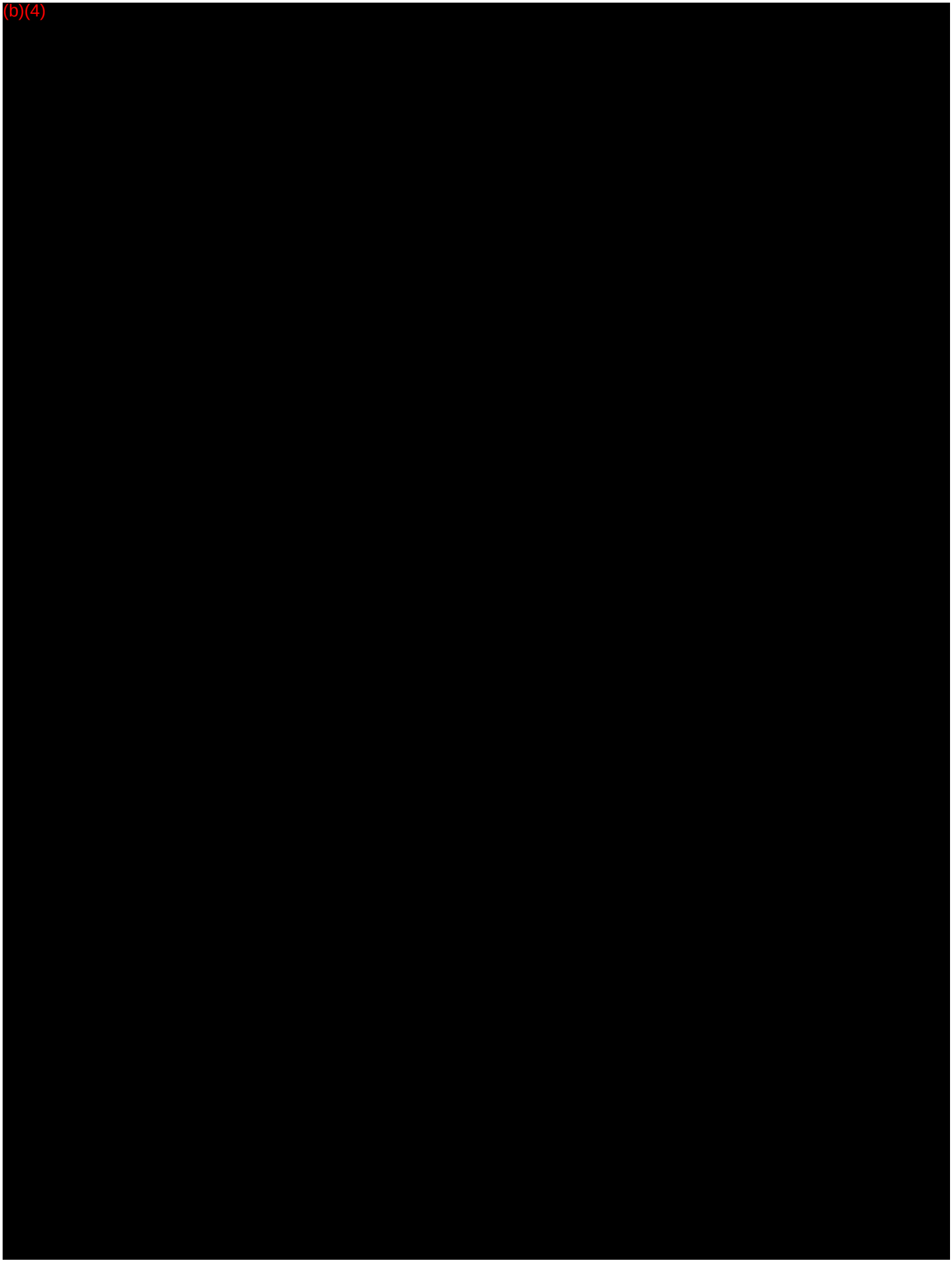
Validation Result – (b)(4)

(b)(4)



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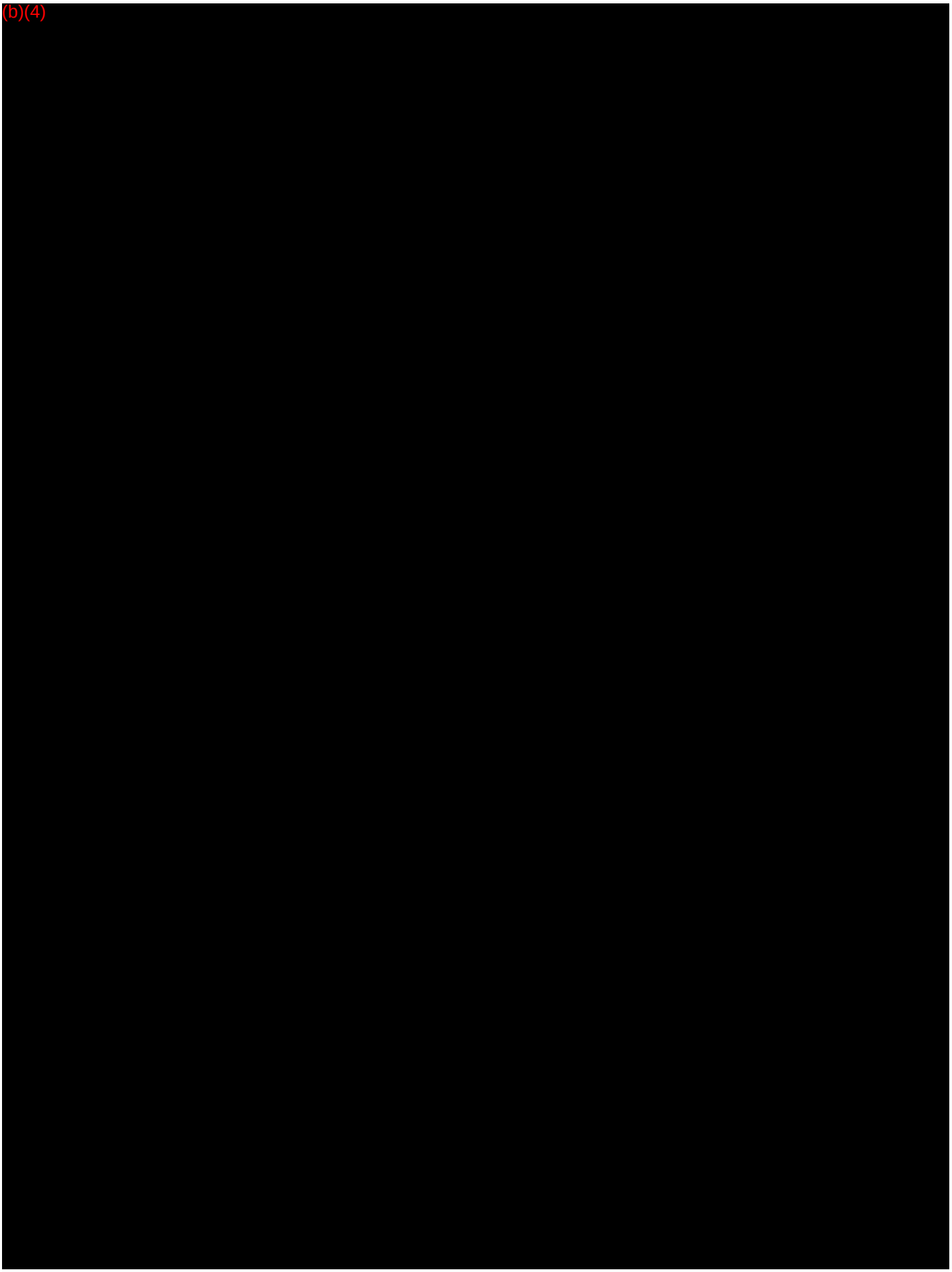

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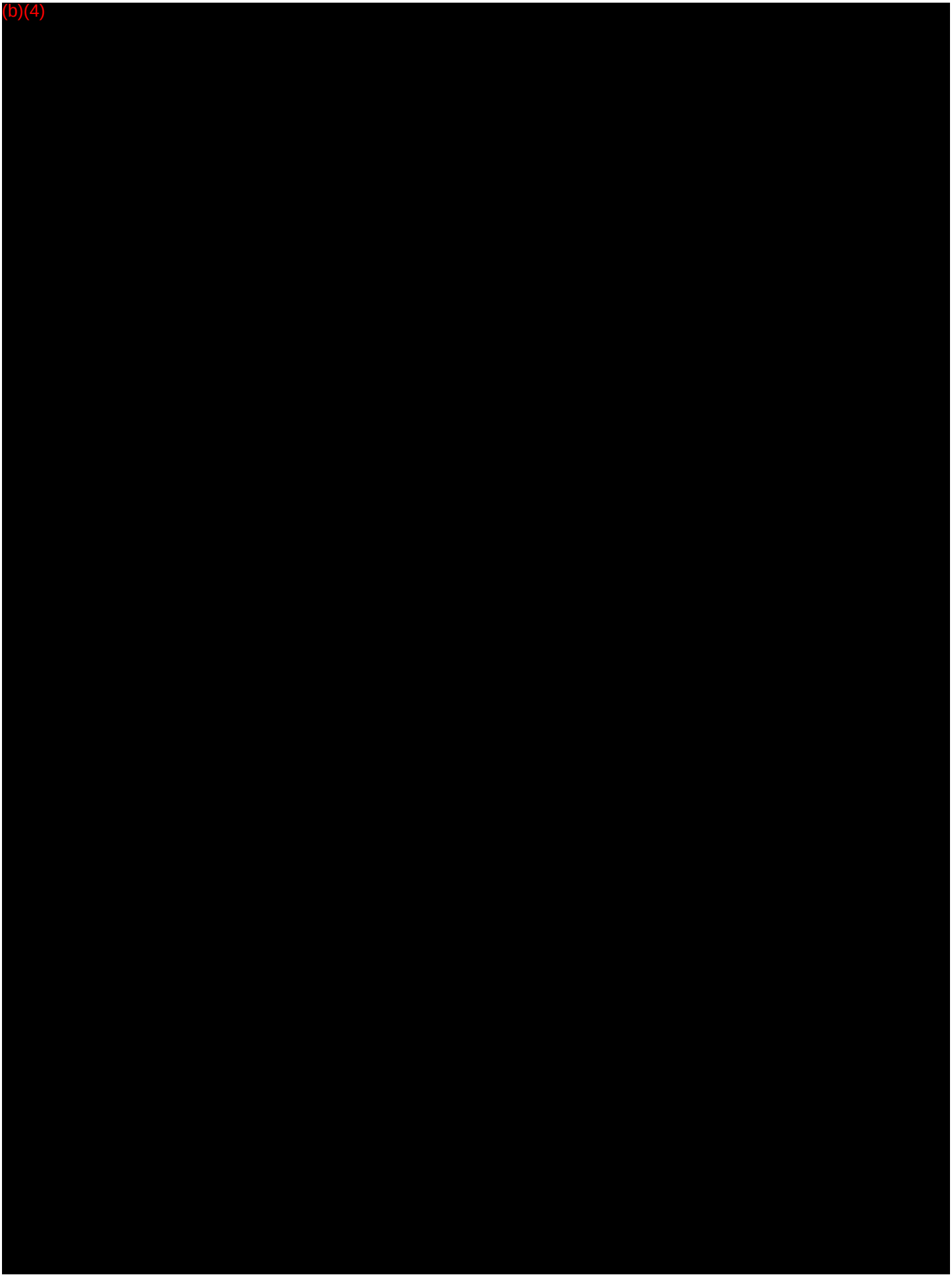

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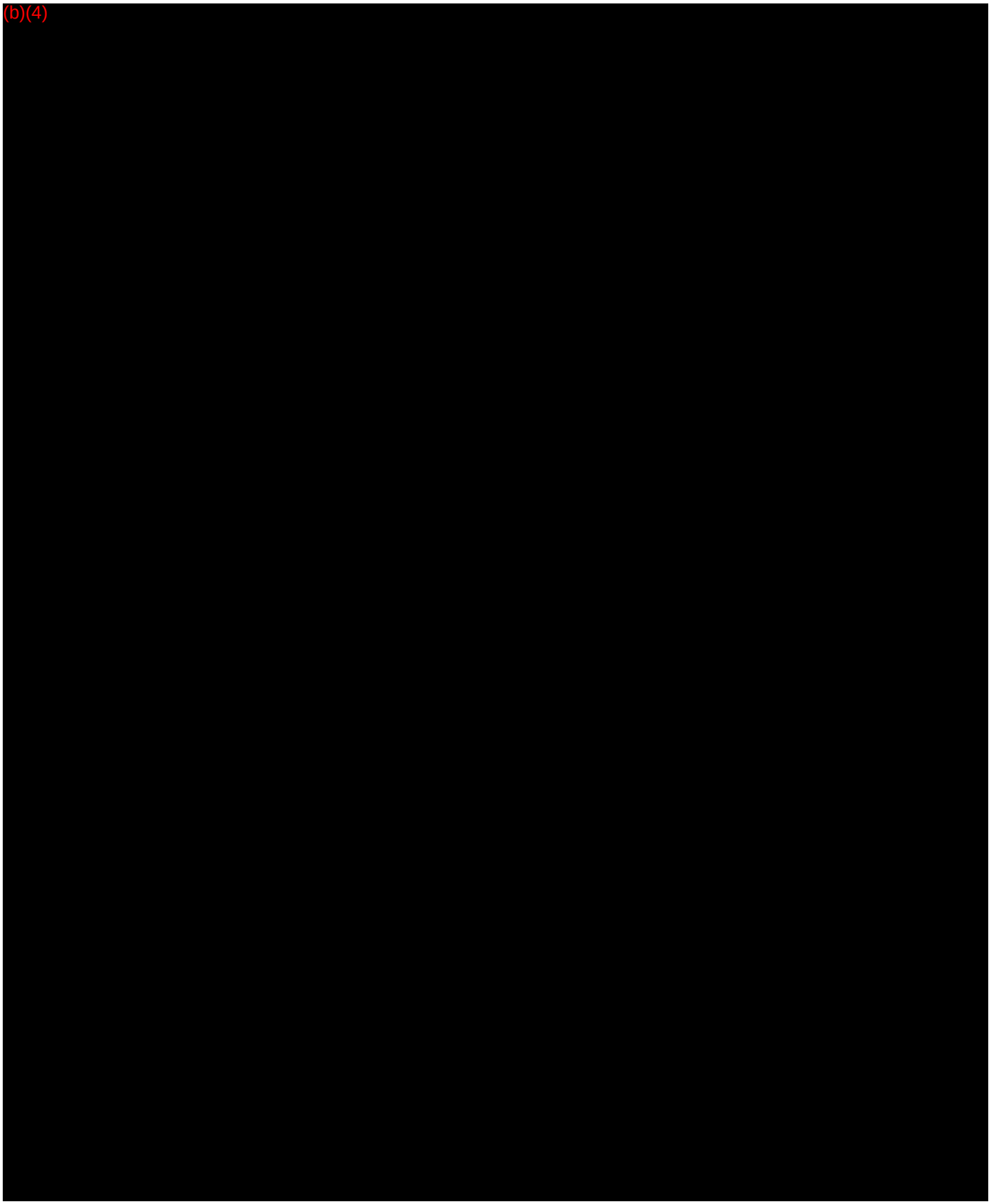

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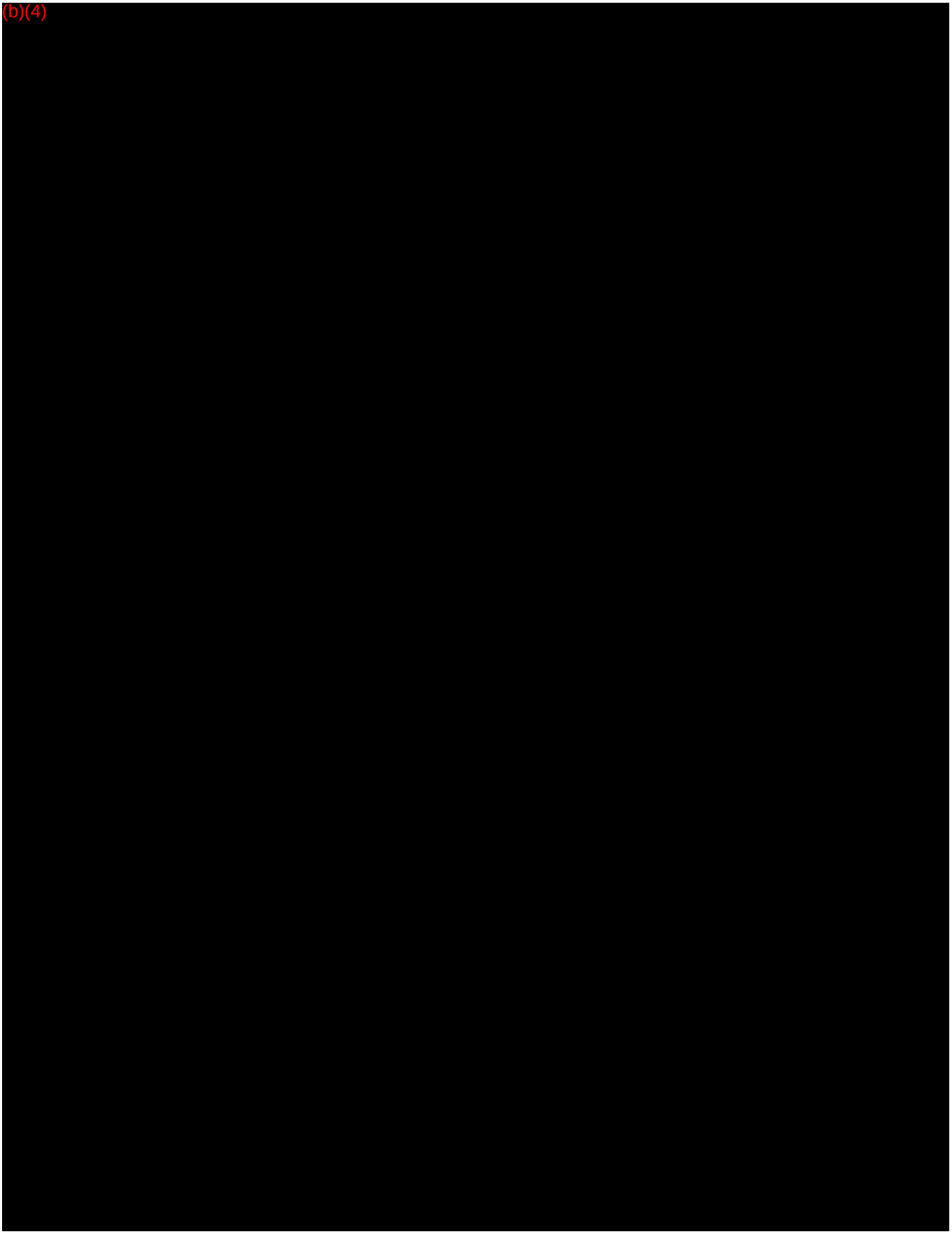

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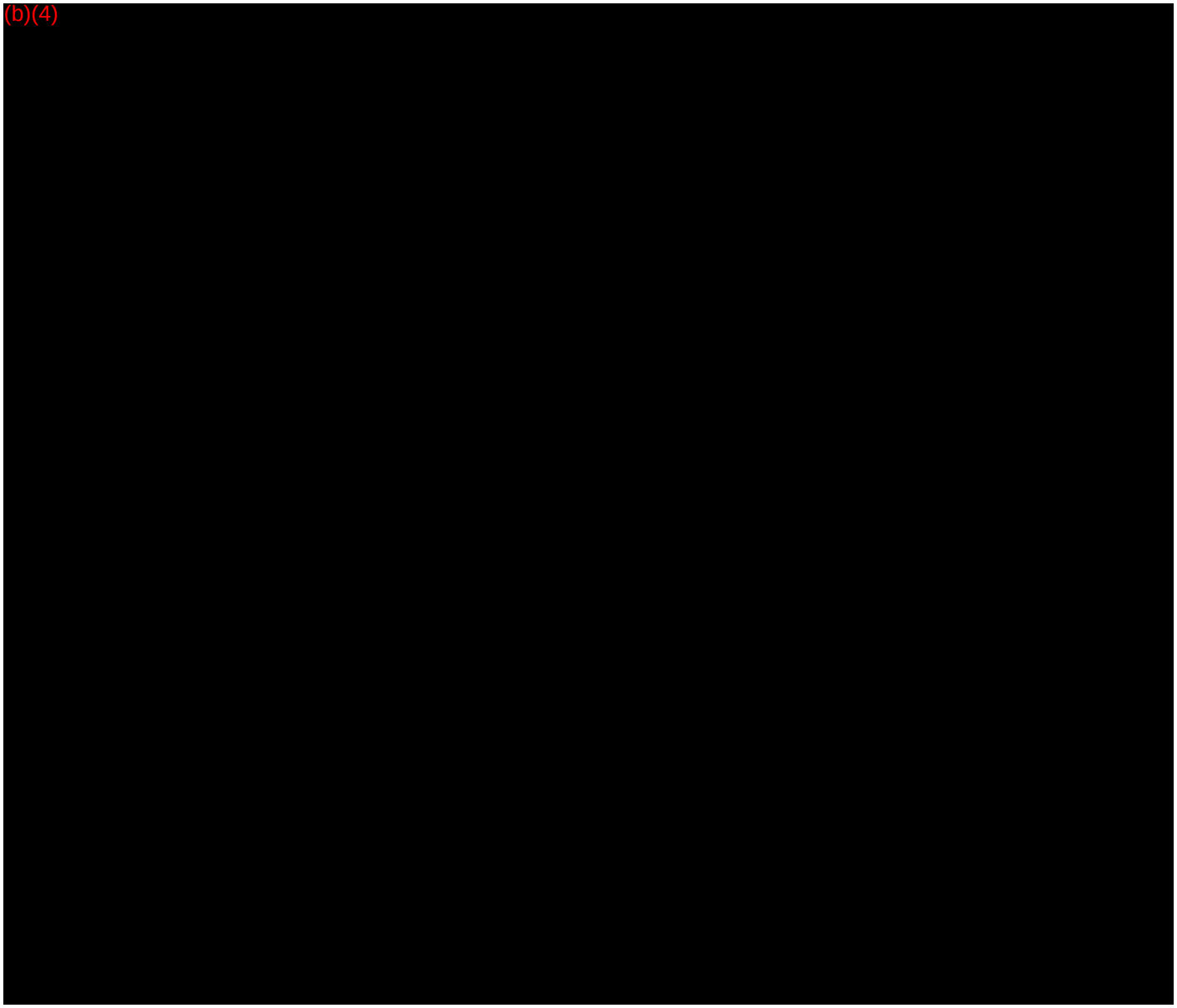

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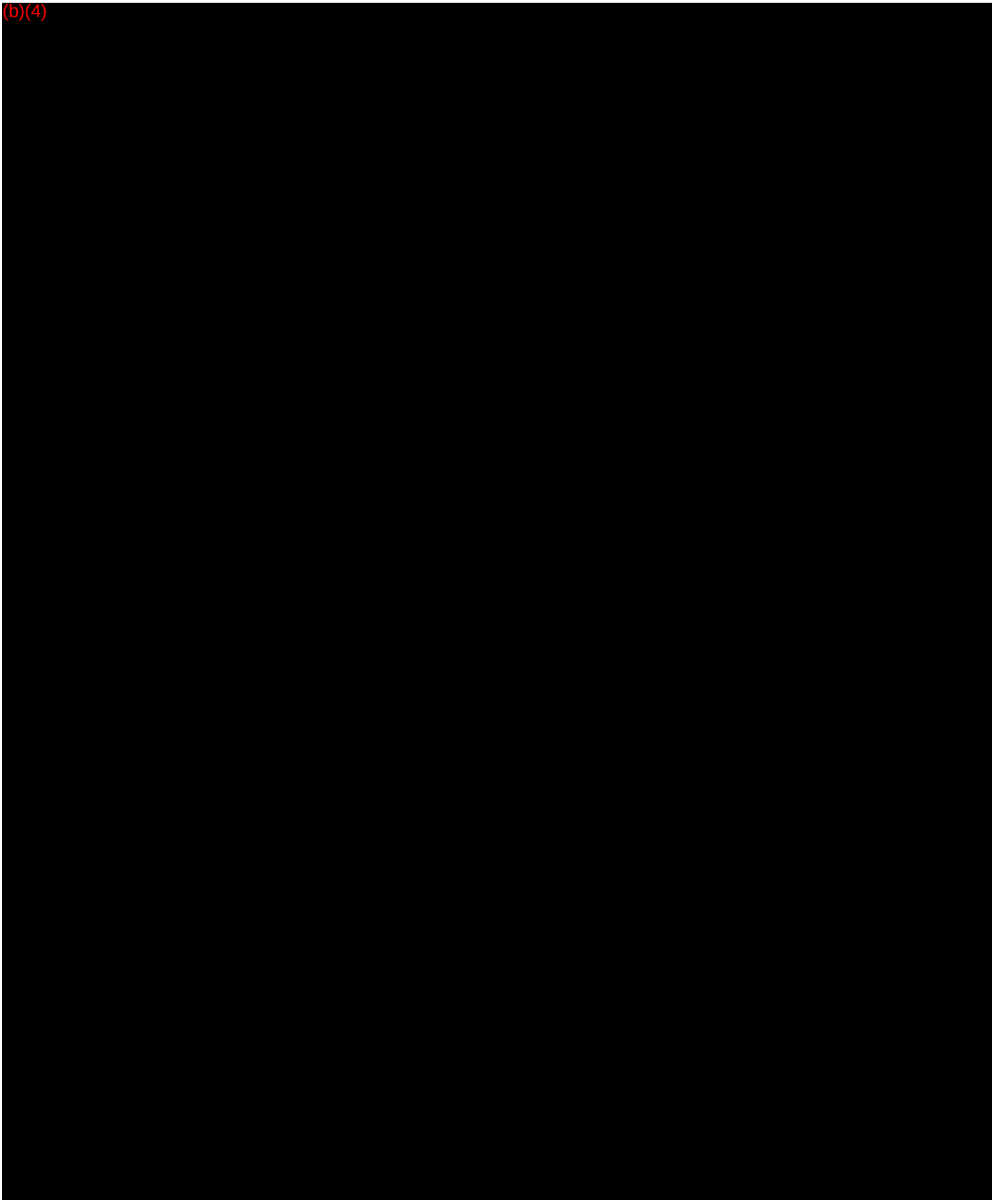

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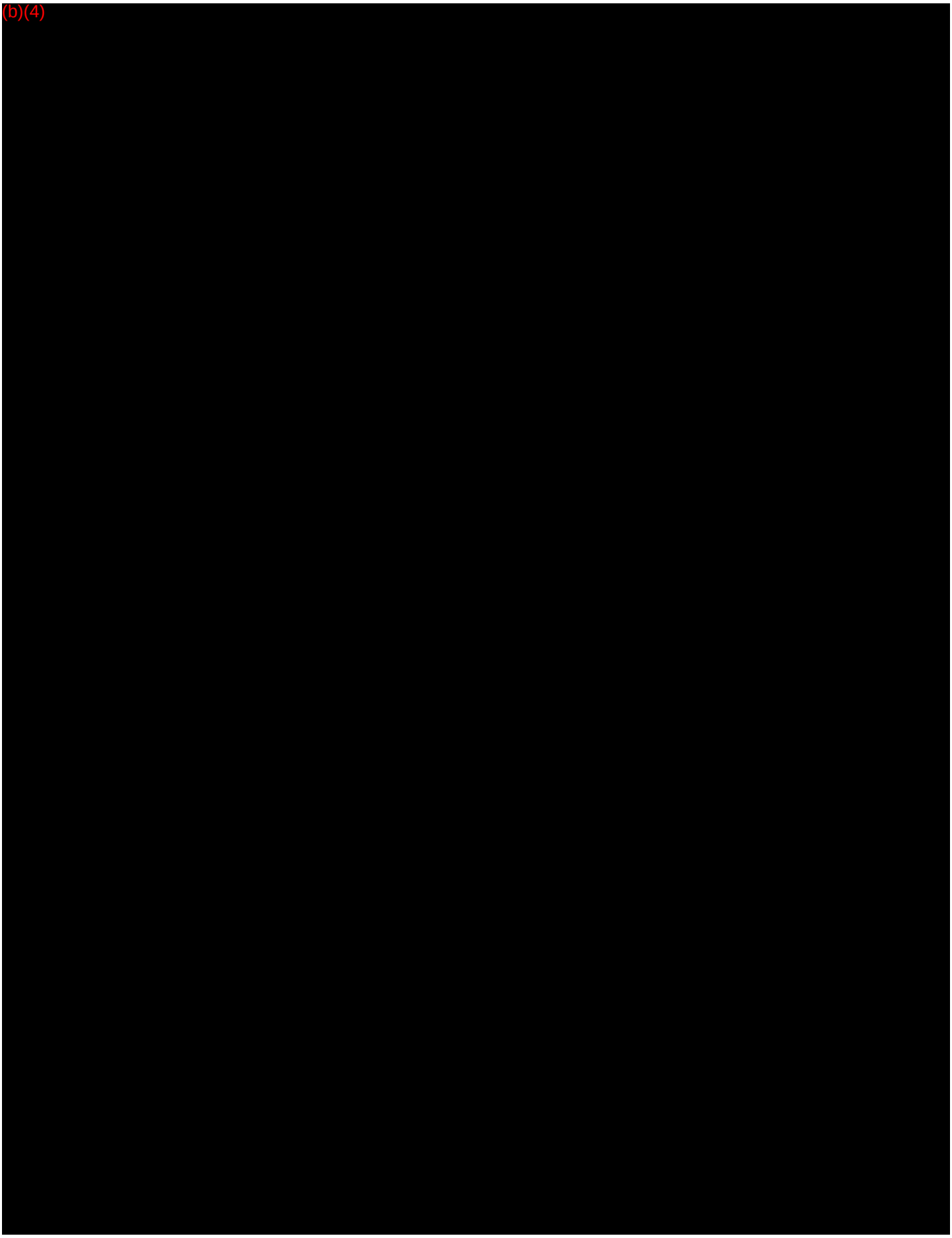

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Verification Result – (b)(4)

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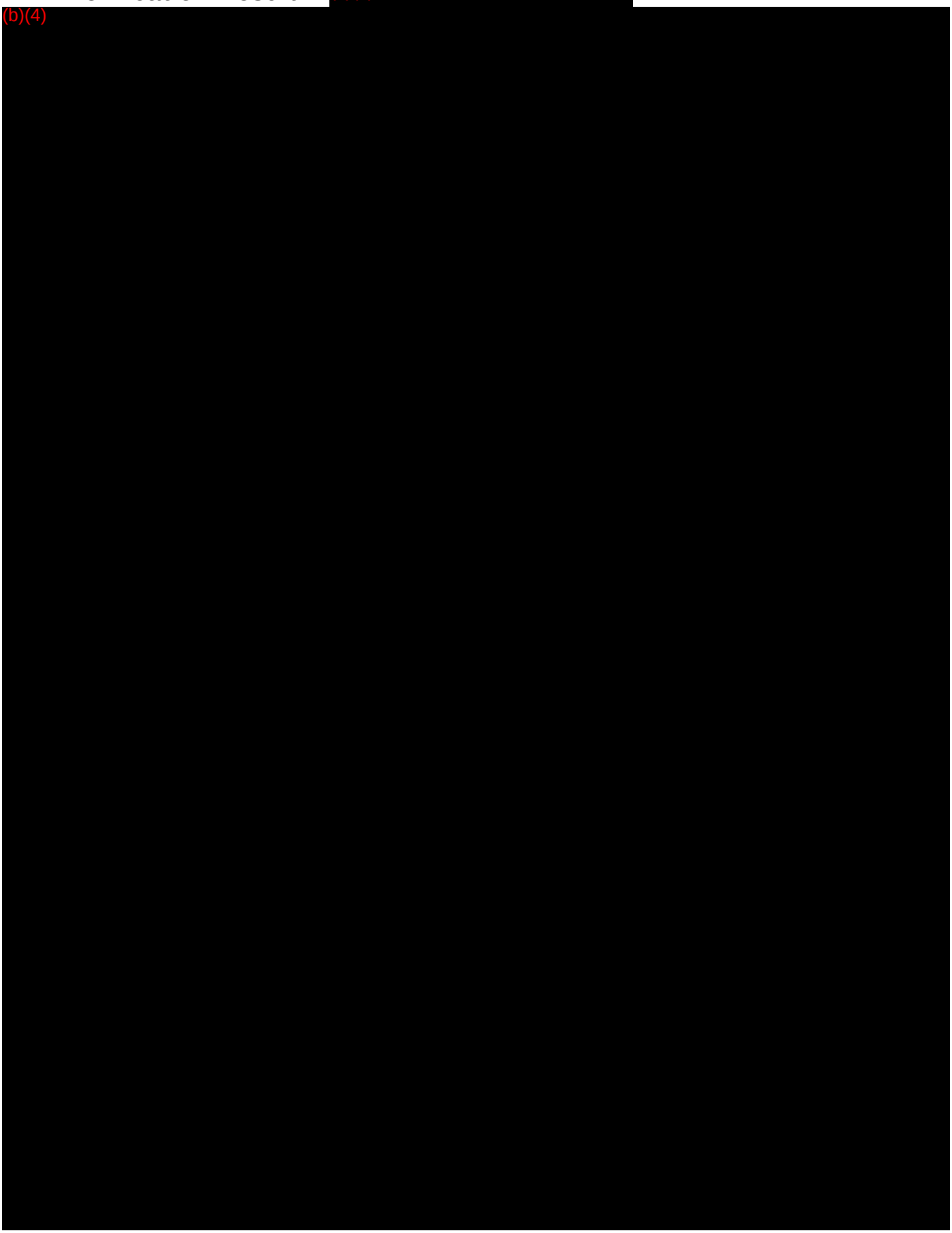

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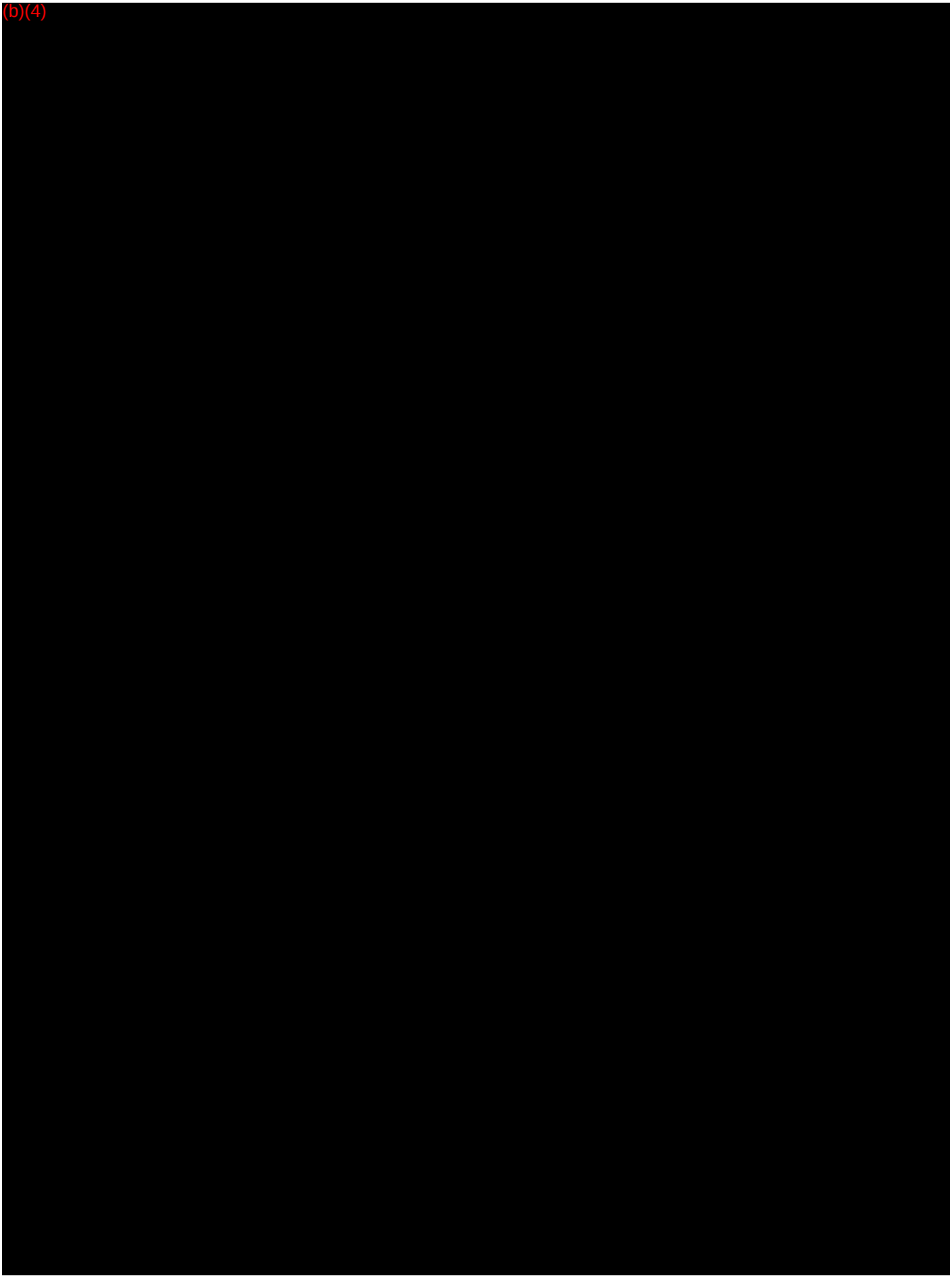

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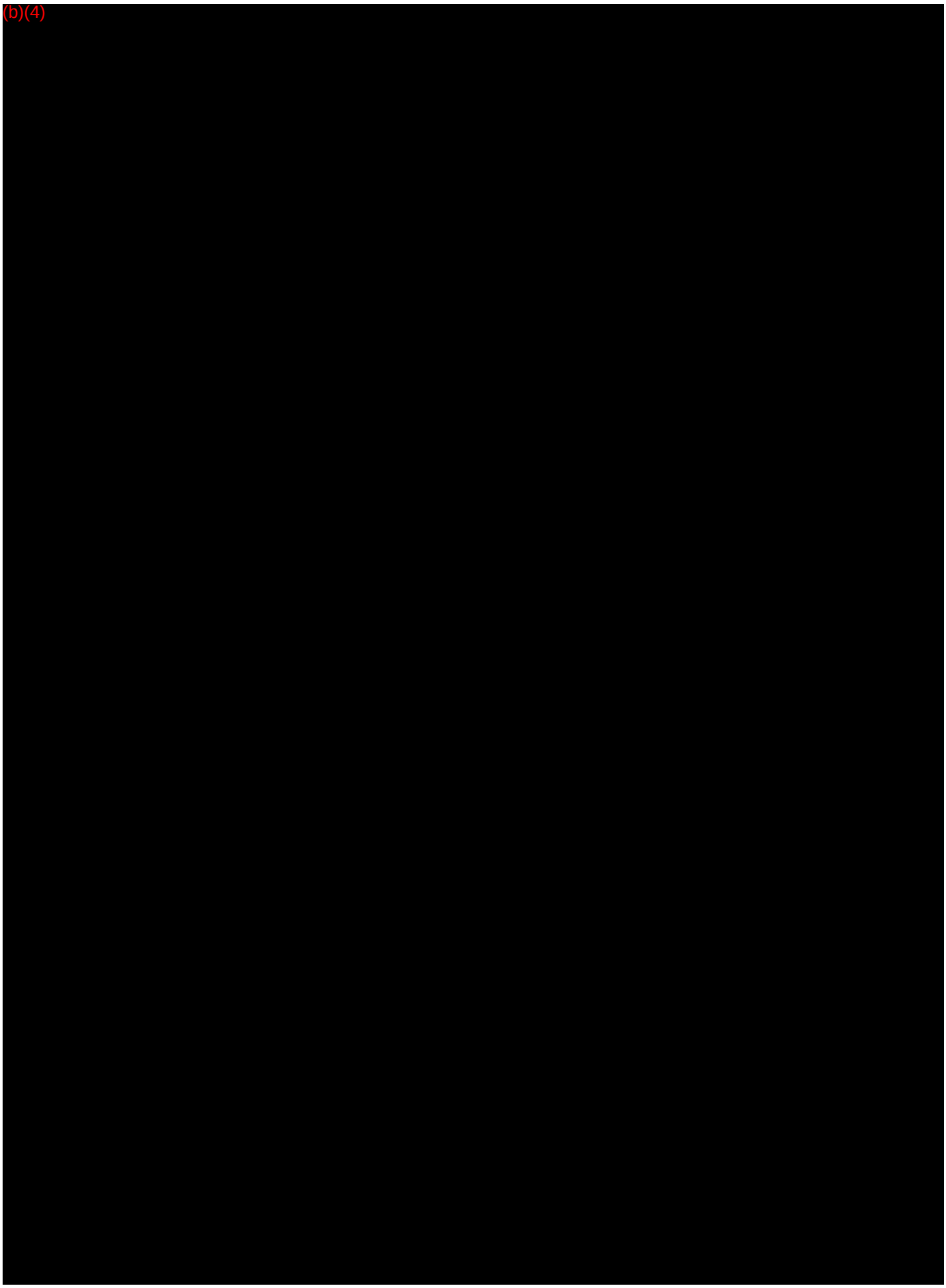

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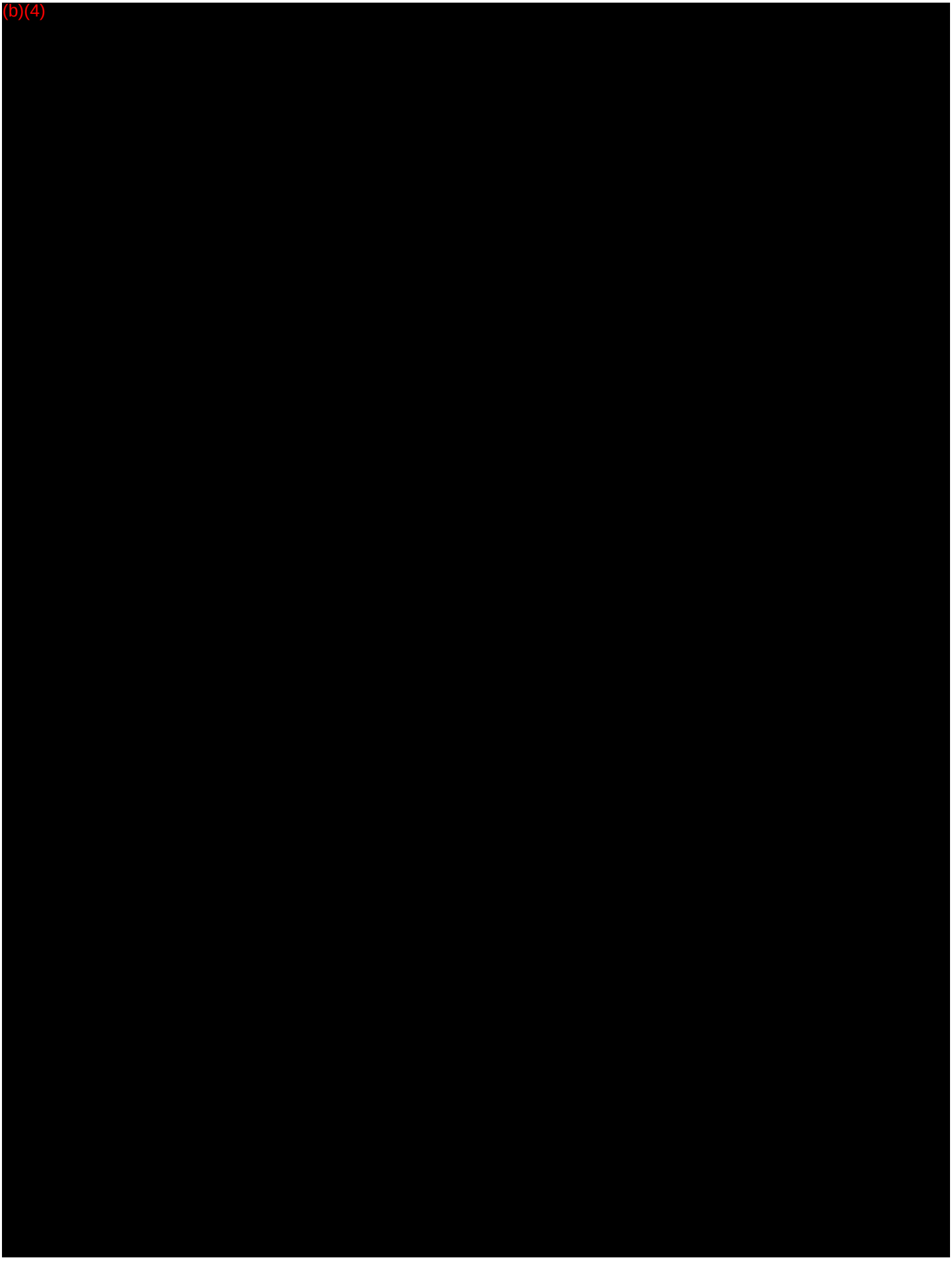

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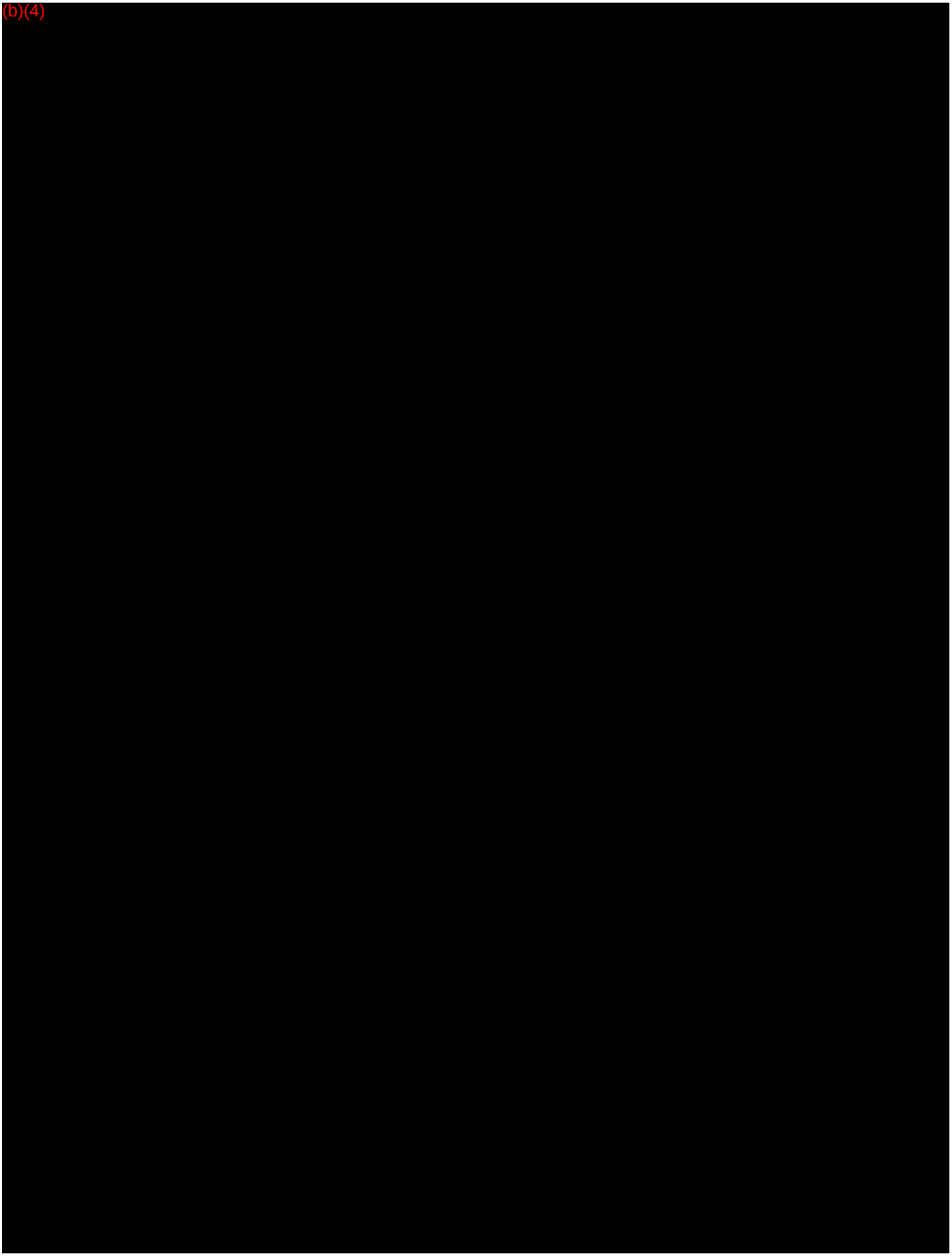

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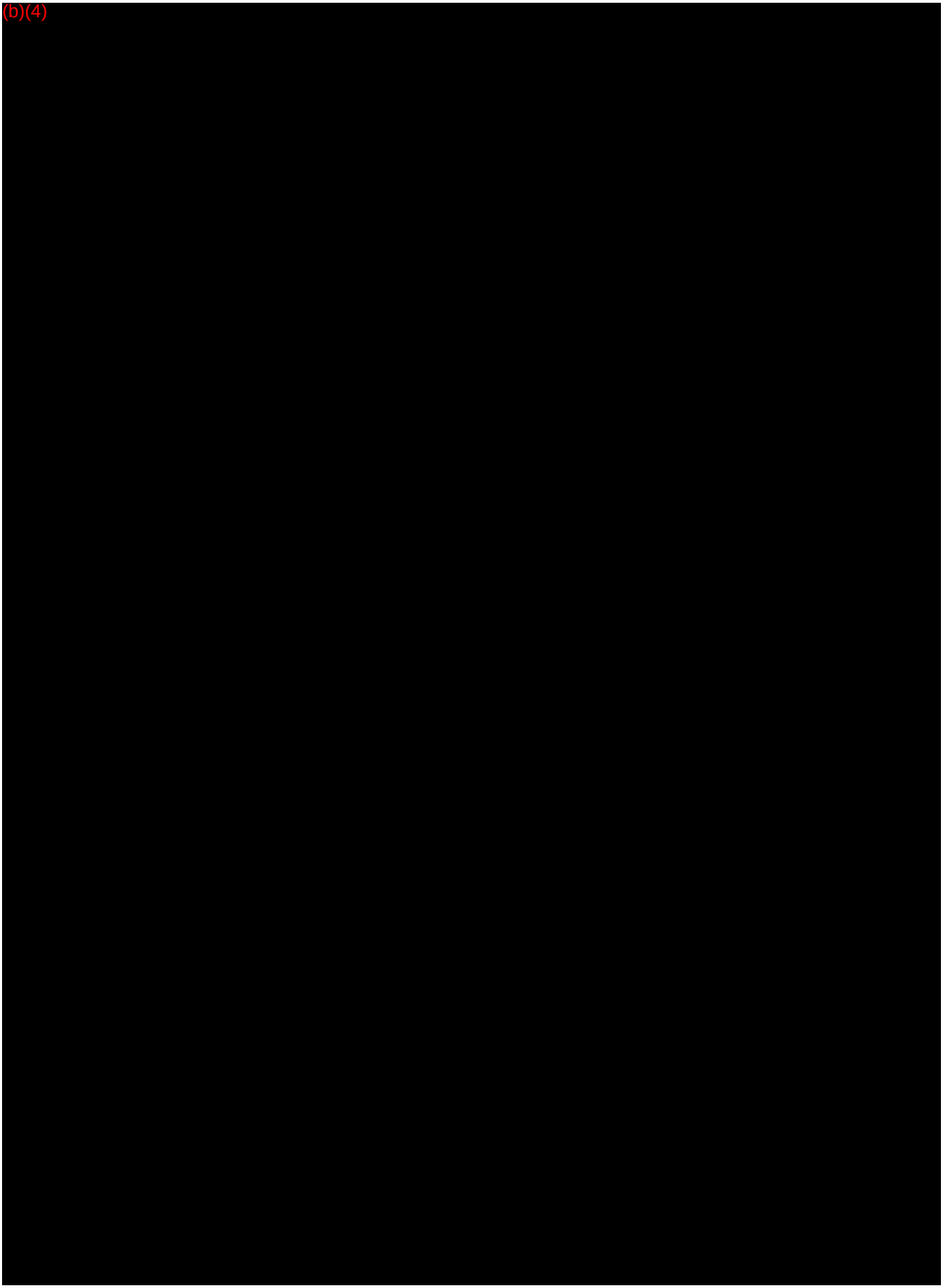

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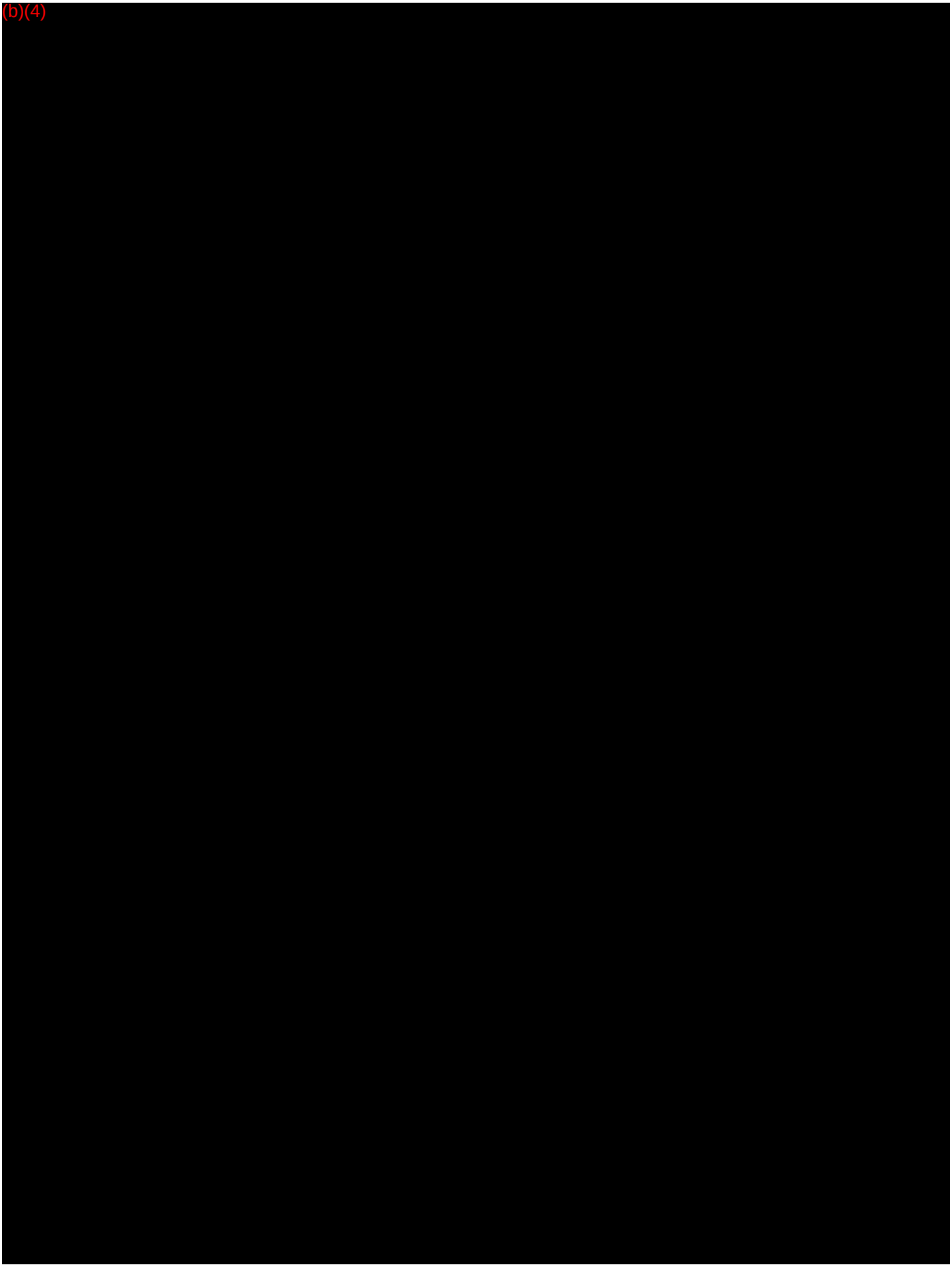

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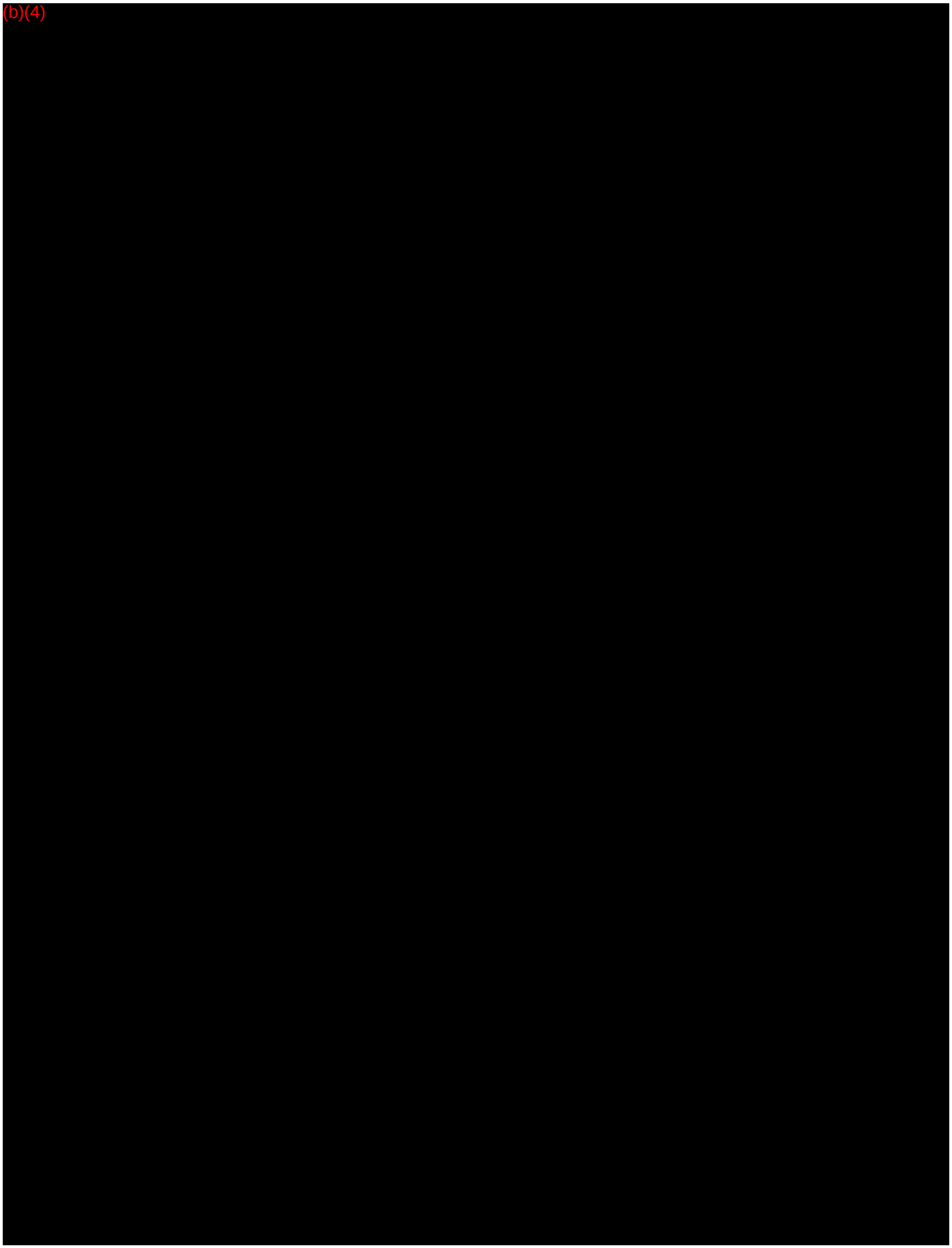

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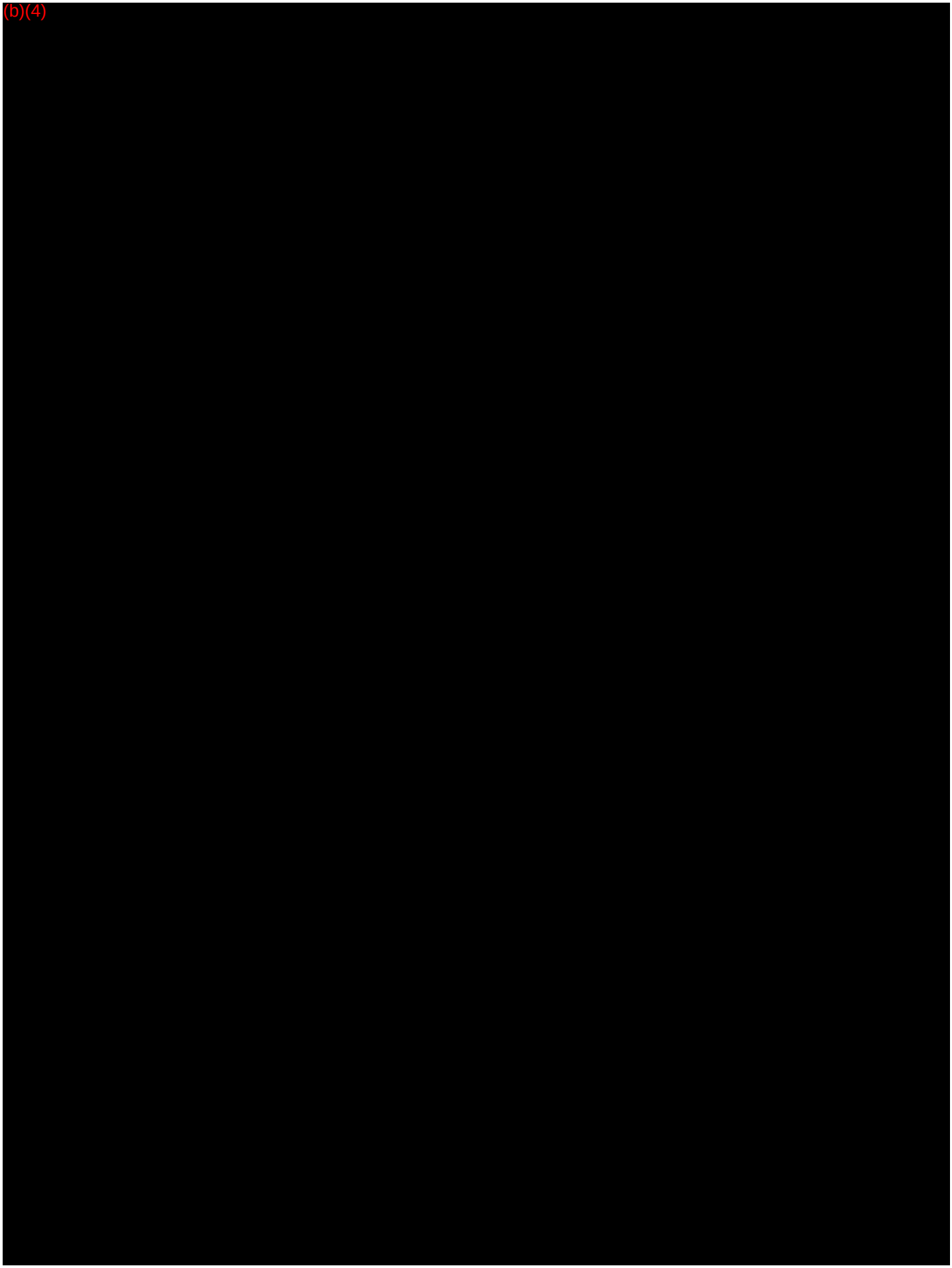

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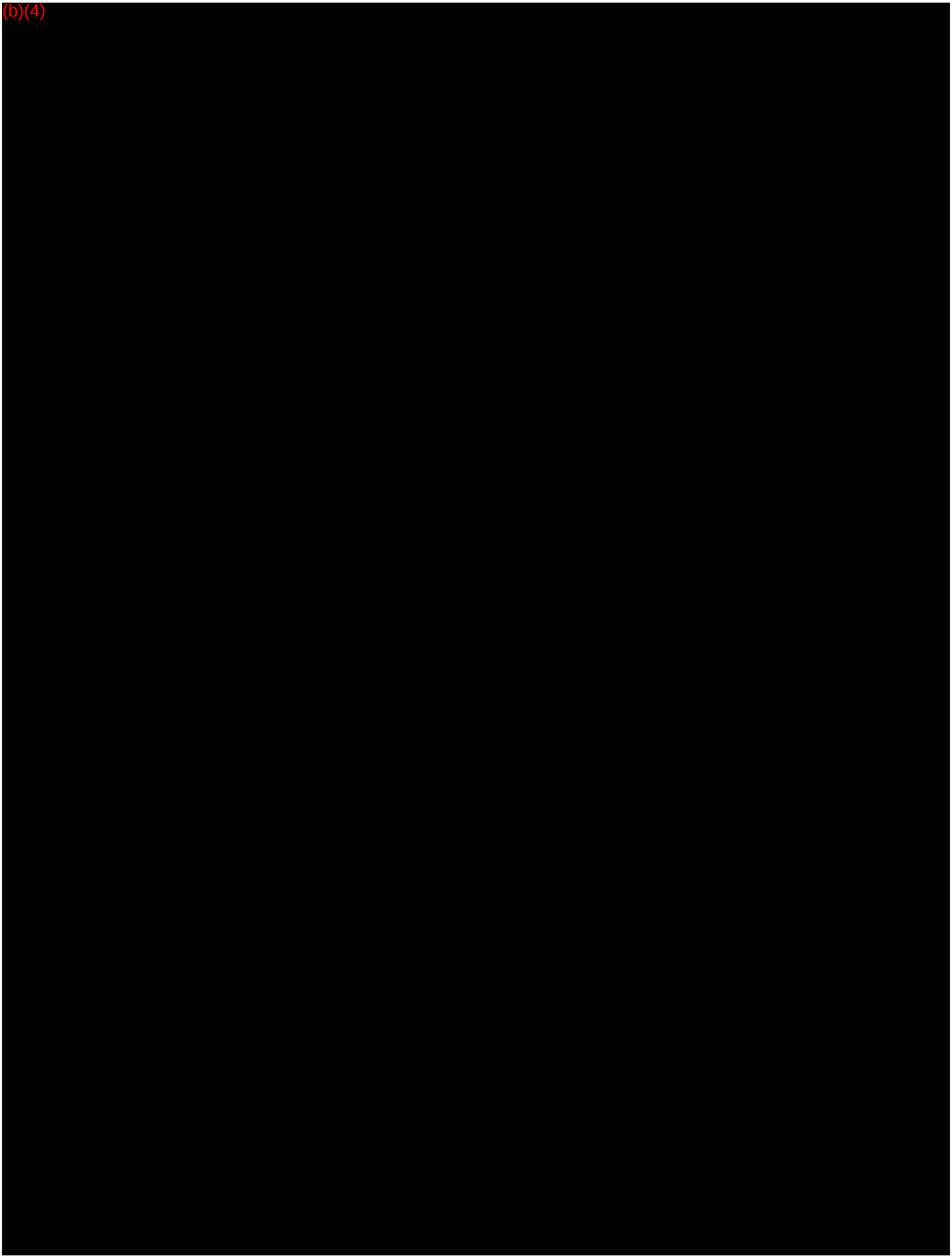

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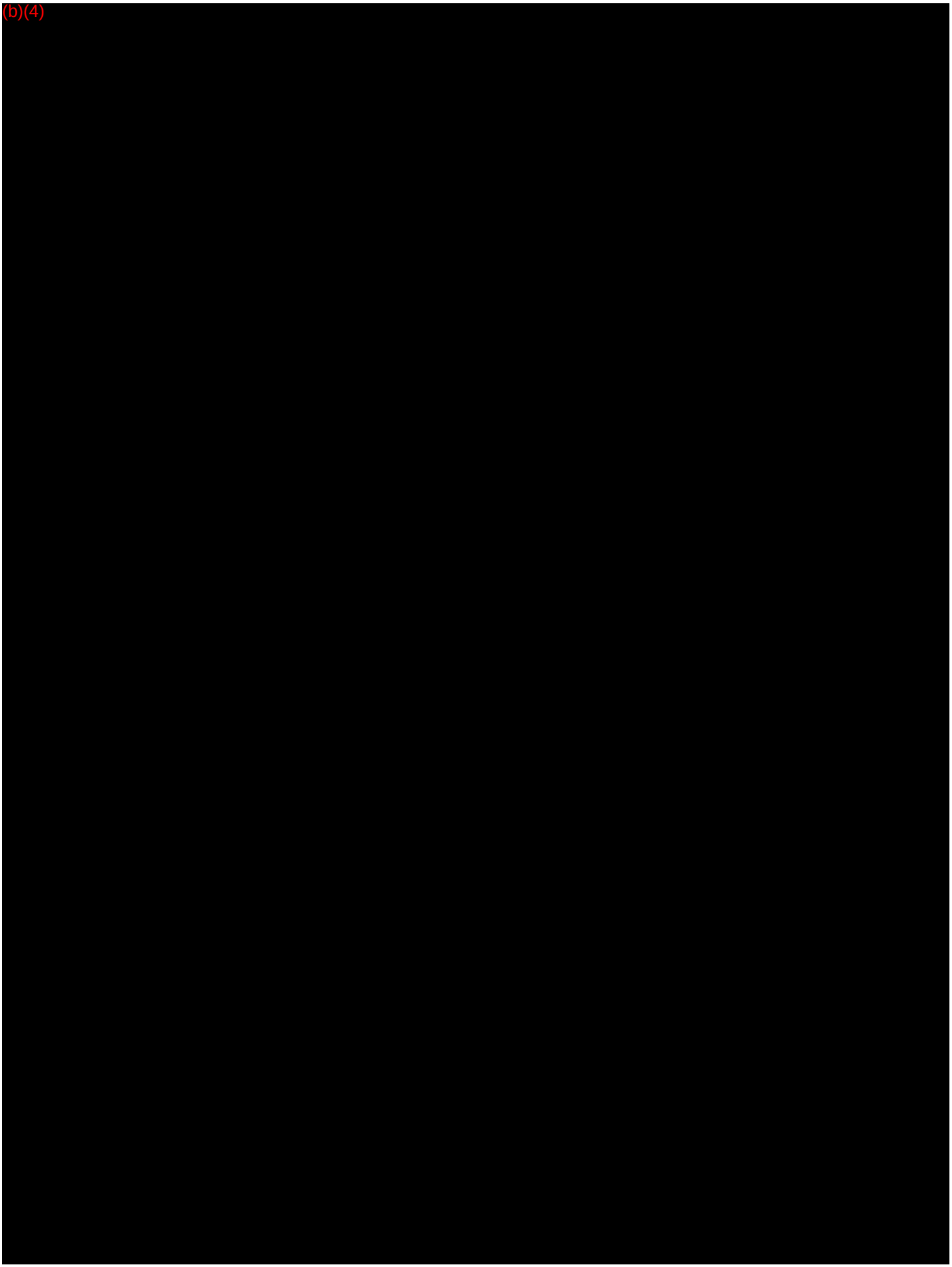

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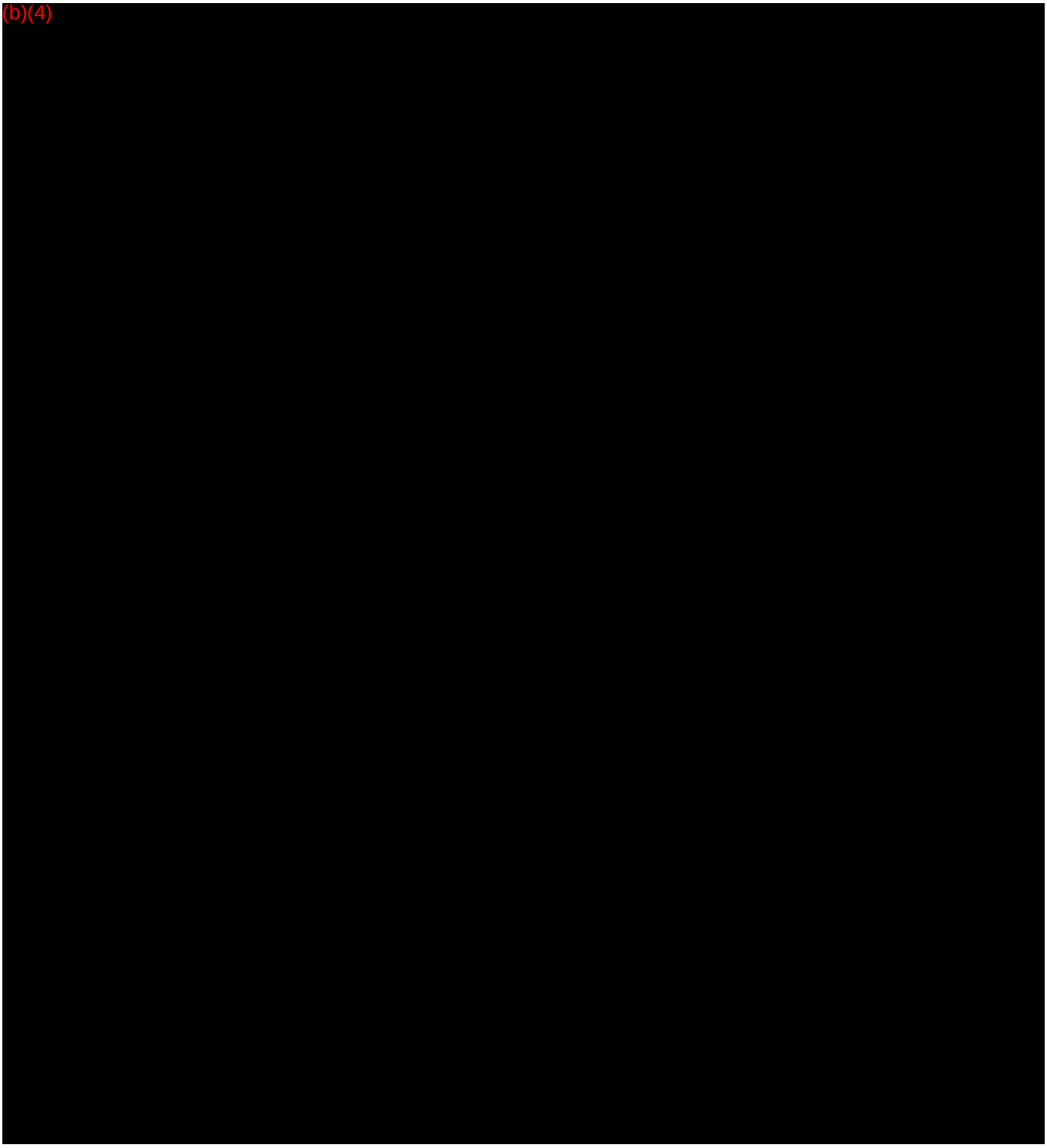

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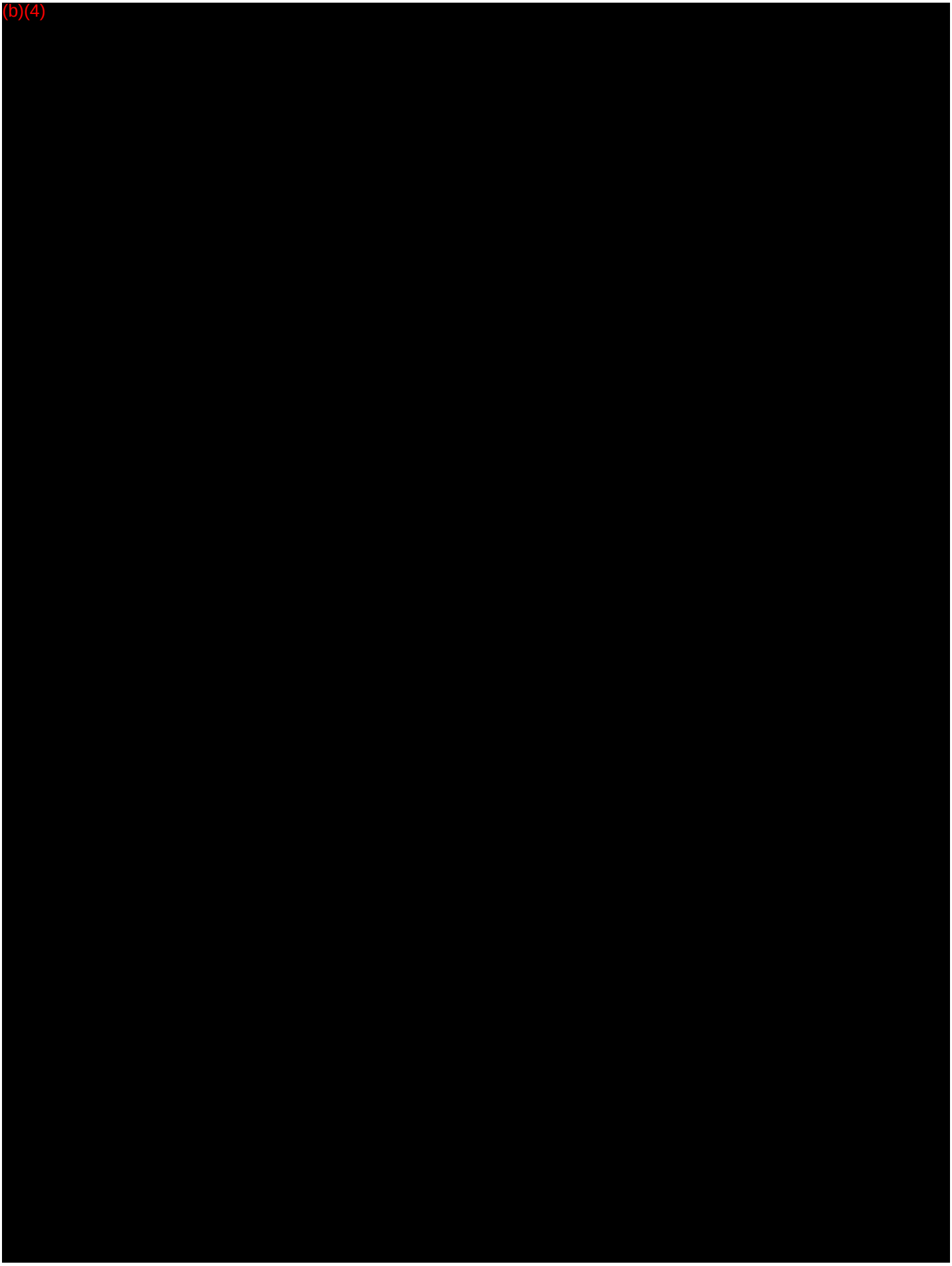

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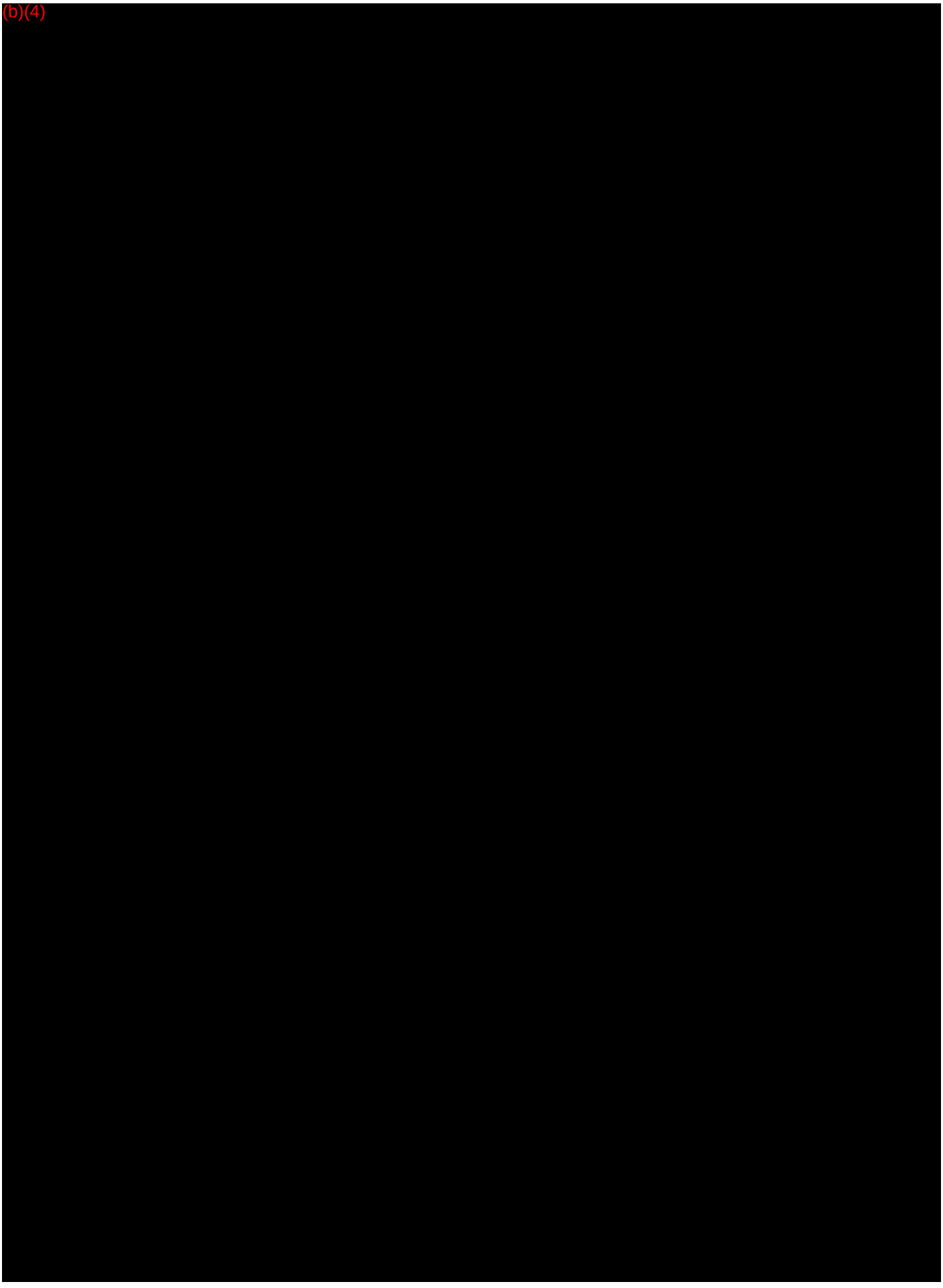

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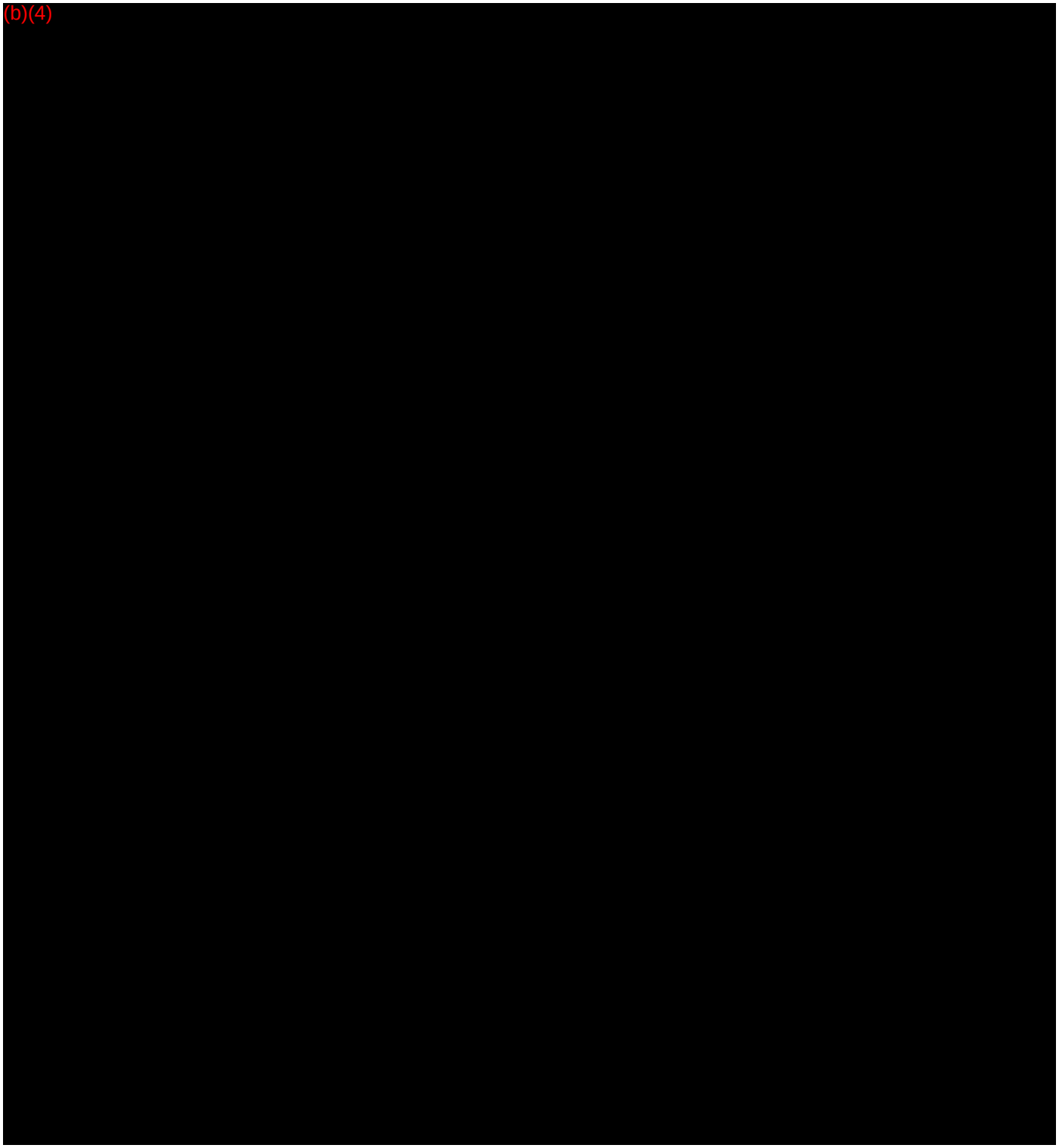

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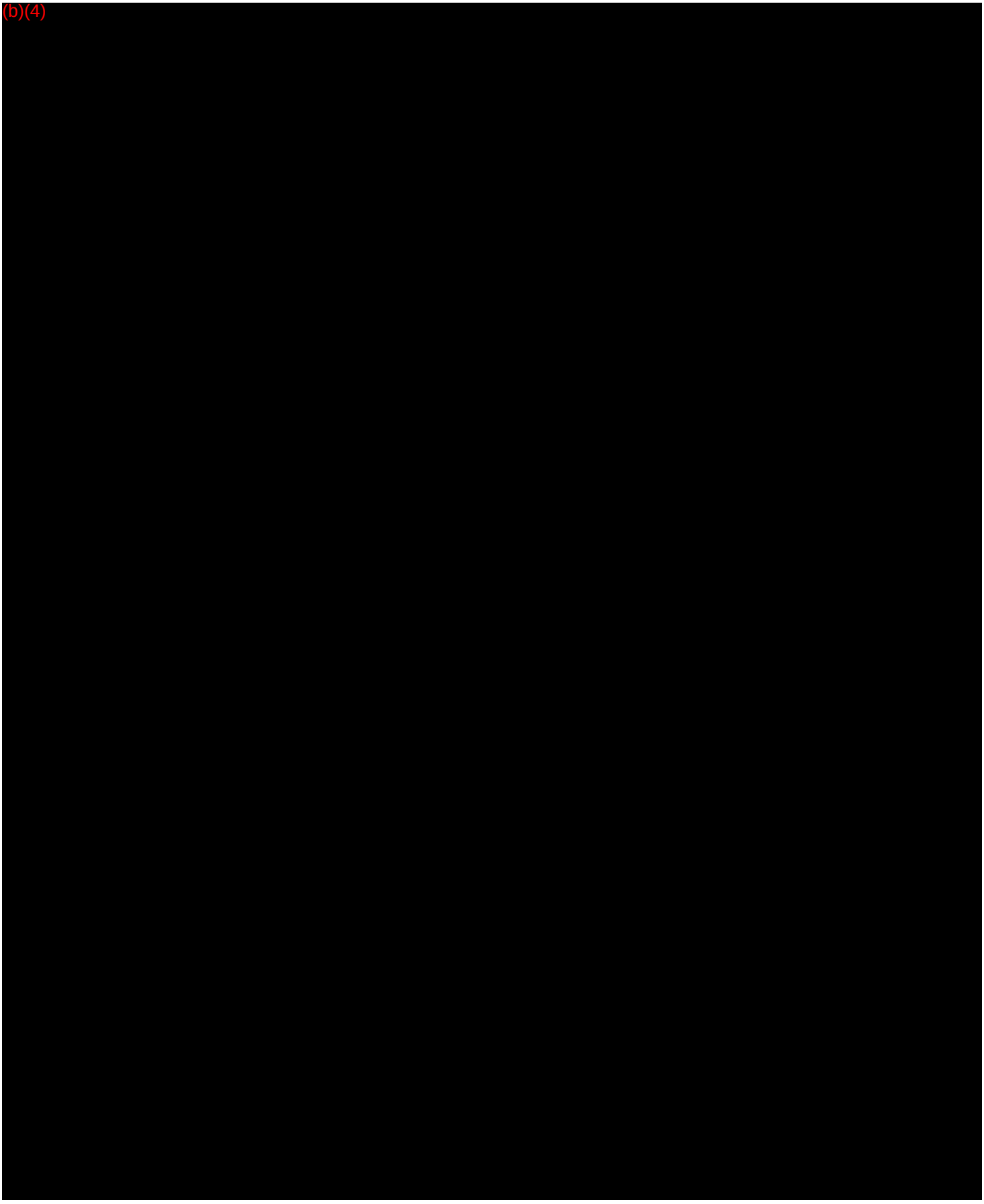

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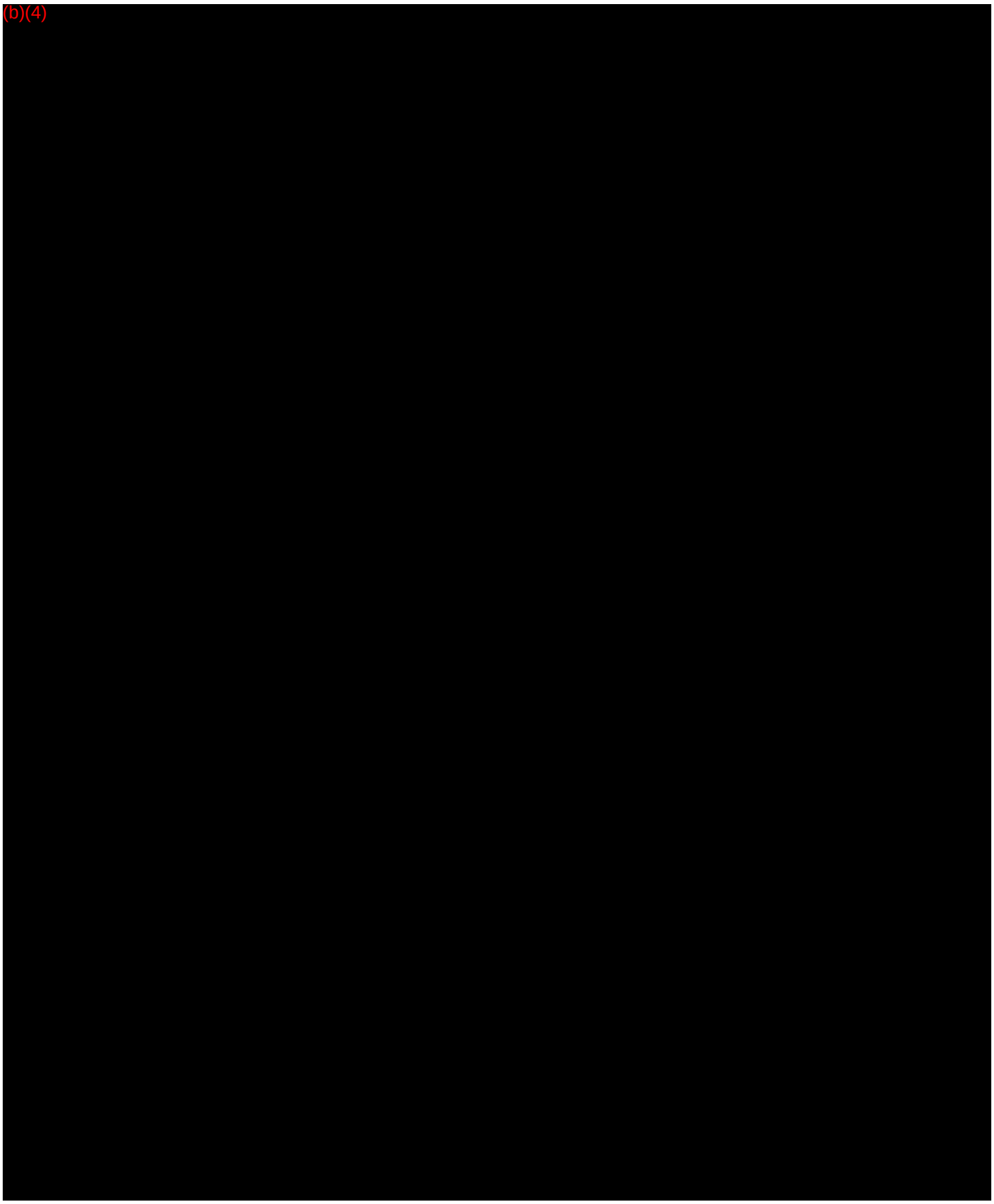

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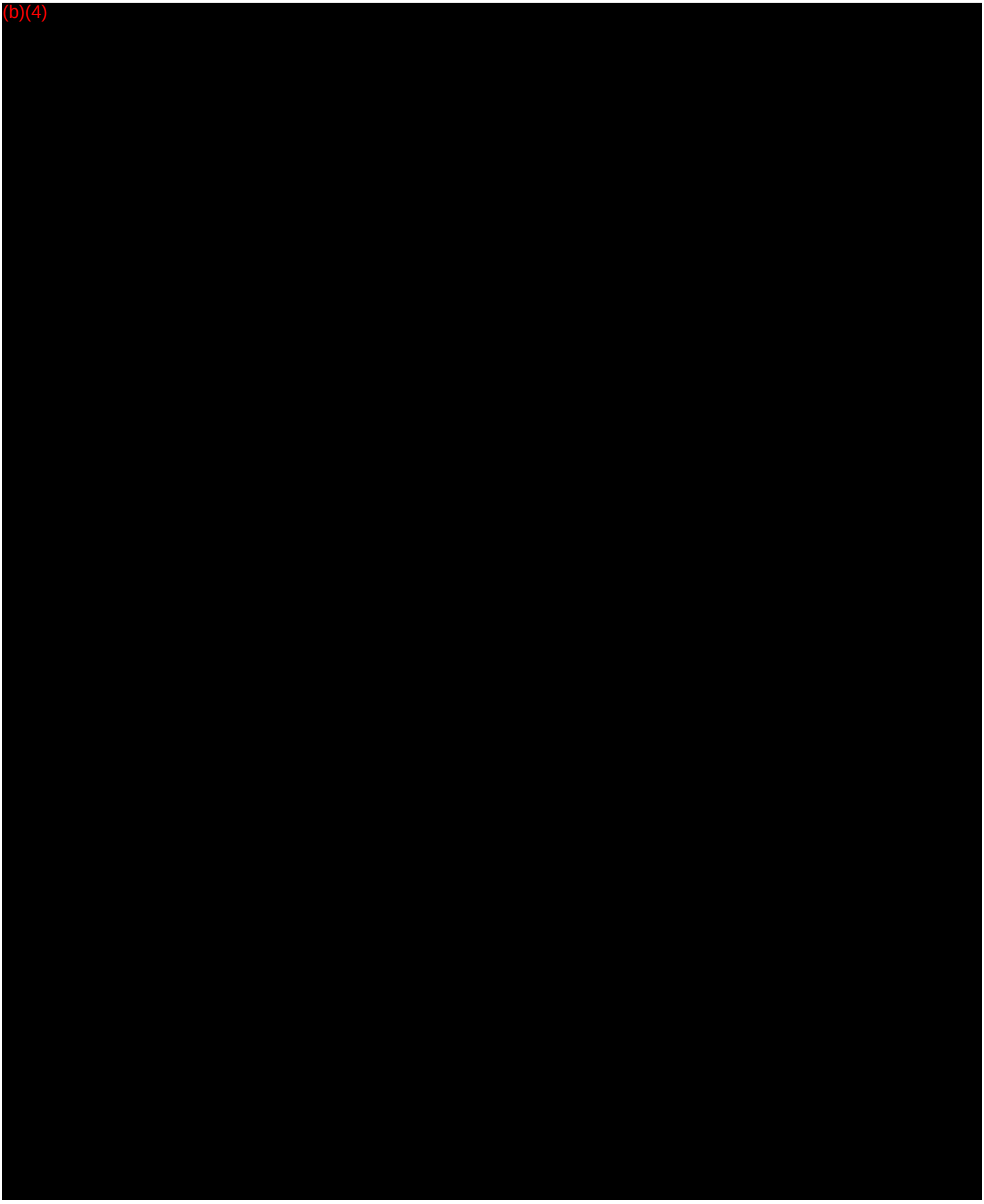

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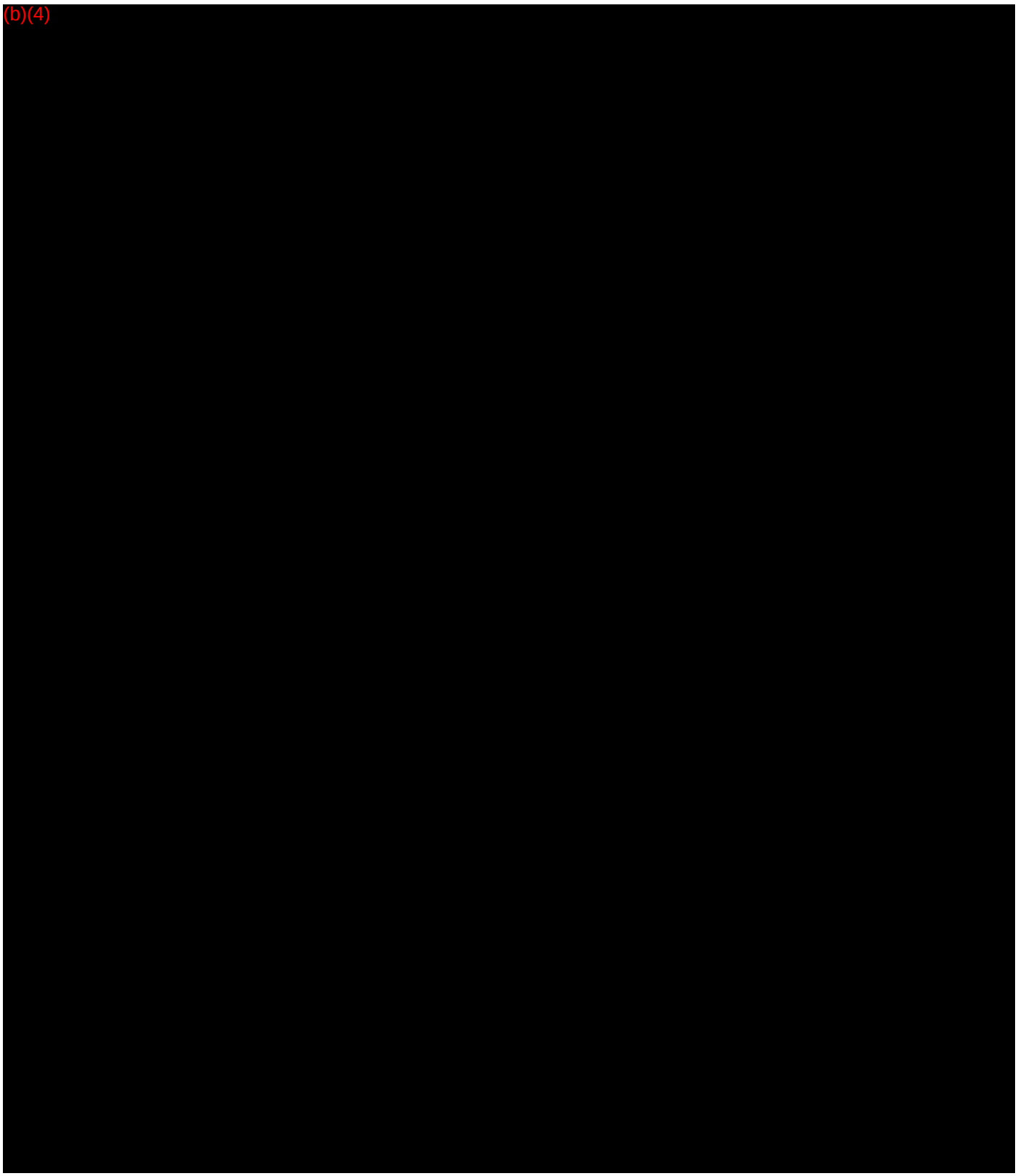

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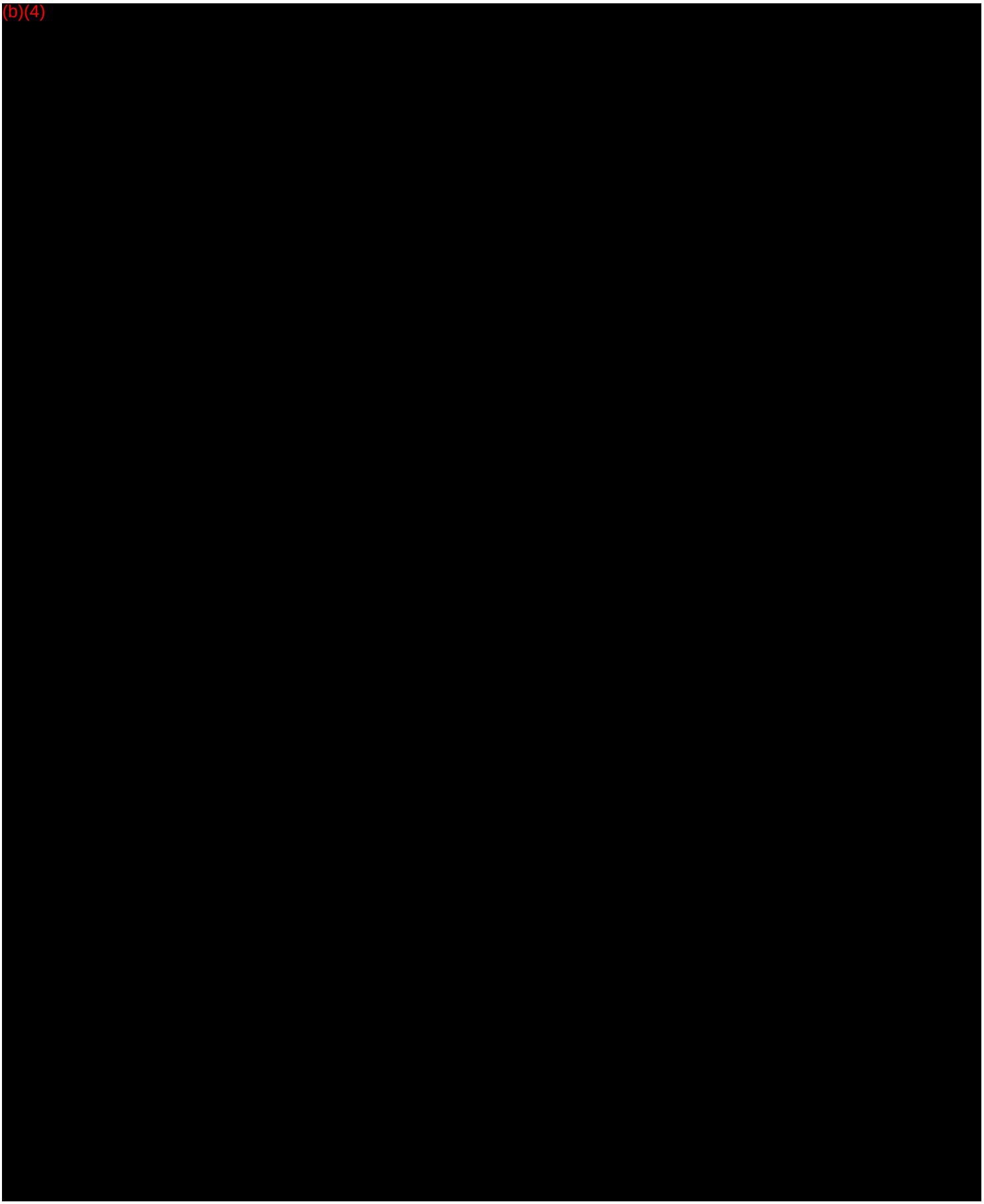

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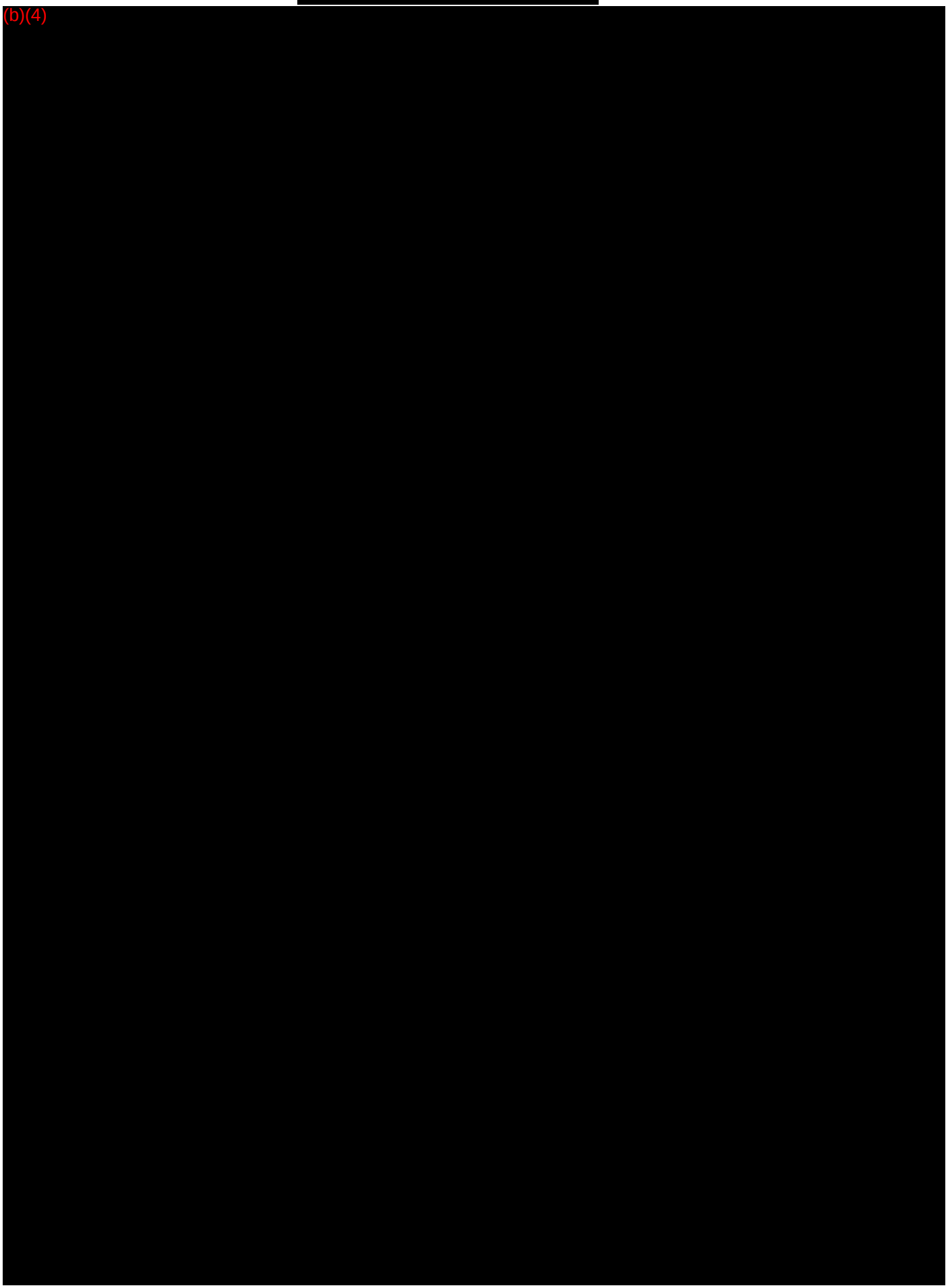

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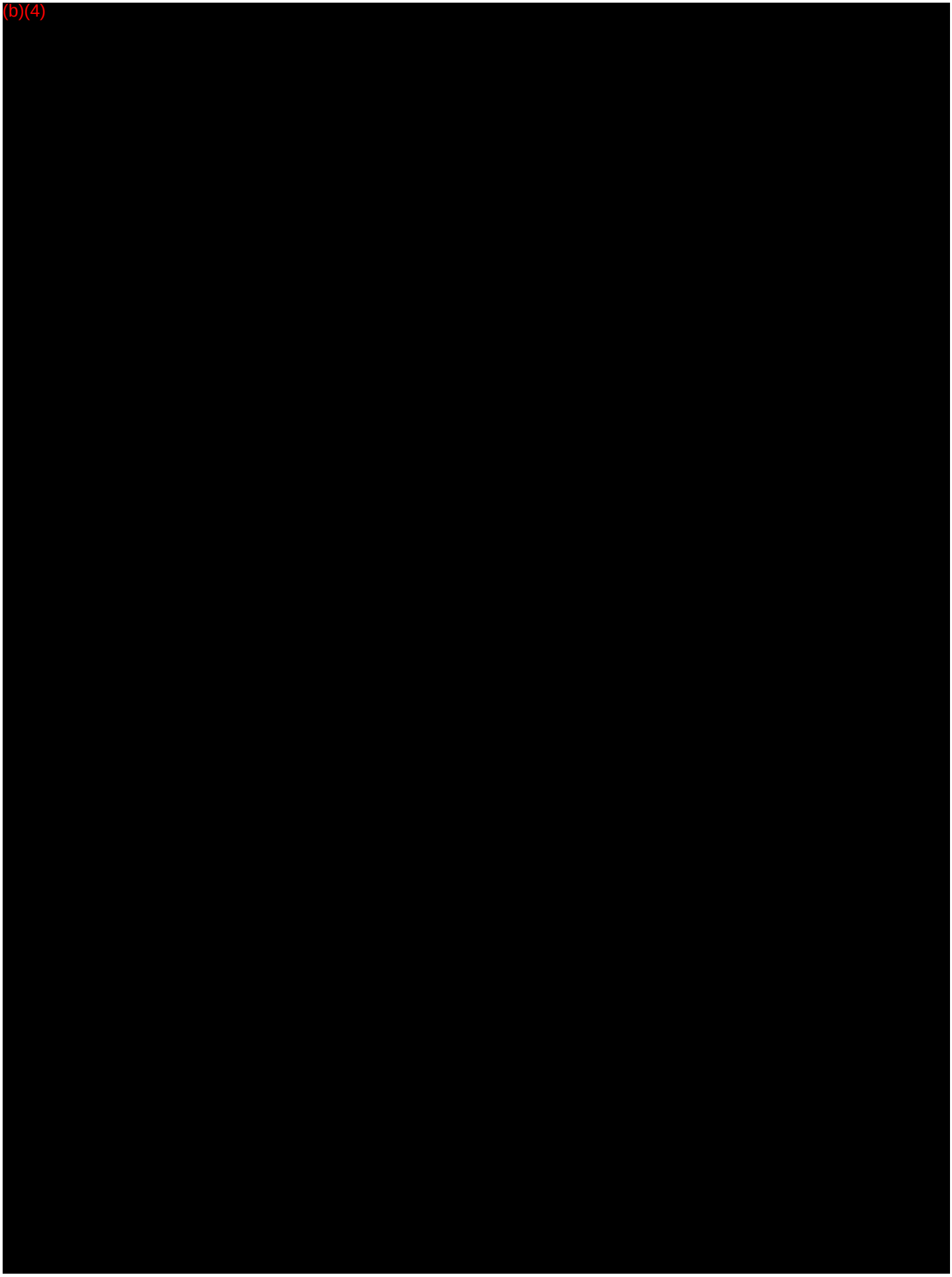

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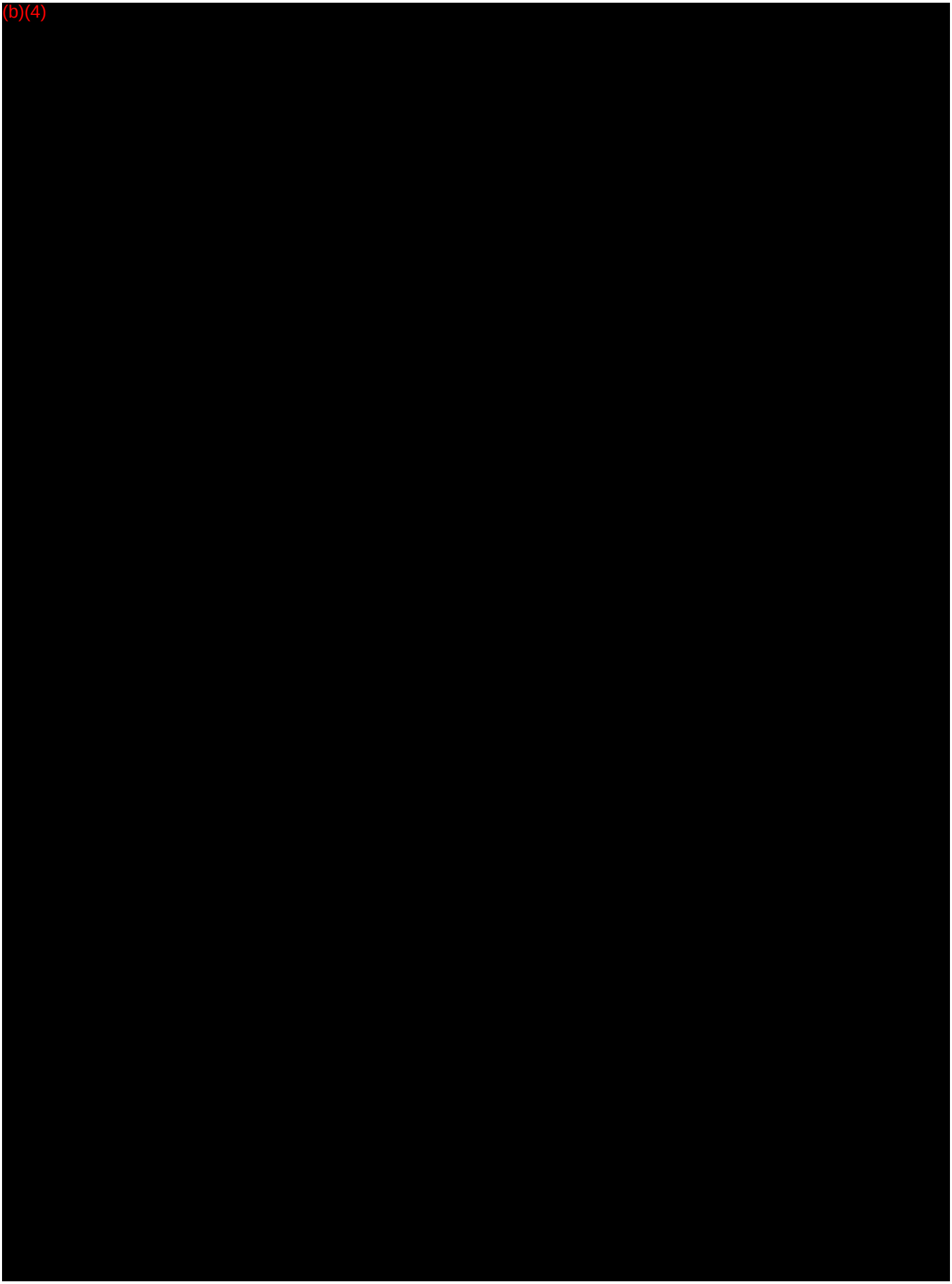

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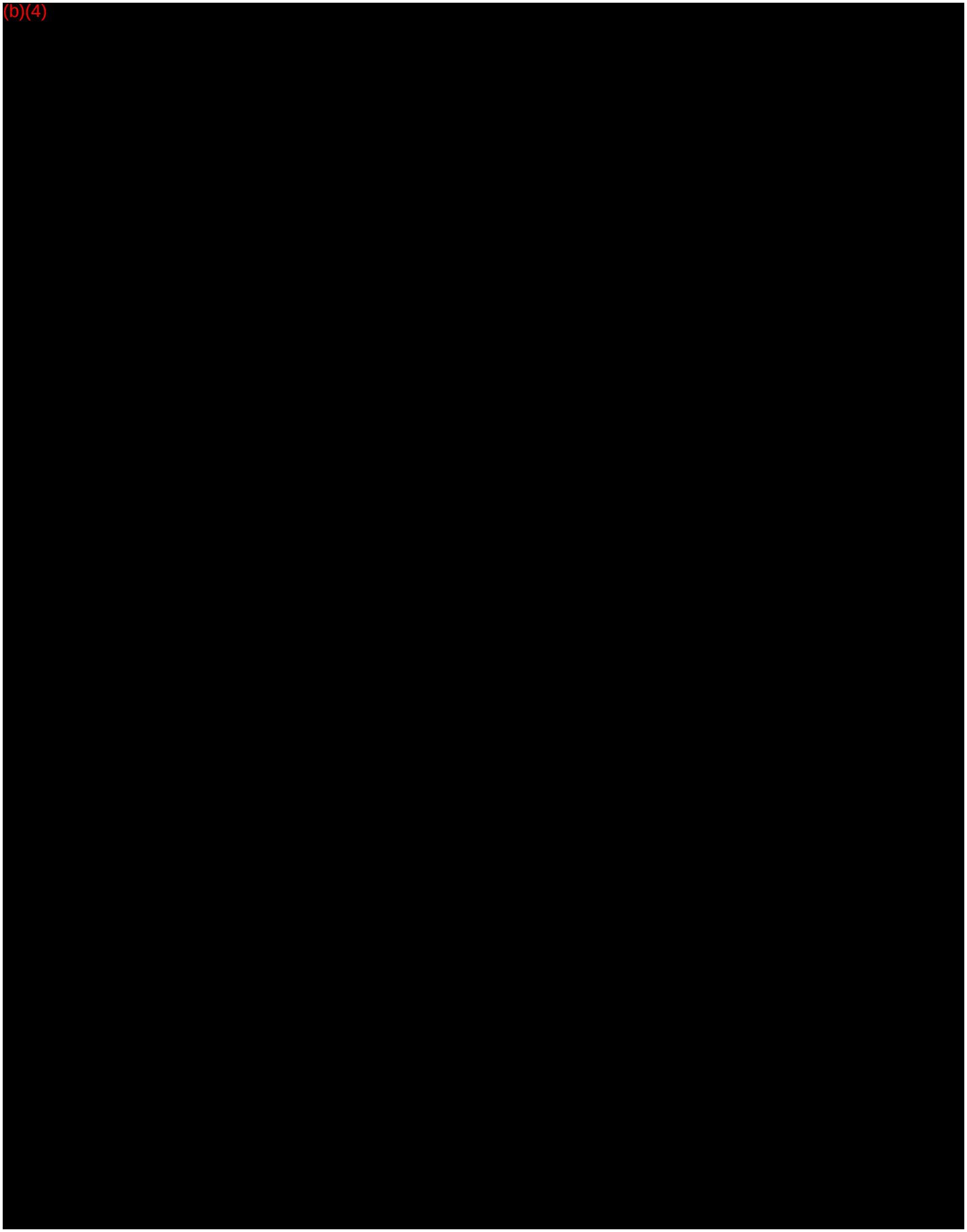

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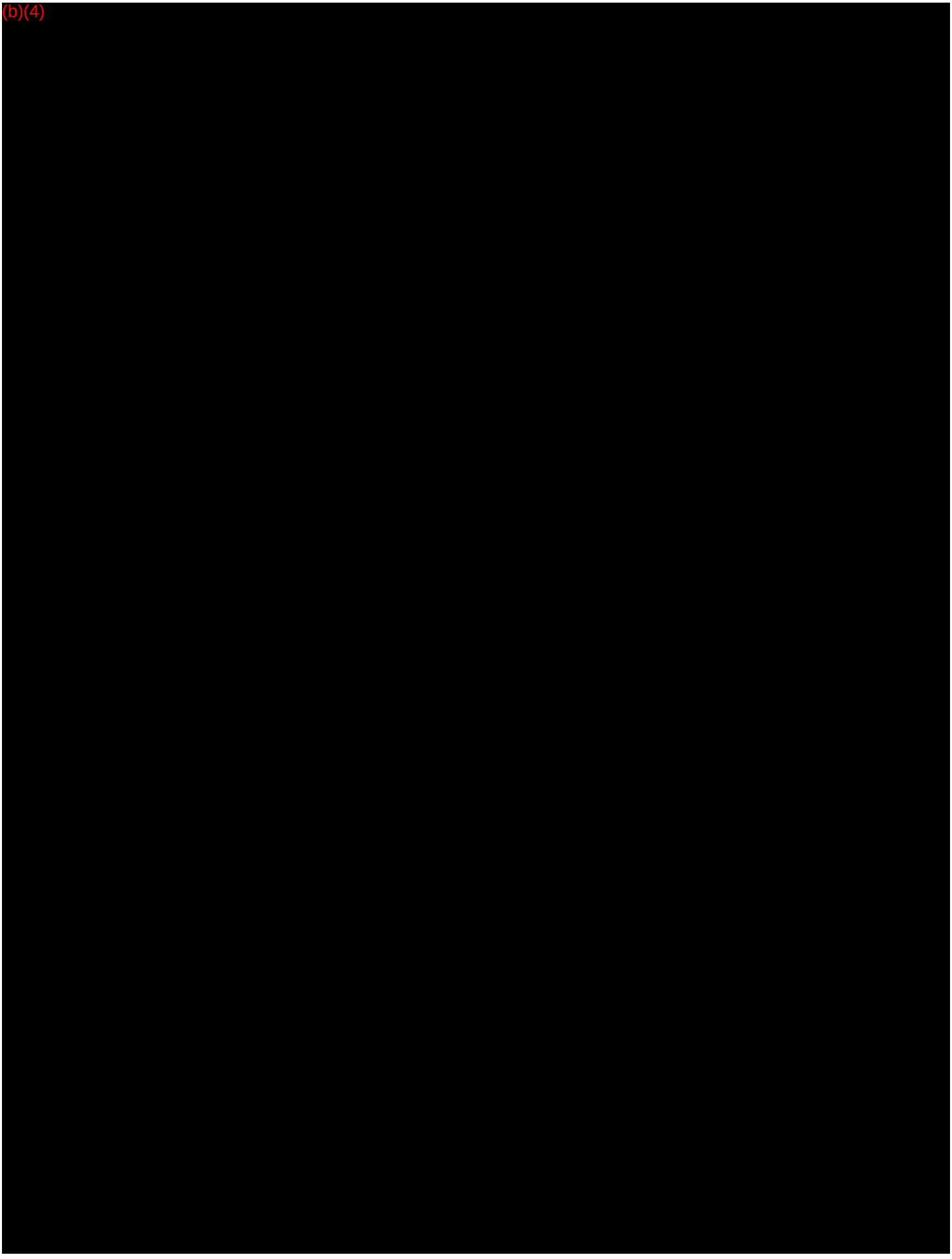

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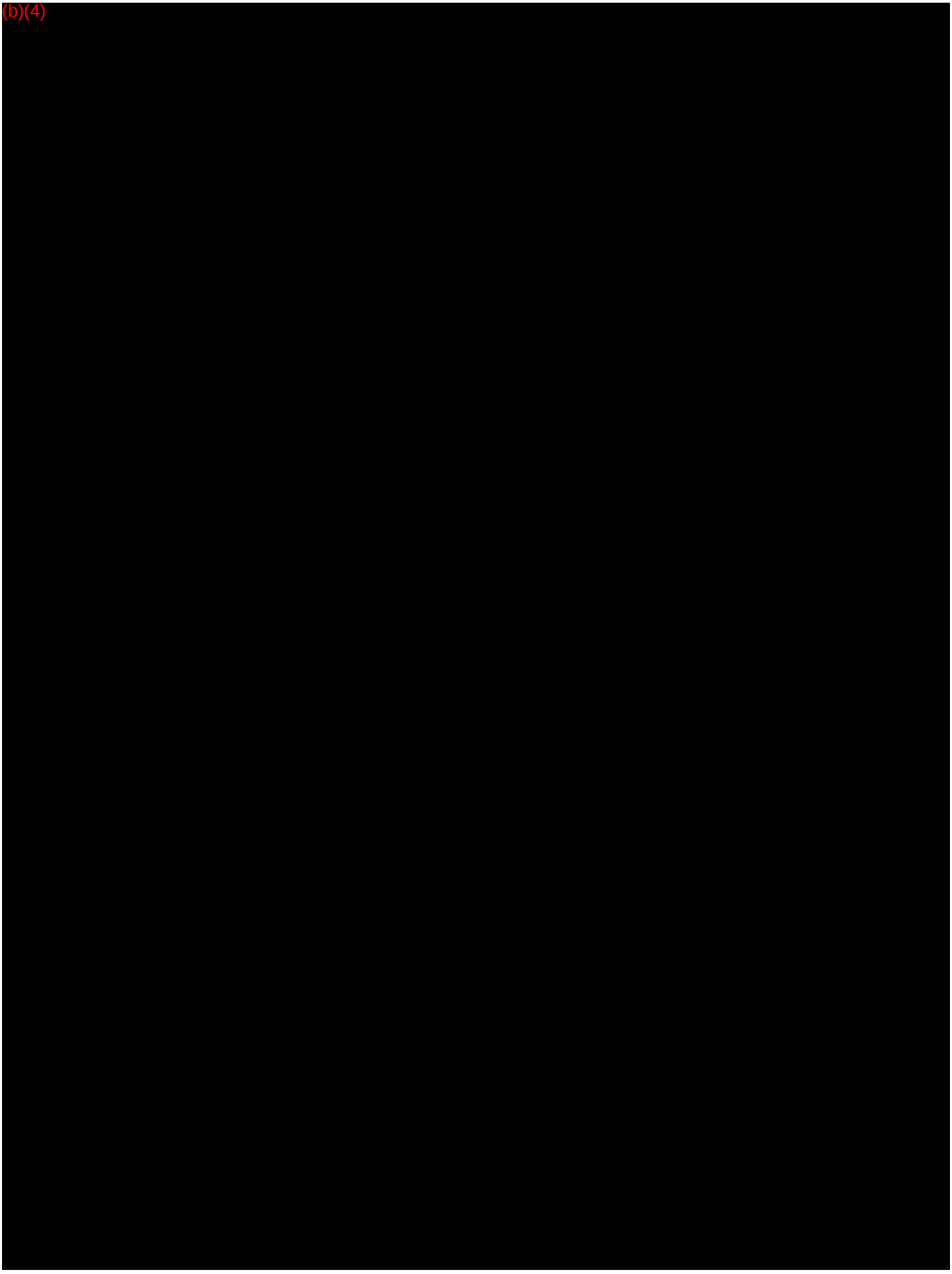

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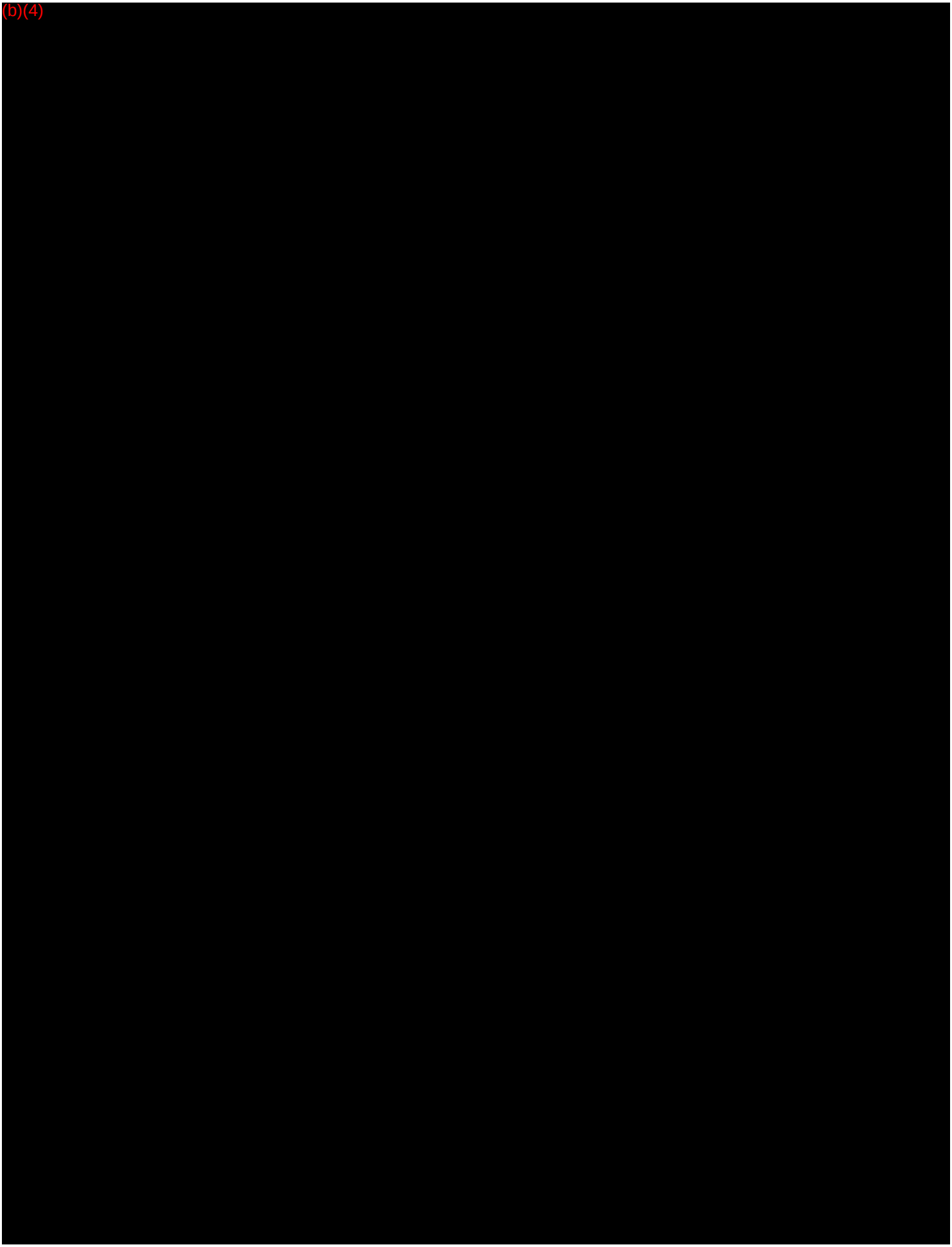

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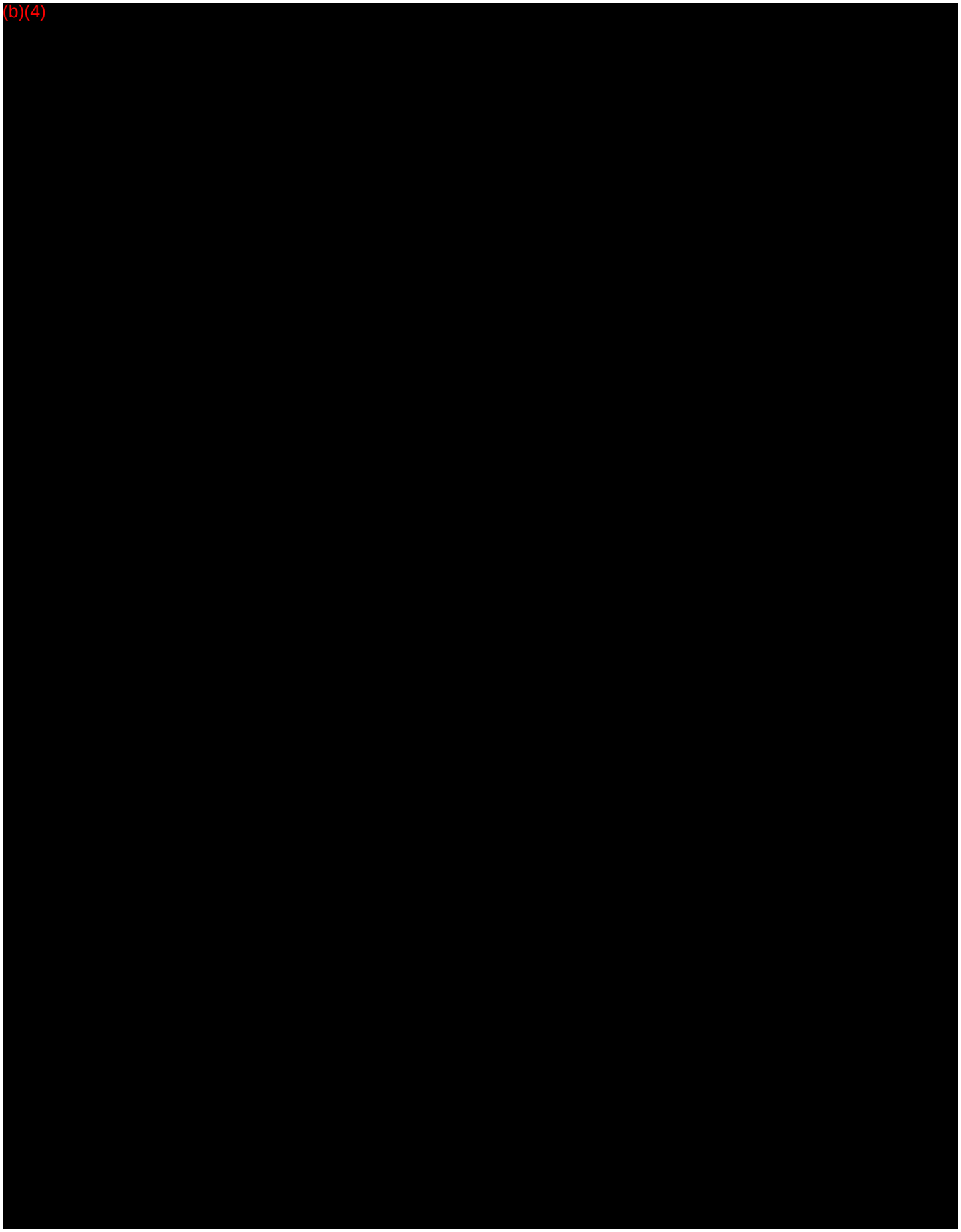

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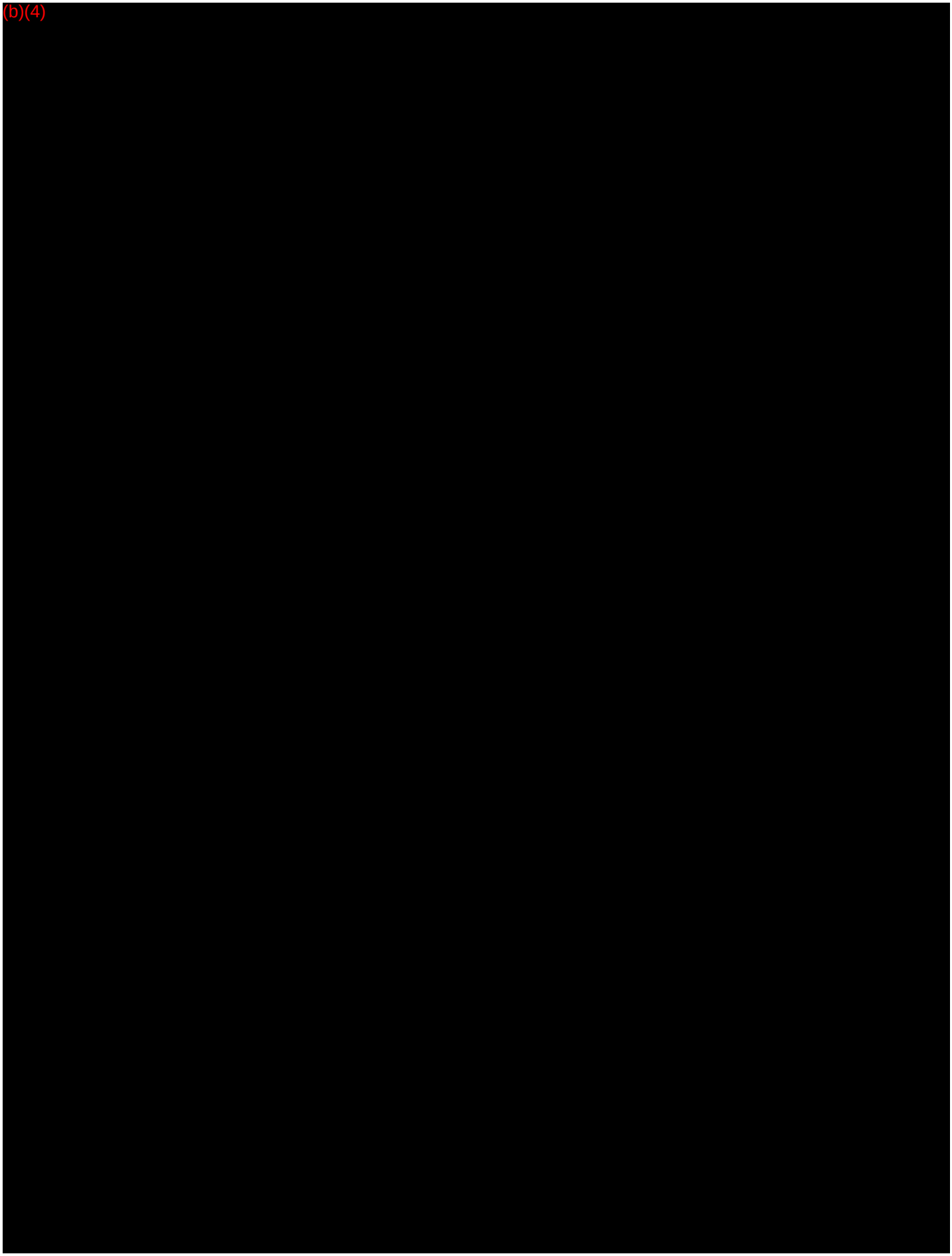

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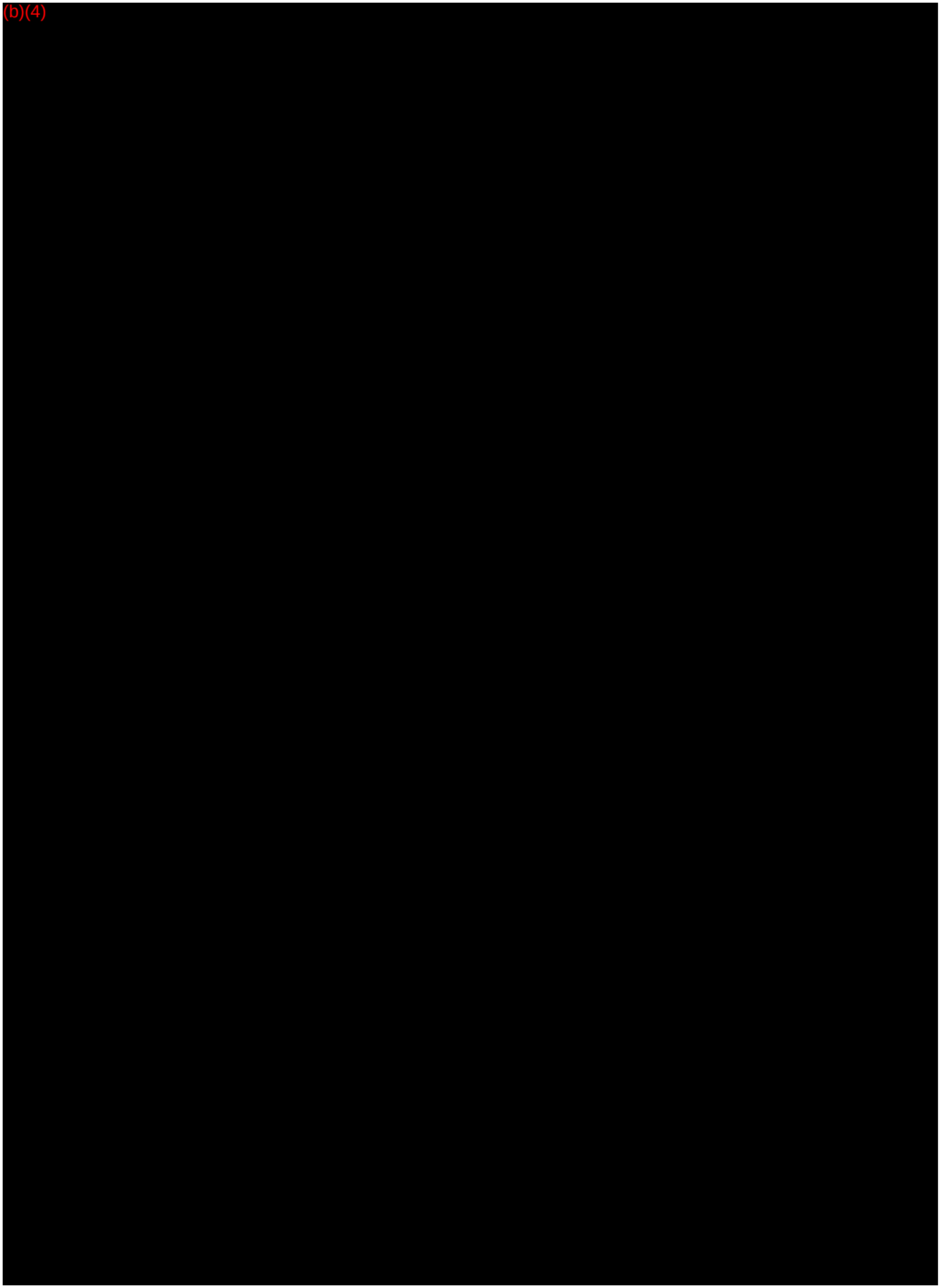

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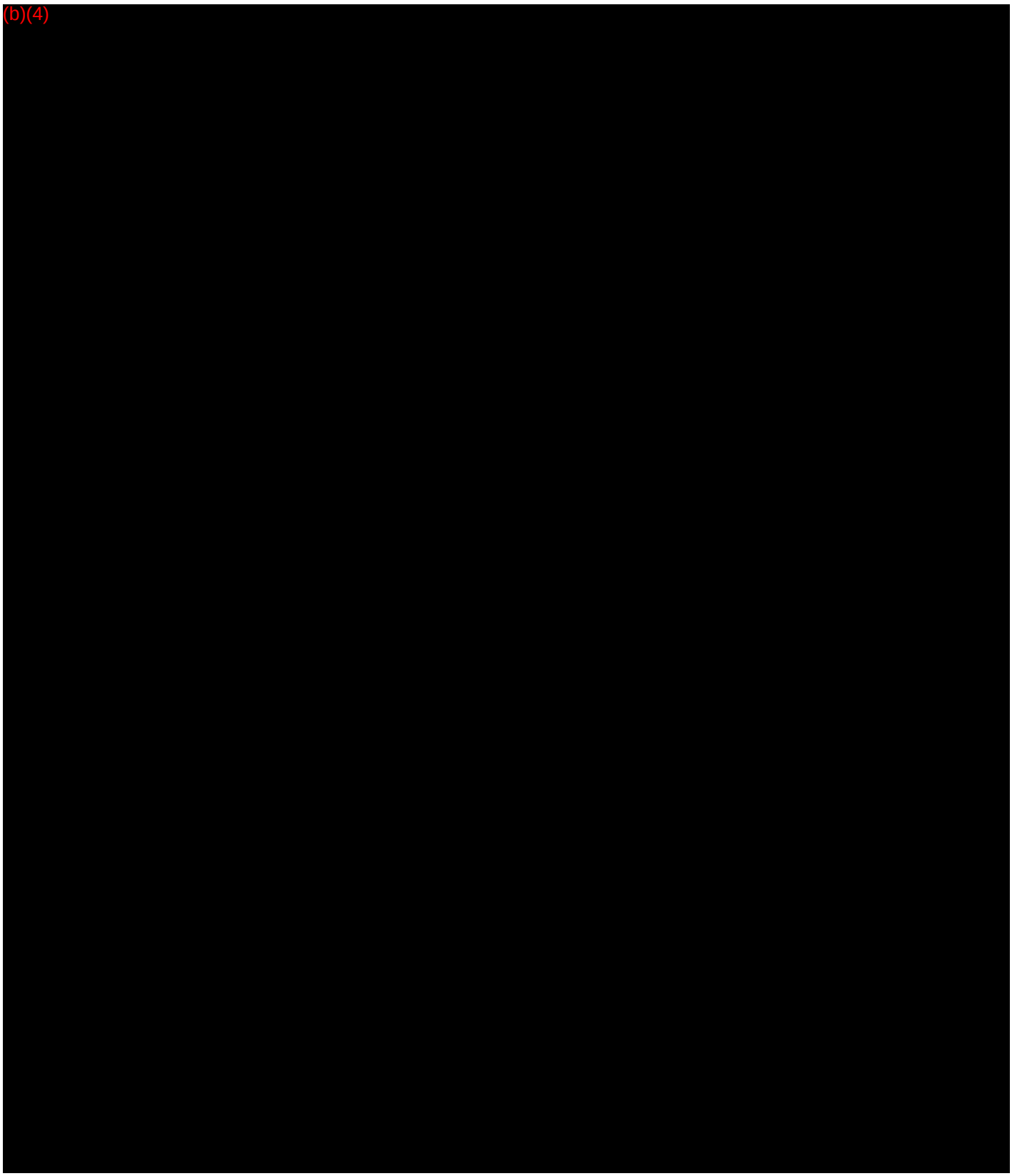

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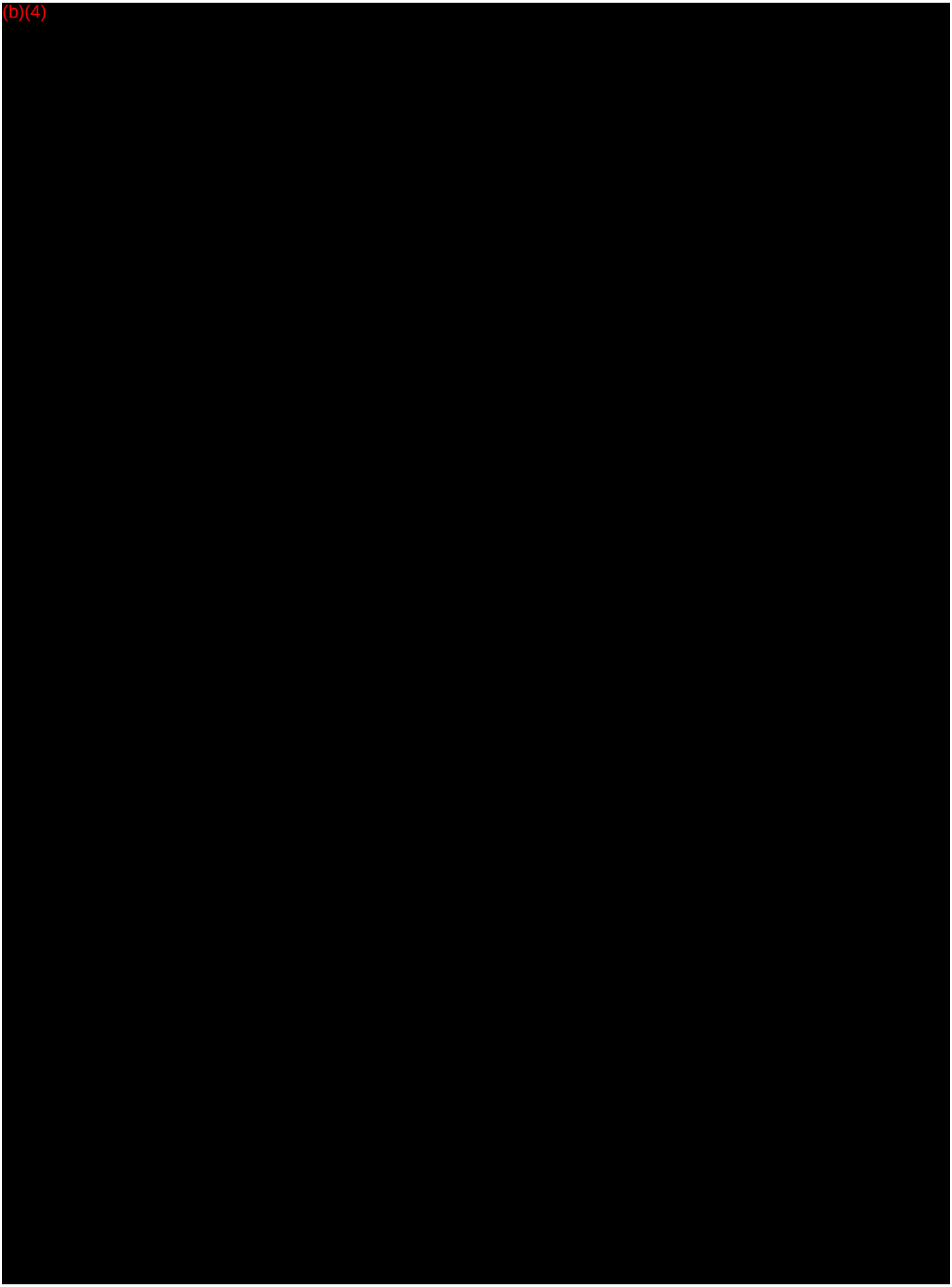

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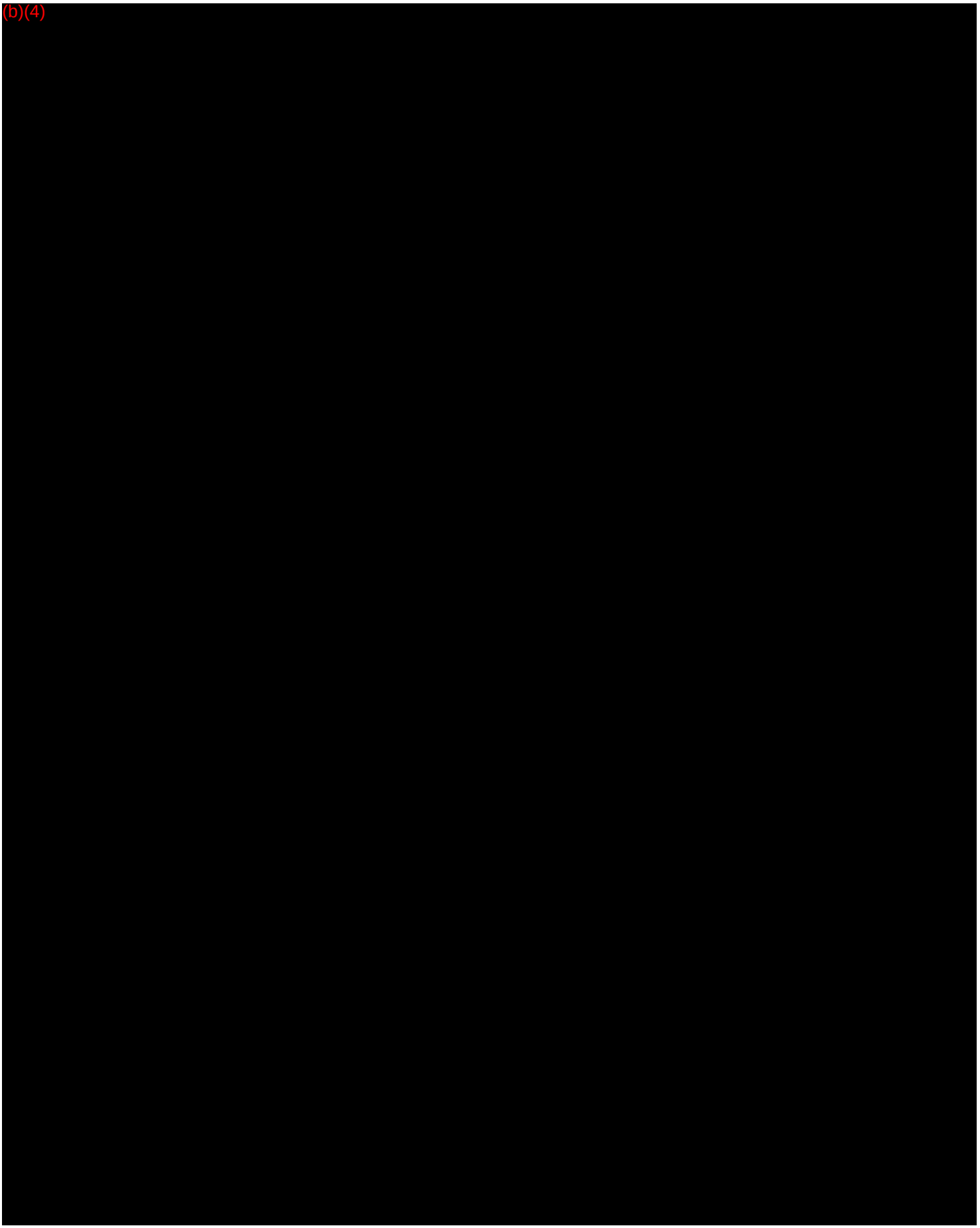

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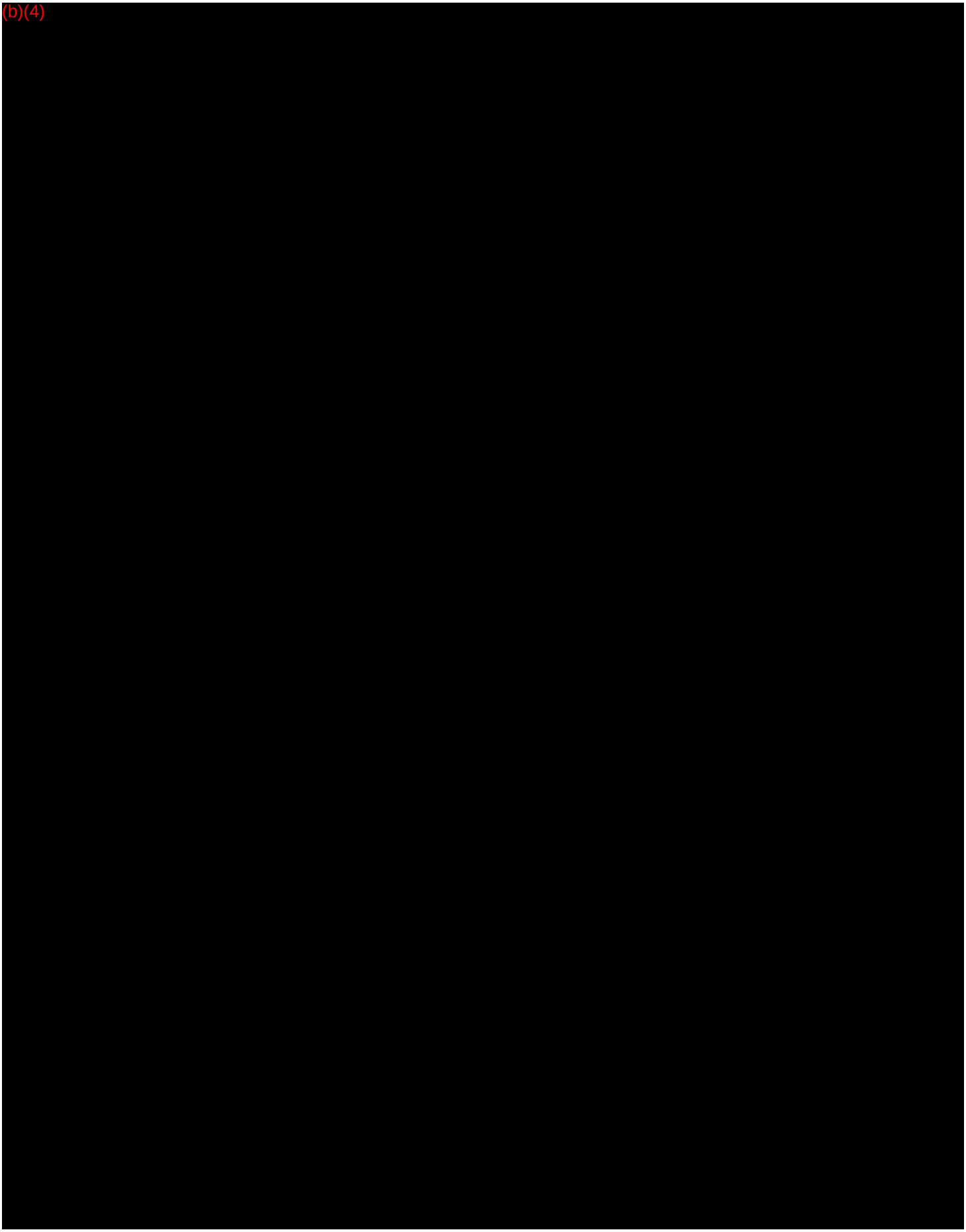

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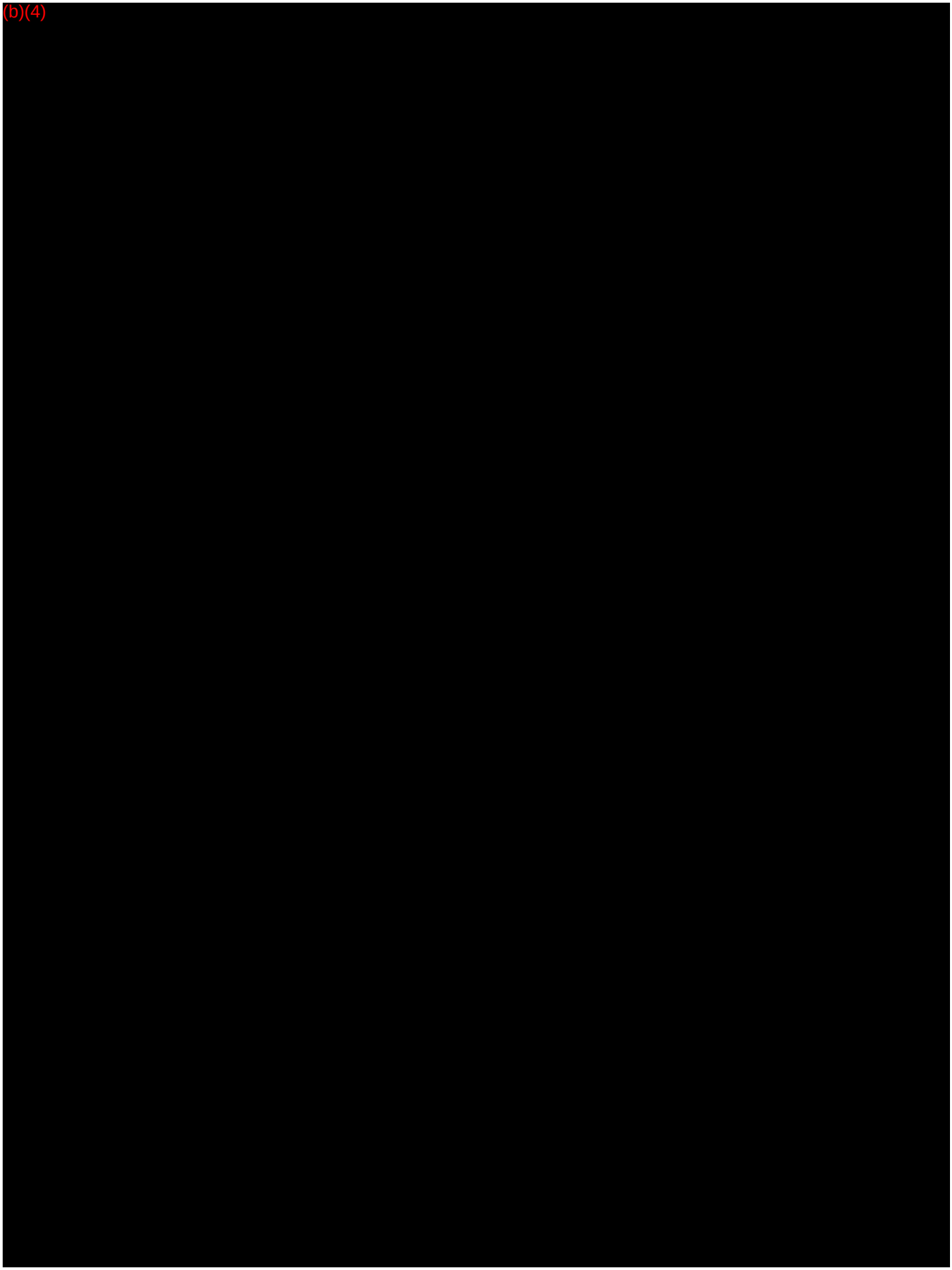

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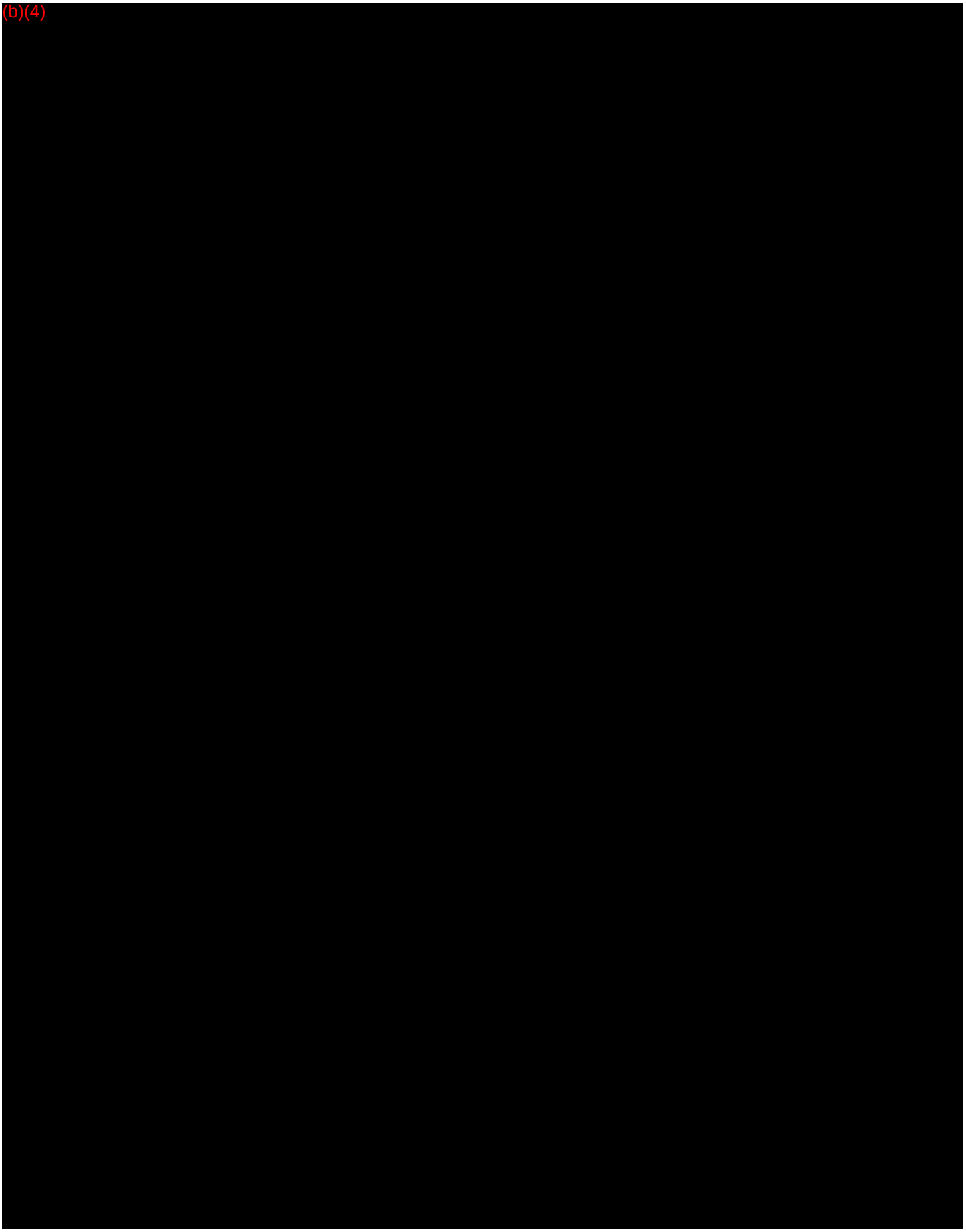

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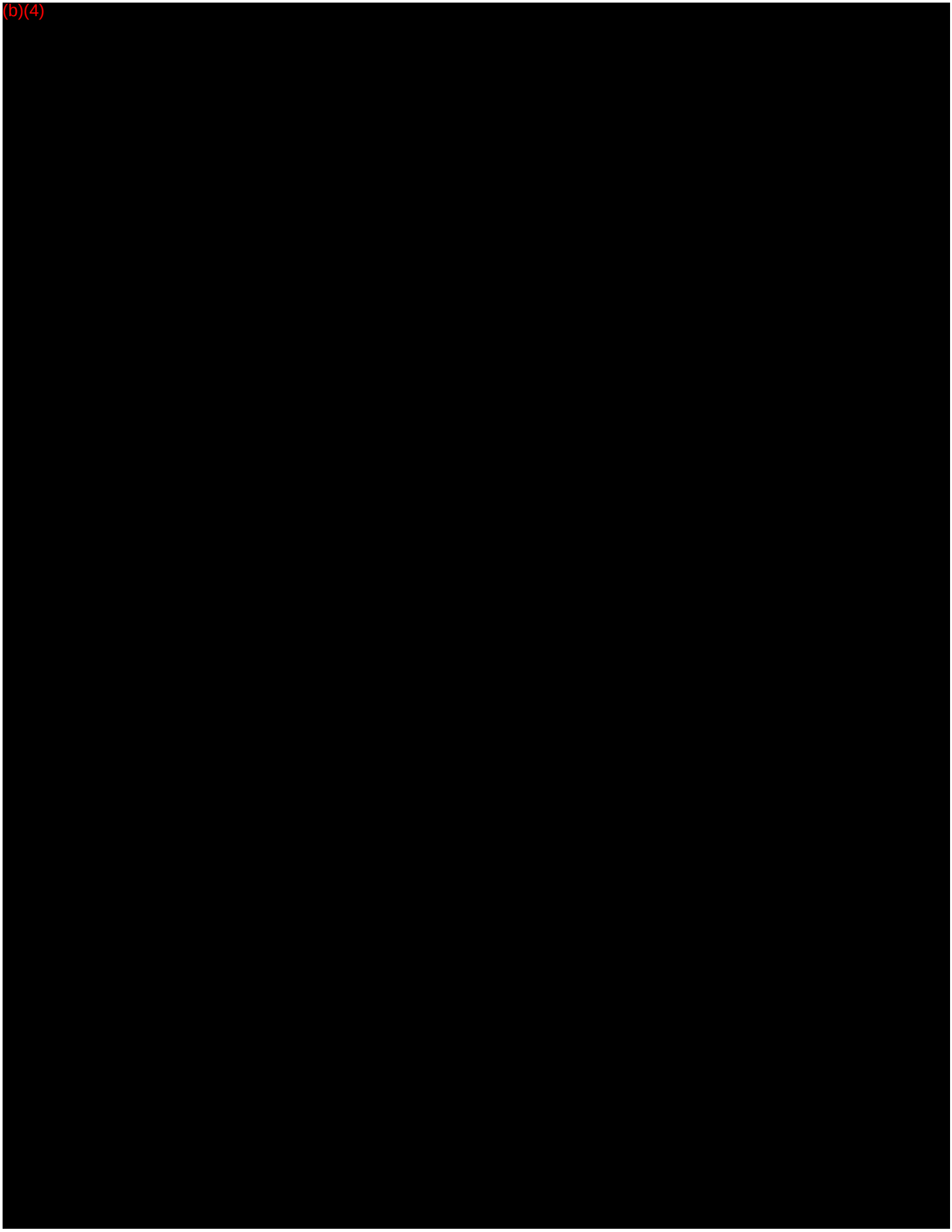

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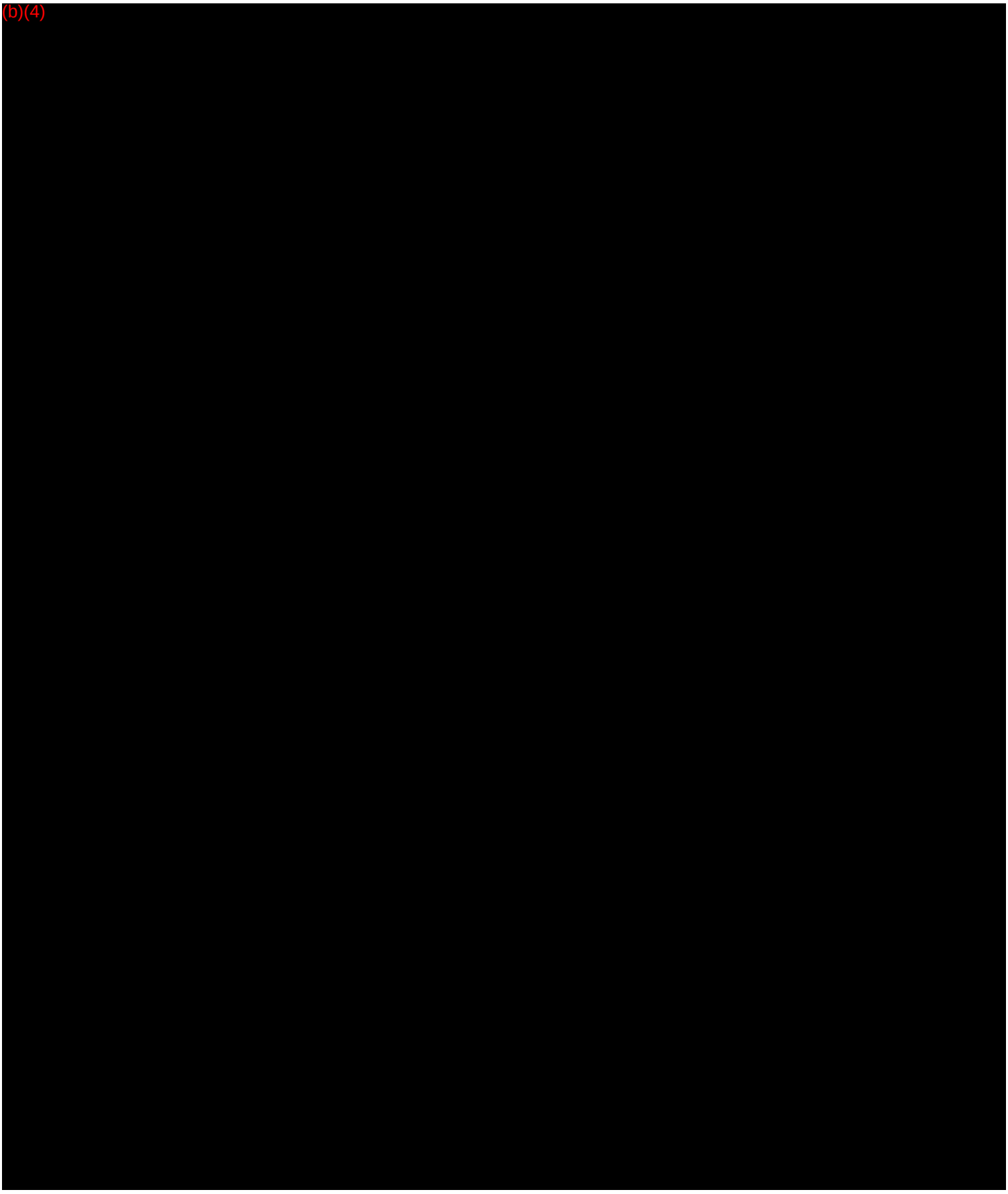

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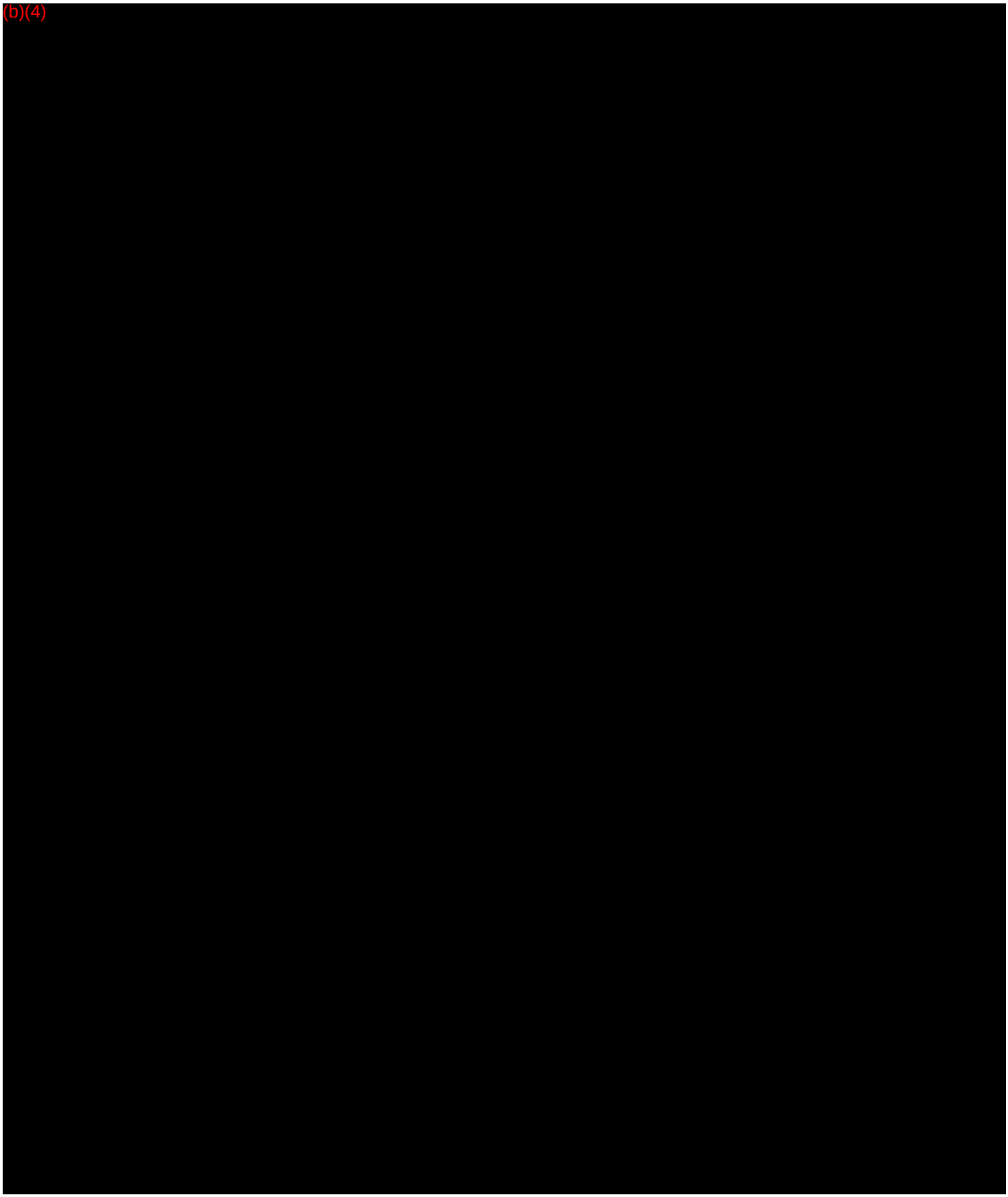

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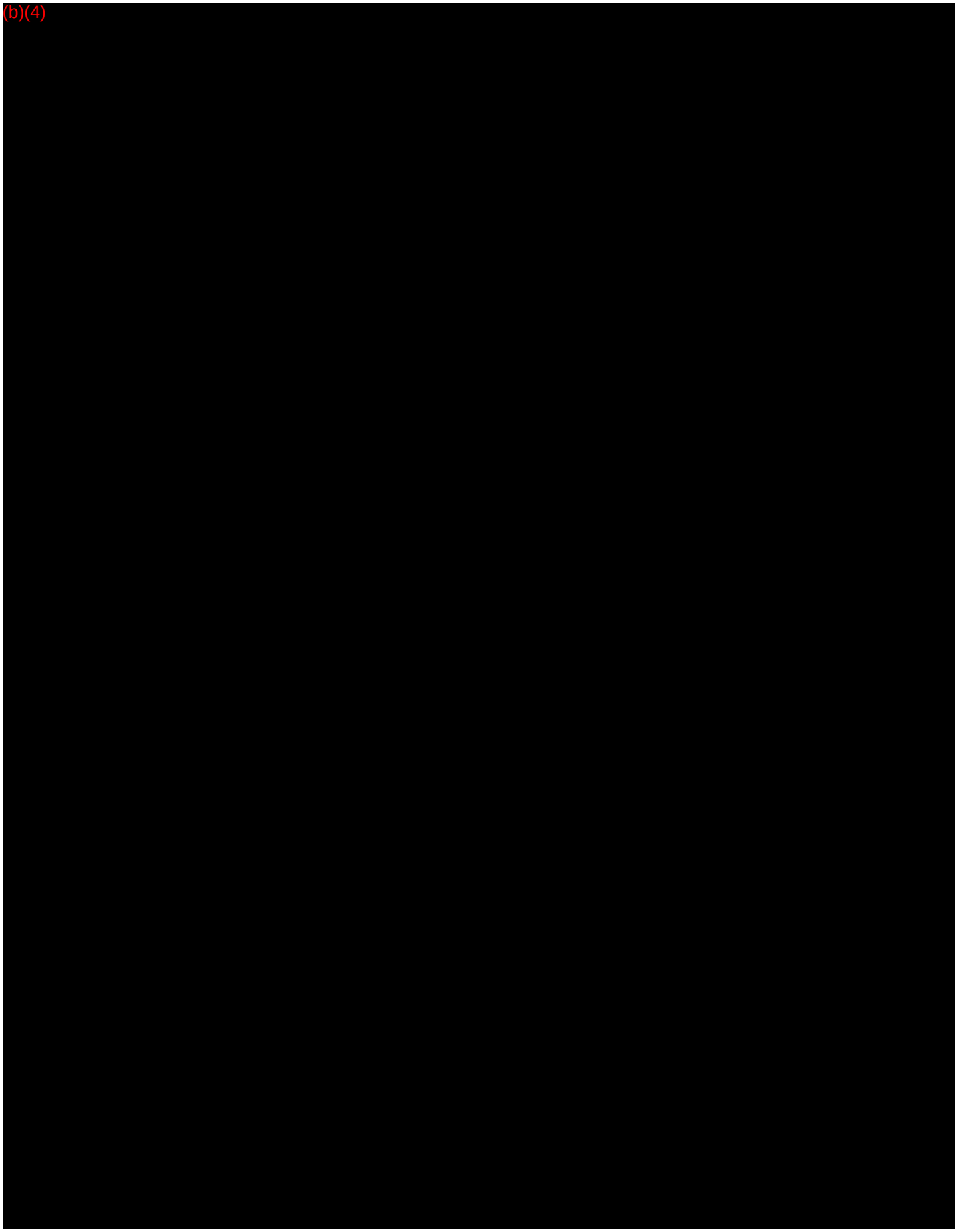

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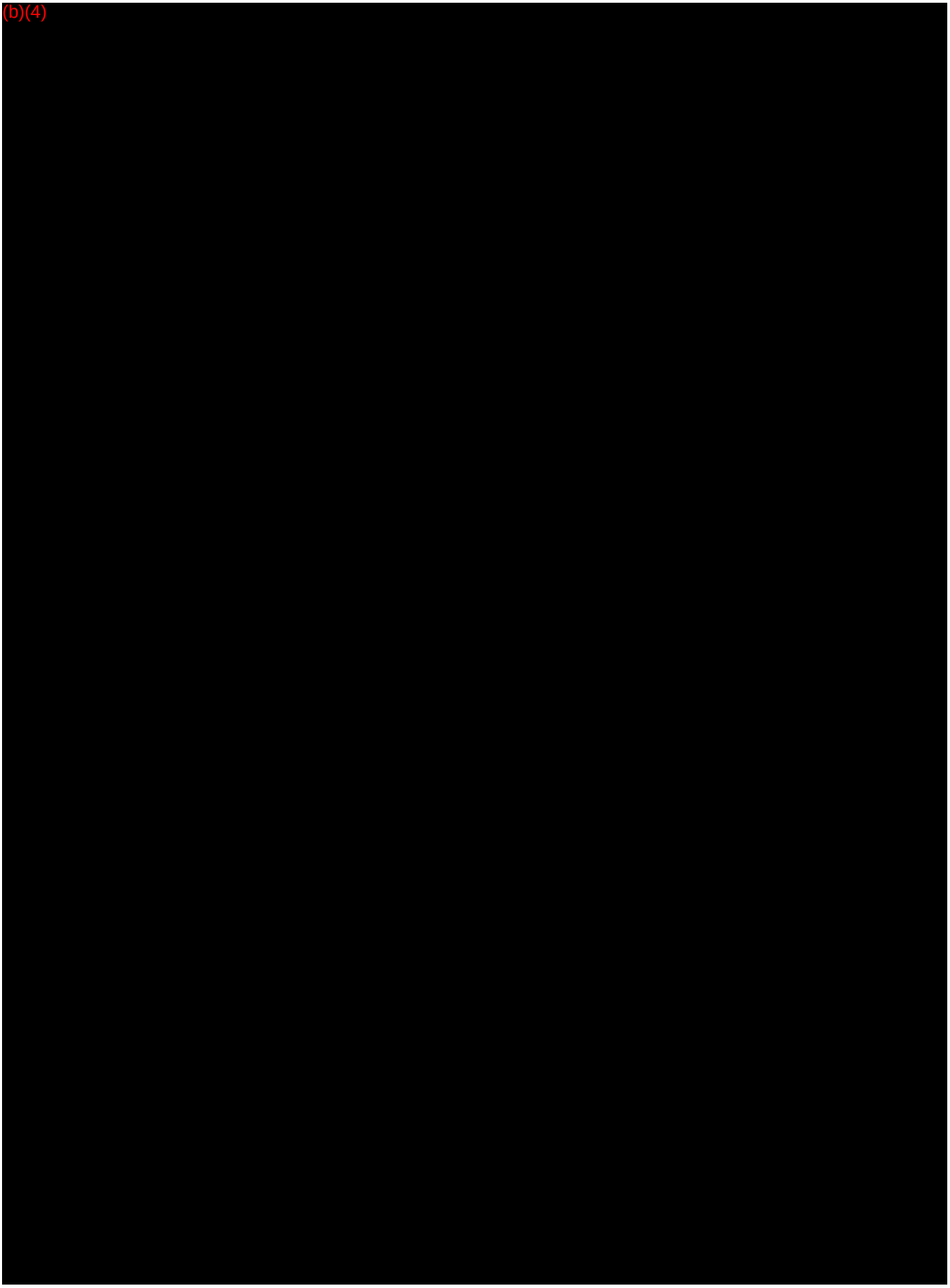

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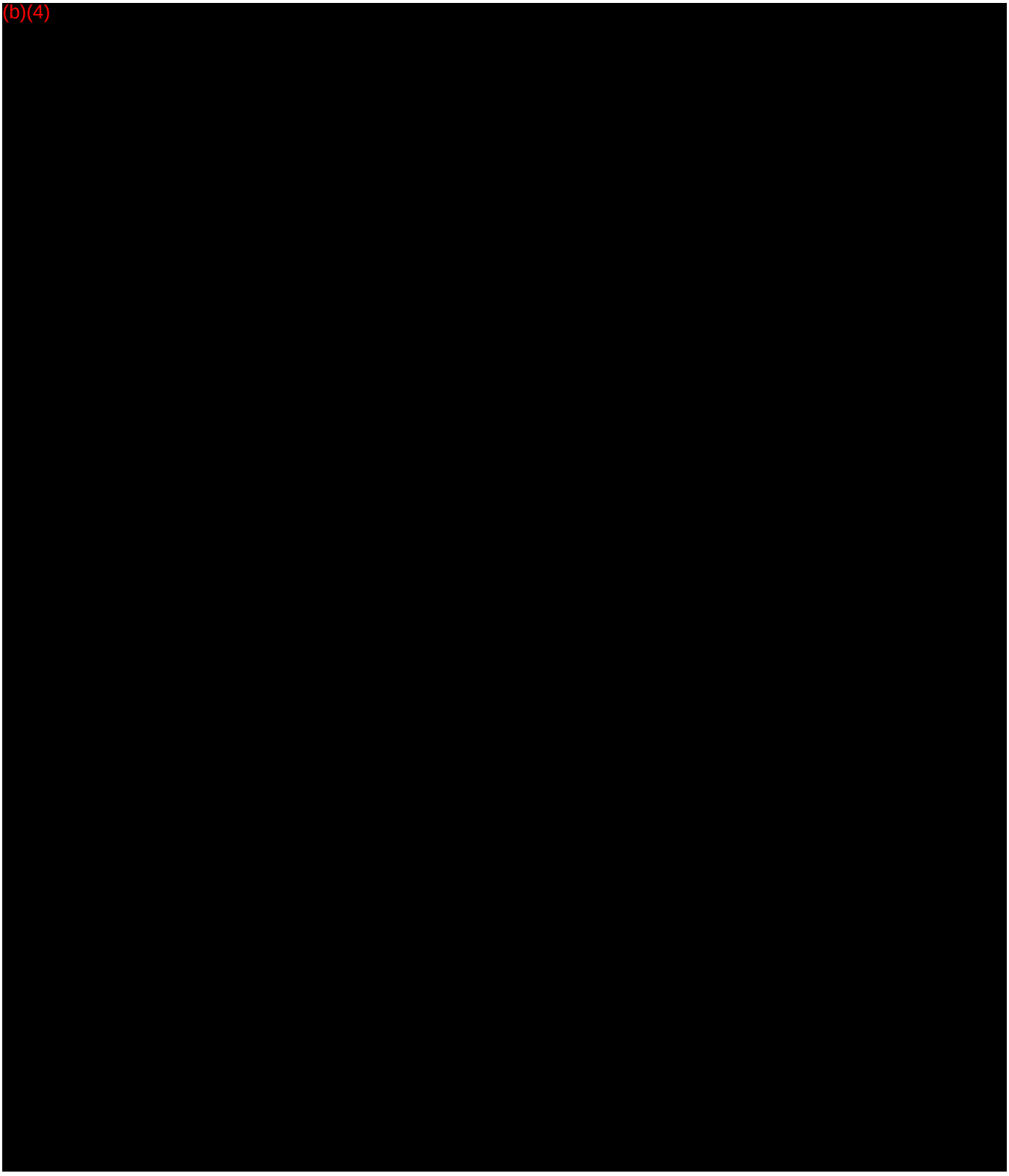

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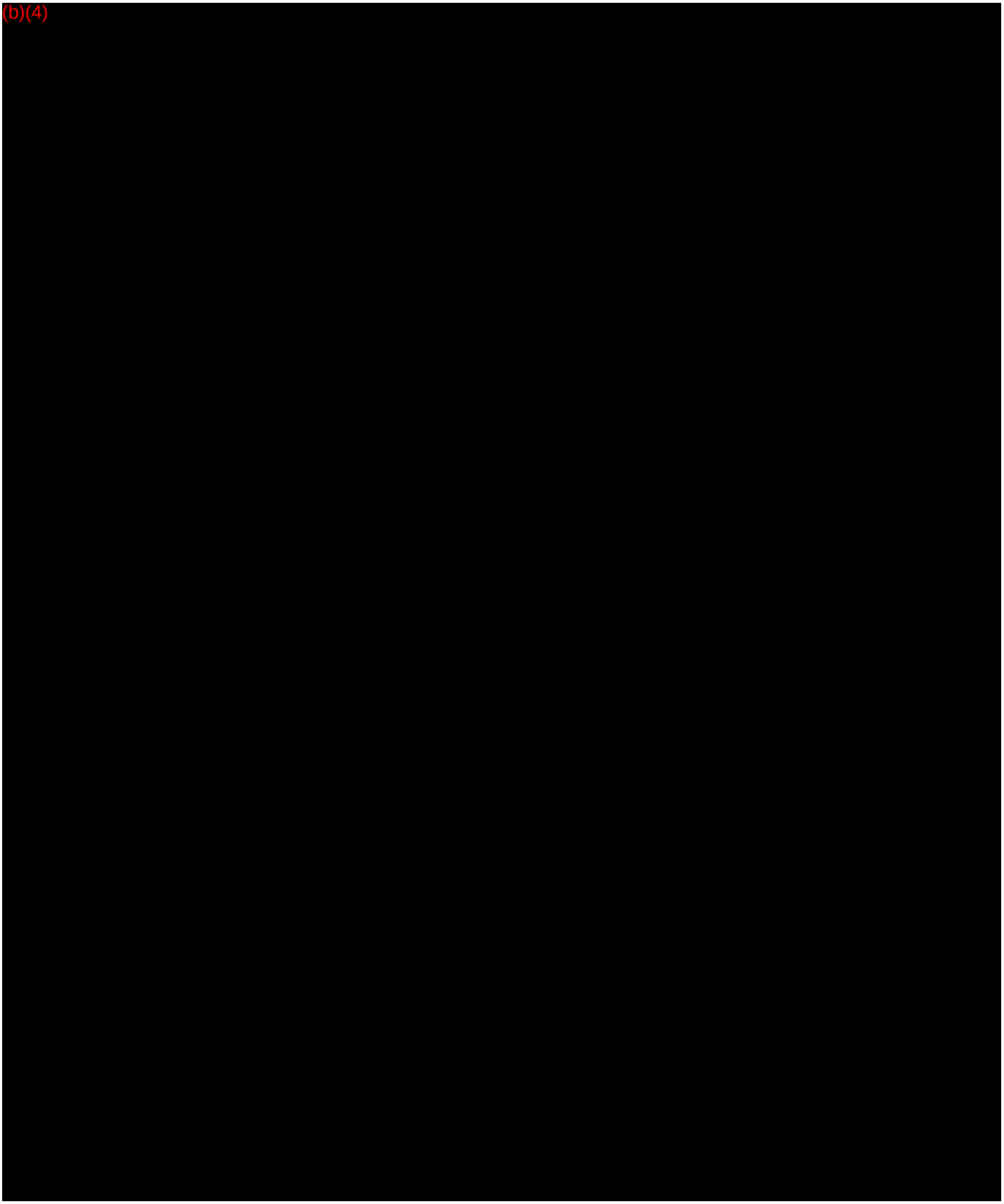

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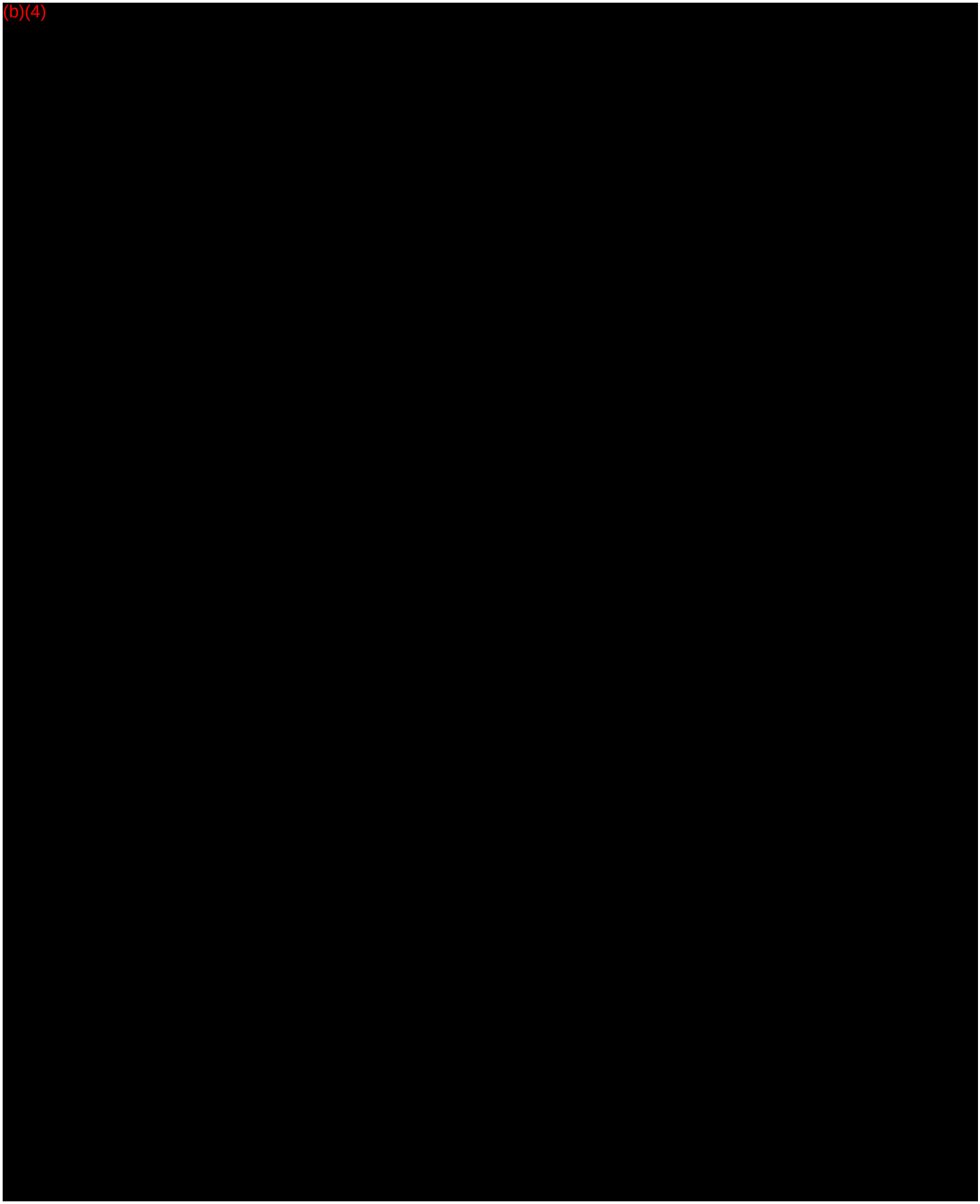

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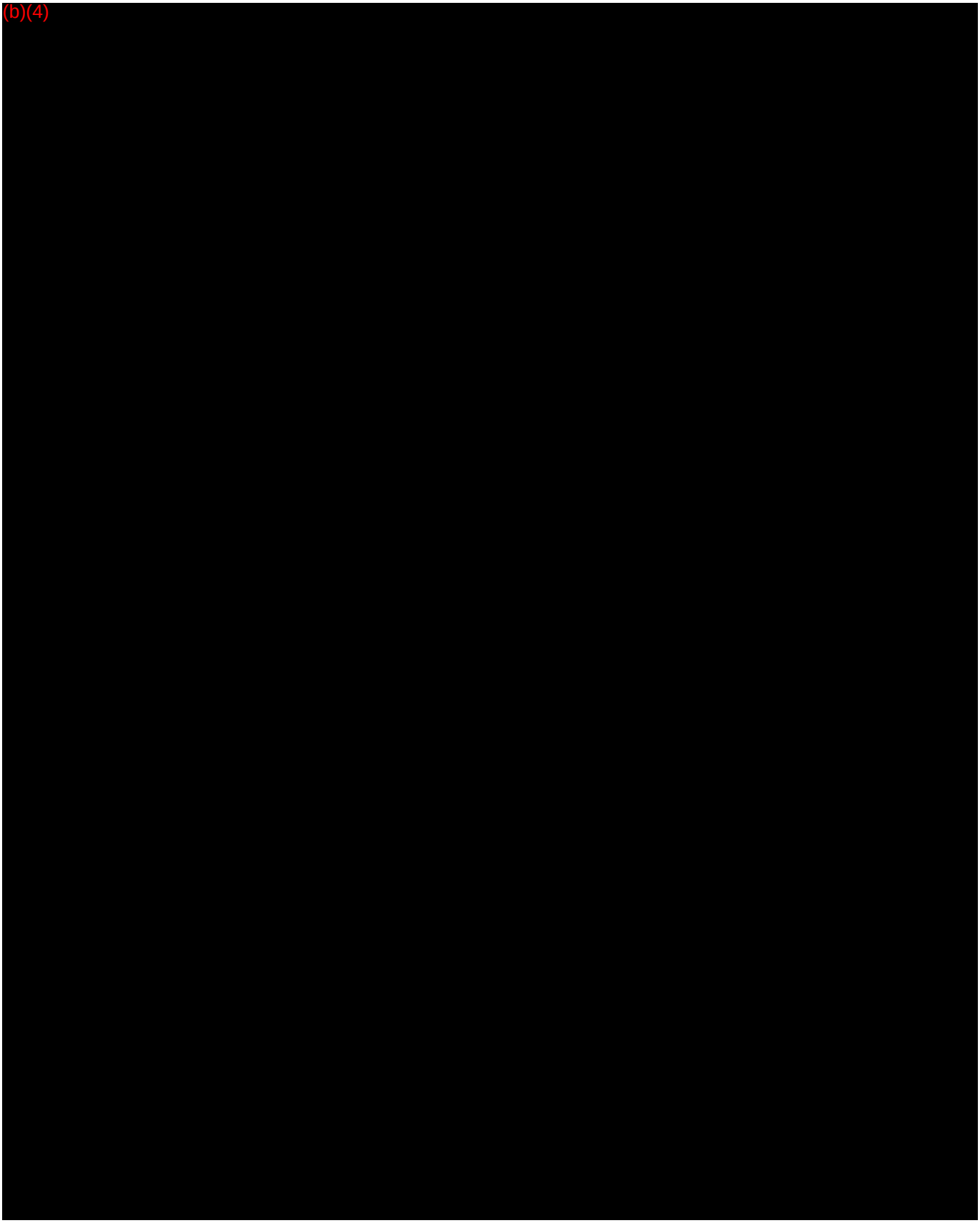

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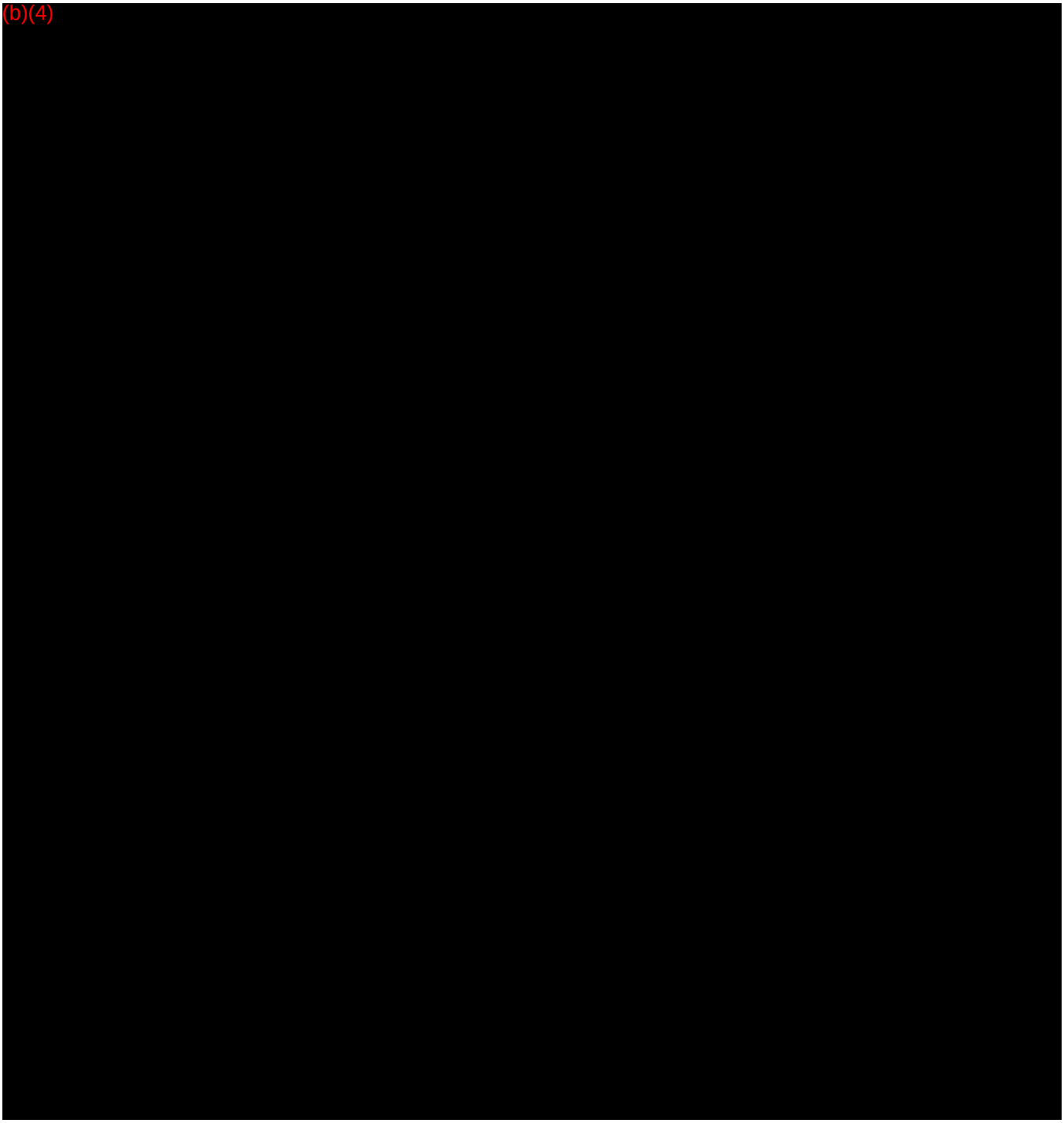

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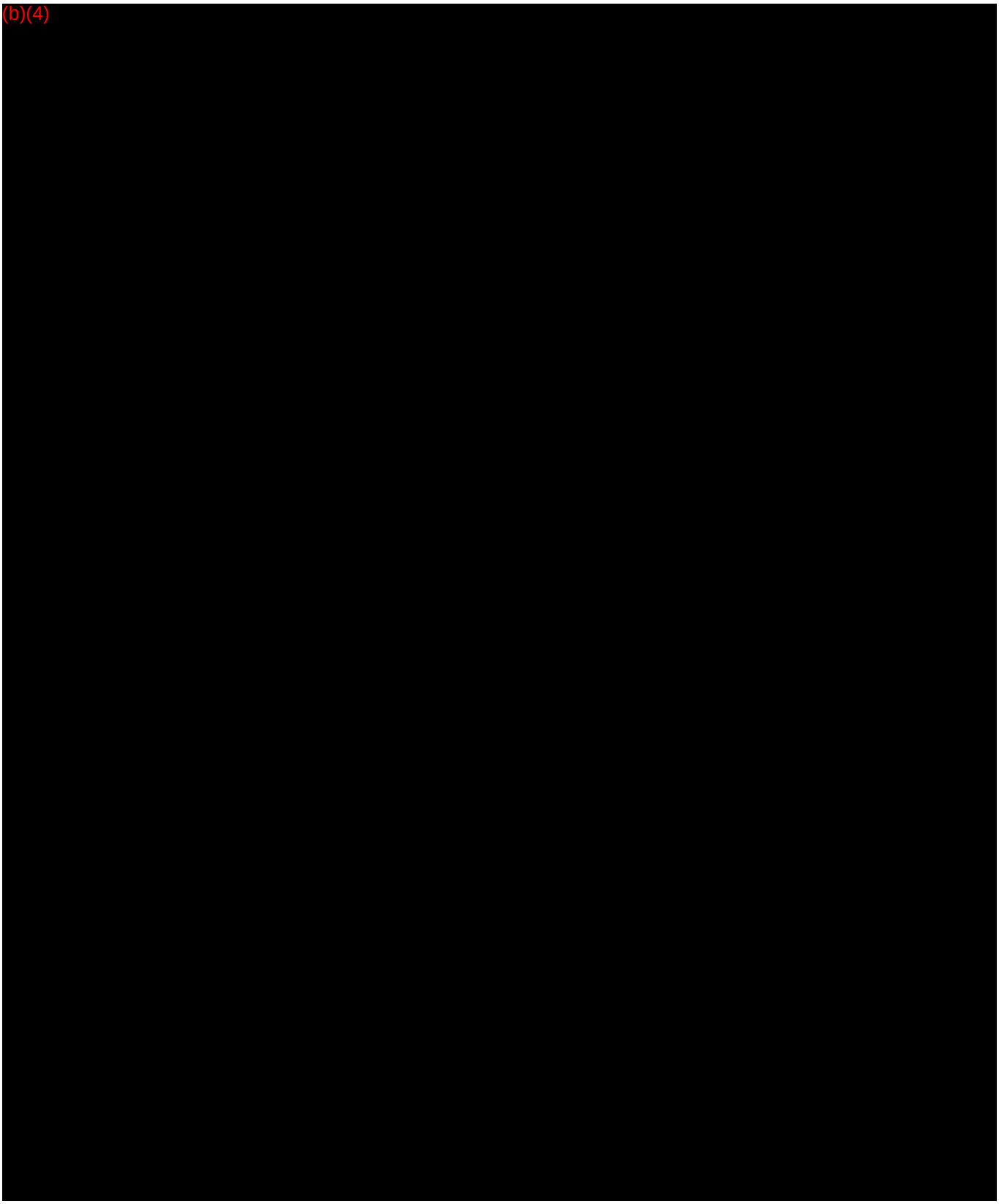

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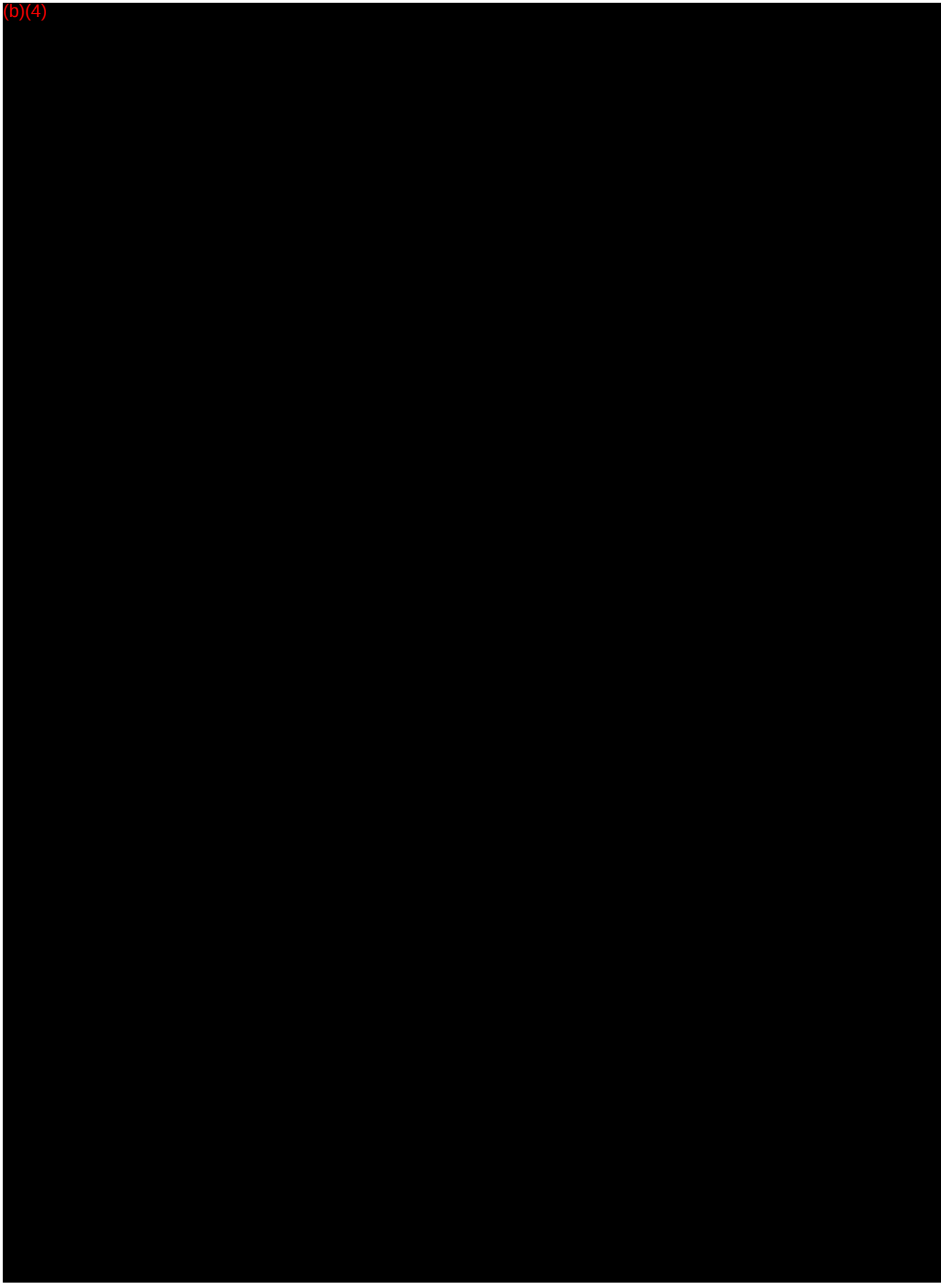

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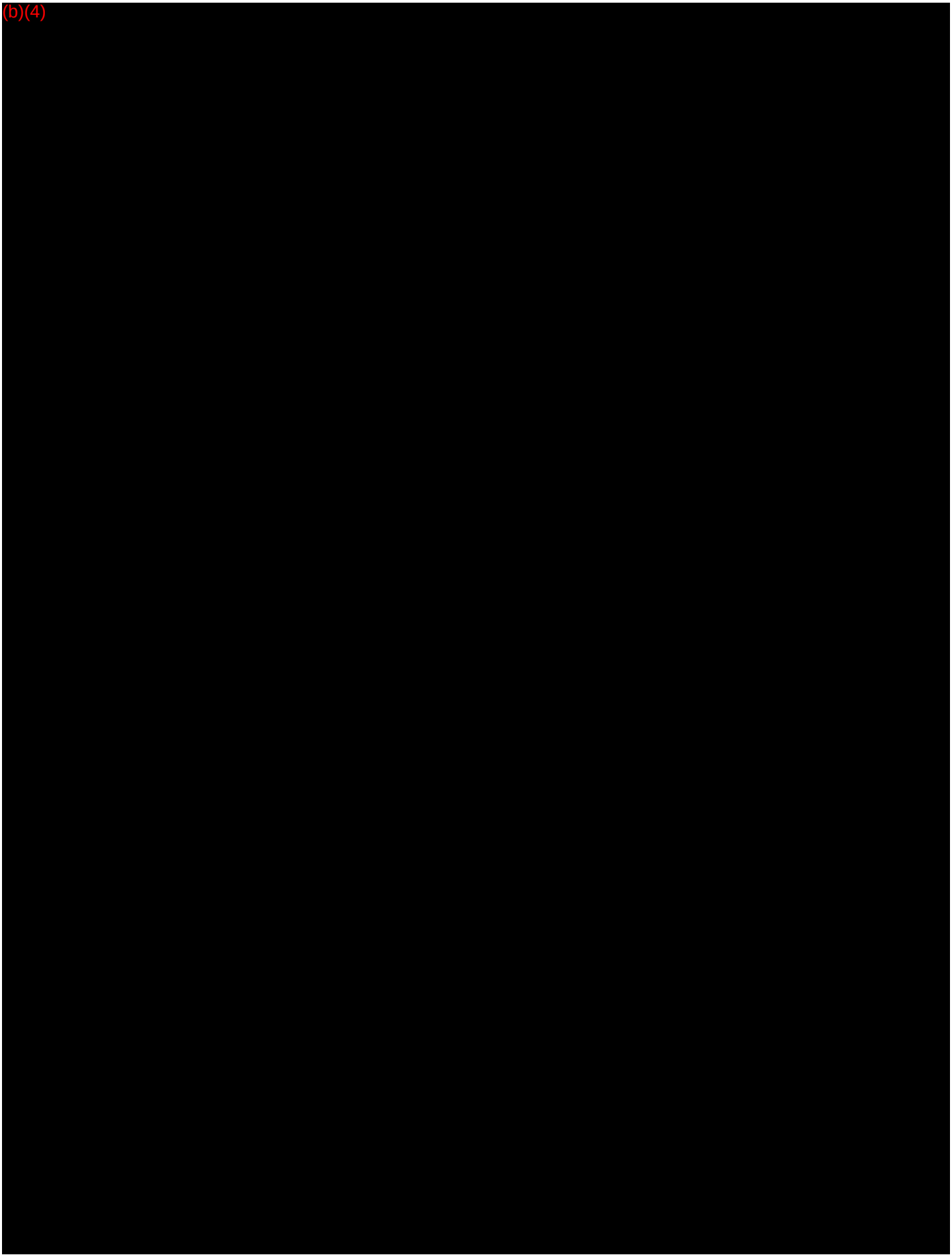

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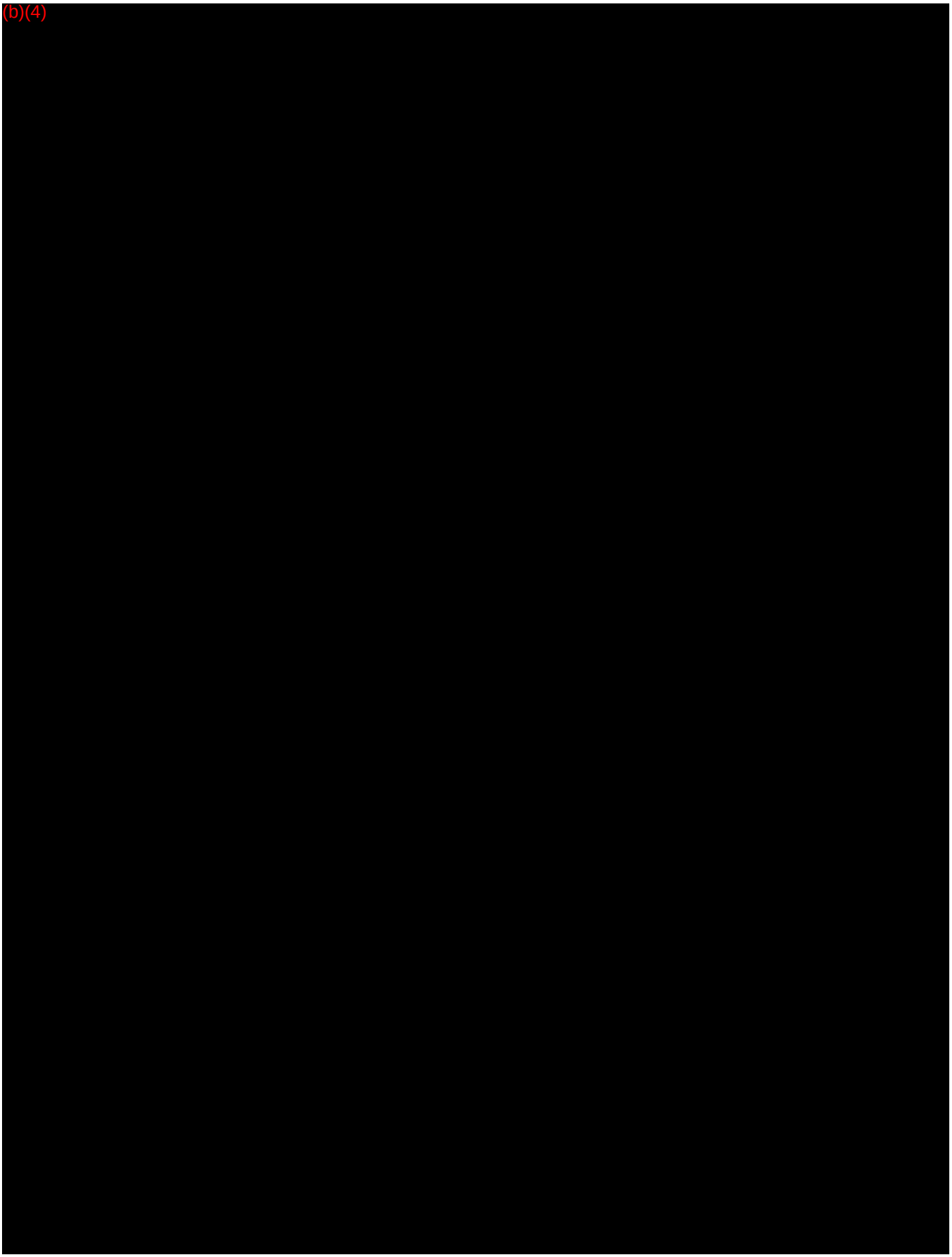

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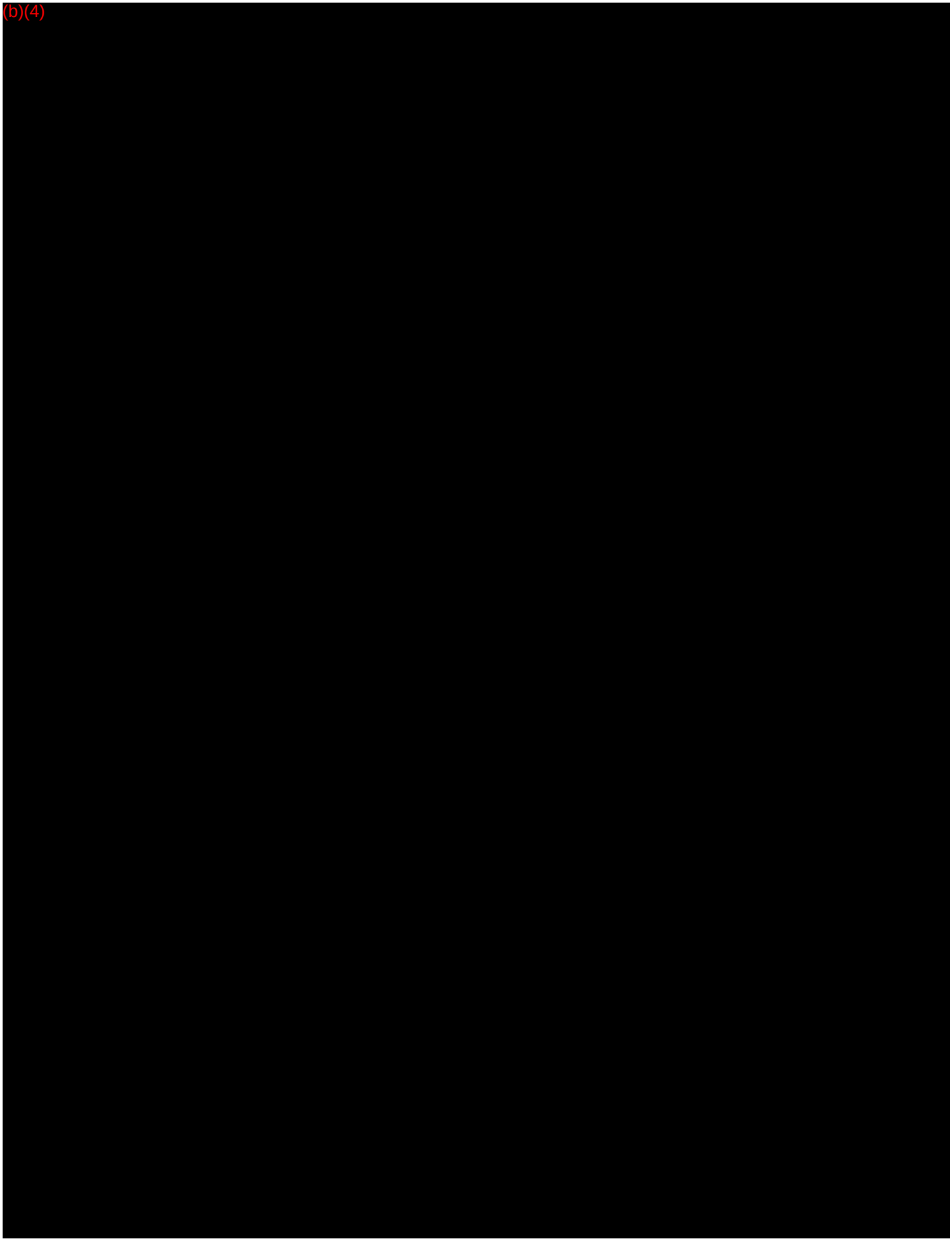

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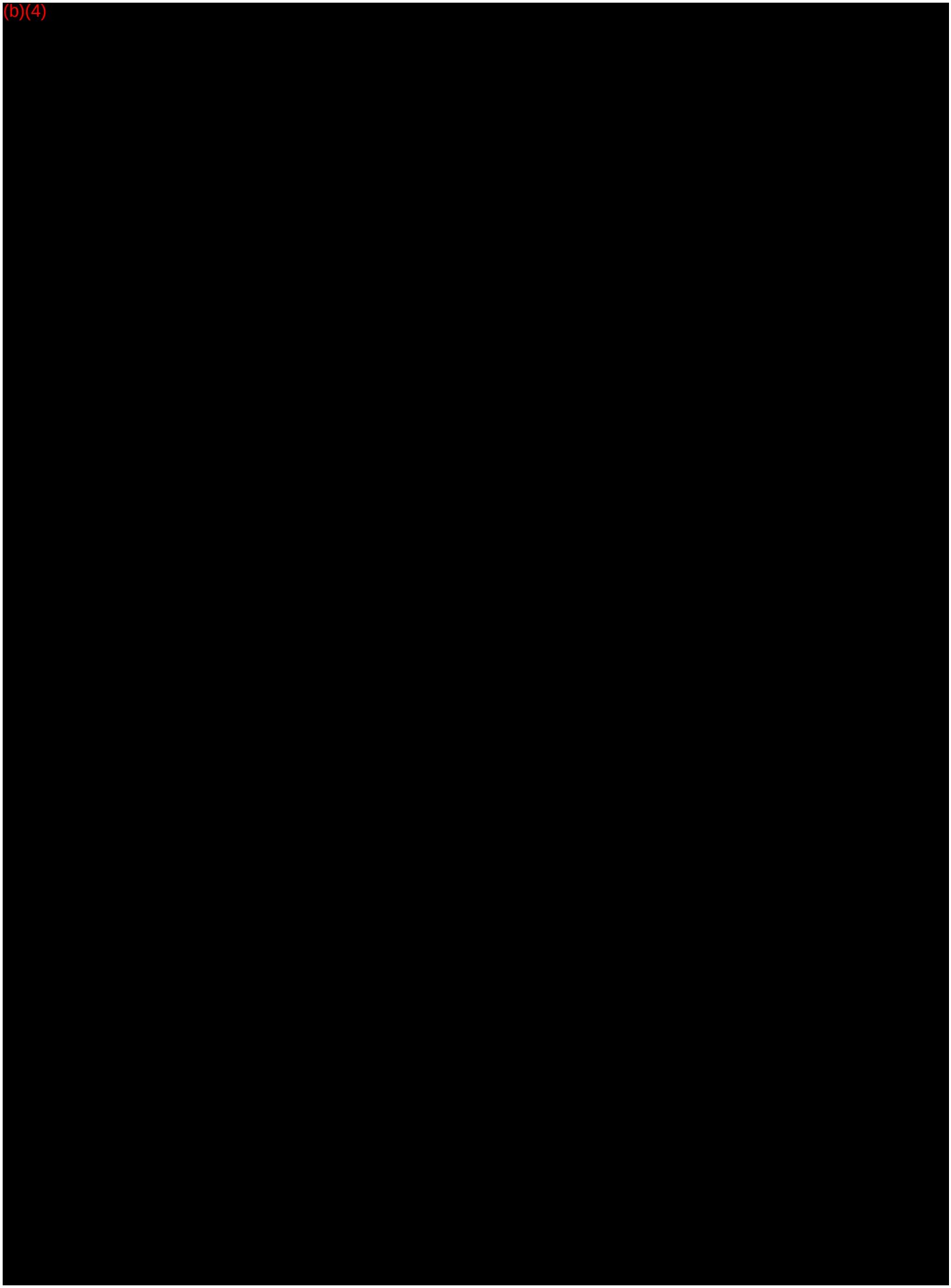

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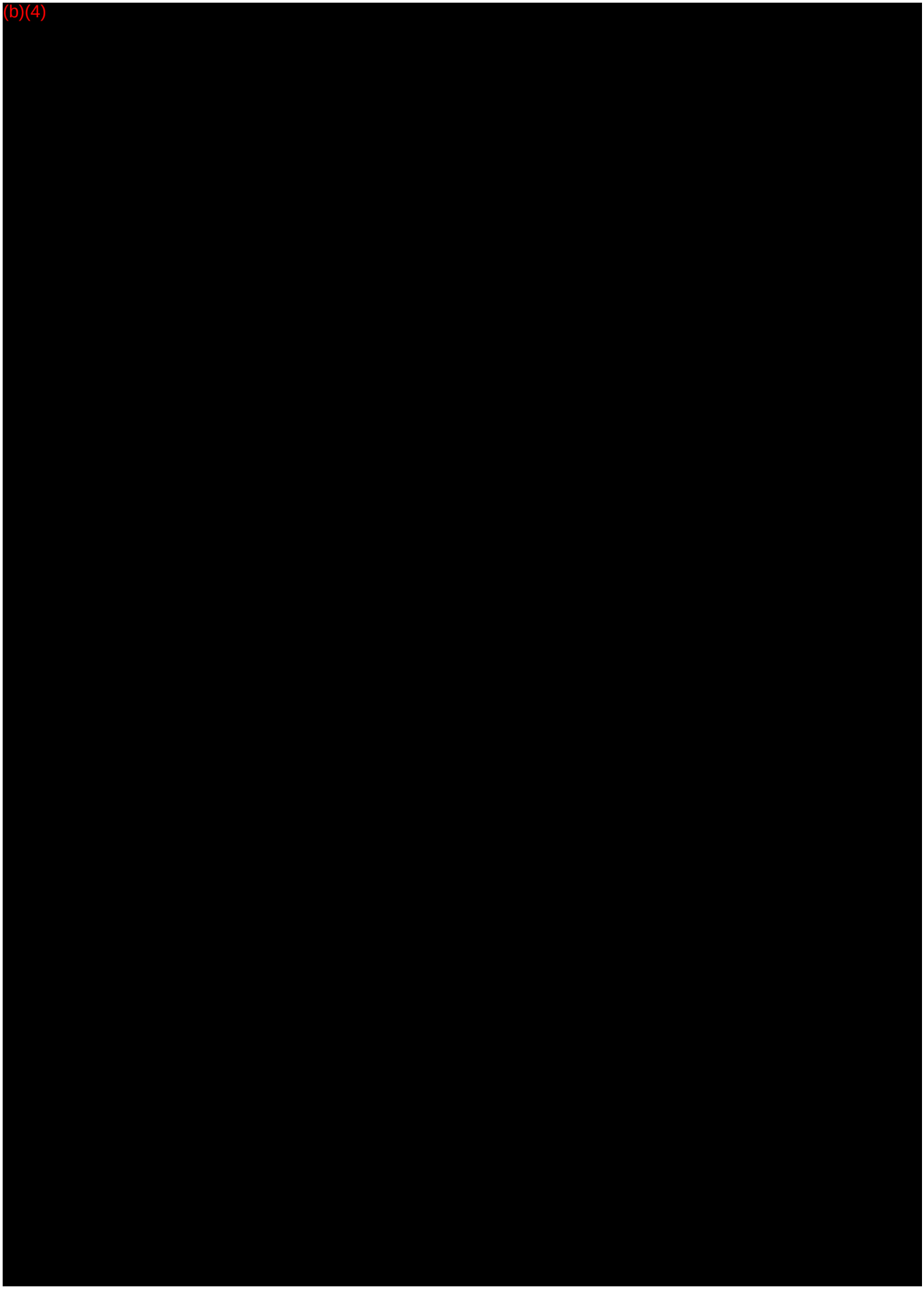

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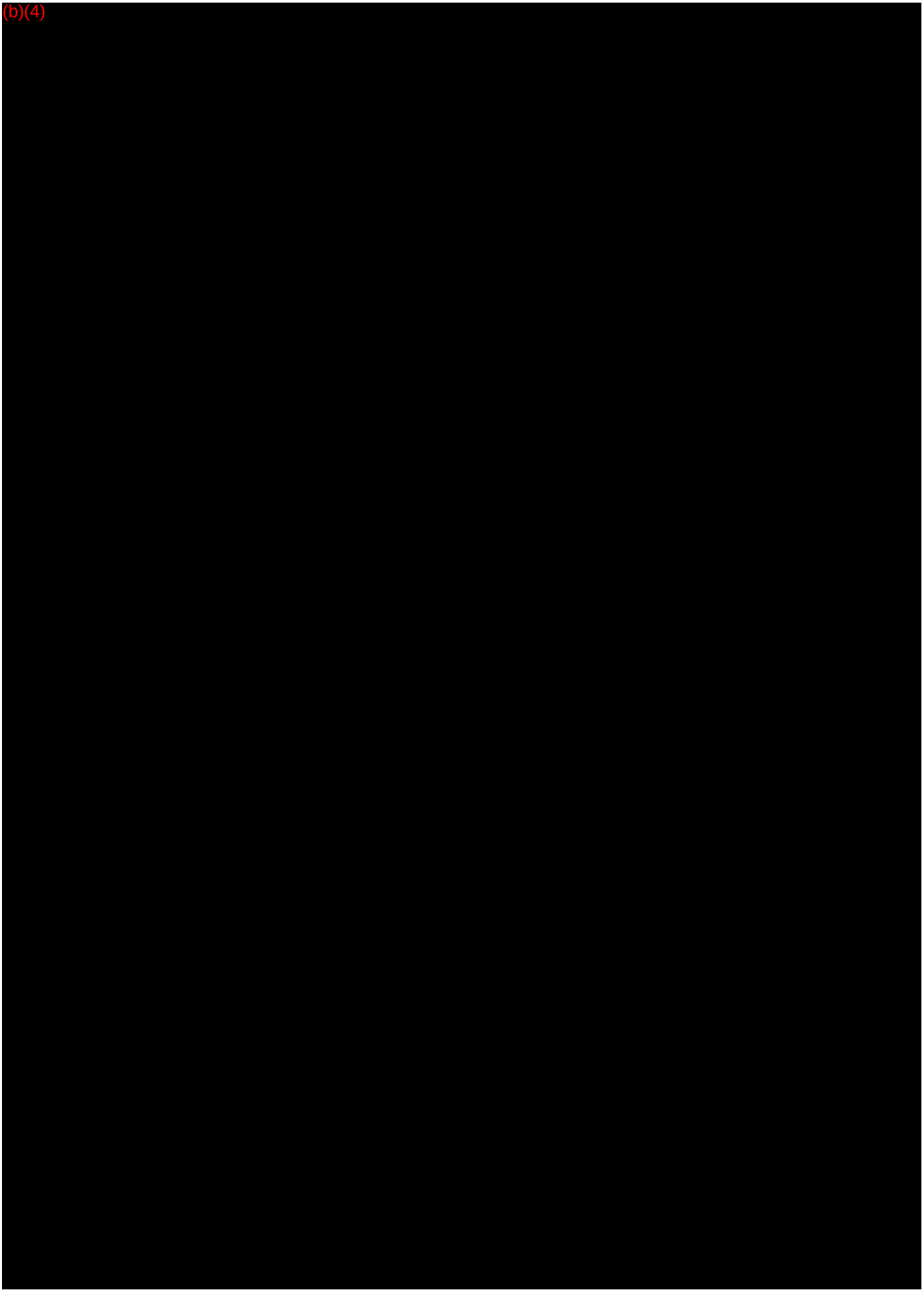

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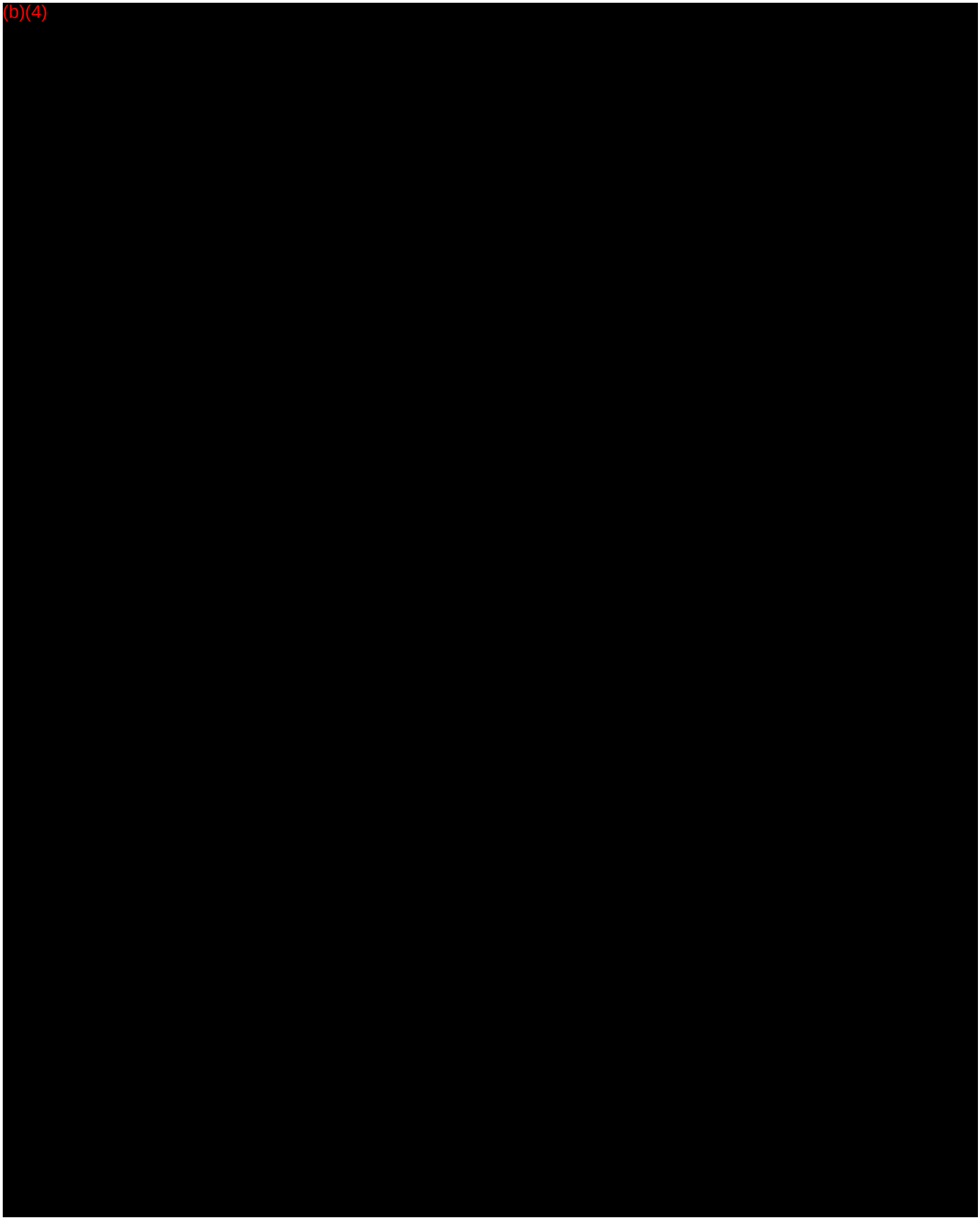

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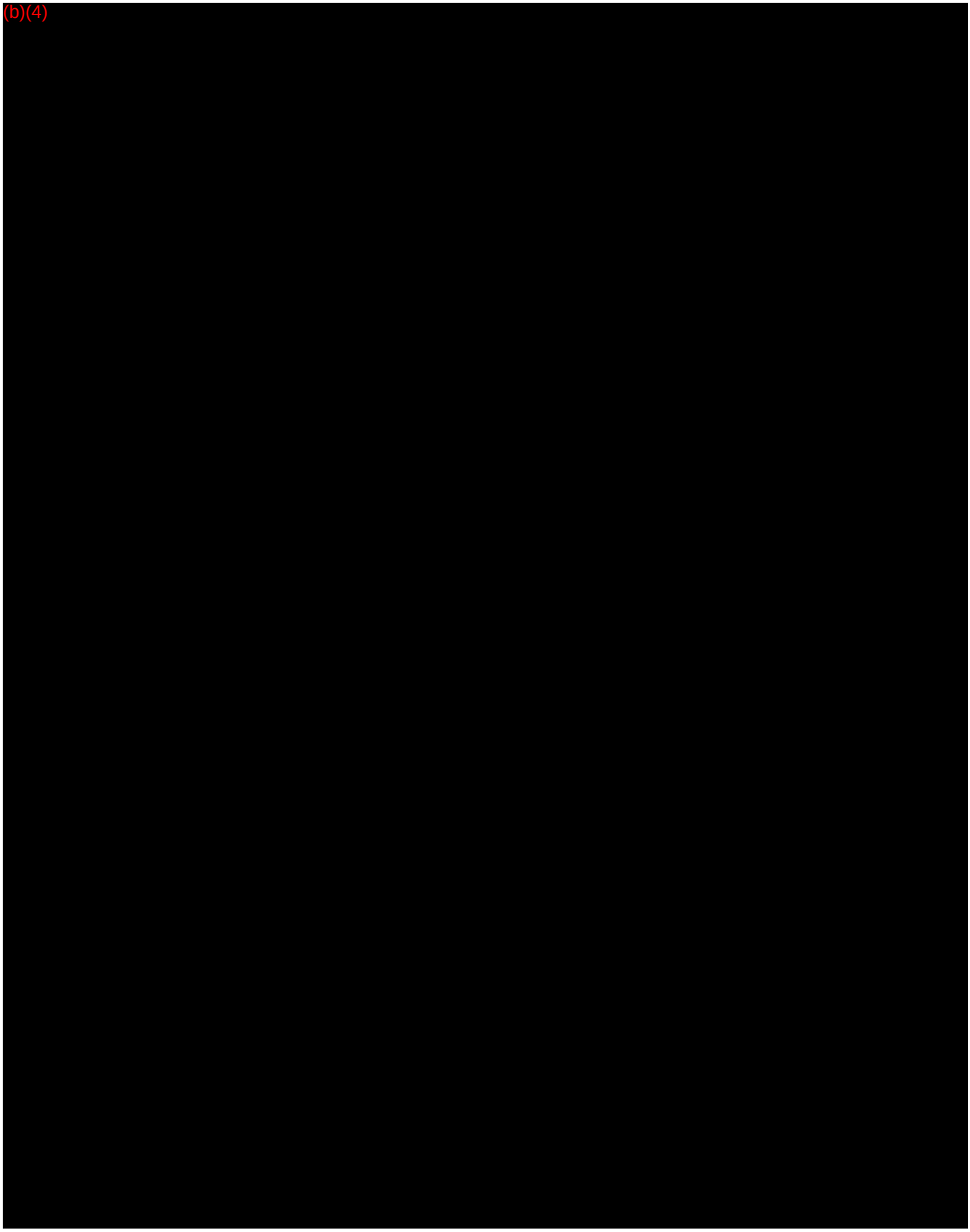

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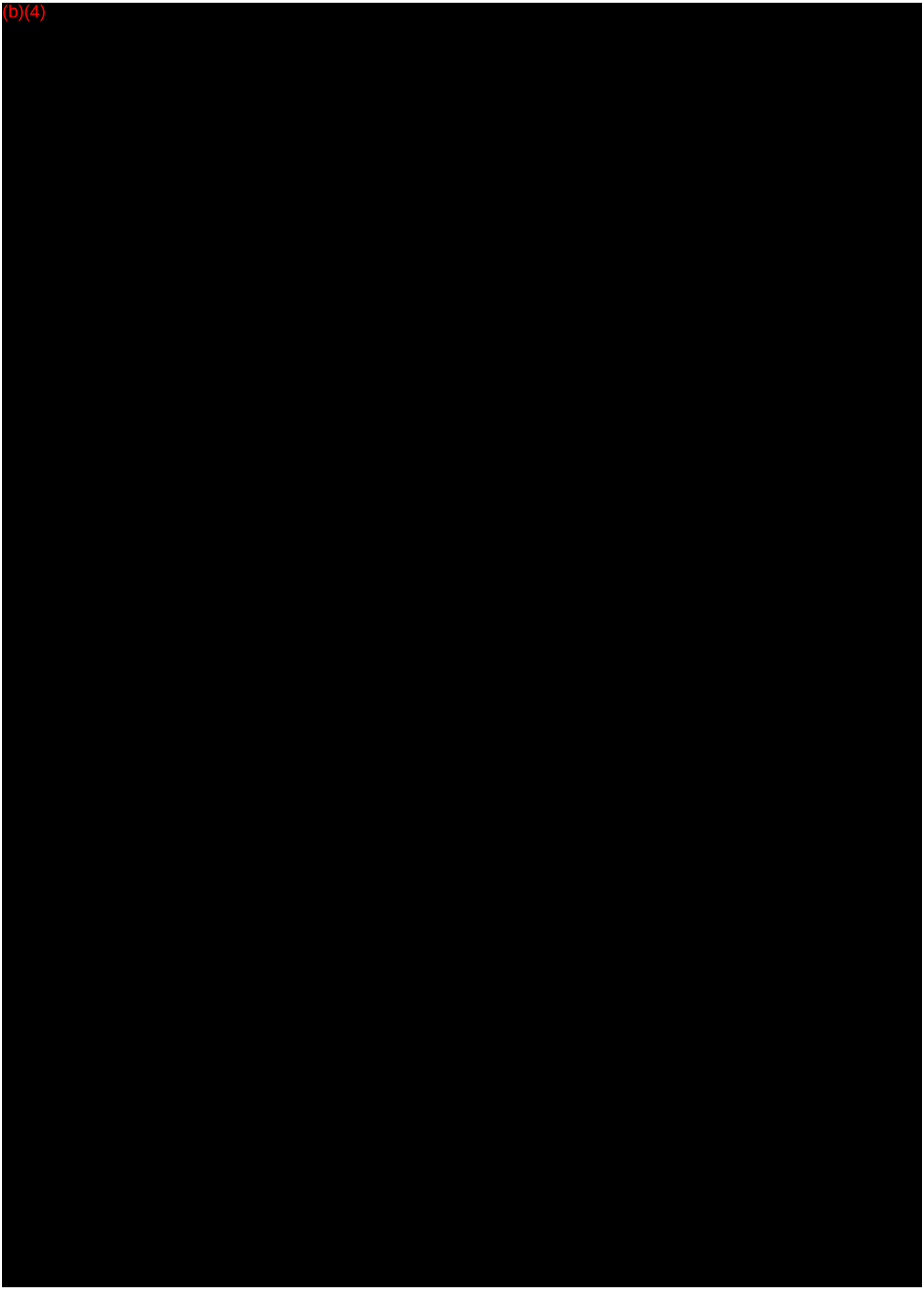

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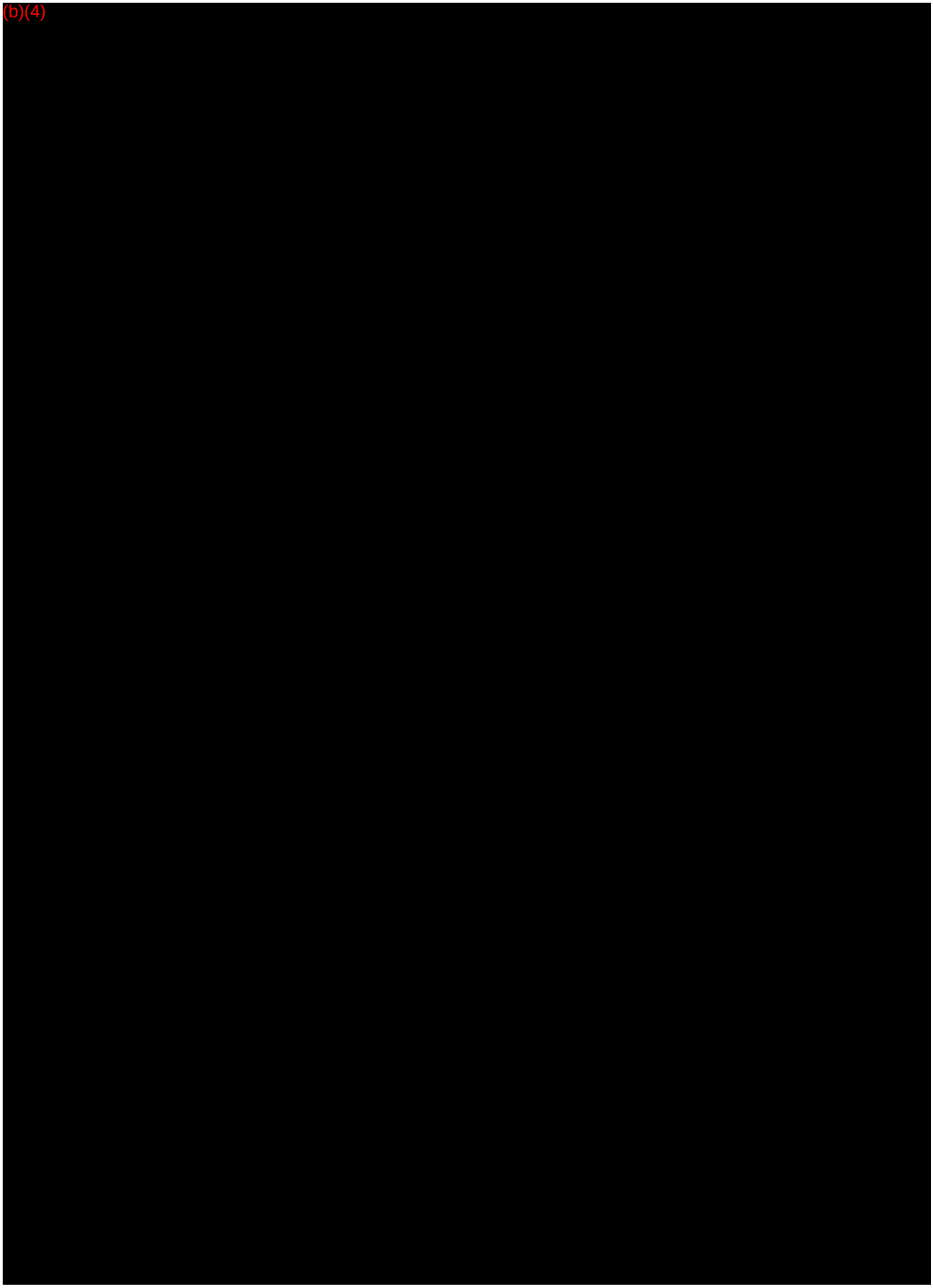

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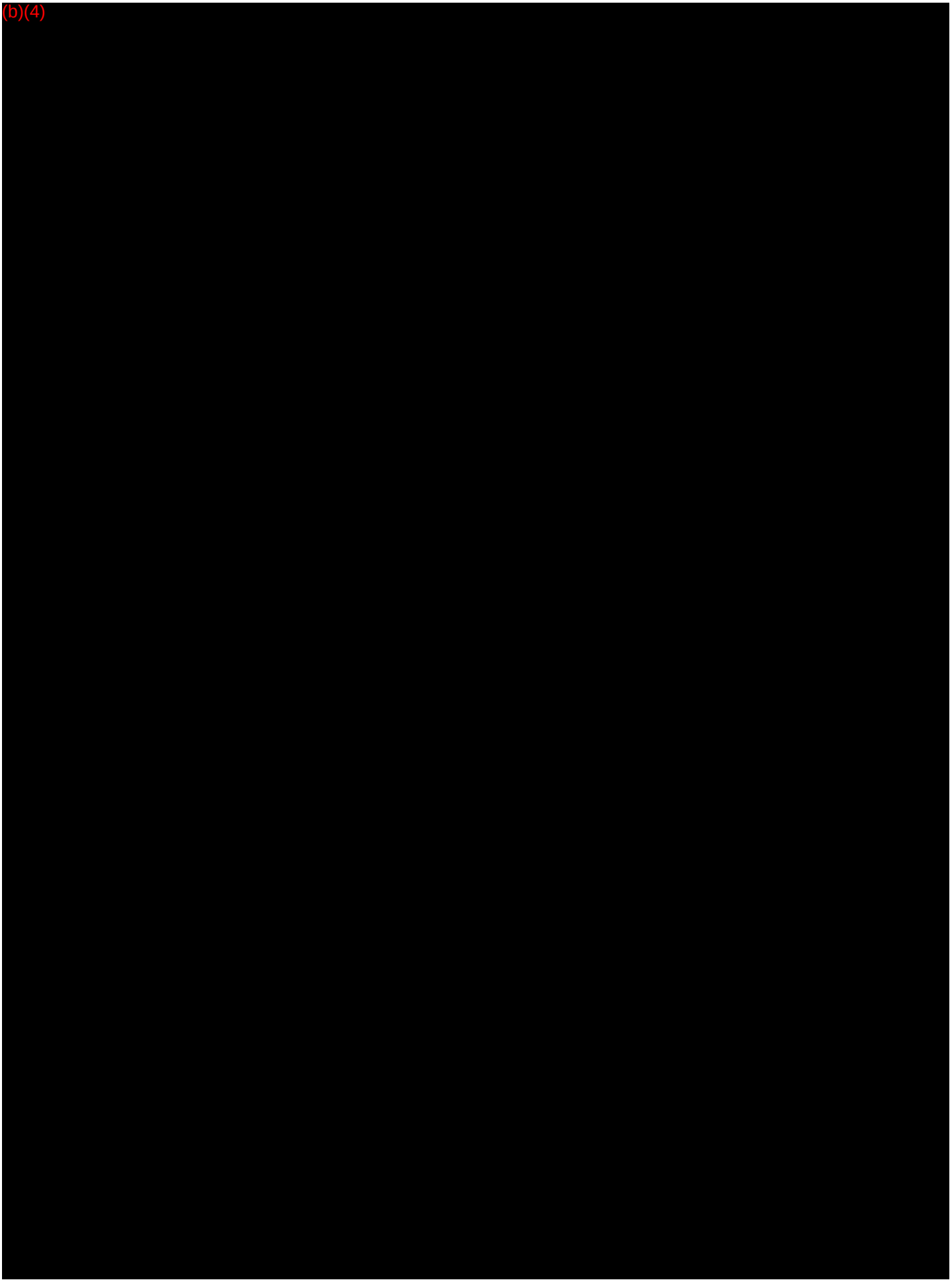

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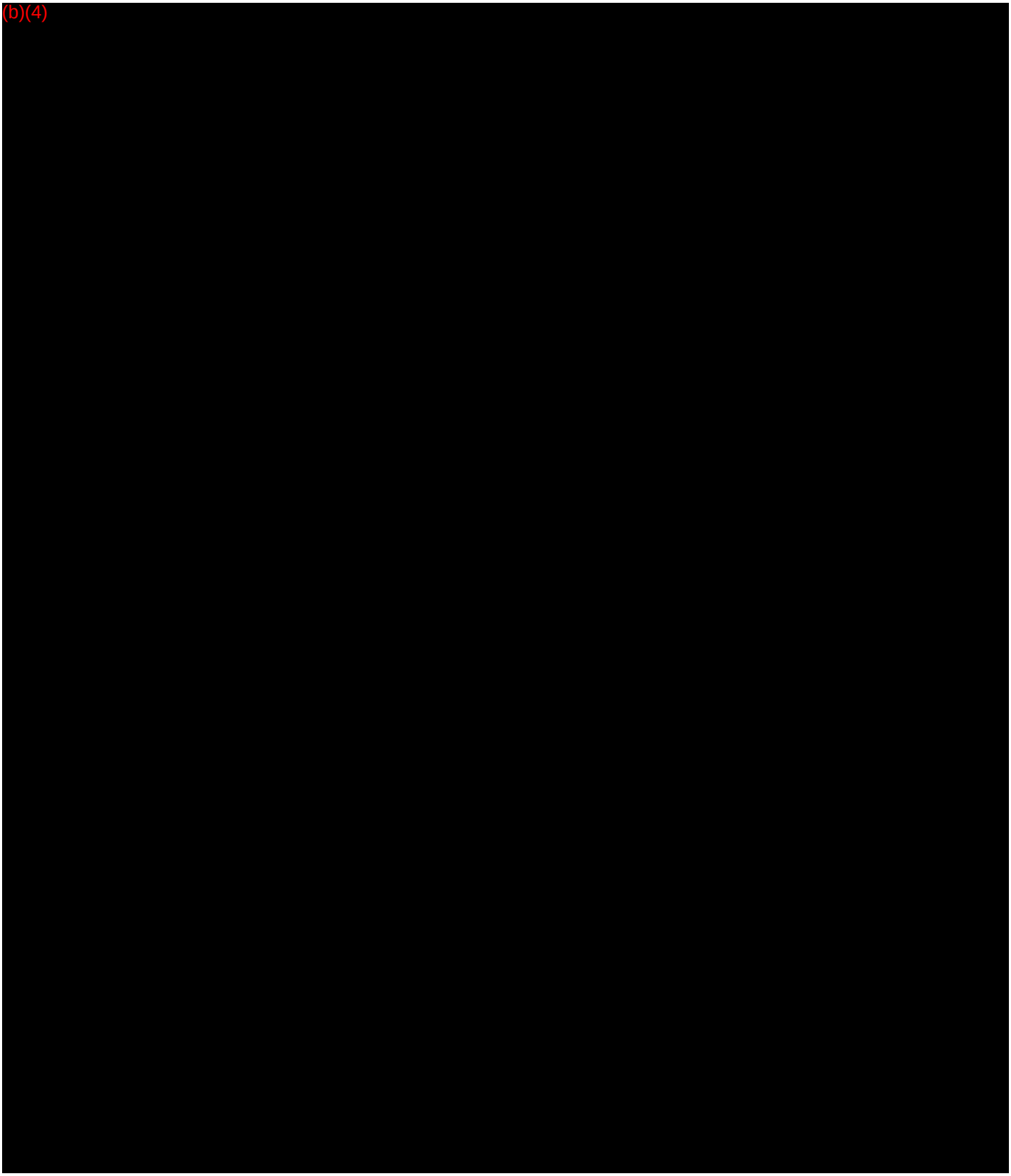

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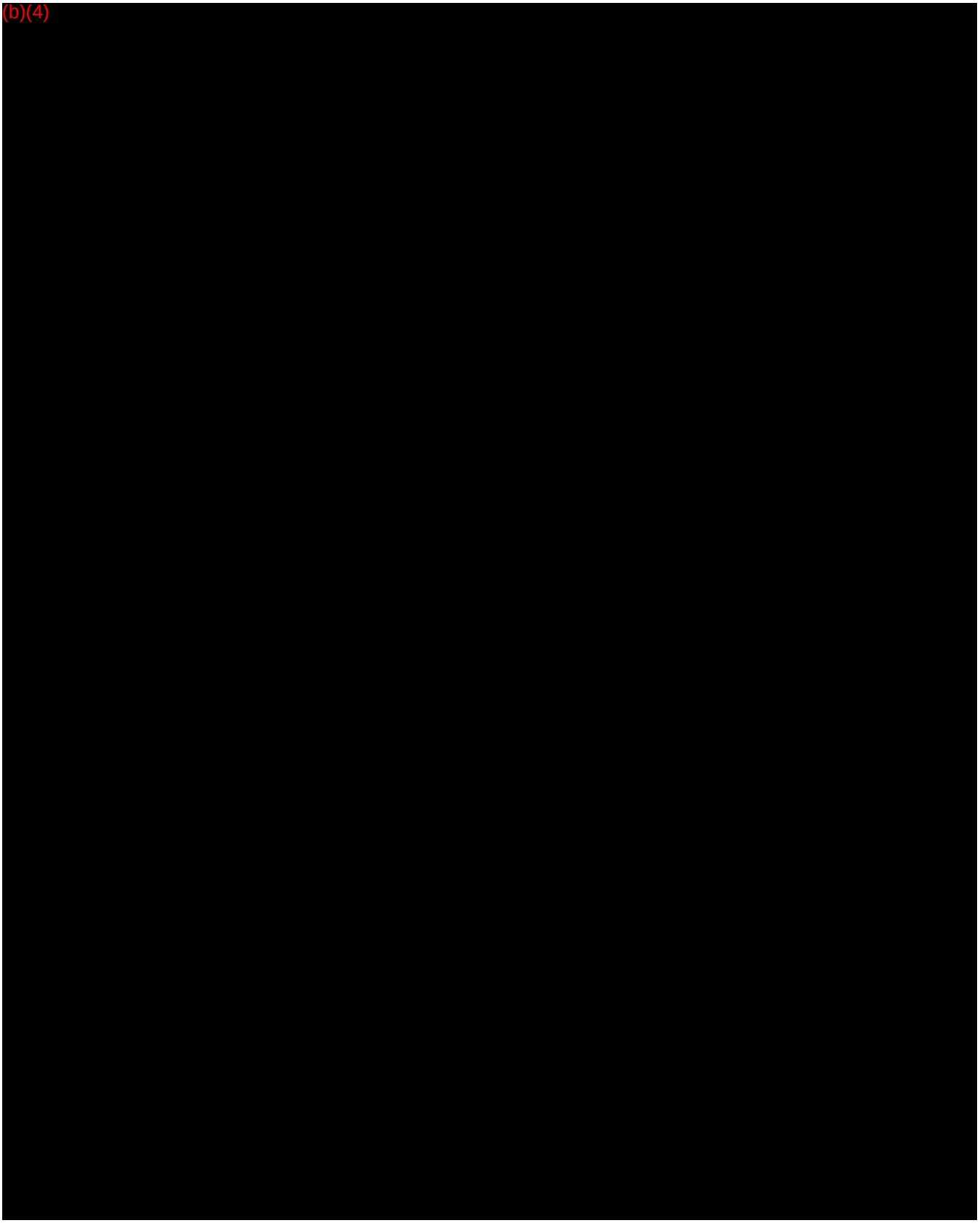

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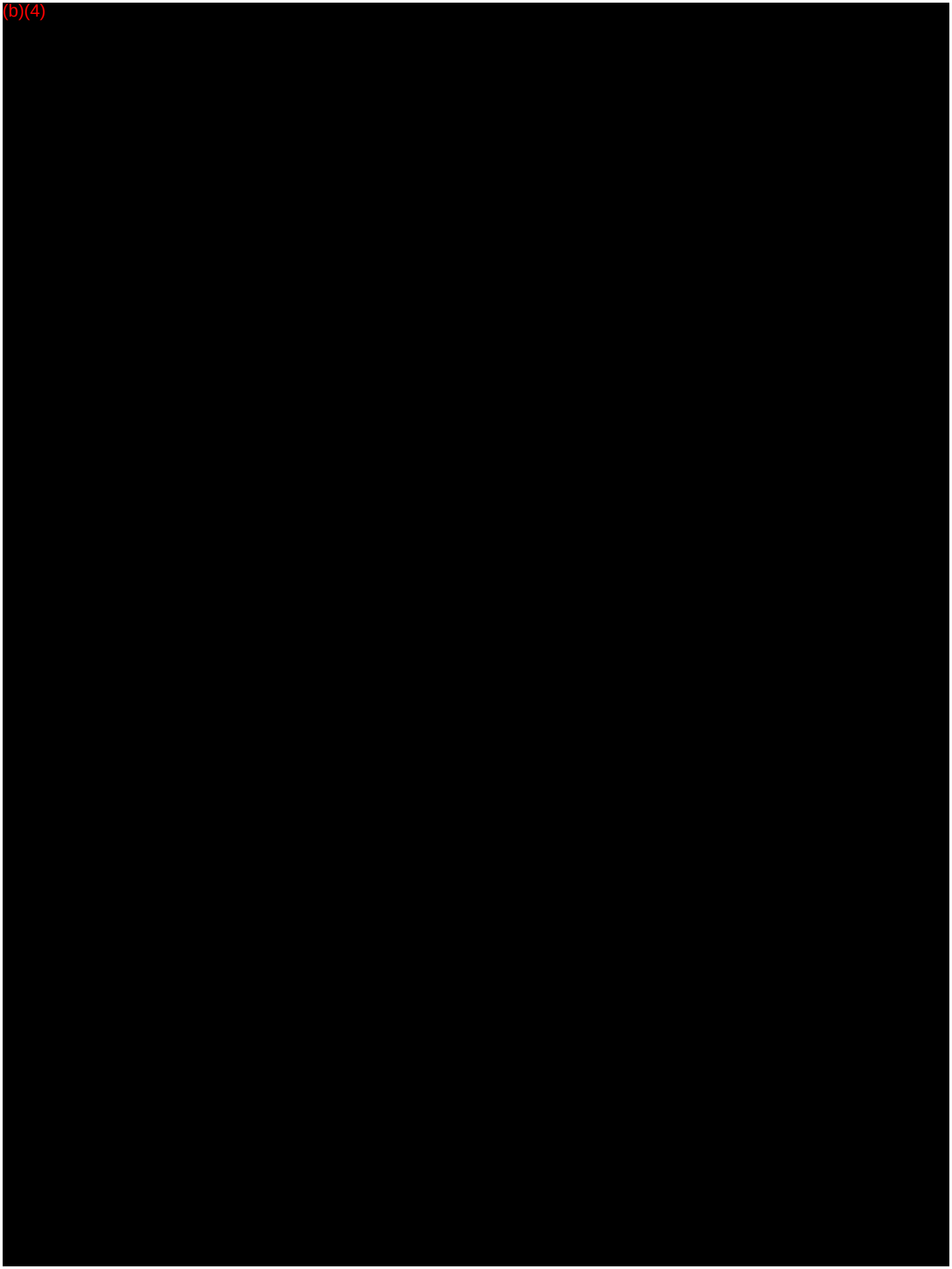

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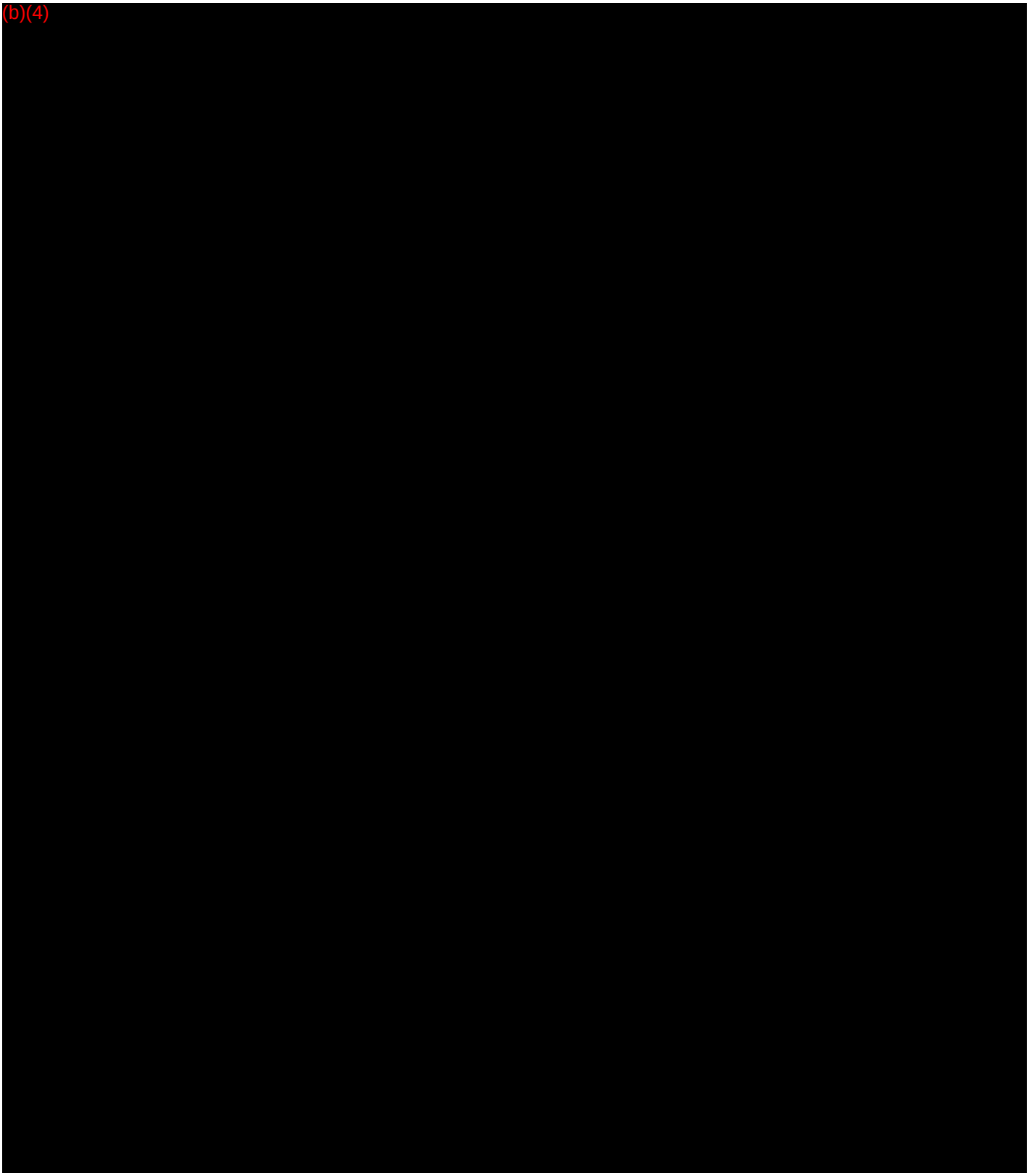

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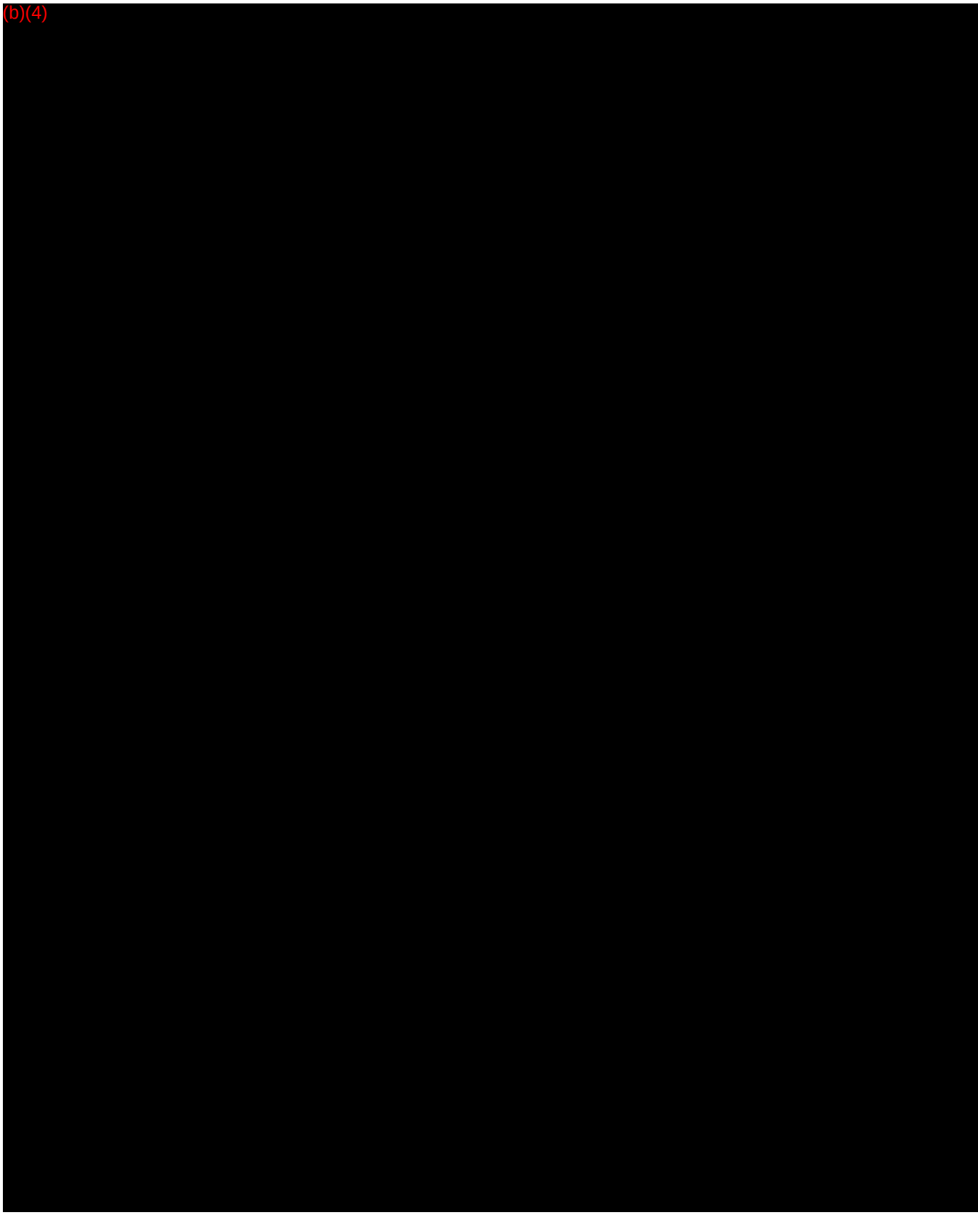

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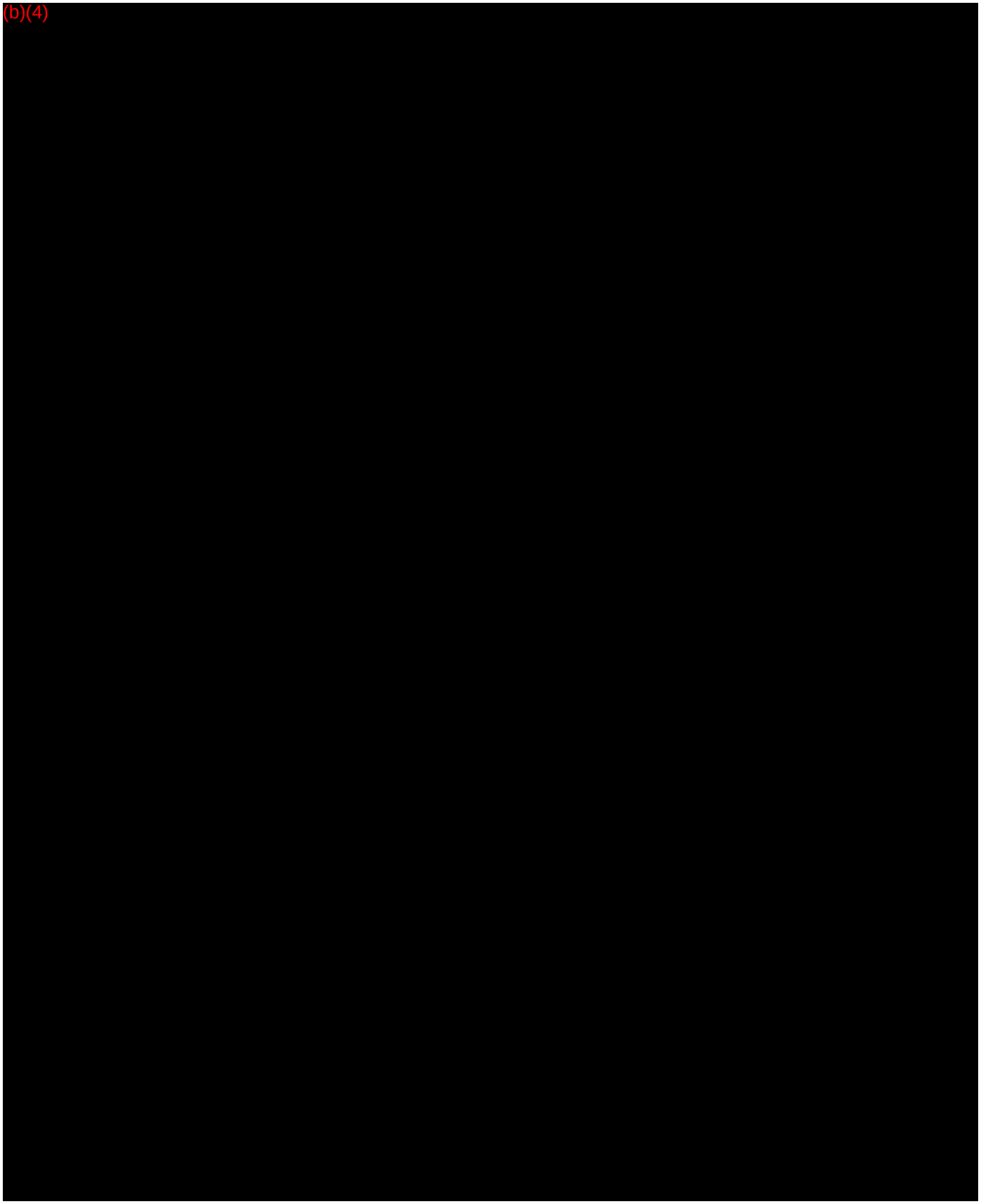

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Software Specification – (b)(4)

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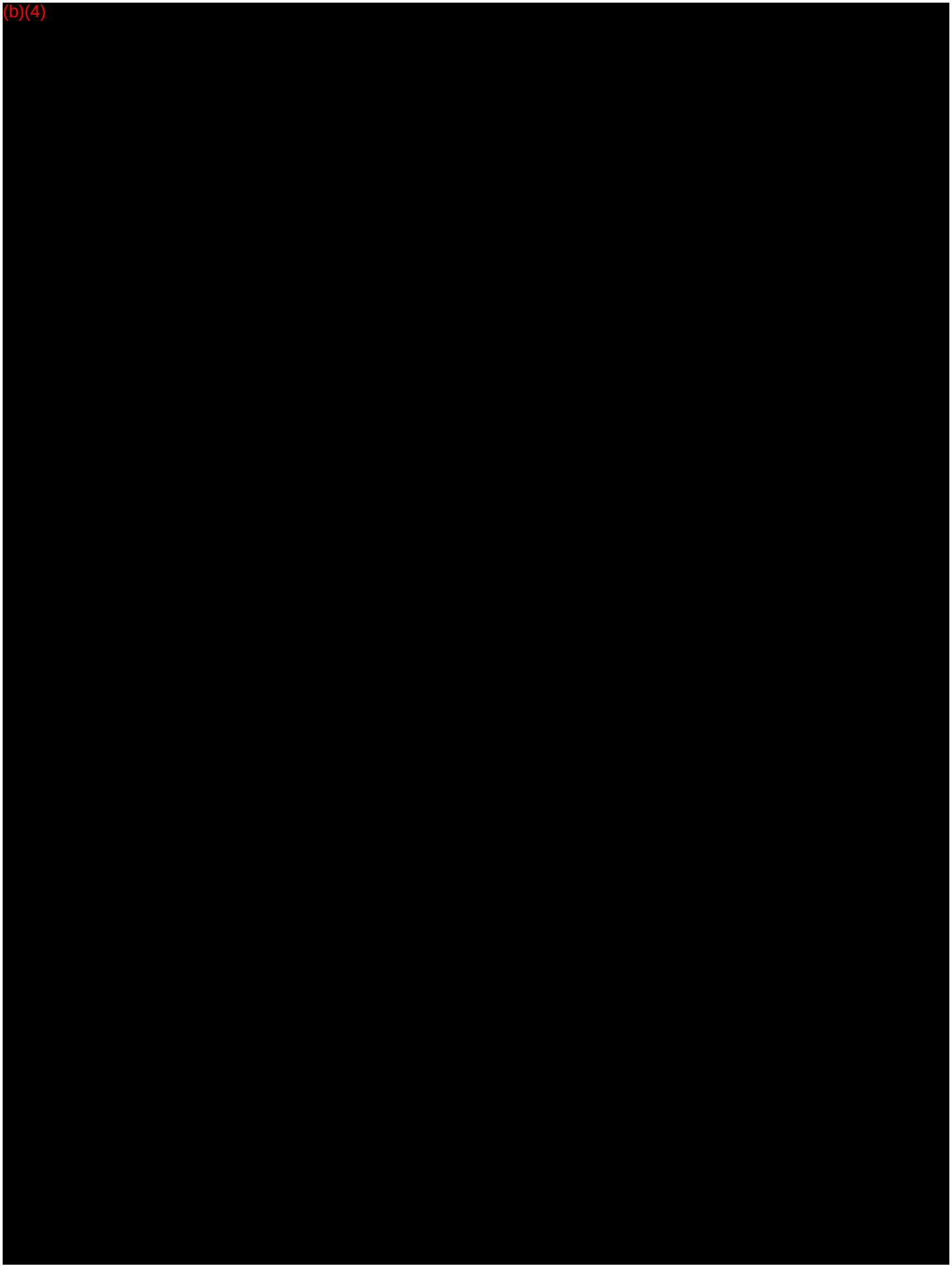

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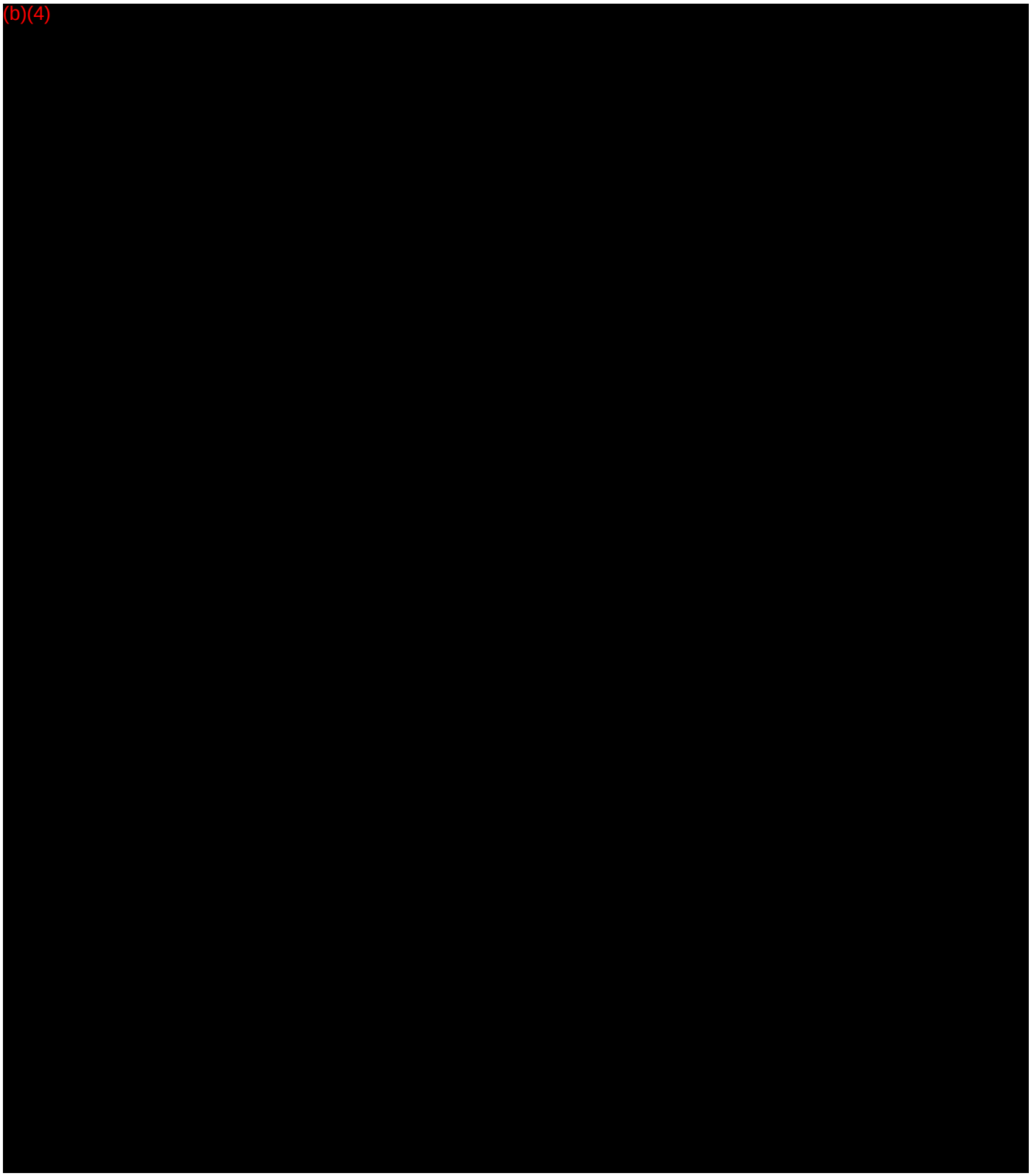

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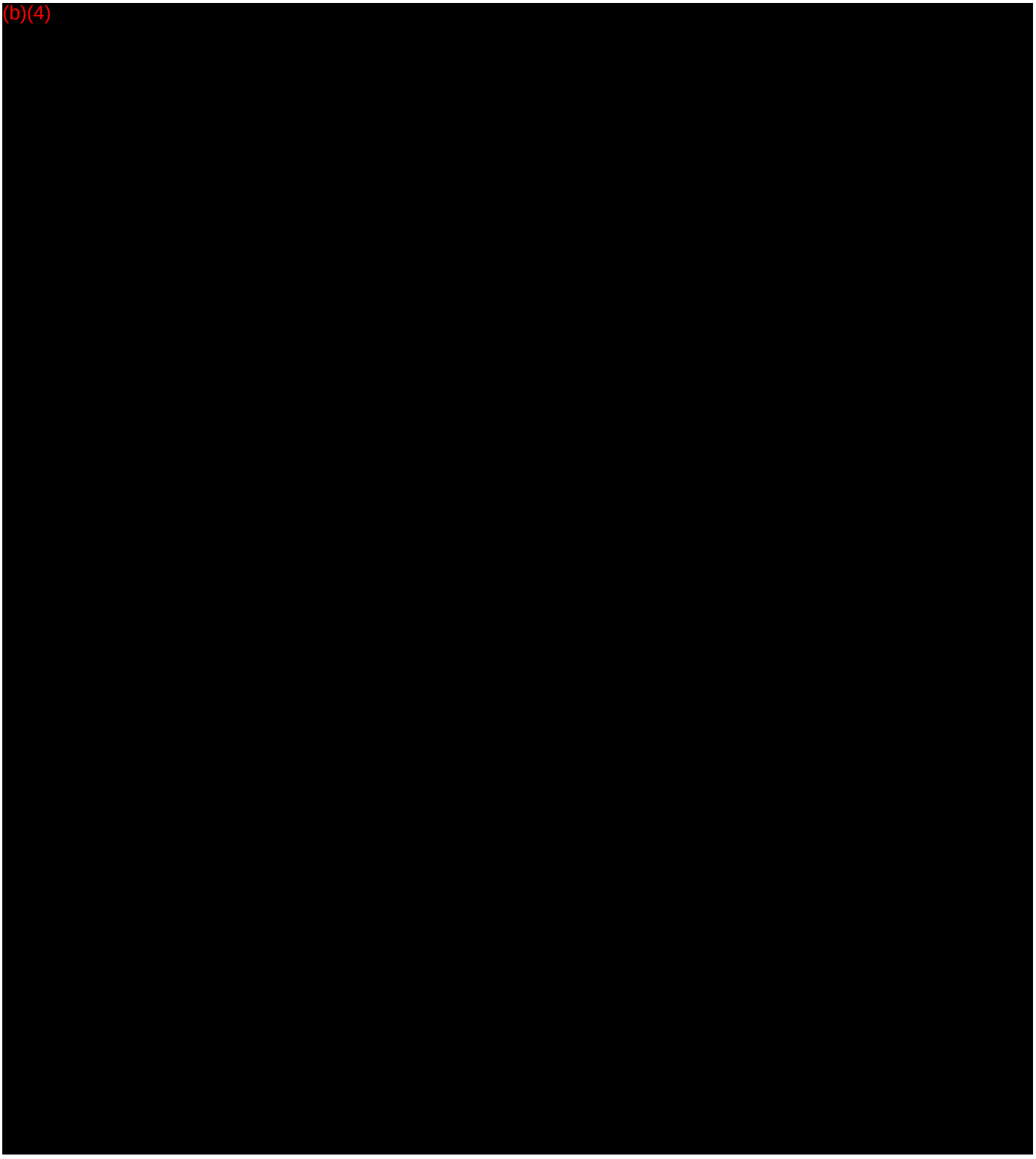

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PRODUCT RISK ASSESSMENT

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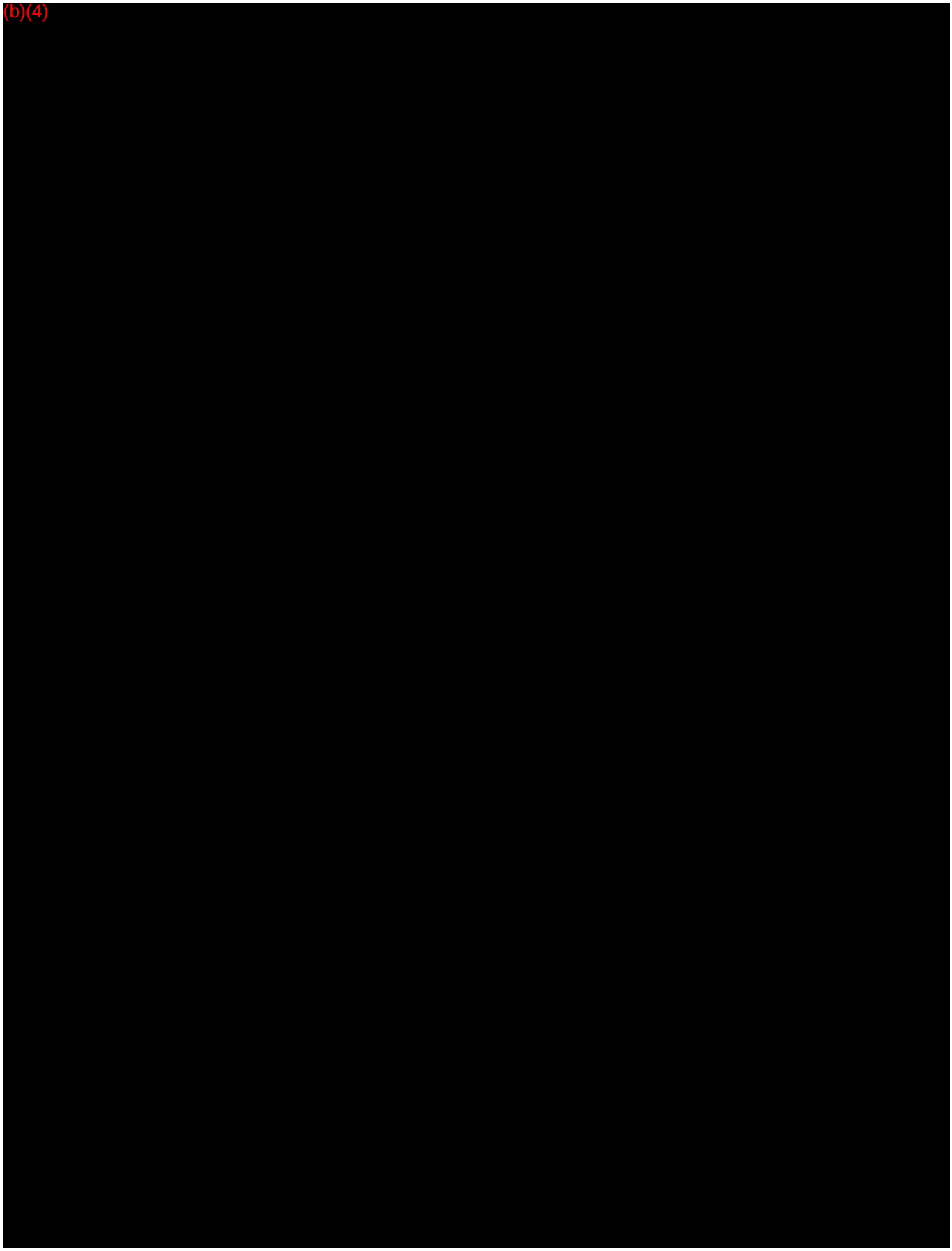

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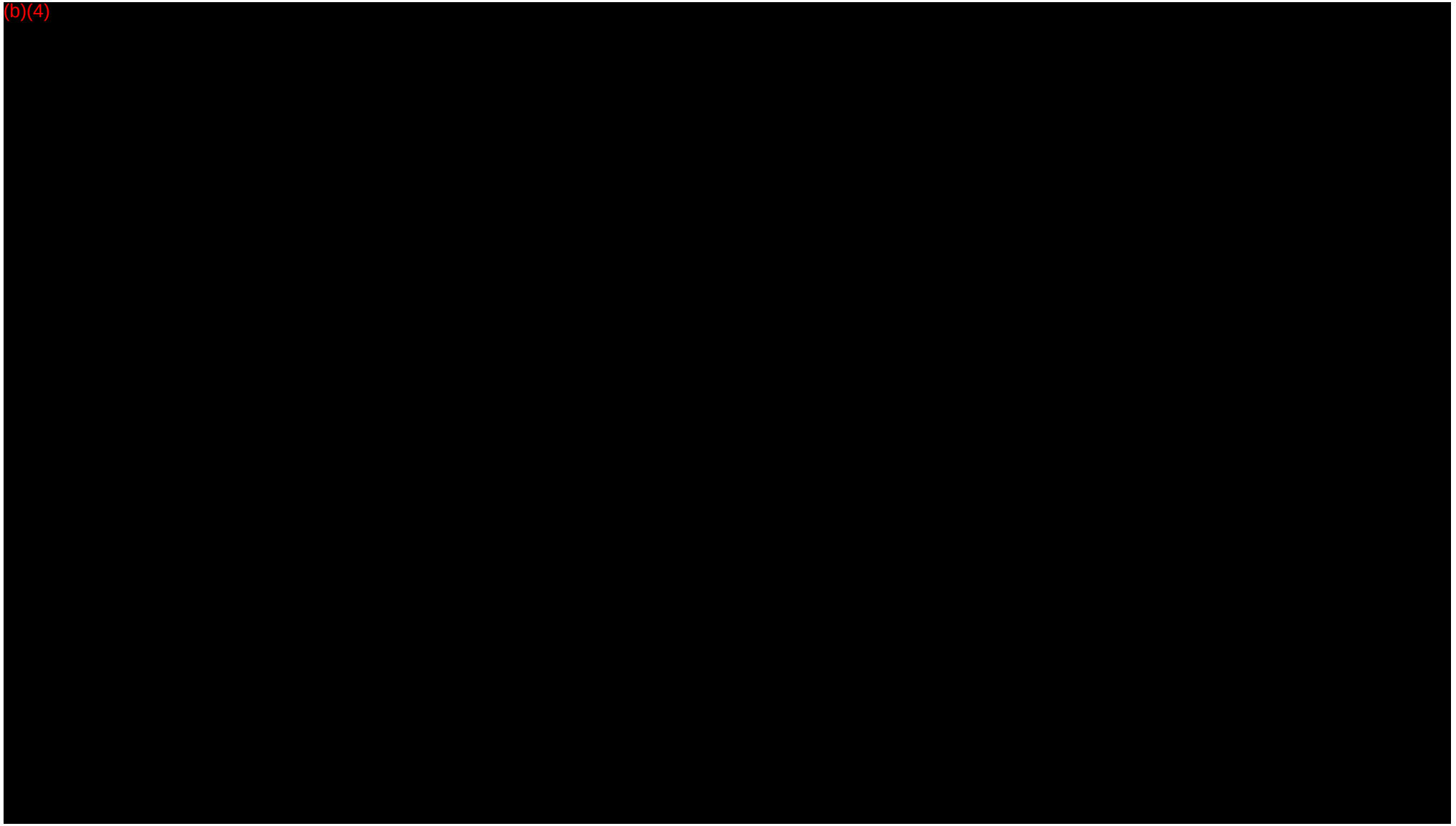

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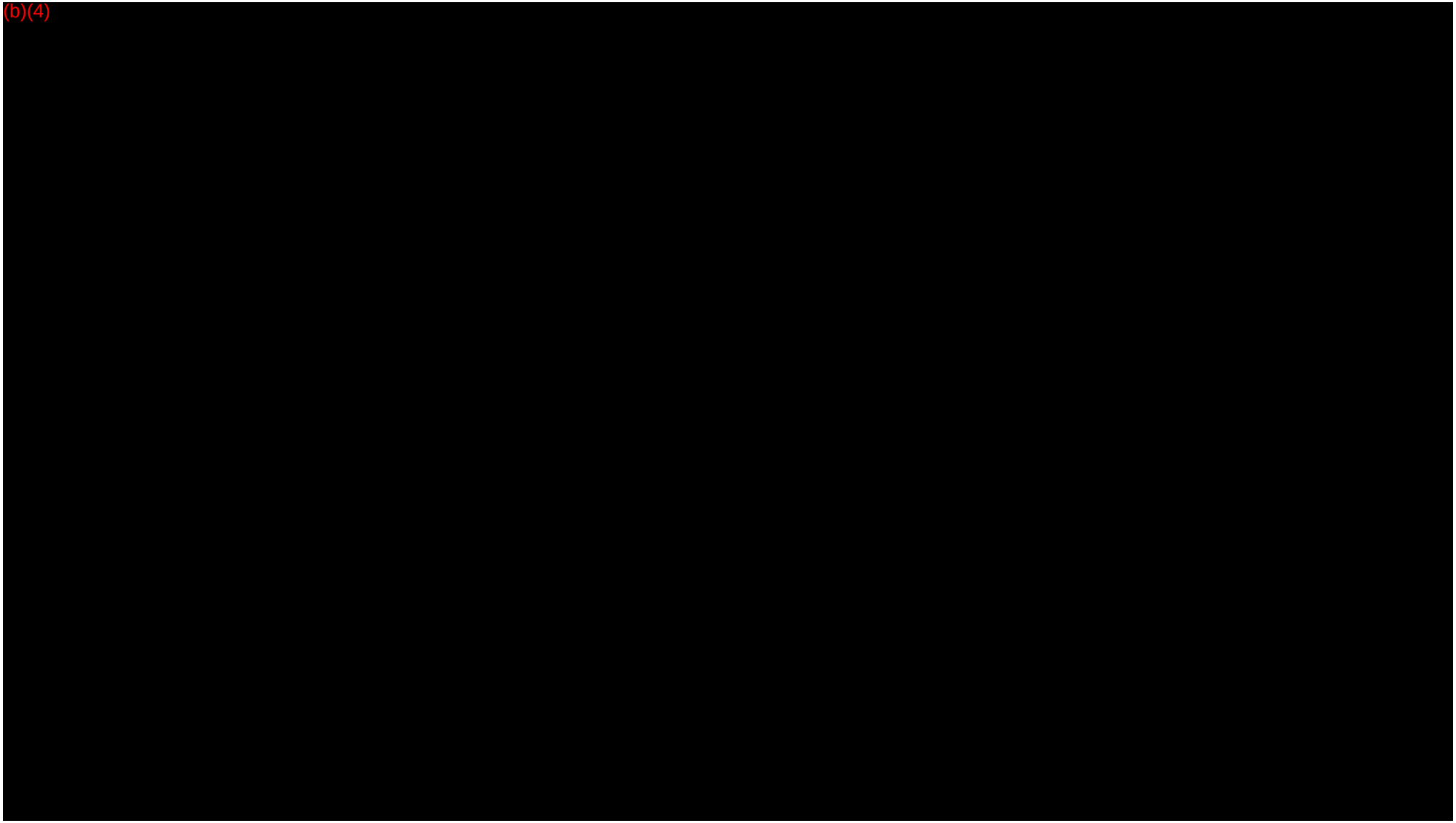

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Handling of FDA Cleared Implant Libraries

1. Introduction

Please refer to the Standard Operating Procedure enclosed in this volume.

2. Table of Contents

(b)(4)	Handling of FDA Cleared Implant Libraries in 3Shape Software

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Standard Operating Procedure – (b)(4)

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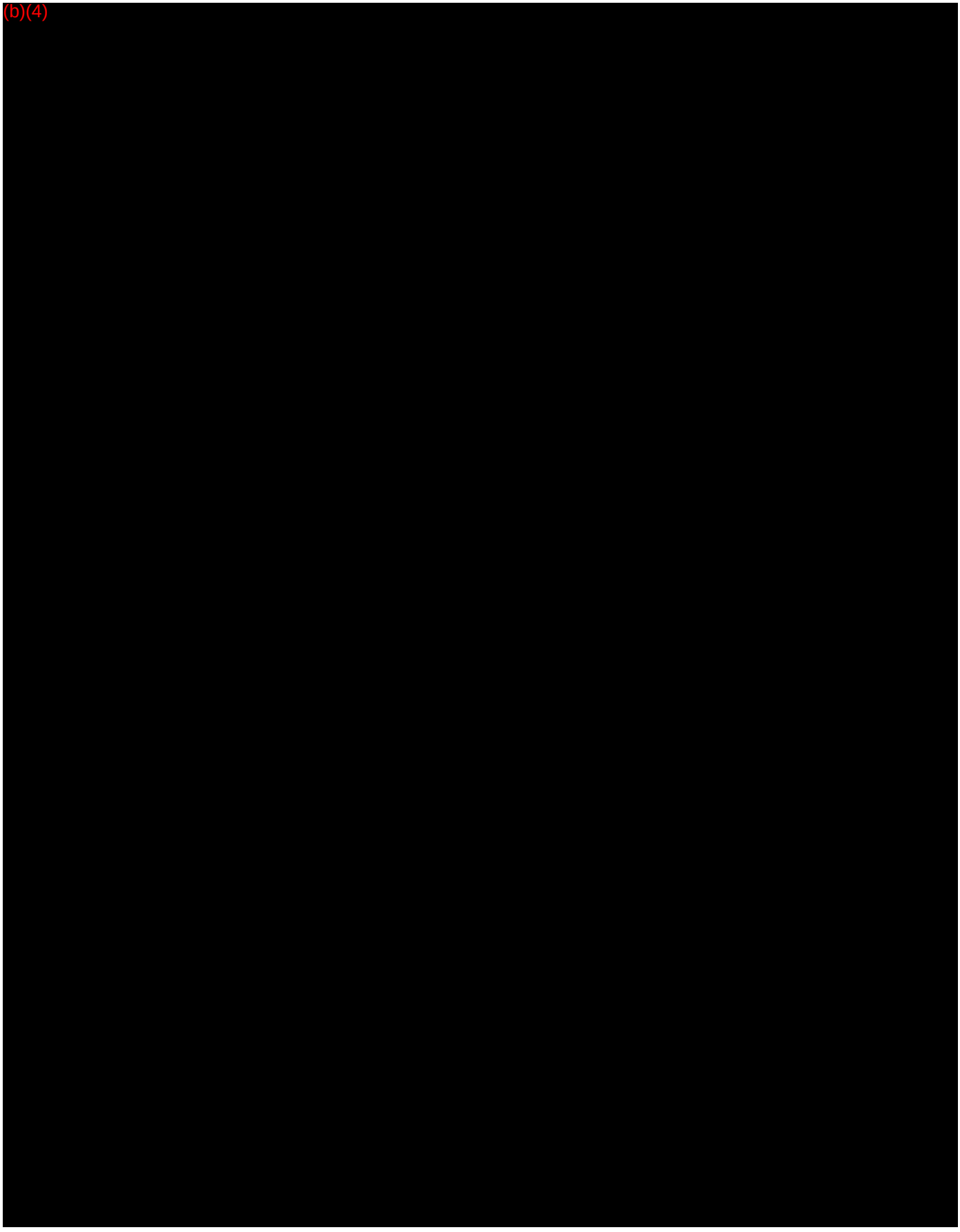

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Appendix 2 – User Manual

1. Introduction

Please refer to the labelling enclosed in this appendix.

2. Table of Contents

Dental System Technical Guidelines
(b)(4) - User Manual - Abutment Designer Except version

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Dental System™ 2015 Technical Guidelines

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Dental System Technical Guidelines

(b)(4) Draft Technical Guidelines

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(b)(4) Draft Technical Guidelines

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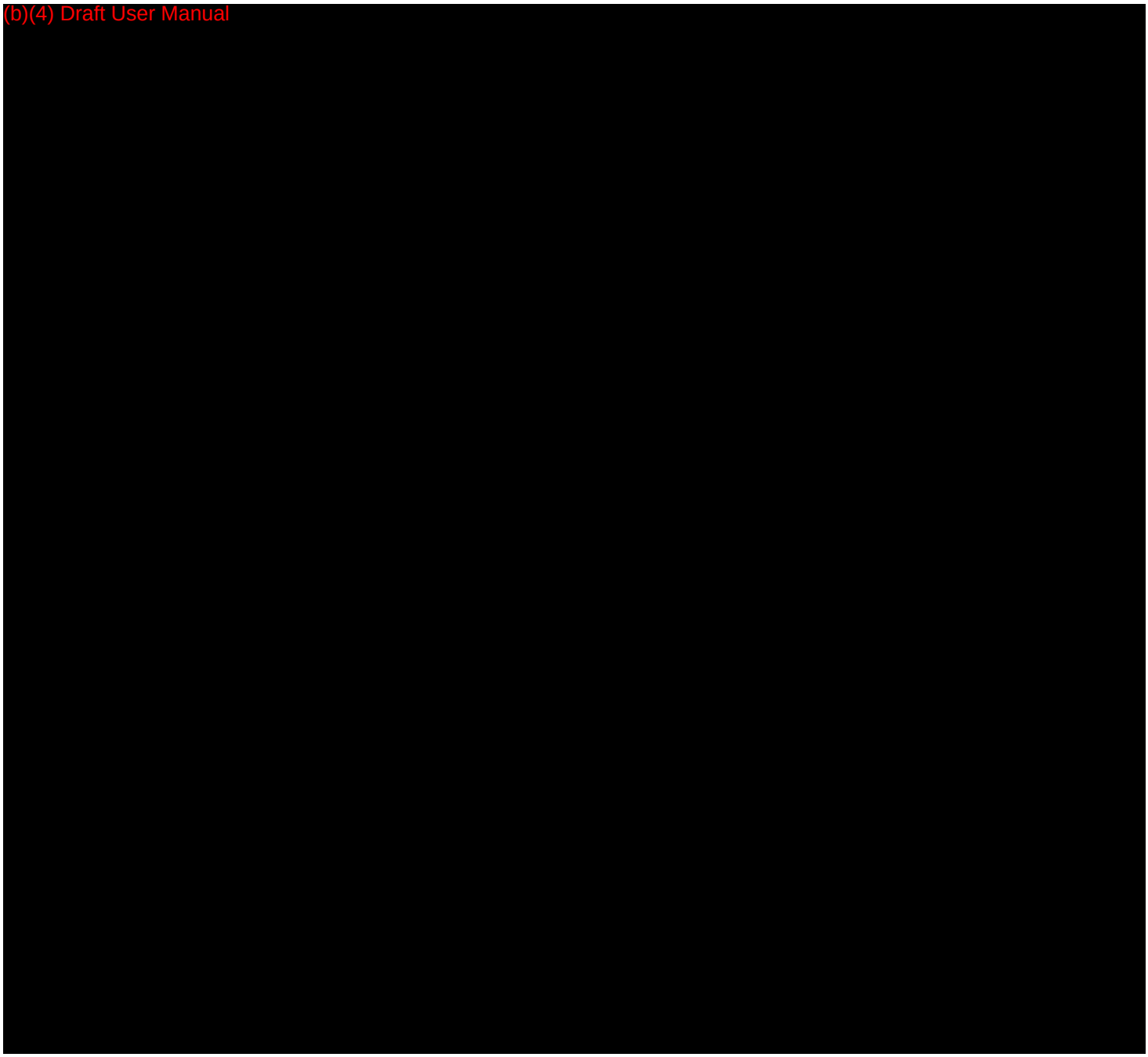
3Shape Dental System 2015

User Manual

(b)(4) Draft User Manual



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(b)(4) Draft User Manual

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Appendix G: Implant Libraries for 3Shape Dental System™

Providers of Implant Solutions	Implant Systems								Implant Solutions					Manufacturing		Consumables (for local use)				Additional info
	Nobel Biocare	Biomet3i	Straumann	Zimmer Dental	Astra Tech DENTSPLY	Friadent DENTSPLY	CAMLOG	Other systems	1-Piece (Titanium)	1-Piece (Zirconia)	2-Piece (Ti base+ ZrAbutm)	Implant Bars & Bridges	Digital implant models	Providers milling center	Local milling by 3rd Party	Blanks with pre-milled interface	Titanium bases	Intraoral Scan bodies	Digital model analogs	Comments
Alpha Bio-Tec. (IL) www.alpha-bio.net								- Alpha Bio Tec	X		X	X	X		X	X	X			
Argen (US) www.argen.com	+	+	+	+	+	+			X		X			X		X	X	X	X	- FDA, CE
ATLANTIS™ (SE) www.dentsplyimplants.com	+	+	+	+	+	+	+	- Keystone Dental - BioHorizons	X	X				X						- FDA, CE
BEGO (DE) www.bego.com	+	+	+	+	+	+	+	- BEGO Implant Systems - and more	X	X	X	X		X			X	X		- FDA, CE - CE-labelled prosthetic screws
BioComp (NL) www.biocomp.eu								- BioComp	X		X				X	X	X	X	X	- CE, ISO
Biodenta (CH) www.biodenta.com	+	+	+	+	+		+	- Biodenta	X		X	X	X	X				X	X	- FDA, CE pending
BioHorizons (US) www.biohorizons.com	+		+	+				- BioHorizon	X		X				X	X	X	X		- FDA, CE
Biomet (US) www.biomet.com	+	+	+						X	X	X			X				X		- FDA, CE - Encode® healing abutments
Biotech International (FR) www.biotech-dental.com								- Biotech			X		X		X		X	X	X	- CE

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Bredent (DE) www.bredent.com								- Sky			X				X		X	X	X	- FDA, CE
CADBLU (US) www.cadbludental.com	+	+	+	+	+			- Bio Horizons - MIS Implants	X		X	X	X	X				X	X	- FDA
CAMLOG (CH) www.camlog.com							+	- CONELOG - iSy	X		X	X		X	X		X	X		
CAP (US) www.cap-us.com	+	+	+	+	+	+			X		X	X	X	X	X	X	X		X	
CMC (US) www.custom-milling.com	+	+	+	+	+	+	+	- Bio Horizons - Osstem - LifeCore - Ultra-Lock - Neoss	X	X	X	X		X				X		- FDA, CE
Core3D International (NL) www.core3dcenters.com	+	+	+	+	+	+	+	- Avinent - BioComp - BioHorizons - MIS Implants - and many more	X		X	X	X	X	X	X	X	X	X	- FDA, CE, Health Canadà, TGA (AUS), Taiwan regulatory - MHLW:Ministry of Health, Labour and Welfare (JP)
C-Tech Implant (IT) www.c-tech-implant.com								- C-Tech Implant	X		X	X			X		X			- CE
Degudent (DE) www.degudent.com	+	+	+	+	+	+	+	- Medentika	X	X	X			X	X		X			
Dental Consulting (DE) www.gadau-consulting.com	+		+	+	+	+	+	- ICX-Medentis - Osstem	X		X	X	X	X	X	X	X	X	X	- FDA pending, CE
Dentaurum Implants (DE) www.dentaurum-implants.de								- Dentaurum Implants			X				X		X	X		- CE, PAL
Dentegris Deutschland (DE) www.dentegris.de								- Dentegris Implants			X	X			X		X			
Dentsply-Friadent (DE) www.dentsply-friadent.com							+	- Xive - Ankylos	X	X	X			X						- CE
DESS (ES) www.dess-abutments.com	+	+	+	+	+	+		- BioHorizon	X		X			X	X		X	X		- CE - ISO 13485 - ISO 9001

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Digital Dental Group-DDG (ISR) www.ddg-scanlab.com	+	+	+	+	+	+	+	- Microdent - BioHorizons - MIS-Implants - and more	X	X	X	X			X	X	X	X	X	- FDA pending, CE
DIO-Implants (KR) www.dioimplant.com	+							- DIO Implants	X	X	X	X		X	X					- FDA,CE, KFDA, SFDA
Elos Medtech Pinol (DK) www.elosmedtech.com	+	+	+	+	+	+	+	- Neoss	X		X	X	X	X	X	X		X	X	- FDA, CE
EuroTeknika (FR) www.euroteknika.com	+	+	+	+	+			- Anthogyr - Biotech - Easy Implant - MIS Implants - and more	X		X	X	X	X		X	X	X	X	- FDA, CE
GC Advanced Technologies (US) www.gc-at.com	+	+	+	+	+			- BioHorizons - Sybron	X	X	X			X						
Glidewell (US) www.glidewelldental.com	+	+	+	+	+	+	+	- Prismatik DentalCraft - Keystone Dental - Neoss	X	X	X	X	X	X			X	X	X	- FDA, CE pending
Heraeus Kulzer (DE) www.heraeus.com	+	+	+	+	+	+	+	- Thommen	X	X	X		X	X						
Ivocar Wieland (DE)	+	+	+	+	+	+		- Dentaurum Implants	X		X	X		X	X		X		X	
LaStruttura (IT) www.lastruttura.it	+	+	+	+	+	+		- Sweden&Martina - Megagen - Prodent - and many more	X	X		X	X	X				X	X	- CE 93/42
Medentika (DE) www.medentika.de	+	+	+	+	+	+	+	- Medentika M-Implant	X		X	X		X	X	X	X	X		- CE
Medentis Medical (DE) www.medentis.de	+		+		+	+		- ICX Templant	X		X	X	X	X			X	X		- CE
Medical Production (FR) www.medical-production.eu					+			- Euroteknika	X		X	X	X		X	X	X	X		- CEO 499 - ISO 9001 - ISO 13485
MIS Implants Technology (IL) www.mis-implants.com								- MIS Implants			X				X		X			- FDA, CE

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Neodent (BR) www.neodent.com.br	+		+					- Neodent Implant Systems	X	X	X	X			X			X			
Neoss (UK) www.neoss.com	+	+	+	+	+			- Neoss	X		X	X	X	X	X	X	X		X	- FDA, CE
Nobel Biocare (CH) www.nobelbiocare.com	+	+	+	+	+				X	X	X			X						- FDA, CE
NT Trading (DE) www.nt-trading.com	+	+	+	+	+	+	+	- Thommen - Sweden&Martina - BEGO	X		X	X		X	X	X	X	X	X	- FDA, CE, CMDCAS, GOST R, TGC - Mexico Certification
Phibo (ES) www.phibo.com	+	+	+	+	+	+	+	- PHIBO - BTI - Sweden&Martina - MIS Implants - and many more	X	X	X	X	X	X				X	X	- FDA, CE - ISO 13485 - ISO 9001
Prowital (DE) www.prowital.de								- Prowital			X				X		X	X	X	- CE - EN-ISO 9001-V472008 - EN ISO-13485-2003AC2009 - Certificate Directive-93-42 EWG
Ritter Implants (DE) www.ritterimplants.com			+	+				- Alpha-BioTec. - MIS Implants	X		X		X		X		X	X	X	- FDA, CE
Straumann (CH) www.straumann.com			+						X	X	X			X	X		X	X		- CE
Sweden&Martina S.p.A (IT) www.sweden-martina.com								- Sweden&Martina	X	X	X	X	X	X			X	X	X	
Target3D (USA) www.target3d.com	+	+	+	+	+	+	+	- Osstem - Bio Horizons - MIS-Implants - and more	X	X	X	X	X		X	X	X	X	X	- FDA, CE
Thommen Medical (CH) www.thommenmedical.com								- Thommen			X	X					X	X		- FDA, CE
TRI Implants (CH) www.tri-implants.com								- TRI Implants			X						X	X	X	
3dental (ES) www.3dental.es	+	+	+	+	+	+		- BioComp - Sweden&Martina - DYNA	X	X		X	X	X					X	

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+ -Available for Dental System™
x -Available from the manufacturer

Note! All information is given without guarantee and based exclusively on information made available by the implant system providers. Please contact your local 3Shape re-seller to obtain the most current list.

Note! Only Implant Libraries based on Dental Implants with 510(k) clearance can be used in Abutment Designer™ in the United States. Cleared libraries must be activated by 3Shape. Please ask your Implant Library Provider to contact 3Shape if you wish to use a cleared library that has not already been activated. The software will block any attempt to use a non-cleared library.

Note! In the United States, implant cases may only be manufactured by manufacturers that hold an implant abutment 510(k) or are milling per the specific instructions provided by the holder of a 510(k) for a patient specific implant abutment.

Appendix H: Terms and Abbreviations

The following table explains file type abbreviations used in 3Shape Dental System.

File Format	Description
3ML	Zipped, compressed XML file typically used for setup and customization. 3Shape proprietary format.
3SE	3Shape and Sirona proprietary format for exported orders. Orders from Sirona system, can be imported into 3Shape system.
3OX	3Shape Communicate Order Exchange format used by partners and customers to retrieve and send orders. 3Shape proprietary format.
3OXZ	Zipped archive containing 3OX file and references to DCM models. 3Shape proprietary format.
3SI	3Shape and Sirona proprietary format for imported orders. Orders exported from 3Shape system, can be imported into Sirona system.
DCM	Dental Compressed Model file. Contains compressed 3D model data, attached objects (splines, annotations, etc.), marks and additional string properties. 3Shape proprietary format used for scans and CAD designs.
DLL	Dynamic-link library, Microsoft shared library concept.
DME	Dental System Material Export file. Contains materials, references to materials and external files. The file can be imported into another 3Shape Dental System. 3Shape proprietary format.
STL	Describes surface geometry of three-dimensional objects. Used for scans and CAD designs. Industry standard.
ULDC	3M Lava proprietary format. Order files from 3M scanners can be imported into 3Shape System.
XML	Extensible Markup Language, used for configuration files, etc.

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Appendix I: Contact Information

3Shape Headquarters

Europe, Middle East & Africa Sales
Holmens Kanal 7
1060 Copenhagen K
Denmark

P: +45 70 27 26 20

3Shape North America

North American Sales
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10 Independence Boulevard,
Suite 150
Warren, New Jersey 07059, USA

P: +1 908 867 0144

3Shape (Shanghai) Co., Ltd

Asian Sales
Room 906, Tower A of Eton Place
No. 69, Dongfang Road
200120 Shanghai, China

P: +86 21 5835 2281

3Shape South America

Latin American and Caribbean Sales
Carrera 13 # 82-91
Oficina 401
110221 Bogotá, Colombia

P: +57 1 691 95 08

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510(K) SUMMARY – Traditional 510(K)

Submitter Information

A Company Name:	3Shape A/S
B Company Address:	Holmens Kanal 7 DK-1060 Copenhagen K
C Company Phone: Company Fax:	+45 7027 2620 +45 7027 2621
D Contact Person:	Hanne Nielsen Regulatory Affairs Manager
E Date Summary Prepared:	June 28, 2016

Device Identification

A Trade/proprietary Name:	3Shape Abutment Designer™ Software
B Common Name:	Abutment design software for dental laboratory
C Device Classification Name:	Endosseous Dental Implant Abutment
C Regulation Number:	872.3630
C Classification:	Class II
D Product Code:	PNP

Predicate Device

Sirona Dental CAD/CAM System (K100152).

Intended Use

The 3Shape Abutment Designer Software is intended as an aid to the restoration of chewing function in partially or fully edentulous mandibles and maxillae. The 3Shape Abutment Designer Software is intended for use by a dental practitioner or dental laboratory staff for designing the patient specific component of a two-piece, one-piece or hybrid dental

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implant abutment. The single or multi-unit abutment design is intended to be used by the manufacturer of an endosseous dental implant abutment to create the final device.

Device Description

The 3Shape Abutment Designer™ Software receives scan data containing topographical characteristics of real teeth, dental impressions, or stone models. The software provides the user with the ability to create matching endosseous dental implant abutments using computer aided design.

The output of the device is a computer file containing the abutment(s) in digital form which can be used by manufacturers that hold an implant abutment 510(k) or are milling per the specific instructions provided by the holder of a 510(k) marketing clearance for a patient specific implant abutment. The 3Shape Abutment Designer Software output is restricted in the U.S. to be manufactured by a holder of an implant abutment 510(k) or milled per the specific instructions provided by the holder of a 510(k) marketing clearance for a patient specific implant abutment.

The 3Shape Abutment Designer™ Software can be run on properly configured "off-the-shelf" PC hardware running Microsoft® Windows and using a standard keyboard and mouse.

The 3Shape Abutment Designer™ Software requires the loading of implant libraries, which includes information such as implant type, maximum and minimum dimensional parameters for abutments, etc., created by separate abutment manufacturers and cleared by the FDA. In the US, the Implant Libraries are obtained via a 3Shape server after demonstration to 3Shape of the FDA clearance of the Implant Library.

Summary of the technological characteristics

The 3Shape Abutment Designer™ is a software only device programmed in the Delphi programming language and has the following PC/laptop requirements and other technological characteristics as compared to the predicate device:

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Item	Submission Device Minimum Requirements	Submission Device Recommended	Predicate Device
OS	Windows 7 32-bit Professional*	Windows 7 64-bit Professional	Windows Vista 32- bit
RAM	4GB	8GB (16GB)	6GB
Video Card	512MB DirectX 10 (1GB DirectX 10)	1GB DirectX 11 (2GB DirectX 11)	512 MB DirectX 10 NVIDIA Quadro
Available HDD Space	250GB	500GB (1TB)	500GB
CPU	Intel Core i5 or equivalent	Intel Core i7 or equivalent	Intel Core i7
Monitor resolution	1440 x 900 pixels	1920 x 1080 pixels	Unknown
3D Mouse	None	3DConnexion SpaceMouse™	Unknown
Network	Internet connection		Unknown
Ports	USB 2.0 port for 3Shape desktop scanner		Serial Port PCI card for inEOS scanner
Mouse	Mouse with wheel button support		Unknown

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Indications for Use	The 3Shape Abutment Designer Software is intended as an aid in the restoration of chewing function in partially or fully edentulous mandibles and maxillae. The 3Shape Abutment Designer Software is intended for use by a dental practitioner or dental laboratory staff for designing the patient specific component of a two-piece, one-piece or hybrid dental implant abutment. The single or multi-unit abutment design is intended to be used by the manufacturer of an endosseous dental implant abutment to create the final device.	The Sirona Dental CAD/CAM System is intended for use in partially or fully edentulous mandibles and maxillae in support of single or multi-unti cement retained restorations. The system consists of three major parts: TiBase, InCoris mesostructure, and CAD/CAM software. Specifically, the InCoris mesostructure and TiBase components make up a two-piece abutment which is used in conjunction with endosseous dental implants to restore the function and asesthetics in the oral cavity. The InCoris mesostructure may also be used in conjunction with the CAMlog Titanium base CAD/CAM (types K2244.xxxx) (K083496) in the Camlog Implant System. The CAD/CAM software is intended to design and fabricate the InCoris mesostructure. The InCoris mesostructure and TiBase two-piece abutment is compatible with the following implant systems: Nobel Biocare Replace (K020646), Nobel Biocare Branemark (K022562), Friadent Xive (K013867), Biomet 3i Osseotite (K980549), Astra Tech Osseospeed (K091239), Zimmer Tapered Screw-Vent (K061410), and Straumann SynOcta (K061176).
Software Output	Digital encrypted or non-encrypted proprietary or .STL file including only the patient-specific abutment component for one-piece, two-piece, or hybrid abutment designs. The digital output does not include the abutment-to-implant connection interface.	.STL file of the ceramic mesostrucutre sent to Sirona Dental CAD/CAM System milling unit
Physical - Output	N/A – Submission device relies on separate regulatory clearance and manufacture of the abutment by a separate company	Two-piece Tibase abutment – pre-milled titanium base combined with ceramic mesostructure designed in Sirona CAD/CAM software.
Milling Location	Abutment Manufacturer or Dental laboratory per the 510(k) clearance of the dental abutment	Local milling of the ceramic abutment component.

The predicate Sirona device includes in the marketing clearance the two-piece TiBase Abutments (titanium bases and ceramic blocks) as a physical output as well as a validated milling unit and directions for assembly of the final dental abutment. The 3Shape Abutment Designer™ Software does not provide any physical parts that can come into contact with the patient. The 3Shape Abutment Designer Software instead provides only the digital design as an accessory to the physical dental abutment systems cleared by other manufacturers. The differences between the Indications for Use

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Statement of the submission device and the predicate are related to the lack of physical output from the submission device and reliance on previous or subsequent FDA clearance of the physical abutment by a separate manufacturer. However, the difference does not change the intended use of the device.

Nonclinical Testing

Software, hardware, and integration verification and validation testing was performed in accordance with the FDA Guidance Document "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" (Issued on May 11, 2005) as well as the FDA Guidance Document "Off-The-Shelf Software Use in Medical Devices (Issued on September 9, 1999).

Prior to release, verification and validation testing of the 3Shape Abutment Designer™ Software has been completed using the approved acceptance criteria: Each user need has its own validation acceptance criteria; each specification has its own verification acceptance criteria; bug verification consists in ensuring issue is not reproducible; issues reported by beta partners must be reviewed and handled appropriately; beta partners must report functionality to be an improvement over previous version.

The validation suite includes validation of implemented mitigations related to device hazards identified in the risk management procedures.

Conclusion

Based on a comparison of intended use, principle of operations, features and technical data, and the verification/validation test results, the 3Shape Abutment Designer™ Software is found to be substantially equivalent with the Predicate Device.

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Accuracy of 3Shape lab scanners

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Introduction

What is scanner accuracy?

The term *accuracy* is used in a number of senses, depending on the context and application. In the context of 3D scanning, accuracy relates to the capability of a 3D scanner to reproduce digitally the physical surface of a free form object.

In order to quantify this key property, the following measures are defined:

> **Reproducibility:** The ability of a 3D scanner to reproduce a specific measurable dimension of a reference object of known dimensions. Mathematically, reproducibility is expressed as the standard deviation of a series of measurements of the dimension in question.
>
> **Repeatability:** The ability of a 3D scanner to reproduce a specific measurable dimension of a reference object. Mathematically, repeatability is expressed as the difference between the average of a series of measurements (scans) and a true measured value. Repeatability is sometimes referred to as *trueness*.
>
> See also *ISO12836;2012: Dentistry – Digitizing devices for CAD/CAM systems for indirect dental restorations – Test methods for assessing accuracy*

As for any physical quantity, dimensional measurements are affected by the environmental conditions in which they take place. For 3D scanning applications, key environmental conditions include relative humidity and temperature. All materials contract and expand with temperature; some more than others. The *coefficient of thermal expansion* is an intrinsic material property that dictates the sensitivity of a material to temperature changes.

However, not only will the object under investigation change size with temperature – also the 3D scanner system is subject to thermal effects; not least due to internal heat sources. In order to demonstrate the effect, consider the following example:

> A caliper, made of steel, is used to measure the distance between two molars on a dental model in a laboratory. The caliper was produced at 20 degrees, and it is assumed that the scale on the ruler was absolutely correct at the time of production. In the laboratory, the temperature is now 25 degrees, and the dental model is produced at that temperature. The model is assumed to be an absolutely correct model of the patient teeth.
>
> Using the caliper to measure the molar distance, the technician obtains the result 55 mm. However, steel has an expansion coefficient of around 12 µm/m/degree, so in reality, the molar to molar distance has to be corrected by the amount of
>
> 5 deg × 12 µm/m/deg × 0,055 m = 3.3 µm

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> As temperature increases, the caliper expands. As the scale expands with the caliper, this means that any object measured with the caliper seems to be smaller than it really is; in case of decreasing temperature, an object will seem to be larger than it really is.
>
> If the object was realized at a different temperature, this would either reduce or increase the magnitude of the induced measurement error, due to the dimensional change of the object itself.

So, the origin of the error from thermal effects is a combination of the object and the scanning system.

Accuracy in dental applications

While the above example is trivial in some sense, it clearly demonstrates that effects due to temperature changes can easily be on the same order of magnitude as the accuracy specified by many 3D scanner system vendors. Therefore, any claim of scanner system accuracy must be with reference to test conditions in which the claimed accuracy can be obtained; including the allowed temperature interval from e.g. a system calibration temperature. With no such specifications, accuracy claims have no relevance to reality and should generally not be trusted.

As such effects scale linearly with the size of the case at hand, they may safely be ignored for small cases. However, in cases where large distances are involved, e.g. multi-unit bridges or implant bars, the end result will depend on the accuracy of the scanning and design process.

Determination of accuracy

Reference objects

Definition

As a reference object for 3D scanning may serve any object that represents the relevant scanning application. As such, in order to be relevant, the object must expose certain geometrical features that relate to the application. This can be free-form as well as standard geometrical shapes such as spheres, cylinders, cones etc.

Calibration and traceability

Most importantly, it shall be possible to determine the position, size and orientation of any such scannable feature using an application-independent measurement device. Frequently, coordinate measurement machines (CMMs) are used to perform such measurements. However, only to the extent that this reference measurement is traceable to national standards should it be used to provide objective evidence for the accuracy of the scanner in question. Hence, for any reference object, a calibration certificate referring to the accreditation of the measurement laboratory, the equipment used, and its calibration status should be provided.

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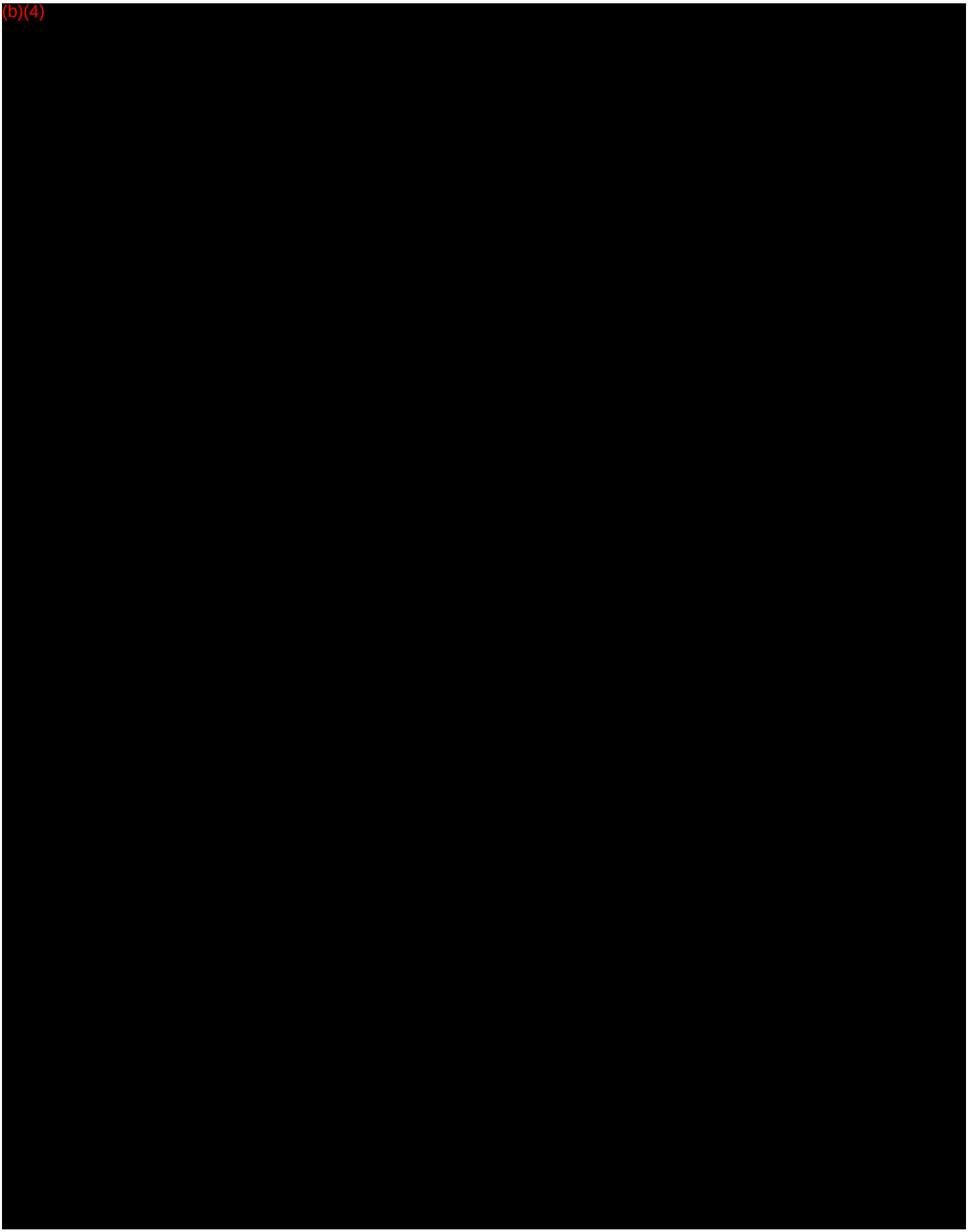

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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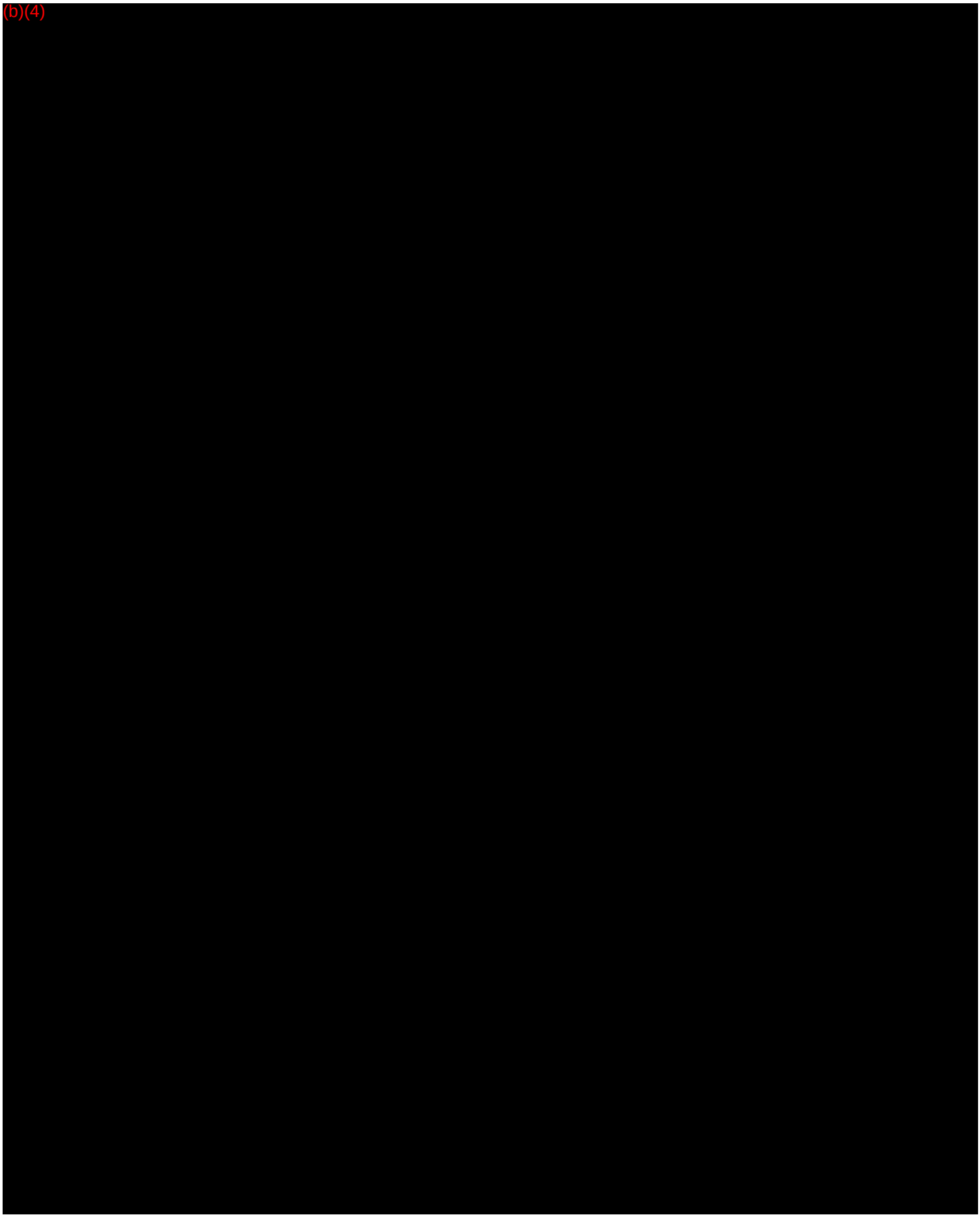

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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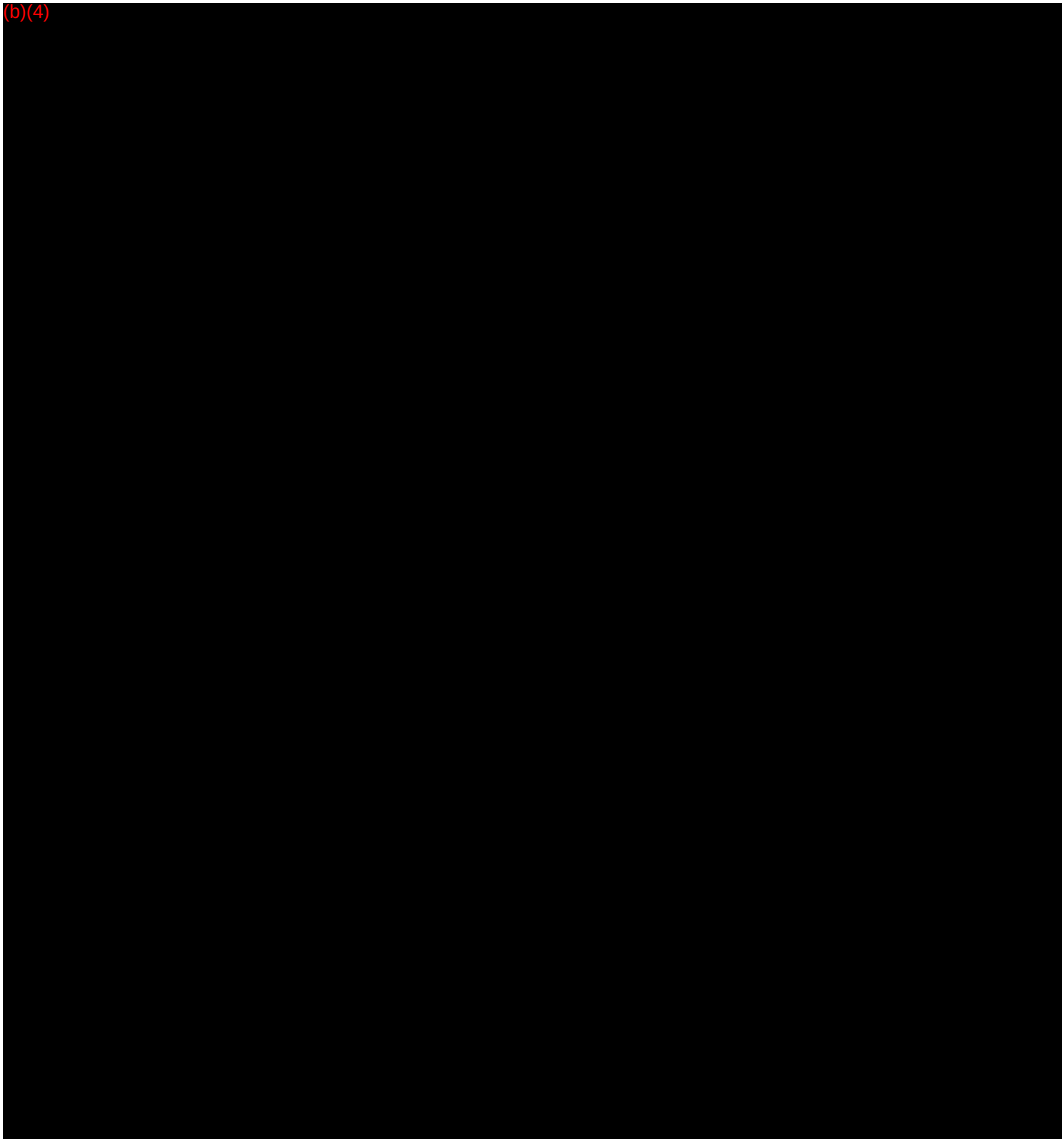

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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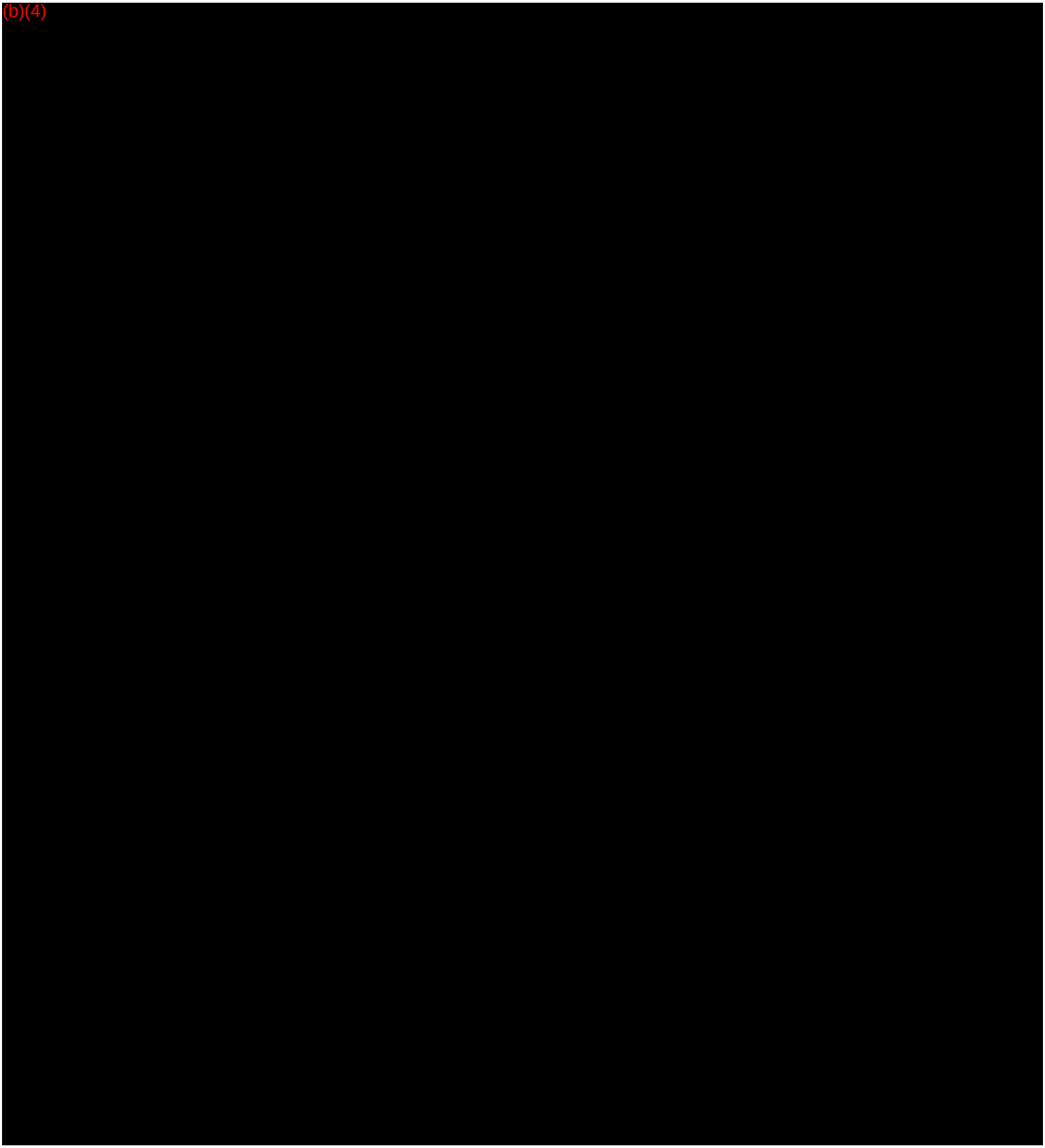

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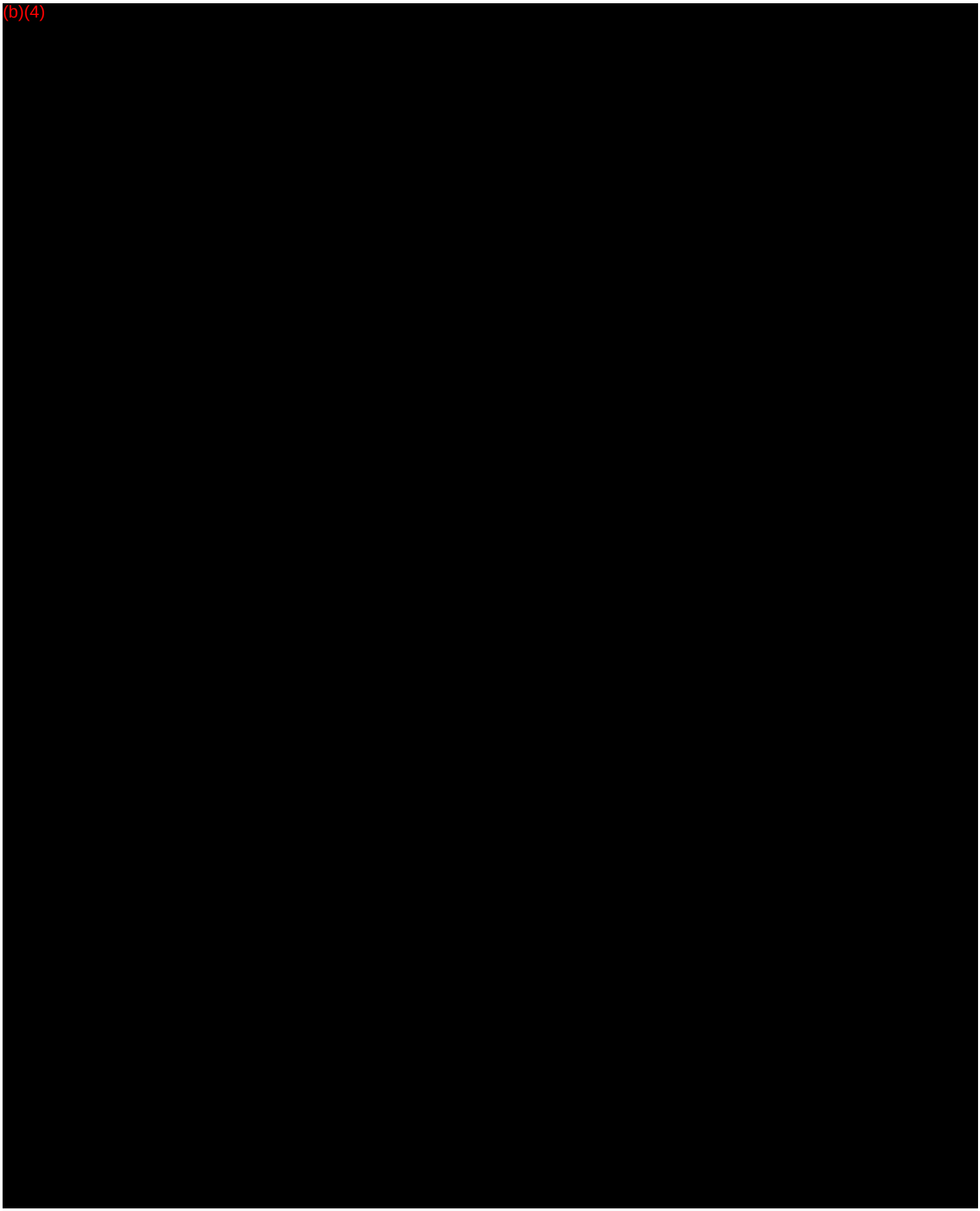

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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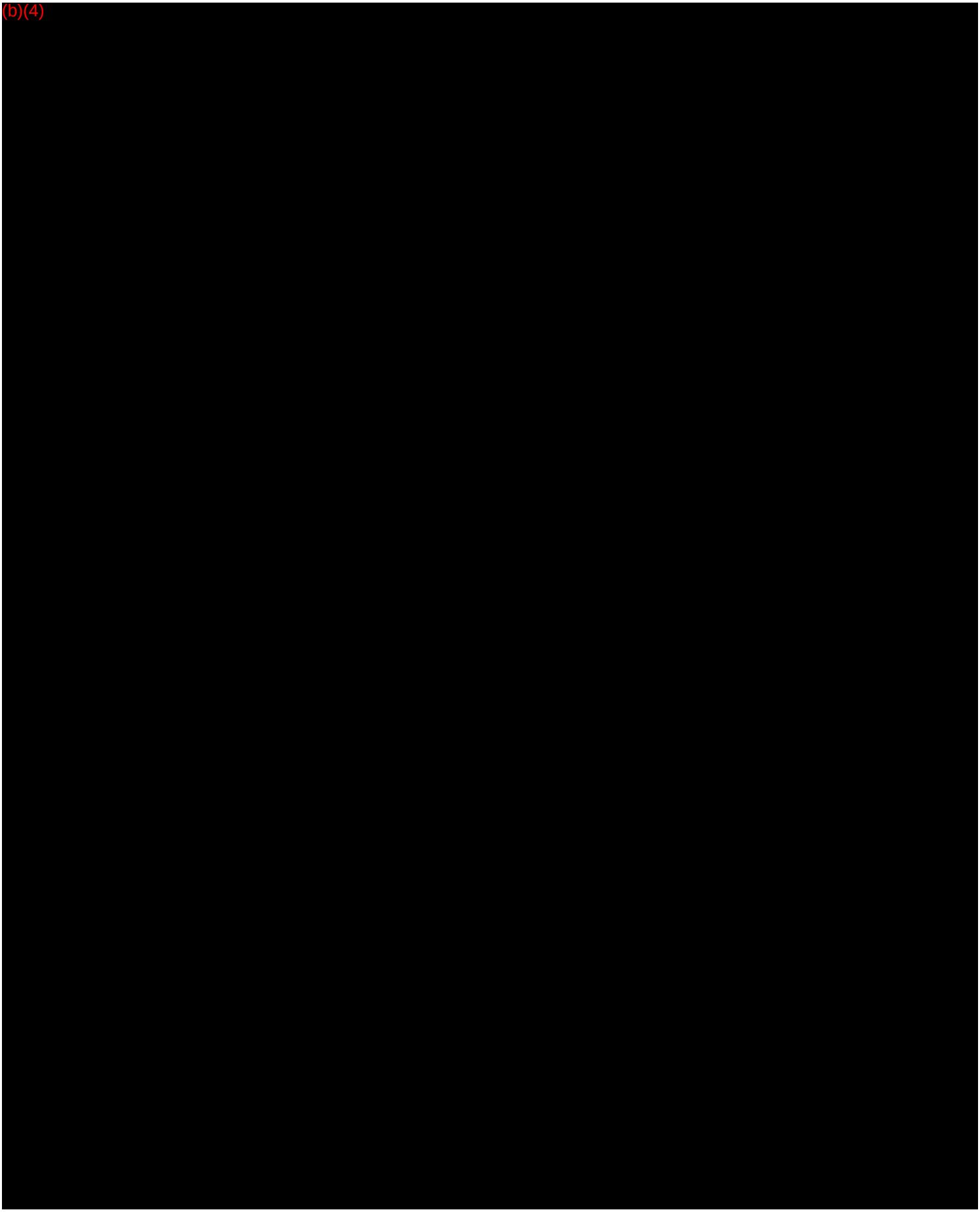

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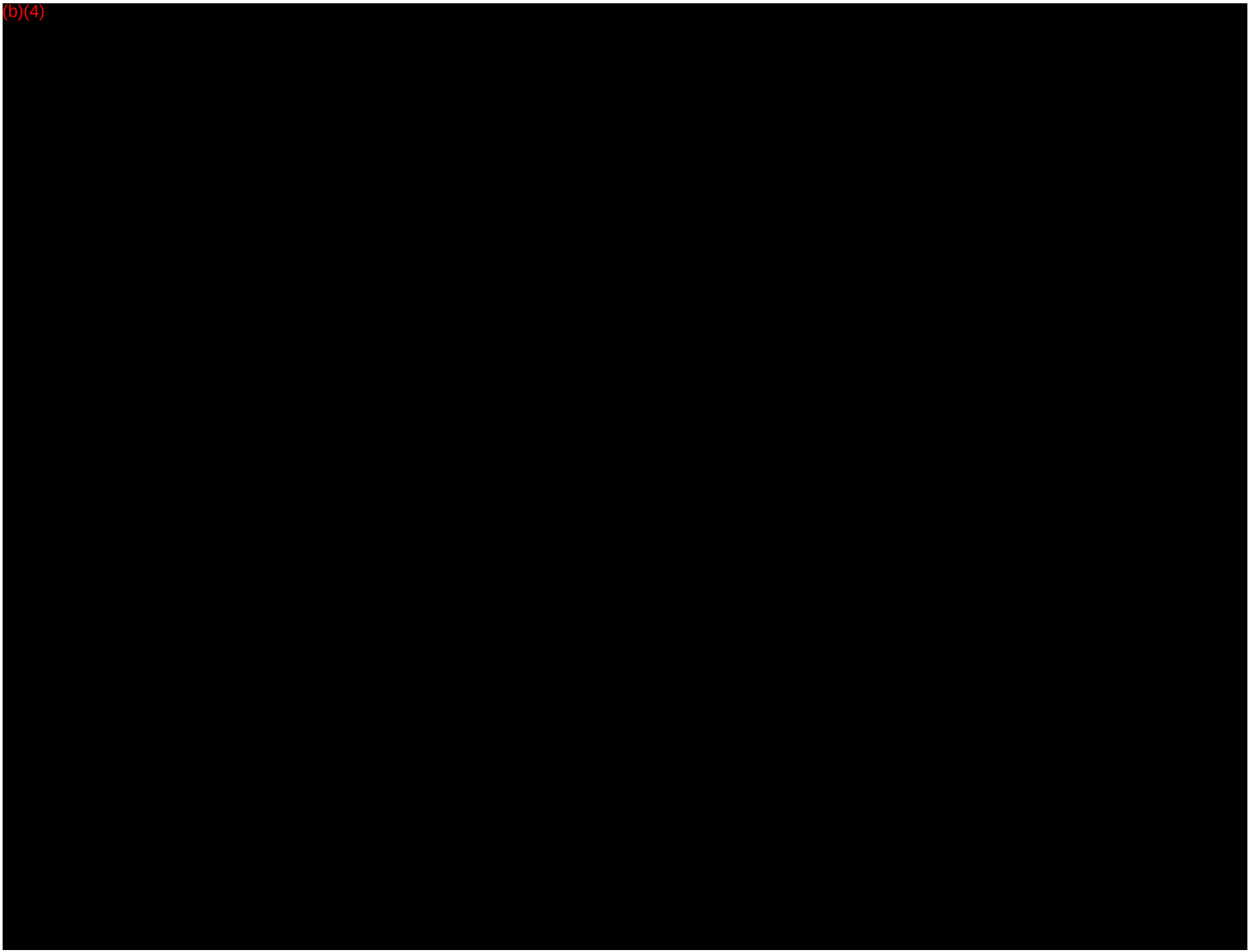

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Appendix 1 – Library Confirmation Letters

1. Introduction

Please refer to the Library Confirmation Letters enclosed in this appendix.

2. Table of Contents

Name	Comment
3IImplantSignature1	
3ShapeImplantSystem	Internal 3Shape library
ArgenImplantSystems	
AtlantisSystems	
BEGOSystemsFDA	
Bicon Implant Systems	
BiodentaCorporationImplants(C)FDA	
BiodentaCorporationImplants(E)	
BioHorizons	
BioHorizonsLibrary	
BlueSkyBioImplantSystems	
Camlog Implant Systems	
Camlog	
CAP Implant Systems	510k exempt
CAP Implants	510k exempt
CMC Implants	
Core3d Abutments Implant Library	
Core3d Implant Library Open	

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Name	Comment
Core3d Implant Library	
Cortex Dental Implant System	
Creodental Implant System	New Library. Implant Library Clearance Document attached as well.
Dentium Implant System	New Library. Implant Library Clearance Document attached as well.
ETK Implant Library	
GlidewellAbutmentKit	Error in confirmation letter. K08340 should be K083480 and 141923 should be K141923
GlidewellAnatomyLibrary	Error in confirmation letter. K08340 should be K083480 and 141923 should be K141923
GlidewellBarKit	Error in confirmation letter. K08340 should be K083480 and 141923 should be K141923
GlidewellHybridKit	Error in confirmation letter. K08340 should be K083480 and 141923 should be K141923
Hiossen Implant Library	
ImplantDirectSystems	
Intra-lock implant library	
Medentika Implant Systems	
MegaGEN Implant System	New Library. Implant Library Clearance Document attached as well.
MIS Implant System	
Neodent Implant Systems	New Library. Implant Library Clearance Document attached as well.
Neoss Implant Library	
NobelBiocare Abutments	
NT-Trading Implants	
Paltop Implant Systems (C)	New Library. Implant Library Clearance Document attached as well.
Straumann One Piece Abutments	

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Name	Comment
Sweden-Martina implant library	
TFI Systems Implant Library	New Library. Implant Library Clearance Document attached as well.
ThommenMedical Abutment kit	
TruCrown Implant System	New Library. Implant Library Clearance Document attached as well.
Zimmer Zfx Implant System	
Zimmer Zfx	
ZimmerAbutmentKit	
ZimmerImplantSignature1	
ZimmerImplantSystemC	
Zirlux Implant Systems	Error in confirmation letter. K08340 should be K083480 and 141923 should be K141923. New Library. Implant Library Clearance Document attached as well.

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Architecture Design Chart

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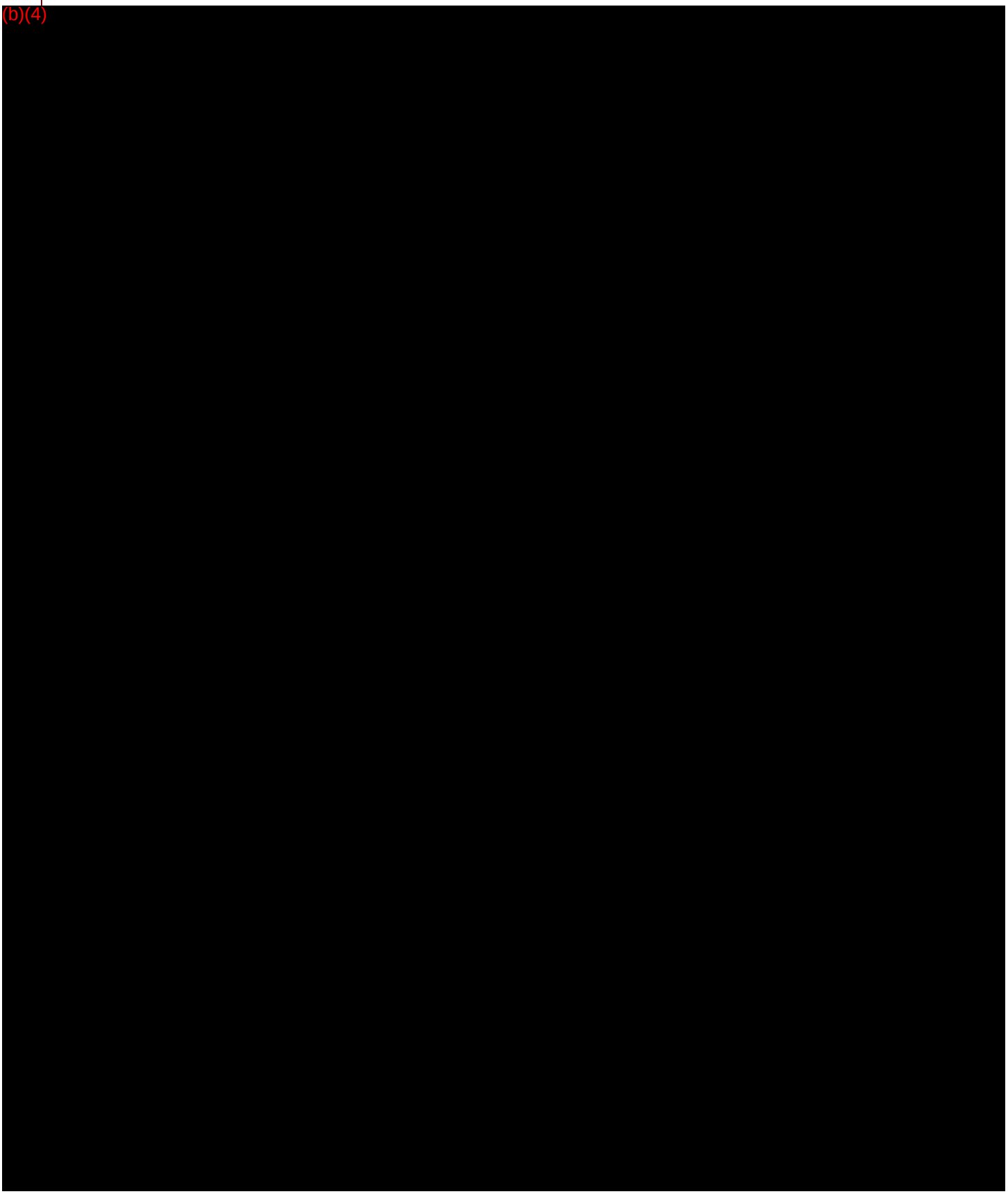

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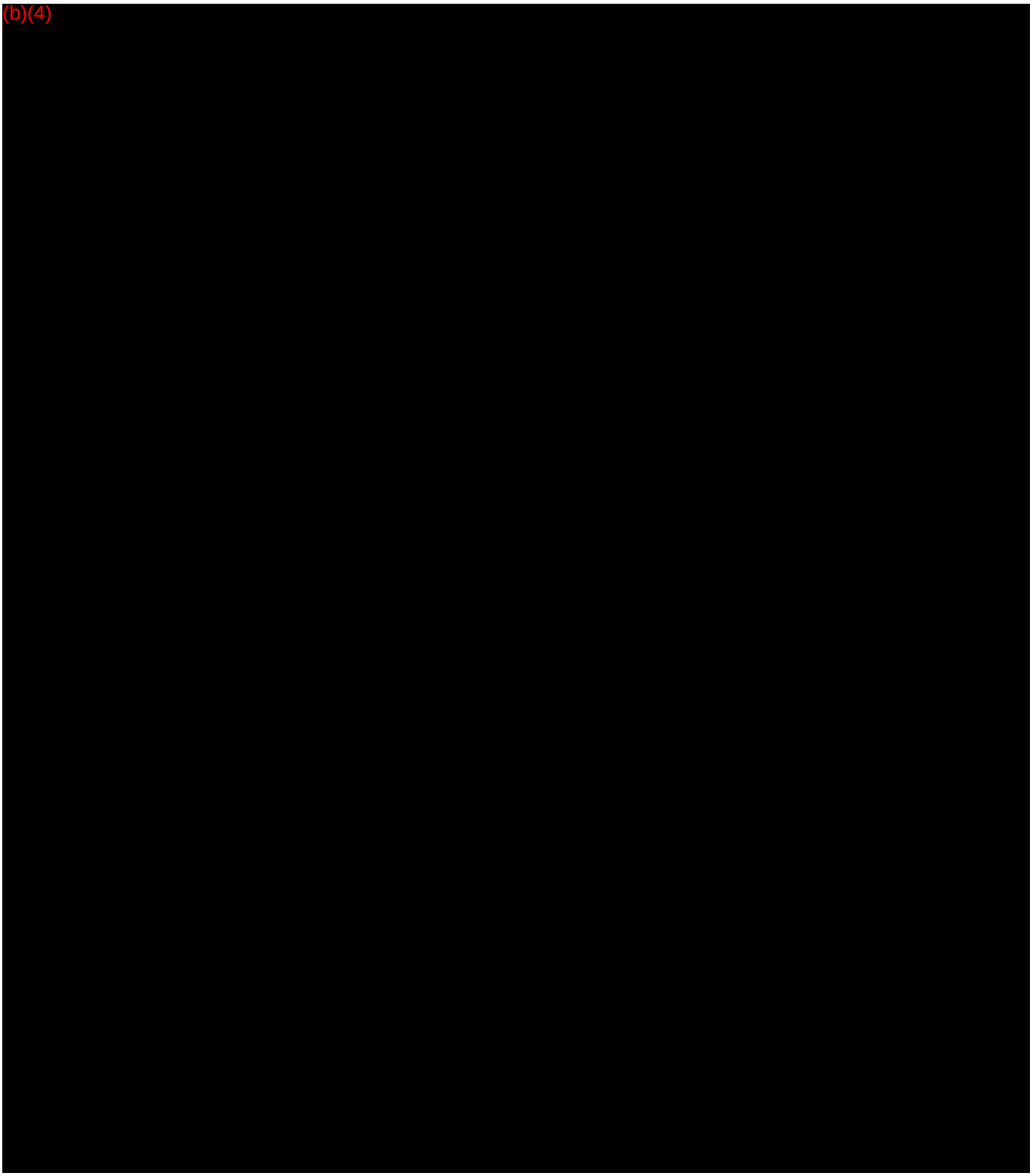
TITLE: ARCHITECTURE DESIGN CHART

(b)(4)



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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TITLE: ARCHITECTURE DESIGN CHART

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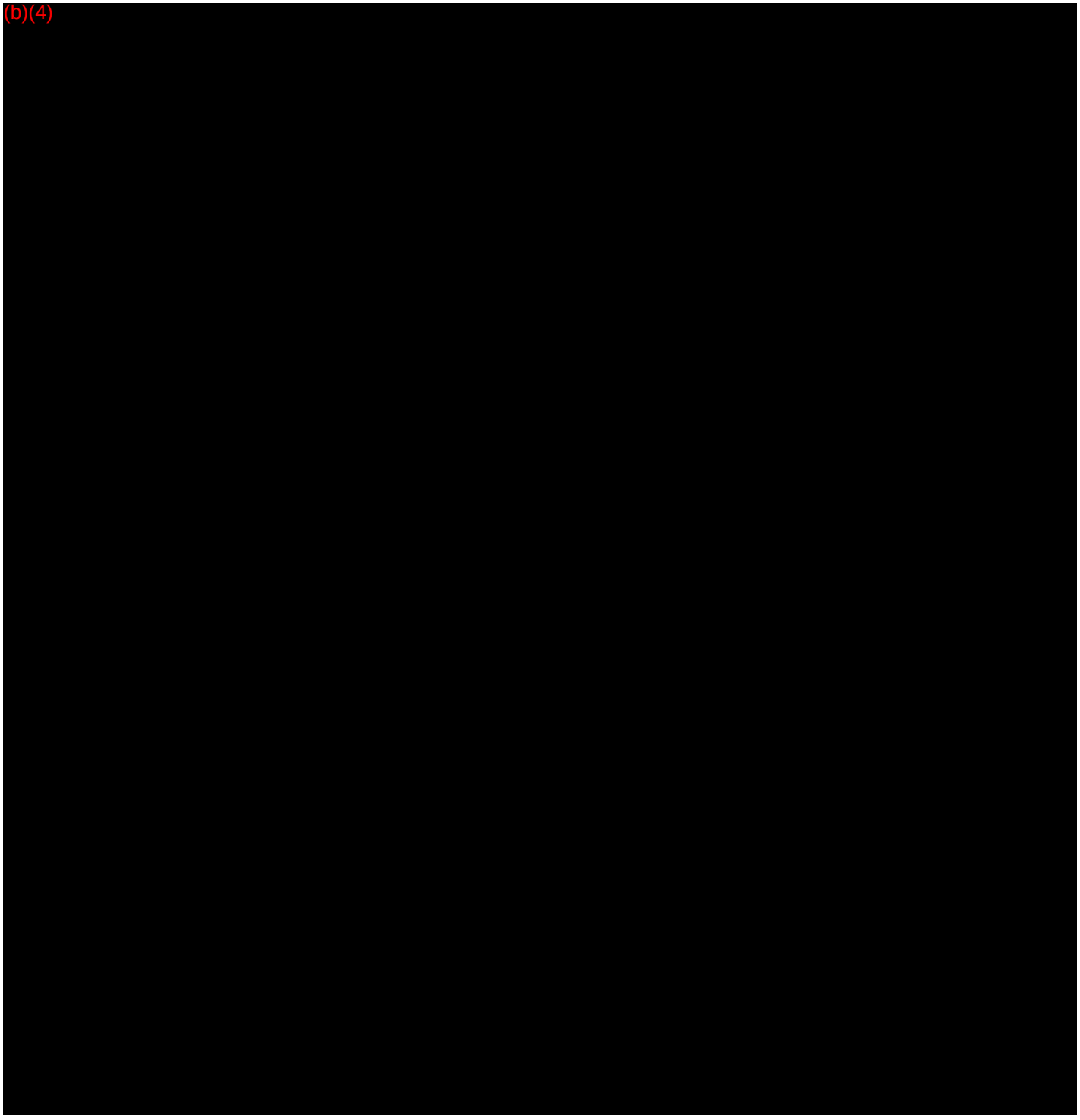

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TITLE: ARCHITECTURE DESIGN CHART

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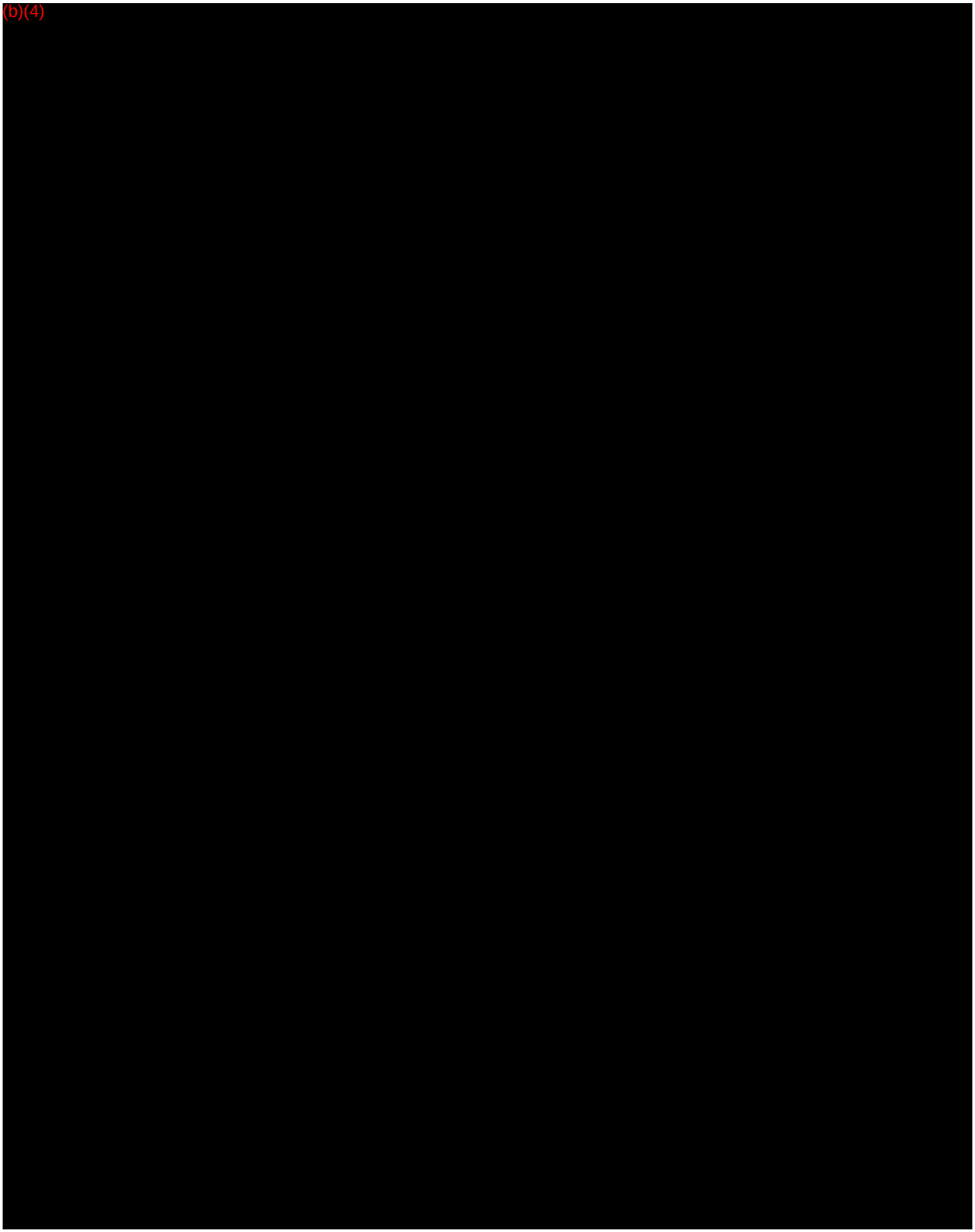

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TITLE: ARCHITECTURE DESIGN CHART

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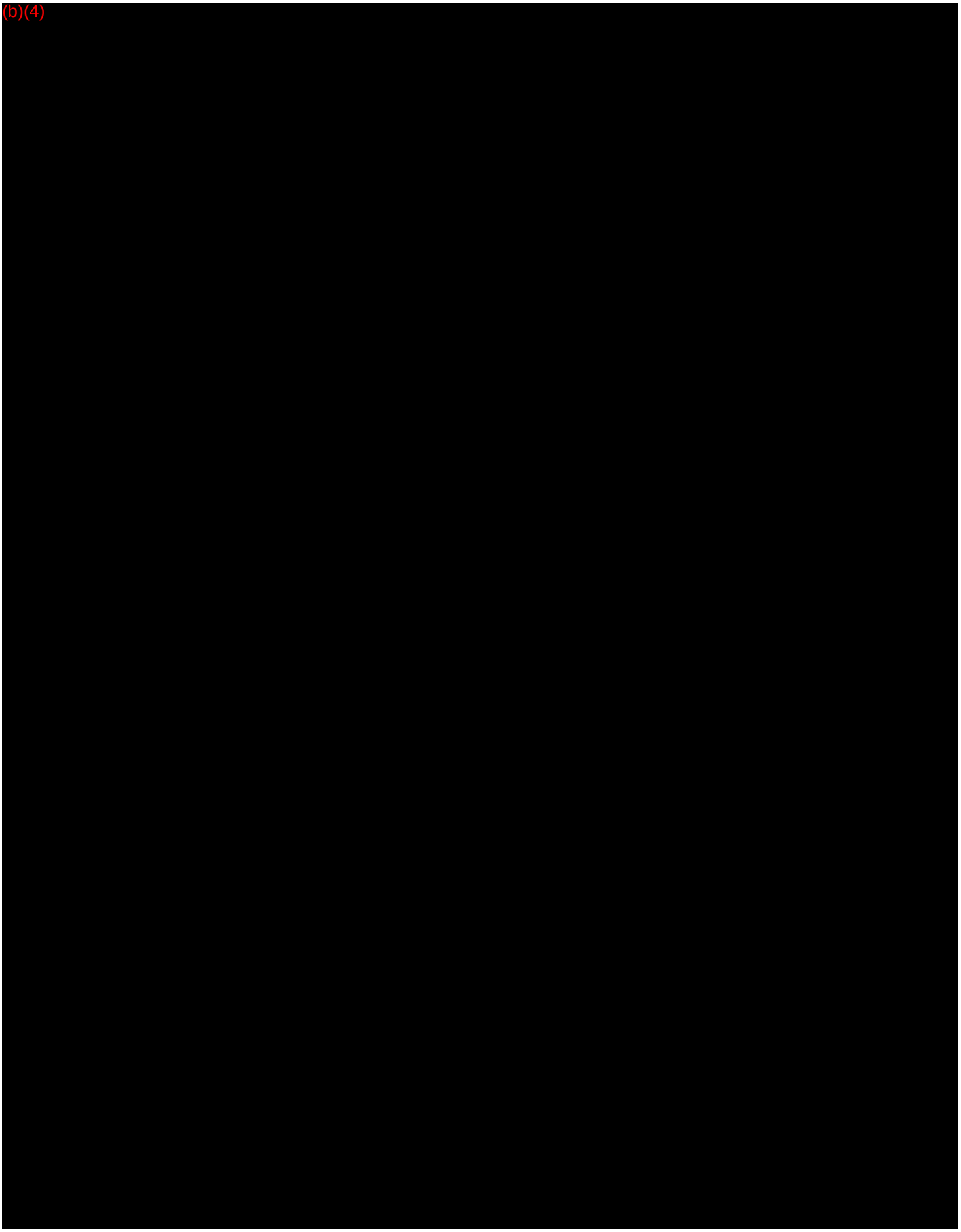

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TITLE: ARCHITECTURE DESIGN CHART

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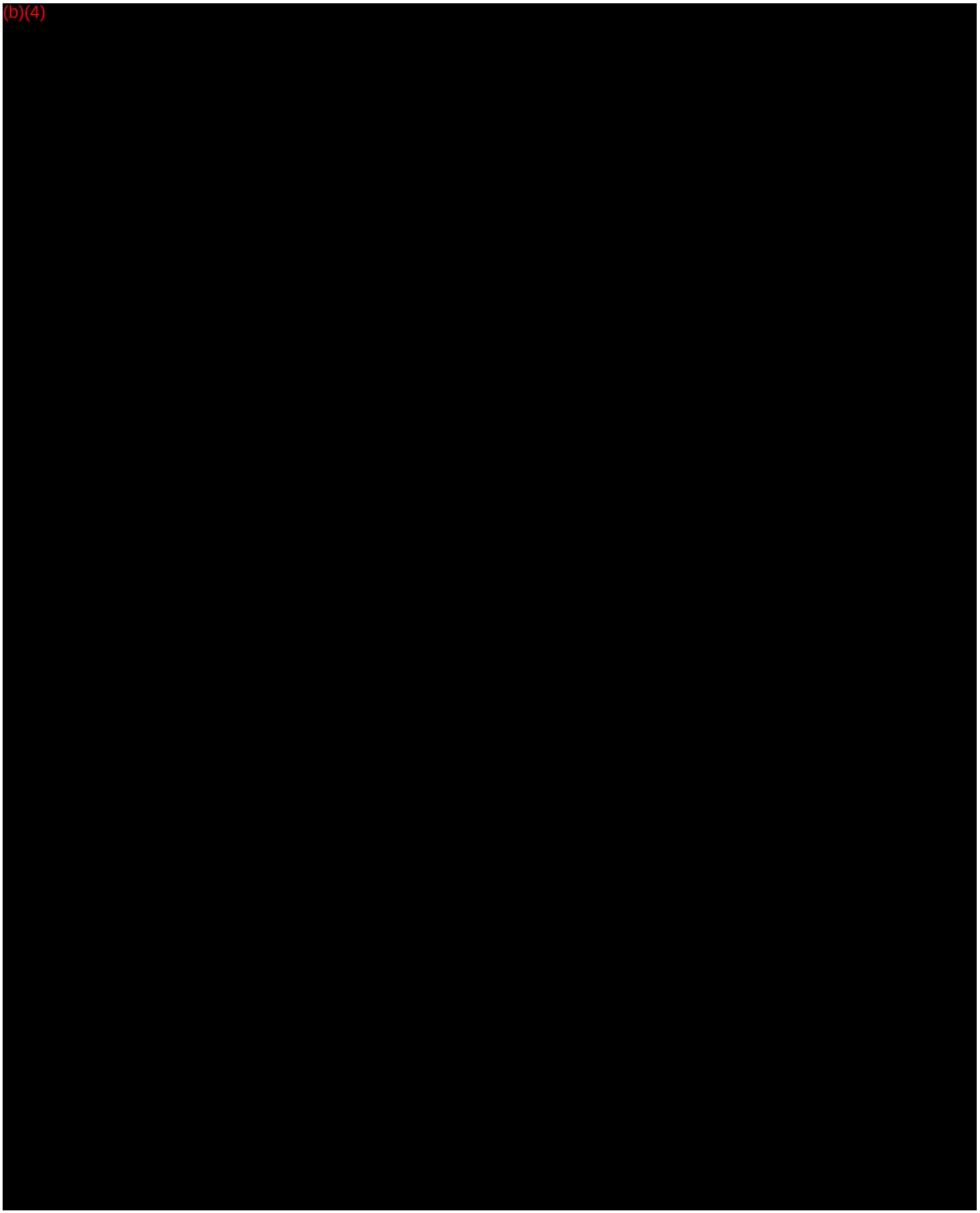

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3shape

May 9, 2016

Creating an implant library for the 3Shape Dental System™

Version 1.0

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3shape

May 9, 2016

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May 9, 2016

1 Introduction

In order to create an implant library for the design of customized abutments, implant bars and bridges in the Dental System™, 3Shape specific requirements must be met.
This document is a detailed description of the requirements and will guide the implant library provider through the library creation.

2 3Shape´s implant library distribution policy

3Shape is supporting the creation, distribution and promotion of original and compatible-with implant libraries under the following requirements:

- The implant library provider is the legal entity providing the Implant library.
- The implant library provider is responsible for obtaining all regulatory clearances relevant to the library and the parts thereof. Documentation for said clearance must be supplied to 3Shape where applicable.
- The implant library provider is responsible for the creation, the validation and any IP violation in relation to the library
- 3Shape only supports the distribution of the library to end customers if the providers has signed the implant library contract with 3Shape and the library has been provided to 3Shape
- The 3Shape reseller must approve the distribution of the implant library to his end-customers

3 Implant library and implant system concept

Implant Systems in the Dental System Control Panel are organized as following:

- An **implant library** is a digital representation of one or more **implant systems**.
- An **implant system** typically corresponds to a given implant type. In addition a number of implant systems can be grouped in a category, see sect. 5.5.
- Each **implant system** contains a number of **parts** – implants, scan abutments, screws, bases, interfaces, analog interfaces, etc. See sect. 4.1 for details.
- An **abutment kit** typically corresponds to a specific implant connection/diameter of the implant type. An abutment kit is an assembly of parts needed to complete the design of the customized abutment. Abutment kits are created by referencing the models added to a given implant system. Multiple abutment kits can reference the same parts and these kits, hence, allow you to easily combine the various parts belonging to a given implant system.

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The diagram below illustrates the example of an implant system and one of its abutment kits:

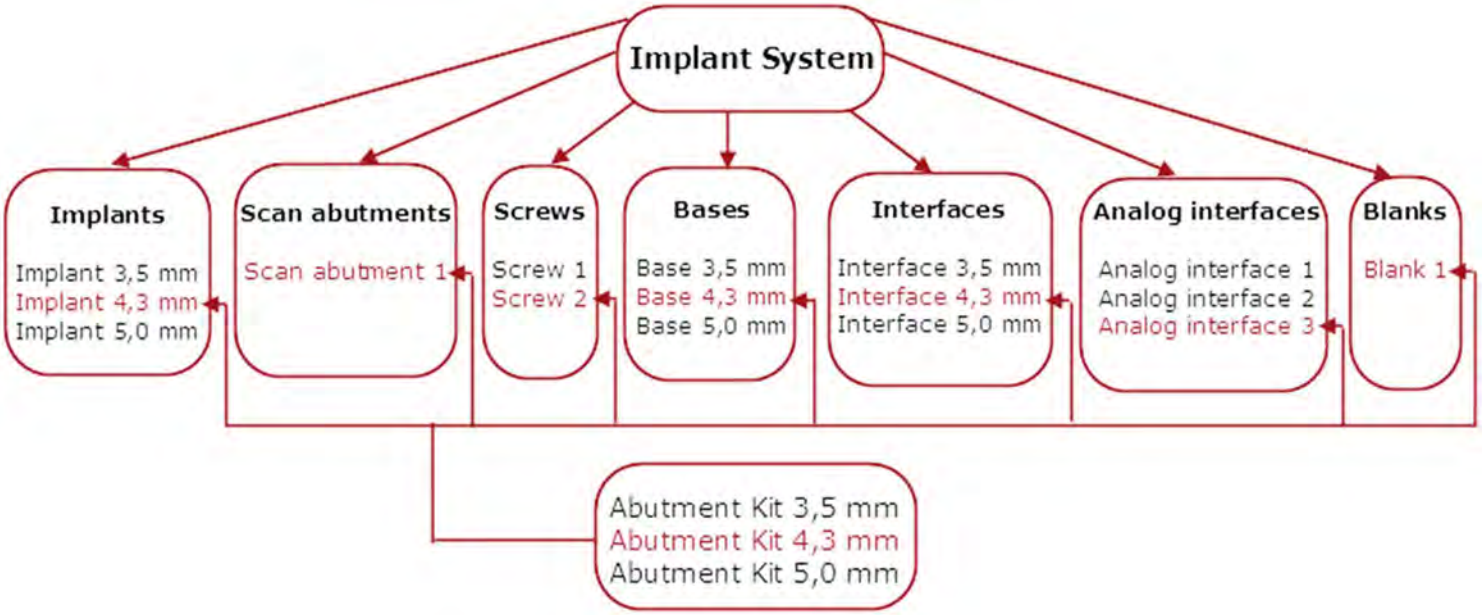

Figure 3-1: Implant system structure in the Dental System™.

4 The implant library installation workflow

Below figure illustrates the workflow for the installation of the implant libraries by the dental laboratory and the creation and provision of the implant library by the implant library provider.

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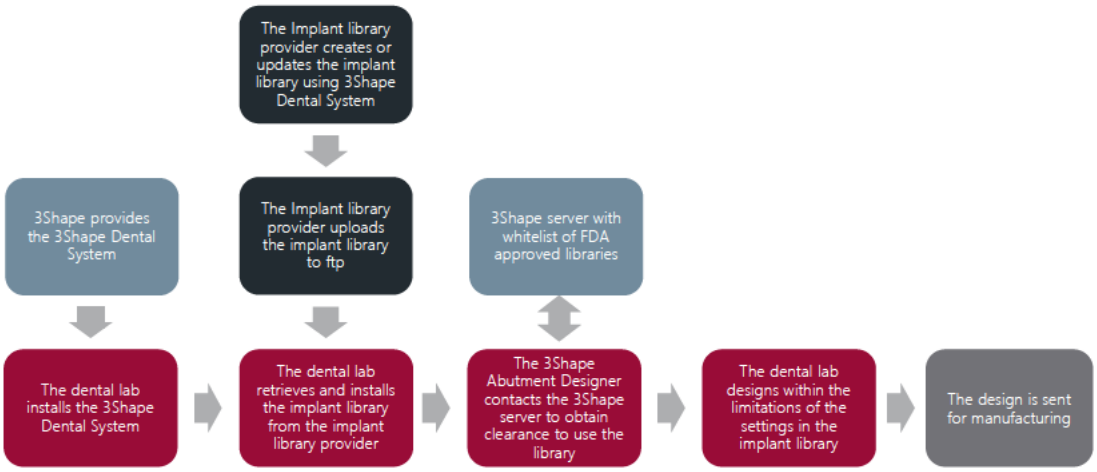

Please see section 6 for a description how to create and update the implant library.

The dental lab has two ways to retrieve the implant library from the implant library provider:

1. **Manual import of the implant library**
2. **Download over ftp**

4.1 Manual import of the implant library

In the Control Panel the under Tools –> Import / export it is possible to import the implant library by selecting "Import materials".

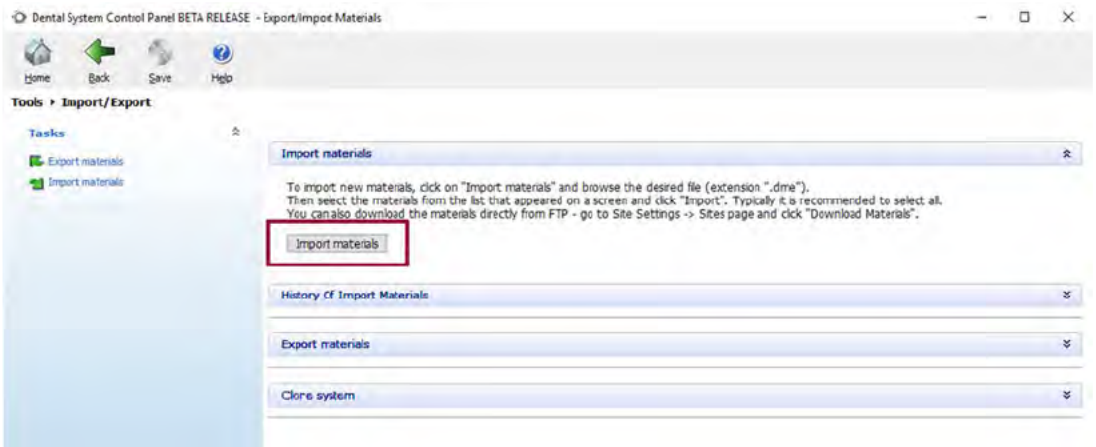

Figure 4-1: Implant library import in the Dental System™.

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After locating and selecting the implant library file a dialogue shows the contents i.e. the implant systems that the implant library file contains. The appropriate implant systems are then selected for import.

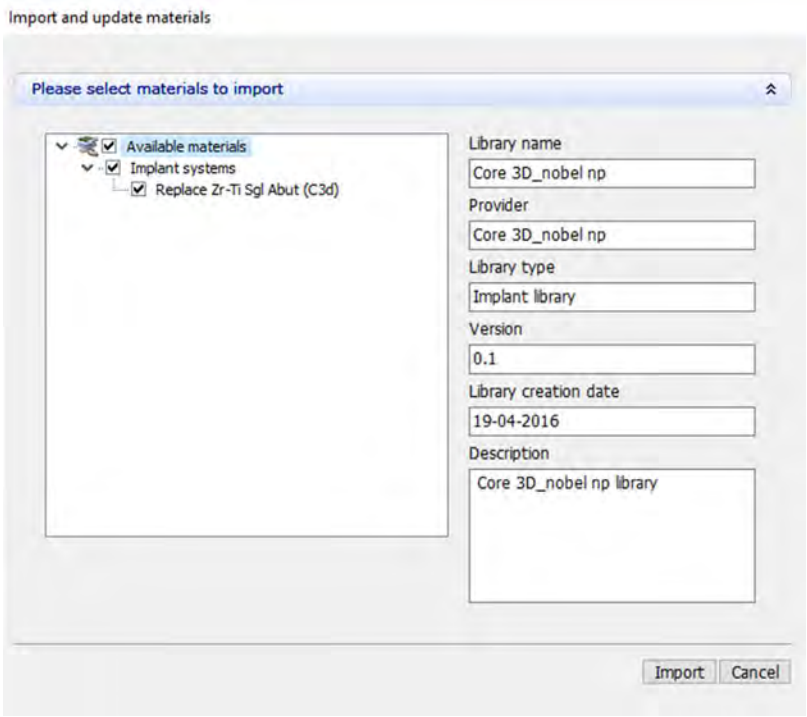

Figure 4-2: Import and update materials.

4.2 Download over ftp

In the Control Panel the under Tools –> Download center it is possible to retrieve materials from ftp either by selecting the Download materials or the Download libraries option.

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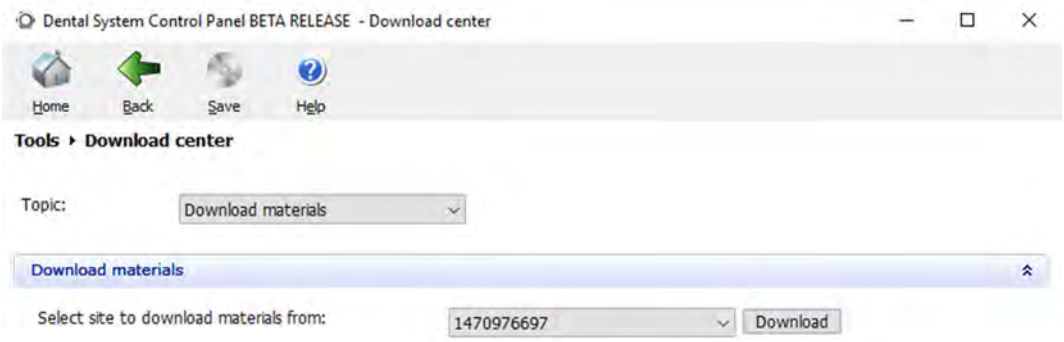

Figure 4-3: Materials download.

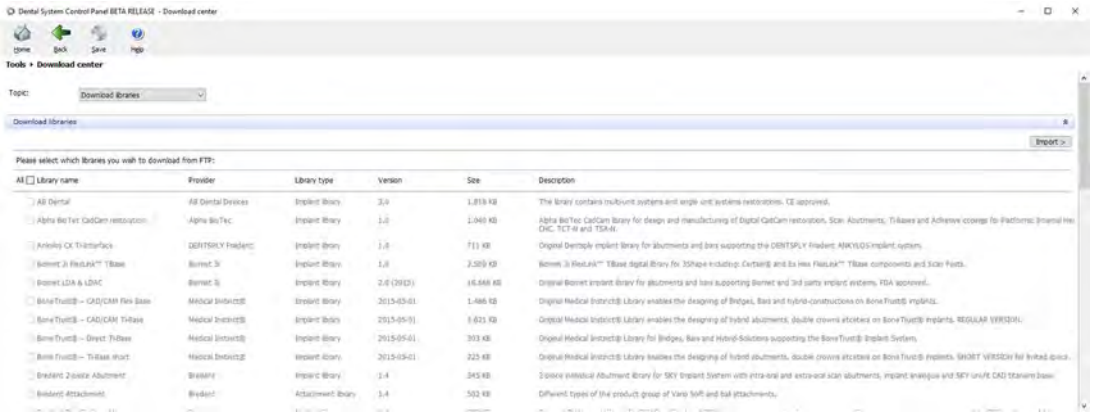

Figure 4-4: Implant library download.

In the Download libraries option it is possible to select which library should be retrieved and installed. Please see section 14 on how to identify if a library is cleared for use in the US by FDA.

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Implant

There are no specific requirements for the model of the implant. This model is used for visualization purposes only.

Scan abutment

The model corresponds to the physical scan abutment.
However, the non-visible part of the model -such as the inside of the screw hole and the interface- should be deleted to maximize alignment accuracy.

The design of the scan abutment is important for achieving an accurate fit, which is particular important for implant bridges.

Screw

There are no specific requirements for the model of the screw.
The model of the screw is used to automatically generate a correctly shaped hole through the abutment.

In case of using a pre-milled blank with pre-defined screw hole, the generated screw hole can be automatically removed from the CAM output (see sect. 3.2).

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Blank

The blank model should be a cylinder without screw hole and interface. This model is used to visualize the size of the blank.

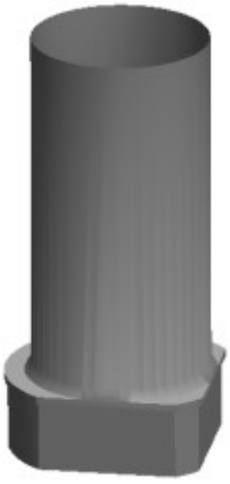
Digital model analog interface (optional)

Digital model analog interface is used for creating a hole, where model analog is inserted.
The model should contain either

- **two** boundaries (model analog interface with the **bottom** insertion)

OR

- **one** boundary at the top of the model (model



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analog interface with insertion from the **top**)

Inner limit (optional)

The inner limit model should be a cylinder without screw hole. This model is used to visualize the limitations for the minimum geometry of the abutment.

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5.1.2 Two-piece abutments

Implant

There are no specific requirements for the model of the implant. This model is used for visualization purposes only.

Scan abutment

The model corresponds to the physical scan abutment.
However, the non-visible part of the model -such as the inside of the screw hole and the interface - should be deleted to maximize alignment accuracy.

The design of the scan abutment is important for achieving an accurate fit, which is particular important for implant bridges.

Screw

There are no specific requirements for the model of the screw.
The model of the screw is used to automatically generate a correctly shaped hole through the abutment.

In case of using a pre-milled blank with pre-defined screw hole, the generated screw hole can be automatically removed from the CAM output (see sect. 3.2).

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Abutment interface

There are no specific requirements for the model of the interface.

This file is for visualization only, the 3Shape software does not allow any changes by the end-user to this file during the abutment design process.

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Blank (optional)

The blank model should be a cylinder without screw hole and interface. This model is used to visualize the size of the blank.

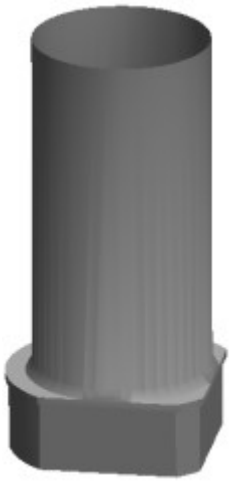
Digital model analog interface (optional)

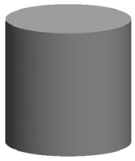
Digital model analog interface is used for creating a hole, model analog is inserted.
The model should contain either

- **two** boundaries (model analog interface with the **bottom** insertion)

OR

- **one** boundary at the top of the model (model analog interface with insertion from the **top**)





Inner limit (optional)

The inner limit model should be a cylinder without a screw hole. This model is used to visualize the limitations for the minimum geometry of the abutment.

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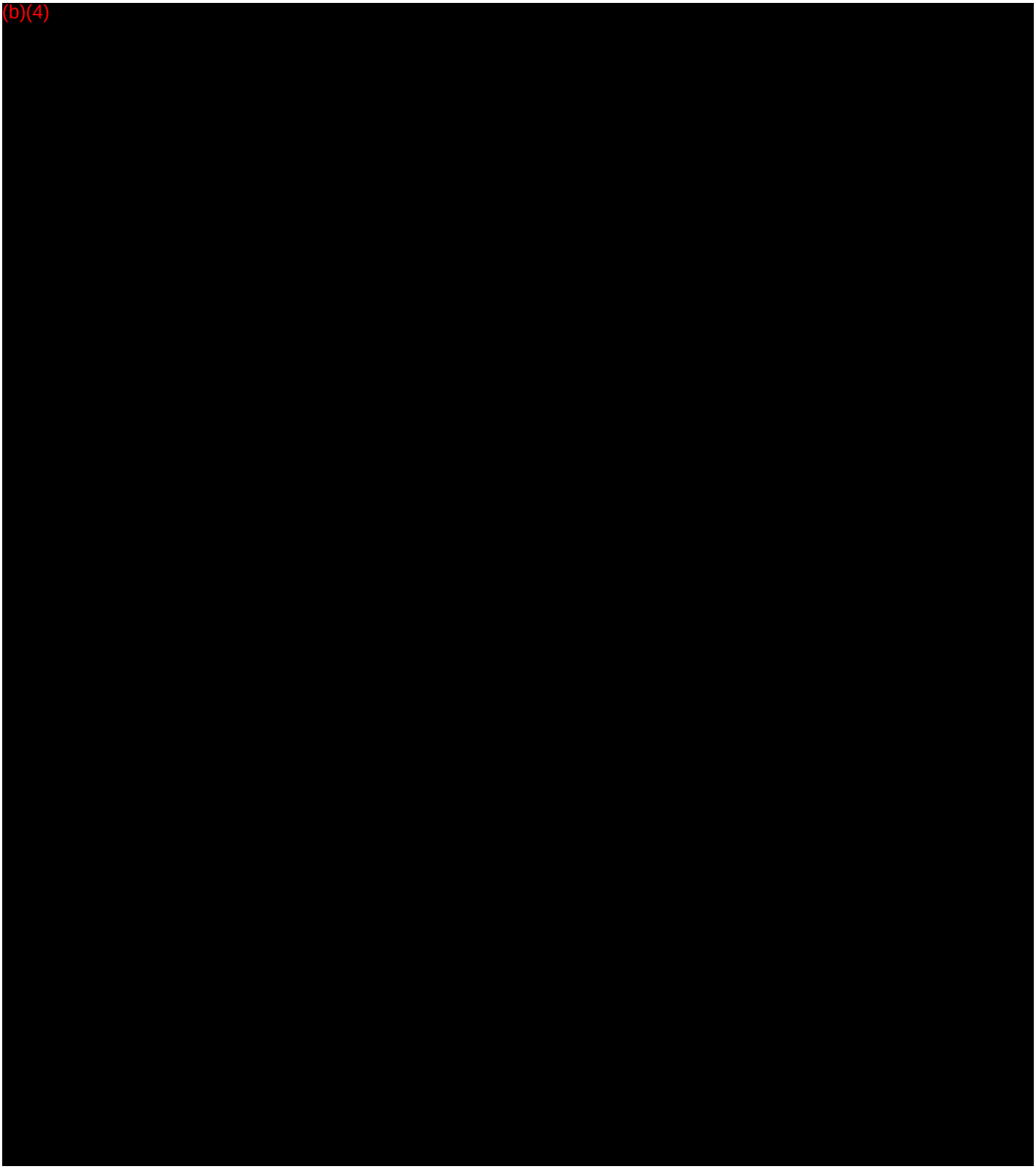

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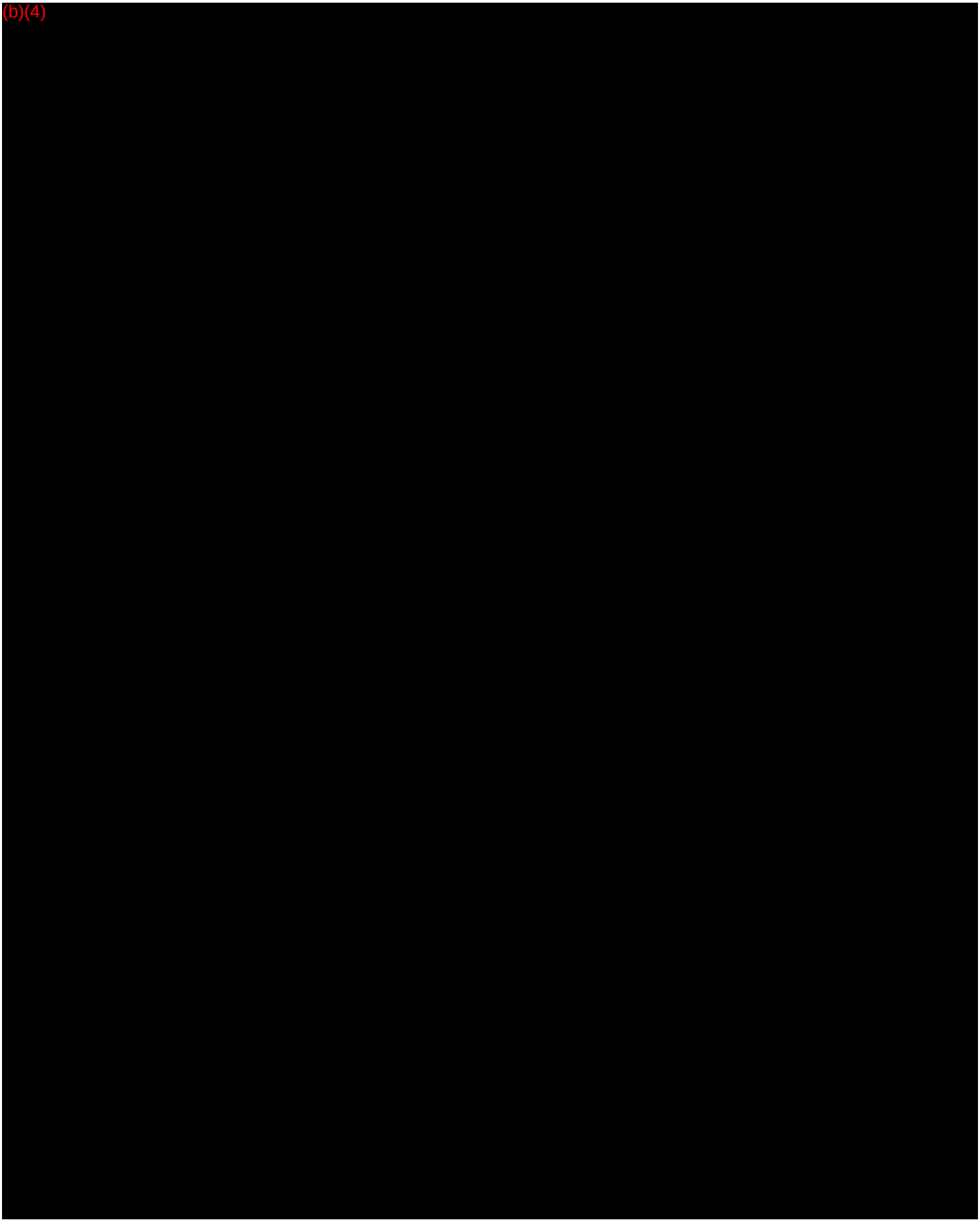

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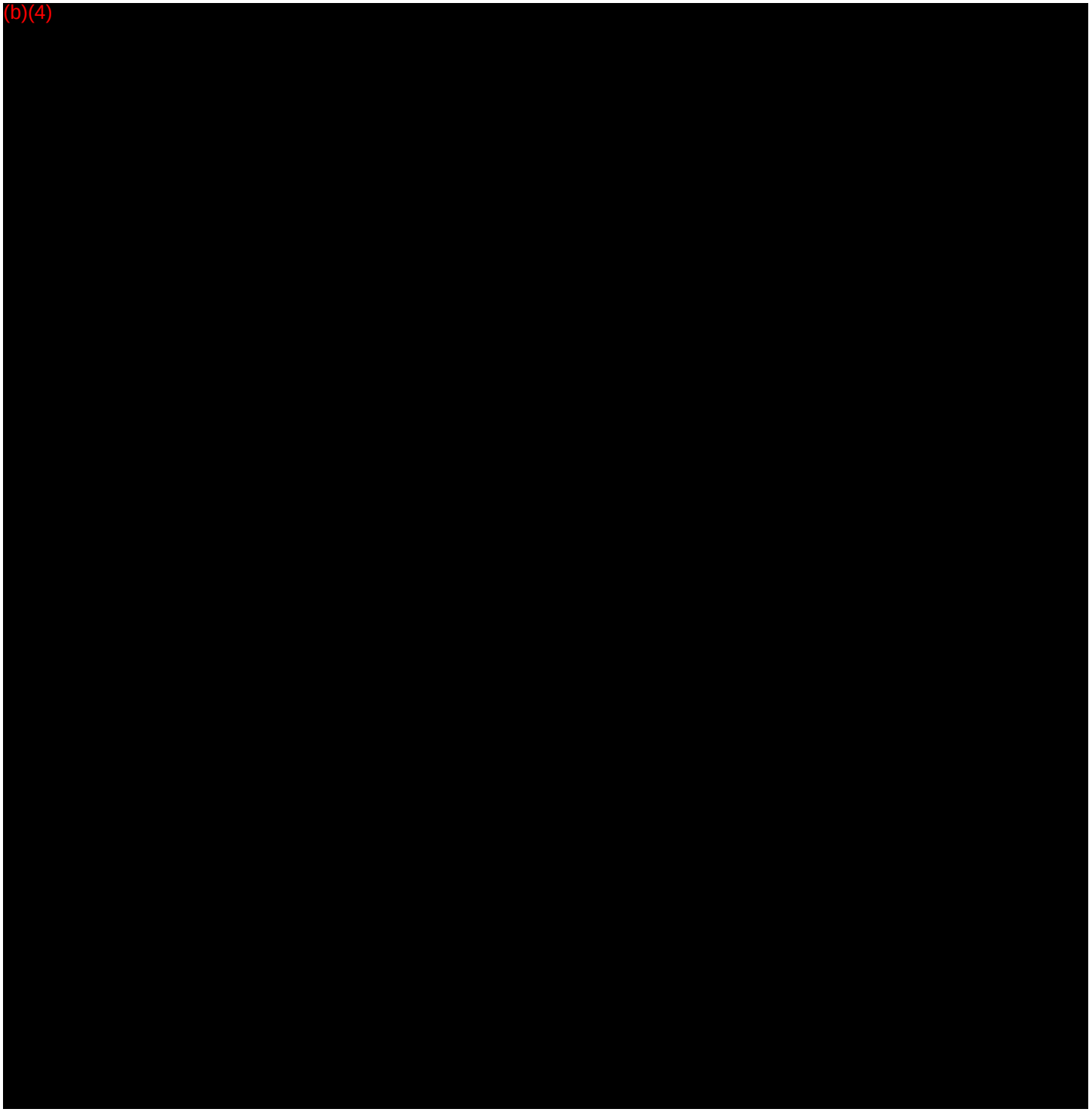

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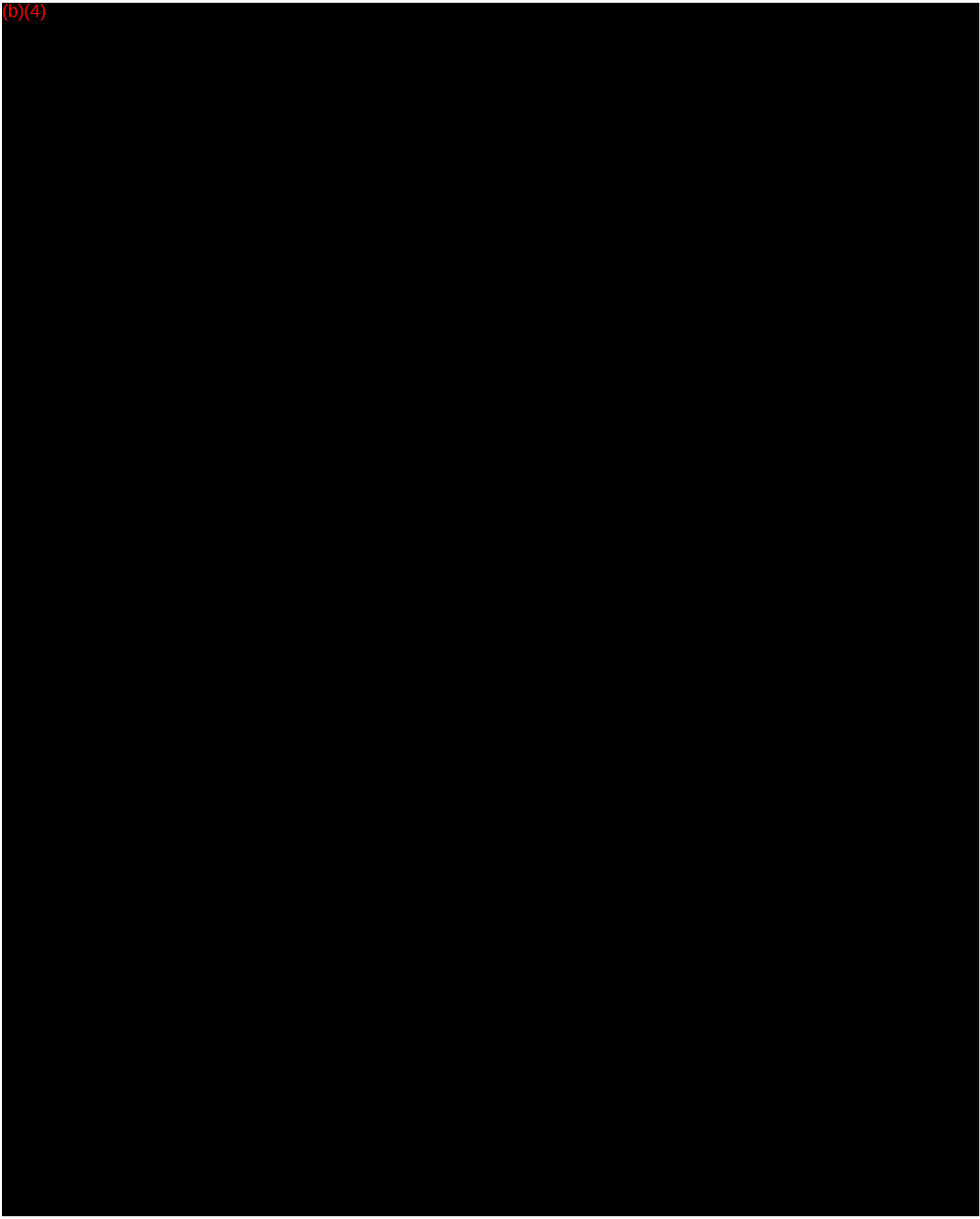

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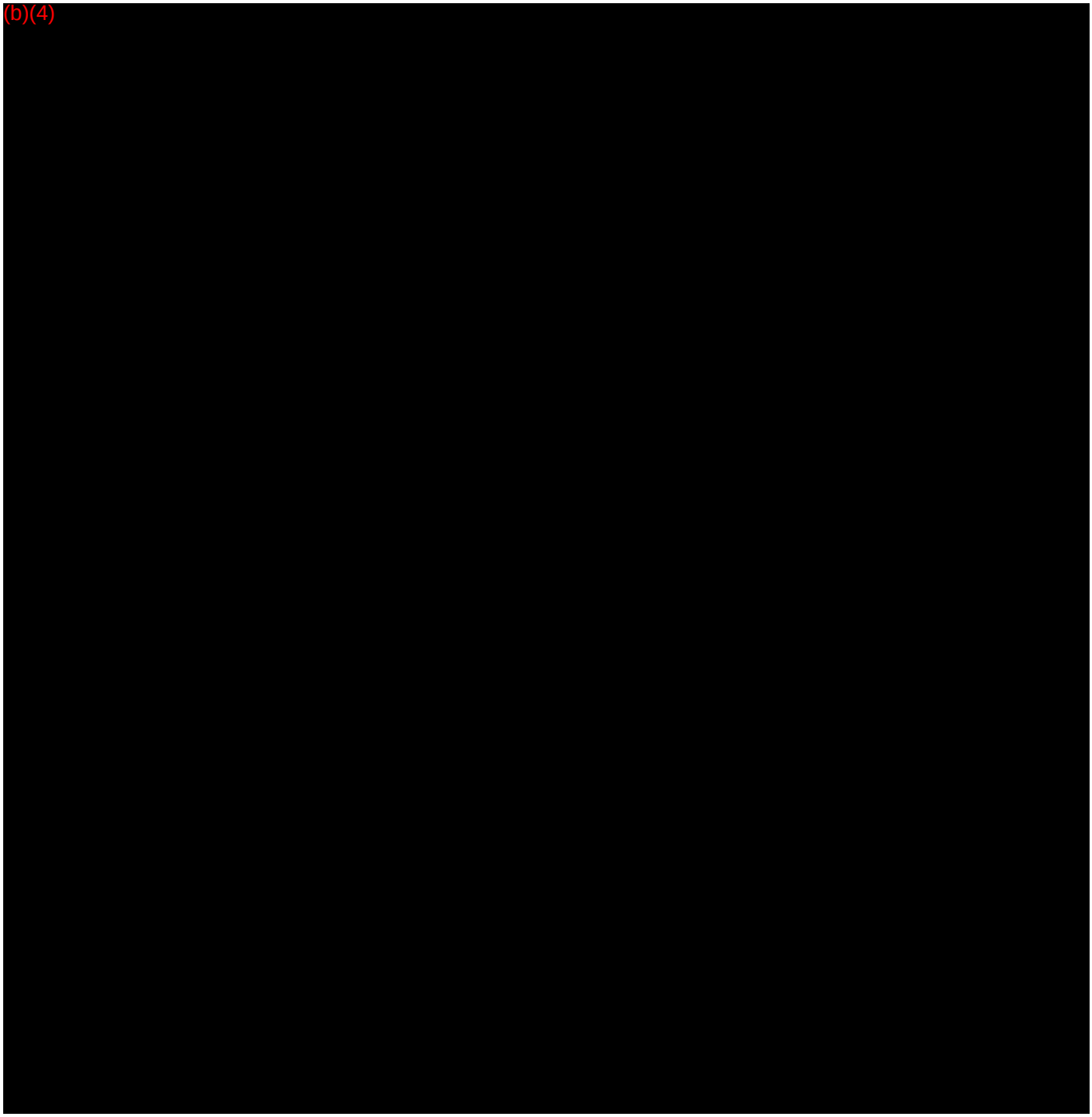

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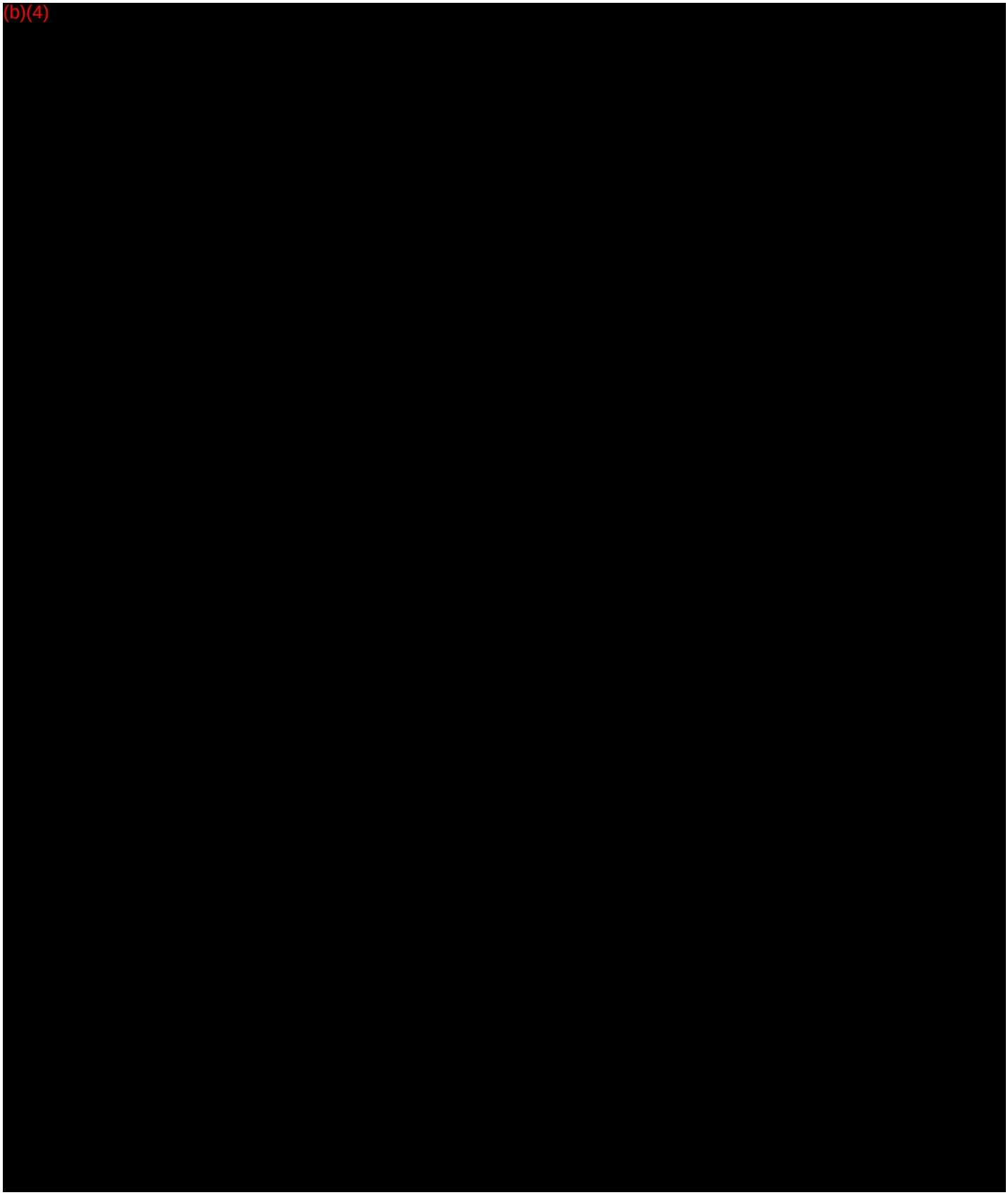

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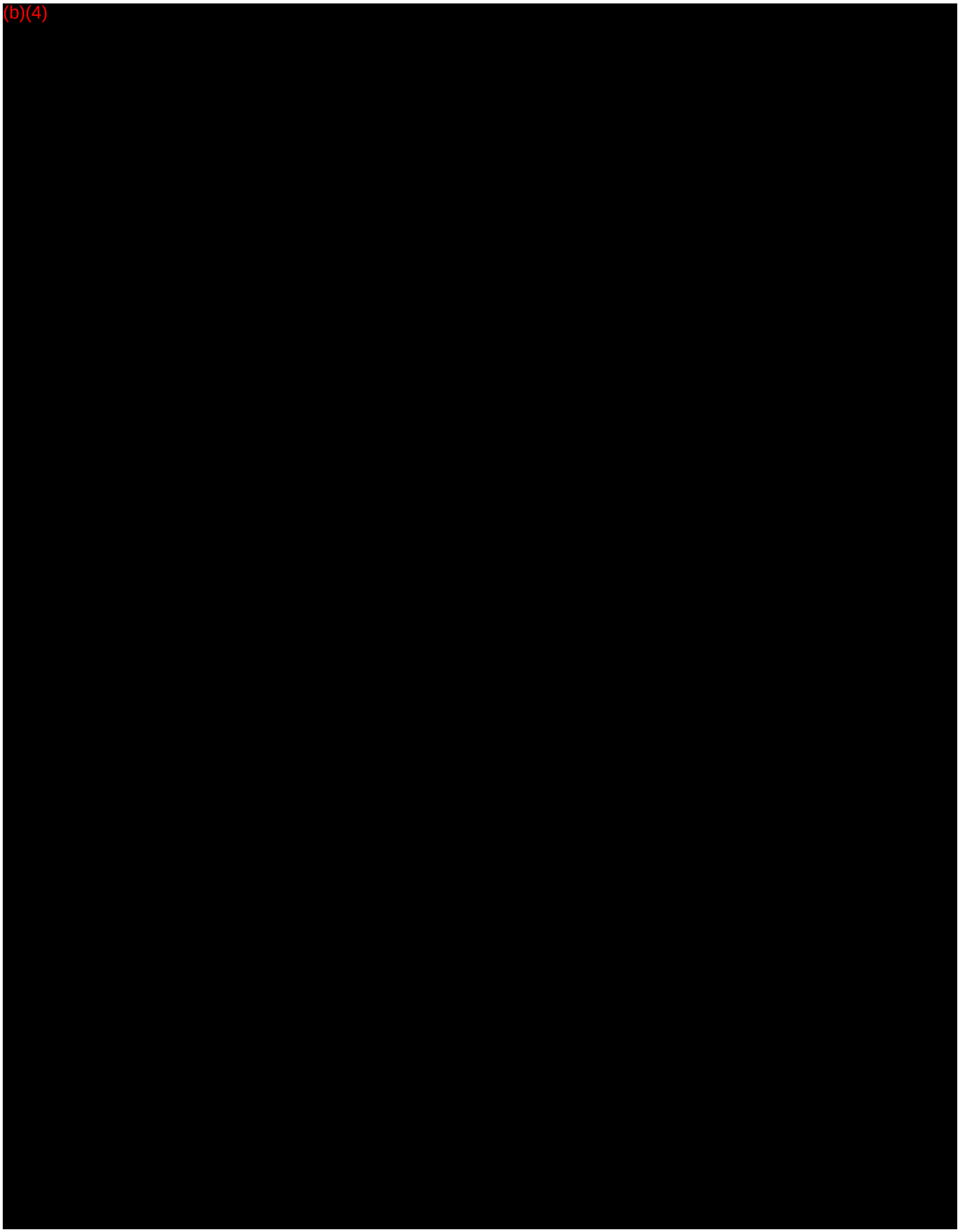

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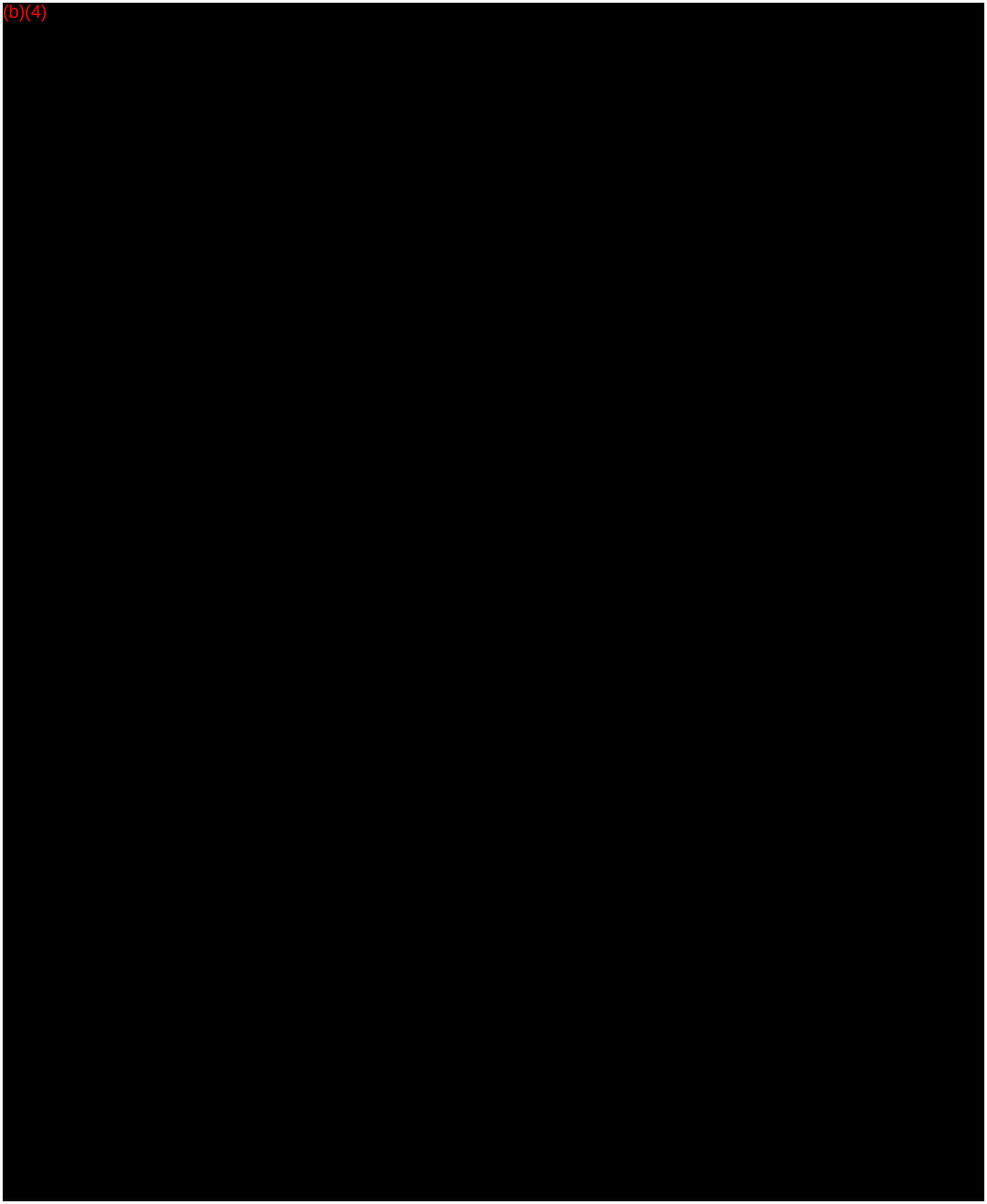

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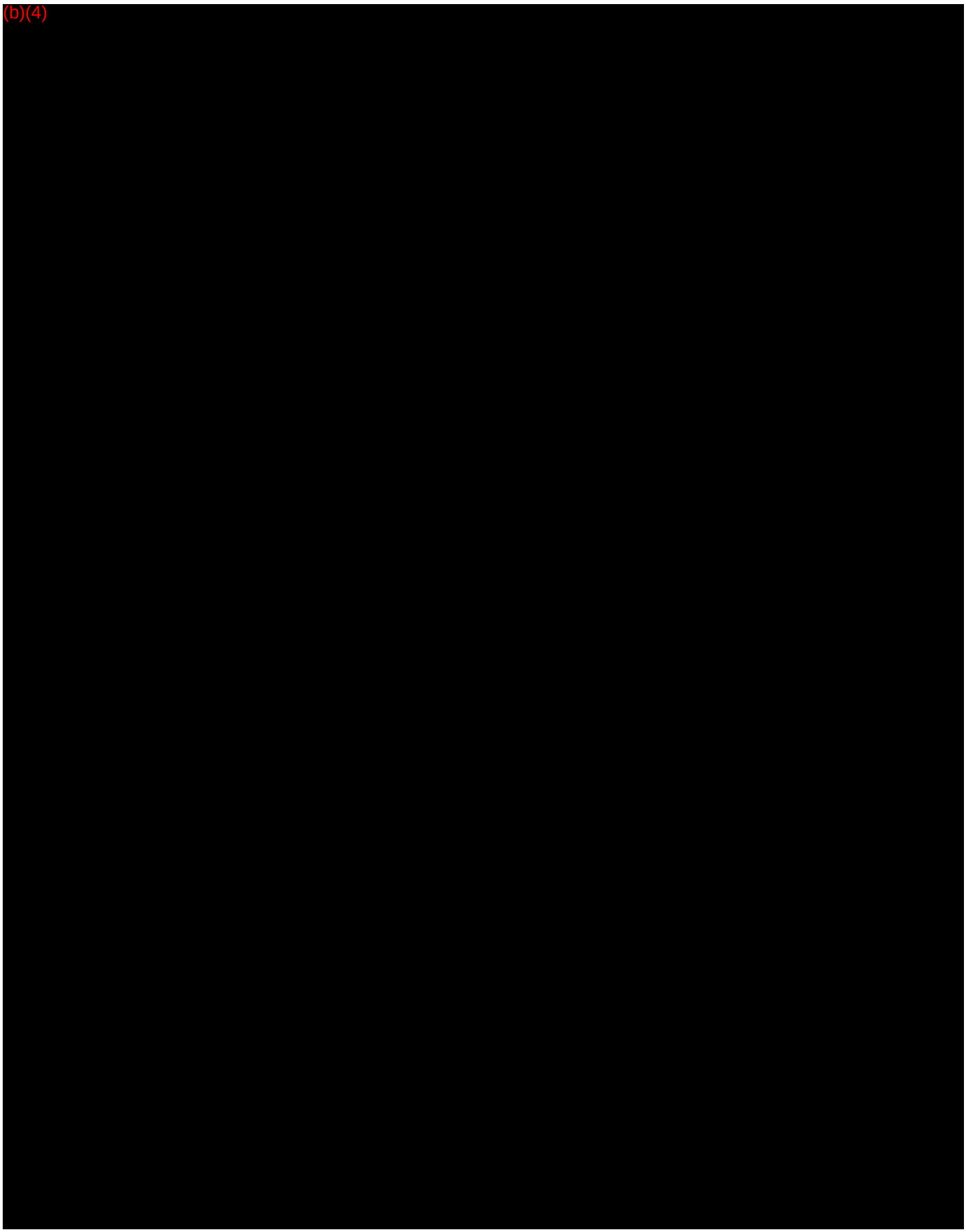

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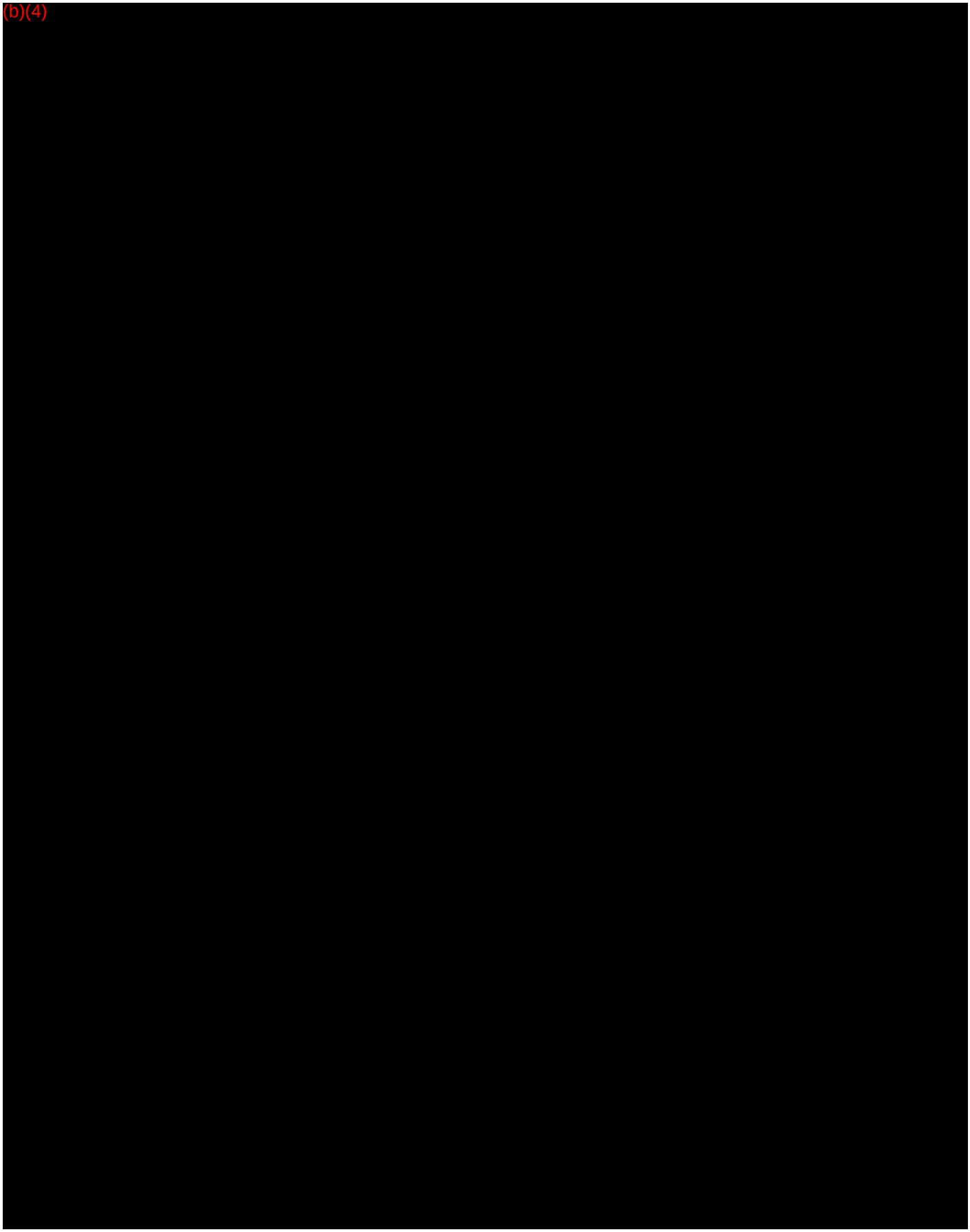

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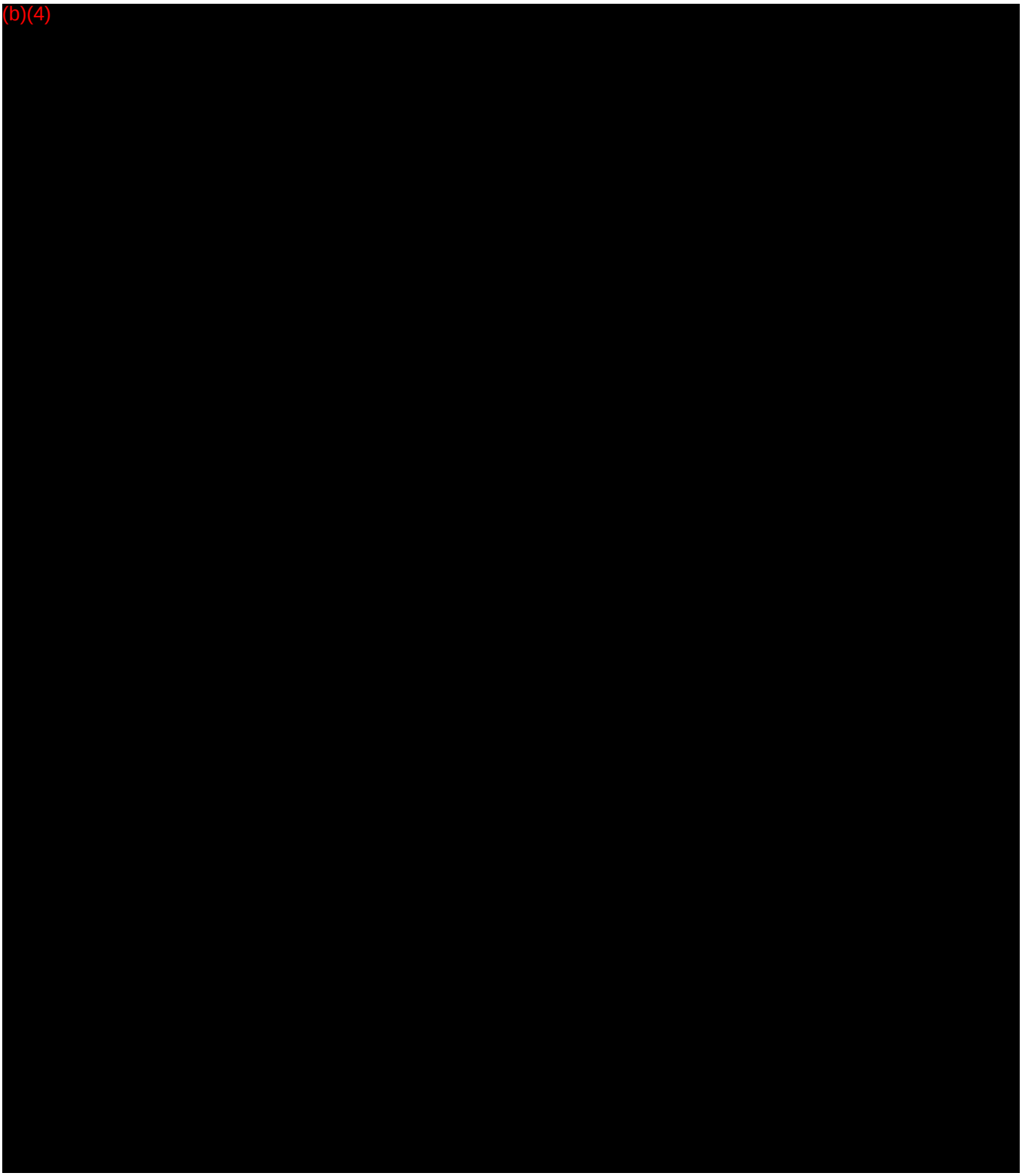

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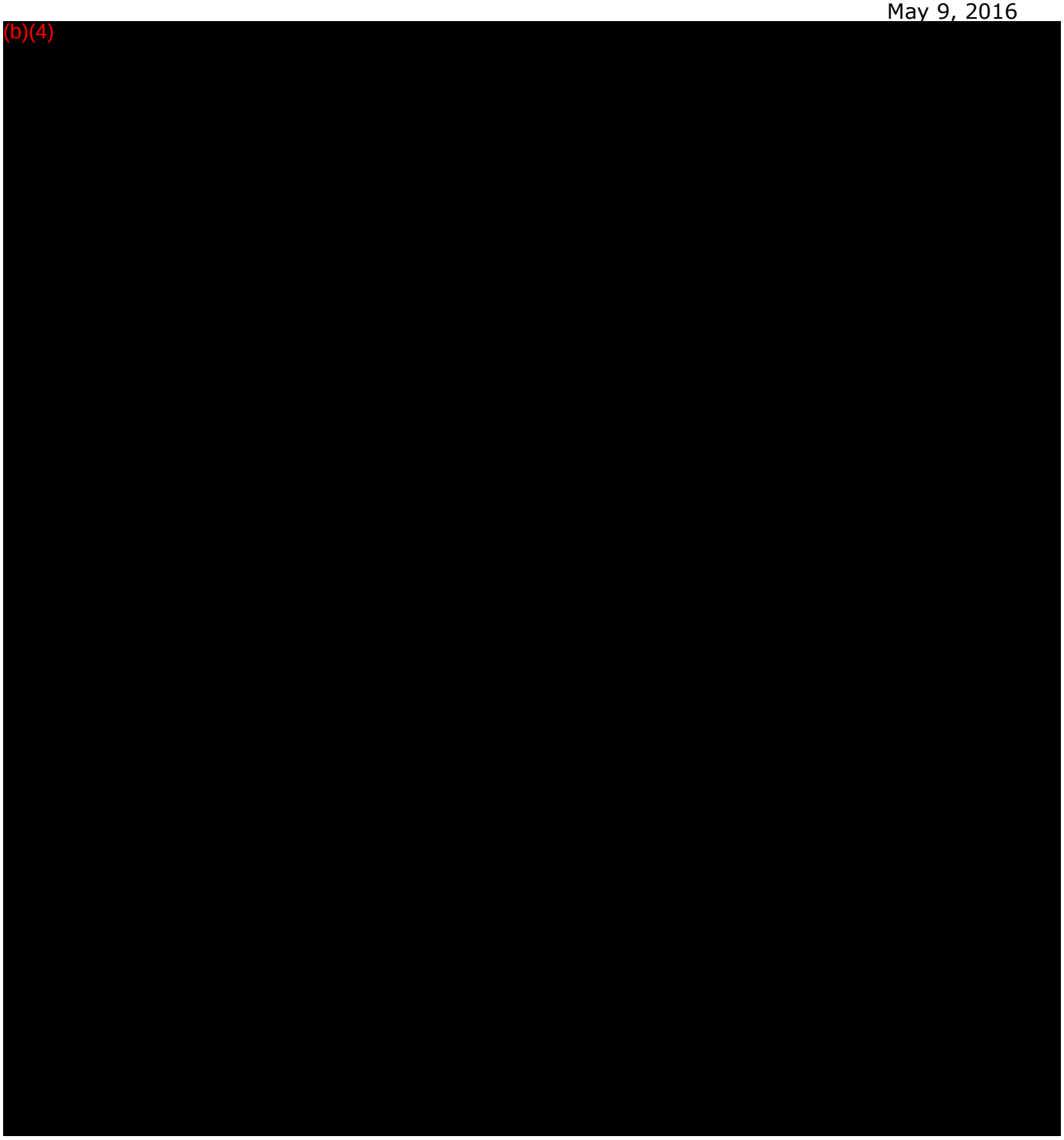

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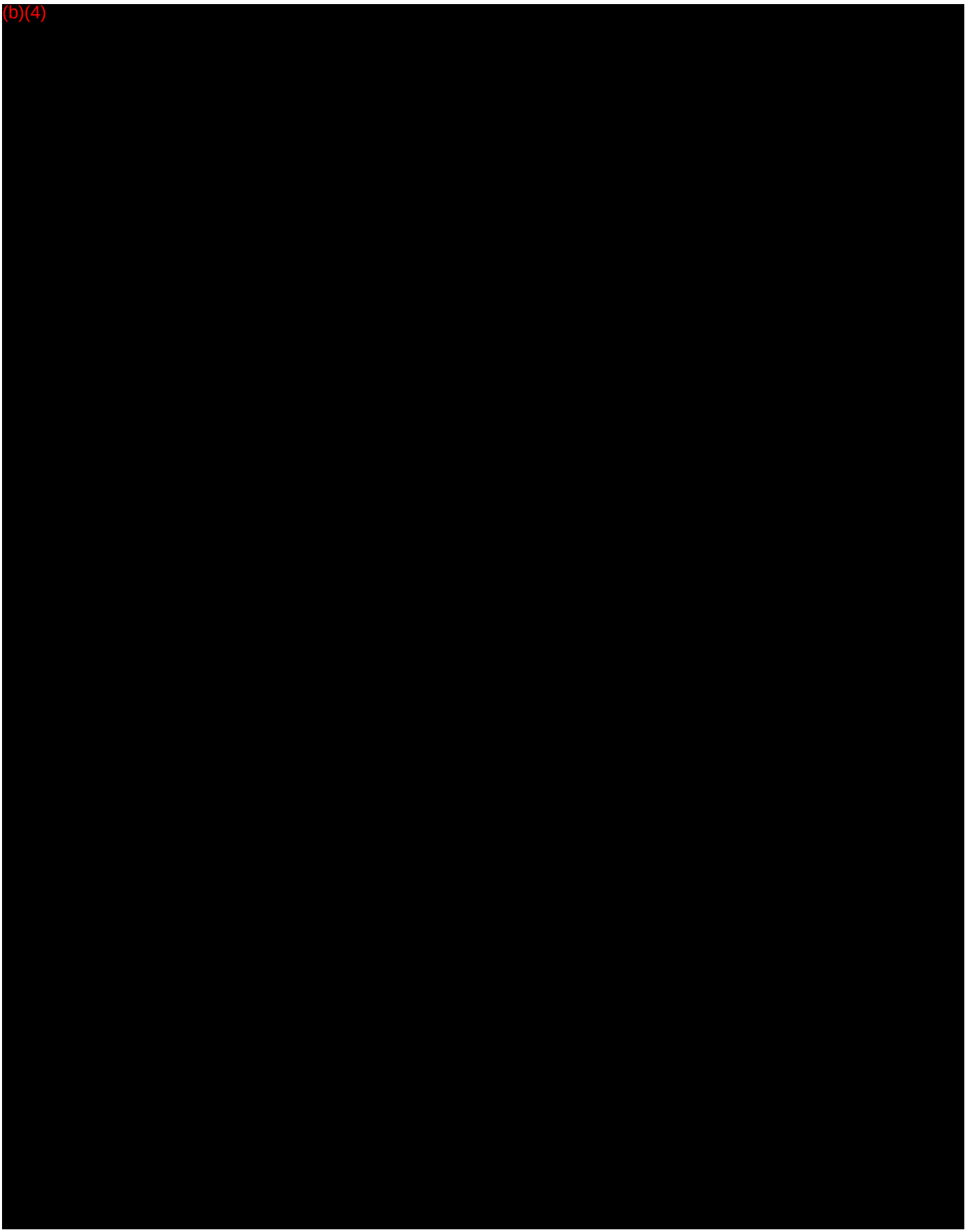

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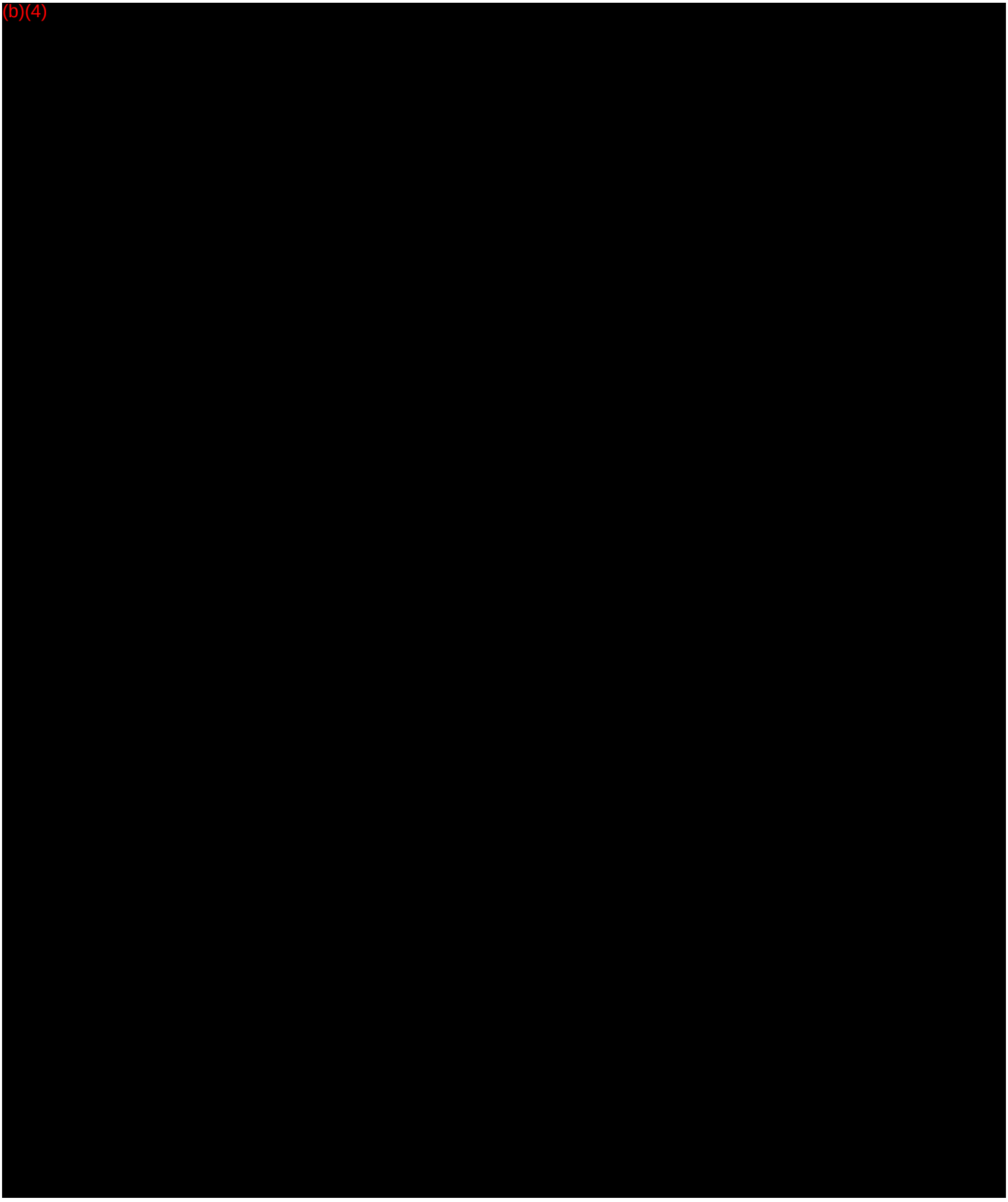

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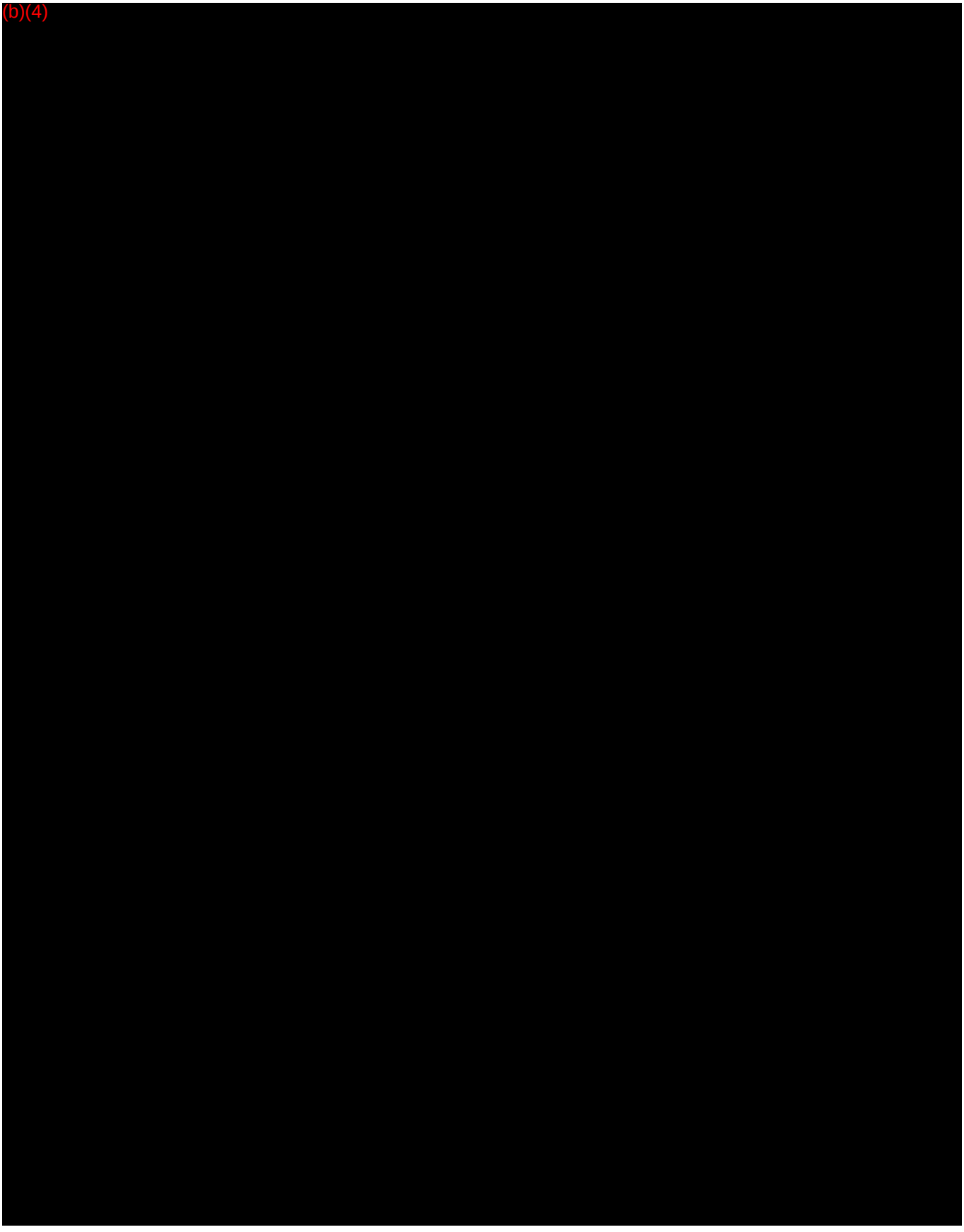

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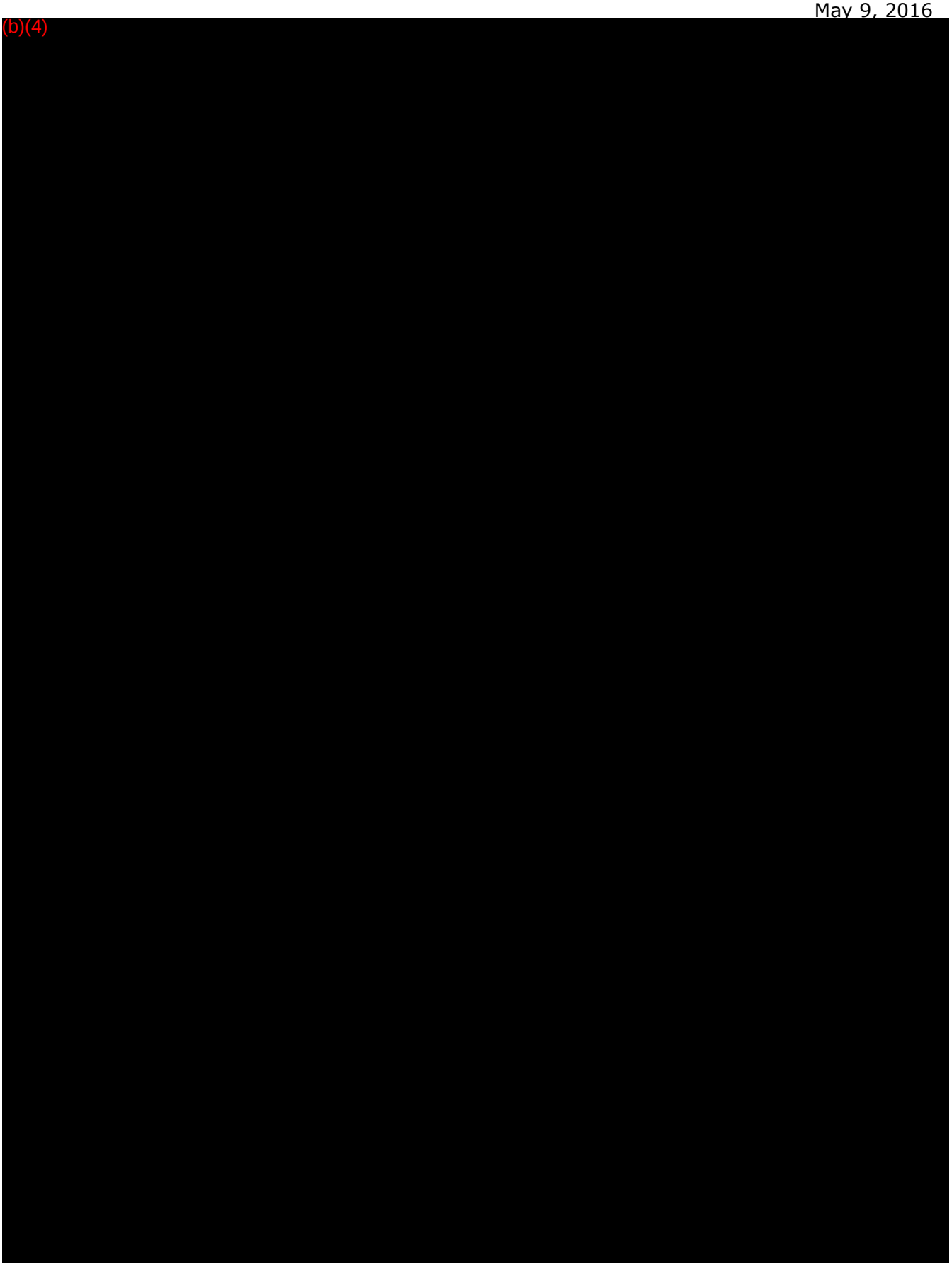

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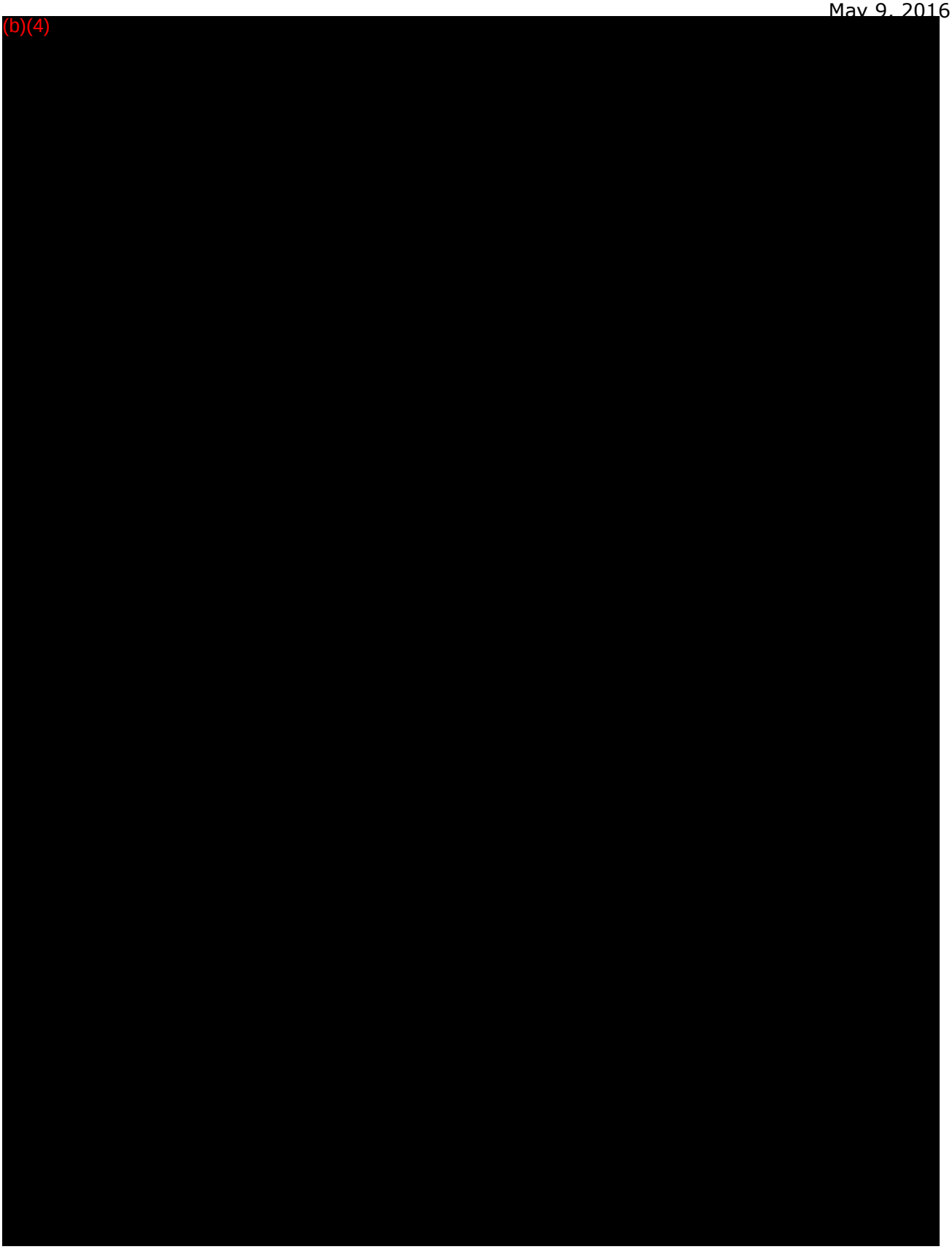

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6 Defining an Implant System in the Dental System™

Creating implant systems is easily done using the Dental System™ Control Panel. How to configure abutment kits for the customized abutment design is described step by step in the following section.

Please note, that implant libraries are forward compatible.

If you create a library, using Dental System 2014 version, it won't be possible to use it in older version of the software – Dental System 2013, while Dental System 2014 and newer would be able to import it.

We are constantly adding new features, such as 3Shape Global Coordinate System for implant systems (see chapter 4.2), and 3Shape Global Implant Connection ID (see chapter 6), so it's important to use the latest version in order to use new functions.
However, older version would provide implant library with wider compatibility over different versions.

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6.1 Importing CAD files and creating abutment kits

Open the Dental System™ Control Panel and go to Abutments > *Implant Systems*. This will bring up the Details mode of the implant systems:

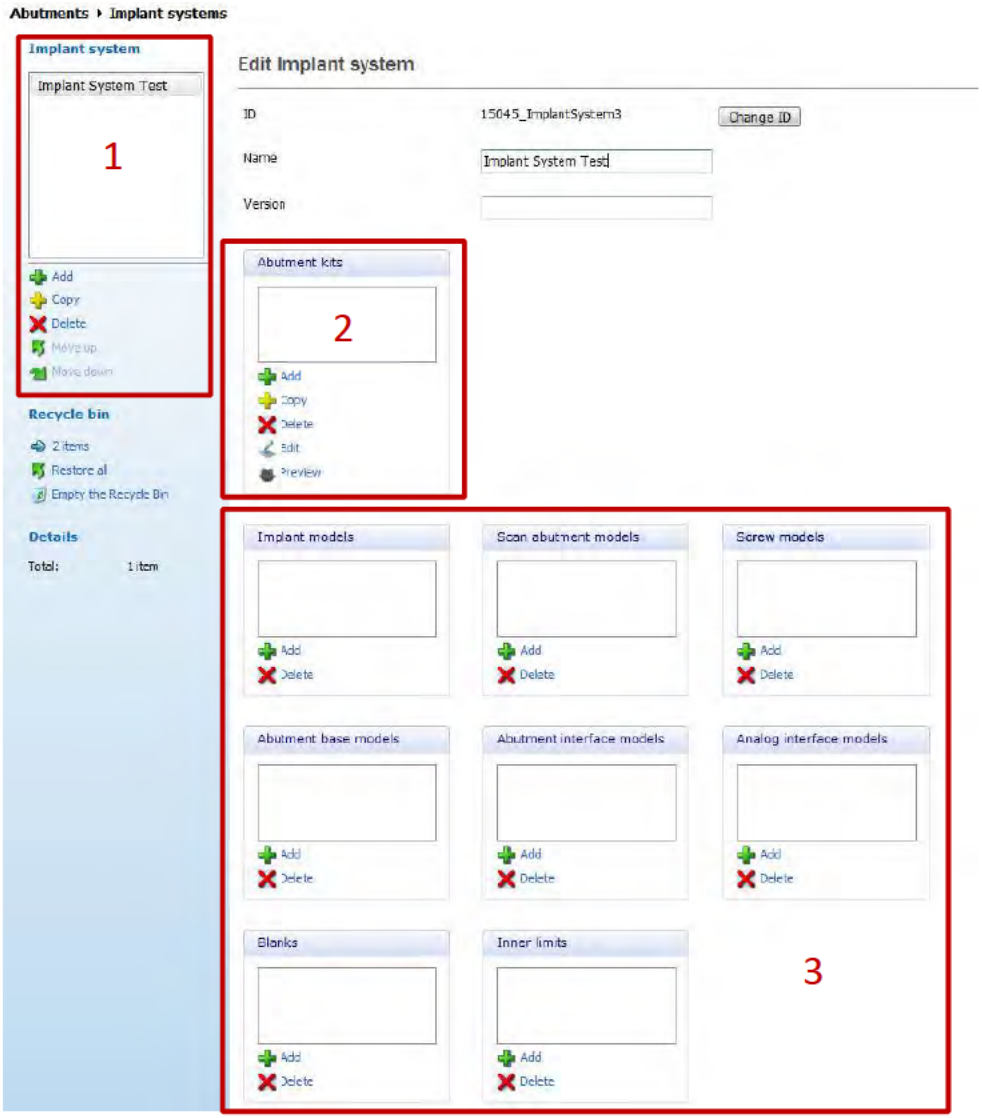

Figure 5-5: Defining implant systems and abutment kits in the Control Panel

1. To add a new implant system, press the ***Add*** button under Implant System - (1) - and enter a unique ID, the name for the new system and a version number.
2. To add parts/CAD files to the selected implant system, press ***Add*** under the implant system parts - (3) - and browse the file. Import all the desired parts before proceeding to the next step.

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3. To create abutment kits from the parts of the active implant system, click the ***Add*** button under Abutment kits - **(2)**. This will bring up a **wizard** which will guide you through the part selection.

A **Table mode** for the implant systems has been implemented for a better overview and an easier and faster editing of abutment kits. A double-click activates the fields and values can be changed.

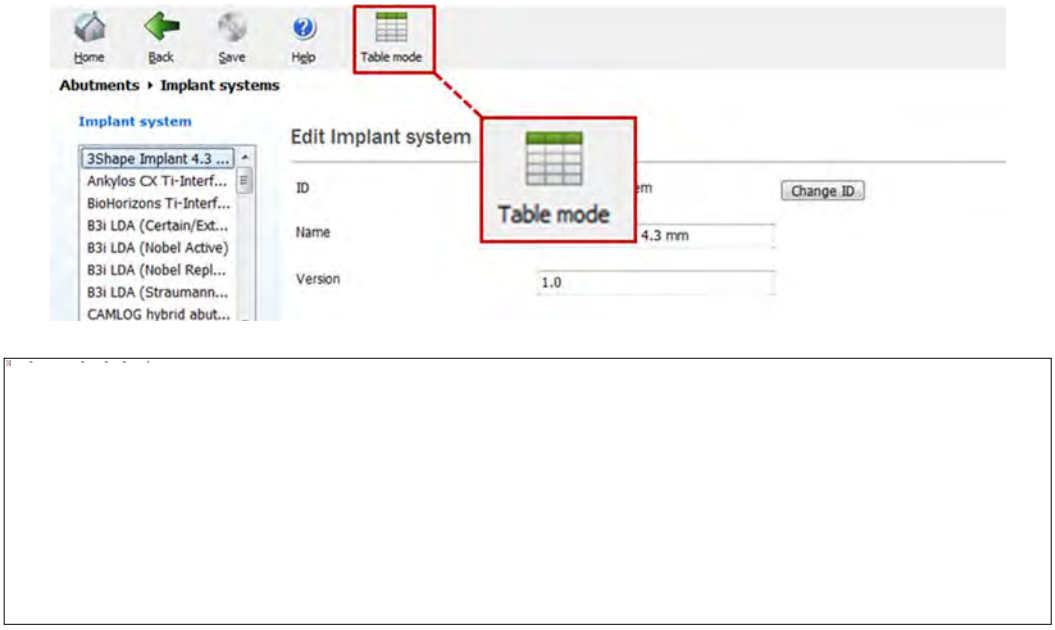

Figure 5-6: Table mode for implant systems

Browsing CAD files and creating abutment kits have still to be done in the details mode as shown and described above.

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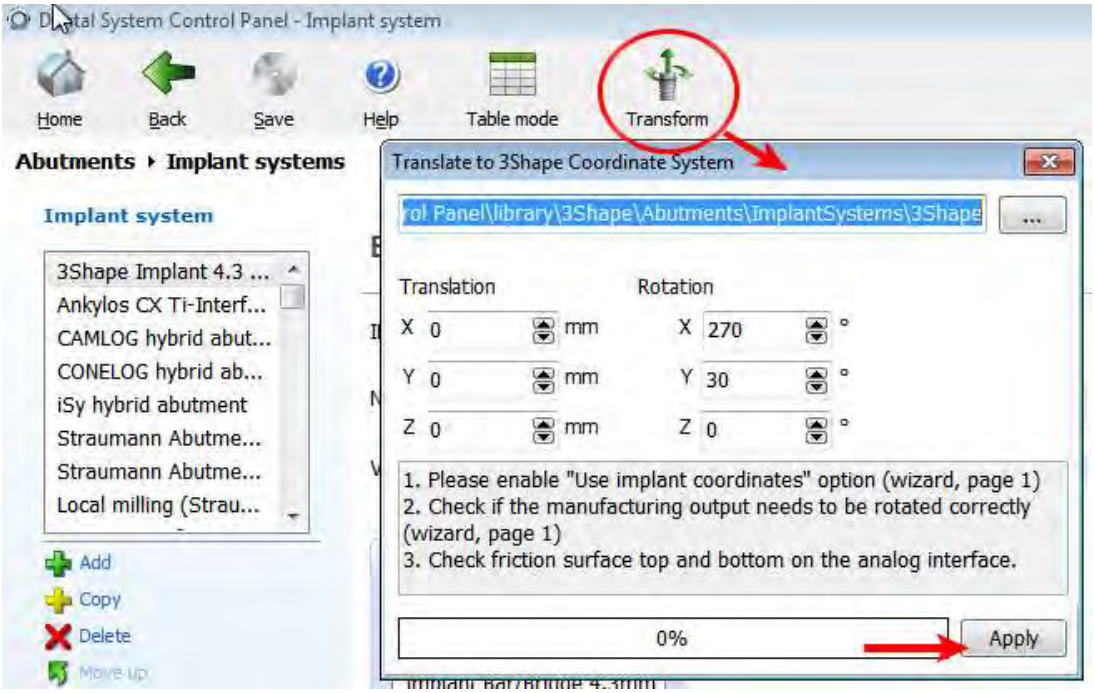
6.2 Rotate and translate a group of CAD files

New feature “Transform”, allows rotating and repositioning of entire set of models with the same transformation saving time and reducing the number of errors.

Select folder with models, and click “Apply”. Files would be updated in the same folder.



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6.3 Align scan abutment on top surface

The alignment algorithm has been improved in order to achieve better results mainly for the alignment of scan abutments with a horizontal top surface. This improvement ensures a better vertical locking of the implant position as well as the locking of the scan abutment rotation.

Implant system providers can enable the option *Align with top surface* when browsing their scan abutment CAD file (see sect. 5.1 step 2).

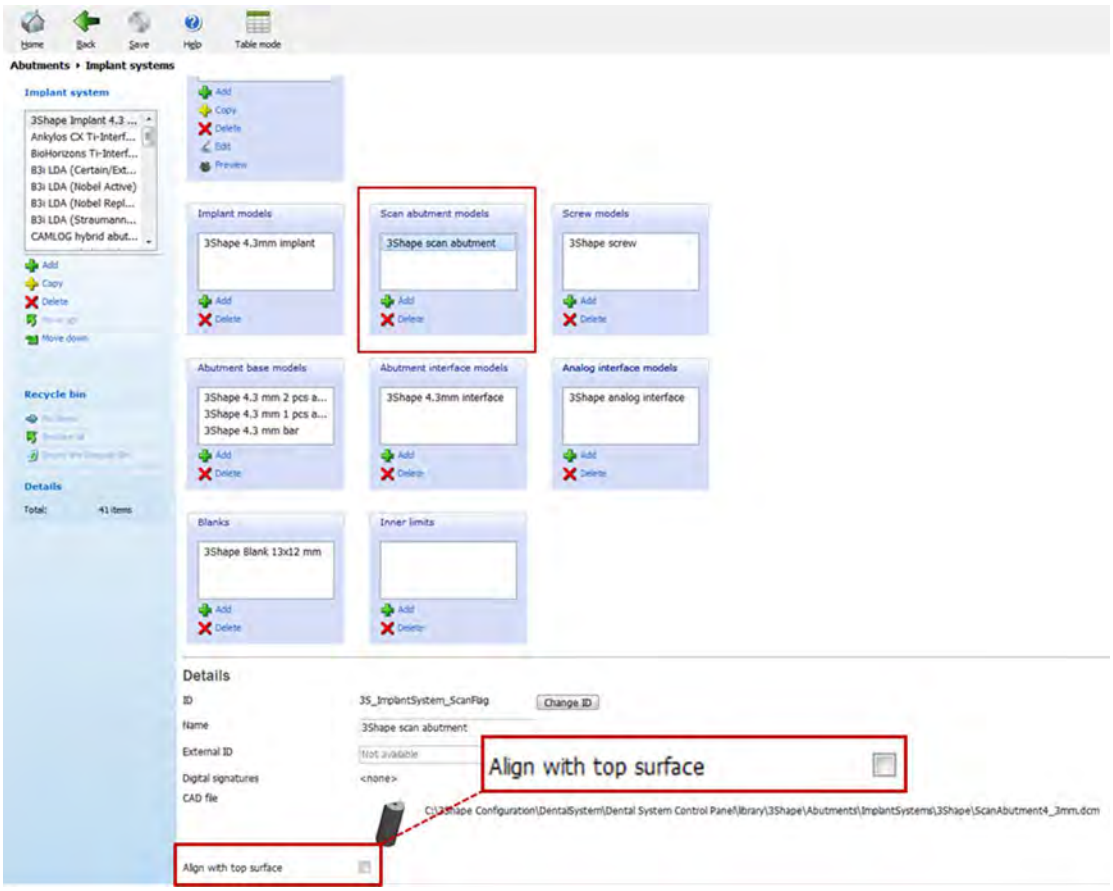

Figure 5-7: Align with top surface option

To read more about the requirements of scan abutments in order to achieve optimized scan results, please refer to sect. 10.

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6.4 Configuration of manufacturing options

The abutment manufacturing options allow the user to specify how abutments designed using the abutment kit in question should be exported.

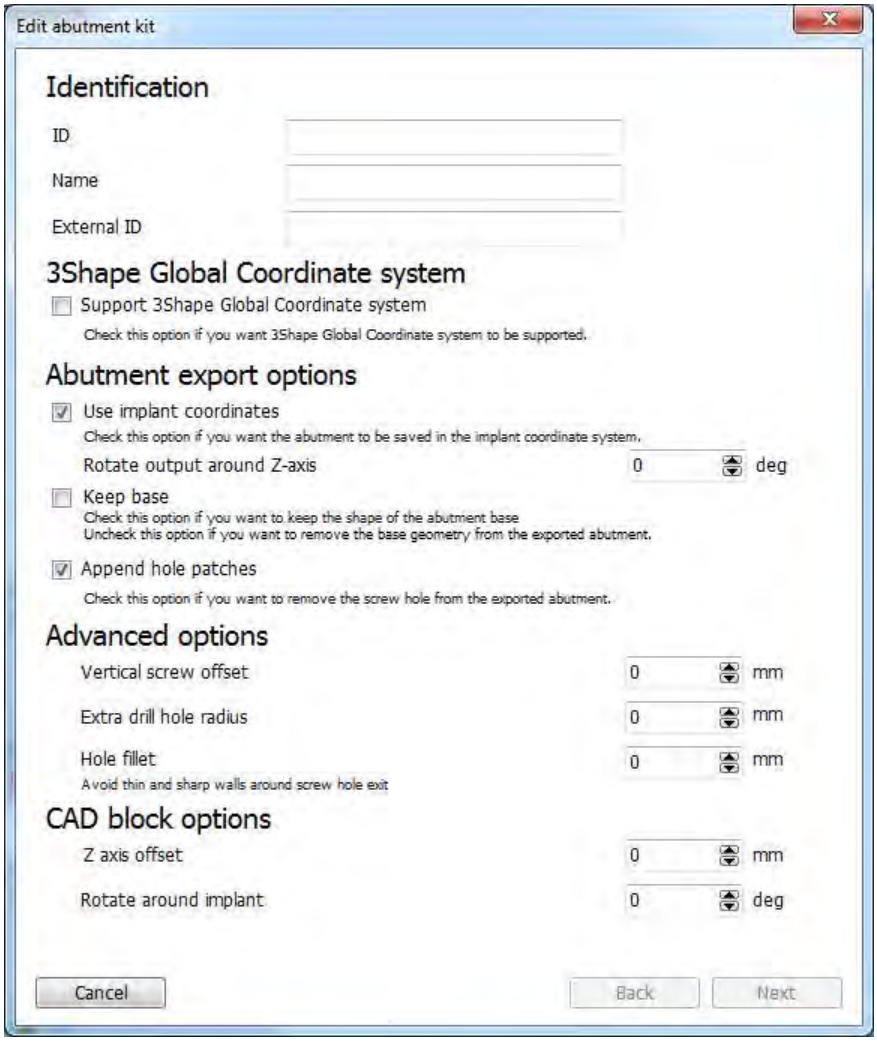

Figure 5-10: Manufacturing options

Use implant coordinates - when checked, the final abutment geometry is stored in the common coordinate system of the implant system parts. Furthermore, it allows rotating the output around the z-axis, if required for the production.
If this option is not checked, the final implant will be stored in the coordinate system of the preparation scan used for designing the abutment.

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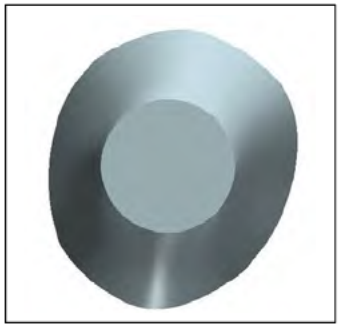
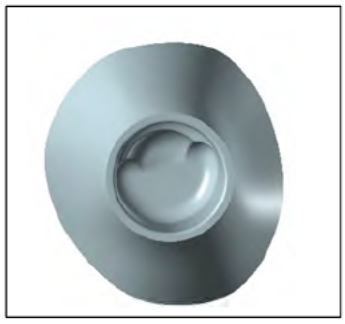
Keep base - when unchecked, the base geometry is removed from the exported model and replaced with a planar surface.

Note: For regulatory reasons, the 3Shape software will refuse to output the connector base if the end user is located in the United States.

This allows the use of milling blanks with the pre-milled base geometry.
The base geometry will be removed for one-piece abutments and kept for two-piece abutments.

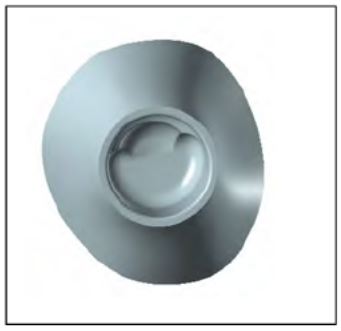


Base geometry removed

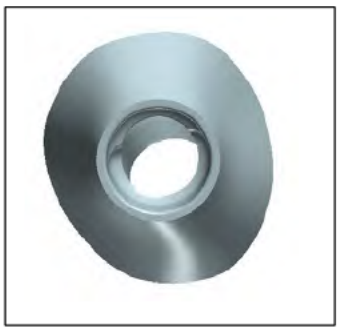


Base geometry included

Append hole patches - when checked, the screw hole of the abutment is closed in the exported geometry. This allows the use of milling blanks with the pre-drilled screw holes.



Screw hole closed



Screw hole appended

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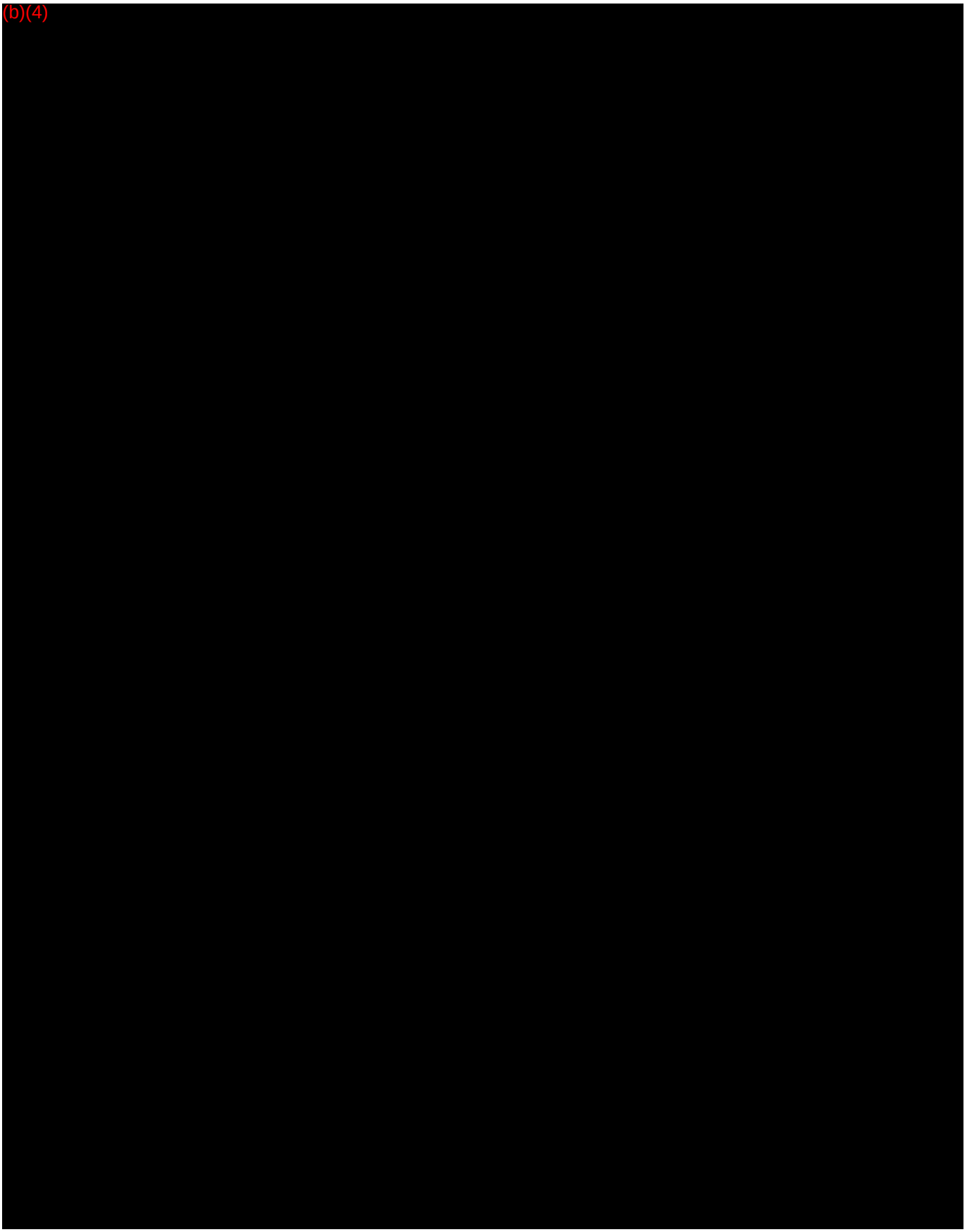

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6.6 Define scan abutment alignment points

Implant system providers can now pre- define alignment points to ensure an optimal alignment of the scan abutment during the scanning process.

The alignment points can be set under Preview **(1)** in the Abutment Kit box. In the preview window, 1-point or 3-point alignment **(2)** can be selected. By clicking on *Set point* or *Set points*, the alignment points can be pre-defined on the scan abutment.

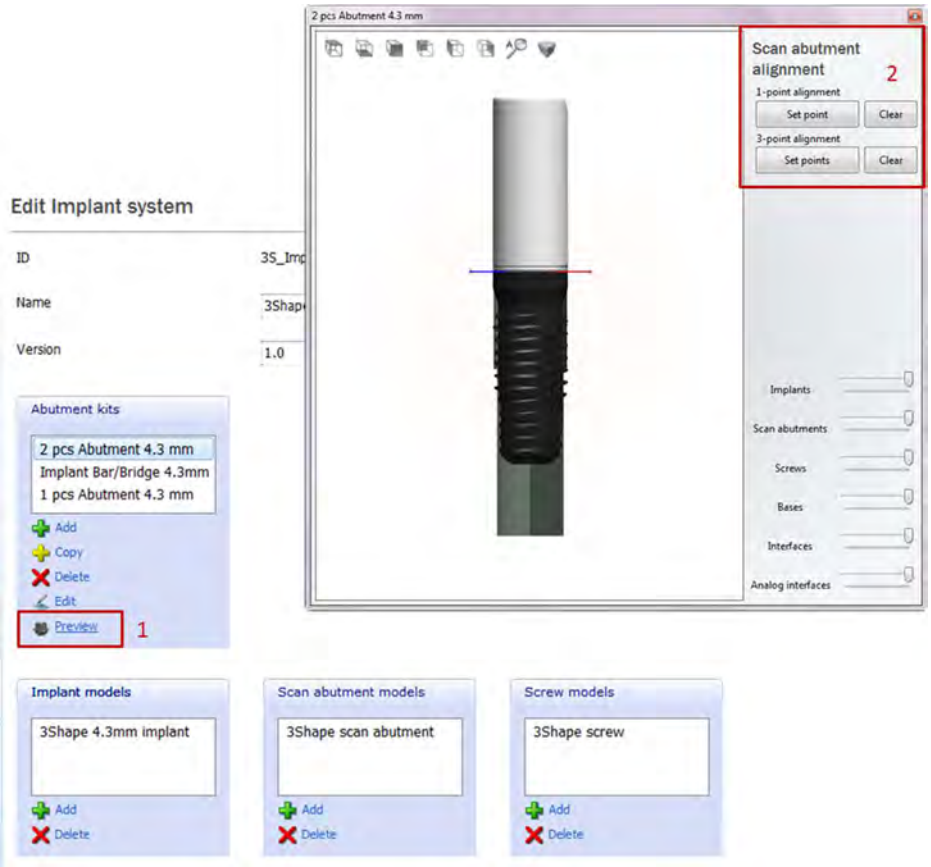

Figure 5-13: Set alignment points

The following should be taken into account when pre-defining the scan abutment alignment points:

- The alignment points can be set on any sufficient and visible surface – the placement in deep indentations as e.g. screw channels are to be avoided
- The alignment points should not be placed close to or on any edge
- The placement of the points should be considered as an easy-to-match position for the user

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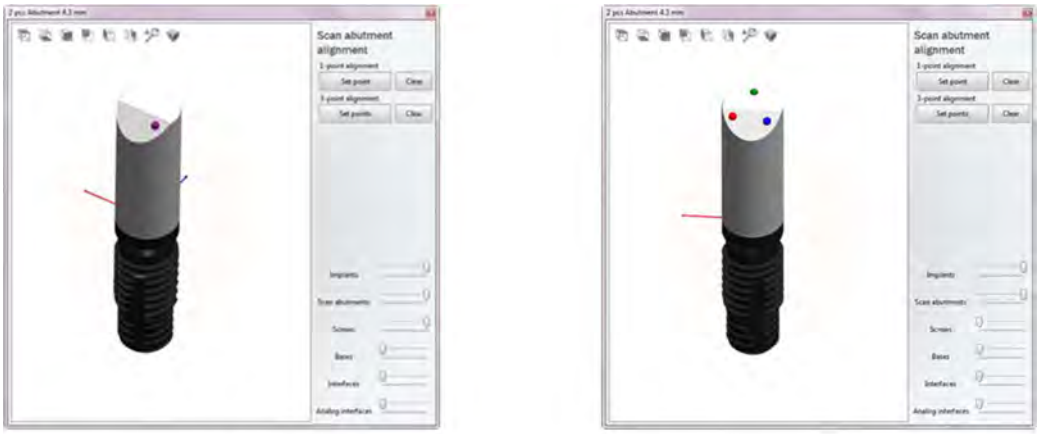

Figure 5-14: Recommended alignment point setting

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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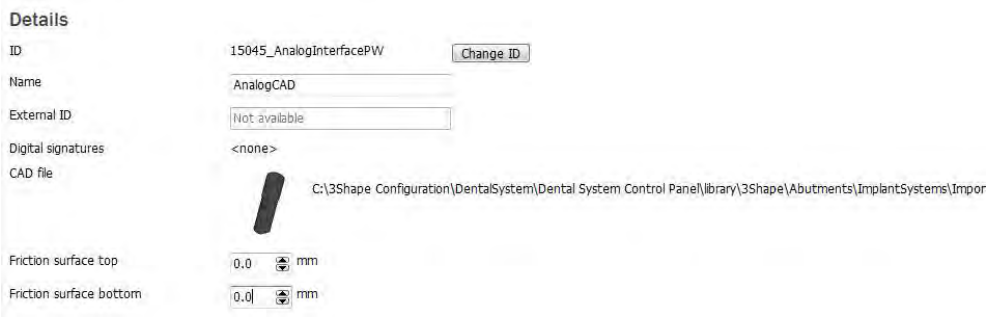
6.7 Settings for implant analog friction bars

When importing a model analog for the production of implant models additional parameters can be defined as shown below.



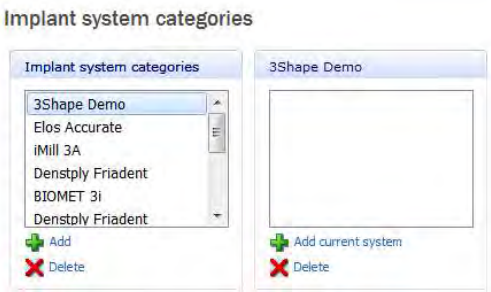
Friction surface top - The distance from Y= 0 mm to the top of the friction bar. If for instance you want the friction bar to have its top point in Y= -1 mm, set the parameter to 1.0 mm.

Friction surface bottom - The distance from Y= 0 mm to the bottom of the friction bar. If for instance you want the friction bar to have its bottom point in Y= -6 mm, set the parameter to 6.0 mm.

6.8 Implant system categories

Implant systems can be organized into categories for an easier selection in the Dental Manager Order form.

1. Click the ***Add*** button in the *Implant system categories* window.
2. Enter a name for your category in the appeared form.
3. Click ***OK***.
4. Click the ***Add current system*** button to include the implant system you are currently working with into the selected category.
5. Every implant system page contains **Implant system categories**, so you can click on your category and add that implant system to the list.



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7 3Shape Global Implant Connection ID

In order to ensure the automatic mapping of implant selections between the 3Shape applications Dental System™, TRIOS® and Implant Studio™, a Global Implant Connection ID has to be defined for each original implant brand.

Implant system providers are responsible for generating Global Implant Connection IDs when creating the implant library in the Dental System™ Control Panel.

By providing the requested information as described below, the Global Implant Connection ID will be automatically generated according to the naming convention of the 3Shape Global ID:

Manufacturer_System_Connection

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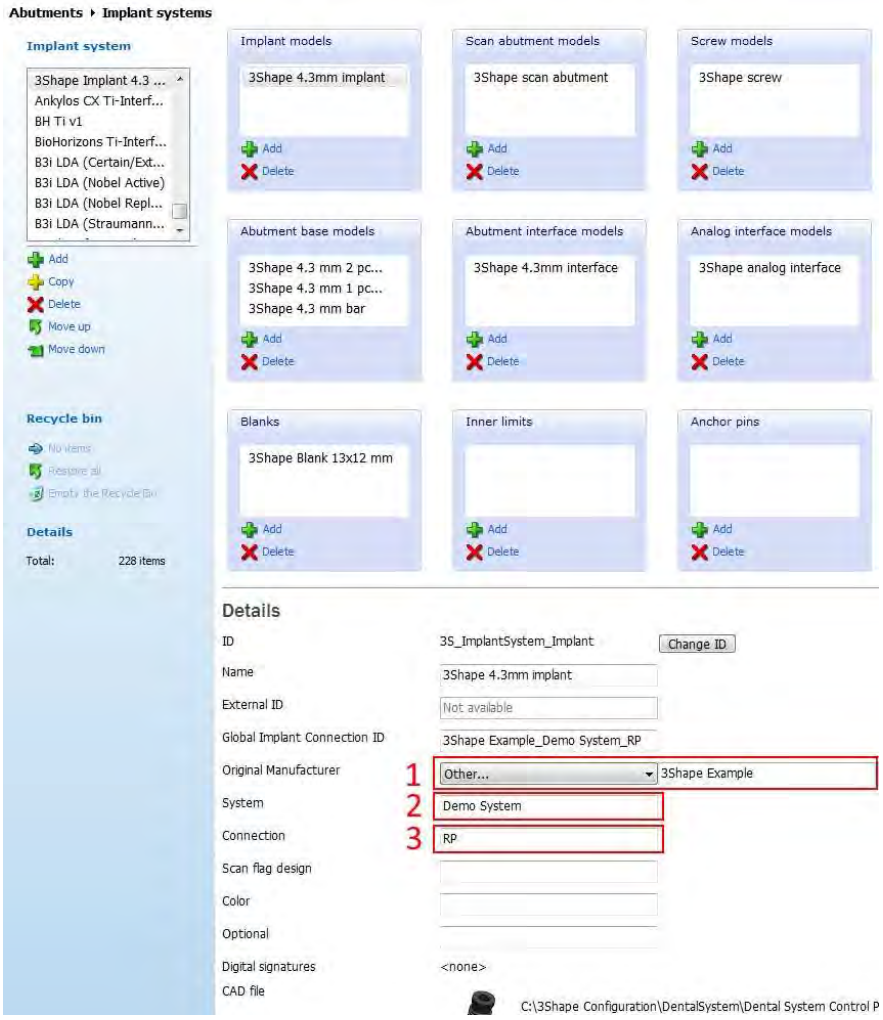

Figure 6-15: Creation of Global Implant Connection ID in the Control Panel

The following information has to be provided by the implant system provider:

(1) Original Manufacturer: Select one of the listed implant manufacturers (*e.g. Nobel Biocare, Straumann, Phibo or Avinent*)

(2) System: Insert the implant brand (*e.g. NobelActive, SLA, TSA Advance or Coral HI*)

(3) Connection: Type the name or dimension of the interface or platform on the implant shoulder level (*e.g. NP, RN, S4 or 4.1*)

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Example of Global Implant Connection IDs:

Manufacturer	System	Connection	Global Implant Connection ID
Straumann	Soft Tissue Level	RN	Straumann_Soft Tissue Level_RN
Straumann	Soft Tissue Level	WN	Straumann_Soft Tissue Level_WN
Straumann	Soft Tissue Level	NNC	Straumann_Soft Tissue Level_NNC
Straumann	Bone Level	RC	Straumann_Bone Level_RC
Straumann	Bone Level	NC	Straumann_Bone Level_NC
Nobel Biocare	Replace	NP	Nobel Biocare_Replace_NP
Nobel Biocare	Replace	RP	Nobel Biocare_Replace_RP
Nobel Biocare	Replace	WP	Nobel Biocare_Replace_WP
Nobel Biocare	Replace	6.0	Nobel Biocare_Replace_6.0
Nobel Biocare	Branemark	NP	Nobel Biocare_Branemark_NP
Nobel Biocare	Branemark	RP	Nobel Biocare_Branemark_RP
Nobel Biocare	Branemark	WP	Nobel Biocare_Branemark_WP
Nobel Biocare	Conical Connection	NP	Nobel Biocare_Conical Connection_NP
Nobel Biocare	Conical Connection	RP	Nobel Biocare_Conical Connection_RP
Nobel Biocare	Conical Connection	30	Nobel Biocare_Conical Connection_3.0
BEGO	S-Line	5.5	BEGO_S-Line_5.5
Biodenta	BL	B0	Biodenta_BL_B0
CAMLOG	iSy	3.8	CAMLOG_iSy_3.8
Phibo	TSA/ADV	S5	Phibo_TSA/ADV_S5
Euroteknika	Naturactis	NP	Euroteknika_Naturactis_NP

Important: In order to ensure the compatibility of implant libraries with the 3Shape applications Dental System™, TRIOS® and Implant Studio™, the implant libraries must be created in conformity with the requirements of the 3Shape Global Coordinate System described in sect. 4.2.

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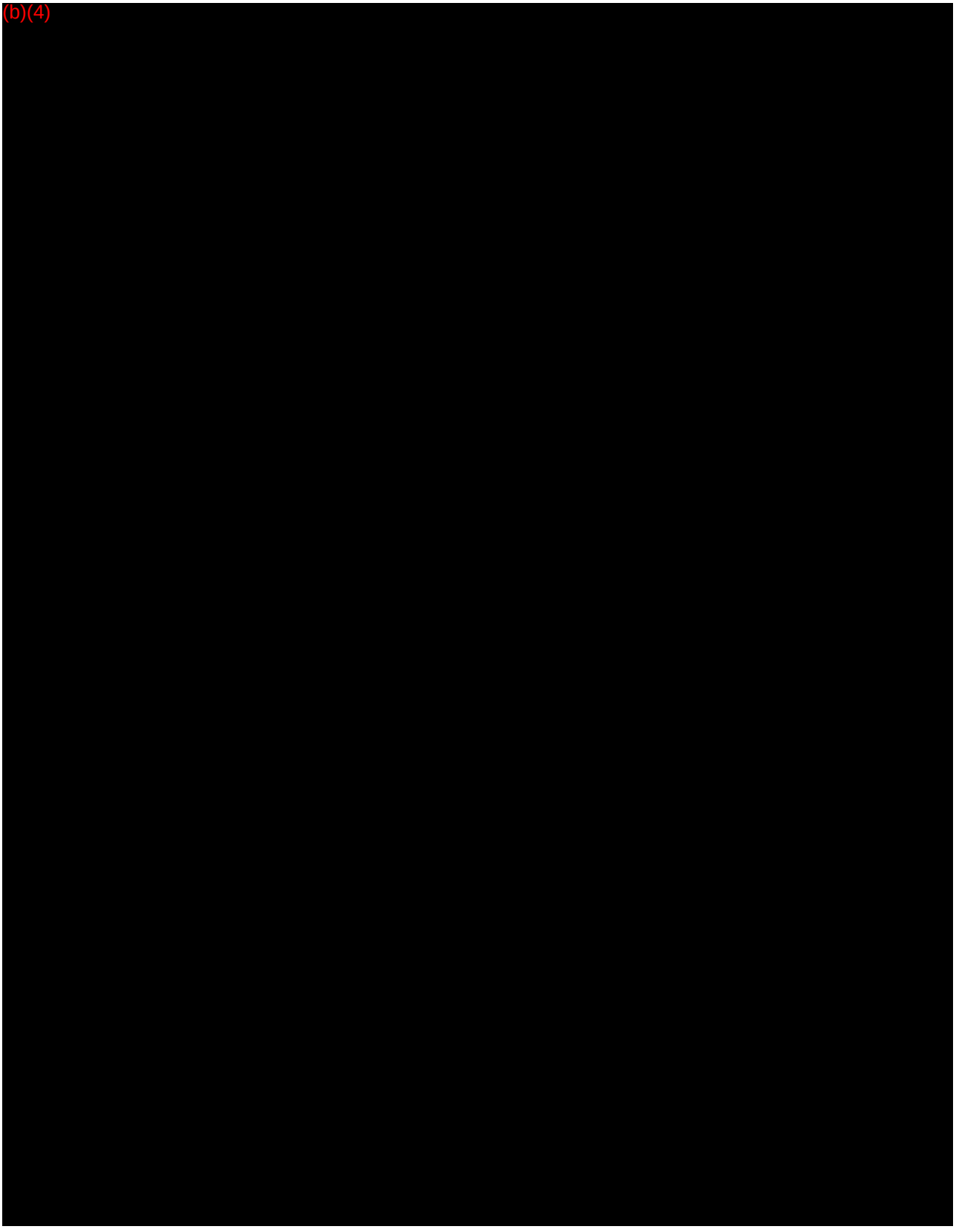

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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[redacted]

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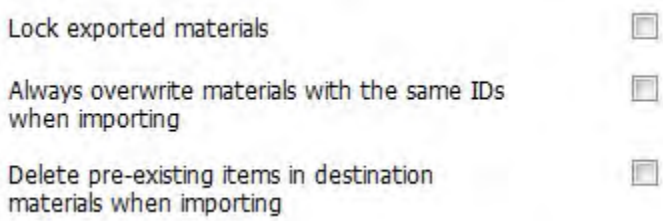
9 Exporting an implant library

The export functionality in Dental System™ Control Panel provides an easy exchange of materials. Go to **Tools** > *Export/Import* button and click on "Export materials"

Select the desired materials from the list. Before exporting the implant library the following options can be selected:



Lock exported materials- when this option is checked, the material settings cannot be changed at the receiving end (recommended).

FDA cleared libraries are locked: All implant libraries that have been cleared for use in the US are automatically locked so that the end user is not able to change the implant library settings.

Always overwrite materials with the same IDs when importing- when this option is checked, materials with the same ID will automatically be replaced at the receiving end.

Delete pre-existing items in destination materials- when this option is checked, all existing materials at the receiving end will be deleted when importing new materials.

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Click on the “Export to File” button to export the implant library in .dme format.

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10 Creating Implant Libraries for use the United States

If the end-user is located in the United States, only FDA-cleared abutment components/libraries are available for use in 3Shape Dental System™.

This is due to a request from the FDA and thus only applies for installations in the United States.

In order to make a library available in Dental System™ the Implant Library Provider is required to send documentation to 3Shape in form of an electronic copy of the relevant 510(k) clearance letters.

The Implant Library Provider also needs to sign and forward a confirmation letter stating that the library only consists of FDA-cleared components to the extent that clearance is required for said component.

Please be aware that the Implant Library Provider is responsible for ensuring that the library only contains FDA-cleared components to the extent that clearance is required for said component.

Implant Libraries for use in the United States will only function in the 3Shape Dental System™ if they are encrypted and locked, and have been approved by 3Shape.

Please contact implant@3shape.com for more information.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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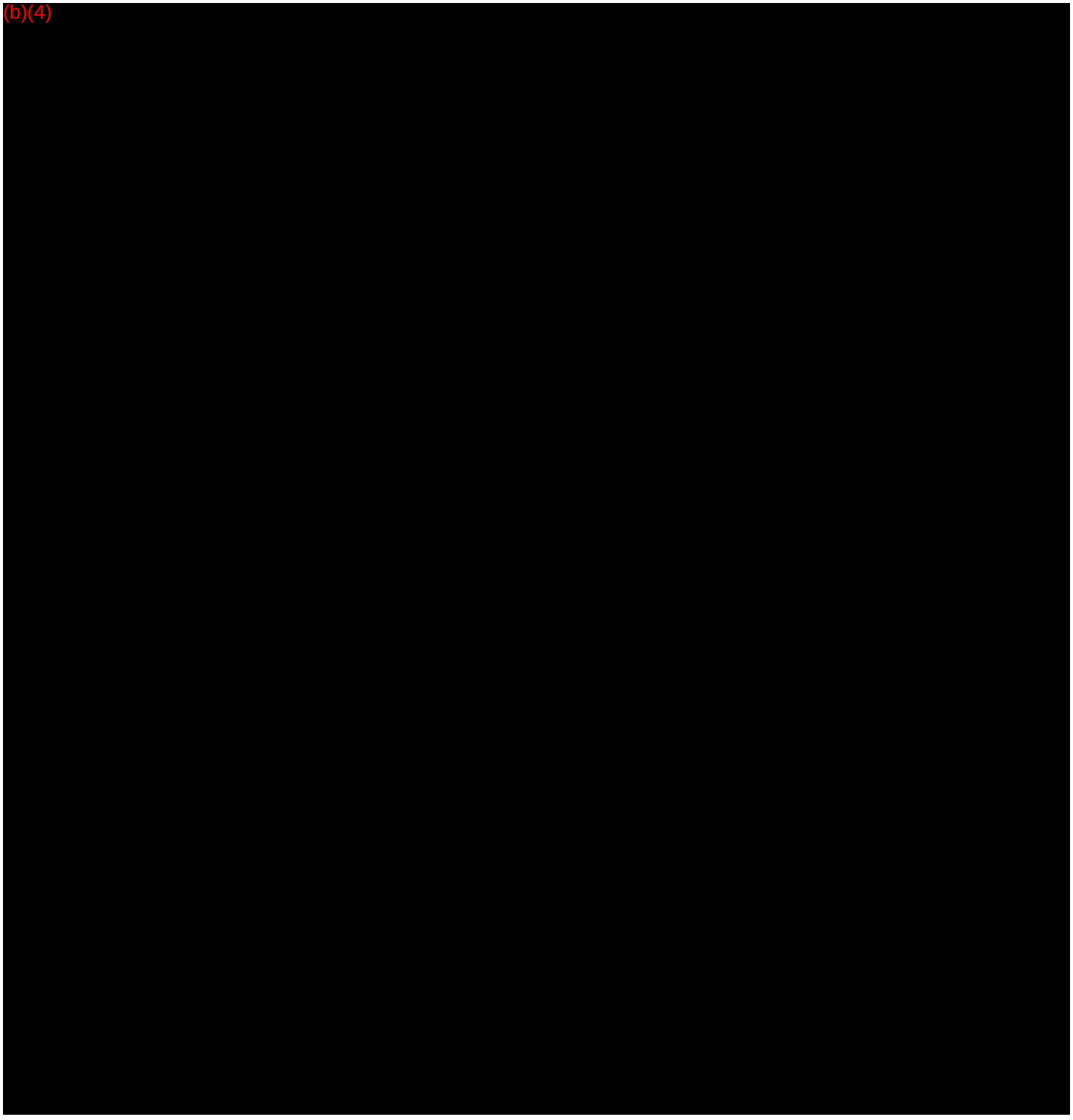

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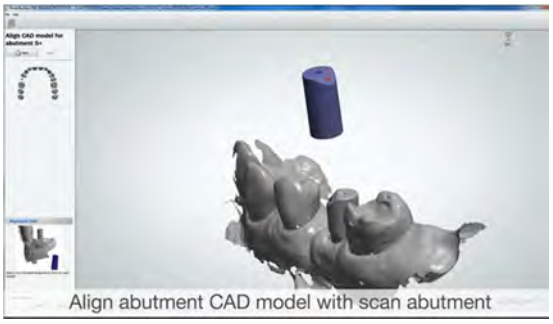
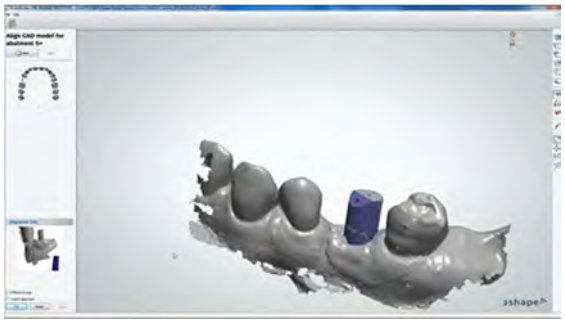
12 How to design a good scan abutment

When designing a scan body it is very important to understand how the scanners work. Basically the scan body is scanned and the scanned surface is matched to the CAD of the scan flag minimizing the difference between the 2 surfaces. During this matching it is critical that the scanned surface has sufficient surfaces to lock all positions and orientations.





Dental System™ 2012 - Model Builder™ (min. 2.14)
http://www.youtube.com/watch?v=kQ8DA6wD9aM&list=UUxEI9LrUl3A7SjkOPbDLPpg&index=3&feature=plcp

The following should take in account when designing a scan abutment for the 3Shape Dental System™:

- Sufficient horizontal surface for vertical locking of the implant position
- Conical scan abutment are to be avoid in order to achieve better results in the vertical alignment
- A non-symmetric feature, preferred a limited vertical flat surface or sufficient bevel surface to lock the rotation of the scan abutment
- Avoid sharp edges to ensure an accurate alignment of the scan abutment and the CAD file of the scan abutment
- Scanable material, e.g. Peek, which has sufficient scan properties, but notice that there are different types of peek with varying scan quality
- Make sure to use intraoral approved material to ensure the usability for intraoral and lab scanner

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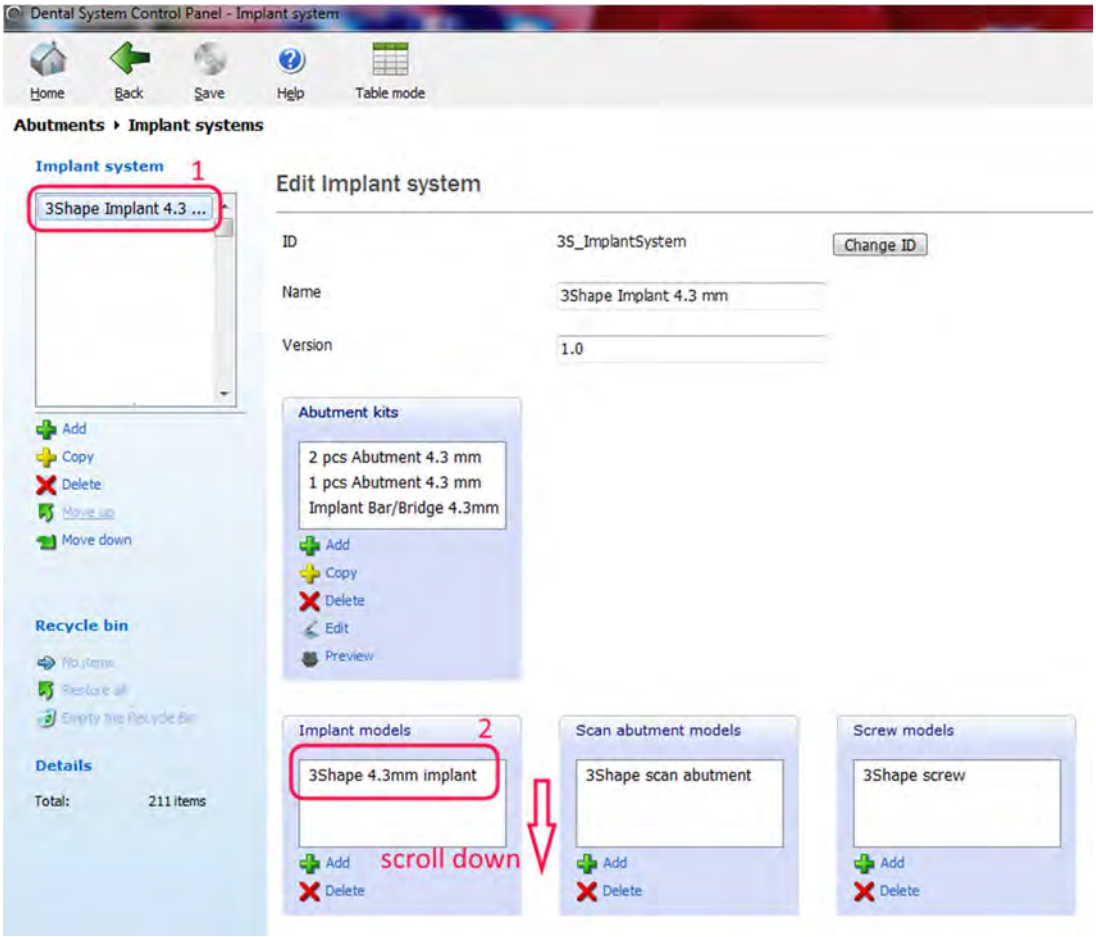
13 How to see if a system is digitally signed

Digital signature is essential for protection of intellectual rights and for FDA clearance mechanism.
Please ensure, that your implant library models are digitally signed with following steps:

1. Open Dental System Control Panel, and navigate to Abutments -> Implant Systems. Select your implant system.
2. Choose model file – implant model, for example, and scroll down to details.
3. Check “Digital signature” value.



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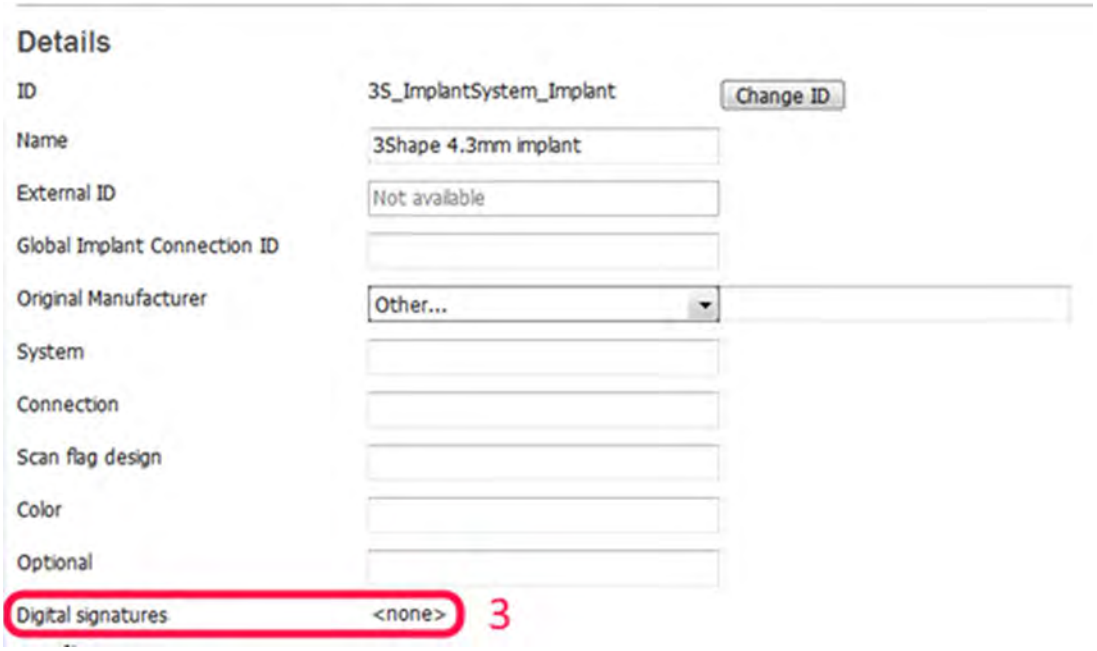
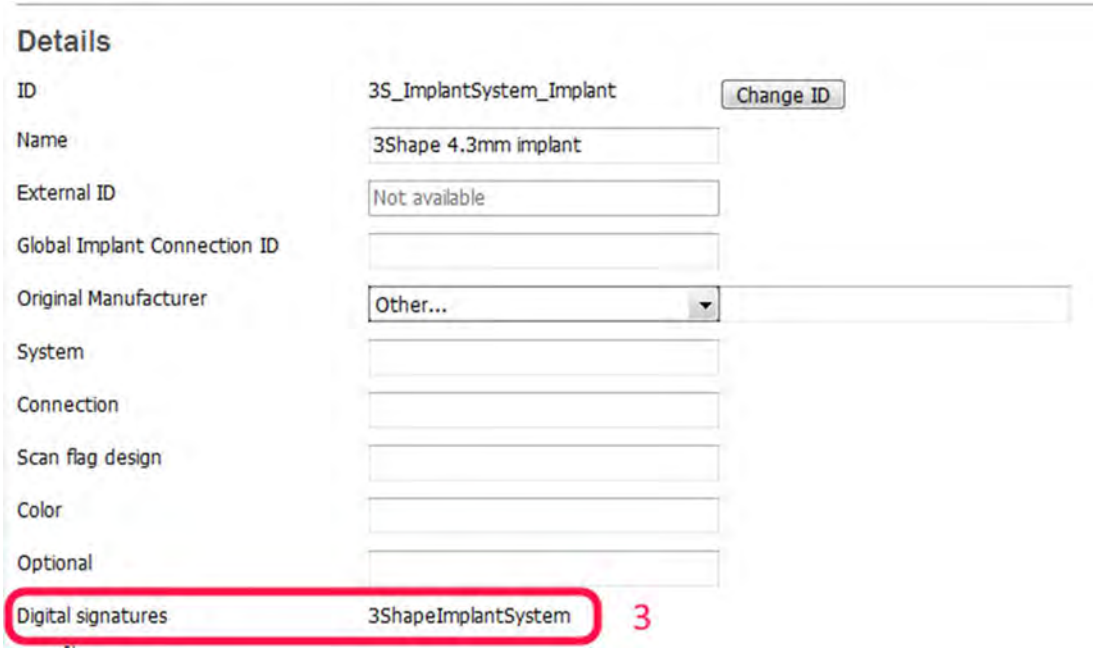


This is an example of a file that is **NOT signed**



Digitally signed. The signature used is "3ShapeImplantSystem"

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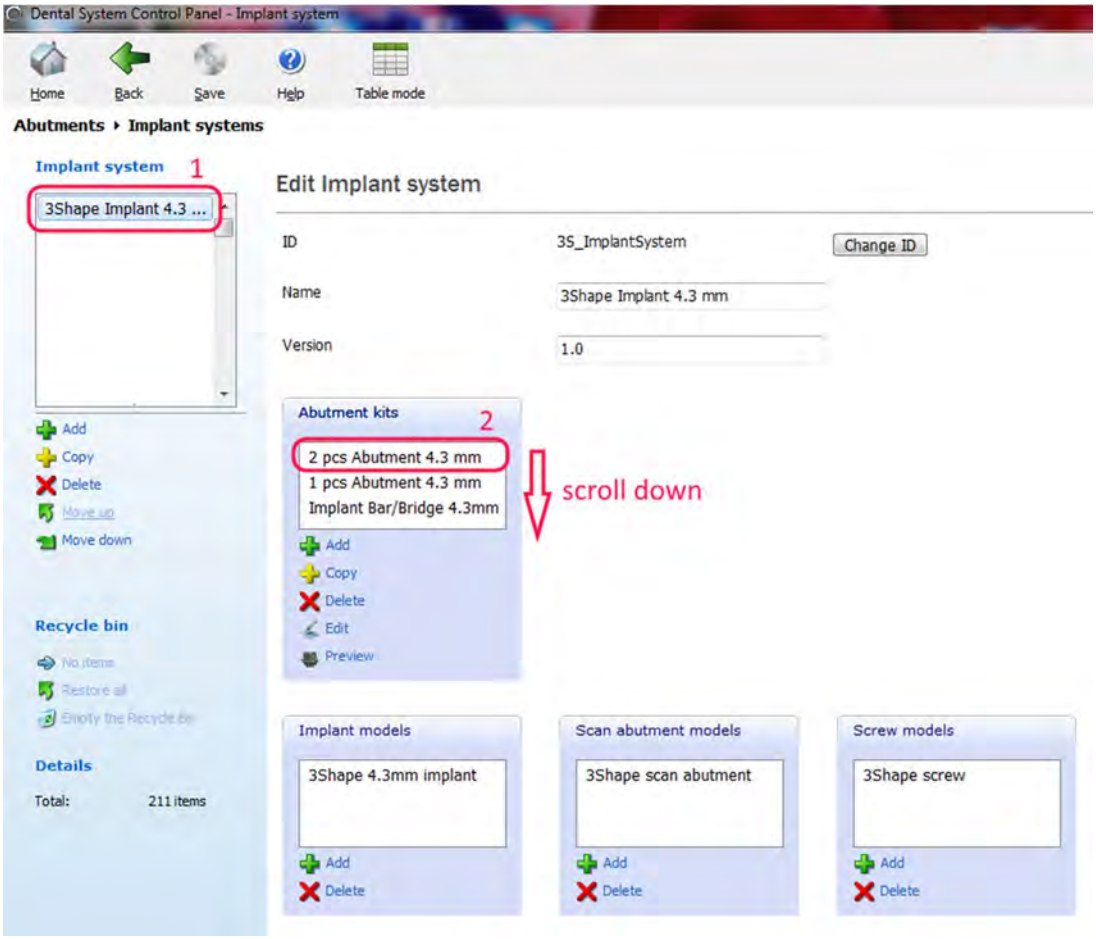
14 How to see if a library is FDA cleared

1. Open Dental System Control Panel, and navigate to Abutments -> Implant Systems. Select your implant system.
2. Choose abutment kit and scroll down to details.
3. Check FDA logo presence.



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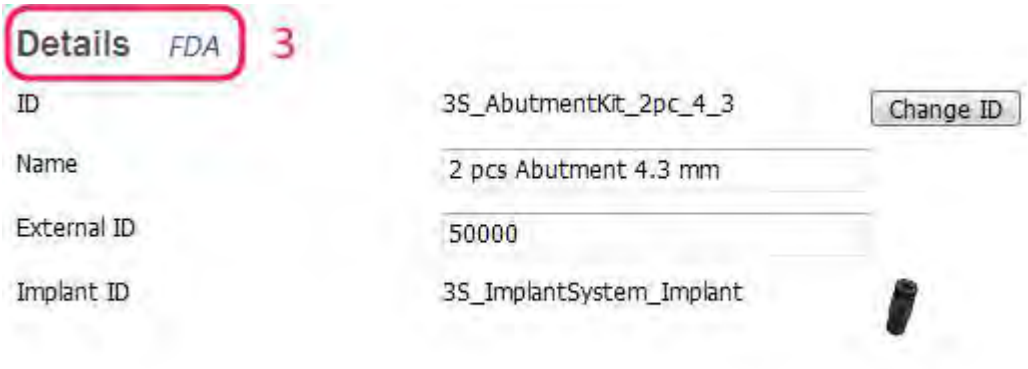

Please note that the library in the figures above is the 3Shape internal test and demo library which cannot be used for production.

15 Example of Implant library

This section provides an example of an Implant library setting; the standard 3Shape Implant 4.3mm library which is provided with the software.

The library contains two abutment kits:

- 1 pcs Abutment 4.3 mm
- 2 pcs Abutment 4.3 mm

By selecting on of the kits the contents of the implant kit is shown. Below illustrates the 1 pcs Abutment 4.3 mm implant kit content and preview of the 3d models:

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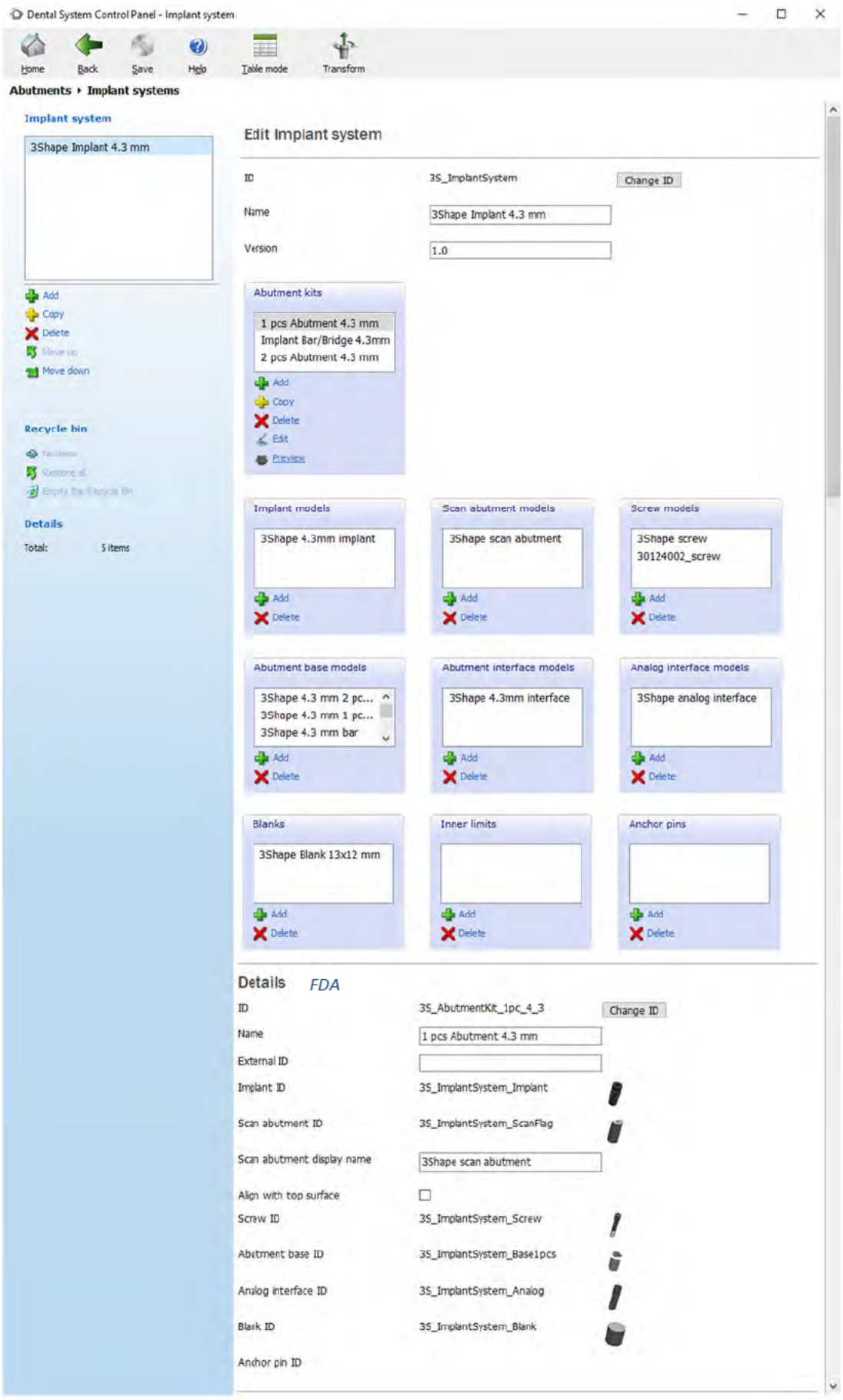

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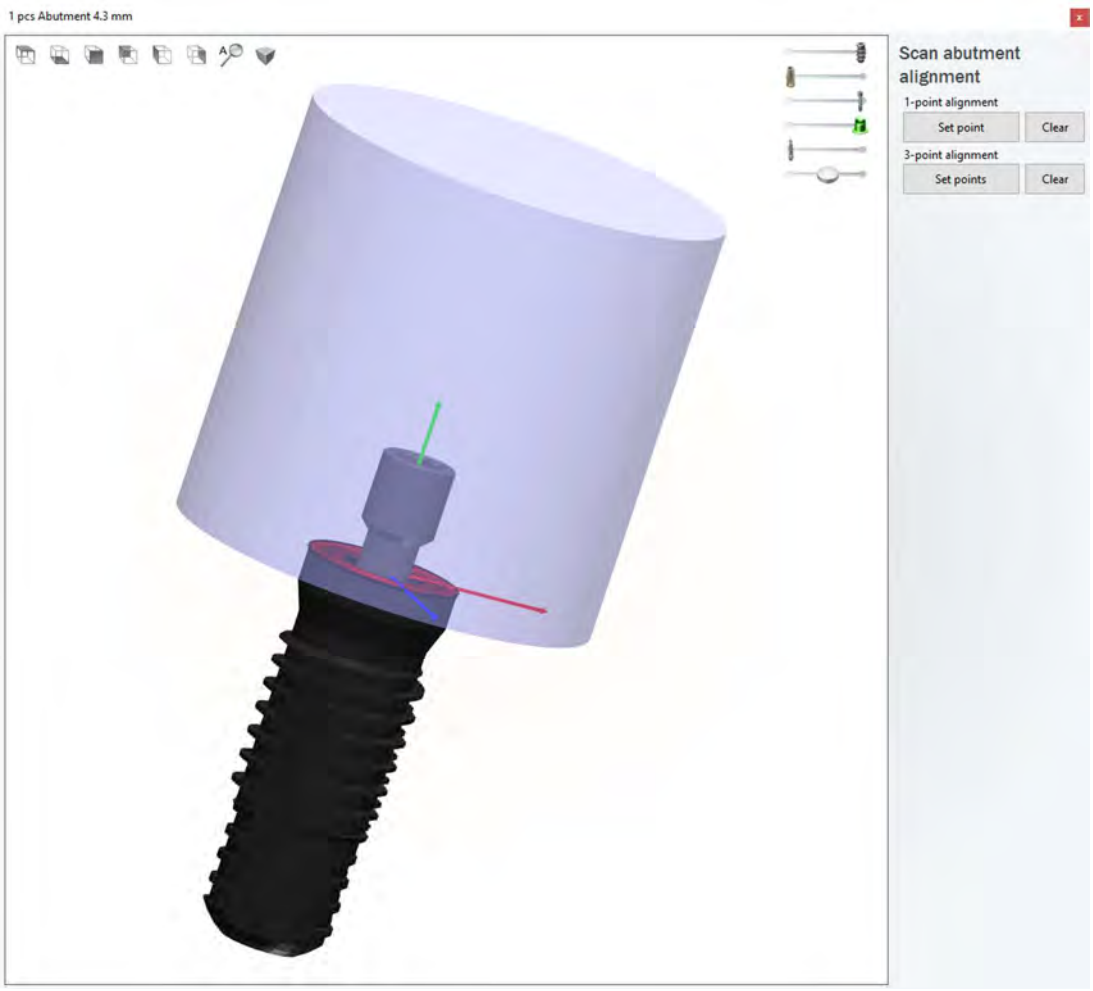

Below shows the settings for the 3Shape 1 pcs Abutment 4.3 mm implant kit. For details on the specific settings and how to maintain these please see section 6.

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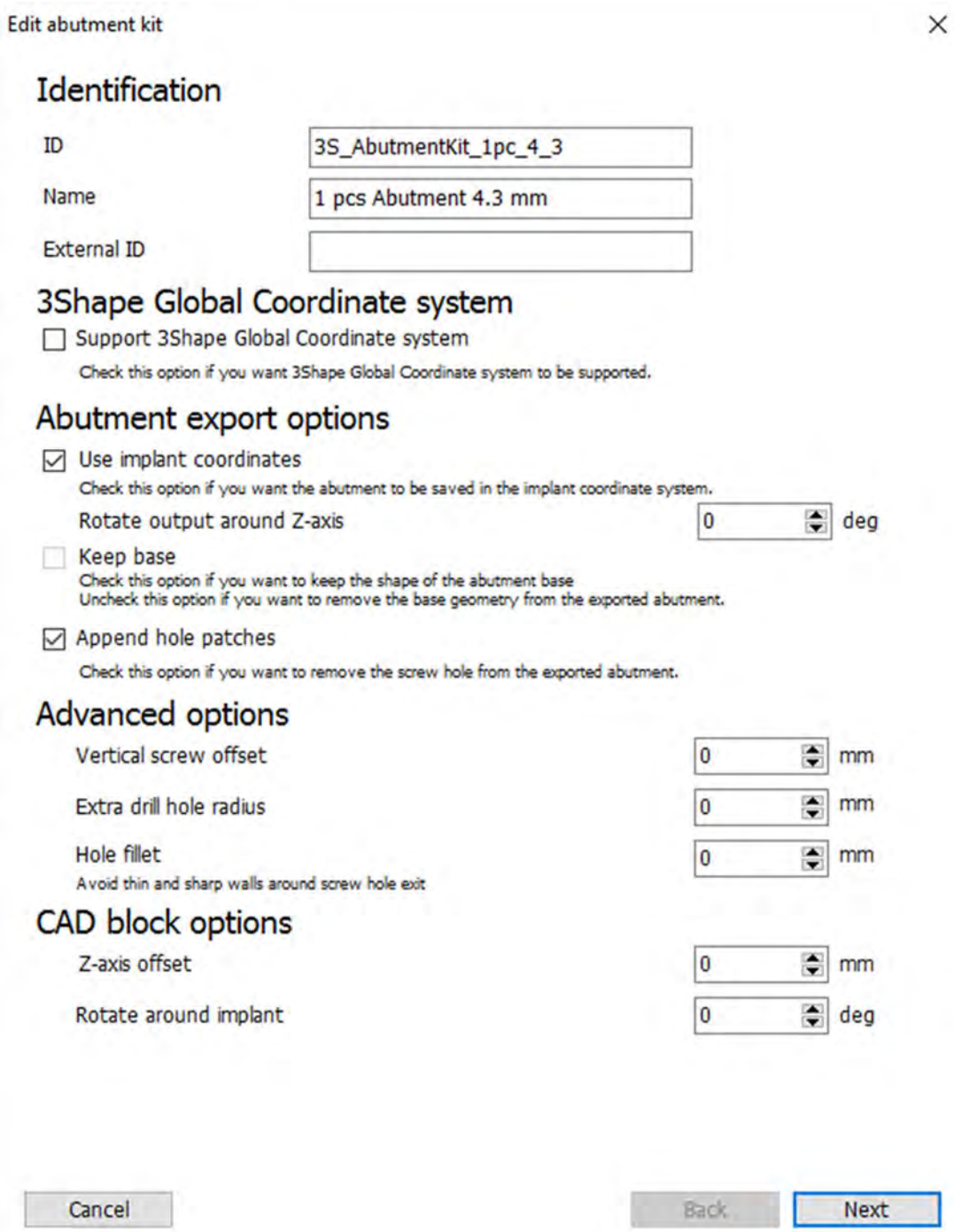

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Edit abutment kit

Implants

3Shape 4.3mm implant

ID 3S_ImplantSystem_Implant

Name 3Shape 4.3mm implant

CAD model

Cancel Back Next

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Edit abutment kit

Scan Abutments

☑ 3Shape scan abutment

Please select the different scan abutments which this kit can use

ID 3S_ImplantSystem_ScanFlag

Name 3Shape scan abutment

CAD model

Cancel Back Next

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Edit abutment kit

Screws

3Shape screw
30124002_screw

ID 3S_ImplantSystem_Screw

Name 3Shape screw

CAD model

Cancel Back Next

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3shape

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Edit abutment kit

Interfaces (optional)

3Shape 4.3mm interface

ID 3S_ImplantSystem_Interface

Name 3Shape 4.3mm interface

CAD model

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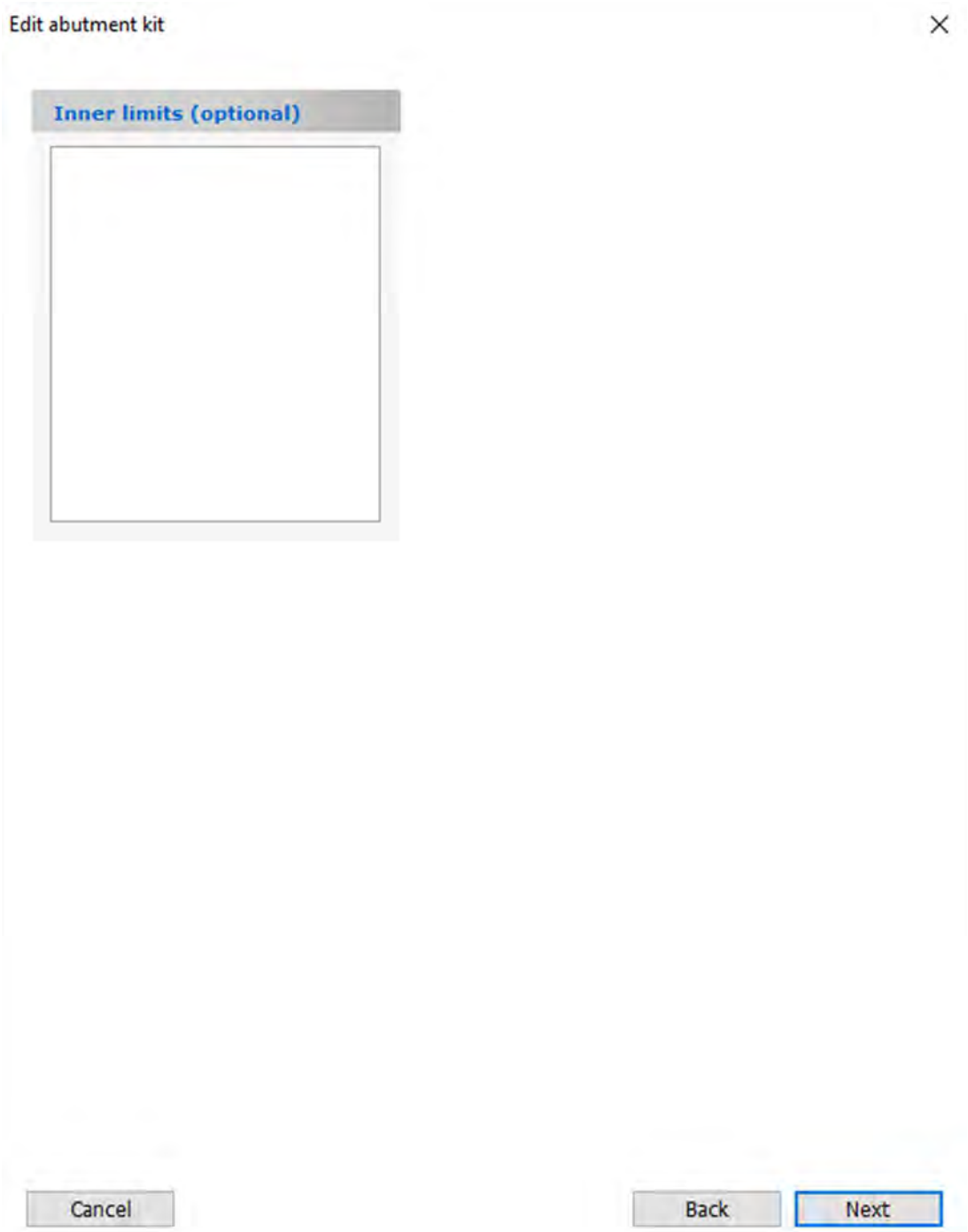

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Edit abutment kit

Blanks (optional)

3Shape Blank 13x12 mm

ID 3S_ImplantSystem_Blank

Name 3Shape Blank 13x12 mm

CAD model

Cancel Back Next

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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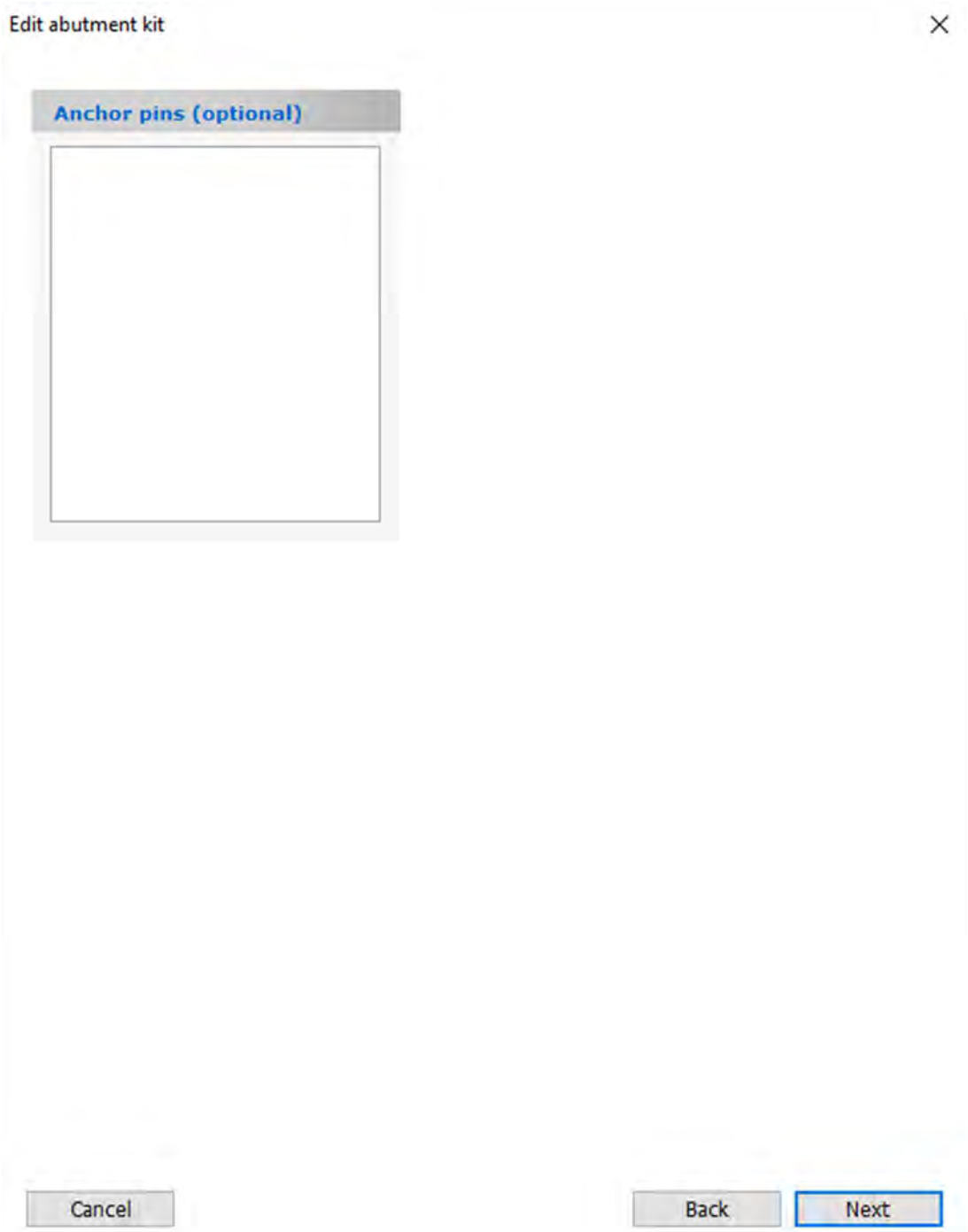

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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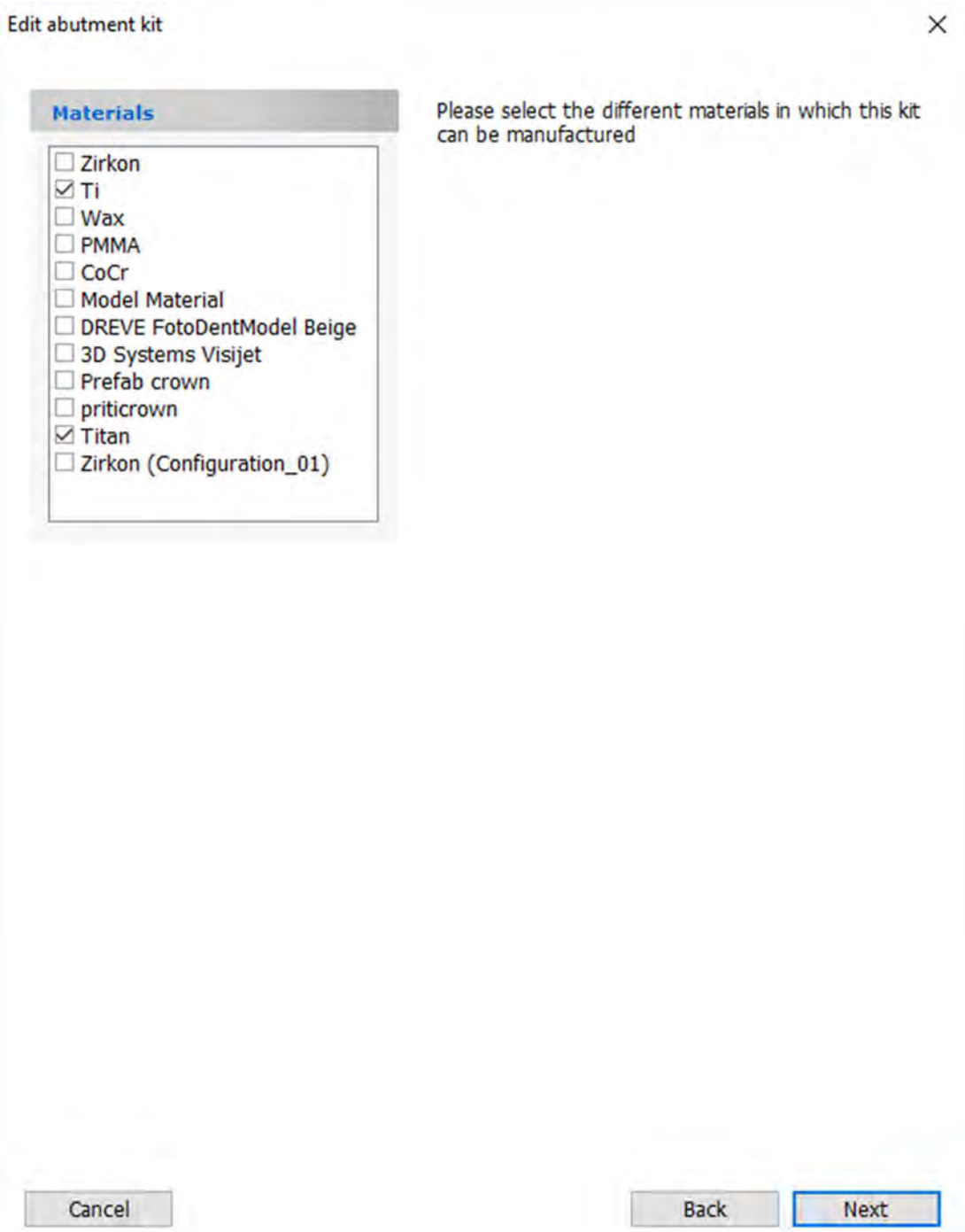
3shape

May 9, 2016



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(b)(4) Testing, Performance, Technical Data

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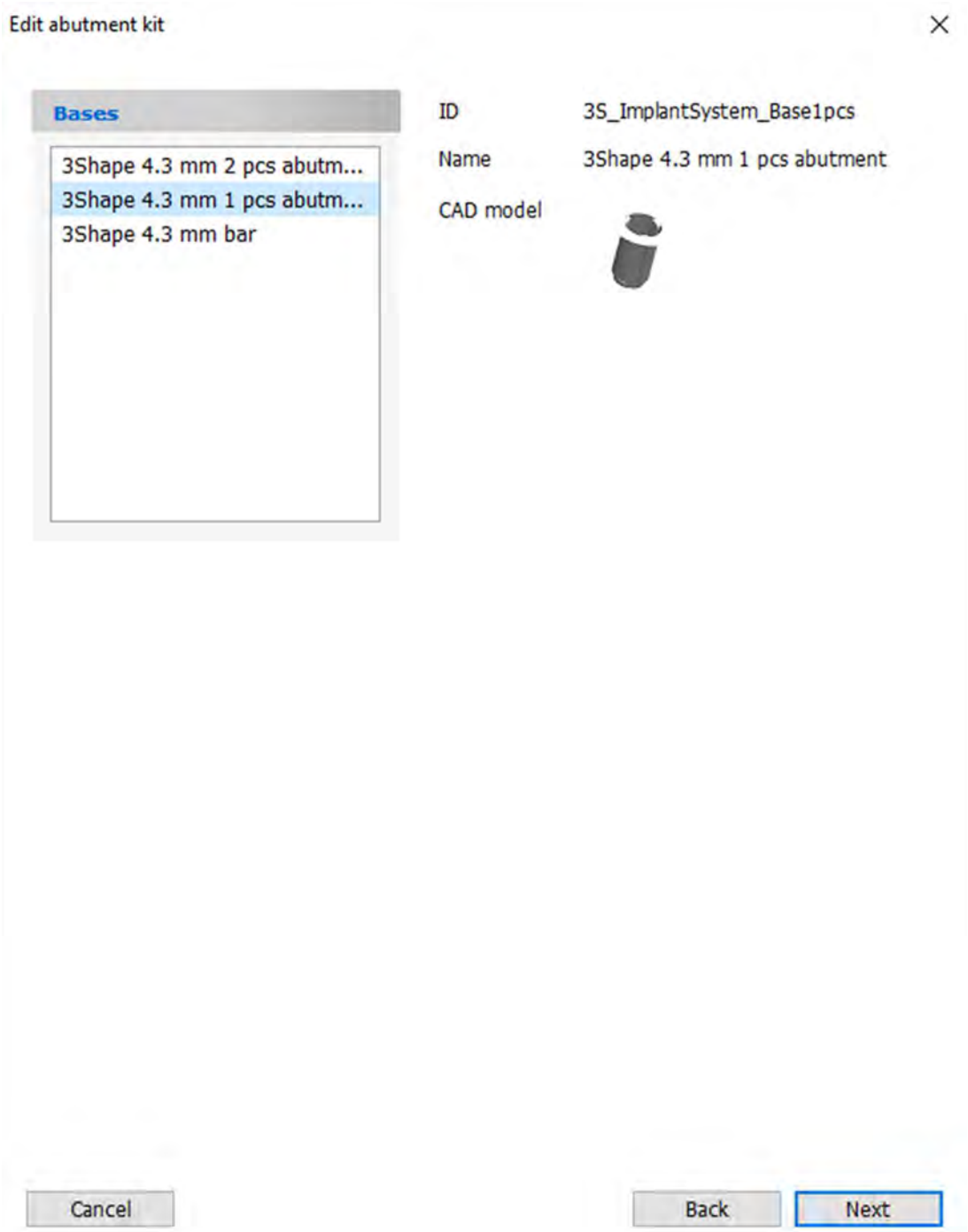

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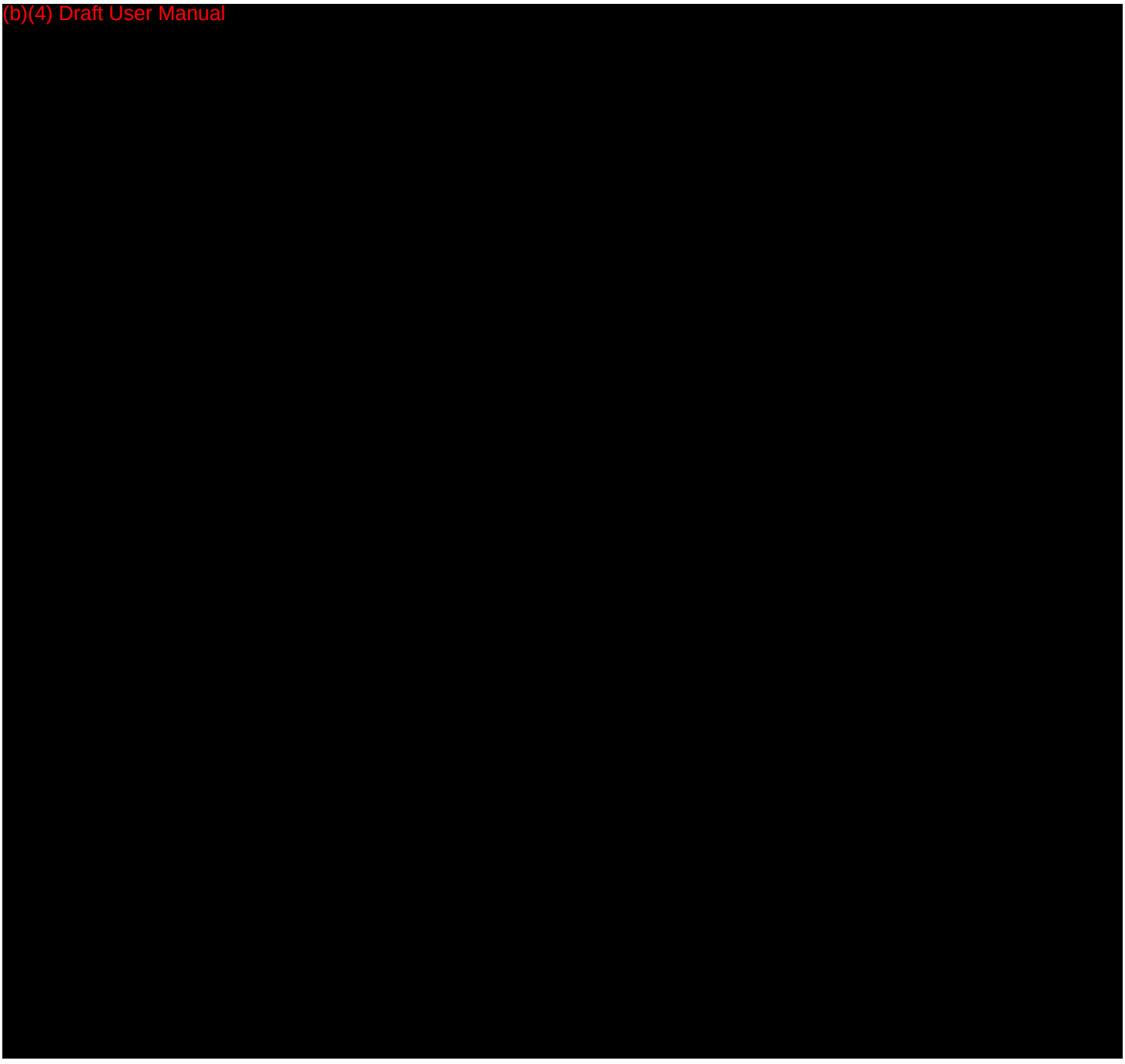
3Shape Dental System 2015

User Manual



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b)(4) Draft User Manual

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Appendi G Implan Librarie fo 3Shap Denta System™

Th lates lis o Implan Librarie fo 3Shap Denta System ca b foun o thi we page: http://support.3shape.com/media/547752/Implan _librarie _fo _th _3shap _denta _system.pdf.

Note! A l informati n s giv n witho t guarant e a d bas d exclusive y n informati n ma e availab e y t e impla t syst m provider . Plea e conta t yo r loc l 3Sha e re-sell r o obta n t e mo t curre t list.

Note! O ly Impl nt Librar es ba ed on Den al Impla ts w th 510 k) cleara ce an be u ed in Abutm nt Design r™ in he Uni ed Stat s. Clea ed librar es m st be activa ed by 3Sha e. Ple se sk y ur Impl nt Libr ry Provi er to cont ct 3Sh pe if ou w sh to s a clea ed libr ry t at as ot alre dy b en activat d. he softw re w ll bl ck ny atte pt to s a non-clea ed library.

Warning In the Un ted Sta es, imp ant c ses may nl be manufact re by manufactu ers hat ol an imp ant abut ent 51 (k or are de tal laborato ies mil ing per the spec fic instruct ons f r a pat ent spec fic imp ant abut ent prov de by the ho de f a 51 (k) specific lly cle red for de tal labora ory mill ng. Pl ase c eck ith the imp ant lib ary prov de to en ur an appropr ate loca ion for sen ing the dig tal f le.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Appendix H: Terms and Abbreviations

The following table explains file type abbreviations used in 3Shape Dental System.

File Format	Description
3ML	Zipped, compressed XML file typically used for setup and customization. 3Shape proprietary format.
3SE	3Shape and Sirona proprietary format for exported orders. Orders from Sirona system, can be imported into 3Shape system.
3OX	3Shape Communicate Order Exchange format used by partners and customers to retrieve and send orders. 3Shape proprietary format.
3OXZ	Zipped archive containing 3OX file and references to DCM models. 3Shape proprietary format.
3SI	3Shape and Sirona proprietary format for imported orders. Orders exported from 3Shape system, can be imported into Sirona system.
DCM	Dental Compressed Model file. Contains compressed 3D model data, attached objects (splines, annotations, etc.), marks and additional string properties. 3Shape proprietary format used for scans and CAD designs.
DLL	Dynamic-link library, Microsoft shared library concept.
DME	Dental System Material Export file. Contains materials, references to materials and external files. The file can be imported into another 3Shape Dental System. 3Shape proprietary format.
STL	Describes surface geometry of three-dimensional objects. Used for scans and CAD designs. Industry standard.
ULDC	3M Lava proprietary format. Order files from 3M scanners can be imported into 3Shape System.
XML	Extensible Markup Language, used for configuration files, etc.

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Appendix I: Contact Information

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3Shape (Shanghai) Co., Ltd

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3Shape South America

Latin American and Caribbean Sales
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110221 Bogotá, Colombia

P: +57 1 691 95 08

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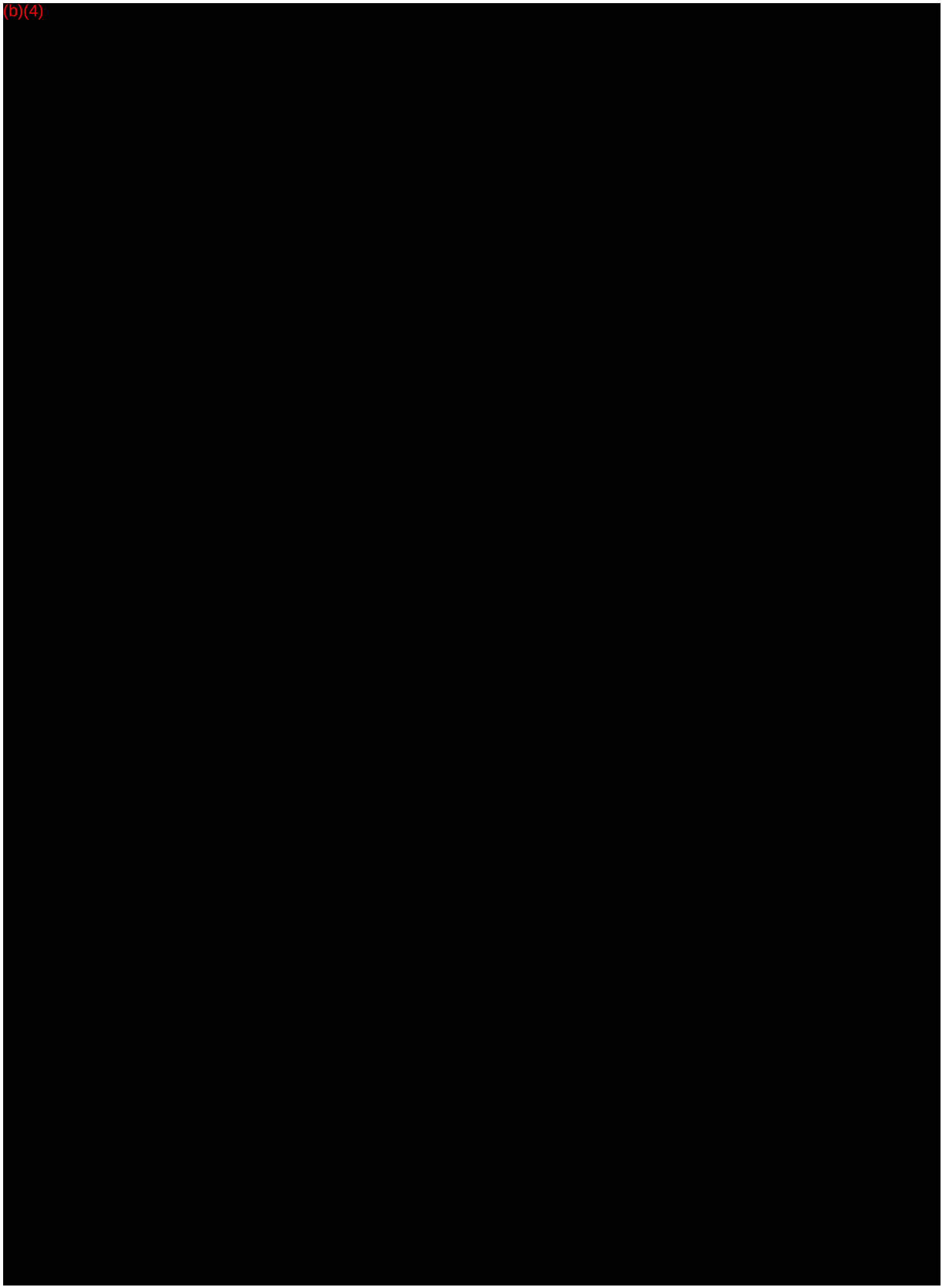

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3shape

Implant libraries for the 3Shape Dental System™

May, 2016

Implant systems / Providers of implant solutions	Implant systems: Nobel Biocare	Biomet 3i	Straumann	Zimmer Dental	DENTSPLY - Astra Tech	DENTSPLY - Friadent	CAMLOG	Other systems	Implant Solutions: 1- Piece (Titanium)	1- Piece (Zirconia)	2- Piece (Ti base + Zr abutment)	Implant Bars & Bridges	Digital implant models	Manu-facturing: Providers milling center	Local milling by 3rd party	Consumables (for local use): Blanks with pre-milled interface (for 1-piece abutment)	Titanium bases (for 2-piece abutments)	Intraoral Scan bodies	Digital model analogs	Multi-unit abutments	Cleared for use in US	Additional info: Comments
3dental (ES) www.3dental.es	3shape reseller	3shape reseller	3shape reseller	3shape reseller	3shape reseller	3shape reseller	3shape reseller	- BioComp - Sweden & Martina - DYNA	X	X		X	X	X					X			
AB-Dental (IL) www.ab-dent.com				3shape reseller				- MIS Alpha Bio	X		X		X			X	X	X	X	X		- CE
Abutments4life (DE) www.abutments4life.de	3shape reseller	3shape reseller	3shape reseller	3shape reseller	3shape reseller	3shape reseller	3shape reseller	- BioHorizons - Osstem - ICX-Templant - and more	X		X	X	X	X	X	X	X	X	X			- CE
Alpha-Bio Tec (IL) www.alpha-bio.net								- Alpha Bio Tec.	X		X	X	X		X	X	X					- CE
Argen (US) www.argen.com	3shape reseller	3shape reseller	3shape reseller	3shape reseller	3shape reseller	3shape reseller			X		X			X		X	X	X	X		X	- CE
ATLANTIS™ (SE) - FDA cleared only www.dentsplyimplants.com	Awaiting information from the provider				3shape reseller	3shape reseller	Awaiting information from the provider														X	- CE
ATLANTIS™ (SE) - all libraries www.dentsplyimplants.com	3shape reseller	3shape reseller	3shape reseller	3shape reseller	3shape reseller	3shape reseller	3shape reseller	- DENTSPLY ANKYLOS XiVE® FRIALIT™ - Keystone Dental - BioHorizons	X	X				X								- CE
BEGO (DE) www.bego.com	3shape reseller	3shape reseller	3shape reseller	3shape reseller	3shape reseller	3shape reseller	3shape reseller	- BEGO Implant Systems - and more	X	X	X	X		X			X	X				- CE - CE-labelled prosthetic screws
BioComp (NL) www.biocomp.eu								- BioComp	X		X				X	X	X	X	X			- CE ISO
Bicon (US) www.bicon.com								- Bicon			X	X			X			X			X	- CE Health Canada
Biodenta (CH) - FDA cleared only www.biodenta.com	Awaiting information from the provider							- Biodenta	Awaiting information from the provider												X	- CE pending
Biodenta (CH) - all libraries www.biodenta.com	3shape reseller	3shape reseller	3shape reseller	3shape reseller	3shape reseller		3shape reseller	- Biodenta	X		X	X	X	X				X	X			- CE pending
Biomet (US) - FDA cleared only www.biomet.com	Awaiting information from the provider	3shape reseller	Awaiting information from the provider																		X	- CE - encode healing abutments
Biomet (US) - all libraries www.biomet.com	3shape reseller	3shape reseller	3shape reseller						X	X	X			X				X				- CE - encode healing abutments
Biotech Dental (FR) www.biotech-dental.com								- Biotech			X		X		X		X	X	X	X		- CE
BlueSkyBio (US) blueskybio.com	3shape reseller		3shape reseller	3shape reseller	3shape reseller			- BlueSkyBio	X		X				X	X	X			X	X	- CE, Health Canada
Bredent (DE) www.bredent.com								- Sky			X				X		X	X	X			- CE
CADBLU (US) www.cadbludental.com	3shape reseller	3shape reseller	3shape reseller	3shape reseller	3shape reseller			- Bio Horizons - MIS Implants	X		X	X	X	X				X	X			
CADstar (AT) www.cadstar.dental	3shape reseller	3shape reseller	3shape reseller	3shape reseller	3shape reseller	3shape reseller	3shape reseller	BREDENT DENTSPLY XiVE CONELOG MEDENTIS ICX NEOSS PROWITAL SIC ALPHATECH and others	X		X	X		X			X		X	X		- CE (0297) - ISO 13485 - Certificate Directive 93-42-EEC - (Annex II)
CAMLOG (CH) - FDA cleared only www.camlog.com							3shape reseller	- CONELOG - iSy	Awaiting information from the provider												X	
CAMLOG (CH) - all libraries www.camlog.com							3shape reseller	- CONELOG - iSy	X		X	X		X	X		X	X				
CAP (US) www.cap-us.com	3shape reseller	3shape reseller	3shape reseller	3shape reseller	3shape reseller	3shape reseller			X		X	X	X	X	X	X	X		X		X	

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3shape

Implant systems / Providers of implant solutions	Implant systems								Implant Solutions					Manu-facturing		Consumables (for local use)						Additional info
	Nobel Biocare	Biomet 3i	Straumann	Zimmer Dental	DENTSPLY - Astra Tech	DENTSPLY - Friadent	CAMLOG	Other systems	1- Piece (Titanium)	1- Piece (Zirconia)	2- Piece (Ti base + Zr abutment)	Implant Bars & Bridges	Digital implant models	Providers milling center	Local milling by 3rd party	Blanks with pre-milled interface (for 1-piece abutment)	Titanium bases (for 2-piece abutments)	Intraoral Scan bodies	Digital model analogs	Multi-unit abutments	Cleared for use in US	Comments
CMC (US) 3shape reseller - FDA cleared only www.custom-milling.com	👍	👍	👍	👍	👍	👍	👍	- BioHorizons - Osstem - LifeCore - Intra-Lock - Neoss	X	X	X	X		X				X			X	- CE
CMC (US) 3shape reseller - all libraries www.custom-milling.com	👍	👍	👍	👍	👍	👍	👍	- BioHorizons - Osstem - LifeCore - Intra-Lock - Neoss	X	X	X	X		X				X				- CE
Conmet (RU) conmet.ru								- Conmet	X		X		X				X	X	X			- Dental implants have a bioactive surface - CE ISO 9001 and ISO 13485
Conexão Sistemas de Protese (BR) www.conexao.com.br	👍		👍					- Conexão Sistema de Protese	X	X	X			X			X	X	X	X		- ANVISA CE
Core3D International (NL) 3shape reseller - FDA cleared only www.core3dcenters.com	Awaiting information from the provider								Awaiting information from the provider												X	- CE Health Canada TGA (AUS) Taiwan regulatory - MHLW:Ministry of Health Labour and Welfare (JP)
Core3D International (NL) 3shape reseller - all libraries www.core3dcenters.com	👍	👍	👍	👍	👍	👍	👍	- Avinent - BioComp - BioHorizons - MIS Implants - and many more	X		X	X	X	X	X	X	X	X	X			- CE Health Canada TGA (AUS) Taiwan regulatory - MHLW:Ministry of Health Labour and Welfare (JP)
Cortex Dental (IL) www.cortex-dental.com				👍				- Cortex Dental			X	X			X	X	X	X	X	X	X	- CE
Creodent (US) www.Creomc.com	👍	👍	👍	👍	👍			- Hiossen	X		X	X		X			X				X	
C-Tech Implant (IT) www.c-tech-implant.com								- C-Tech Implant	X		X	X			X		X			X		- CE
Degudent (DE) 3shape reseller www.degudent.com	👍	👍	👍	👍	👍	👍	👍	- Medentika	X	X	X			X	X		X					
Dental Consulting (DE) www.gadau-consulting.com	👍		👍	👍	👍	👍	👍	- ICX-Medentis - Osstem	X		X	X	X	X	X	X	X	X	X			- CE
Dentaurum Implants (DE) www.dentaurum-implants.de								- Dentaurum Implants			X				X		X	X				- CE PAL
Dentegris Deutschland (DE) www.dentegris.de								- Dentegris Implants			X	X			X		X					
Dentium (KR) www.dentium.com								- Implantium - SuperLine - SimpleLine II NR Line Custom Abutment	X	X	X	X		X	X						X	- CE CFDA PMDA TFDA GOST
Dentsply-Friadent (DE) 3shape reseller www.dentsply-friadent.com						👍		- Xive - Ankylos	X	X	X			X								- CE
DESS (ES) www.dess-abutments.com	👍	👍	👍	👍	👍	👍		- BioHorizons - Ankylos - Mis	X		X	X		X	X		X	X		X		- CE - ISO 13485 - ISO 9001 - Health Canada pending.
DIO-Implants (KR) 3shape reseller www.dioimplant.com	👍							- DIO Implants	X	X	X	X		X	X							- CE, KFDA, SFDA
Dynamic Abutment Solutions (ES) www.dynamicabutment.com	👍	👍	👍	👍	👍	👍	👍	- Osstem - MIS Implants - Megagen - Biohorizons - and more	X		X	X		X	X	X	X			X		- CE, ISO 9001, ISO13485, CMDCAS
Easy Implant (FR) www.easyimplant.com									X		X	X		X			X			X		- CE
Elos Medtech Pinol (DK) www.elosmedtech.com	👍	👍	👍	👍	👍	👍	👍	- Neoss	X		X	X	X	X	X	X		X	X			- CE
Euroteknika (FR) www.euroteknika.com	👍	👍	👍	👍	👍			- Anthogyr - Biotech - Easy Implant - MIS Implants - and more	X		X	X	X	X		X	X	X	X	X	X	- CE
GC Advanced Technologies (US) 3shape reseller www.gc-at.com	👍	👍	👍	👍	👍			- BioHorizons - Sybron	X	X	X			X								

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Implant systems / Providers of implant solutions	Implant systems								Implant Solutions					Manu-facturing		Consumables (for local use)						Additional info
	Nobel Biocare	Biomet 3i	Straumann	Zimmer Dental	DENTSPLY - Astra Tech	DENTSPLY - Friadent	CAMLOG	Other systems	1- Piece (Titanium)	1- Piece (Zirconia)	2- Piece (Ti base + Zr abutment)	Implant Bars & Bridges	Digital implant models	Providers milling center	Local milling by 3rd party	Blanks with pre-milled interface (for 1-piece abutment)	Titanium bases (for 2-piece abutments)	Intraoral Scan bodies	Digital model analogs	Multi-unit abutments	Cleared for use in US	Comments
Glidewell (US) 3shape reseller www.glidewelldental.com	👍	👍	👍	👍	👍	👍	👍	- Prismat k - DentalCraft - Keystone Dental - Neoss	X	X	X	X	X	X			X	X	X		X	- CE pending
Green DenTech / Denracle (TW) www.denracle.com	👍	👍	👍	👍	👍	👍		- Biohorizons - Dentium - Osstem and more..	X							X	X					- CE
Heraeus Kulzer (DE) 3shape reseller www.heraeus.com	👍	👍	👍	👍	👍	👍	👍	- Thommen	X	X	X		X	X								
Implant Direct (US) www.implantdirect.com/custom-direct	👍		👍	👍				- Biohorizons	X			X	X	X					X		X	- CE Health Canada
Intra-Lock International (US) www.intra-lock.com								- INTRA-LOCK	X		X	X				X	X	X	X	X	X	- CE Health Canada
Ivoclar Wieland (DE) 3shape reseller www.wieland-dental.de	👍	👍	👍	👍	👍	👍		- Dentaurum Implants	X		X	X		X	X		X		X			
Lasak (CZ) www.lasak.com	👍		👍		👍			- Lasak BioniQ - Lasak Impladent	X	X	X	X		X		X	X			X		- CE - ISO 13485 - ISO 9001
LaStruttura (IT) 3shape reseller www.lastruttura.it	👍	👍	👍	👍	👍	👍		- Sweden & Martina - Megagen - Prodent - and many more	X	X		X	X	X				X	X			- CE 93/42
Medentika (DE) www.medentika.de	👍	👍	👍	👍	👍	👍	👍	- Medentika M-Implant	X		X	X		X	X	X	X	X			X	- CE
Medentis Medical (DE) www.medentis.de	👍		👍		👍	👍		- ICX Templant	X		X	X	X	X			X	X				- CE
Medical Instinct (DE) www.medical-instinct.de								- Medical Instinct	X	X	X	X			X	X	X	X		X		- CE
Médical Production (FR) www.medical-production.eu		👍	👍	👍	👍	👍		- Euroteknika	X		X	X	X		X	X	X	X		X		- CE0499 - ISO 9001 - ISO 13485
Megagen Implant (KR) www.imegagen.com								- AnyRidge Internal - AnyOne Internal - MINI Internal - Octa Level			X		X	X	X		X	X	X		X	- CE - KFDA
MIS Implants Technology (IL) - FDA cleared only www.mis-implants.com								- MIS Implants	Awaiting information from the provider												X	- CE
MIS Implants Technology (IL) - all libraries www.mis-implants.com								- MIS Implants	X		X			X	X	X	X	X		X		- CE
Neodent (BR) www.neodent.com.br	👍		👍					- Neodent Implant Systems	X	X	X	X			X			X			X	
Neoss (UK) - FDA cleared only www.neoss.com	Awaiting information from the provider							- Neoss	Awaiting information from the provider												X	- CE
Neoss (UK) - all libraries www.neoss.com	👍	👍	👍	👍	👍			- Neoss	X		X	X	X	X	X	X	X	X	X	X		- CE
Nobel Biocare (CH) www.nobelbiocare.com	👍	👍	👍	👍	👍				X	X	X			X							X	- CE
NT Trading (DE) www.nt-trading.com	👍	👍	👍	👍	👍	👍	👍	- Thommen - Sweden & Martina - BEGO	X		X	X		X	X	X	X	X	X		X	- CE, CMDCAS, GOST R, TGC - Mexico Certfication
Phibo (ES) 3shape reseller www.phibo.com	👍	👍	👍	👍	👍	👍	👍	- BTI - Sweden&Martina - MIS Implants - and many more	X	X	X	X	X	X				X	X			- CE - ISO 13485 - ISO 9001
Prowital (DE) www.prowital.de								- Prowital			X				X		X	X	X			- CE - EN-ISO 9001-V472008 - EN ISO-13485-2003AC2009 - Certificate Directive-93-42 EWG
Ritter Implants (DE) www.ritterimplants.com			👍	👍				- Alpha -Bio Tec. - MIS Implants	X		X		X		X		X	X	X			- CE

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Straumann (CH) - FDA cleared only www.straumann.com			👍						Awaiting information from the provider												X	- CE
Straumann (CH) - all libraries www.straumann.com			👍						X	X	X			X	X		X	X	X			- CE
Sweden&Martina S.p.A (IT) www.sweden-martina.com								- Sweden&Martina	X	X	X	X	X	X			X	X	X			
Target3D (US) www.target3d.com	👍	👍	👍	👍	👍	👍	👍	- Osstem - BioHorizons - MIS-Implants - and more	X	X	X	X	X	X	X	X	X	X	X	X		- CE
T.F.I. System srl (IT) www.tfisystem.it								- Easy Grip			X	X			X		X	X	X	X	X	- CE
Thommen Medical (CH) www.thommenmedical.com								- Thommen			X	X					X	X			X	- CE
TRI Implants (CH) www.tri-implants.com								- TRI Implants			X						X	X	X			
Vulcan Custom Dental (US) www.vulcandental.com				👍				- BioHorizons	X		X	X	X	X	X	X	X	X	X	X	X	
Zfx (DE) www.zfx-dental.com	👍	👍	👍	👍	👍	👍	👍	- Megagen - Thommen Medical - Microdent - Osstem - and more	X	X	X	X	X	X	X		X		X			- CE
Zimmer Dental (US) www.zimmerdental.com				👍					X	X				X							X	- CE

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Implant libraries for the 3Shape Dental System™

June, 2016

Implant systems / Providers of implant solutions	Implant systems								Implant Solutions					Manu-facturing		Consumables (for local use)						Additional info
	Nobel Biocare	Biomet 3i	Straumann	Zimmer Dental	DENTSPLY - Astra Tech	DENTSPLY - Friadent	CAMLOG	Other systems	1- Piece (Titanium)	1- Piece (Zirconia)	2- Piece (Ti base + Zr abutment)	Implant Bars & Bridges	Digital implant models	Providers milling center	Local milling by 3rd party	Blanks with pre-milled interface (for 1-piece abutment)	Titanium bases (for 2-piece abutments)	Intraoral Scan bodies	Digital model analogs	Multi-unit abutments	Cleared for use in US	Comments
3dental (ES) reseller www.3dental.es	👍	👍	👍	👍	👍	👍	👍	- BioComp - Sweden & Martina - DYNA	X	X		X	X	X					X			
AB-Dental (IL) www.ab-dent.com				👍				- MIS Alpha Bio	X		X		X			X	X	X	X	X		- CE
Abutments4life (DE) www.abutments4life.de	👍	👍	👍	👍	👍	👍	👍	- BioHorizons - Osstem - ICX-Templant - and more	X		X	X	X	X	X	X	X	X	X			- CE
Alpha-Bio Tec (IL) www.alpha-bio.net								- Alpha Bio Tec.	X		X	X	X		X	X	X					- CE
Argen (US) reseller www.argen.com	👍	👍	👍	👍	👍	👍			X		X			X		X	X	X	X		X	- CE
ATLANTIS™ (SE) reseller - FDA cleared only www.dentsplyimplants.com	Awaiting information from the provider				👍	👍	Awaiting information from the provider														X	- CE
ATLANTIS™ (SE) reseller - all libraries www.dentsplyimplants.com	👍	👍	👍	👍	👍	👍	👍	- DENTSPLY ANKYLOS XIVE® FRIALIT™ - Keystone Dental - BioHorizons	X	X				X									- CE
BEGO (DE) reseller www.bego.com	👍	👍	👍	👍	👍	👍	👍	- BEGO Implant Systems - and more	X	X	X	X		X			X	X				- CE - CE-labelled prosthetic screws
BioComp (NL) www.biocomp.eu								- BioComp	X		X				X	X	X	X	X			- CE ISO
Bicon (US) www.bicon.com								- Bicon			X	X			X			X			X	- CE Health Canada
Biodenta (CH) reseller - FDA cleared only www.biodenta.com	👍	👍	👍	👍	👍			Straumann Bone Level (no Tissue Level) BioHorizons Internal Osstem (Hiossen) TSIII Biodenta Bone Level and Tapered	X		X	X	X	X	X	X	X	X	X	X	X	- Implant Bridges only available for Abutment Level not implant level. - 3rd party milling center must become Biodenta Contract Manufacturer and comply to QSR
Biodenta (CH) reseller - all libraries www.biodenta.com	👍	👍	👍	👍	👍			Straumann Bone Level (no Tissue Level) BioHorizons Internal Osstem (Hiossen) TSIII Biodenta Bone Level and Tapered	X		X	X	X	X	X	X	X	X	X	X		- CE CFDA TFDA
Biomet (US) reseller - FDA cleared only www.biomet.com	Awaiting information from the provider	👍	Awaiting information from the provider																		X	- CE - encode healing abutments
Biomet (US) reseller - all libraries www.biomet.com	👍	👍	👍						X	X	X			X				X				- CE - encode healing abutments
Biotech Dental (FR) www.biotech-dental.com								- Biotech			X		X		X		X	X	X	X		- CE
BlueSkyBio (US) blueskybio.com	👍		👍	👍	👍			- BlueSkyBio	X		X				X	X	X			X	X	- CE Health Canada
Bredent (DE) www.bredent.com								- Sky			X				X		X	X	X			- CE
CADBLU (US) reseller www.cadbludental.com	👍	👍	👍	👍	👍			- Bio Horizons - MIS Implants	X		X	X	X	X				X	X			
CADstar (AT) www.cadstar.dental	👍	👍	👍	👍	👍	👍	👍	BREDENT DENTSPLY XIVE CONELOG MEDENTIS ICX NEOSS PROWITAL SIC ALPHATECH and others	X		X	X		X			X		X	X		- CE (0297) - ISO 13485 - Certificate Directive 93-42-EEC - (Annex II)
CAMLOG (CH) - FDA cleared only www.camlog.com							👍	- CONELOG - iSy									X	X			X	
CAMLOG (CH) - all libraries www.camlog.com							👍	- CONELOG - iSy	X		X	X		X	X		X	X				

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CAP (US) reseller www.cap-us.com	👍	👍	👍	👍	👍	👍			X		X	X	X	X	X	X	X		X		X	
CMC (US) reseller - FDA cleared only www.custom-milling.com	👍	👍	👍	👍	👍	👍	👍	- BioHorizons - Osstem - LifeCore - Intra-Lock - Neoss	X	X	X	X		X				X			X	- CE
CMC (US) reseller - all libraries www.custom-milling.com	👍	👍	👍	👍	👍	👍	👍	- BioHorizons - Osstem - LifeCore - Intra-Lock - Neoss	X	X	X	X		X				X				- CE
Conmet (RU) conmet.ru								- Conmet	X		X		X				X	X	X			- Dental implants have a bioactive surface - CE ISO 9001 and ISO 13485
Conexão Sistemas de Prótese (BR) www.conexao.com.br	👍		👍					- Conexão Sistema de Prótese	X	X	X			X			X	X	X	X		- ANVISA CE
Core3D International (NL) reseller - FDA cleared only www.core3dcenters.com	Awaiting information from the provider								Awaiting information from the provider												X	- CE Health Canada TGA (AUS) Taiwan regulatory - MHLW:Ministry of Health Labour and Welfare (JP)
Core3D International (NL) reseller - all libraries www.core3dcenters.com	👍	👍	👍	👍	👍	👍	👍	- Avinent - BioComp - BioHorizons - MIS Implants - and many more	X		X	X	X	X	X	X	X	X	X			- CE Health Canada TGA (AUS) Taiwan regulatory - MHLW:Ministry of Health Labour and Welfare (JP)
Cortex Dental (IL) www.cortex-dental.com				👍				- Cortex Dental			X	X			X	X	X	X	X	X	X	- CE
Creodent (US) www.Creomc.com	👍	👍	👍	👍	👍			- Hiossen	X		X	X		X			X				X	
C-Tech Implant (IT) www.c-tech-implant.com								- C-Tech Implant	X		X	X			X		X			X		- CE
Degudent (DE) reseller www.degudent.com	👍	👍	👍	👍	👍	👍	👍	- Medentika	X	X	X			X	X		X					
Dental Consulting (DE) www.gadau-consulting.com	👍		👍	👍	👍	👍	👍	- ICX-Medentis - Osstem	X		X	X	X	X	X	X	X	X	X			- CE
Dentaurum Implants (DE) www.dentaurum-implants.de								- Dentaurum Implants			X				X		X	X				- CE PAL
Dentegris Deutschland (DE) www.dentegris.de								- Dentegris Implants			X	X			X		X					
Dentium (KR) www.dentium.com								- Implantium - SuperLine - SimpleLine II NR Line Custom Abutment	X	X	X	X		X	X						X	- CE CFDA PMDA TFDA GOST
Dentsply-Friadent (DE) reseller www.dentsply-friadent.com						👍		- Xive - Ankylos	X	X	X			X								- CE
DESS (ES) www.dess-abutments.com	👍	👍	👍	👍	👍	👍		- BioHorizons - Ankylos - Mis	X		X	X		X	X		X	X			X	- CE - ISO 13485 - ISO 9001 - Health Canada pending.
DIO-Implants (KR) reseller www.dioimplant.com	👍							- DIO Implants	X	X	X	X		X	X							- CE KFDA SFDA
Dynamic Abutment Solutions (ES) www.dynamicabutment.com	👍	👍	👍	👍	👍	👍	👍	- Osstem - MIS Implants - Megagen - Biohorizons - and more	X		X	X		X	X	X	X				X	- CE, ISO 9001, ISO13485,CMDCAS
Easy Implant (FR) www.easyimplant.com									X		X	X		X			X				X	- CE
Elos Medtech Pinol (DK) www.elosmedtech.com	👍	👍	👍	👍	👍	👍	👍	- Neoss	X		X	X	X	X	X	X		X	X			- CE
Euroteknika (FR) www.euroteknika.com	👍	👍	👍	👍	👍			- Anthogyr - Biotech - Easy Implant - MIS Implants - and more	X		X	X	X	X		X	X	X	X	X	X	- CE

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GC Advanced Technologies (US) reseller www.gc-at.com	👍	👍	👍	👍	👍			- BioHorizons - Sybron	X	X	X			X								
Glidewell (US) reseller www.glidewelldental.com	👍	👍	👍	👍	👍	👍	👍	- Prismat k - DentalCraft - Keystone Dental - Neoss	X	X	X	X	X	X			X	X	X		X	- CE pending
Green DenTech / Denracle (TW) www.denracle.com	👍	👍	👍	👍	👍	👍		- Biohorizons - Dentium - Osstem and more...	X							X	X					- CE
Heraeus Kulzer (DE) reseller www.heraeus.com	👍	👍	👍	👍	👍	👍	👍	- Thommen	X	X	X		X	X								
Implant Direct (US) www.implantdirect.com/custom-direct	👍		👍	👍				- Biohorizons	X			X	X	X					X		X	- CE Health Canada
Intra-Lock International (US) www.intra-lock.com								- INTRA-LOCK	X		X	X				X	X	X	X	X	X	- CE Health Canada
Ivoclar Wieland (DE) reseller www.wieland-dental.de	👍	👍	👍	👍	👍	👍		- Dentaurum Implants	X		X	X		X	X		X		X			
Lasak (CZ) www.lasak.com	👍		👍		👍			- Lasak BionIQ - Lasak Impladent	X	X	X	X		X		X	X			X		- CE - ISO 13485 - ISO 9001
LaStruttura (IT) reseller www.lastruttura.it	👍	👍	👍	👍	👍	👍		- Sweden & Martina - Megagen - Prodent - and many more	X	X		X	X	X				X	X			- CE 93/42
Medentika (DE) www.medentika.de	👍	👍	👍	👍	👍	👍	👍	- Medentika M-Implant	X		X	X		X	X	X	X	X			X	- CE
Medentis Medical (DE) www.medentis.de	👍		👍		👍	👍		- ICX Templant	X		X	X	X	X			X	X				- CE
Medical Instinct (DE) www.medical-instinct.de								- Medical Instinct	X	X	X	X			X	X	X	X		X		- CE
Médical Production (FR) www.medical-production.eu		👍	👍	👍	👍	👍		- Euroteknika	X		X	X	X		X	X	X	X		X		- CE0499 - ISO 9001 - ISO 13485
Megagen Implant (KR) www.imegagen.com								- AnyRidge Internal - AnyOne Internal - MINI Internal - Octa Level			X		X	X	X		X	X	X		X	- CE - KFDA
MIS Implants Technologies Ltd. (IL) - FDA cleared only www.mis-implants.com								- MIS Implants			X	X		X	X	X	X	X		X	X	- CE
MIS Implants Technologies Ltd. (IL) - all libraries www.mis-implants.com								- MIS Implants			X	X		X	X	X	X	X		X		- CE
Neodent (BR) www.neodent.com.br	👍		👍					- Neodent Implant Systems	X	X	X	X			X			X			X	
Neoss (UK) - all libraries www.neoss.com	👍	👍	👍	👍	👍			- Neoss	X		X	X	X	X	X	X	X	X	X	X	X	- CE
Nobel Biocare (CH) www.nobelbiocare.com	👍	👍	👍	👍	👍				X	X	X			X							X	- CE
NT Trading (DE) www.nt-trading.com	👍	👍	👍	👍	👍	👍	👍	- Thommen - Sweden & Martina - BEGO	X		X	X		X	X	X	X	X	X		X	- CE CMDCAS GOST R TGC - Mexico Certification
Phibo (ES) reseller www.phibo.com	👍	👍	👍	👍	👍	👍	👍	- BTI - Sweden&Martina - MIS Implants - and many more	X	X	X	X	X	X				X	X			- CE - ISO 13485 - ISO 9001
Prowital (DE) www.prowital.de								- Prowital			X				X		X	X	X			- CE - EN-ISO 9001-V472008 - EN ISO-13485-2003AC2009 - Certificate Directive-93-42 EWG

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Ritter Implants (DE) www.ritterimplants.com			👍	👍				- Alpha -Bio Tec. - MIS Implants	x		x		x		x		x	x	x			- CE
Straumann (CH) - FDA cleared only www.straumann.com			👍						x	x	x			x							x	- CE
Straumann (CH) - all libraries www.straumann.com			👍						x	x	x			x	x	x	x	x	x			- CE
Sweden&Martina S.p.A (IT) www.sweden-martina.com								- Sweden&Martina	x	x	x	x	x	x			x	x	x			
Target3D (US) www.target3d.com	👍	👍	👍	👍	👍	👍	👍	- Osstem - BioHorizons - MIS-Implants - and more	x	x	x	x	x	x	x	x	x	x	x	x		- CE
T.F.I. System srl (IT) www.tfisystem.it								- Easy Grip			x	x			x		x	x	x	x	x	- CE
Thommen Medical (CH) www.thommenmedical.com								- Thommen			x	x					x	x			x	- CE
TRI Implants (CH) www.tri-implants.com								- TRI Implants			x						x	x	x			
Vulcan Custom Dental (US) www.vulcandental.com				👍				- BioHorizons	x		x	x	x	x	x	x	x	x	x	x	x	
Zfx (DE) www.zfx-dental.com	👍	👍	👍	👍	👍	👍	👍	- Megagen - Thommen Medical - Microdent - Osstem - and more	x	x	x	x	x	x	x		x		x			- CE
Zimmer Dental (US) www.zimmerdental.com				👍					x	x				x							x	- CE

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K151455

Device Name
3Shape Abutment Designer™ Software

Indications for Use *(Describe)*
The 3Shape Abutment Designer Software is intended as an aid to the restoration of chewing function in partially or fully edentulous mandibles and maxillae. The 3Shape Abutment Designer Software is intended for use by a dental practitioner or dental laboratory staff for designing the patient specific component of a two-piece, one-piece, or hybrid dental implant abutment. The single or multi-unit abutment design is intended to be used by the manufacturer of an endosseous dental implant abutment to create the final device.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2016-8070; Released by CDRH on 10/5/2017

510(K) SUMMARY – Traditional 510(K)

Submitter Information

A Company Name:	3Shape A/S
B Company Address:	Holmens Kanal 7 DK-1060 Copenhagen K
C Company Phone: Company Fax:	+45 7027 2620 +45 7027 2621
D Contact Person:	Hanne Nielsen Regulatory Affairs Manager
E Date Summary Prepared:	June 28, 2016

Device Identification

A Trade/proprietary Name:	3Shape Abutment Designer™ Software
B Common Name:	Abutment design software for dental laboratory
C Device Classification Name:	Endosseous Dental Implant Abutment
C Regulation Number:	872.3630
C Classification:	Class II
D Product Code:	PNP

Predicate Device

Sirona Dental CAD/CAM System (K100152).

Intended Use

The 3Shape Abutment Designer Software is intended as an aid to the restoration of chewing function in partially or fully edentulous mandibles and maxillae. The 3Shape Abutment Designer Software is intended for use by a dental practitioner or dental laboratory staff for designing the patient specific component of a two-piece, one-piece or hybrid dental

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implant abutment. The single or multi-unit abutment design is intended to be used by the manufacturer of an endosseous dental implant abutment to create the final device.

Device Description

The 3Shape Abutment Designer™ Software receives scan data containing topographical characteristics of real teeth, dental impressions, or stone models. The software provides the user with the ability to create matching endosseous dental implant abutments using computer aided design.

The output of the device is a computer file containing the abutment(s) in digital form which can be used by manufacturers that hold an implant abutment 510(k) or are milling per the specific instructions provided by the holder of a 510(k) marketing clearance for a patient specific implant abutment. The 3Shape Abutment Designer Software output is restricted in the U.S. to be manufactured by a holder of an implant abutment 510(k) or milled per the specific instructions provided by the holder of a 510(k) marketing clearance for a patient specific implant abutment.

The 3Shape Abutment Designer™ Software can be run on properly configured "off-the-shelf" PC hardware running Microsoft® Windows and using a standard keyboard and mouse.

The 3Shape Abutment Designer™ Software requires the loading of implant libraries, which includes information such as implant type, maximum and minimum dimensional parameters for abutments, etc., created by separate abutment manufacturers and cleared by the FDA. In the US, the Implant Libraries are obtained via a 3Shape server after demonstration to 3Shape of the FDA clearance of the Implant Library.

Summary of the technological characteristics

The 3Shape Abutment Designer™ is a software only device programmed in the Delphi programming language and has the following PC/laptop requirements and other technological characteristics as compared to the predicate device:

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Records processed under FOIA Request 2016-8070; Released by CDRH on 10/5/2017

Item	Submission Device Minimum Requirements	Submission Device Recommended	Predicate Device
OS	Windows 7 32-bit Professional*	Windows 7 64-bit Professional	Windows Vista 32- bit
RAM	4GB	8GB (16GB)	6GB
Video Card	512MB DirectX 10 (1GB DirectX 10)	1GB DirectX 11 (2GB DirectX 11)	512 MB DirectX 10 NVIDIA Quadro
Available HDD Space	250GB	500GB (1TB)	500GB
CPU	Intel Core i5 or equivalent	Intel Core i7 or equivalent	Intel Core i7
Monitor resolution	1440 x 900 pixels	1920 x 1080 pixels	Unknown
3D Mouse	None	3DConnexion SpaceMouse™	Unknown
Network	Internet connection		Unknown
Ports	USB 2.0 port for 3Shape desktop scanner		Serial Port PCI card for inEOS scanner
Mouse	Mouse with wheel button support		Unknown

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Indications for Use	The 3Shape Abutment Designer Software is intended as an aid in the restoration of chewing function in partially or fully edentulous mandibles and maxillae. The 3Shape Abutment Designer Software is intended for use by a dental practitioner or dental laboratory staff for designing the patient specific component of a two-piece, one-piece or hybrid dental implant abutment. The single or multi-unit abutment design is intended to be used by the manufacturer of an endosseous dental implant abutment to create the final device.	The Sirona Dental CAD/CAM System is intended for use in partially or fully edentulous mandibles and maxillae in support of single or multi-unti cement retained restorations. The system consists of three major parts: TiBase, InCoris mesostructure, and CAD/CAM software. Specifically, the InCoris mesostructure and TiBase components make up a two-piece abutment which is used in conjunction with endosseous dental implants to restore the function and asesthetics in the oral cavity. The InCoris mesostructure may also be used in conjunction with the CAMlog Titanium base CAD/CAM (types K2244.xxxx) (K083496) in the Camlog Implant System. The CAD/CAM software is intended to design and fabricate the InCoris mesostructure. The InCoris mesostructure and TiBase two-piece abutment is compatible with the following implant systems: Nobel Biocare Replace (K020646), Nobel Biocare Branemark (K022562), Friadent Xive (K013867), Biomet 3i Osseotite (K980549), Astra Tech Osseospeed (K091239), Zimmer Tapered Screw-Vent (K061410), and Straumann SynOcta (K061176).
Software Output	Digital encrypted or non-encrypted proprietary or .STL file including only the patient-specific abutment component for one-piece, two-piece, or hybrid abutment designs. The digital output does not include the abutment-to-implant connection interface.	.STL file of the ceramic mesostrucutre sent to Sirona Dental CAD/CAM System milling unit
Physical - Output	N/A – Submission device relies on separate regulatory clearance and manufacture of the abutment by a separate company	Two-piece Tibase abutment – pre-milled titanium base combined with ceramic mesostructure designed in Sirona CAD/CAM software.
Milling Location	Abutment Manufacturer or Dental laboratory per the 510(k) clearance of the dental abutment	Local milling of the ceramic abutment component.

The predicate Sirona device includes in the marketing clearance the two-piece TiBase Abutments (titanium bases and ceramic blocks) as a physical output as well as a validated milling unit and directions for assembly of the final dental abutment. The 3Shape Abutment Designer™ Software does not provide any physical parts that can come into contact with the patient. The 3Shape Abutment Designer Software instead provides only the digital design as an accessory to the physical dental abutment systems cleared by other manufacturers. The differences between the Indications for Use

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Statement of the submission device and the predicate are related to the lack of physical output from the submission device and reliance on previous or subsequent FDA clearance of the physical abutment by a separate manufacturer. However, the difference does not change the intended use of the device.

Nonclinical Testing

Software, hardware, and integration verification and validation testing was performed in accordance with the FDA Guidance Document "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" (Issued on May 11, 2005) as well as the FDA Guidance Document "Off-The-Shelf Software Use in Medical Devices (Issued on September 9, 1999).

Prior to release, verification and validation testing of the 3Shape Abutment Designer™ Software has been completed using the approved acceptance criteria: Each user need has its own validation acceptance criteria; each specification has its own verification acceptance criteria; bug verification consists in ensuring issue is not reproducible; issues reported by beta partners must be reviewed and handled appropriately; beta partners must report functionality to be an improvement over previous version.

The validation suite includes validation of implemented mitigations related to device hazards identified in the risk management procedures.

Conclusion

Based on a comparison of intended use, principle of operations, features and technical data, and the verification/validation test results, the 3Shape Abutment Designer™ Software is found to be substantially equivalent with the Predicate Device.

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Physical - Output	N/A – Submission device relies on separate regulatory clearance and manufacture of the abutment by a separate company	Two-piece Tibase abutment – pre-milled titanium base combined with ceramic mesostructure designed in Sirona CAD/CAM software.
Milling Location	Abutment Manufacturer or Dental laboratory per the 510(k) clearance of the dental abutment	Local milling of the ceramic abutment component.

The predicate Sirona device includes in the marketing clearance the two-piece TiBase Abutments (titanium bases and ceramic blocks) as a physical output as well as a validated milling unit and directions for assembly of the final dental abutment. The 3Shape Abutment Designer™ Software does not provide any physical parts that can come into contact with the patient. The 3Shape Abutment Designer Software instead provides only the digital design as an accessory to the physical dental abutment systems cleared by other manufacturers. The differences between the Indications for Use

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Conclusion

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K151455

Device Name
3Shape Abutment Designer™ Software

Indications for Use *(Describe)*
The 3Shape Abutment Designer Software is intended as an aid to the restoration of chewing function in partially or fully edentulous mandibles and maxillae. The 3Shape Abutment Designer Software is intended for use by a dental practitioner or dental laboratory staff for designing the patient specific component of a two-piece, one-piece, or hybrid dental implant abutment. The single or multi-unit abutment design is intended to be used by the manufacturer of an endosseous dental implant abutment to create the final device.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K151455

Device Name
3Shape Abutment Designer™ Software

Indications for Use *(Describe)*
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DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

September 6, 2016

3Shape A/S
Hanne Nielsen
Regulatory Affairs Manager
Holmens Kanal 7
Copenhagen, 1060
DENMARK

Re: K151455
Trade/Device Name: 3Shape Abutment Designer™ Software
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: PNP
Dated: January 8, 2016
Received: January 11, 2016

Dear Hanne Nielsen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Tina Kiang -S

Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K151455

Device Name
3Shape Abutment Designer™ Software

Indications for Use *(Describe)*
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Summary of the technological characteristics

The 3Shape Abutment Designer™ is a software only device programmed in the Delphi programming language and has the following PC/laptop requirements and other technological characteristics as compared to the predicate device:

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Item	Submission Device Minimum Requirements	Submission Device Recommended	Predicate Device
OS	Windows 7 32-bit Professional*	Windows 7 64-bit Professional	Windows Vista 32- bit
RAM	4GB	8GB (16GB)	6GB
Video Card	512MB DirectX 10 (1GB DirectX 10)	1GB DirectX 11 (2GB DirectX 11)	512 MB DirectX 10 NVIDIA Quadro
Available HDD Space	250GB	500GB (1TB)	500GB
CPU	Intel Core i5 or equivalent	Intel Core i7 or equivalent	Intel Core i7
Monitor resolution	1440 x 900 pixels	1920 x 1080 pixels	Unknown
3D Mouse	None	3DConnexion SpaceMouse™	Unknown
Network	Internet connection		Unknown
Ports	USB 2.0 port for 3Shape desktop scanner		Serial Port PCI card for inEOS scanner
Mouse	Mouse with wheel button support		Unknown

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Indications for Use	The 3Shape Abutment Designer Software is intended as an aid in the restoration of chewing function in partially or fully edentulous mandibles and maxillae. The 3Shape Abutment Designer Software is intended for use by a dental practitioner or dental laboratory staff for designing the patient specific component of a two-piece, one-piece or hybrid dental implant abutment. The single or multi-unit abutment design is intended to be used by the manufacturer of an endosseous dental implant abutment to create the final device.	The Sirona Dental CAD/CAM System is intended for use in partially or fully edentulous mandibles and maxillae in support of single or multi-unti cement retained restorations. The system consists of three major parts: TiBase, InCoris mesostructure, and CAD/CAM software. Specifically, the InCoris mesostructure and TiBase components make up a two-piece abutment which is used in conjunction with endosseous dental implants to restore the function and asesthetics in the oral cavity. The InCoris mesostructure may also be used in conjunction with the CAMlog Titanium base CAD/CAM (types K2244.xxxx) (K083496) in the Camlog Implant System. The CAD/CAM software is intended to design and fabricate the InCoris mesostructure. The InCoris mesostructure and TiBase two-piece abutment is compatible with the following implant systems: Nobel Biocare Replace (K020646), Nobel Biocare Branemark (K022562), Friadent Xive (K013867), Biomet 3i Osseotite (K980549), Astra Tech Osseospeed (K091239), Zimmer Tapered Screw-Vent (K061410), and Straumann SynOcta (K061176).
Software Output	Digital encrypted or non-encrypted proprietary or .STL file including only the patient-specific abutment component for one-piece, two-piece, or hybrid abutment designs. The digital output does not include the abutment-to-implant connection interface.	.STL file of the ceramic mesostrucutre sent to Sirona Dental CAD/CAM System milling unit
Physical - Output	N/A – Submission device relies on separate regulatory clearance and manufacture of the abutment by a separate company	Two-piece Tibase abutment – pre-milled titanium base combined with ceramic mesostructure designed in Sirona CAD/CAM software.
Milling Location	Abutment Manufacturer or Dental laboratory per the 510(k) clearance of the dental abutment	Local milling of the ceramic abutment component.

The predicate Sirona device includes in the marketing clearance the two-piece TiBase Abutments (titanium bases and ceramic blocks) as a physical output as well as a validated milling unit and directions for assembly of the final dental abutment. The 3Shape Abutment Designer™ Software does not provide any physical parts that can come into contact with the patient. The 3Shape Abutment Designer Software instead provides only the digital design as an accessory to the physical dental abutment systems cleared by other manufacturers. The differences between the Indications for Use

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Statement of the submission device and the predicate are related to the lack of physical output from the submission device and reliance on previous or subsequent FDA clearance of the physical abutment by a separate manufacturer. However, the difference does not change the intended use of the device.

Nonclinical Testing

Software, hardware, and integration verification and validation testing was performed in accordance with the FDA Guidance Document "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" (Issued on May 11, 2005) as well as the FDA Guidance Document "Off-The-Shelf Software Use in Medical Devices (Issued on September 9, 1999).

Prior to release, verification and validation testing of the 3Shape Abutment Designer™ Software has been completed using the approved acceptance criteria: Each user need has its own validation acceptance criteria; each specification has its own verification acceptance criteria; bug verification consists in ensuring issue is not reproducible; issues reported by beta partners must be reviewed and handled appropriately; beta partners must report functionality to be an improvement over previous version.

The validation suite includes validation of implemented mitigations related to device hazards identified in the risk management procedures.

Conclusion

Based on a comparison of intended use, principle of operations, features and technical data, and the verification/validation test results, the 3Shape Abutment Designer™ Software is found to be substantially equivalent with the Predicate Device.

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Substantial Equivalence Comparison

1. Predicates

The 3Shape Abutment Designer™ Software has the same intended uses and technical characteristics as the Sirona Dental CAD/CAM System (K100152) as listed in "Table 1: Predicate"

Table 1: Predicate

Predicate	Manufacturer	510(k) number	Product code
Dental CAD/CAM System	Sirona	K100152	NHA*

* Endosseous dental implant abutments, 21CFR872.3630

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2. Intended Use Comparison

2.1. 3Shape Abutment Designer™ Software

The Device's Intended Use, Intended users, and Intended Operational is stated in the "VOL_001_Administrative Documents" volume of this submission and reproduced here:

> *"The 3Shape Abutment Designer™ Software is intended for designing endosseous dental implant abutments based on digital scans of 3D models.*
>
> *Intended users are Dental Practitioners and Dental Laboratory staff.*
>
> *Intended Operational Environment is Dental Laboratories."*

In the following sections, the similarities with the predicate are discussed.

2.2. Dental CAD/CAM System

The predicate's Intended Use can be extracted from the FDA 510(k) Premarket Notification Database:

> *"The Sirona Dental CAD/CAM System is intended for use in partially or fully edentulous mandibles and maxillae in support of single or multiple-unit cement retained restorations. The system consists of three major parts: TiBase, InCoris mesostructure, and CAD/CAM software. Specifically, the InCoris mesostructure and TiBase components make up a two-piece abutment which is used in conjunction with endosseous dental implants to restore the function and aesthetics in the oral cavity.*
>
> *The InCoris mesostructure may also be used in conjunction with the Camlog Titanium base CAD/CAM (types K2244.xxxx) (K083496) in the Canmlog Implant System. The CAD/CAM software is intended to design and fabricate the InCoris mesostructure. The InCoris mesostructure and TiBase two-piece abutment is compatible with the following implants systems:*
>
> *[List of compatible implant systems omitted for brevity]*

Underlined segments indicate similarity with 3Shape Abutment Designer™ Software.

Note, the predicate is a CAD/CAM System bundled with physical two-piece abutments; the 3Shape Abutment Designer™ Software is CAD/CAM only.

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3. Characteristics Comparison

A Characteristics Comparison can be seen in "Table 2: Substantial Equivalence Chart".

Table 2: Substantial Equivalence Chart

Feature name	3Shape Abutment Designer ™ Software	Sirona Dental CAD/CAM System (K100152)	Detailed information
Graphical UI	Yes	Yes	See section 3.1
Windows OS platform	Yes	Yes	See section 3.2
Uses standard PC hardware	Yes	Yes	See section 3.3
Main software components	Order Management, Scan, Design, Production	Administration, Scan, Model, Design, Production	See section 3.4
Input data: Digitally imports topography of teeth by 3D Scan	Yes	Yes	See section 3.5
3D CAD design tools	Yes	Yes	See section 3.6
Custom abutment design	Yes	Yes	See intended use discussion in section 2.
Screw retained designs	Yes	Yes	See section 3.7
Implant Bridge design	Yes	Yes	See section 3.8
Patient safety measurements	Yes	Yes	See section 3.9
Export to milling	Yes	Yes	See section 3.10
Configurations and settings	Locked for end-users in the US	Proprietary information	See section 3.11
Technical documentation for 3rd party software manufacturers	None	Proprietary information	N/A
Intended users	Dental practitioners and dental labs	Dental Technician or dentist	See section 3.12.
Output type	Computer file containing CAD model	Computer file containing CAD model	See section 3.10
Device submission includes pre-manufactured prosthetics*	No	Yes	See 510(k) summary of both devices.

* Endosseous dental implant abutments as per 21CFR872.3630

Note: The comparison is made using the current publicly available labelling of Sirona Dental CAD/CAM System from the company's website (http://manuals.sirona.com/en/digital-dentistry/). The Predicate 510(k) summary lists the following components that is used for software comparison: CEREC MCXL, and inLab MCXL (labelling indicates rebranding as CEREC SW / CEREC SW Premium and inLab SW).

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3.1. Graphical UI

Both devices utilizes a Graphical User Interface with a large 3D-based main window, a workflow progress bar, and various tools to manipulate the shape of the designed dental prosthetic / abutment.

Predicate device:

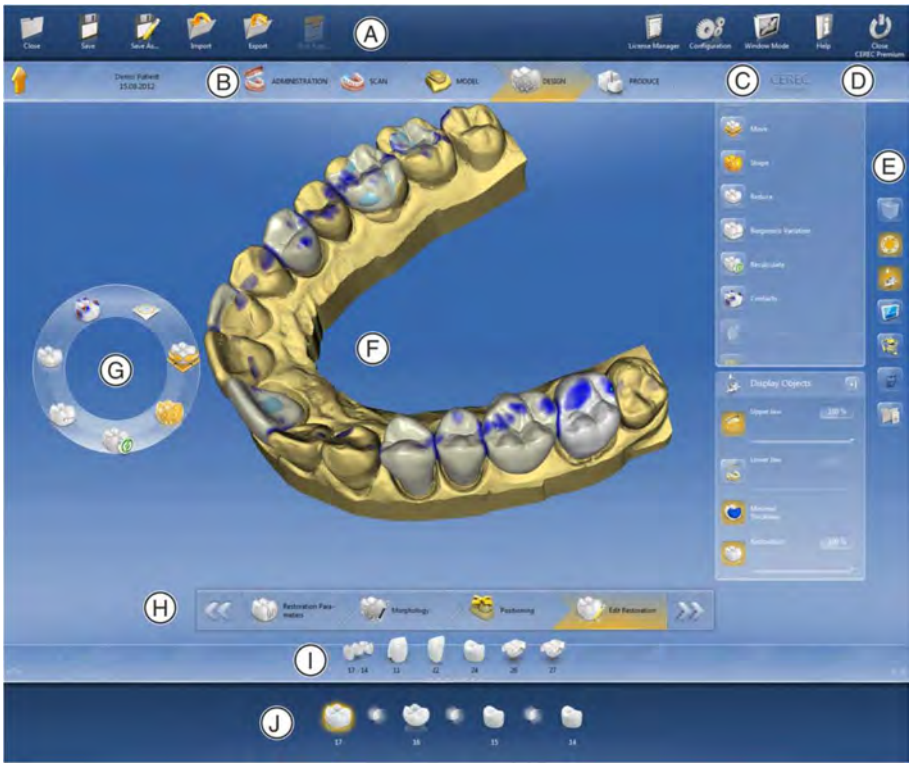

Figure 1: Sirona Dental CAD/CAM System CEREC PREMIUM SW 4.4.x, -USA only-, 02.2016, Version: 121847

3Shape Abutment Designer™:

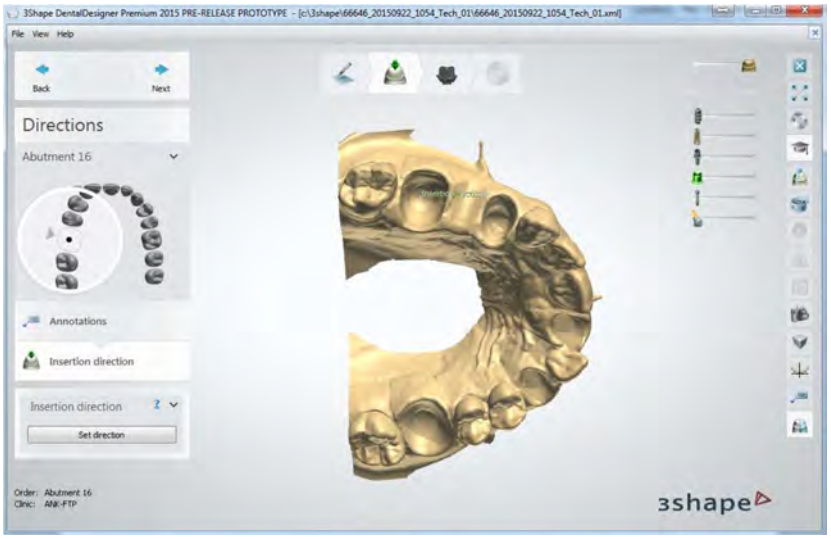

Figure 2: 3Shape Abutment Designer User interface as specified in requirements (See DS2015-1-RS0100 in the Additional Information 1 part of this submission).

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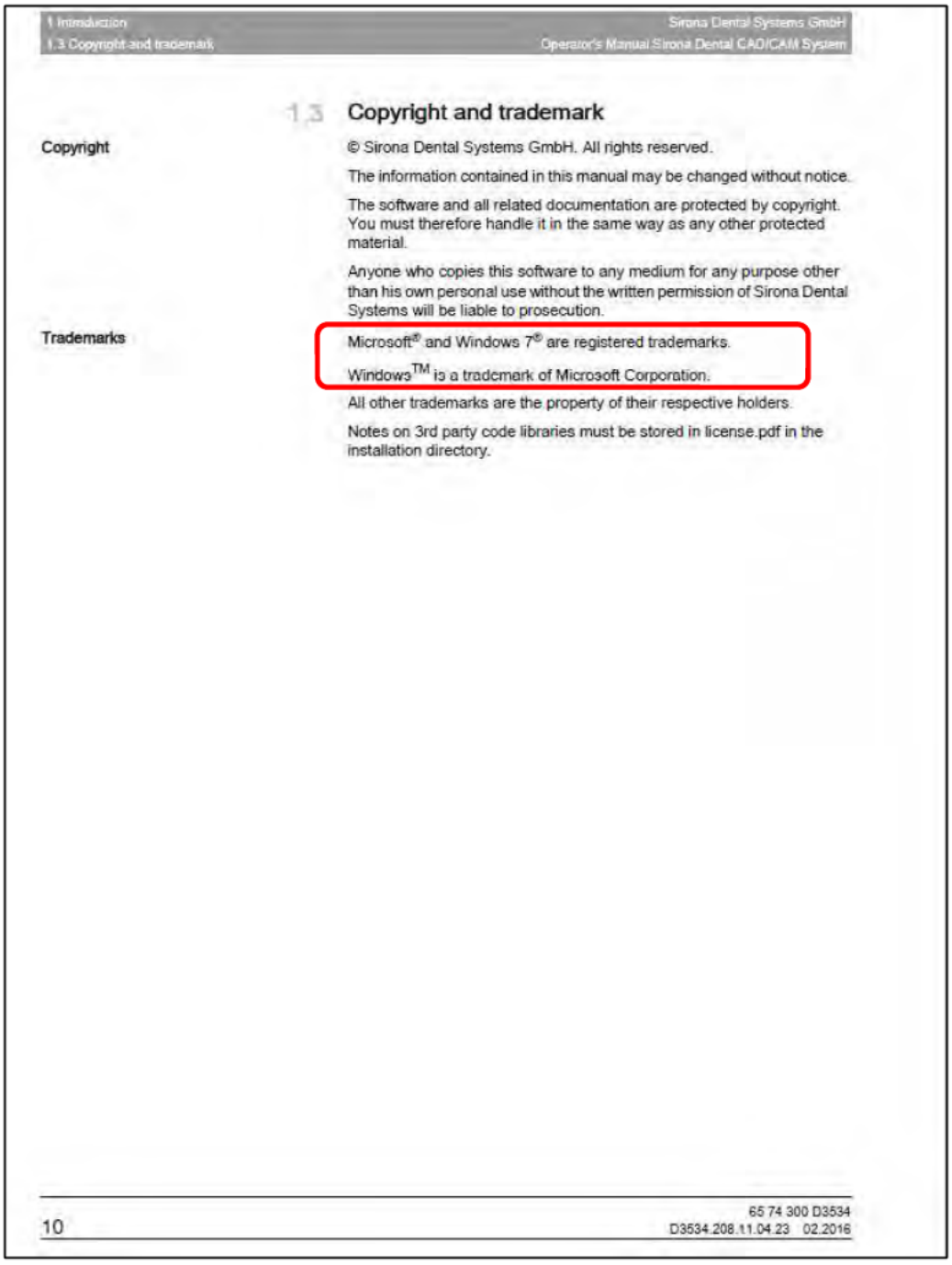
3.2. OS Platform

Both the predicate and the device run on the Windows OS platform.

Predicate Device:



1 Introduction
1.3 Copyright and trademark

Sirona Dental Systems GmbH
Operator's Manual Sirona Dental CAD/CAM System

1.3 Copyright and trademark

Copyright

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Trademarks

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Windows™ is a trademark of Microsoft Corporation.

All other trademarks are the property of their respective holders.

Notes on 3rd party code libraries must be stored in license.pdf in the installation directory.

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Figure 3: Sirona Dental CAD/CAM System CEREC PREMIUM SW 4.4.x, -USA only-, 02.2016, Version: 121847

3Shape Abutment Designer™:

3Shape Abutment Designer™ is compatible with Microsoft Windows 7 (64bit) /Microsoft Windows 8 (64bit) as specified in the *Architecture Design Chart* of the original submission.

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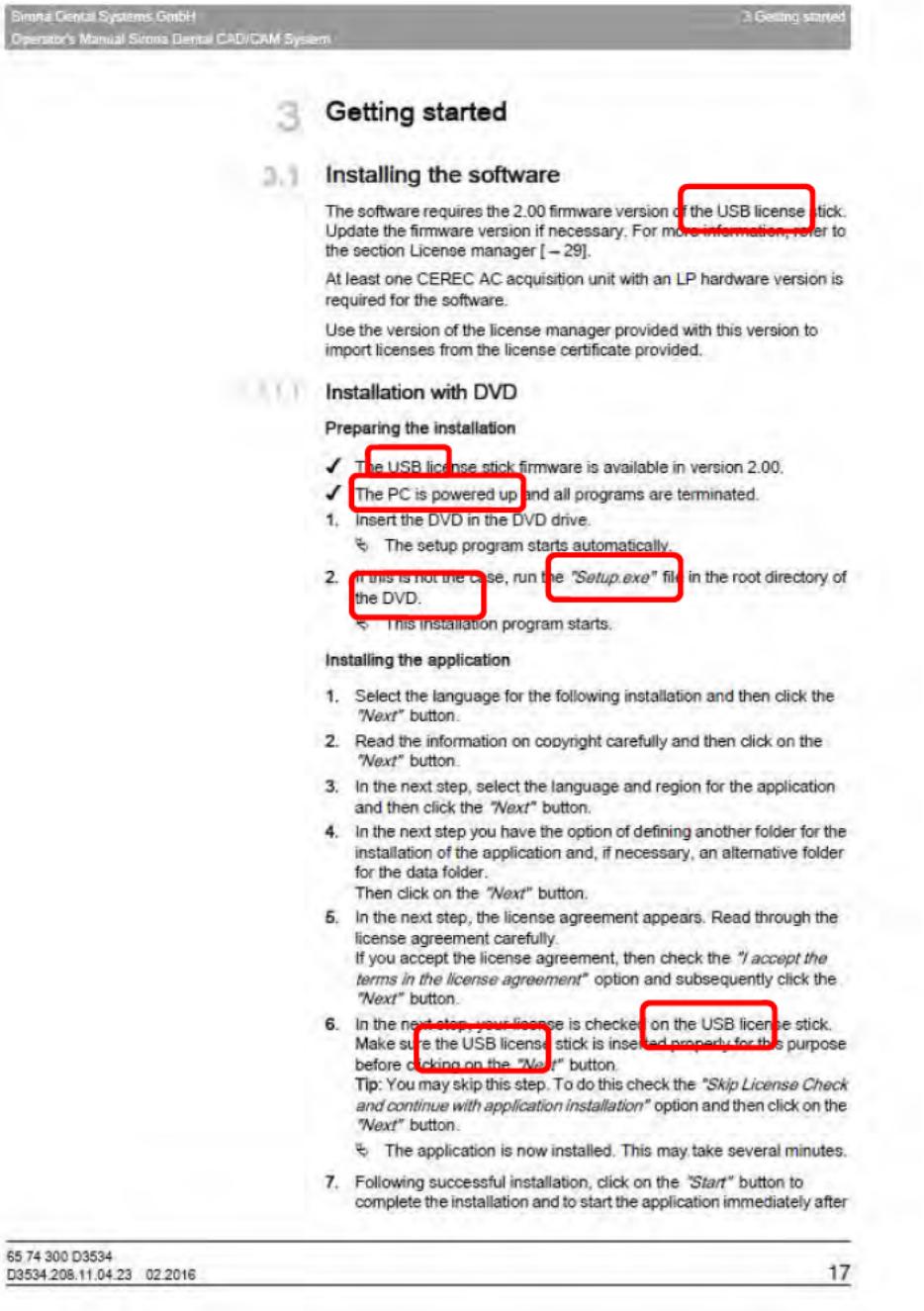
3.3. Hardware Platform

Both devices runs on standard consumer PCs running Microsoft® Windows.

Predicate Device:

The Predicate Device fails to specify system requirements in the publically available labelling. However, the labelling repeatedly refers to the "PC", DVD and USB mediums, and the *Setup.exe* file (which is a format specific to PCs running Microsoft® Windows OS). The license is read from a USB stick attached to the PC.



Sirona Dental Systems GmbH — 3 Getting started
Operator's Manual Sirona Dental CAD/CAM System

3 Getting started

3.1 Installing the software

The software requires the 2.00 firmware version of the USB license stick. Update the firmware version if necessary. For more information, refer to the section License manager [→ 29].

At least one CEREC AC acquisition unit with an LP hardware version is required for the software.

Use the version of the license manager provided with this version to import licenses from the license certificate provided.

3.1.1 Installation with DVD

Preparing the installation

✓ The USB license stick firmware is available in version 2.00.
✓ The PC is powered up and all programs are terminated.
1. Insert the DVD in the DVD drive.
   ↳ The setup program starts automatically.
2. If this is not the case, run the *"Setup.exe"* file in the root directory of the DVD.
   ↳ The installation program starts.

Installing the application

1. Select the language for the following installation and then click the *"Next"* button.
2. Read the information on copyright carefully and then click on the *"Next"* button.
3. In the next step, select the language and region for the application and then click the *"Next"* button.
4. In the next step you have the option of defining another folder for the installation of the application and, if necessary, an alternative folder for the data folder.
   Then click on the *"Next"* button.
5. In the next step, the license agreement appears. Read through the license agreement carefully.
   If you accept the license agreement, then check the *"I accept the terms in the license agreement"* option and subsequently click the *"Next"* button.
6. In the next step, your license is checked on the USB license stick. Make sure the USB license stick is inserted properly for this purpose before clicking on the *"Next"* button.
   Tip: You may skip this step. To do this check the *"Skip License Check and continue with application installation"* option and then click on the *"Next"* button.
   ↳ The application is now installed. This may take several minutes.
7. Following successful installation, click on the *"Start"* button to complete the installation and to start the application immediately after

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Figure 4: Sirona Dental CAD/CAM System CEREC PREMIUM SW 4.4.x, -USA only-, 02.2016, Version: 121847

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3Shape Abutment Designer™:

3Shape Abutment Designer™ is compatible with Microsoft® Windows 7 (64bit) / Microsoft® Windows 8 (64bit) as specified in the *Architecture Design Chart* of the original submission. The license is read from a USB dongle attached to a PC.

3.4. Main software components

Both the device and the predicate device are part of a larger system, which include Order Management, scan acquisition, General CAD tools, and Manufacturing interfaces. All these components are classified under product code NOF (510(k) exempt) with the exception of the Abutment design software.

The workflow and architecture of the two devices are almost identical as shown below. Note, the precise software architecture of the predicate device is proprietary information.

Predicate Device:

The Software part of the Predicate comes in two flavours: CEREC™ targeted for Dentists / chair-side milling and InLab for Dental Laboratories. Publically available labelling for the two devices are essentially the same (see http://manuals.sirona.com/en/digital-dentistry/).

The predicate devices uses the following components of software represented by the workflow:

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Figure 5: Sirona Dental CAD/CAM System inLab SW 15.0, -USA only-, 08-2015, version: 120975

3Shape Abutment Designer™:

As specified in the *Architecture Design Chart* of the original submission, the system, of which the device is a part of, consist of a number of components that match the following workflow:

- Dental Manager (Order Management / Administration)
- ScanIt (3D Scan acquisition, also includes the "Model" part of the Predicate Device)
- Dental Designer (CAD design)
- Manufacturing Interfaces (Production)

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3.5. Input Data

Both devices rely on imports of digital topography of teeth produced by 3D Scanners. Both device manufacturers also market 3D Scanners.

Both devices use proprietary file formats, but can import the internationally recognized STL-format.

Predicate Device:

The Predicate Device labelling refers to the inEos line of 3D scanners for acquisition of the digital topography of teeth (refer to *Sirona Dental CAD/CAM System inLab SW 15.0, -USA only-, 08-2015, version: 120975* on manufacturer website).

The file formats used internally by the predicate is proprietary information and not available to 3Shape. However, the labelling states "*models or restorations can also be exported in *.stl format for the further processing of this data in other software*".

3Shape Abutment Designer™:

The device output is a 3D surface file in proprietary or STL-format.

3.6. 3D CAD design tools

Both the Device and the Predicate are part of a system with a long workflow process where at some point 3D CAD Design tools are used to design an abutment.

In the Predicate device, it happens in the DESIGN phase of the system. In 3Shape Abutment Designer™ this is done in Abutment Designer™ itself.

Predicate Device:

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Finishing the phase

✓ The next phase is can be selected.
➢ Click on the next phase.
or
➢ Click on the double arrow.
↳ The program switches over to the next phase.

7.6 DESIGN phase

Tip. In the DESIGN phase you can group with the following key combinations:

- Ctrl + left mouse button
- Shift key + left mouse button

7.6.1 Adjusting parameters

Before further editing, you can check the parameters for this restoration and make any changes that are necessary. The values set here refer only to the current restoration.

This step is optional. If you skip this step, the global parameters will be used.

You can set the parameters as described in the "Parameters [→ 28]" section.

7.6.2 Morphology step

The *"Morphology"* step offers you the following options:

- Whether the restorations should be calculated fully by the biogenerics
- Whether you want to specify the tooth shape (for anterior teeth)
- Whether the suggestion should be made using a database tooth in this version, the databases of VITA, Candulor, and Merz are available.

The morphology is selected separately according to anterior and posterior teeth.

To do this, click on tooth shape to specify a tooth shape for anterior teeth or select the tooth database to select a database tooth.

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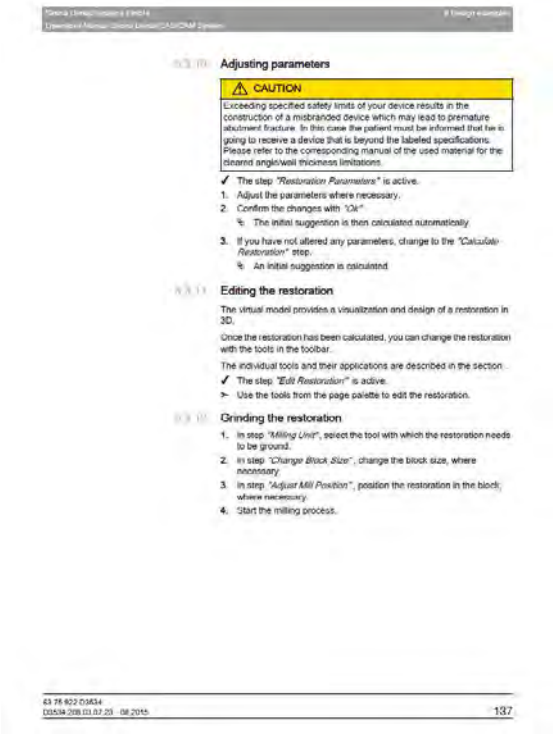
Figure 6: Example of 3D manipulation tools from Sirona Dental CAD/CAM System inLab SW 15.0, -USA only-, 08-2015, version: 120975



Adjusting parameters

⚠ CAUTION

Exceeding specified safety limits of your device results in the construction of a misbranded device which may lead to premature abutment fracture. In this case the patient must be informed that he is going to receive a device that is beyond the labeled specifications. Please refer to the corresponding manual of the used material for the cleared angle/wall thickness limitations.

✓ The step *"Restoration Parameters"* is active.
1. Adjust the parameters where necessary.
2. Confirm the changes with *"Ok"*.
↳ The initial suggestion is then calculated automatically.
3. If you have not altered any parameters, change to the *"Calculate Restoration"* step.
↳ An initial suggestion is calculated.

Editing the restoration

The virtual model provides a visualization and design of a restoration in 3D.

Once the restoration has been calculated, you can change the restoration with the tools in the toolbar.

The individual tools and their applications are described in the section.

✓ The step *"Edit Restoration"* is active.
➢ Use the tools from the page palette to edit the restoration.

Grinding the restoration

1. In step *"Milling Unit"*, select the tool with which the restoration needs to be ground.
2. In step *"Change Block Size"*, change the block size, where necessary.
3. In step *"Adjust Mill Position"*, position the restoration in the block, where necessary.
4. Start the milling process.

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D3634.208.03.07.23 08.2015 137

Figure 7: Example of 3D manipulation tools from Sirona Dental CAD/CAM System inLab SW 15.0, -USA only-, 08-2015, version: 120975

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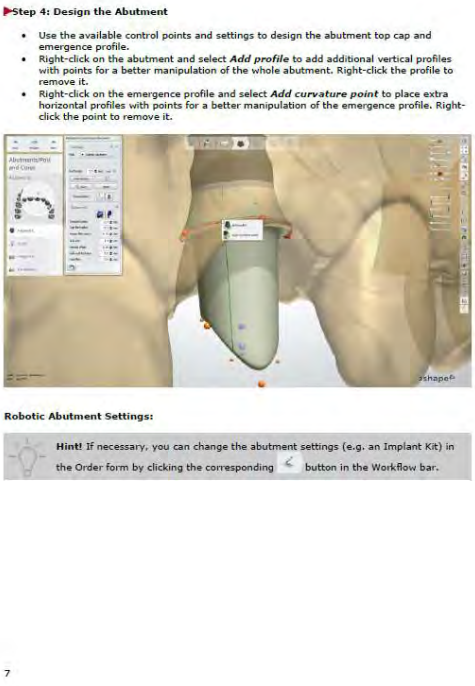
3Shape Abutment Designer™:



Step 4: Design the Abutment

- Use the available control points and settings to design the abutment top cap and emergence profile.
- Right-click on the abutment and select ***Add profile*** to add additional vertical profiles with points for a better manipulation of the whole abutment. Right-click the profile to remove it.
- Right-click on the emergence profile and select ***Add curvature point*** to place extra horizontal profiles with points for a better manipulation of the emergence profile. Right-click the point to remove it.

Robotic Abutment Settings:

Hint! If necessary, you can change the abutment settings (e.g. an Implant Kit) in the Order form by clicking the corresponding button in the Workflow bar.

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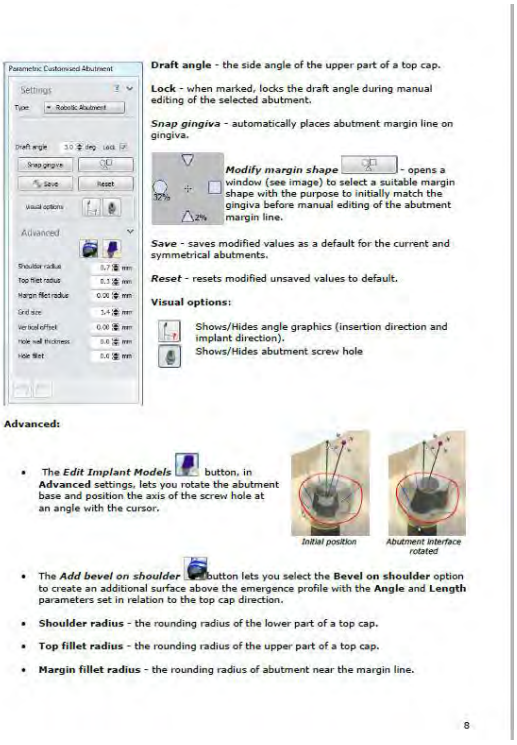
Figure 8: Example of 3D manipulation tools from DS-2.15.2.0-A-EN_Abutment_Designer_Excerpt_Version included in the original submission



Draft angle - the side angle of the upper part of a top cap.

Lock - when marked, locks the draft angle during manual editing of the selected abutment.

Snap gingiva - automatically places abutment margin line on gingiva.

Modify margin shape - opens a window (see image) to select a suitable margin shape with the purpose to initially match the gingiva before manual editing of the abutment margin line.

Save - saves modified values as a default for the current and symmetrical abutments.

Reset - resets modified unsaved values to default.

Visual options:

Shows/Hides angle graphics (insertion direction and implant direction).

Shows/Hides abutment screw hole

Advanced:

- The ***Edit Implant Models*** button, in **Advanced** settings, lets you rotate the abutment base and position the axis of the screw hole at an angle with the cursor.

Initial position *Abutment interface rotated*

- The ***Add bevel on shoulder*** button lets you select the **Bevel on shoulder** option to create an additional surface above the emergence profile with the **Angle** and **Length** parameters set in relation to the top cap direction.
- **Shoulder radius** - the rounding radius of the lower part of a top cap.
- **Top fillet radius** - the rounding radius of the upper part of a top cap.
- **Margin fillet radius** - the rounding radius of abutment near the margin line.

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Figure 9: Example of 3D manipulation tools from DS-2.15.2.0-A-EN_Abutment_Designer_Excerpt_Version included in the original submission

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3.7. Screw Retained Designs

Both the Predicate Device and the Device offers abutments that are fixed to the implant with a screw. There is some subtle differences in how the design tools work, but the basic concept is the same.

Predicate Device:

The 510(k) summary states "*The two piece abutment is mounted onto the implant and fixed with a screw.*"

3Shape Abutment Designer™:

Screw retained design is part of the requirements as described in the SRS (see DS2015-1-RS0121 of the original submission).

3.8. Implant Bridge Design

Both devices offer the user the possibility of designing a Bridge restoration that can be mounted on top of implant abutments.

Predicate Device:

See section 8.7: "*Anatomical or reduced directly screwed-on bridges*" in the publically available labelling: "*Sirona Dental CAD/CAM System inLab SW 15.0, -USA only-, 08-2015, version: 120975*"

3Shape Abutment Designer™:

See requirements in the SRS (DS2015-1-RS0127) and section 1.18: "*Implant Bars and Bridges*" of "*DS-2.15.2.0-A-EN_Abutment_Designer_Excerpt_Version*" included in the original submission.

3.9. Patient Safety Measures

The safety measures of this device includes and expands on those of the predicate device's. Where the predicate device only detects the angle of the designed abutment, 3Shape Abutment Designer™ checks a number of safety limitations as described below.

Where the predicate device only warns the user, 3Shape Abutment Designer™ forces a hard stop in the design process.

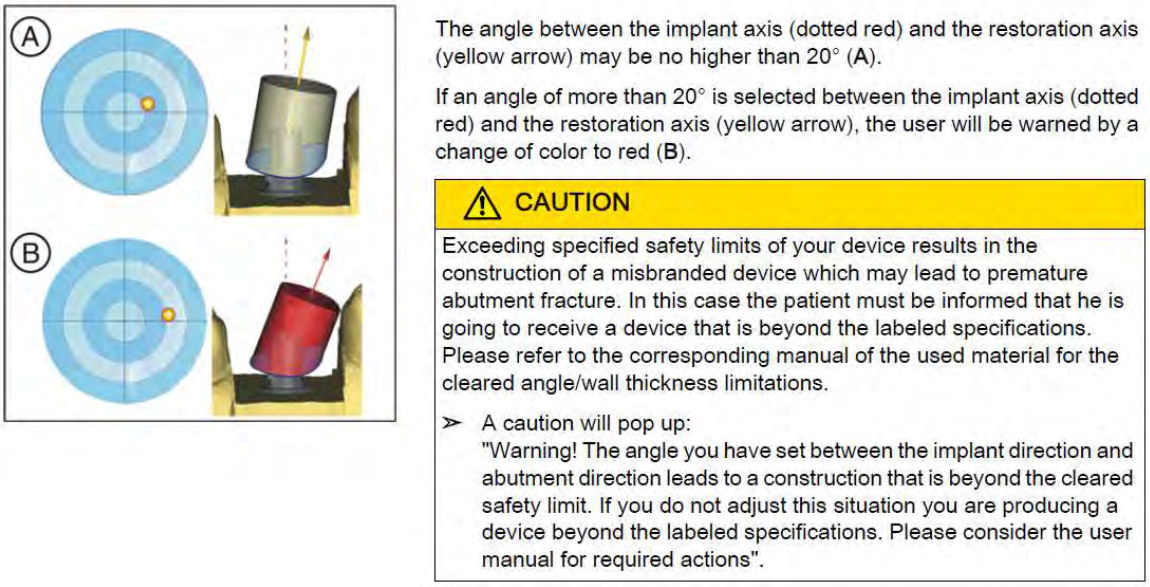
Predicate Device:

When designing abutments on the Predicate Device, the user receives a warning when the abutment exceeds the specified safety limits, but the user is allowed to continue designing.

From the official labelling on the Predicate Device, the device only has an Abutment Angle warning.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2016-8070; Released by CDRH on 10/5/2017



9.1.9 Define restoration axis

The angle between the implant axis (dotted red) and the restoration axis (yellow arrow) may be no higher than 20° (A).

If an angle of more than 20° is selected between the implant axis (dotted red) and the restoration axis (yellow arrow), the user will be warned by a change of color to red (B).

CAUTION

Exceeding specified safety limits of your device results in the construction of a misbranded device which may lead to premature abutment fracture. In this case the patient must be informed that he is going to receive a device that is beyond the labeled specifications. Please refer to the corresponding manual of the used material for the cleared angle/wall thickness limitations.

➢ A caution will pop up:
"Warning! The angle you have set between the implant direction and abutment direction leads to a construction that is beyond the cleared safety limit. If you do not adjust this situation you are producing a device beyond the labeled specifications. Please consider the user manual for required actions".

Figure 10 Sirona Dental CAD/CAM System CEREC PREMIUM SW 4.4.x, -USA only-, 02.2016, Version: 121847

3Shape Abutment Designer™:

When designing an abutment using Abutment Designer™, the user experiences both a warning and a 'hard stop', meaning that the user cannot continue designing if the abutment design exceeds the safety limits (DS2015-1-RS0121 and DS2015-1-RS0127 from the original submission).

3Shape Abutment Designer™ also holds some safety measures in the configuration and settings (see Section 3.11).

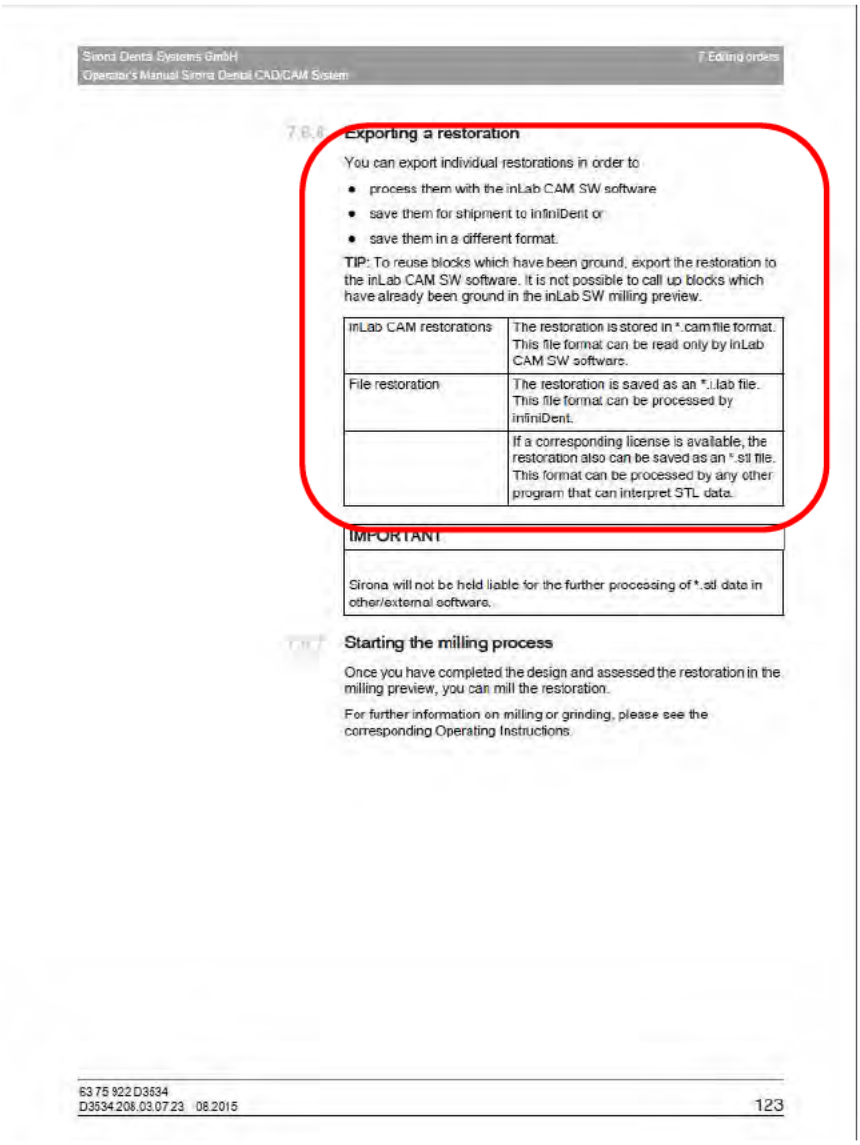
3.10. Export to milling (output type)

Both devices are capable of exporting the digital file containing the completed abutment to a milling machine (**Note**, the Predicate Device manufacturer also markets milling machinery, 3Shape does not) either by means of a proprietary format or the STL-format.

Predicate Device:

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2016-8070; Released by CDRH on 10/5/2017



Sirona Dental Systems GmbH — 7 Editing orders
Operator's Manual Sirona Dental CAD/CAM System

7.6.6 **Exporting a restoration**

You can export individual restorations in order to

- process them with the inLab CAM SW software
- save them for shipment to infiniDent or
- save them in a different format.

TIP: To reuse blocks which have been ground, export the restoration to the inLab CAM SW software. It is not possible to call up blocks which have already been ground in the inLab SW milling preview.

inLab CAM restorations	The restoration is stored in *.cam file format. This file format can be read only by inLab CAM SW software.
File restoration	The restoration is saved as an *.i.lab file. This file format can be processed by infiniDent.
	If a corresponding license is available, the restoration also can be saved as an *.stl file. This format can be processed by any other program that can interpret STL data.

IMPORTANT

Sirona will not be held liable for the further processing of *.stl data in other/external software.

7.6.7 **Starting the milling process**

Once you have completed the design and assessed the restoration in the milling preview, you can mill the restoration.

For further information on milling or grinding, please see the corresponding Operating Instructions.

63 75 922 D3534
D3534.208.03.07.23 08.2015 123

Figure 11: Sirona Dental CAD/CAM System inLab SW 15.0, -USA only-, 08-2015, version: 120975

3Shape Abutment Designer™:

See "*Device Description*" in the submitted 510(k) summary:

> "*The output of the device is a computer file containing the abutment(s) in digital form which can be used by 3rd party providers of milling machines and/or rapid prototyping machines to manufacture physical abutments.*"

3.11. Configuration and settings

The 3Shape Device does not allow changing of Implant settings by the end-user for Implant Libraries cleared for use in the United States.

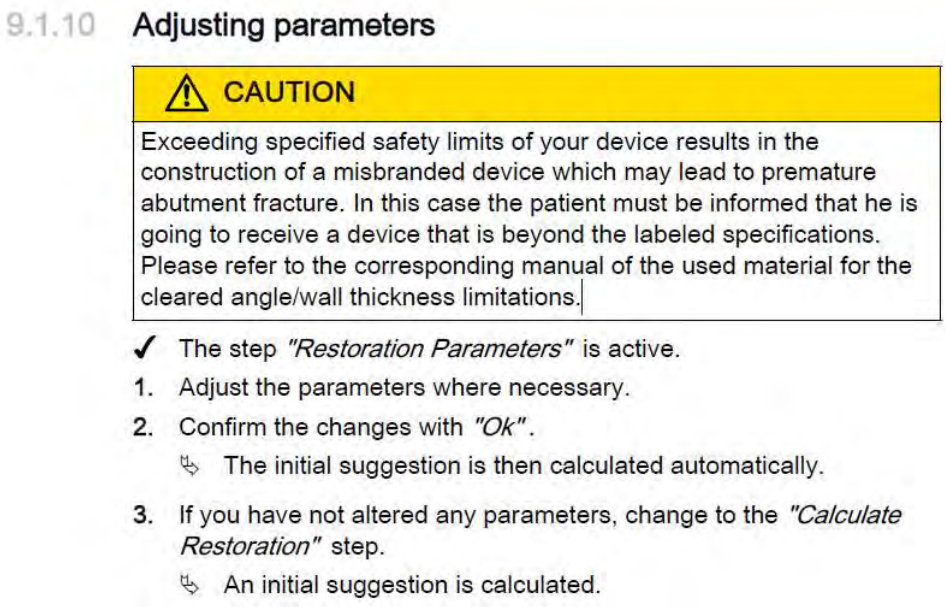
The Predicate device's handling of configurations is not discernible from the publically available labelling. However, labelling contains warnings that may be relevant.

Predicate Device:

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2016-8070; Released by CDRH on 10/5/2017

From the official labelling of the Predicate Device the user can change the configuration and is advised only to consult the manual of the individual implant system.



9.1.10 Adjusting parameters

CAUTION

Exceeding specified safety limits of your device results in the construction of a misbranded device which may lead to premature abutment fracture. In this case the patient must be informed that he is going to receive a device that is beyond the labeled specifications. Please refer to the corresponding manual of the used material for the cleared angle/wall thickness limitations.

✓ The step *"Restoration Parameters"* is active.

1. Adjust the parameters where necessary.
2. Confirm the changes with *"Ok"*.
   ↳ The initial suggestion is then calculated automatically.
3. If you have not altered any parameters, change to the *"Calculate Restoration"* step.
   ↳ An initial suggestion is calculated.

Figure 12 Sirona Dental CAD/CAM System CEREC PREMIUM SW 4.4.x, -USA only-, 02.2016, Version: 121847

3Shape Abutment Designer™:

3Shape Abutment Designer has a safety measure such that safety limits cannot be altered by the user, but is set by the implant provider (See DS2015-1-SS0012 and DS2015-1-SS0044).

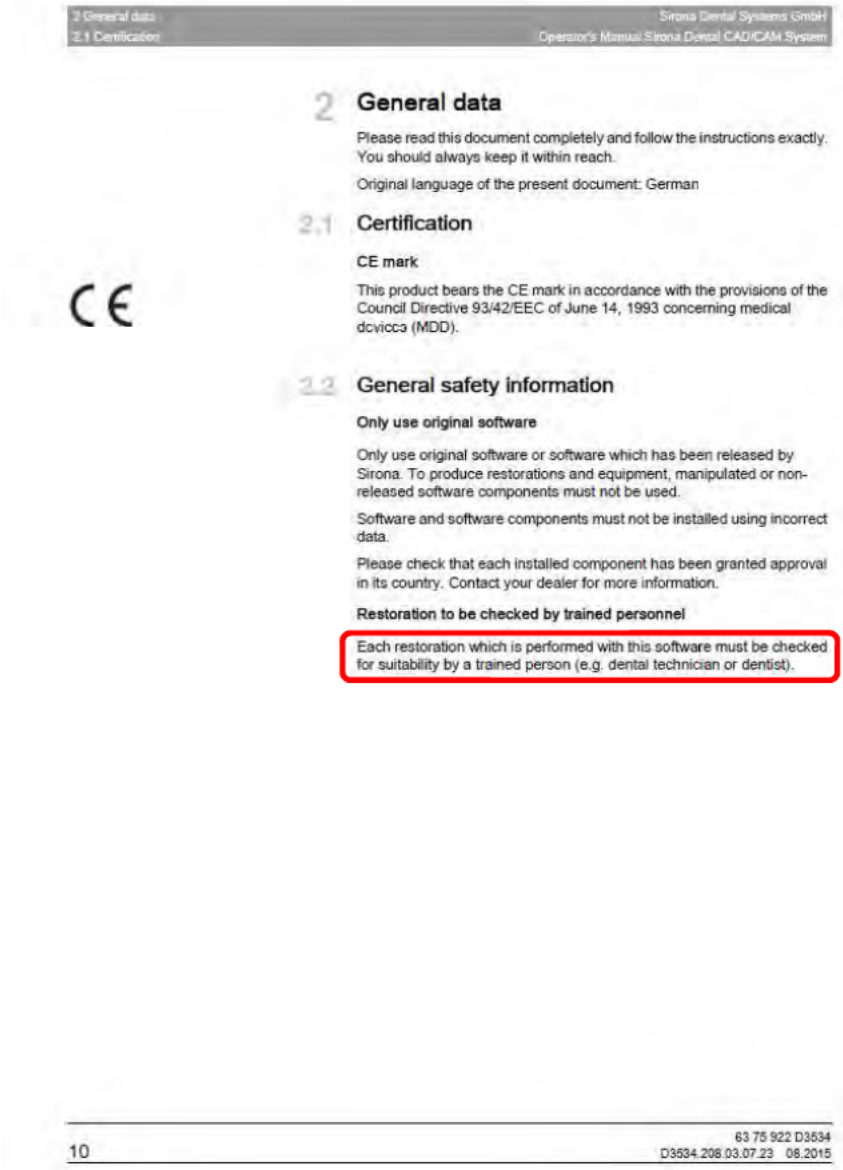
3.12. Intended users

The intended users differ only in wording, "*dental technician or dentist*" vs. "*dental practitioners and dental laboratory staff*".

Predicate Device:

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2016-8070; Released by CDRH on 10/5/2017



2 General data — Sirona Dental Systems GmbH
2.1 Certification — Operator's Manual Sirona Dental CAD/CAM System

2 General data

Please read this document completely and follow the instructions exactly. You should always keep it within reach.

Original language of the present document: German

2.1 Certification

CE mark

This product bears the CE mark in accordance with the provisions of the Council Directive 93/42/EEC of June 14, 1993 concerning medical devices (MDD).

2.2 General safety information

Only use original software

Only use original software or software which has been released by Sirona. To produce restorations and equipment, manipulated or non-released software components must not be used.

Software and software components must not be installed using incorrect data.

Please check that each installed component has been granted approval in its country. Contact your dealer for more information.

Restoration to be checked by trained personnel

Each restoration which is performed with this software must be checked for suitability by a trained person (e.g. dental technician or dentist).

10 — 63 75 922 D3534 D3534.208.03.07.23 08.2015

Figure 13: Sirona Dental CAD/CAM System inLab SW 15.0, -USA only-, 08-2015, version: 120975

3Shape Abutment Designer™:

See the Intended Use Comparison in section 2.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2016-8070; Released by CDRH on 10/5/2017

4. Conclusion

The 3Shape Abutment Designer™ Software and the predicate only deviate significantly in the cases where the predicate is bundled with a physical dental implant abutment. 3Shape Abutment Designer™ Software does not provide any physical parts that can come into contact with the patient.

The differences between the 3Shape Abutment Designer™ Software and the predicate do not raise additional concerns with respect to the safety and effectiveness of the 3Shape Abutment Designer™ Software.

Based on the information presented, we conclude Substantial Equivalence between the predicate and the 3Shape Abutment Designer™ Software.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2016-8070; Released by CDRH on 10/5/2017

Standard Operating Procedure – SW-SOP-0011

TITLE: HANDLING OF FDA CLEARED IMPLANT LIBRARIES IN 3SHAPE SOFTWARE

VERSION: 2.0

APPROVAL STATUS:APPROVED

LAST CHANGED: 09-05-2016 07:59:00

LAST CHANGED BY: 3SHAPE\THOMAS CLEMEN

APPROVAL DATE: 09-05-2016 07:59:00

APPROVED BY: 3SHAPE\THOMAS CLEMEN

1 Introduction

3Shape Software Products are locked, so only implant libraries that have been cleared by the FDA can be used by users located in the United States.

An implant library is a set of digital versions of one or more implant systems. Clearing the implant library for use in the United States, will make all the implant systems in said library usable in the United States.

An implant library is created by an Implant Library Provider. The Implant Library Provider must create an implant library, such that it contains only implant systems and components that are cleared by the FDA. It is allowed for an Implant Provider to include implant systems originating from another provider, as long as the Implant System and all its components are cleared by the FDA.

This document describes the process of including an FDA cleared implant library, so it can be used in 3Shape Software Products.

2 Scope

This document applies to the Databank Engineers and Software Project Managers.

3 Description

Upon receiving a request from an Implant Library Provider to enable a specific implant library for use in the US, 3Shape must use the following procedure:

3.1 Create DMS Record

Each implant library, cleared for use in the US, must hold a corresponding DMS (Document Management System) record.

The DMS record must hold information about

- The name of the Implant Library Provider
- The regions in which this library should be cleared for use.

Use the following naming convention when creating the DMS record:
"Implant Library Clearance - <name of digital signature>.docx"

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2016-8070; Released by CDRH on 10/5/2017

3.2 Review documentation from Implant Library Provider

When 3shape receives a request from an Implant Library Provider about enabling an implant library for use in the US, it must contain:

1. A signed confirmation letter from the library provider stating that all components in the implant library are cleared by the FDA
2. FDA 510(k) clearance numbers(s) for the implant library.

If 3Shape holds an official record (such as a User Manual) listing the content of the implant libraries, then the Databank Engineer must ensure that the record corresponds to cleared implant library.

The documentation received from the Implant Library Providers must be stored in the DMS record.

3.3 Create Digital Signature

The Databank Engineer must either update the existing digital signature used by that Implant Library Provider or create a new digital signature that the implant provider can use for encrypting the implant libraries.

The Databank Engineer must ensure setup of the digital signature so the regional setting on the digital signature includes USA.

The name of the digital signature must be stored in the DMS Record.

Step 4: Verify the library in the requested Software Product

A verification of the encryption of the implant library must be performed and included into the DMS record.

Step 5: Approve the DMS Record

The DMS record must be approved by a 3Shape Software Project Manager.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2016-8070; Released by CDRH on 10/5/2017

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

September 6, 2016

3Shape A/S
Hanne Nielsen
Regulatory Affairs Manager
Holmens Kanal 7
Copenhagen, 1060
DENMARK

Re: K151455
Trade/Device Name: 3Shape Abutment Designer™ Software
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: PNP
Dated: January 8, 2016
Received: January 11, 2016

Dear Hanne Nielsen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2016-8070; Released by CDRH on 10/5/2017

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2016-8070; Released by CDRH on 10/5/2017

Contains Nonbinding Recommendations

Print Form

Acceptance Checklist for Traditional 510(k)s

(Should be completed within 15 days of DCC receipt)

The following information is not intended to serve as a comprehensive review.

510(k) #: K151455 Date Received by DCC: June 1, 2015

Lead Reviewer: Andrew I. Steen - Trade Name: 3Shape Abutment Designer Software

Branch: DEDB Division: DAGRID Center/Office: CDRH/ODE

Note: If an element is left blank on the checklist, it does not mean the checklist is incomplete. It means the reviewer did not assess the element during RTA and the element will be assessed during the substantive review.

Preliminary Questions

Answers in the shaded blocks indicate consultations with Center advisor is needed	Yes	No
1) Is the product a device (per section 201(h) of the FD&C Act) or a combination product (per 21 CFR 3.2(e)) with a device constituent part subject to review in a 510(k)? If it appears not to be a device (per section 201(h) of the FD&C Act) or such a combination product, or you are unsure, consult with the CDRH Jurisdictional Officer or the CBER Office Jurisdiction Liaison to determine the appropriate action, and inform division management. *Provide a summary of the Jurisdictional Officer's/Liaison's determination.* If the product does not appear to be a device or such a combination product, mark "No."	X	
Comments?		
2. Is the application with the appropriate Center? If the product is a device or a combination product with a device constituent part, is it subject to review by the Center in which the submission was received? If you believe the application is not with the appropriate Center or you are unsure, consult with the CDRH Jurisdictional Officer or CBER Office Jurisdiction Liaison to determine the appropriate action and inform your division management. *Provide a summary of the Jurisdictional Officer's/Liaison's determination.* If application should not be reviewed by your Center mark "No."	X	
Comments?		
3) If a Request for Designation was submitted for the device or combination product with a device constituent part and assigned to your center, identify the RFD # and confirm the following: a) Is the device or combination product the same (e.g., design, formulation) as that presented in the RFD submission? b) Are the indications for use for the device or combination product identified in the 510(k) the same as those identified in the RFD submission ? If you believe the product or the indications presented in the 510(k) have changed from the RFD, or you are unsure, consult with the CDRH Jurisdictional Officer or appropriate CBER Jurisdiction Liaison to determine the appropriate action and inform your division management. Provide summary of Jurisdictional Officer's/Liaison's determination. If the answer to either question is no, mark "No." If there was no RFD, skip this question.		
Comments?		
4) Is this device type eligible for a 510(k) submission? If a 510(k) does not appear to be appropriate (e.g., Class III type and PMA required, or Class I or II type and 510(k)-exempt), you should consult with the CDRH 510(k) Program Director or appropriate CBER staff during the acceptance review. If 510(k) is not the appropriate regulatory submission, mark "No."	X	
Comments?		

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

5) Is there a pending PMA for the same device with the same indications for use? If yes, consult division management and the CDRH 510(k) Program Director or appropriate CBER staff to determine the appropriate action.		X
Comments?		
6) If clinical studies have been submitted, is the submitter the subject of an Application Integrity Policy (AIP)? If yes, consult with the CDRH Office of Compliance/Division of Bioresearch Monitoring (OC/DBM - BIMO) or CBER Office of Compliance and Biologics Quality/Division of Inspections and Surveillance/Bioresearch Monitoring Branch (OCBQ/DIS/BMB) to determine the appropriate action. Check on web at http://www.fda.gov/ICECI/EnforcementActions/ApplicationIntegrityPolicy/ucm134453.htm		
Comments?		

If the answer to 1 or 2 appears to be "No," then stop review of the 510(k) and issue the "Original Jurisdictional Product" letter.
If the answer to 3a or 3b appears to be "No," then stop the review and contact the CDRH Jurisdictional Officer or CBER Office of Jurisdiction Liaison.
If the answer to 4 is "No," the lead reviewer should consult division management and other Center resources to determine the appropriate action.
If the answer to 5 is "Yes," then stop review of the 510(k), contact the CDRH 510(k) Staff and PMA Staff, or appropriate CBER staff.
If the answer to 6 is "Yes," then contact CDRH/OC/DBM-BIMO or CBER/OCBQ/DIS/BMB, provide a summary of the discussion with the BIMO Staff, and indicate BIMO's recommendation/action.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Organizational Elements

Failure to include these items alone generally should not result in an RTA designation.

	Yes	No
1) Submission contains a Table of Contents	X	
2) Each section is labeled (e.g., headings or tabs designating Device Description section, Labeling section, etc.)	X	
3) All pages of the submission are numbered.	X	
4) Type of 510(k) is identified (i.e., traditional, abbreviated, or special)	X	
Comments?		

Records processed under FOIA Request 2016-8070; Released by CDRH on 10/5/2017

Elements of a Complete Submission (RTA Items)

(21 CFR 807.87 unless otherwise indicated)

Submission should be designated RTA if not addressed.

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.

- Any "No" answer will result in a "Refuse to Accept" decision. - Each element on the checklist should be addressed within the submission. An applicant may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criteria is considered Present (Yes). An assessment of the rationale will be considered during the review of the submission.	Yes	No	N/A	Comment
A. Administrative				
1) All content used to support the submission is written in English (including translations of test reports, literature articles, etc.)	X			
2) Submission identifies the following (such as in CDRH Premarket Review Submission Cover Sheet (Form 3514) or 510(k) cover letter):	X			
a) Device trade name or proprietary name	X			
b) Device common name	X			
c) Device class and panel or Classification regulation or Statement that device has not been classified with rationale for that conclusion	X			
3) Submission contains Indications for Use Statement with Rx and/or OTC designation (see also 21 CFR 801.109).	X			
4) Submission contains 510(k) Summary or 510(k) Statement	X			
a) Summary contains all elements per 21 CFR 807.92 *(See also* 510(k) Summary Checklist*)*			X	
b) Statement contains all elements per 21 CFR 807.93			X	
5) Submission contains Truthful and Accuracy Statement per 21 CFR 807.87(k) *See recommended* format.	X			
6) Submission contains Class III Summary and Certification. *See recommended* content.			X	
7) Submission contains clinical data			X	
8) If submission references use of a national or international standard as part of demonstration of substantial equivalence, submission contains Standards Data Report for 510(k)s (Form 3654) or includes detailed information about how and the extent to which the standard has been followed.	X			
9) The submission identifies prior submissions for the same device for which FDA provided feedback related to the data or information needed to support substantial equivalence (e.g., submission numbers for Pre-Submission, IDE, prior not substantially equivalent (NSE) determination, prior 510(k) that was deleted or withdrawn) or states that there were no prior submissions for the subject device.	X			
a) If there were prior submissions, the submitter has identified where in the current submission any issues related to a determination of substantial equivalence outlined in prior communications are addressed. For additional information regarding the Pre-Submission process, please refer to the Draft Guidance "Medical Devices: The Pre-Submission Program and Meetings with FDA Staff." Once finalized, this guidance will represent the Agency's current thinking on this topic.	X			
B. Device Description				
10)				

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Elements of a Complete Submission (RTA Items)

(21 CFR 807.87 unless otherwise indicated)

Submission should be designated RTA if not addressed.

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.

- Any "No" answer will result in a "Refuse to Accept" decision. - Each element on the checklist should be addressed within the submission. An applicant may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criteria is considered Present (Yes). An assessment of the rationale will be considered during the review of the submission.	Yes	No	N/A	Comment
a) If there are requirements regarding the device description, such as special controls, in a device-specific regulation that are applicable to the device, the submission includes device description information to establish that the submitter has followed the device-specific requirement.			X	
b) If there is a device-specific guidance, other than a special controls guidance document, applicable to the device, the submission includes device description information to establish that the submitter has addressed the recommendations or otherwise has met the applicable statutory or regulatory criteria through an alternative approach.	X			
11) Descriptive information is present and consistent within the submission (e.g., the device description section is consistent with the device description in the labeling), including:				
a) A description of the principle of operation and mechanism of action for achieving the intended effect.	X			
b) A description of proposed conditions of use, such as surgical technique for implants; anatomical location of use; user interface; how the device interacts with other devices; and/or how the device interacts with the patient.	X			
c) A list and description of each device for which clearance is requested.	X			
12) Submission contains representative engineering drawing(s), schematics, illustrations and/or figures of the device that are clear, legible, labeled, and include dimensions.			X	
13) If device is intended to be marketed with multiple components, accessories, and/or as part of a system				
a) Submission includes a list of all components and accessories to be marketed with the subject device.	X			
b) Submission includes a description (as detailed in item 11(a) and (b) and 12 above) of each component or accessory.			X	
c) A 510(k) number is provided for each component or accessory that received a prior 510(k) clearance.			X	
C. Substantial Equivalence Discussion				
14) Submitter has identified a predicate device.	X			
a) Predicate's 510(k) number, trade name, and model number (if applicable) provided. For predicates that are preamendments devices, information is provided to document preamendments status. *Information regarding documenting preamendment status is available online.*	X			
b) The identified predicate(s) is consistent throughout the submission (i.e., the predicate(s) identified in the Substantial Equivalence section is the same as that listed in the 510(k) Summary (if applicable) and that used in comparative performance testing.	X			
15) Submission includes a comparison of the following for the predicate(s) and subject device				
a) Indications for Use	X			
b) Technology, including features, materials, and principles of operation	X			

Records processed under FOIA Request 2016-8070; Released by CDRH on 10/5/2017

Elements of a Complete Submission (RTA Items)

(21 CFR 807.87 unless otherwise indicated)

Submission should be designated RTA if not addressed.

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.

- Any "No" answer will result in a "Refuse to Accept" decision. - Each element on the checklist should be addressed within the submission. An applicant may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criteria is considered Present (Yes). An assessment of the rationale will be considered during the review of the submission.	Yes	No	N/A	Comment
16) Submission includes an analysis of why any differences between the subject device and predicate(s) do not render the device NSE (e.g., does not constitute a new intended use; and any differences in technological characteristics are accompanied by information that demonstrates the device is as safe and effective as the predicate and do not raise different questions of safety and effectiveness than the predicate), affect safety or effectiveness, or raise different questions of safety and effectiveness (see section 513(i)(1)(A) of the FD&C Act and 21 CFR 807.87(f))		X		X
Comments? Reviewer Discretion - the company states the differences do not raise additional concerns but does not explain how or why. This issue will be addressed during the review stage.				
D. Proposed Labeling (see also 21 CFR part 801)				
If *in vitro* diagnostic (IVD) device, criteria 17 & 19 may be omitted.				
17) Submission includes proposed package labels and labeling (e.g., instructions for use, package insert, operator's manual) that include a description of the device, its intended use, and the directions for use.	X			X
a) Indications for use are stated in labeling and are identical to Indications for Use form and 510(k) Summary (if 510(k) Summary provided).		X		
b) Submission includes directions for use that - include statements of all conditions, purposes or uses for which the device is intended (e.g., hazards, warnings, precautions, contraindications) AND - includes directions for layperson (see 21 CFR 801.5) OR submission states that device qualifies for exemption per 21 CFR 801 Subpart D		X		
Comments? Reviewer Discretion. This issue will be addressed during the review				
18) If indicated for prescription use, labeling includes the prescription use statement (see 21 CFR 801.109(b)(1)) or "Rx only" symbol [See also Alternative to Certain Prescription Device Labeling Requirements]	X			
19) General labeling provisions				
a) Labeling includes name and place of business of the manufacturer, packer, or distributor (21 CFR 801.1).	X			
b) Labeling includes device common or usual name. (21 CFR 801.61)			X	
20)				
a) If there are requirements regarding labeling, such as special controls, in a device-specific regulation that are applicable to the device, the submission includes labeling to establish that the submitter has followed the device-specific requirement.			X	
b) If there is a device-specific guidance, other than a special controls guidance document, applicable to the device, the submission includes labeling to establish that the submitter has addressed the recommendations or otherwise has met the applicable statutory or regulatory criteria through an alternative approach.			X	

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Elements of a Complete Submission (RTA Items)

(21 CFR 807.87 unless otherwise indicated)

Submission should be designated RTA if not addressed.

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.

- Any "No" answer will result in a "Refuse to Accept" decision. - Each element on the checklist should be addressed within the submission. An applicant may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criteria is considered Present (Yes). An assessment of the rationale will be considered during the review of the submission.	Yes	No	N/A	Comment
c) If there is a special controls document applicable to the device, the submission includes labeling to establish that the submitter has complied with the particular mitigation measures set forth in the special controls document or uses alternative mitigation measures but provides a rationale to demonstrate that those alternative measures identified by the firm will provide at least an equivalent assurance of safety and effectiveness.	X			
21) If the device is an in vitro diagnostic device, provided labeling includes all applicable information required per 21 CFR 809.10.			X	
E. Sterilization				
If IVD device and sterilization is not applicable, select "N/A" and criteria below will be omitted from checklist.				
Submission states that the device and/or accessories are: (one of the below must be checked)				
provided sterile				
provided non-sterile but sterilized by the end user				
X non-sterile when used				
Information regarding the sterility status of the device is not provided.				
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.				
22) Assessment of the need for sterilization information				
a) Identification of device, and/or accessories, and/or components that are provided sterile.		X		
b) Identification of device, and/or accessories, and/or components that are end user sterilized.			X	
c) Identification of device, and/or accessories, and/or components that are reusable and cleaning /disinfection instructions are provided.			X	
25)				
a) If there are requirements regarding sterility, such as special controls, in a device-specific regulation that are applicable to the device, the submission includes sterility information to establish that the submitter has followed the device-specific requirement.			X	
b) If there is a device-specific guidance, other than a special controls guidance document, applicable to the device, the submission includes sterility information to establish that the submitter has addressed the recommendations or otherwise has met the applicable statutory or regulatory criteria through an alternative approach.			X	
c) If there is a special controls document applicable to the device, the submission includes sterility information to establish that the submitter has complied with the particular mitigation measures set forth in the special controls document or uses alternative mitigation measures but provides a rationale to demonstrate that those alternative measures identified by the firm will provide at least an equivalent assurance of safety and effectiveness.	X			

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Elements of a Complete Submission (RTA Items)

(21 CFR 807.87 unless otherwise indicated)

Submission should be designated RTA if not addressed.

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.

- Any "No" answer will result in a "Refuse to Accept" decision. - Each element on the checklist should be addressed within the submission. An applicant may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criteria is considered Present (Yes). An assessment of the rationale will be considered during the review of the submission.	Yes	No	N/A	Comment
F. Shelf Life				
26) Proposed shelf life/expiration date stated			X	
27) For sterile device, submission includes summary of methods used to establish that device will remain sterile through the proposed shelf life or a rationale for why testing to establish shelf life is not applicable.			X	
28) Submission includes summary of methods used to establish that device performance is not adversely affected by aging or includes a rationale for why the storage conditions are not expected to affect device safety or effectiveness.	X			
G. Biocompatibility				
If IVD device, select "N/A" and the below criteria will be omitted from checklist.				
Submission states that there: (one of the below must be checked)				
are direct or indirect (e.g., through fluid infusion) patient-contacting components.				
X are no direct or indirect (e.g., through fluid infusion) patient-contacting components.				
Information regarding the patient contact status of the device is not provided.				
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.				
H. Software				
Submission states that the device: (one of the below must be checked)				
X does contain software/firmware.				
does not contain software/firmware.				
Information regarding whether the device contains software is not provided.				
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.				
32) Submission includes a statement of software level of concern and rationale for the software level of concern.	X			
33) All applicable software documentation provided based on level of concern identified by the submitter, as described in Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, or the submitter has provided an alternative approach with a rationale.	X			
I. EMC and Electrical Safety				
Submission states that the device: (one of the below must be checked)				
does require EMC and Electrical Safety evaluation.				
X does not require EMC and Electrical Safety evaluation.				

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Elements of a Complete Submission (RTA Items)

(21 CFR 807.87 unless otherwise indicated)

Submission should be designated RTA if not addressed.

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.

- Any "No" answer will result in a "Refuse to Accept" decision. - Each element on the checklist should be addressed within the submission. An applicant may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criteria is considered Present (Yes). An assessment of the rationale will be considered during the review of the submission.	Yes	No	N/A	Comment
Information regarding whether the device requires EMC and Electrical Safety evaluation is not provided.				
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.				
J. Performance Data - General If IVD device, select "N/A" and the below criteria will be omitted from checklist. Performance data criteria relating to IVD devices will be addressed in Section K.				
36) Full test report is provided for each completed test. A full test report includes: objective of the test, description of the test methods and procedures, study endpoint(s), pre-defined pass/fail criteria, results summary, conclusions, and an explanation of how the data generated from the test supports a finding of substantial equivalence.			X	
37)				
a) If there are requirements regarding performance data, such as special controls, in a device-specific regulation that are applicable to the device, the submission includes performance data to establish that the submitter has followed the device-specific requirement.			X	
b) If there is a device-specific guidance, other than a special controls guidance document, applicable to the device, the submission includes performance data to establish that the submitter has addressed the recommendations or otherwise has met the applicable statutory or regulatory criteria through an alternative approach.			X	
c) If there is a special controls document applicable to the device, the submission includes performance data to establish that the submitter has complied with the particular mitigation measures set forth in the special controls document or uses alternative mitigation measures but provides a rationale to demonstrate that those alternative measures identified by the firm will provide at least an equivalent assurance of safety and effectiveness.	X			
38) If literature is referenced in the submission, submission includes:			X	
39) For each completed nonclinical (i.e., animal) study conducted			X	
K. Performance Characteristics - In Vitro Diagnostic Devices Only **(Also see 21 CFR 809.10(b)(12))**				
Submission states that the device: (one of the below must be checked)				
	is an in vitro diagnostic device.			
X	is not an in vitro diagnostic device.			

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Decision: (•) Accept ( ) Refuse to Accept

If Accept, notify applicant.

If Refuse to Accept, notify applicant in writing and include a copy of this checklist.

Digital Signature Concurrence Table

Reviewer Sign-Off	Andrew I. Steen -S 2015.06.16 09:33:24 -04'00'
Branch Chief Sign-Off (digital signature optional)*	
Division Sign-Off (digital signature optional)*	

* Branch and Division review of checklist and concurrence with decision required. Branch and Division digital signature optional.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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MEMO OF SOFTWARE REVIEW

Name of the Device:	3Shape Abutment Designer software
Common Name:	Abutment Designer
Applicant:	3Shape A/S Copenhagen
Device Premarket Path:	K151455
Consult:	CON1512269
Lead Reviewer:	Andrew Steen
Kind of Device:	21 CFR 872.3630; Endosseous dental implant abutment Class II. NNH
Predicate:	K100152 Sirona Dental CAD/CAM System
Date Sent:	7/22/2015
Reviewer:	Catherine Li (CDRH, General Hospital Devices Branch), 301-796-6304, catherine.li@fda.hhs.gov

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

[redacted]

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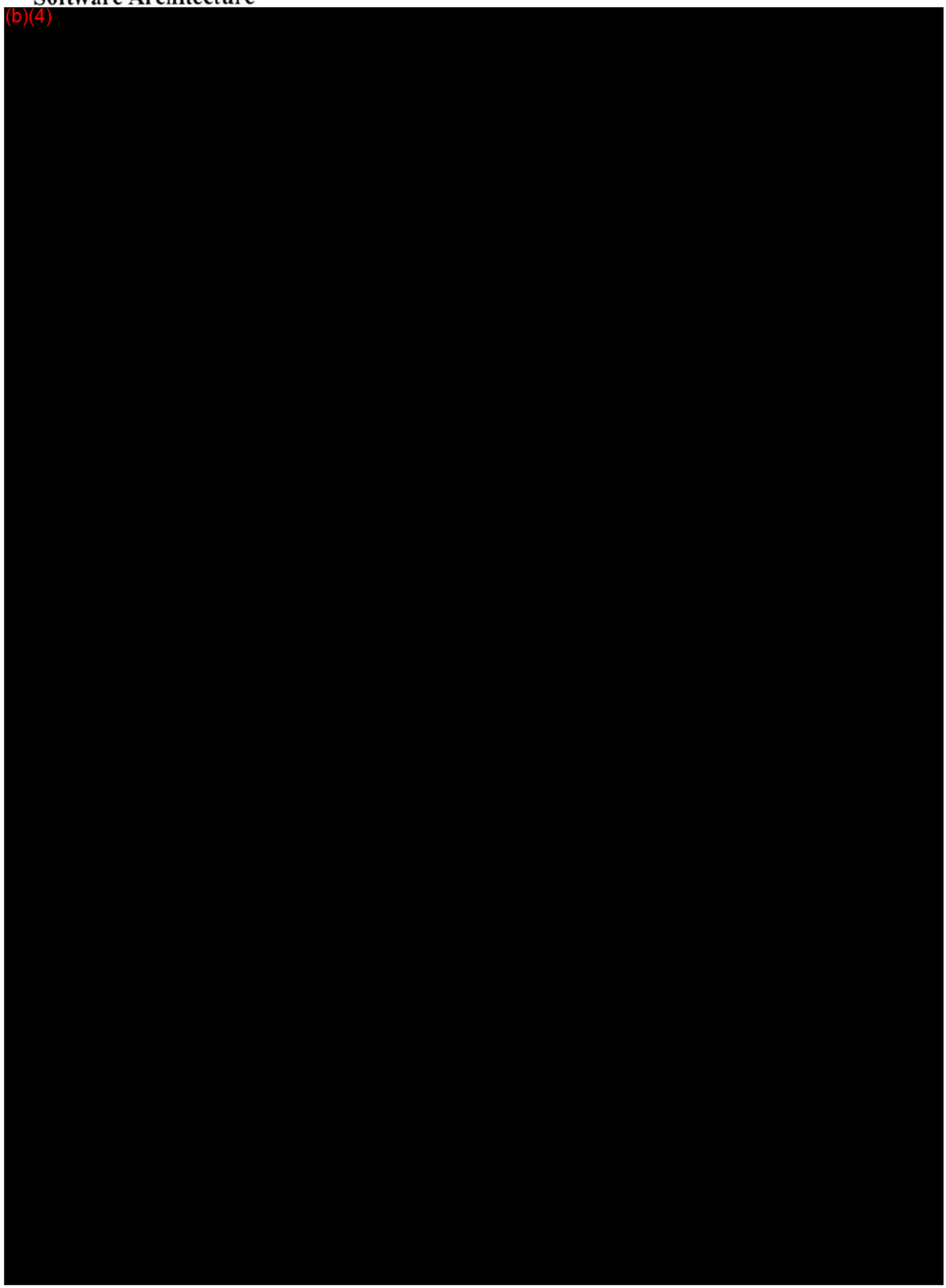
Software Architecture

(b)(4)



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(b)(4)

[redacted]

Original Submission Deficiency

(b)(4)

[redacted]

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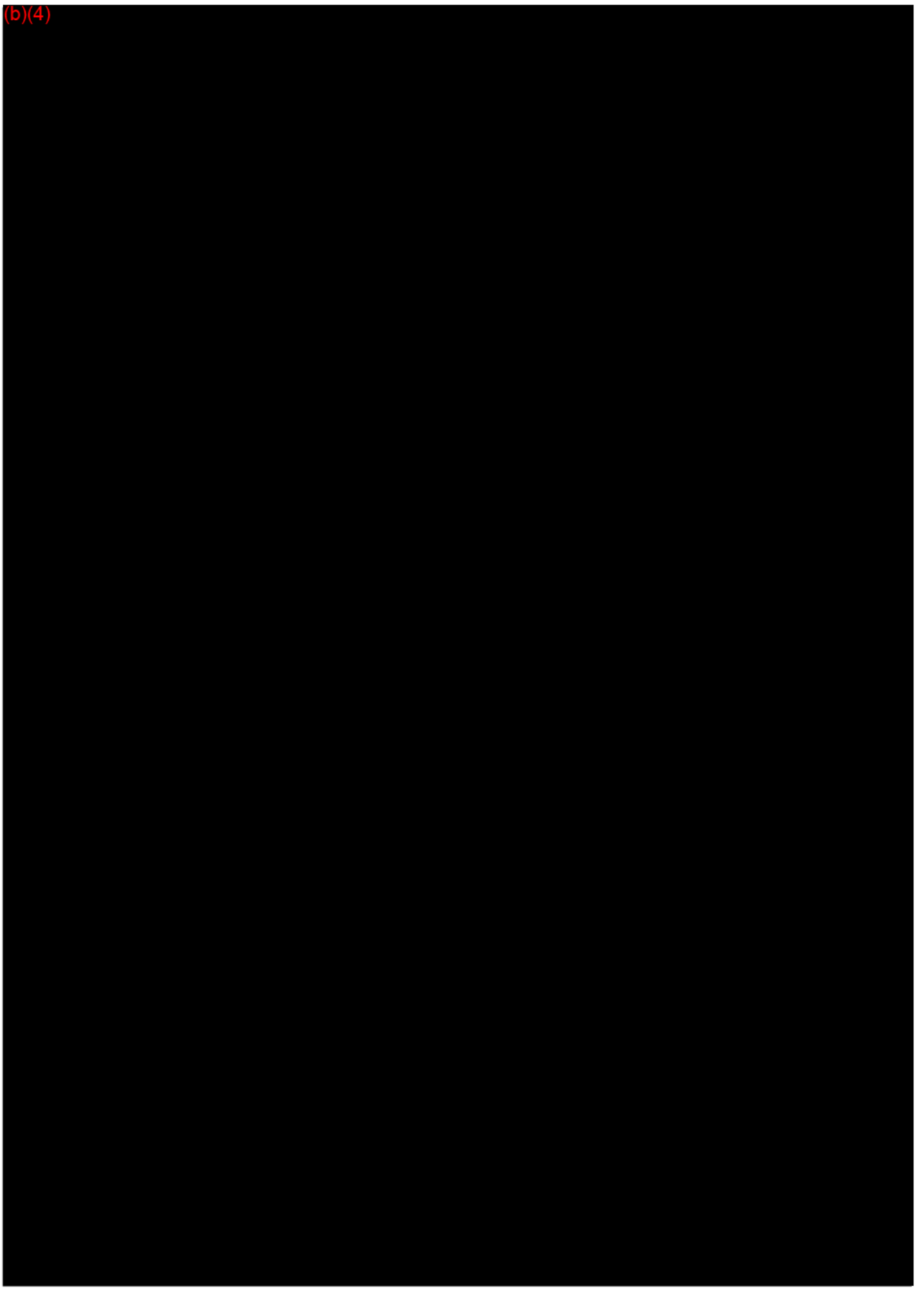

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(b)(4)

Catherine Li
CDRH/DAGRID/GHDB
U.S. Food and Drug Administration
Tel: (301) 796-6304

Digital Signature Concurrence Table	
Reviewer Sign-Off	Catherine Li -A Digitally signed by Catherine Li -A DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Catherine Li -A, 0.9.2342.19200300.100.1.1=2000657465 Date: 2015.07.22 00:47:08 -04'00'
Branch Chief Sign-Off	

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Food and Drug Administration
CDRH/ODE/DAGRID/DEDB
WO66 RM2604
10903 New Hampshire Ave
Silver Spring, MD 20993-0002
301-796-6284

Premarket Notification [510(k)] Review

Date: July 31, 2015
To: FILE
From: Andrew I. Steen, Mechanical Engineer
Subject: Traditional 510(k)# K151455

Applicant: 3Shape A/S

Contact: Hanne Nielsen

Correspondent Firm: 3shape A/S

FDA Received Date: June 1, 2015

Reg #: 872.3630 **Reg Name:** Endosseous Dental Implant Abutment

Device Trade Name: 3Shape Abutment Designer Software

Contact Title: Regulatory Affairs Manager

Phone: 45 (702) 726-20 **Email:** hanne.nielsen@3shape.com

Due Date: August 30, 2015

Class: II **Product Code(s):** NHA

Predicate Devices:

Submission #	Pro Code	Device Trade Name	Owner
K100152	NHA	Sirona Cad/cam System	Sirona Dental Systems Gmbh

Review Summary

The subject device is a Endosseous Dental Implant Abutment with the following Indications for Use: "The 3Shape Abutment Designer Software is intended for designing endosseous dental implant abutments based on digital scans of 3D models. Intended users are Dental Practitioners and Dental Laboratory Staff. Intended Operational Environment is Dental Laboratories." It is for Rx use.

Recommendation

I recommend that the 3Shape Abutment Designer Software is/are
in need of Additional Information (AINN)

Review Team

Lead Reviewer — Andrew I. Steen, Mechanical Engineer (CDRH/ODE/DAGRID/DEDB)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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I. Purpose and History

3Shape A/S, of Copenhagen, Denmark, has submitted a Premarket Notification (510(k)) to introduce into U.S. interstate commerce *3Shape Abutment Designer™ Software,* a dental implant abutment type of device.

The original submission, received on June 1, 2015, 2013, consists of a cover letter, FDA submission cover sheets, an Indications for Use Statement (IFUS), a table of contents, a 510(k) Summary, a Truthful and Accurate Statement, a device description, a substantial equivalence comparison, a biocompatibility justification, EMC and electrical safety justification, shelf life justification, sterilization justification, corrosion testing justification, implant to abutment compatibility justification, material composition justification, deficiencies from previous submission K133457 and applicant's responses, applicable standards and FDA guidance, Standards Data Report forms (SDRs), software description, software verification and validation information, marketing brochure, and a device use manual.

The submission identifies prior submission K133457, CPT1200130, and I120810.

TPLC Information Recall Information Historyfalls

II. Device/System Description

Device Characteristics	Yes	No	Inadequate Or Marked
Is the intended use or fundamental technology new?	☐	☒	☐
Is the device life-supporting or life sustaining?	☐	☒	☐
Are there any direct or indirect patient contacting components?	☒	☐	☐
• Is the device or a component an implant?	☒	☐	☐
Does the device use software/firmware?	☒	☐	☐
• Is the device, or does it contain, a Mobile Medical App?	☐	☒	☐
Does the device or a component need sterilization (by manufacturer or user)?	☒	☐	☐
The device/system uses or is	a single use device(s) (SUD)		☐
Is the device a combination product?	N - Not a Part 3 Combination Product		☐
Is the device electrical (battery or wall powered)?	Yes, it is mains powered Only		☐

Check the attributes that are applicable to this submission.

	Nanotechnology	Reprocessed SUD	Companion Diagnostic
Yes	☐	☐	☐
No	☒	☒	☒
Unknown	☐	☐	☐

Device Description Table: Summary of important device characteristics

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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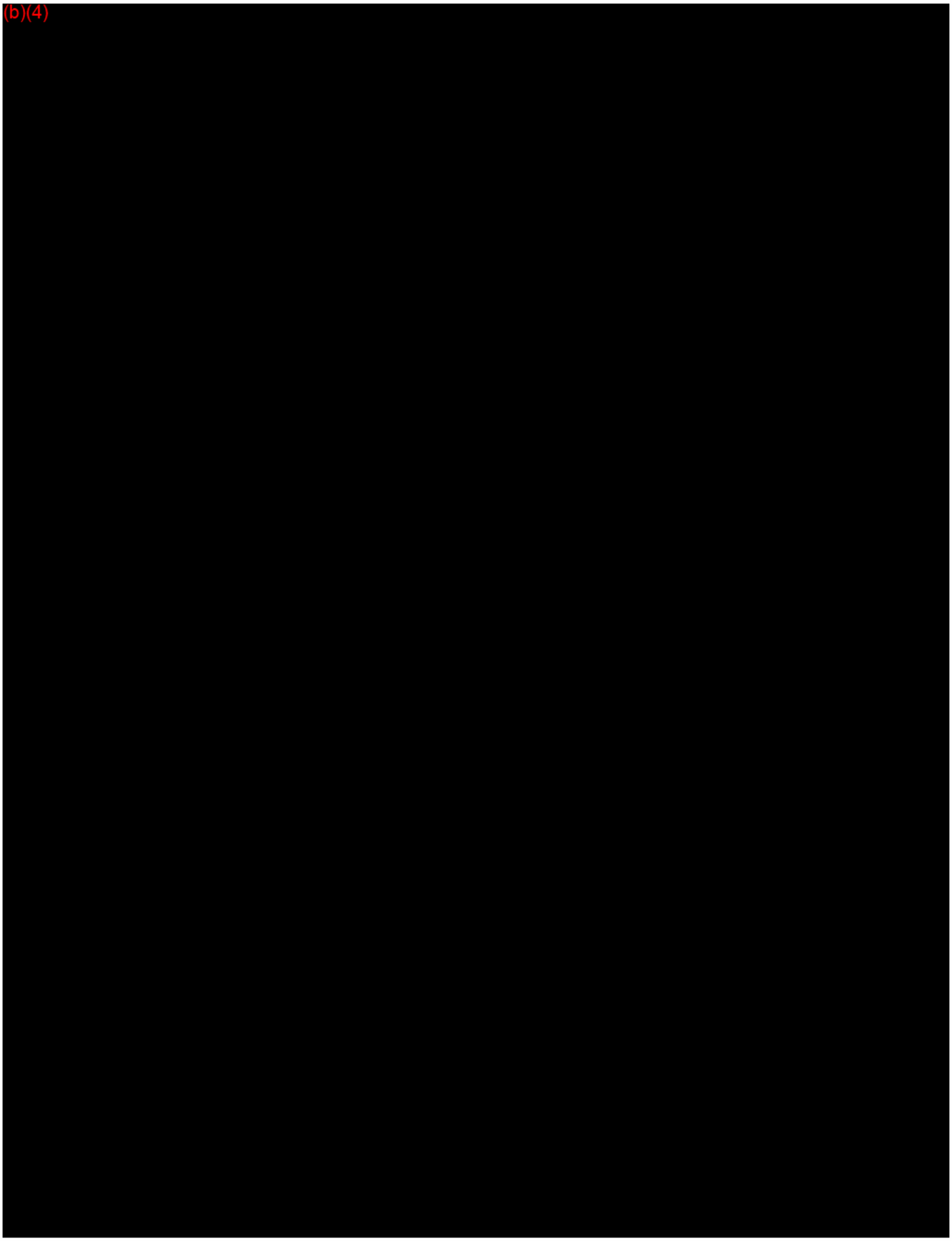

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(b)(4)

[redacted]

III. Comparison of Indications for Use to Predicate Devices

Comparison of Indications for Use								
Subject 510(k) #: K151455					Rx/OTC: Rx			
Intended Population	Adults Only	Adults and Pediatrics	Transitional Adolescent A	Transitional Adolescent B	Adolescent	Child	Infant	Neonate/ Newborn
Yes	☐	☒	☐	☒	☐	☐	☐	☐
No	☒	☐	☒	☐	☒	☒	☒	☒
Unknown	☐	☐	☐	☐	☐	☐	☐	☐

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Comparison of Indications for Use
Indications for Use: "The 3Shape Abutment Designer Software is intended for designing endosseous dental implant abutments based on digital scans of 3D models. Intended users are Dental Practitioners and Dental Laboratory Staff. Intended Operational Environment is Dental Laboratories."
Predicate(s) 510(k)#: K100152 Rx/OTC: Rx Intended Population: Indications for Use: The sirona dental cad/cam system is intended for use in partially or fully edentulous mandibles and maxillae in support of single or miltiple-unit cement retained restorations. The system consists of three major parts: tibase, incoris mesostructure, and cad/cam software. Specifically, the incoris mesostructure and tibase components make up a two-piece abutment which is used in conjunction with endosseous dental implants to restore the function and aesthetics in the oral cavity. The incoris mesostructure may also be used in conjuction with the camlog titanium base cad/cam (types k2244.Xxxx) k083496) in the camlog implant system. The cad/cam software is intended to design and facricate the incoris mesostructure. The incoris mesostructure and tibase two-piece abutment is compatible with the following implants system: nobel biocare replace (k020646) nobel biocare branemark (k022562) fridadent xive (k013876) biomet 3i osseotite (k980549) astra tech osseospeed (k091239) zimmer tapered screw-vent (k061410) straumann synocta (k061176)
Indications for Use Table: Compares the indications for use of the subject and predicate devices.

Reviewer Recommendation

The Comparison of the Indications for Use is **[not]** acceptable.

IV. Comparison of Technology to Predicate Devices

Device & Predicate Device(s):	K151455	K100152
General Device Characteristics		
Trade Name		
Applicant Company		

Predicate is a scanner, milling unit, design software, and a two-piece abutment.

Submission device is CAD/CAM only

Reviewer Recommendation

The Comparison of the Technology to Predicate Devices is **[not]** acceptable.

V. Labeling

Labeling Review Needed?	Yes ☒	No ☐
Usability Consult Needed?	Yes ☐	No ☒

A General Labeling Requirements

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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General Labeling Requirements	Yes	No/N/A	Inadequate or Marked
Is the prescription statement (or "Rx only") included?	☐	☐	☐
The indications for use are consistent with the IFU page?	☐	☐	☐
Appropriate contraindications provided?	☐	☒	☒
Appropriate warnings provided?	☐	☒	☒
Instructions are in accordance with the guidance (if applicable)?	☐	☐	☐
Appropriate labeling inside device?	☐	☒	☐
Appropriate label/indicator outside device?	☐	☒	☐
Appropriate Manual labeling?	☐	☒	☐
What MRI safety information does the labeling contain?		Not Needed	☐

Labeling Table: A summary of the adequacy of several labeling requirements.

Reviewer Recommendation

(b)(4) [redacted]

VI. Cleaning, Disinfection, Sterilization, Shelf-Life and Reuse

Sterility Review Needed?	Yes ☐	No ☒
Sterility Consult Needed?	Yes ☐	No ☒

The submission states that the device is only software and therefore shelf life and sterilization requirements do not apply.

Reviewer Recommendation

Cleaning, Sterilization, Shelf-Life and Reuse descriptions are acceptable.

VII. Biocompatibility

Biocompatibility Review Needed?	Yes ☐	No ☒
Biocompatibility Consult Needed?	Yes ☐	No ☒

The submission states that the device has no patient contacting components and thus biocompatibility requirements are not apply. The submission states that identification of the material is also not applicable.

Reviewer Recommendation

The Biocompatibility is acceptable.

VIII. Software/Firmware

Software Review Needed?	Yes ☒	No ☐
Software Consult Needed?	Yes ☐	No ☒

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

[redacted]

IX. EMC & Electrical, Mechanical and Thermal Safety & Risk Analysis

EMC Review Needed?	Yes ☐	No ☒
EMC Consult Needed?	Yes ☐	No ☒

The submission states that the submission device has not patient or user contacting components as it is just software. The submission states that EMC and Electrical safety evaluation is not applicable.

Reviewer Recommendation

The EMC, EMT and Risk Analysis are acceptable.

X. Performance Testing

(b)(4)

[redacted]

XI. Kit Certification

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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This section is N/A.

XII. Manufacturing Information

This section is N/A.

XIII. References

The submission references the following standards or guidance documents and has provided the appropriate Standards Data Report Forms.

- Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Implants
- ISO 13485:2015 Quality management systems – requirements for regulatory process
- ISO 14971:2012 Application of Risk Management to Medical Devices
- IEC 62304:2012 Software life cycle processes

XIV. SE Flowchart Questions

Substantial Equivalence Determination	Yes	No
Is the predicate device legally marketed?	☒	☐
Do the devices have the same intended use?	☐	☐

XV. Original Deficiencies

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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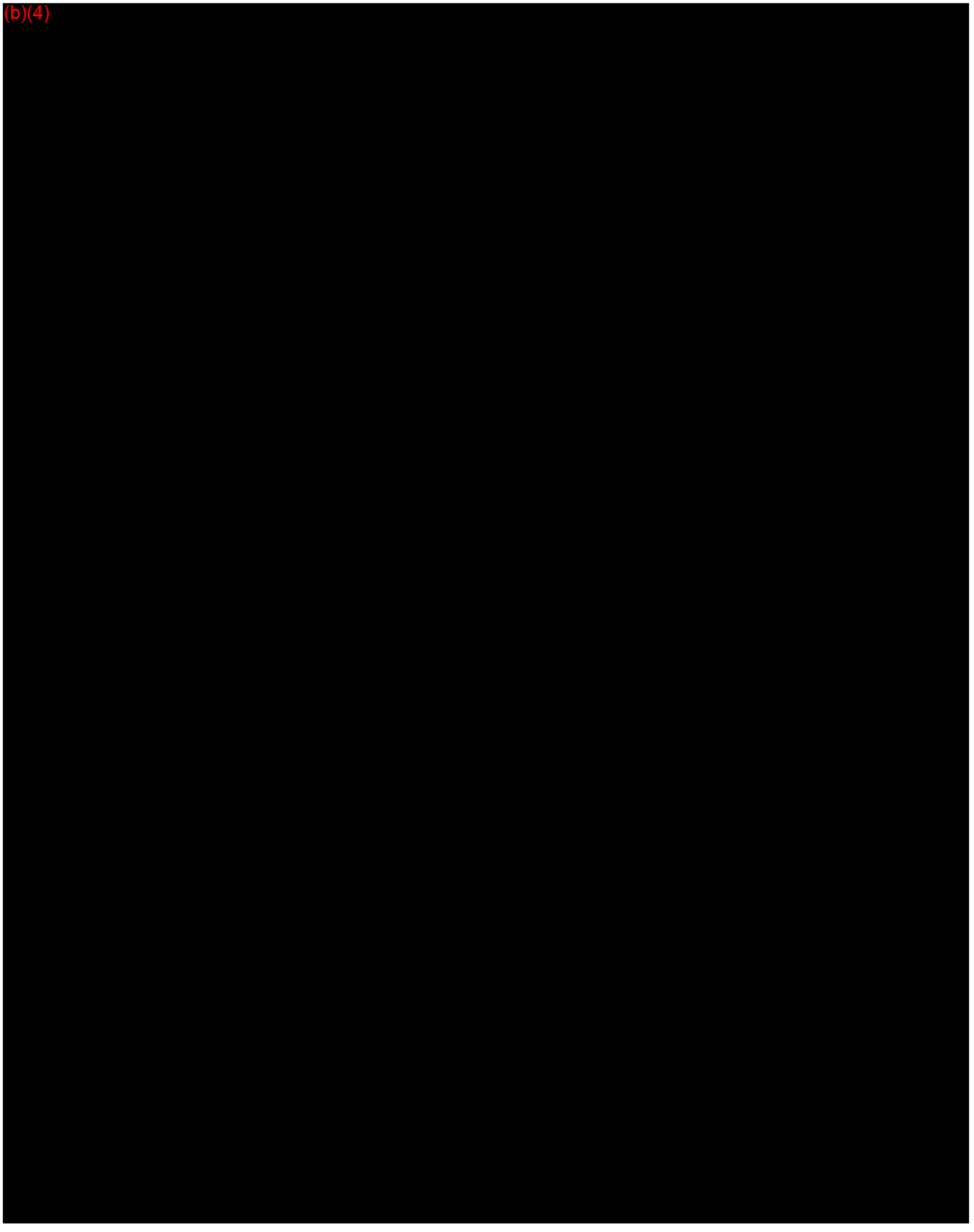

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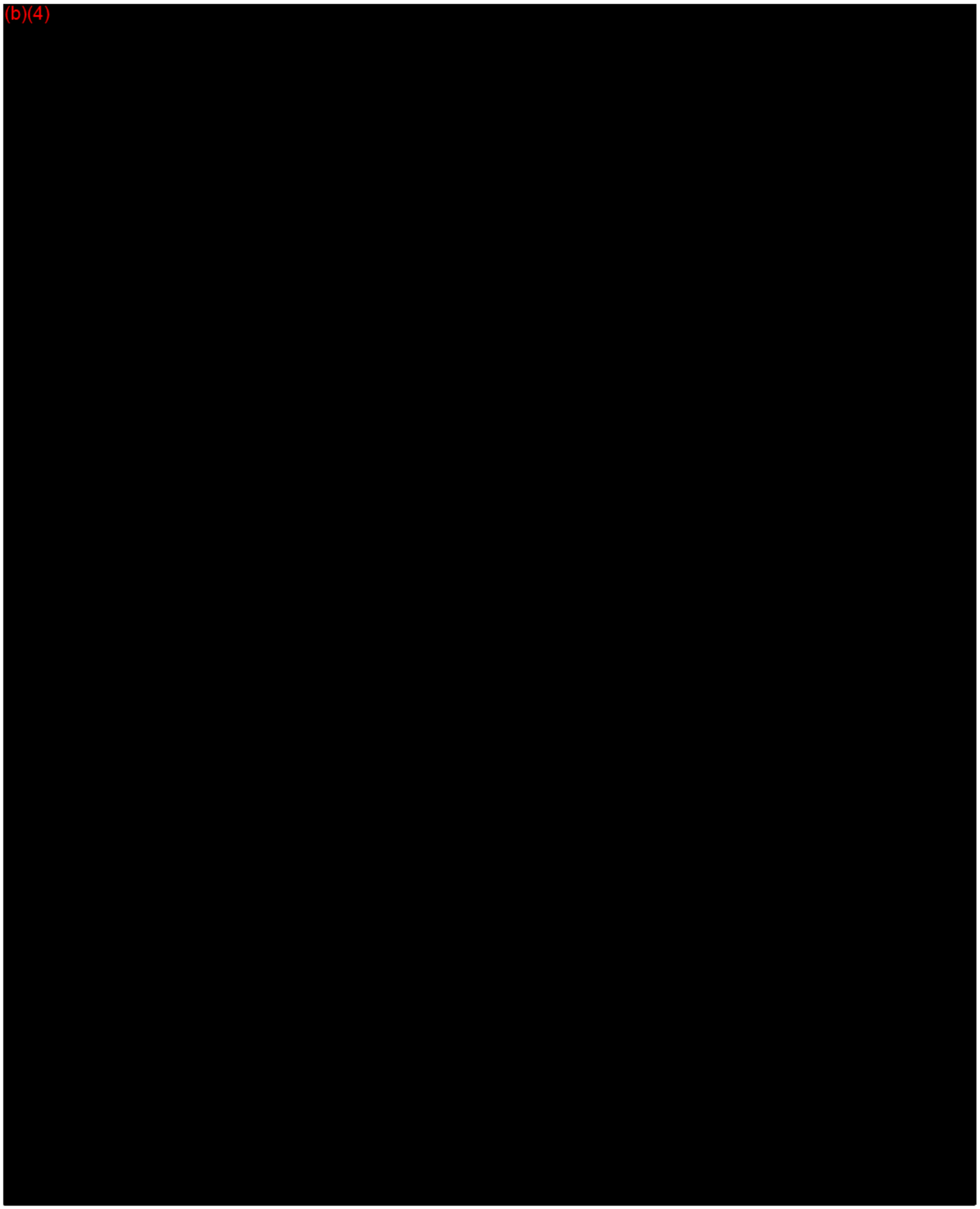

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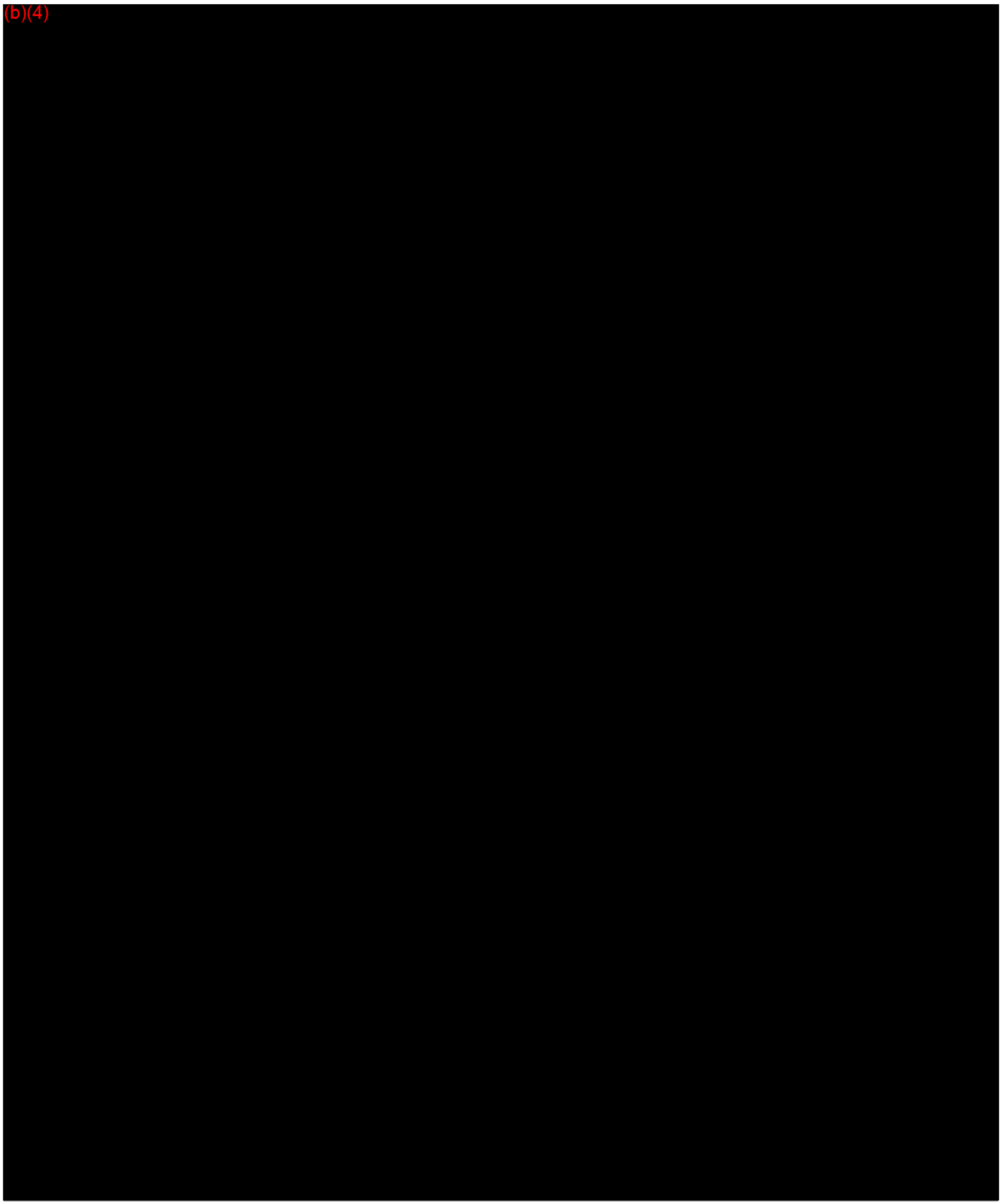

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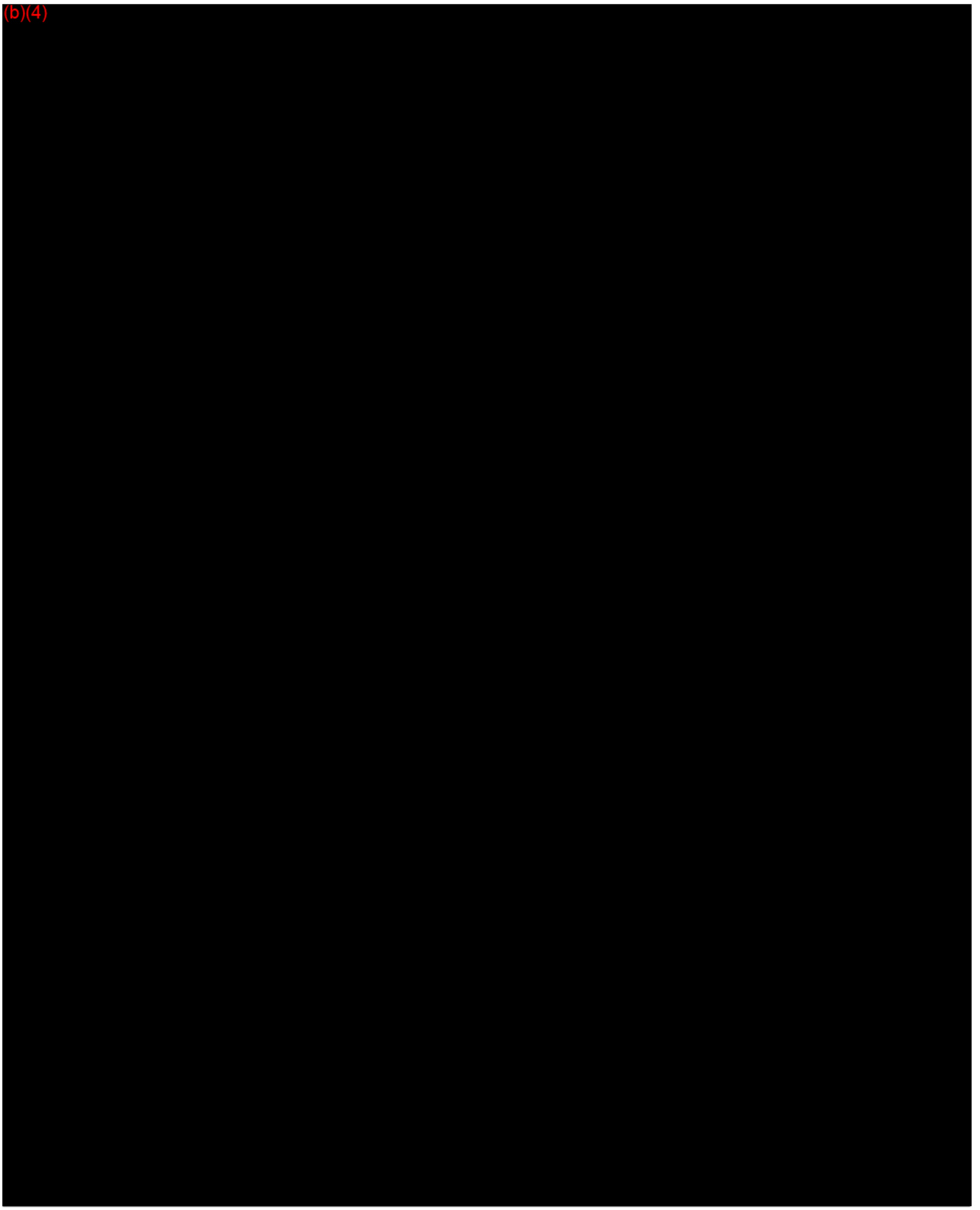

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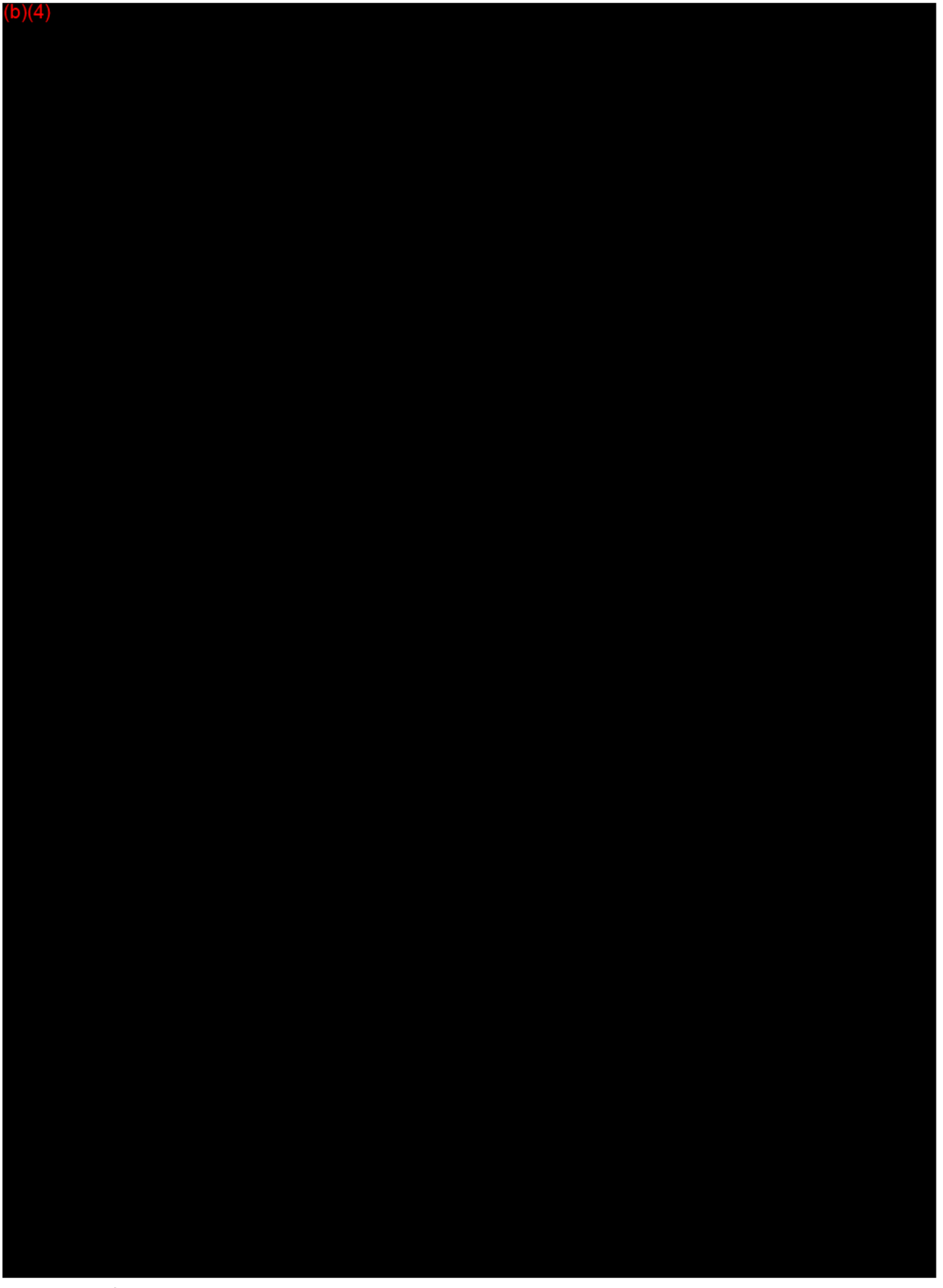

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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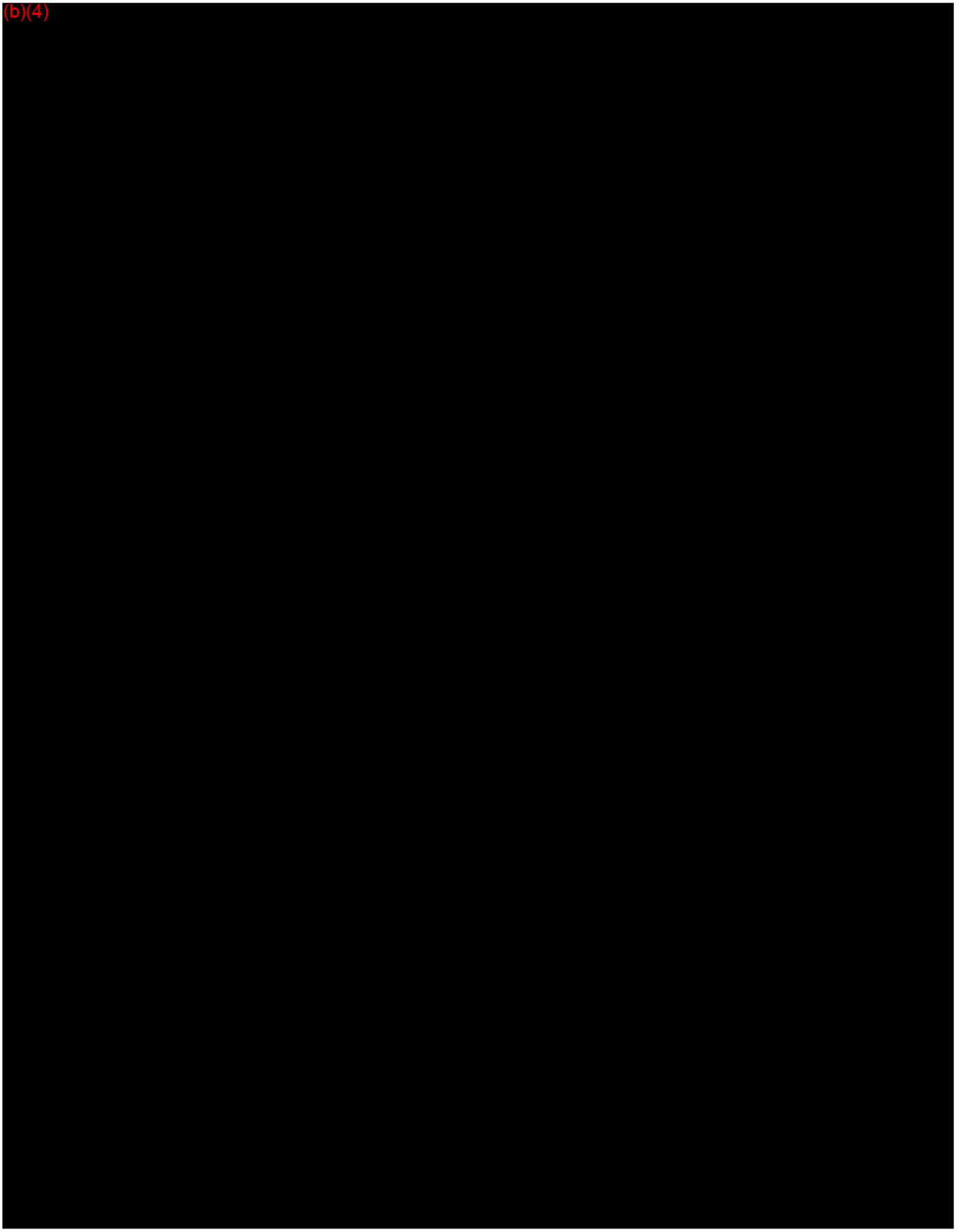

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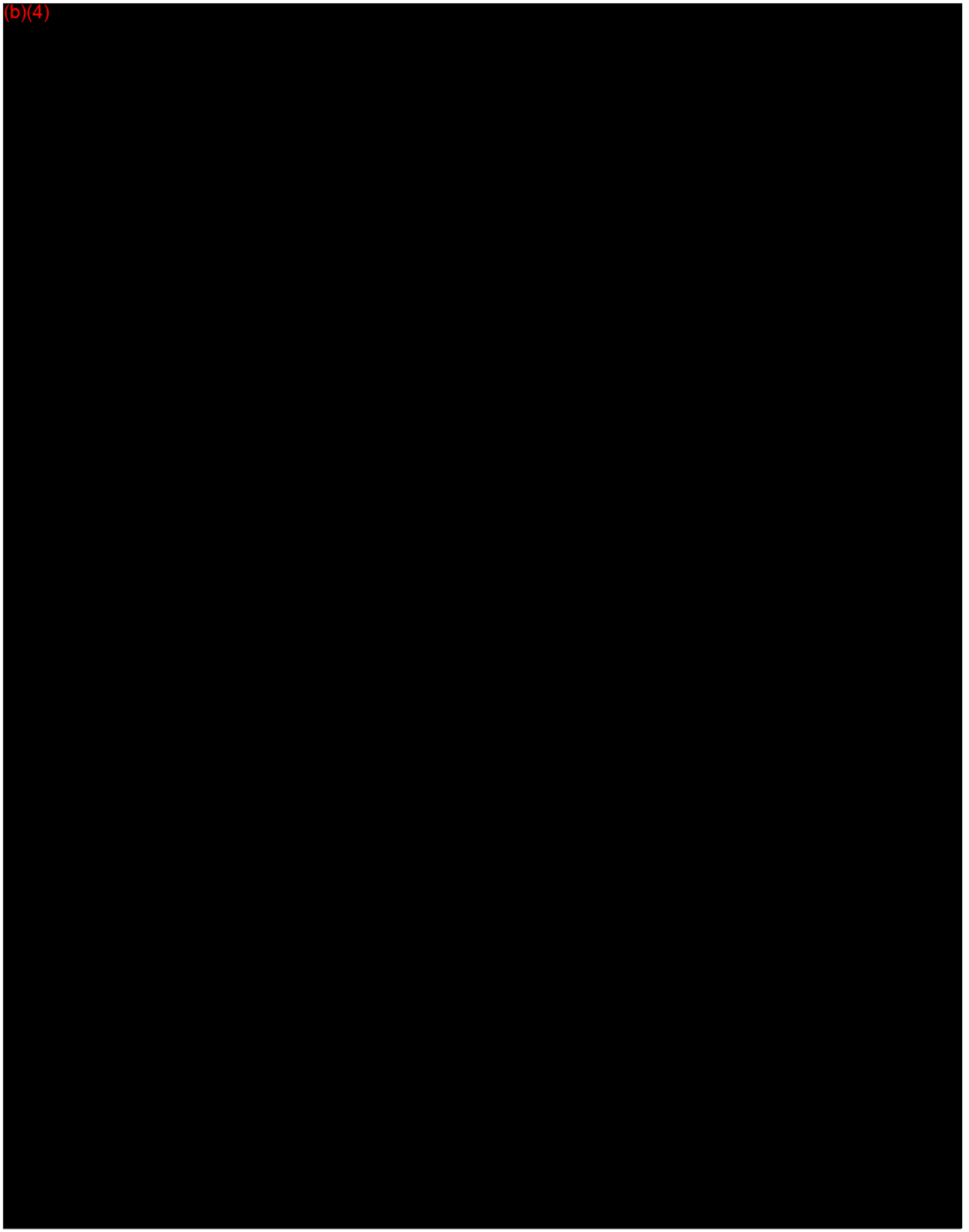

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XVI. Contact History

Digital Signature Concurrence Table	
Reviewer Sign-Off	Andrew I. Steen -S 2015.07.31 12:25:23 -04'00'

Records processed under FOIA Request 2016-8070; Released by CDRH on 10/5/2017

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MEMO OF SOFTWARE REVIEW

Name of the Device:	3Shape Abutment Designer software
Common Name:	Abutment Designer
Applicant:	3Shape A/S Copenhagen
Device Premarket Path:	K151455/S001 Traditional
Consult:	CON162977
Lead Reviewer:	Andrew Steen
Kind of Device:	21 CFR 872.3630; Endosseous dental implant abutment Class II. NNH
Predicate:	K100152 Sirona Dental CAD/CAM System
Date Sent:	1/19/2016
Reviewer:	Catherine Li (CDRH, General Hospital Devices Branch), 301-796-6304, catherine.li@fda.hhs.gov

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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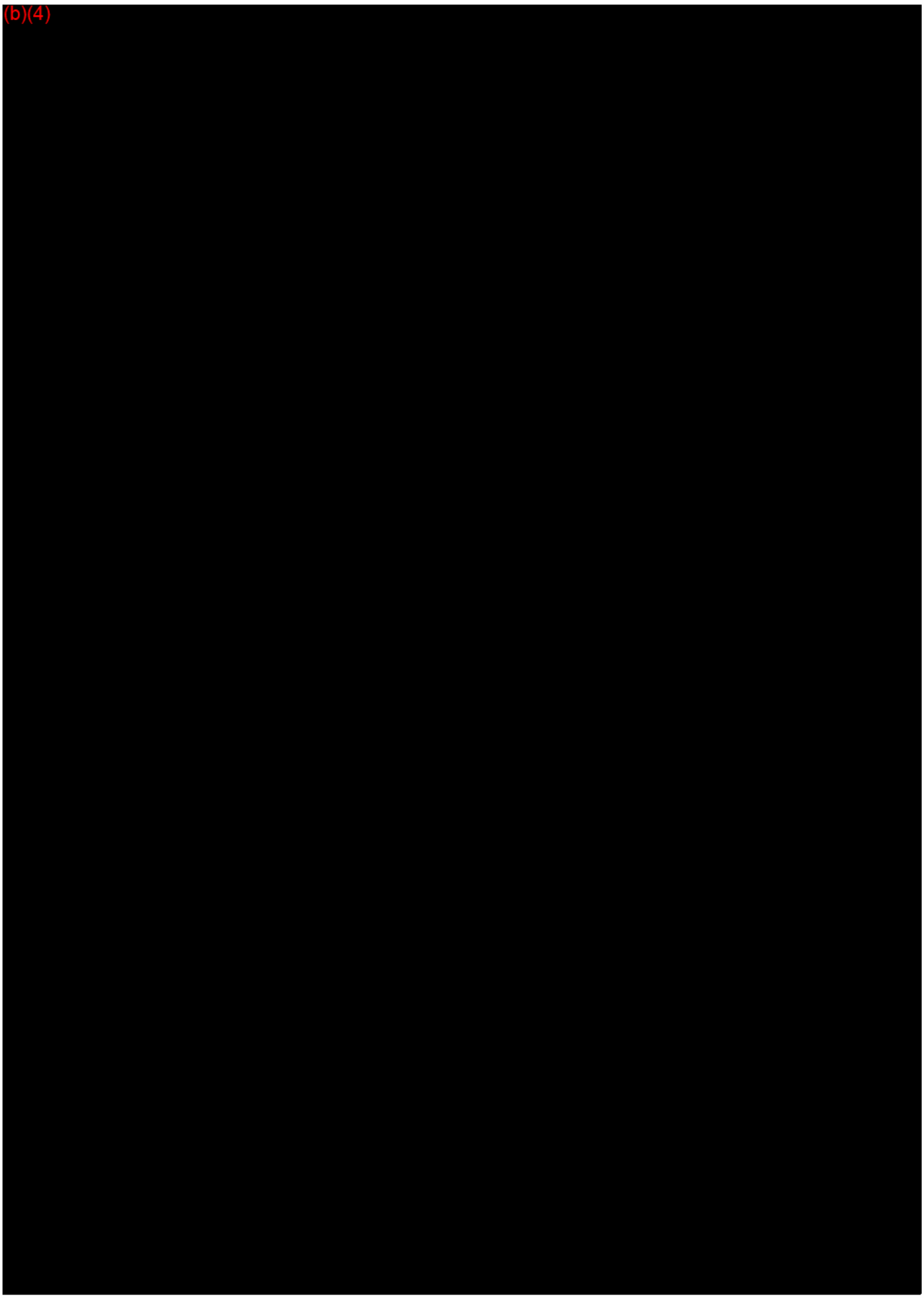

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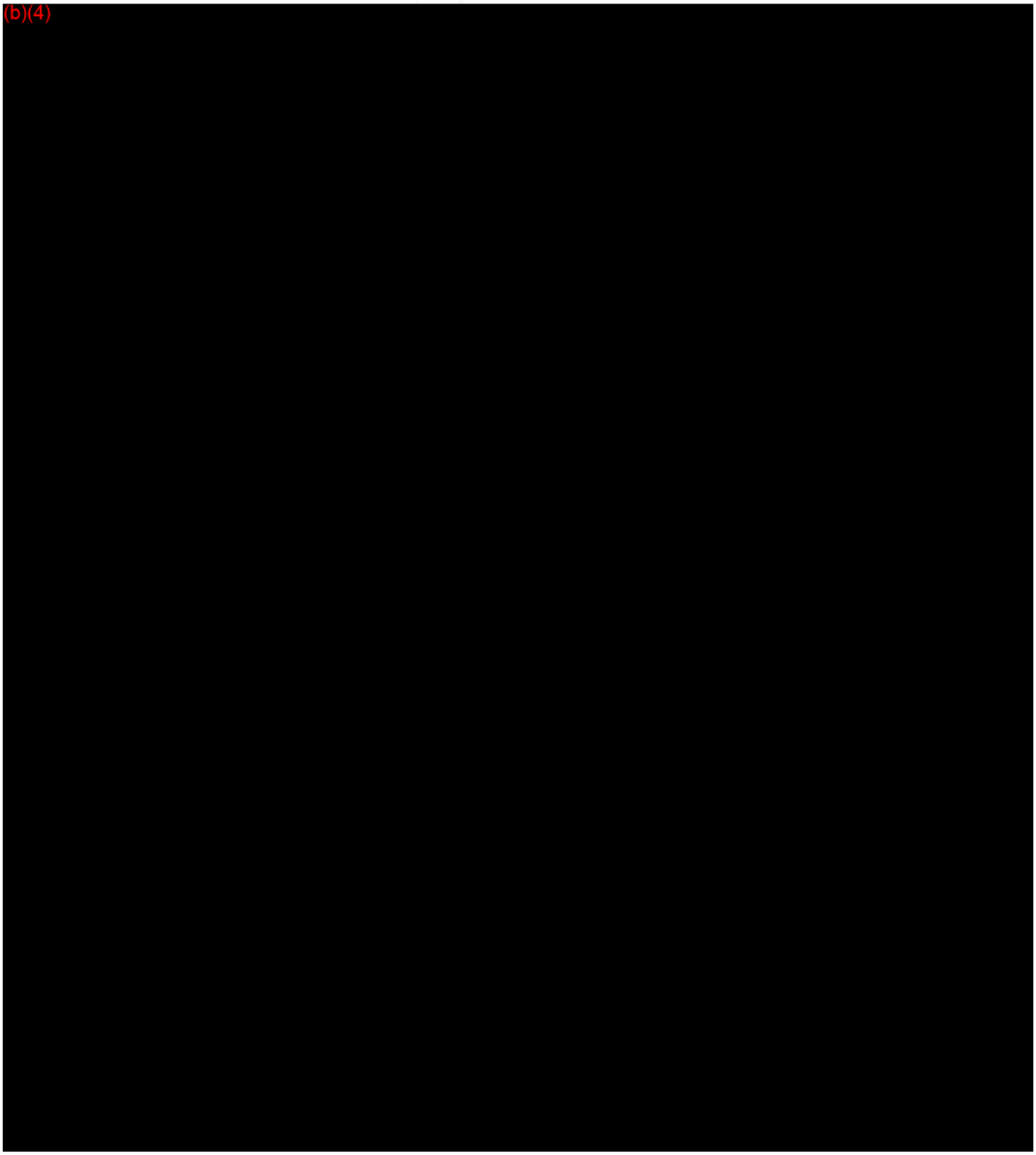

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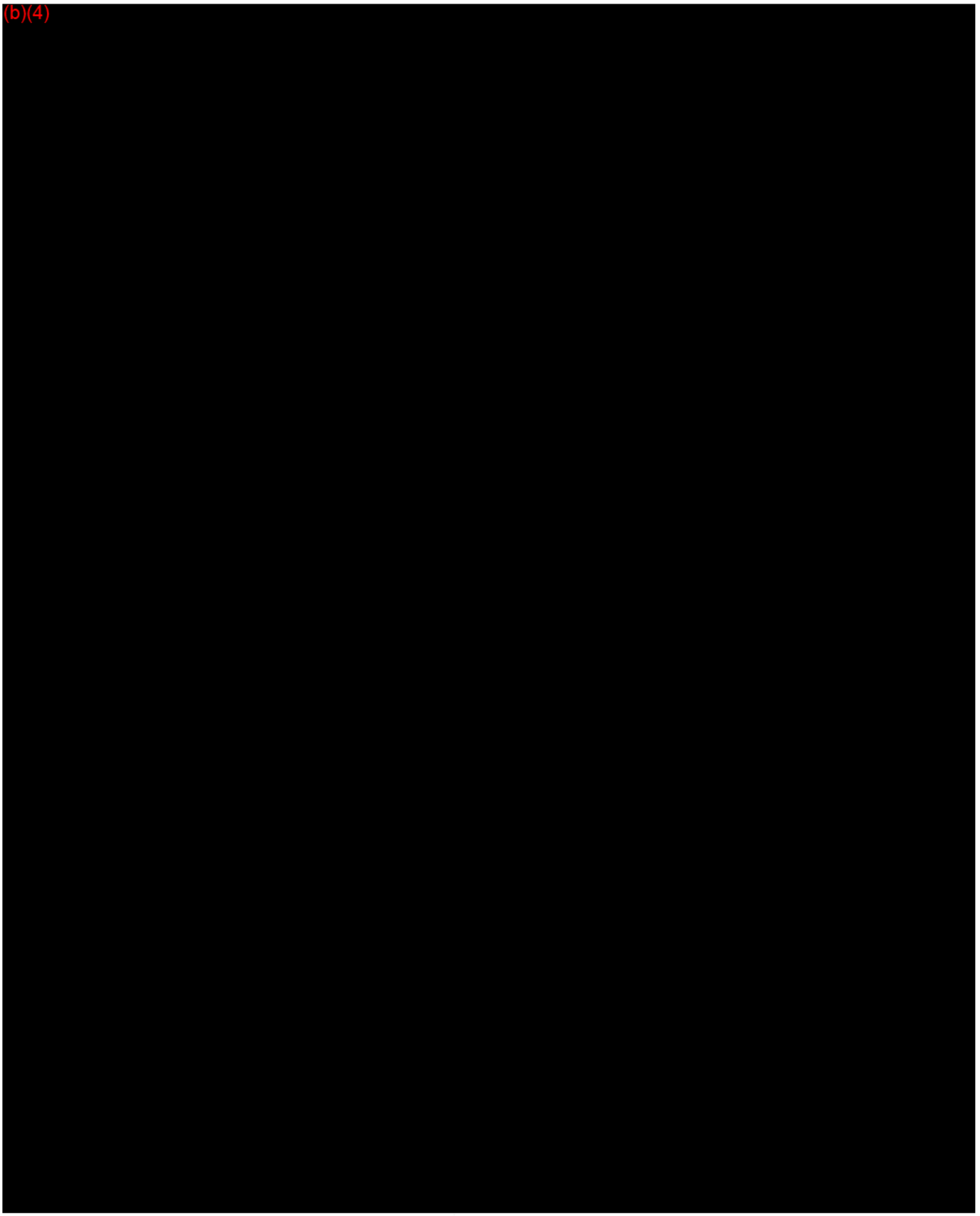

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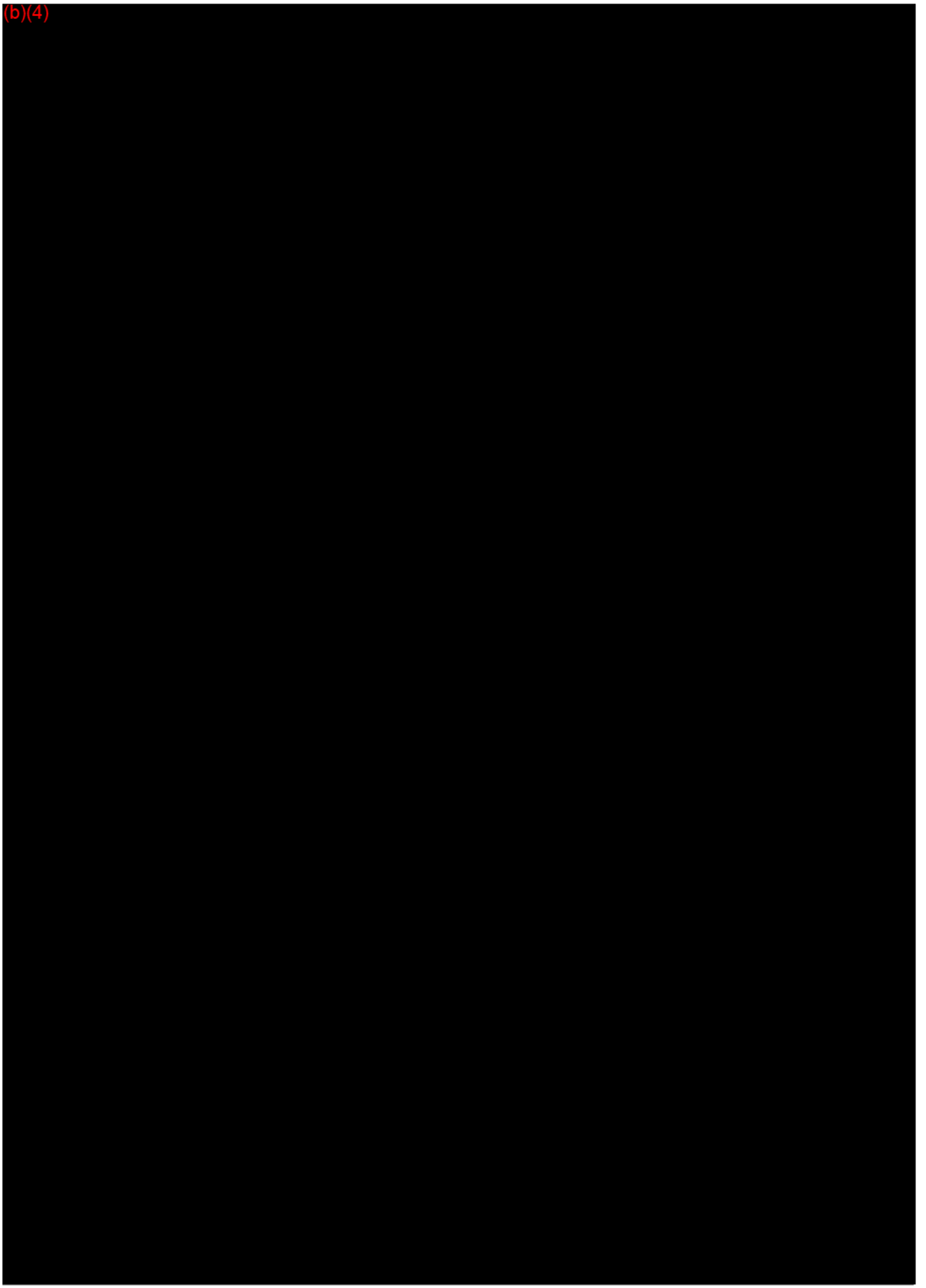

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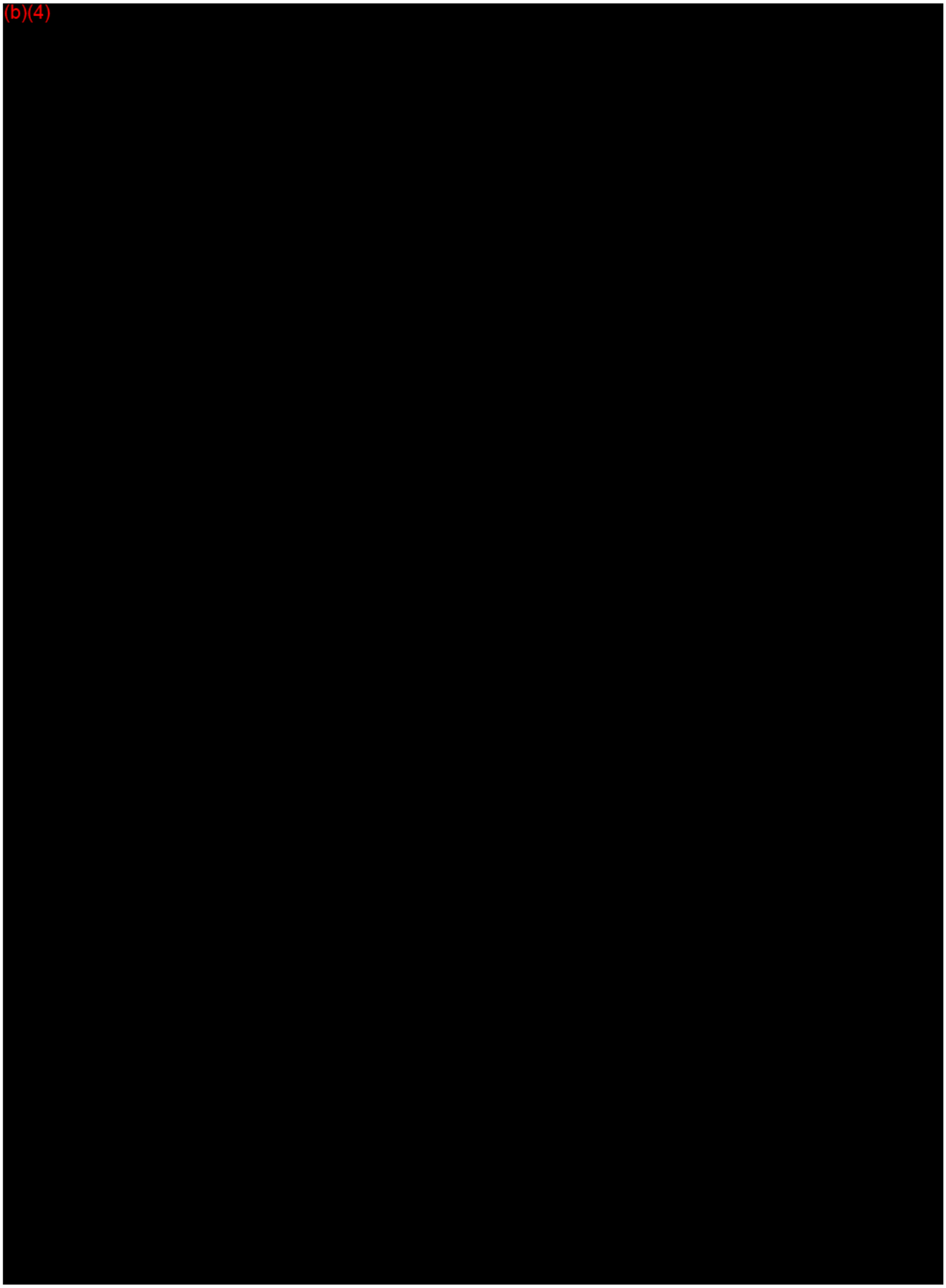

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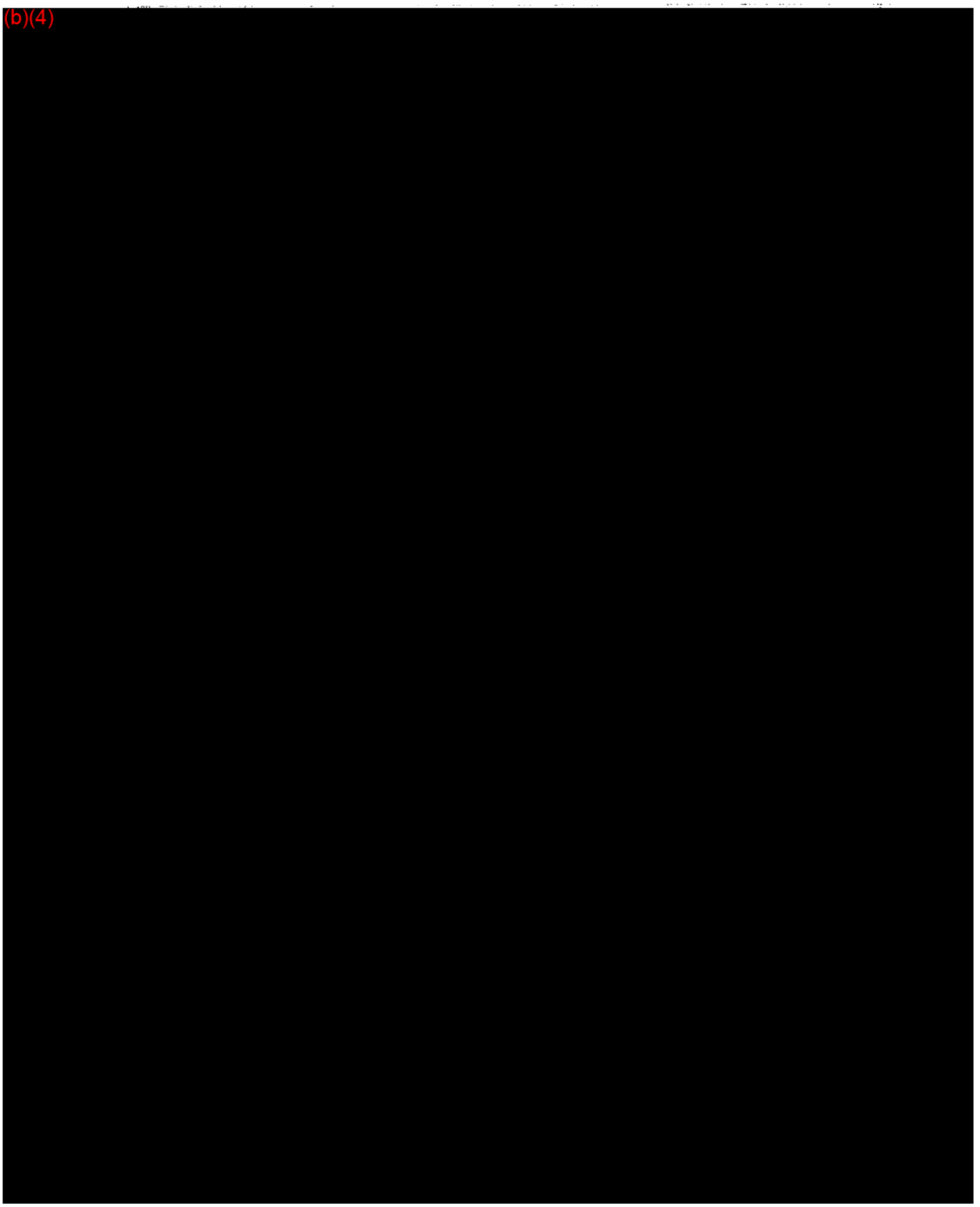

Catherine Li

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Records processed under FOIA Request 2016-8070; Released by CDRH on 10/5/2017

CDRH/DAGRID
U.S. Food and Drug Administration
Tel: (301) 796-6304

Digital Signature Concurrence Table	
Reviewer Sign-Off	Catherine Li -A Digitally signed by Catherine Li -A DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Catherine Li -A, 0.9.2342.19200300.100.1.1=2000657465 Date: 2016.02.19 12:23:26 -05'00'
Branch Chief Sign-Off	

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Applicant:	3Shape A/S Copenhagen
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Consult:	CON162977
Lead Reviewer:	Andrew Steen
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Predicate:	K100152 Sirona Dental CAD/CAM System
Date Sent:	1/19/2016, updated on 3/8/2016
Reviewer:	Catherine Li (CDRH, General Hospital Devices Branch), 301-796-6304, catherine.li@fda.hhs.gov

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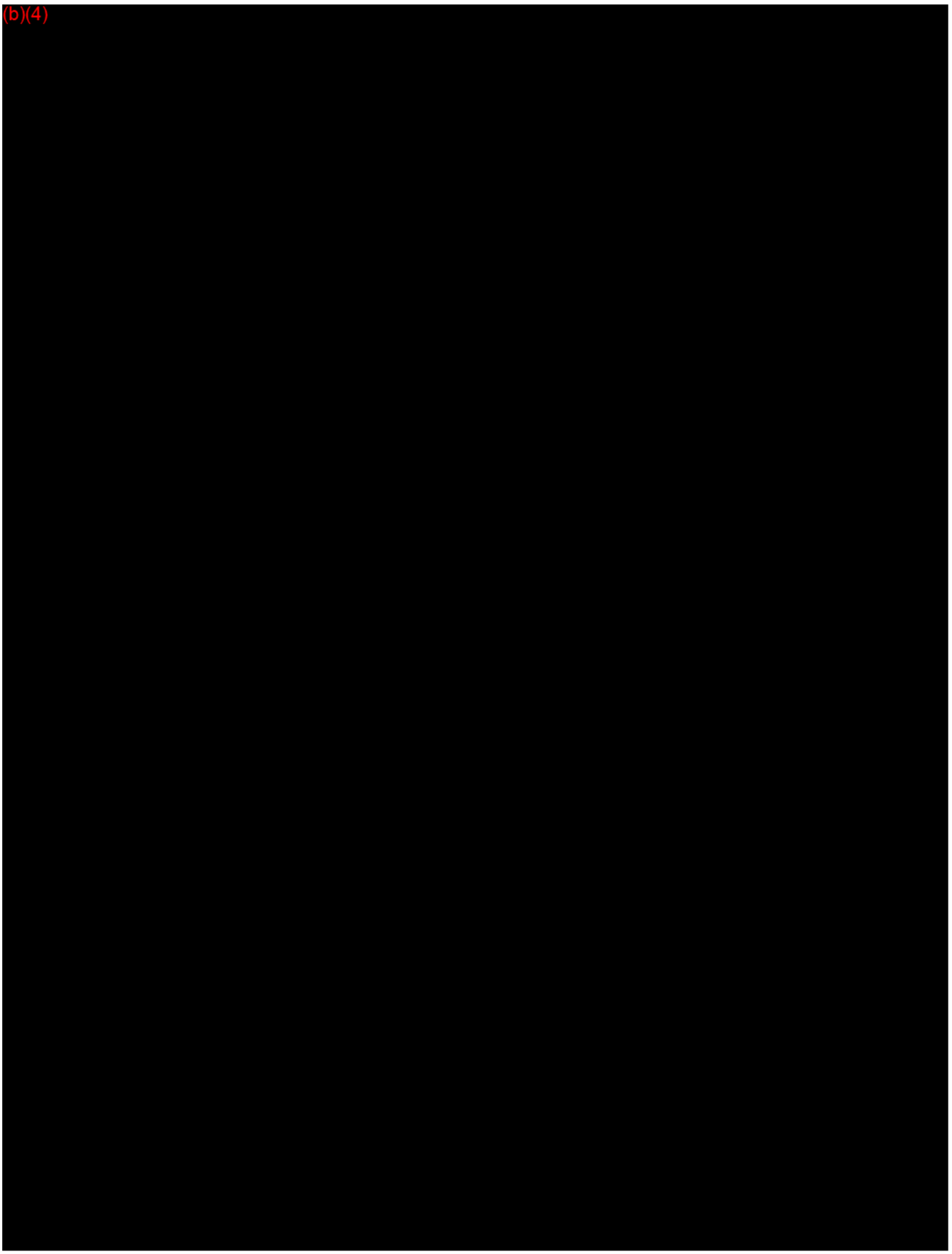

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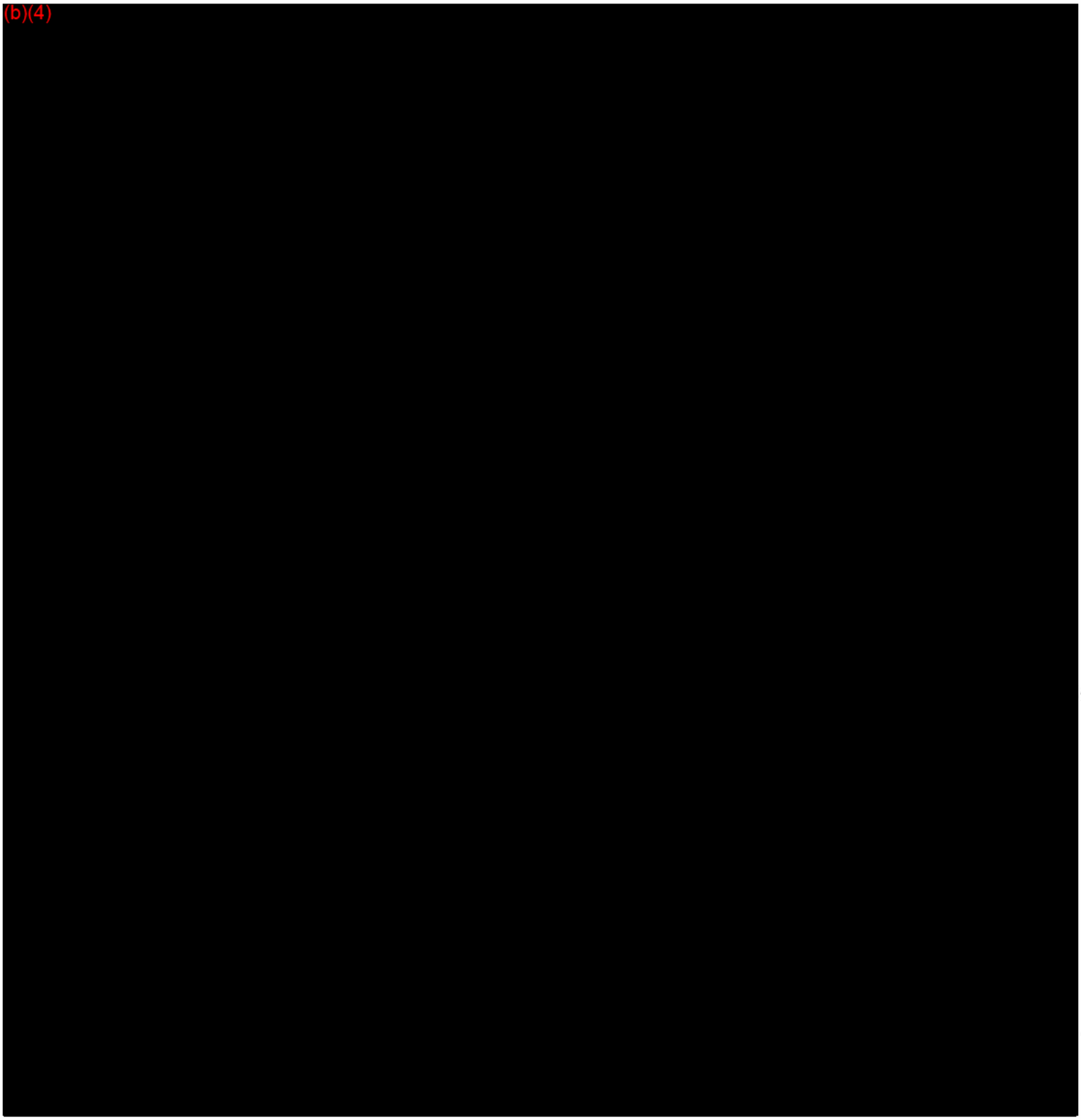

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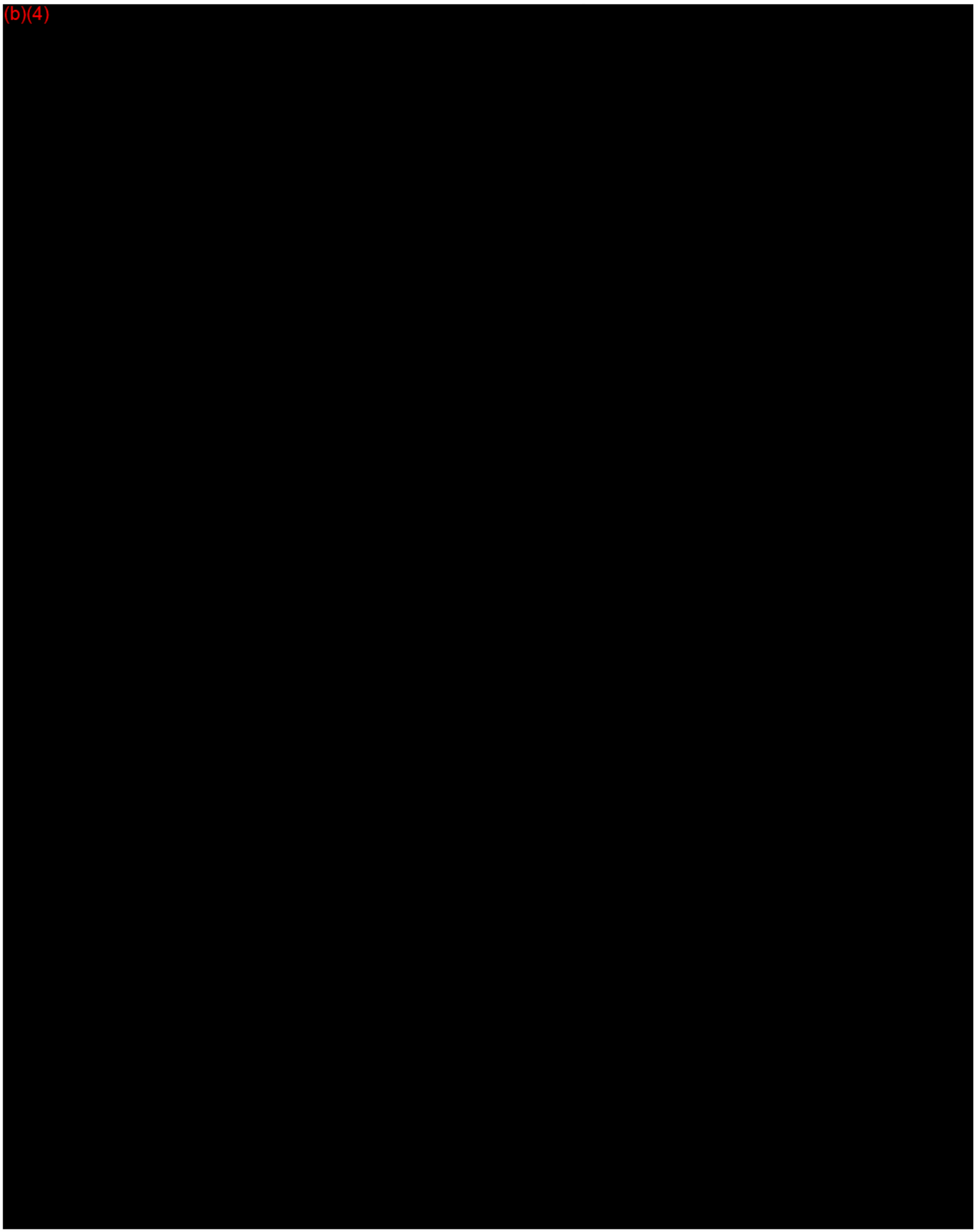

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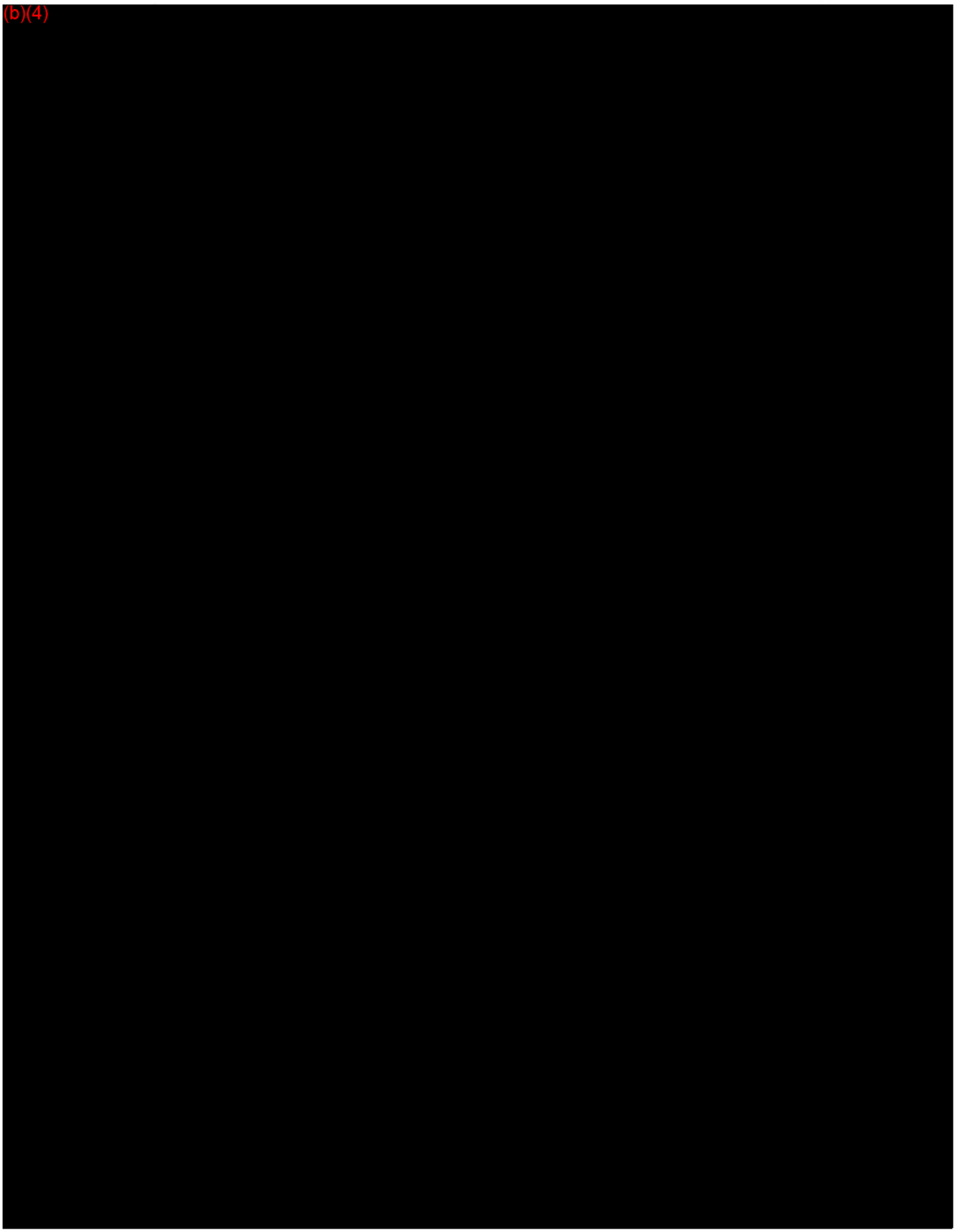

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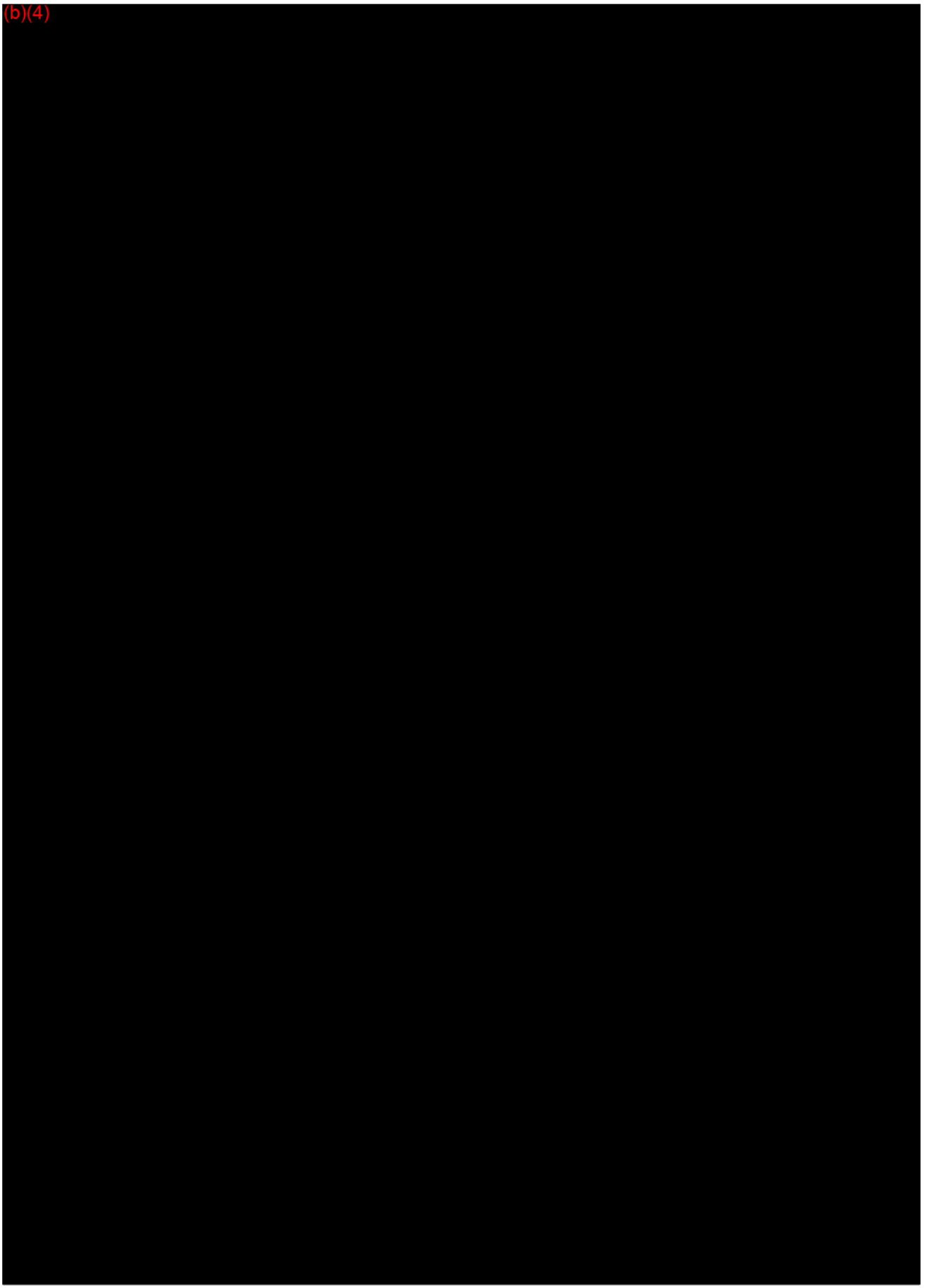

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Catherine Li
CDRH/DAGRID
U.S. Food and Drug Administration
Tel: (301) 796-6304

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Branch Chief Sign-Off	

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ood and Drug Administration
CDRH/ODE/DAGRID/DEDB
WO66 RM2604
10903 New Hampshire Ave
Silver Spring, MD 20993-0002
301-796-6284

Premarket Notification [510(k)] Review

Date: August 18, 2016
To: FILE
From: Andrew I. Steen, Mechanical Engineer
Subject: Traditional 510(k)# K151455/S001

Applicant: 3Shape A/S

Device Trade Name: 3Shape Abutment Designer Software

Contact: Hanne Nielsen

Contact Title: Regulatory Affairs Manager

Correspondent Firm: 3shape A/S

Phone: 45 (702) 726-20 **Email:** hanne.nielsen@3shape.com

FDA Received Date: January 11, 2016

Due Date: February 10, 2016

Reg #: 872.3630 **Reg Name:** Endosseous Dental Implant Abutment

Class: II **Product Code(s):** PNP

Predicate Devices:

Submission #	Pro Code	Device Trade Name	Owner
K100152	NHA	Sirona Cad/cam System	Sirona Dental Systems Gmbh

Review Summary

The subject device is an Endosseous Dental Implant Abutment with the following Indications for Use: "The 3Shape Abutment Designer Software is intended for designing endosseous dental implant abutments based on digital scans of 3D models. Intended users are Dental Practitioners and Dental Laboratory Staff. Intended Operational Environment is Dental Laboratories." It is for Rx use.

Recommendation

I recommend that the 3Shape Abutment Designer Software is/are Substantially Equivalent (SESE)

Review Team

Lead Reviewer	Andrew I. Steen, Mechanical Engineer (CDRH/ODE/DAGRID/DEDB)
Software Consultant	Catherine Li, Electrical Engineer (CDRH/ODE/DAGRID/GHDB)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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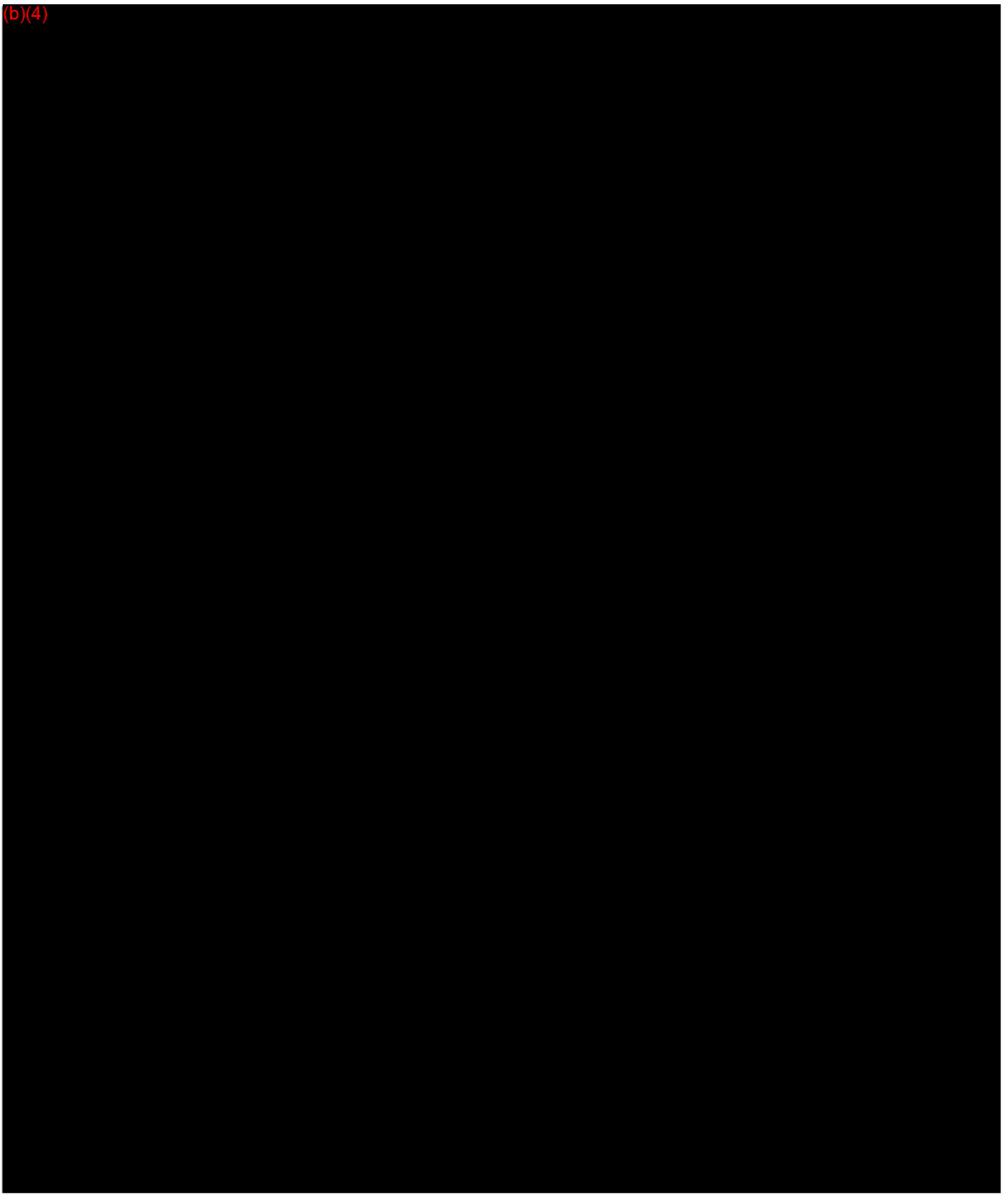

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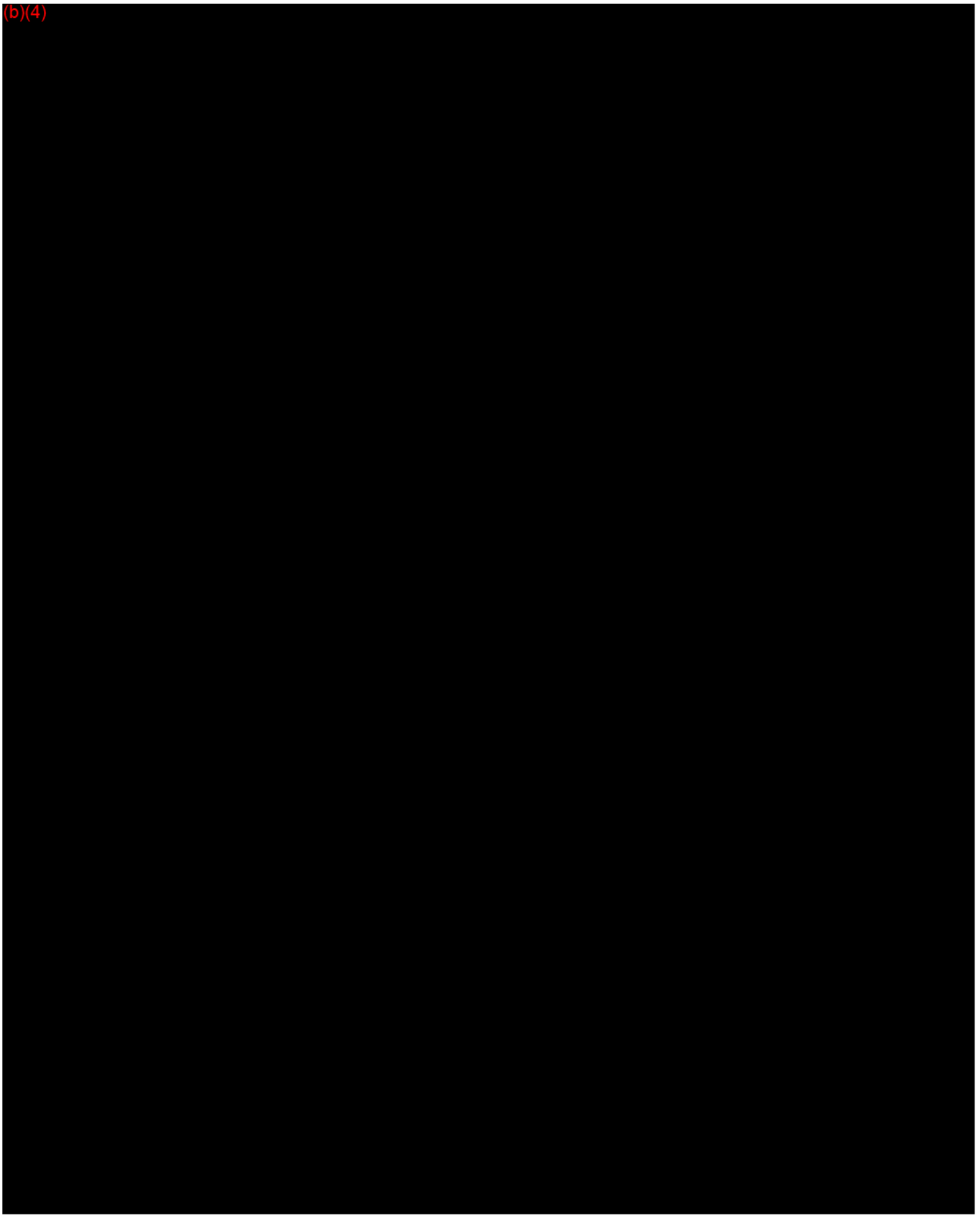

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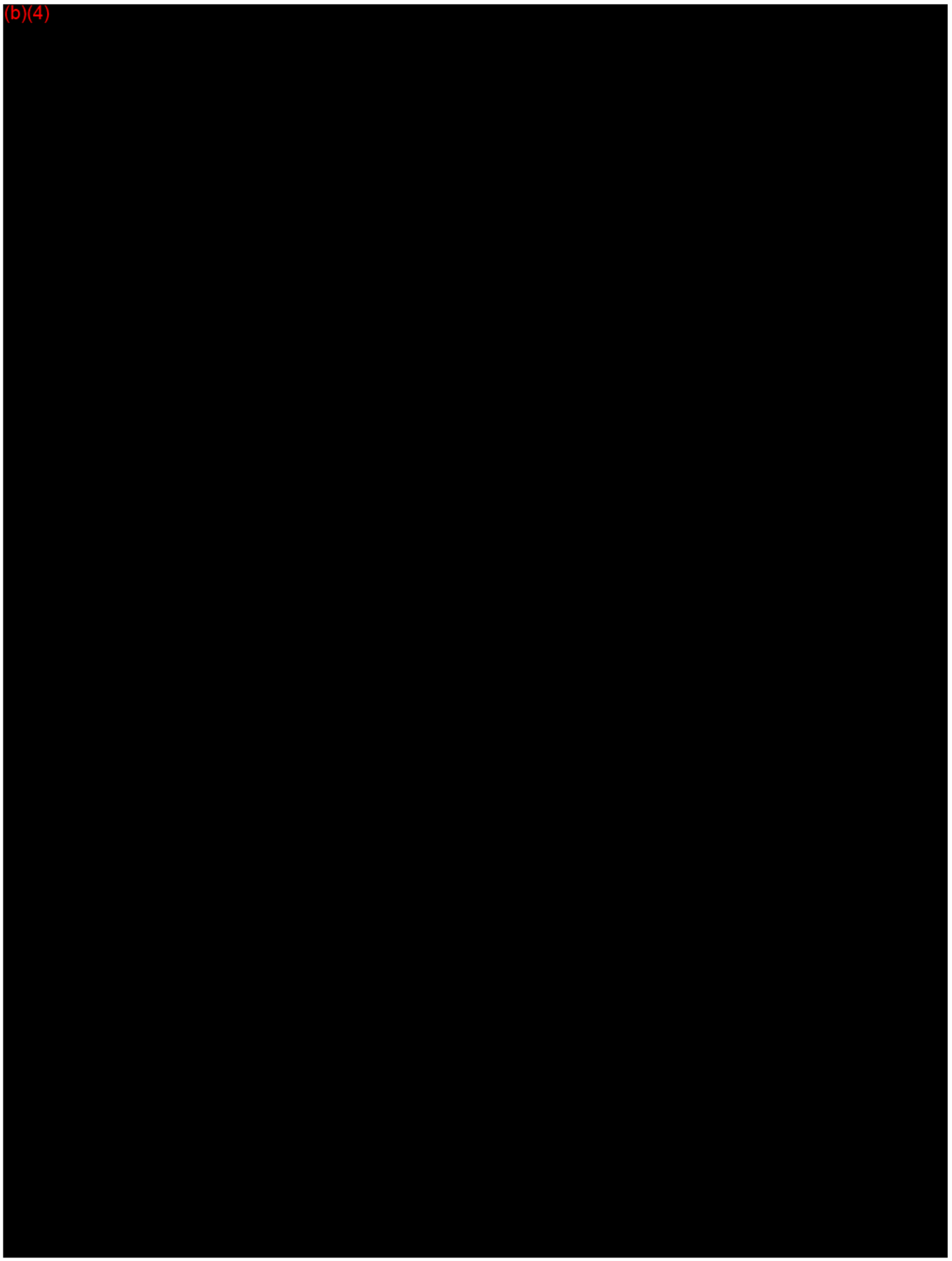

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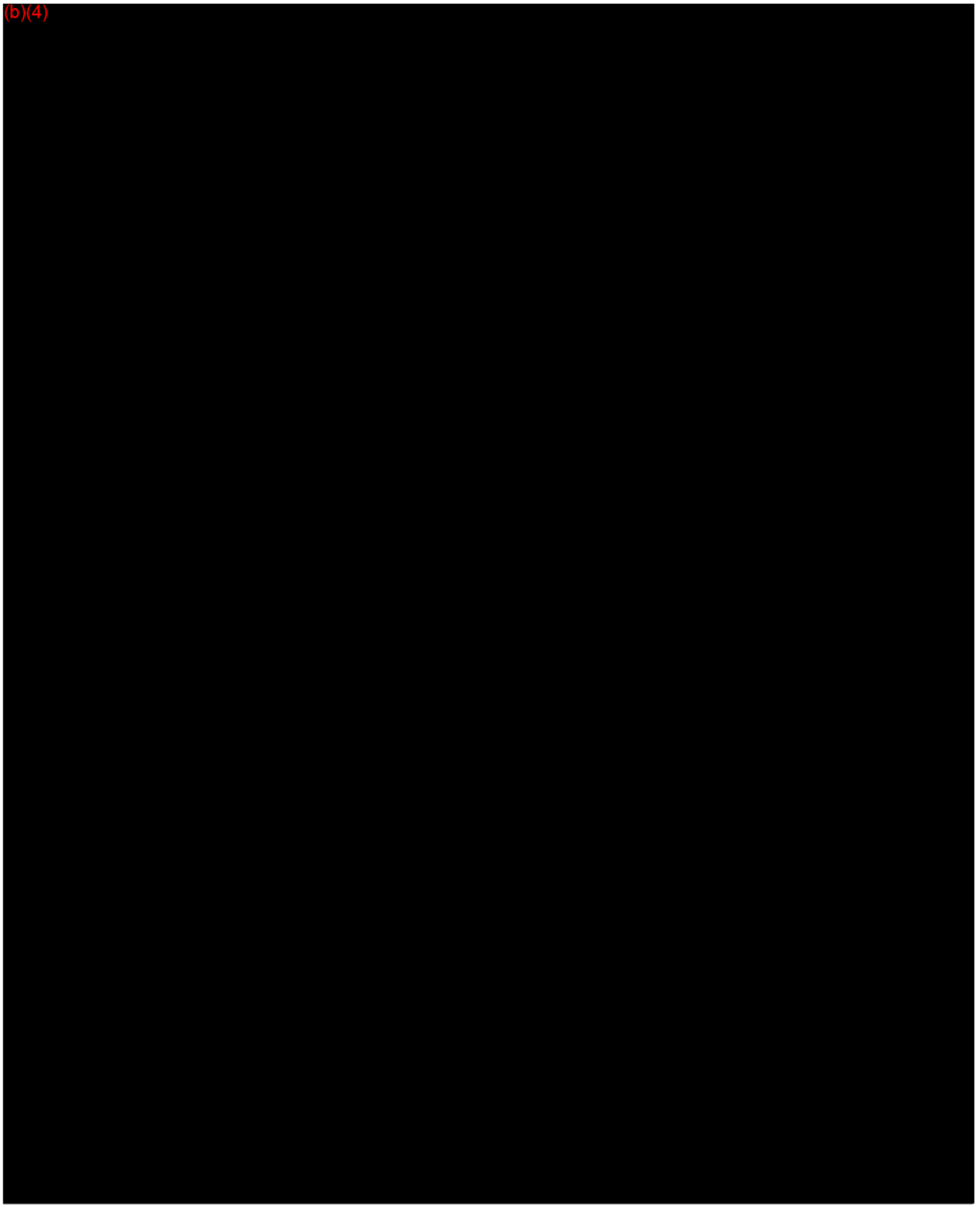

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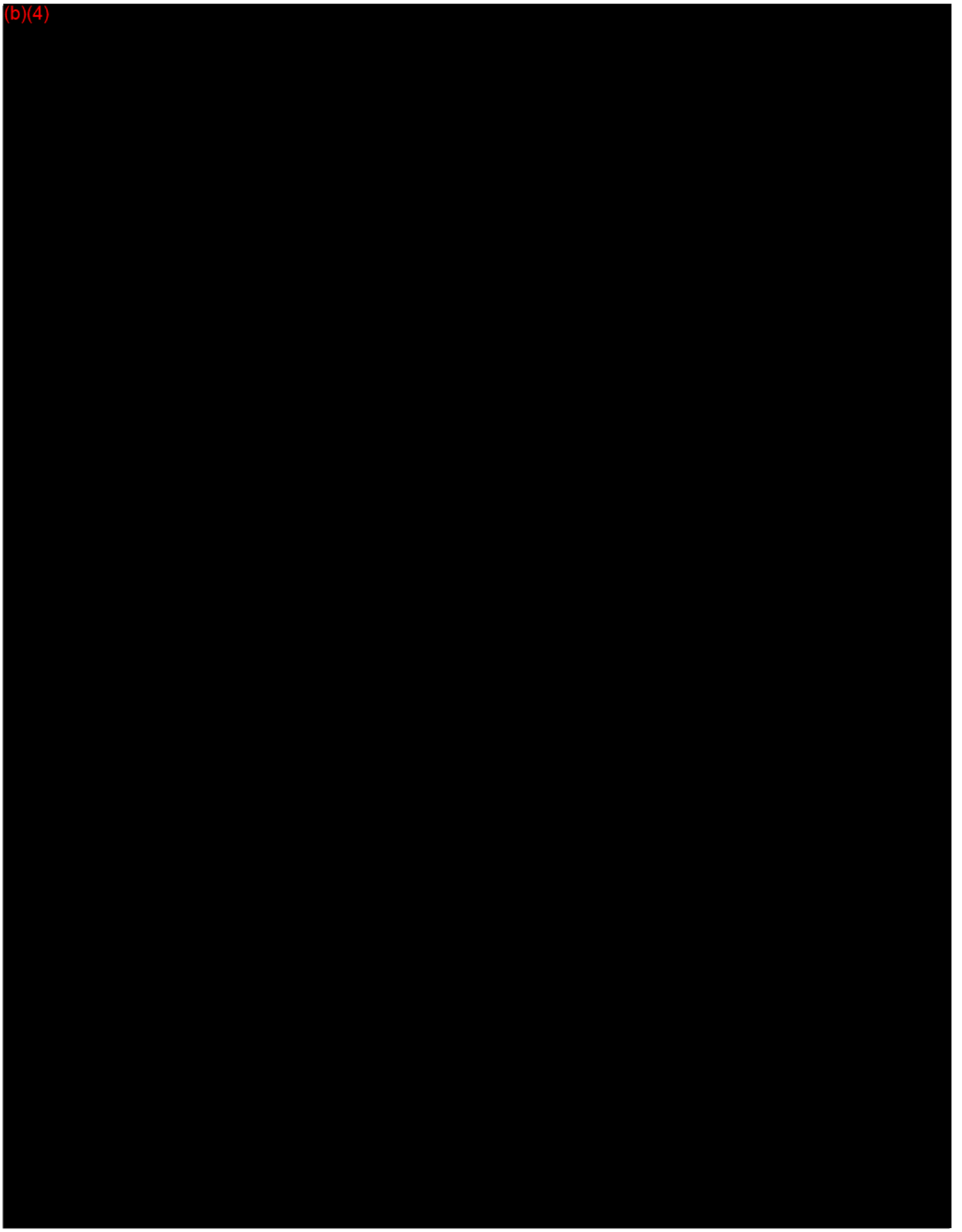

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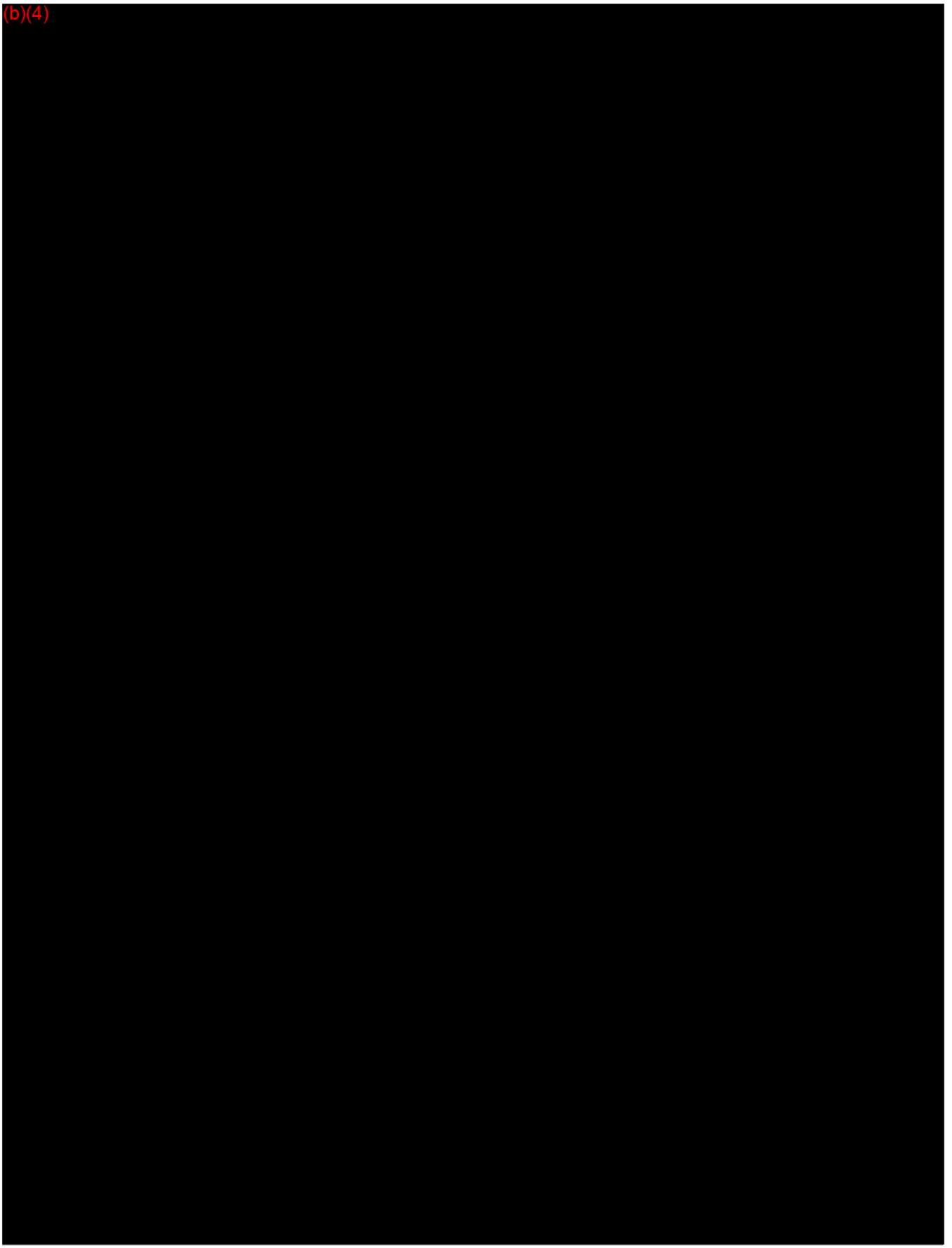

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II

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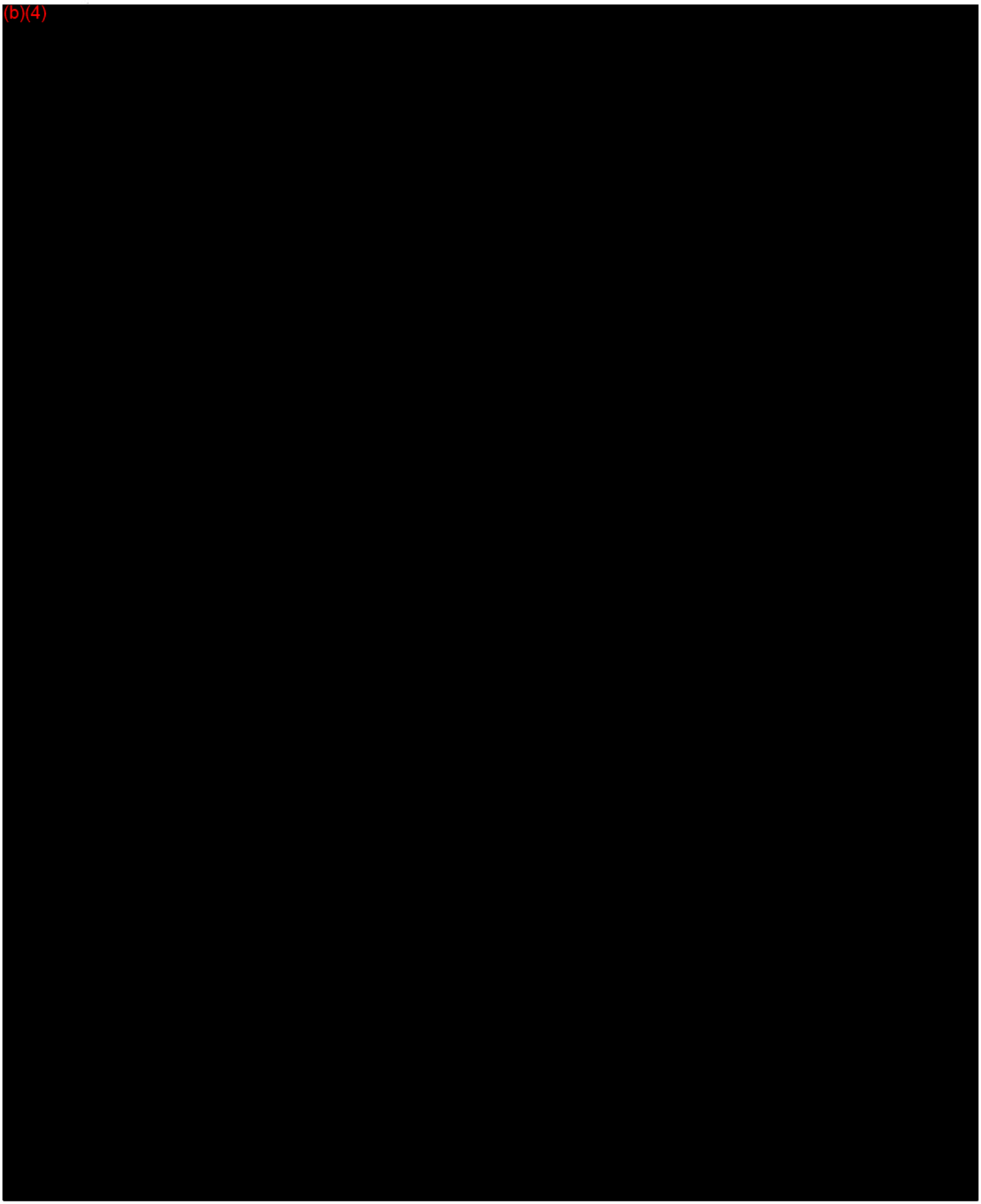

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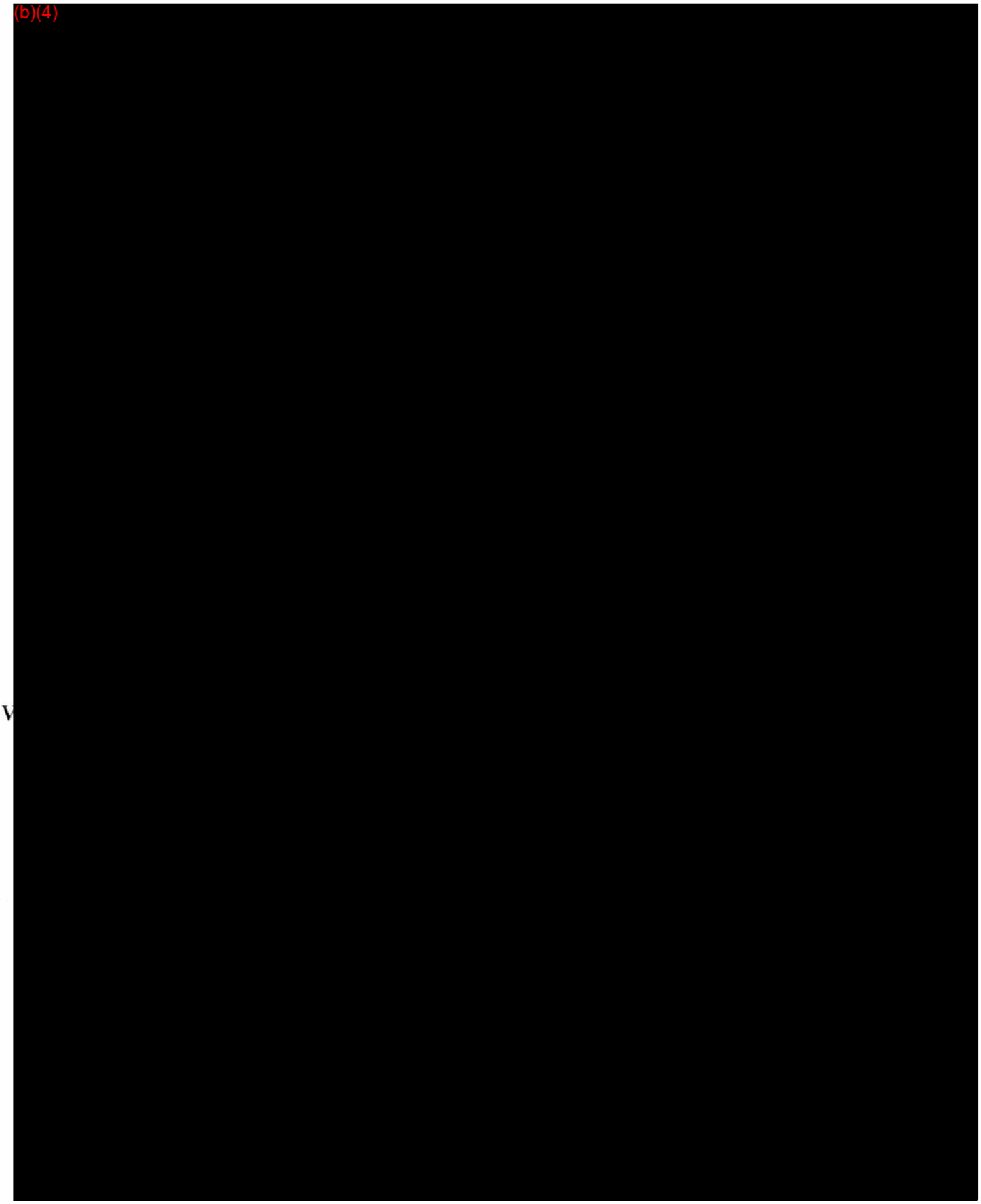

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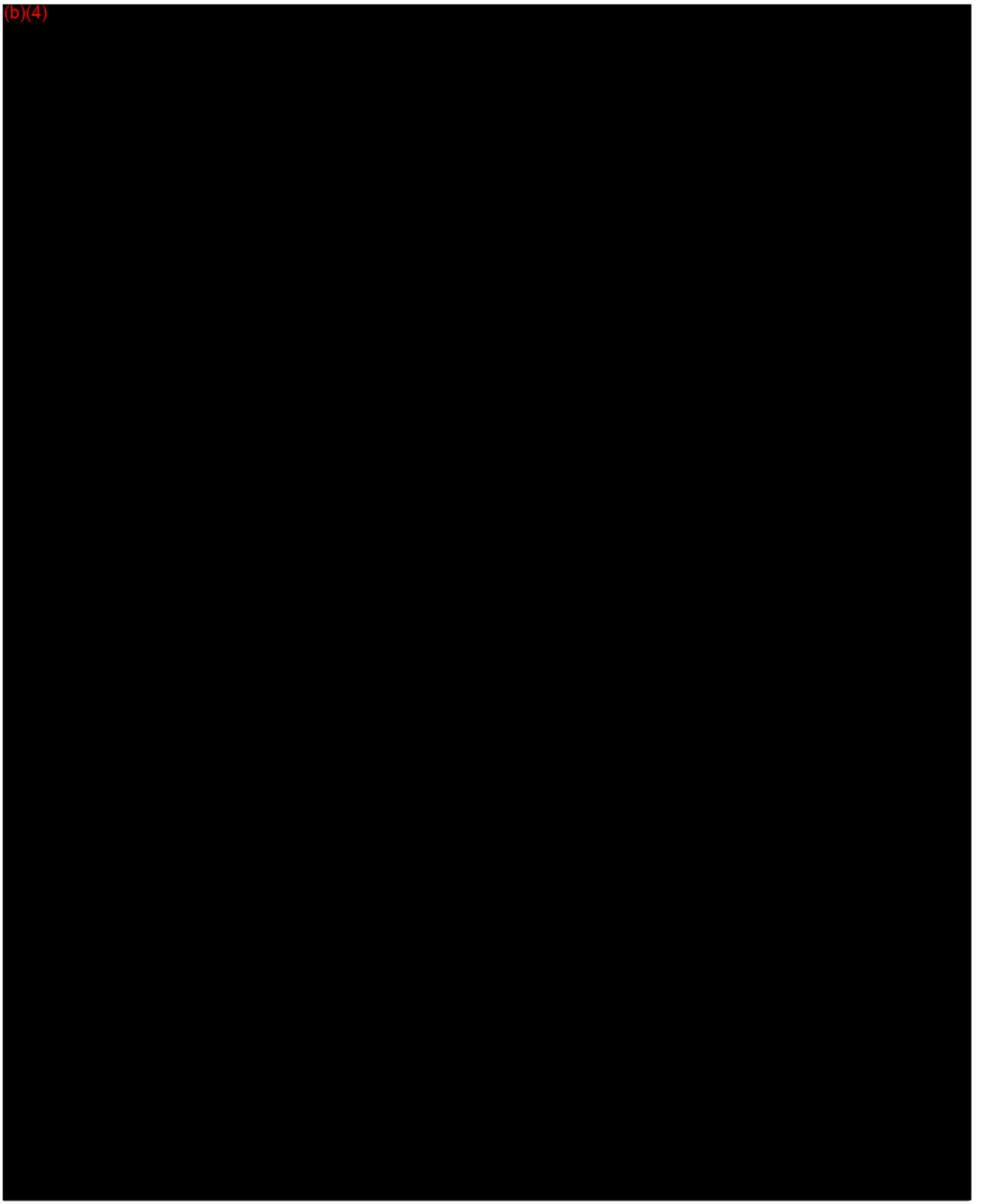

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[redacted]

VII. Biocompatibility

Biocompatibility Review Needed?	Yes ☐	No ☒
Biocompatibility Consult Needed?	Yes ☐	No ☒

The submission states that the device has no patient contacting components and thus biocompatibility requirements are not apply. The submission states that identification of the material is also not applicable.

Reviewer Recommendation

The Biocompatibility is acceptable.

VIII. Software/Firmware

Software Review Needed?	Yes ☒	No ☐
Software Consult Needed?	Yes ☒	No ☐

(b)(4)

[redacted]

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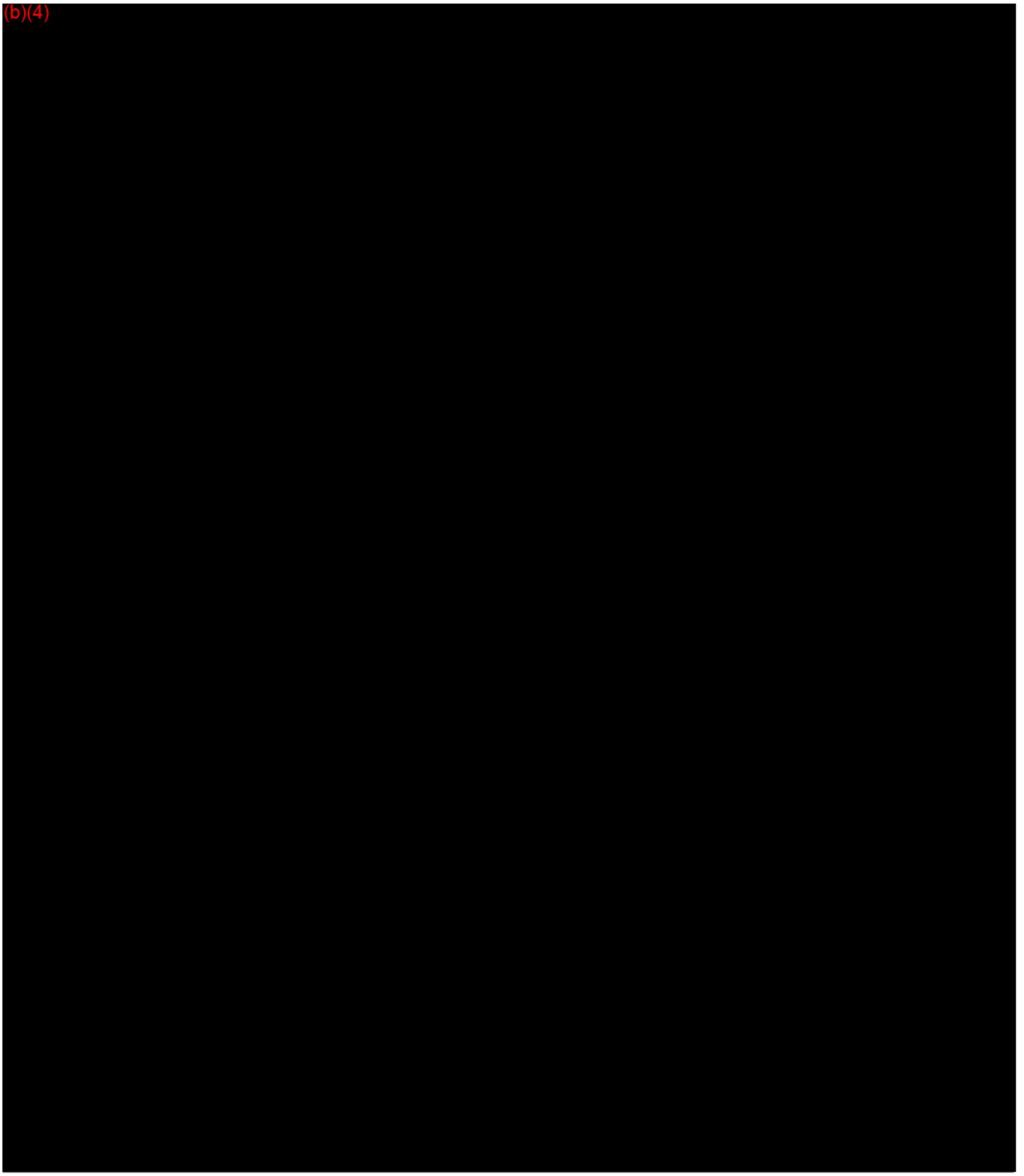

IX. EMC & Electrical, Mechanical and Thermal Safety & Risk Analysis

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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EMC Review Needed?	Yes ☐ No ☒
EMC Consult Needed?	Yes ☐ No ☒

(b)(4)

[redacted]

Reviewer Recommendation
The EMC, EMT and Risk Analysis are acceptable.

X. Performance Testing

(b)(4)

[redacted]

Reviewer Recommendation
The Performance Testing [Verification & Validation] is acceptable.

XI. Kit Certification

This section is N/A.

XII. Manufacturing Information

This section is N/A.

XIII. References

The submission references the following standards or guidance documents and has provided the appropriate Standards Data Report Forms.

- ISO 13485:2015 Quality management systems – requirements for regulatory process
- ISO 14971:2012 Application of Risk Management to Medical Devices
- IEC 62304:2012 Software life cycle processes

XIV. SE Flowchart Questions

Substantial Equivalence Determination	Yes	No

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2016-8070; Released by CDRH on 10/5/2017

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[redacted]

XV. Original Deficiencies

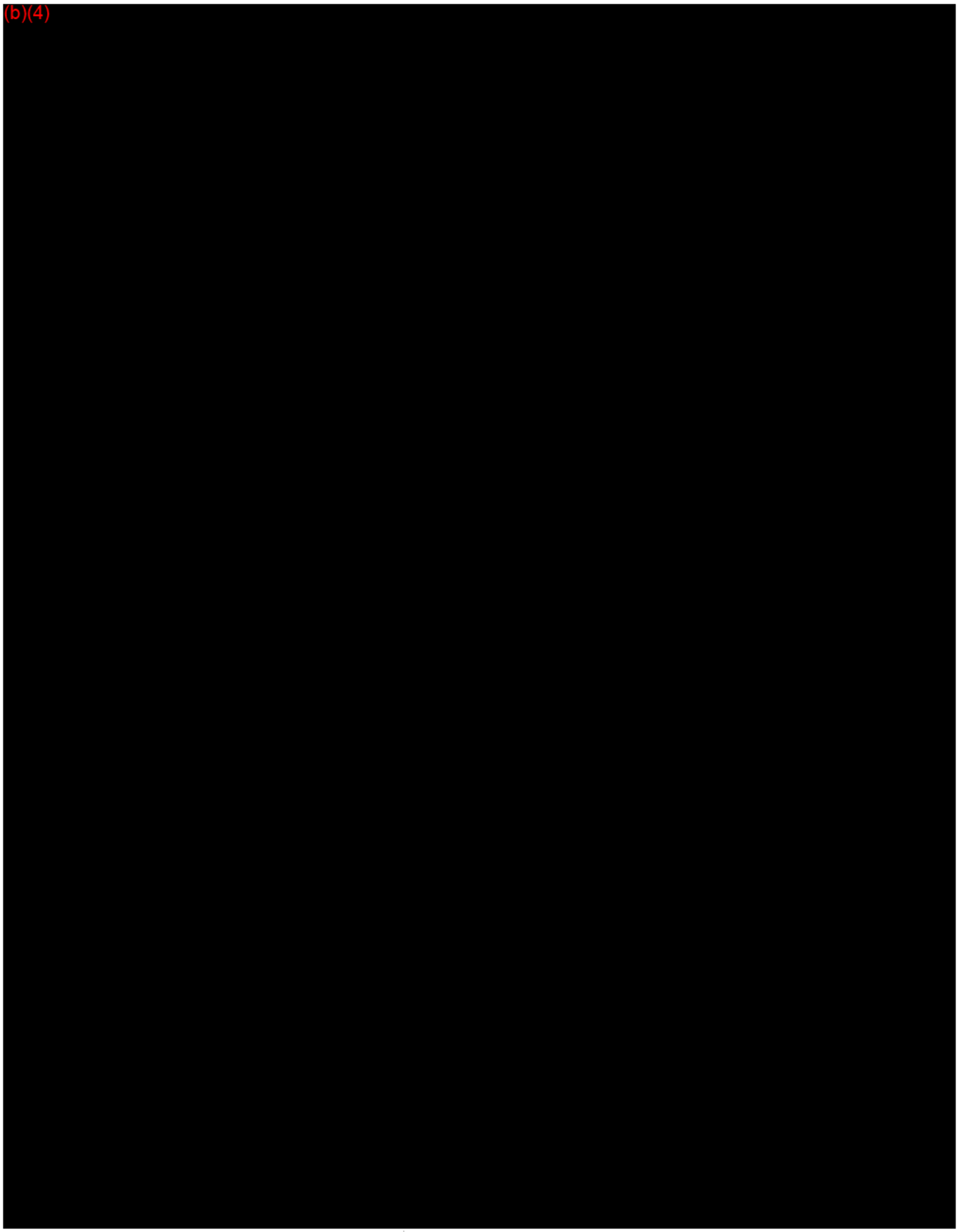
(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2016-8070; Released by CDRH on 10/5/2017

(b)(4)



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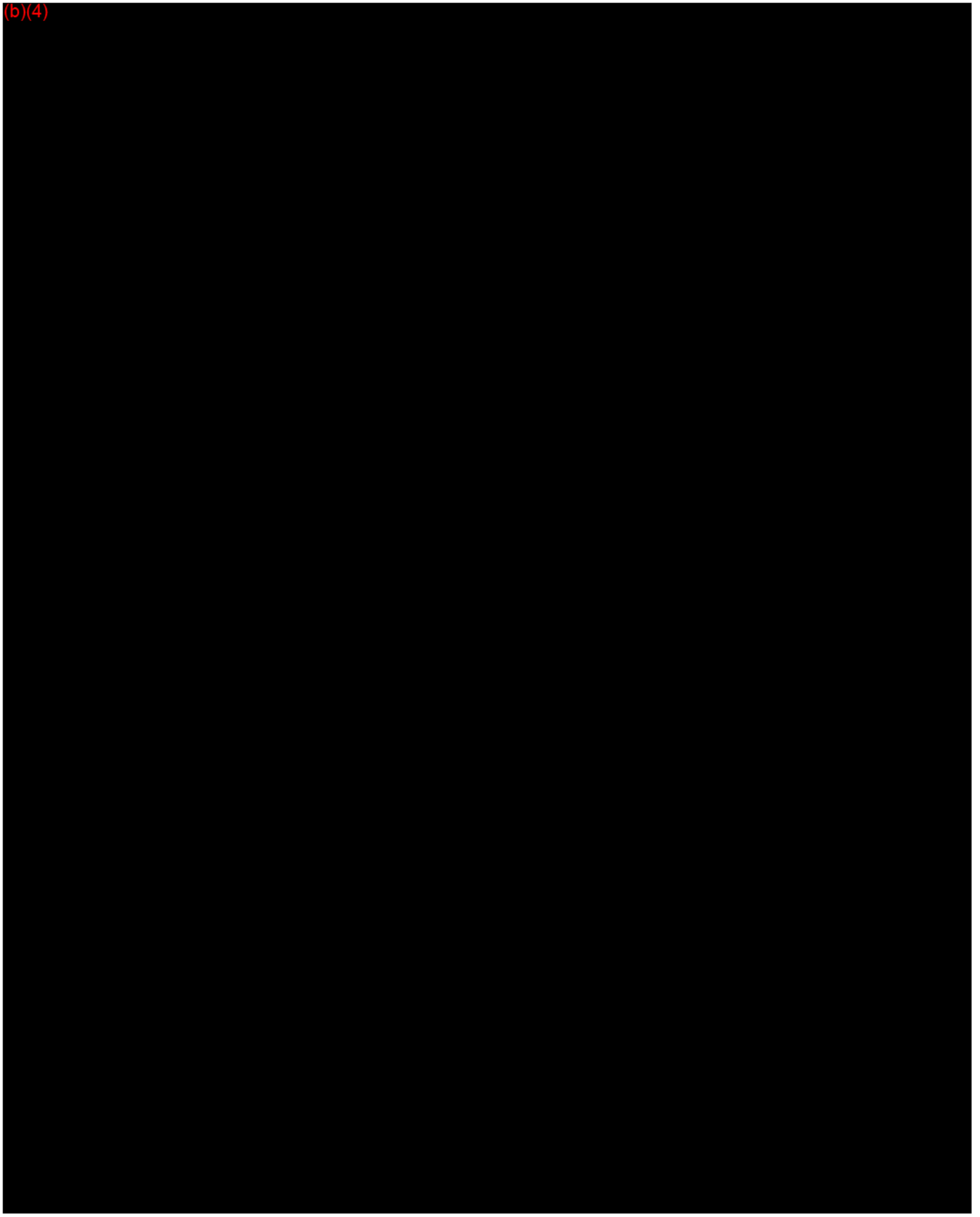
Records processed under FOIA Request 2016-8070; Released by CDRH on 10/5/2017

(b)(4)



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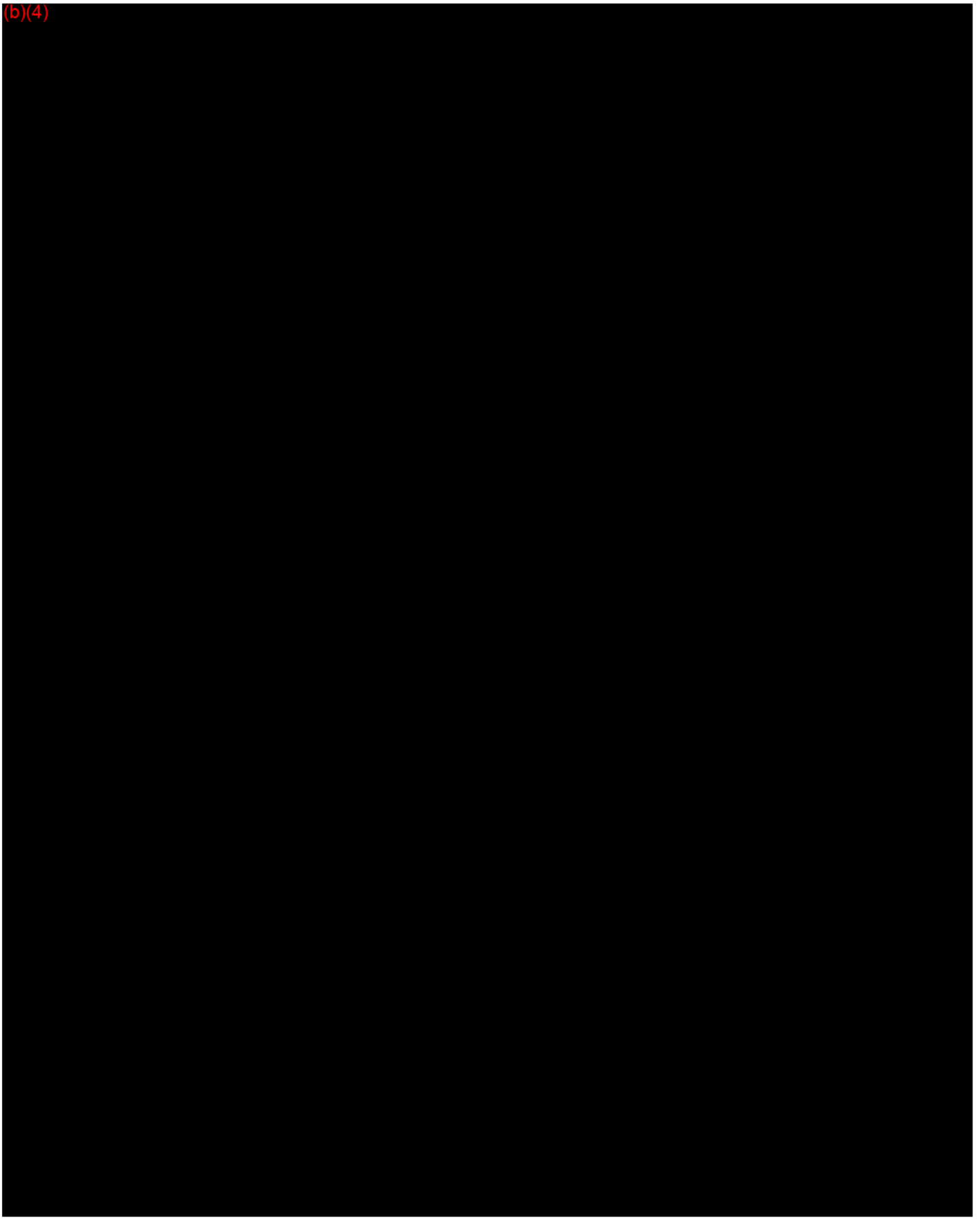
(b)(4)



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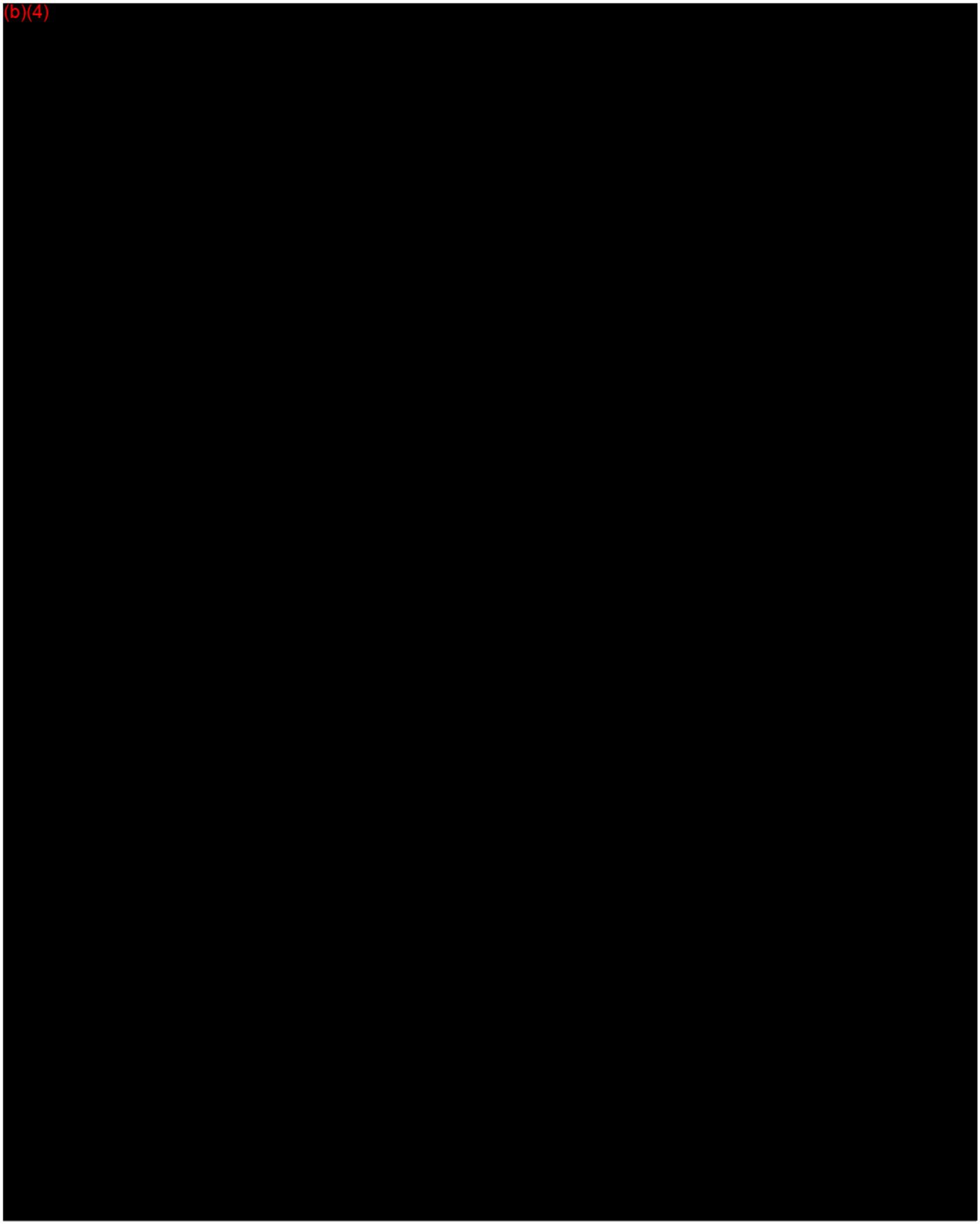
(b)(4)



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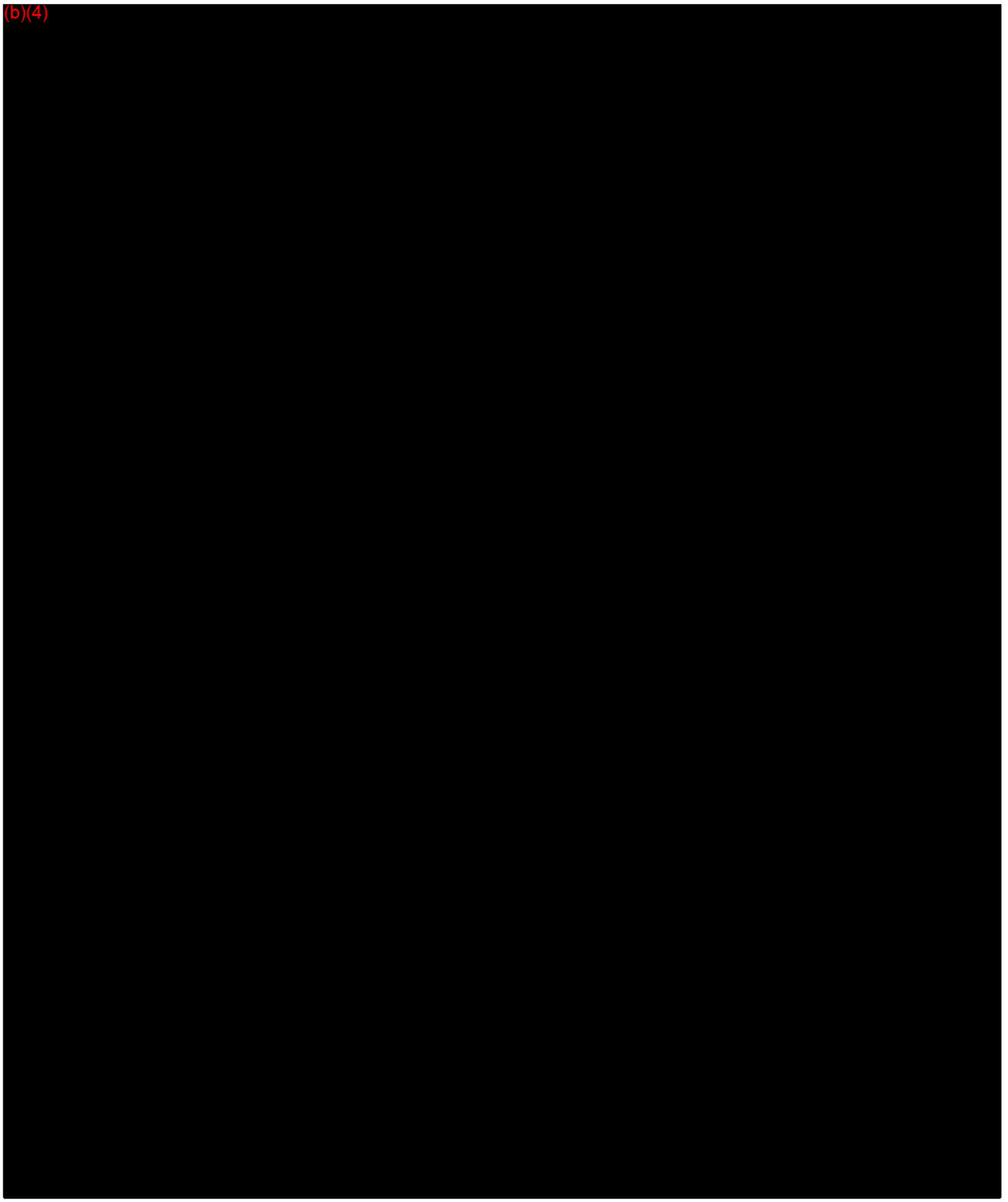

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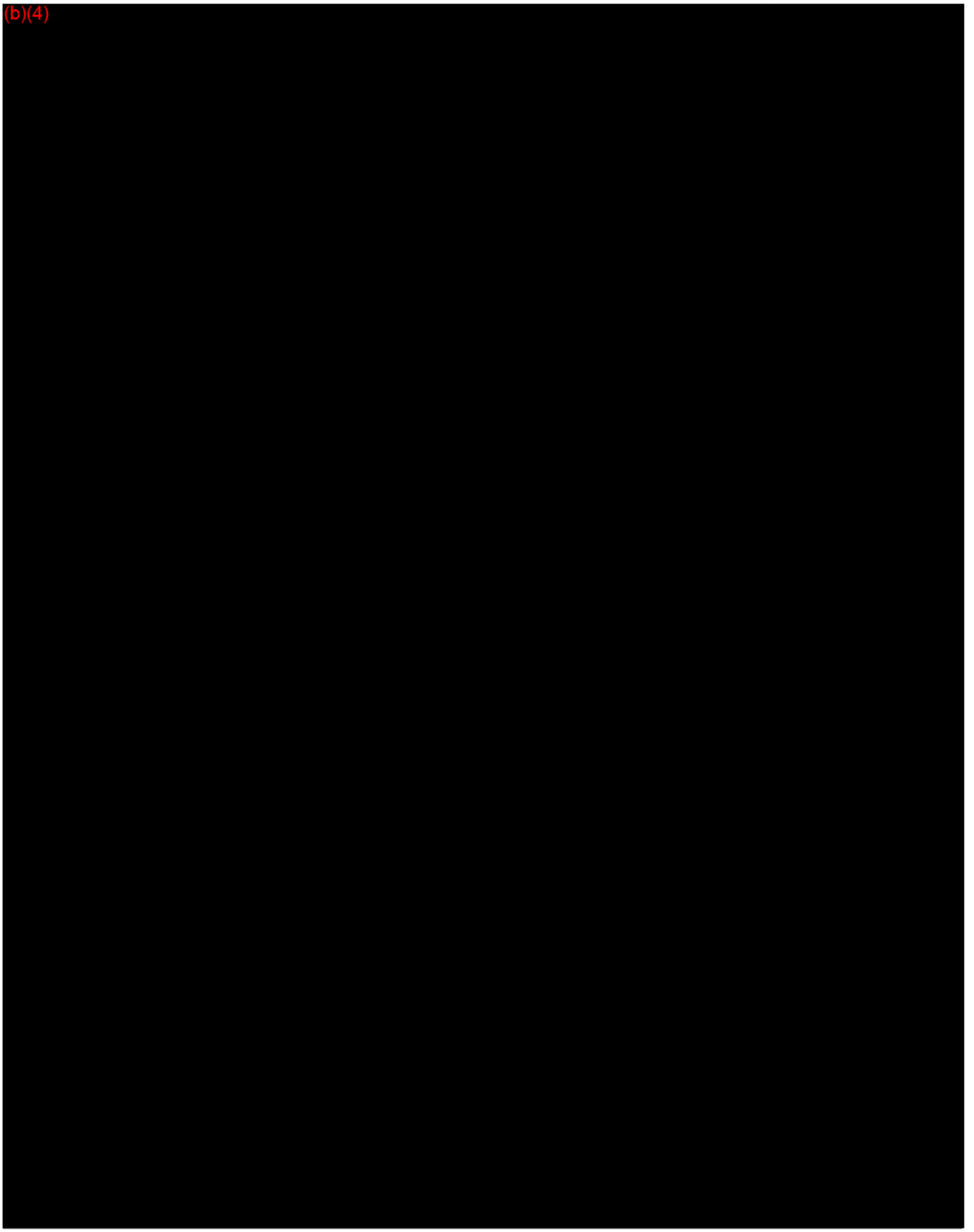
(b)(4)



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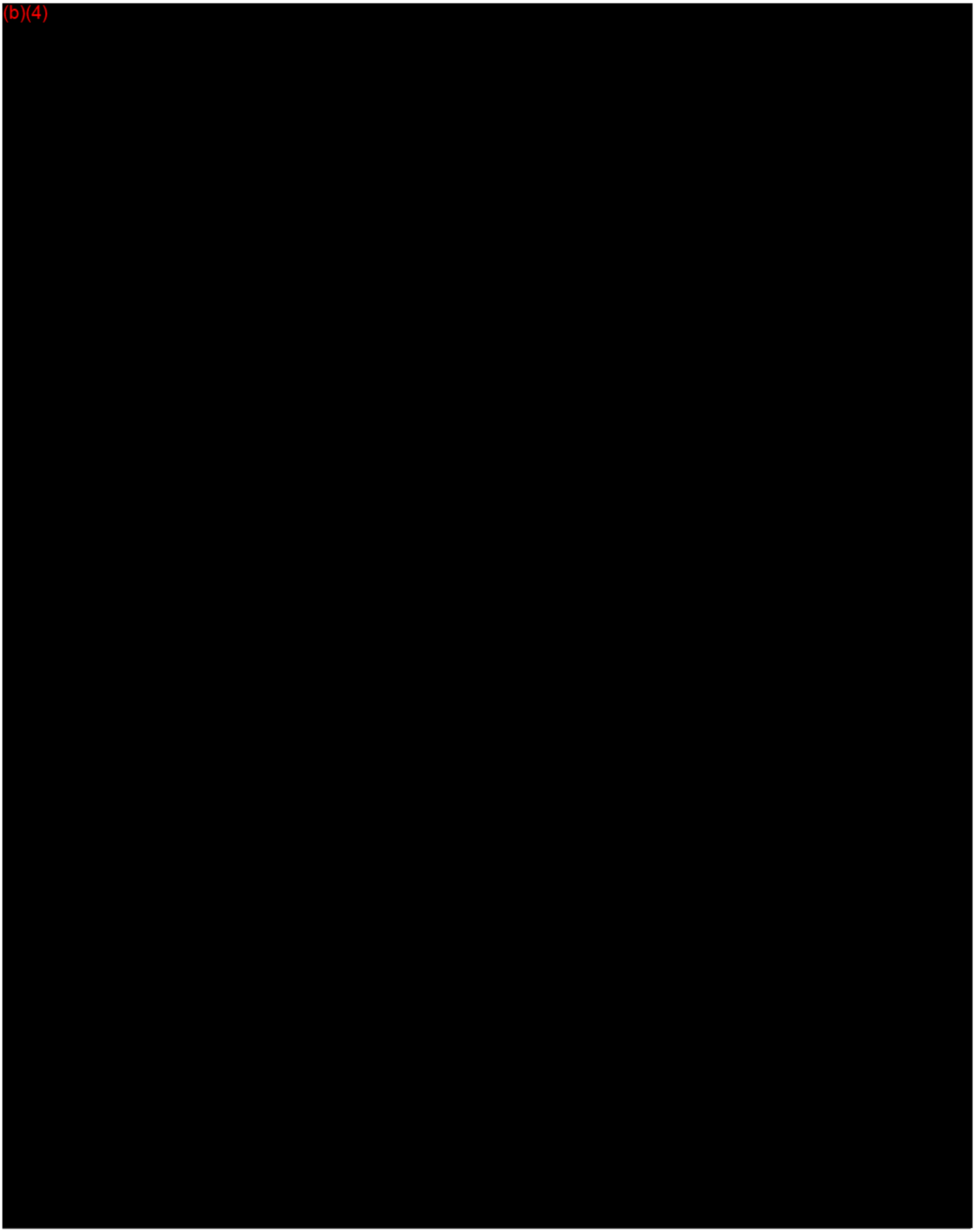

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Records processed under FOIA Request 2016-8070; Released by CDRH on 10/5/2017

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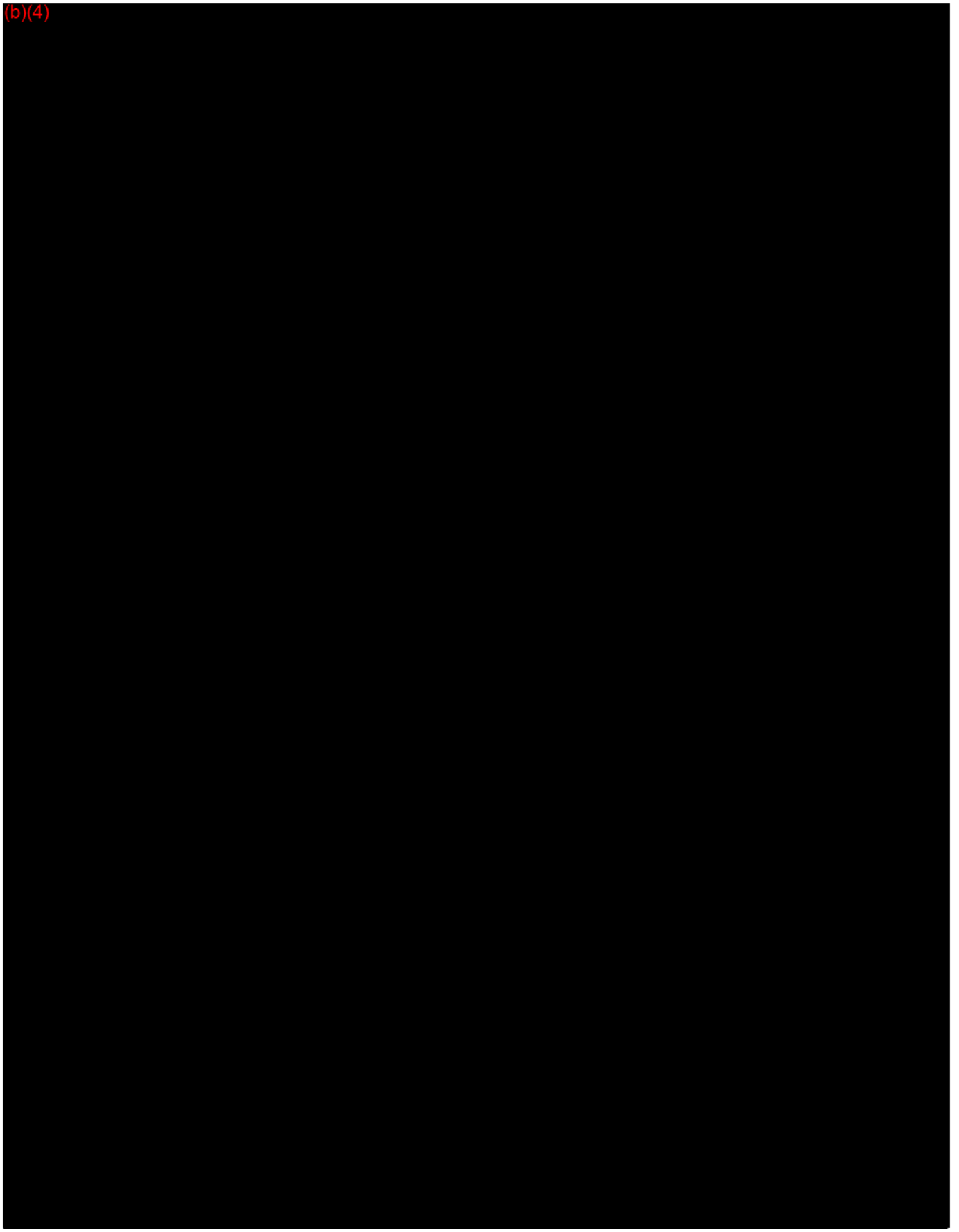
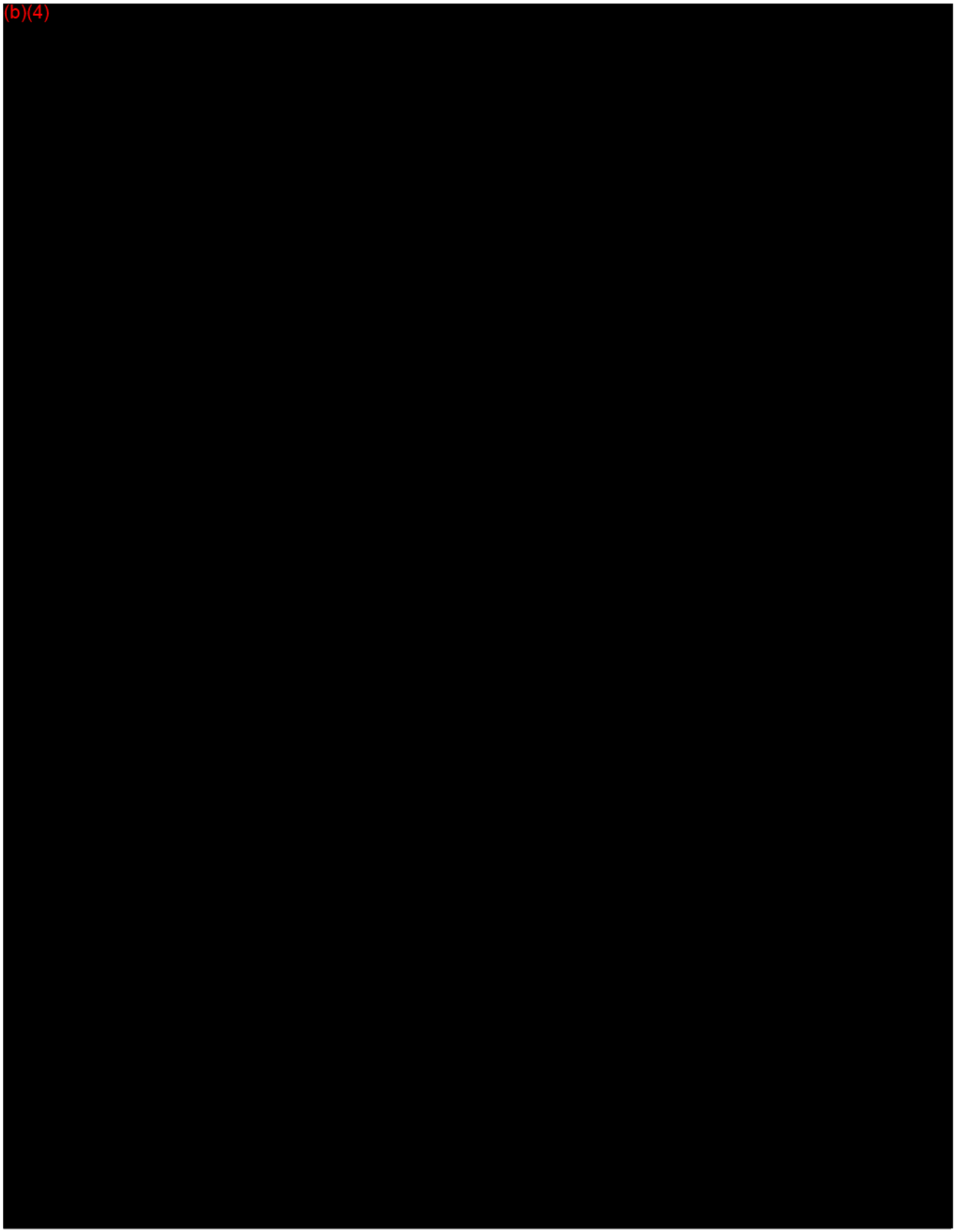


Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2016-8070; Released by CDRH on 10/5/2017

(b)(4)



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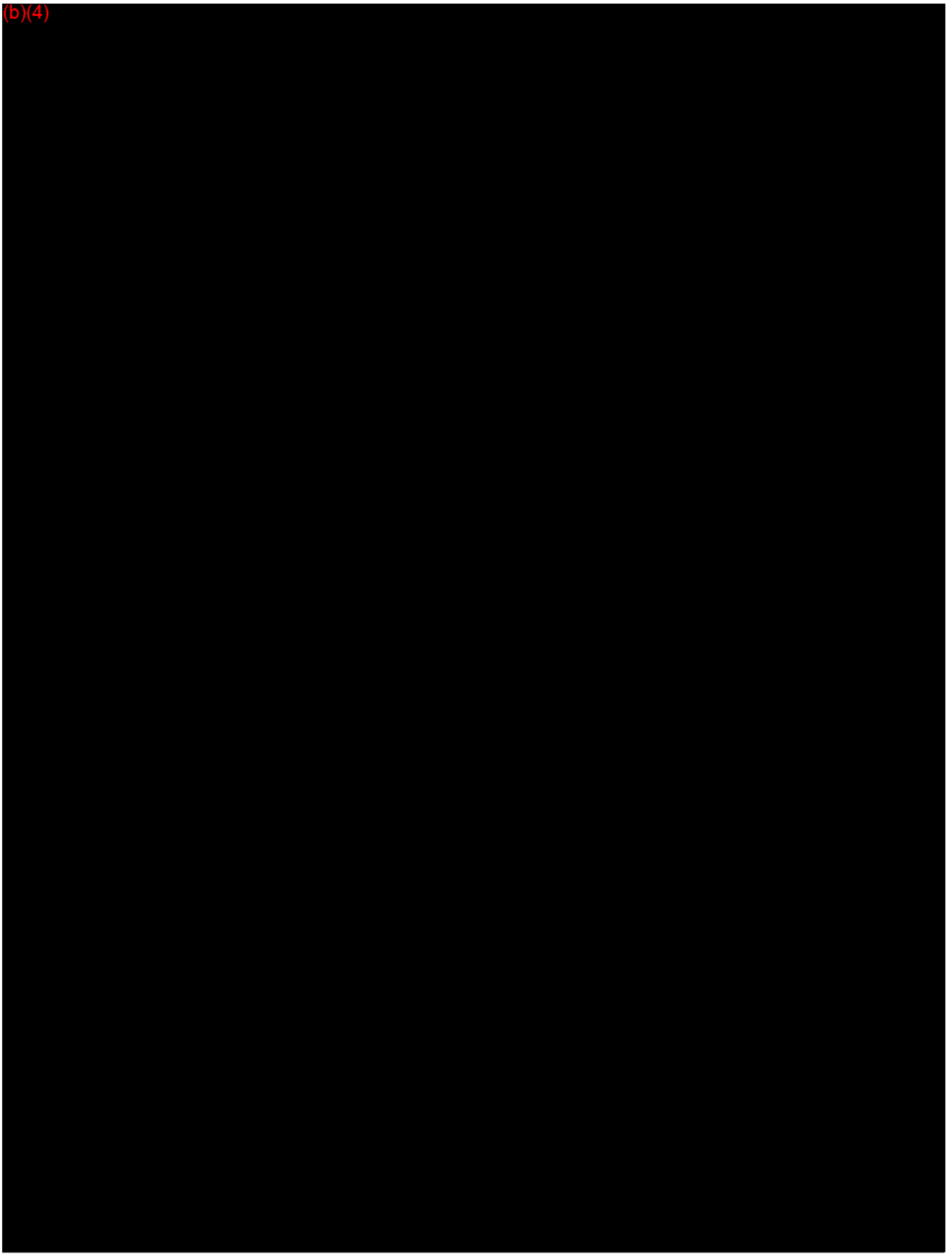
(b)(4)

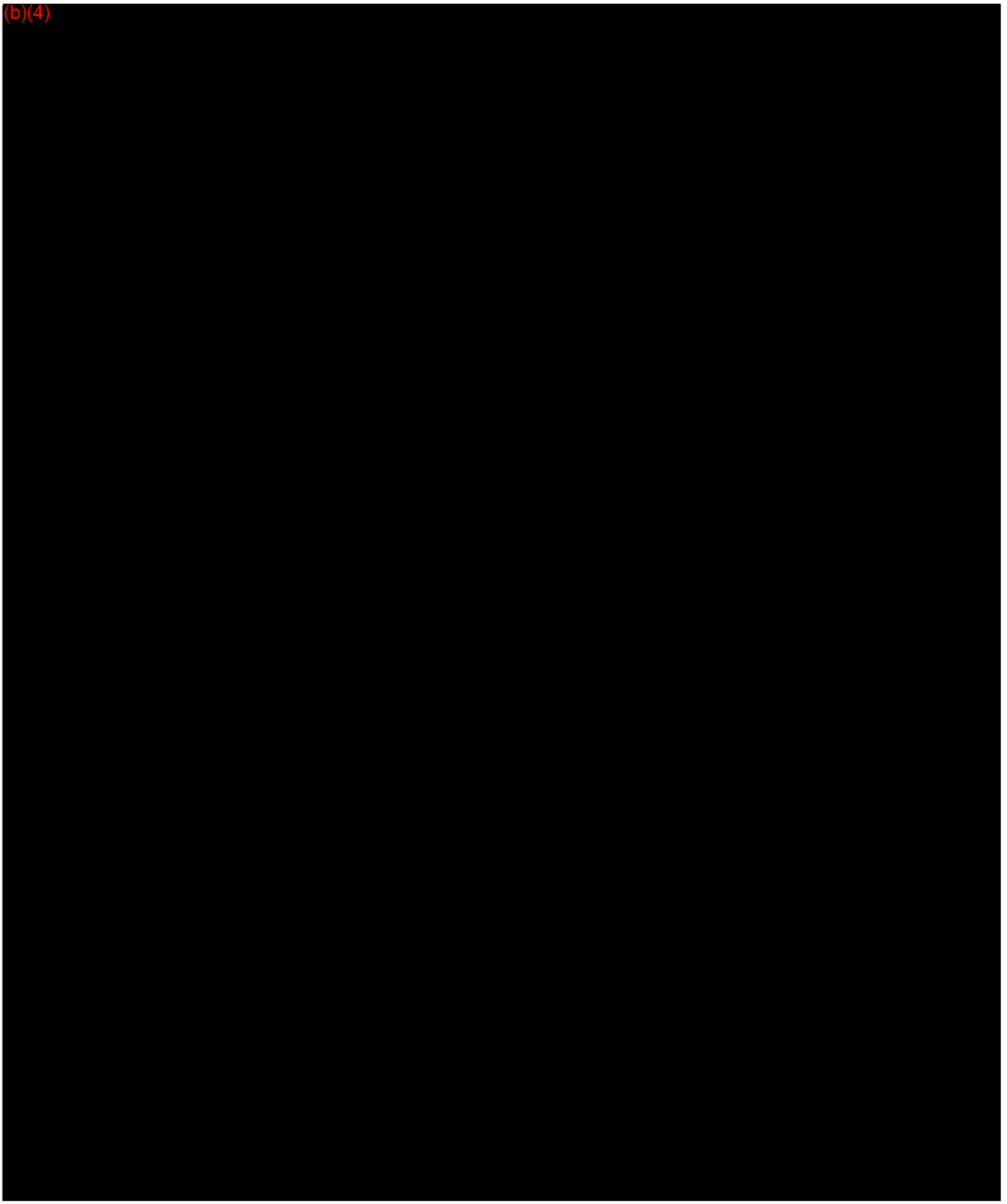


Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2016-8070; Released by CDRH on 10/5/2017

XVI. April 23 Interactive Deficiencies

(b)(4)



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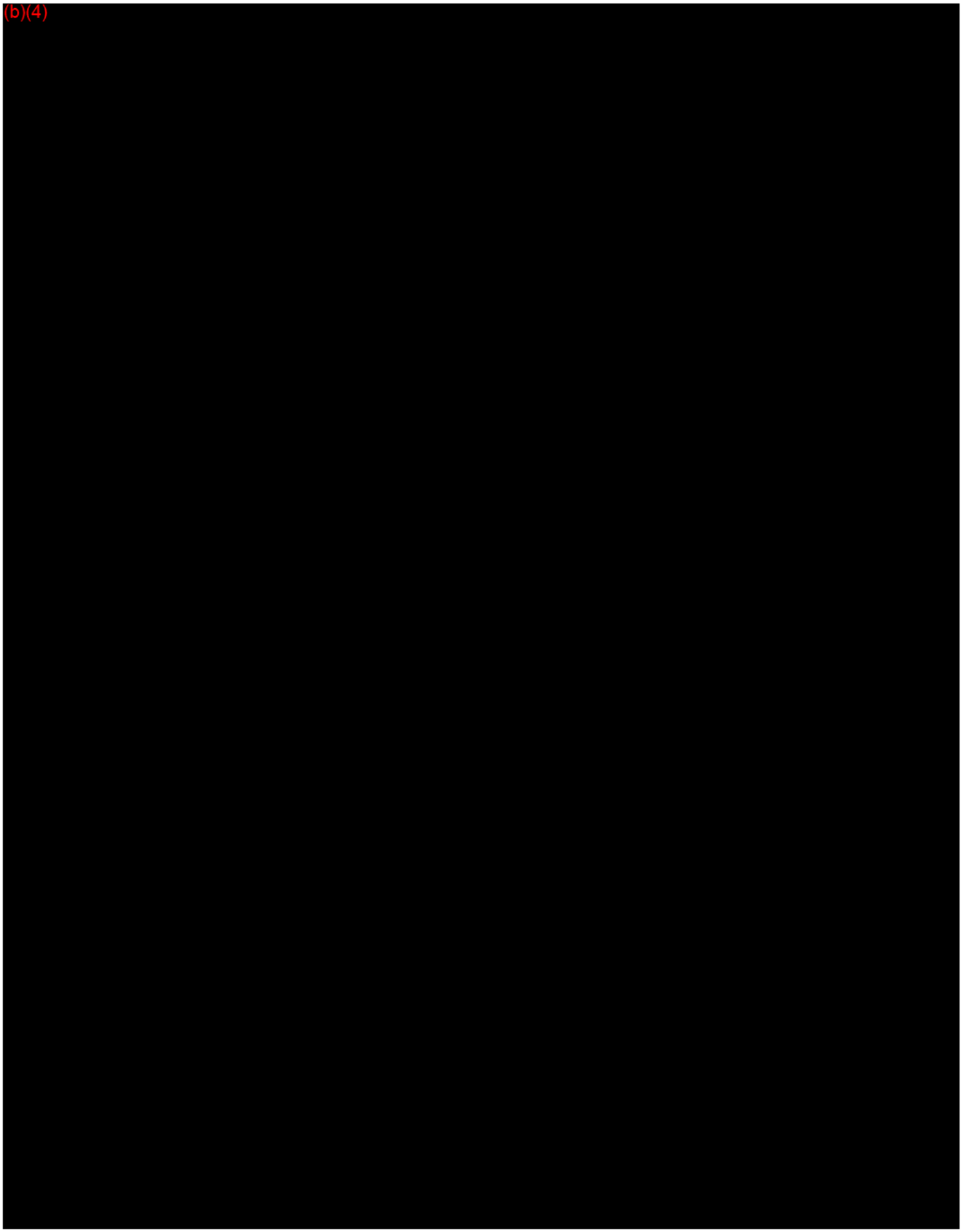
Records processed under FOIA Request 2016-8070; Released by CDRH on 10/5/2017

(b)(4)



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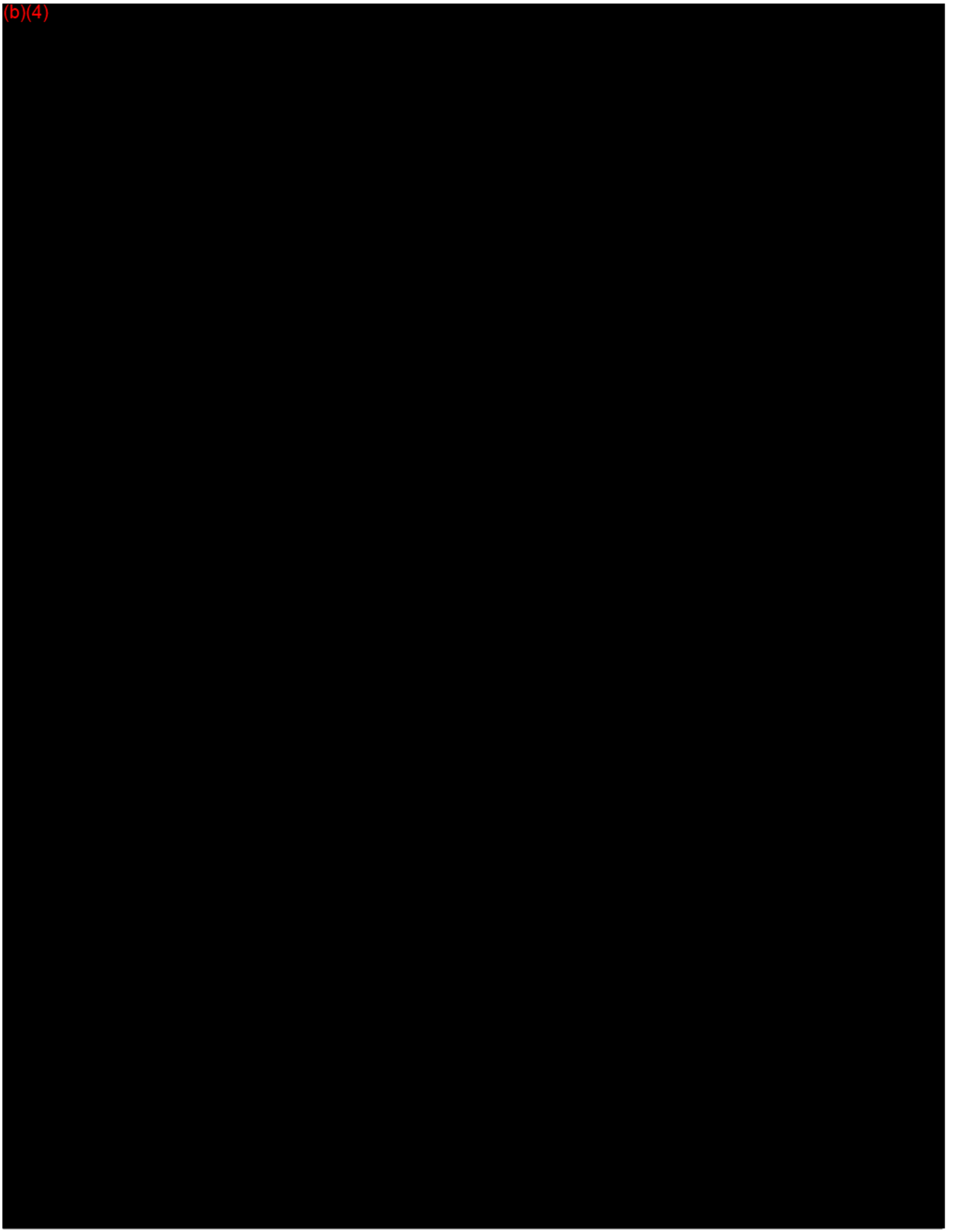
Records processed under FOIA Request 2016-8070; Released by CDRH on 10/5/2017

(b)(4)



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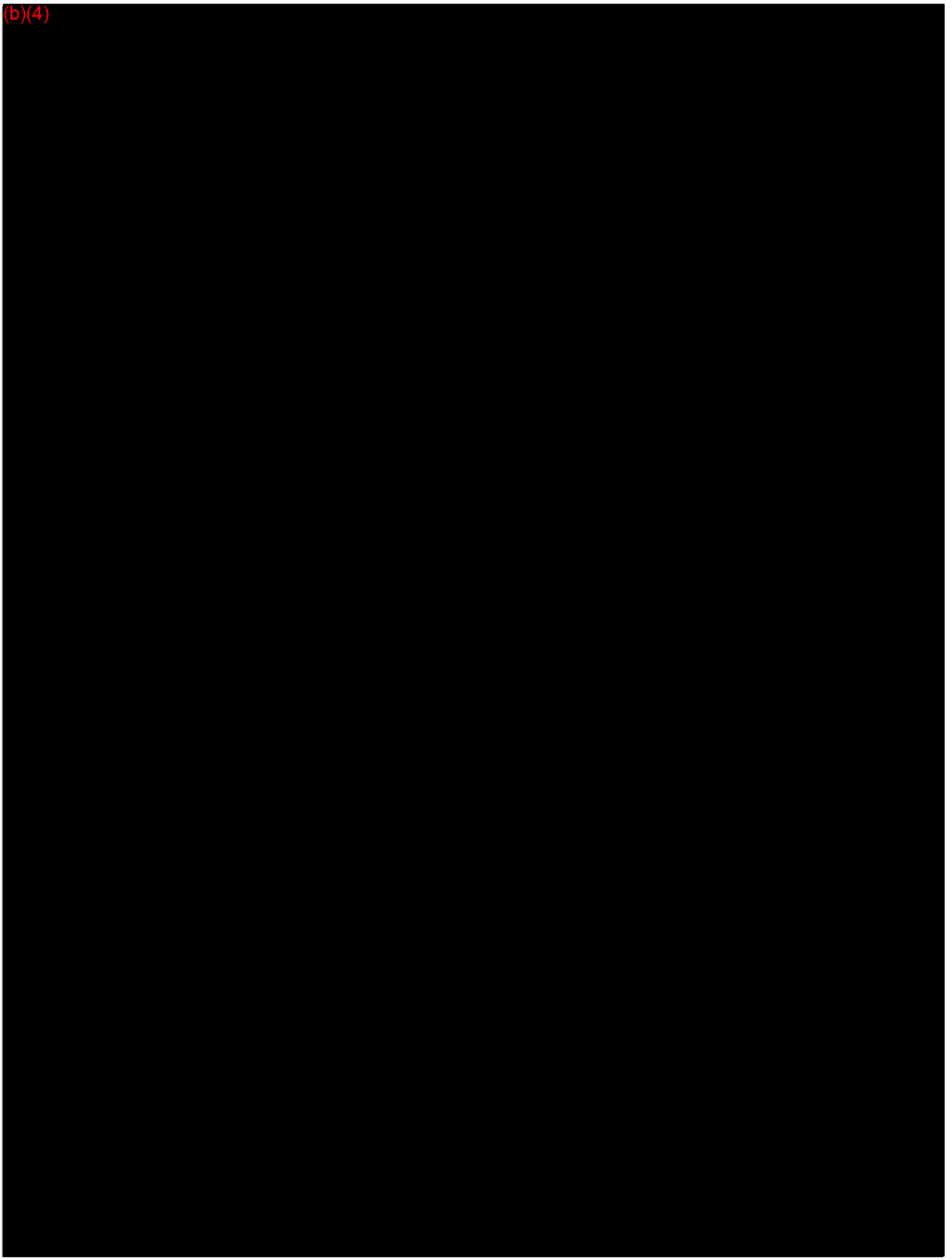
(b)(4)



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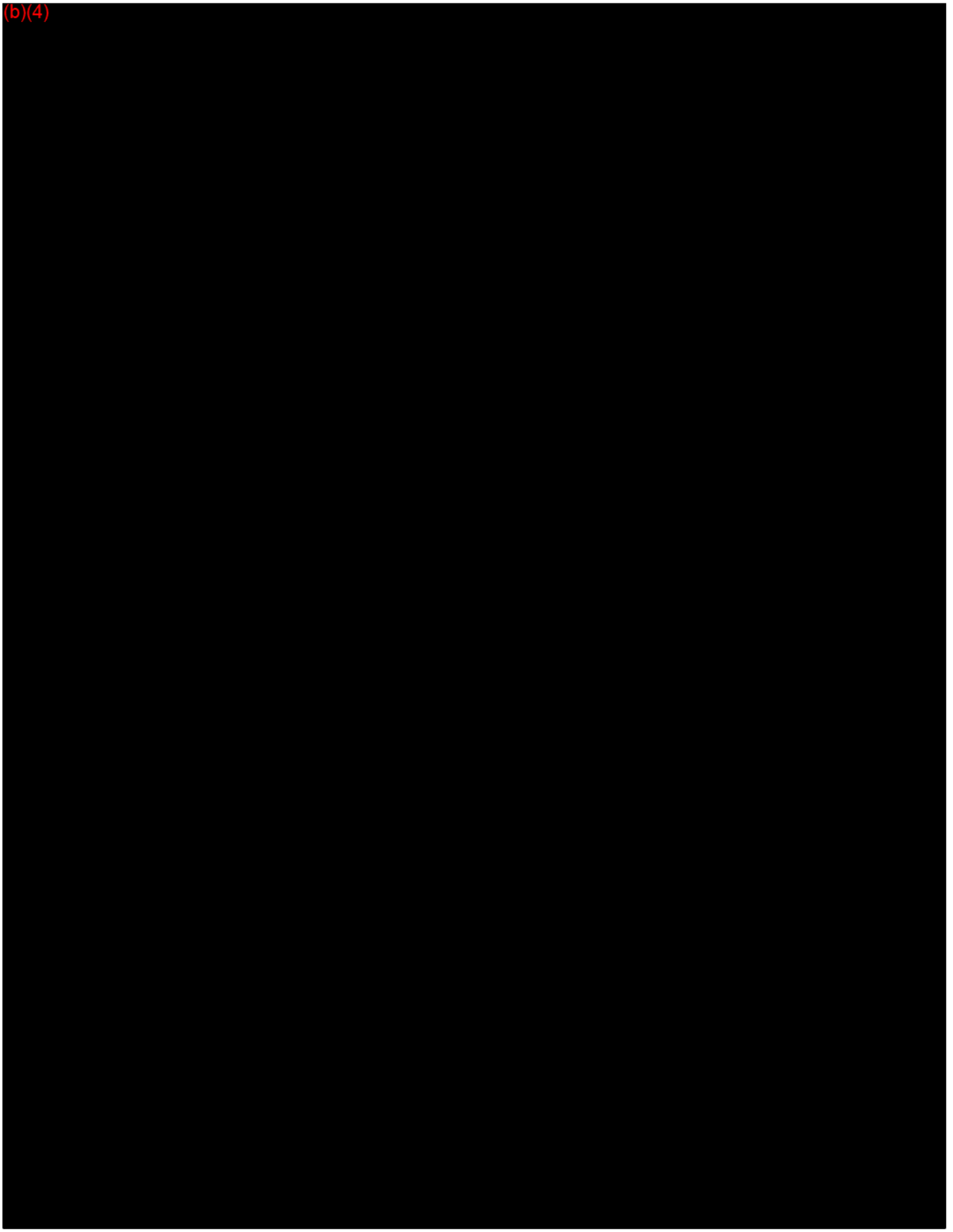

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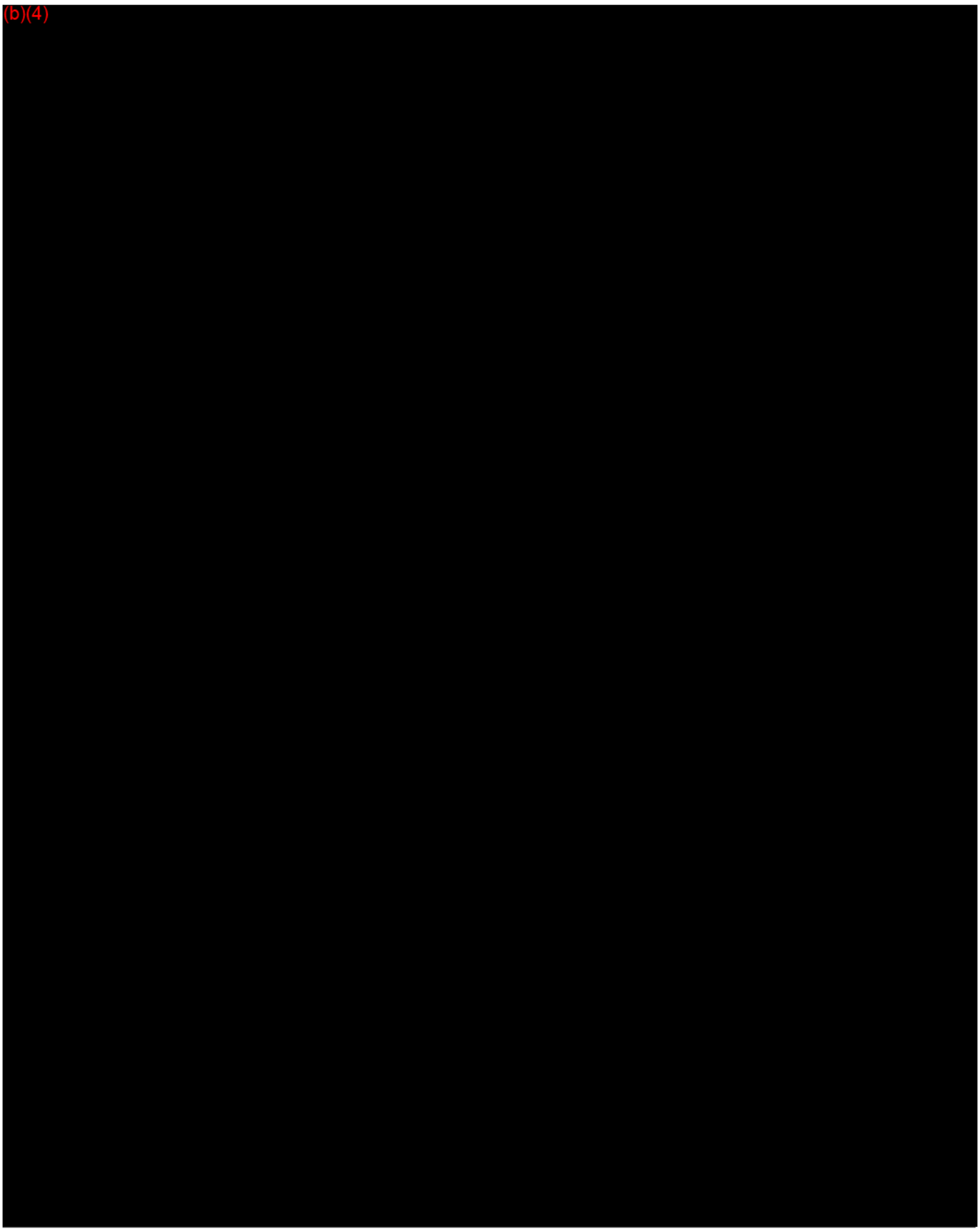

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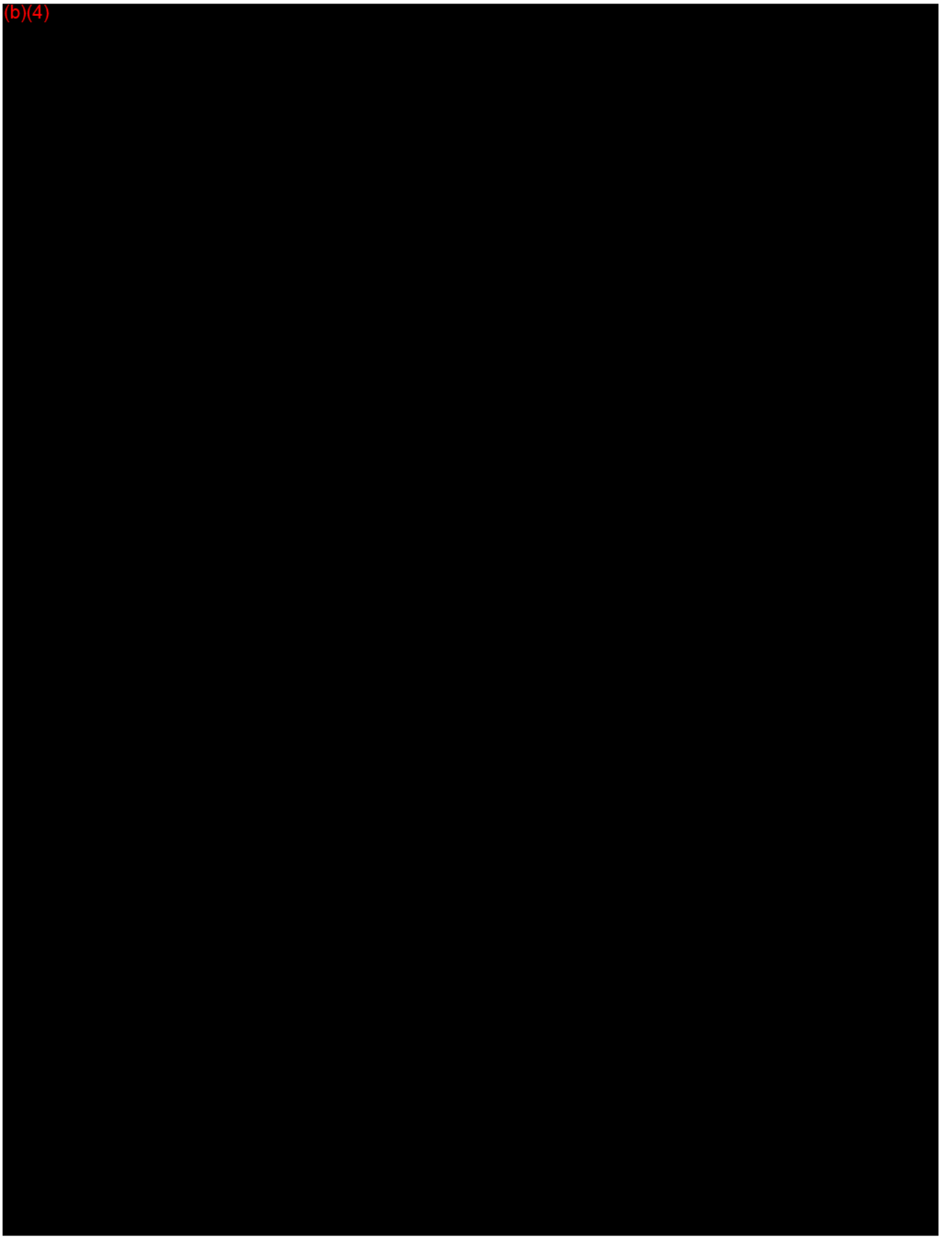

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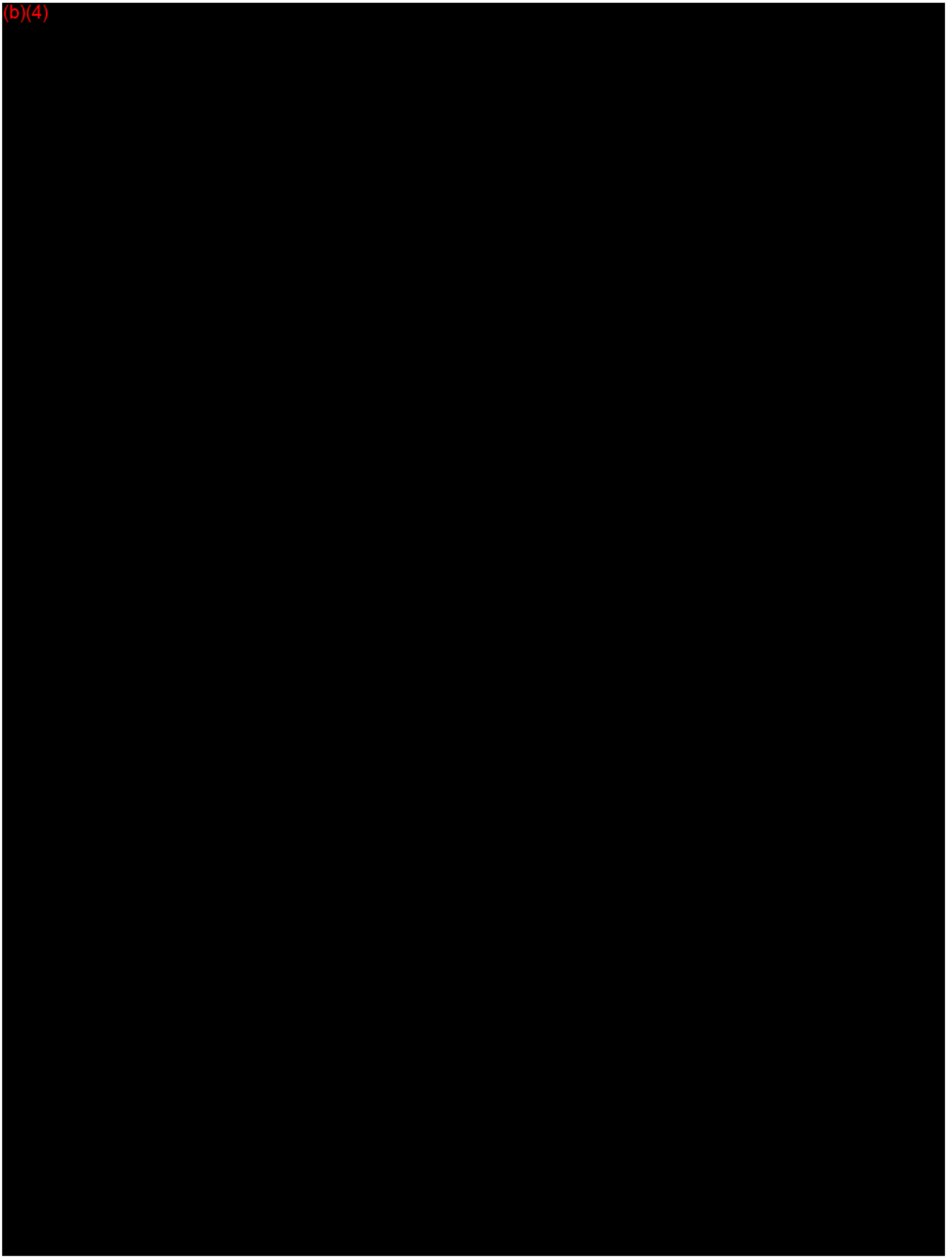

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Records processed under FOIA Request 2016-8070; Released by CDRH on 10/5/2017

(b)(4)

XVII. June 22 Interactive Deficiencies

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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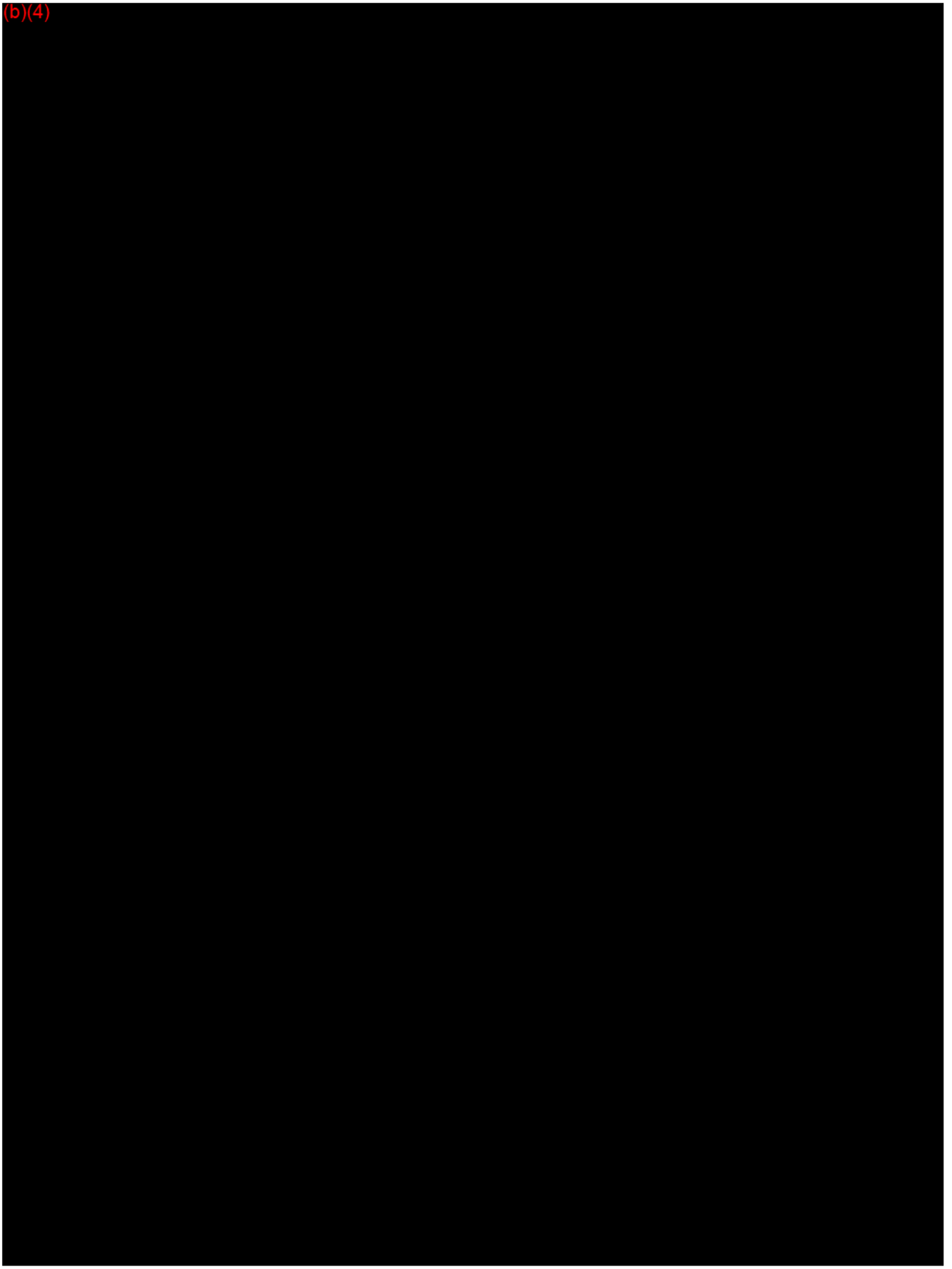

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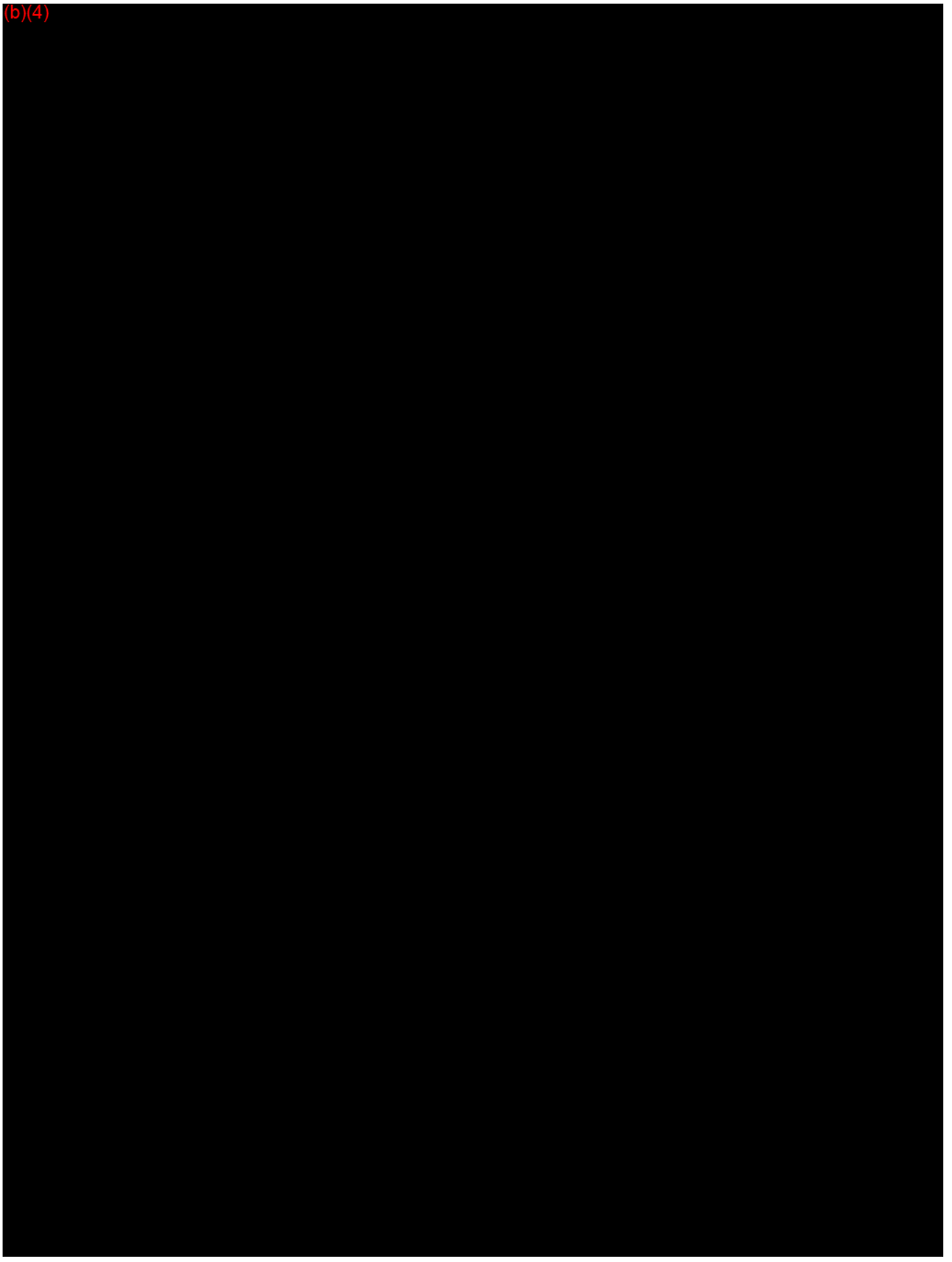

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(b)(4)

[redacted]

XVIII. Contact History

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2016-8070; Released by CDRH on 10/5/2017

(b)(4)

[redacted]

Digital Signature Concurrence Table	
Reviewer Sign-Off	Andrew I. Steen -S 2016.08.18 16:01:08 -04'00'

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2016-8070; Released by CDRH on 10/5/2017

Online Implant Libraries Provider List as of May 25, 2016

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2016-8070; Released by CDRH on 10/5/2017

Implant libraries for the 3Shape Dental System™

March, 2016

Implant systems / Providers of implant solutions	Nobel Biocare	Biomet 3i	Straumann	Zimmer Dental	DENTSPLY - Astra Tech	DENTSPLY - Friadent	CAMLOG	Other systems	1- Piece (Titanium)	1- Piece (Zirconia)	2- Piece (Ti base + Zr abutment)	Implant Bars & Bridges	Digital implant models	Providers' milling center	Local milling by 3rd party	Blanks with pre-milled interface (for 1-piece abutment)	Titanium bases (for 2-piece abutments)	Intraoral Scan bodies	Digital model analogs	Multi-unit abutments	Comments
3dental (ES) www.3dental.es	✓	✓	✓	✓	✓	✓	✓	• BioCemp • Sweden & Martina • OTNA	X	X		X	X	X					X		
AB-Dental (IL) www.ab-dent.com				✓				• M.I.S. Apex Bio	X		X		X			X	X	X	X	X	• CE
Abutments4life (DE) www.abutments4life.de	✓	✓	✓	✓	✓	✓	✓	• Biohorizons • Dekim • DK-Implant • and more	X		X	X	X	X	X	X	X	X	X		• CE
Alpha-Bio Tec (IL) www.alpha-bio.net								• Alpha Bio Tec	X		X	X	X	X	X	X	X				• CE
Argen (US)* shapeR reseller www.argen.com	✓	✓	✓	✓	✓	✓	✓		X		X			X		X	X	X	X		• CE, FDA
ATLANTIS™ (SE)* shapeR reseller www.dentsplyimplants.com	✓	✓	✓	✓	✓	✓	✓	• DENTSPLY ANKYLOS, XiVE®, FRIALIT™ • Keystone Dental • Biohorizons	X	X				X									• CE, FDA
BEGO (DE) shapeR reseller www.bego.com	✓	✓	✓	✓	✓	✓	✓	• BEGO Implant Systems • and more	X	X	X	X		X			X	X	X			• CE • CE-labeled positioning screws
BioComp (NL) www.biocomp.eu								• BioComp	X		X			X	X	X	X	X	X		• CE, ISO
Bicon (US)* www.bicon.com								• Bicon	X		X	X			X			X			• FDA, CE, Health Canada
Biodenta (CH) shapeR reseller www.biodenta.com	✓	✓	✓	✓	✓	✓	✓	• Biocanta	X		X	X		X				X	X		• CE pending
Biomet (US)* shapeR reseller www.biomet.com	✓	✓	✓						X	X	X			X				X			• CE, FDA • provide healing solutions
Biotech Dental (FR) www.biotech-dental.com								• Biotech			X		X		X		X	X	X	X	• CE
BlueSkyBio (US)* blueskybio.com	✓		✓	✓	✓			• BlueSkyBio	X		X				X	X	X			X	• FDA, CE, Health Canada
Bredent (DE) www.bredent.com								• Sky			X				X		X	X	X		• CE
CADBLU (US) shapeR reseller www.cadbludental.com	✓	✓	✓	✓	✓	✓		• Bio Horizons • M.I.S. Implants	X		X	X	X	X				X	X		
CADStar (AT) www.cadstar.dental	✓	✓	✓	✓	✓	✓	✓	BREDENT, DENTSPLY, XiVE, CONELOG, MEDENTIS ICX, NEOSS, FROMMAL, SIC, ALPHATECH and others	X		X	X		X				X		X	X	• CE (0297) • ISO 13485 • Certificate Directive 93-42-EEC • Ukonex III
CAMLOG (CH)* www.camlog.com							✓	• CONELOG • ISY	X		X	X		X	X			X			• FDA
CAP (US)* shapeR reseller www.cap-us.com	✓	✓	✓	✓	✓	✓			X		X	X	X	X	X	X	X		X		• FDA
CMC (US) shapeR reseller www.custom-milling.com	✓	✓	✓	✓	✓	✓	✓	• BioHorizons • Osseotem • Lifecore • Mega-Lock-, Neoss	X	X	X	X		X				X			• CE
Conmet (RU) conmet.ru								• Conmet	X		X		X				X	X	X		• Dental Implants have a bioactive surface. • CE, ISO 9001 and ISO 13485

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1060 Copenhagen, Denmark
Tel: +45 7027 2620

3Shape Asia
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Tel: +86 21 5835 2281

3Shape Latin America
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Oficina 401
110221 Bogotá, Colombia
Tel: +57 1691 9508

3Shape North America
Somerset Hills Corporate Center
10 Independence Boulevard, Suite 150
Warren, New Jersey 07059, USA
Tel: +1 (908) 867 0144

More information at
www.3Shape.com
www.3shapedental.com
info@3shape.com

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2016-8070; Released by CDRH on 10/5/2017

3shape

Implant systems / Providers of implant solutions	Implant systems: Nobel Biocare®	Biomet 3i®	Straumann®	Zimmer Dental®	DENTSPLY - Astra Tech®	DENTSPLY - Friadent®	CAMLOG®	Other systems	Implant Solutions: 1-Piece (Titanium)	1-Piece (Zirconia)	2-Piece (Ti base + Zr abutment)	Implant Bars & Bridges	Digital implant models	Manu-facturing: Providers milling center	Local milling by 3rd party	Consumables (for local use): Blanks with pre-milled interface (for 1-piece abutment)	Titanium bases (for 2-piece abutments)	Intraoral Scan bodies	Digital model analogs	Multi-unit abutments	Additional info: Comments
Conexão Sistemas de Protese (BR) www.conexao.com.br	👍		👍					- Conexão Sistema de Prótese	X	X	X			X			X	X	X	X	- ANVISA, CE
Core3D International (NL)* (3shape reseller) www.core3dcenters.com	👍	👍	👍	👍	👍	👍	👍	- Avinent - BioComp - BioHorizons - MIS Implants - and many more	X		X	X	X	X	X	X	X	X	X		- CE, FDA, Health Canada, TGA (AUS), Taiwan regulatory - MHLW Ministry of Health, Labour and Welfare (JP)
Cortex Dental (IL)* www.cortex-dental.com				👍				- Cortex Dental			X	X			X	X	X	X	X		- CE, FDA
Creodent (US)* www.Creomc.com	👍	👍	👍	👍	👍			- Hiossen	X		X	X		X			X				- FDA
C-Tech Implant (IT) www.c-tech-implant.com								- C-Tech implant	X		X	X			X		X			X	- CE
Degudent (DE) (3shape reseller) www.degudent.com	👍	👍	👍	👍	👍	👍	👍	- Medentika	X	X	X			X	X		X				
Dental Consulting (DE) www.gadau-consulting.com	👍		👍	👍	👍	👍	👍	- ICX-Medentis - Osstem	X		X	X	X	X	X	X	X	X	X		- CE
Dentaurum Implants (DE) www.dentaurum-implants.de								- Dentaurum Implants			X				X		X	X			- CE, PAL
Dentegris Deutschland (DE) www.dentegris.de								- Dentegris Implants			X	X			X		X				
Dentium (KR)* www.dentium.com								- Implantium - SuperLine - SimpleLine II NR Line Custom Abutment	X	X	X	X		X	X						- FDA, CE, CFDA, PMDA, TFDA, GOST
Dentsply-Friadent (DE) (3shape reseller) www.dentsply-friadent.com						👍		- Xive - Ankylos	X	X	X			X							- CE
DESS (ES) www.dess-abutments.com	👍	👍	👍	👍	👍	👍		- BioHorizons - Ankylos - Mis	X		X	X		X	X		X	X		X	- CE - ISO 13485 - ISO 9001 - Health Canada pending
DIO-Implants (KR) (3shape reseller) www.dioimplant.com	👍							- DIO Implants	X	X	X	X		X	X						- CE, KFDA, SFDA
Dynamic Abutment Solutions (ES) www.dynamicabutment.com	👍	👍	👍	👍	👍	👍	👍	- Osstem - MIS Implants - Megagen - Biohorizons - and more	X		X	X		X	X	X	X			X	- CE, ISO 9001, ISO13485, CMDCAS
Easy Implant (FR) www.easyimplant.com									X		X	X		X			X			X	- CE
Elos Medtech Pinol (DK) www.elosmedtech.com	👍	👍	👍	👍	👍	👍	👍	- Neoss	X		X	X	X	X	X	X		X	X		- CE
Euroteknika (FR)* www.euroteknika.com	👍	👍	👍	👍	👍			- Anthogyr - Biotech - Easy Implant - MIS Implants - and more	X		X	X	X	X		X	X	X	X	X	- CE, FDA
GC Advanced Technologies (US) (3shape reseller) www.gc-at.com	👍	👍	👍	👍	👍			- BioHorizons - Sybron	X	X	X			X							
Glidewell (US)* (3shape reseller) www.glidewelldental.com	👍	👍	👍	👍	👍	👍	👍	- Prismatik - DentalCraft - Keystone Dental - Neoss	X	X	X	X	X	X			X	X	X		- CE pending, FDA
Green DenTech / Denracle (TW)* www.denracle.com	👍	👍	👍	👍	👍	👍		- Biohorizons - Dentium - Osstem and more	X							X	X				- TFDA, CE, FDA Class II (Analog Screw)

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Implant systems / Providers of implant solutions	Nobel Biocare®	Biomet 3i®	Straumann®	Zimmer Dental®	DENTSPLY - Astra Tech®	DENTSPLY - Friadent®	CAMLOG®	Other systems	Implant Solutions: 1- Piece (Titanium)	1- Piece (Zirconia)	2- Piece (Ti base + Zr abutment)	Implant Bars & Bridges	Digital Implant models	Manu-facturing: Provides milling center	Manu-facturing: Local milling by 3rd party	Consumables (for local use): Blanks with pre-milled interface (for 1-piece abutment)	Consumables: Titanium bases (for 2-piece abutments)	Consumables: Intraoral Scan bodies	Consumables: Digital model analogs	Consumables: Multi-unit abutments	Additional Info: Comments
Heraeus Kulzer (DE) shape® vendor www.heraeus.com	✓	✓	✓	✓	✓	✓	✓	- Thommen	X	X	X		X	X							
Implant Direct (US)* www.implantdirect.com/us/us-en/ct	✓			✓				- Bio Horizons	X			X	X	X					X		- FDA, CE, Health Canada
Intra-Lock International (US)* www.intra-lock.com								- INTRA-LOCK	X		X	X				X	X	X	X	X	- FDA, CE, Health Canada
Ivoclar Wieland (DE) shape® vendor www.wieland-dental.de	✓	✓	✓	✓	✓	✓	✓	- Dentaurum implants	X		X	X		X	X		X				
Lasak (CZ) www.lasak.com	✓		✓					- Lasak Sigma - Lasak Implantmed	X	X	X	X				X	X			X	- CE - ISO 13485 - ISO 9001
Lastruttura (IT) shape® vendor www.lastruttura.it	✓	✓	✓	✓	✓	✓		- Sweden & Martina - Magnum - Friadent - and many more	X	X		X	X	X			X	X	X		- CE SIMIT
Medentika (DE) www.medentika.de	✓	✓	✓	✓	✓	✓	✓	- Medentika M-implant	X		X	X		X	X	X	X	X			- CE
Medentis Medical (DE) www.medentis.de	✓		✓			✓		- CSX Implant	X		X	X	X	X			X				- CE
Medical Instinct (DE) www.medical-instinct.de								- Medical Instinct	X	X	X	X			X	X	X	X	X	X	- CE
Medical Production (FR) www.medical-production.eu		✓	✓	✓	✓	✓		- Eurotekhna	X		X	X	X		X	X	X	X			- CE DIN 69 - ISO 9001 - ISO 13485
MegaGen Implant (KR)* www.limegaen.com								- Anyridge Internal - Anyone Internal - M Internal - Octa Level			X		X	X	X		X	X	X		- FDA - CE - KFDA
MIS Implants Technology (IL)* www.mis-implants.com								- M IS Implants	X		X			X	X	X	X	X		X	- CE, FDA
Neodent (BR) www.neodent.com.br	✓		✓					- Neodent Implant Systems	X	X	X	X			X			X			
Neoss (UK)* www.neoss.com	✓	✓	✓	✓	✓	✓		- Neoss	X		X	X	X	X	X	X	X	X	X	X	- CE, FDA
Nobel Biocare (CH)* www.nobelbiocare.com	✓	✓	✓	✓	✓				X	X	X			X							- CE, FDA
NT Trading (DE)* www.nt-trading.com	✓	✓	✓	✓	✓	✓	✓	- Thommen - Sweden & Martina - BEGO	X		X	X		X	X	X	X	X	X		- CE, FDA, CMDCAS, GOST R, TGC - Bravo Certification
Phibo (ES) shape® vendor www.phibo.com	✓	✓	✓	✓	✓	✓	✓	- BTI - Sweden&Martina - M IS Implants - and many more	X	X	X	X	X	X				X	X		- CE - ISO 13485 - ISO 9001
Prowital (DE) www.prowital.de								- Prowital			X				X		X	X	X		- CE - EN ISO 9001:V8/2008 - EN ISO-13485-2003/AC2009 - Certificate Directive 93-42 EWG
Ritter Implants (DE) www.ritterimplants.com			✓					- Ape-Bio Tec - M IS Implants	X			X		X			X	X	X		- CE
Straumann (CH)* www.straumann.com			✓						X	X	X			X	X		X	X	X		- CE, FDA

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Implant systems / Providers of implant solutions	Implant systems								Implant Solutions					Manu-facturing		Consumables (for local use)					Additional Info
	Nobel Biocare*	Biomet 3i*	Straumann*	Zimmer Dental*	DENTSPLY - Astra Tech*	DENTSPLY - Friadent*	CAMLOG*	Other systems	1- Piece (Titanium)	1- Piece (Zirconia)	2- Piece (Ti base + Zr abutment)	Implant Bars & Bridges	Digital implant models	Providers milling center	Local milling by 3rd party	Blanks with pre-milled interface (for 1-piece abutment)	Titanium bases (for 2-piece abutments)	Intraoral Scan bodies	Digital model analogs	Multi-unit abutments	Comments
Sweden&Martina S.p.A (IT) www.sweden-martina.com								- Sweden&Martina	X	X	X	X	X	X			X	X	X	X	
Target3D (USA) www.target3d.com	👍	👍	👍	👍	👍	👍	👍	- Osstem - BioHorizons - MIS-implants - and more	X	X	X	X	X	X	X	X	X	X	X	X	- CE
Thommen Medical (CH)* www.thommenmedical.com								- Thommen			X	X					X	X			- CE, FDA
TRI Implants (CH) www.tri-implants.com								- TRI Implants			X						X	X	X		
Vulcan Custom Dental (US)* www.vulcandental.com				👍				- BioHorizons	X		X	X	X	X	X	X	X	X	X	X	- FDA
Zfx (DE) www.zfx-dental.com	👍	👍	👍	👍	👍	👍	👍	- Megagen - Thommen Medical - Microdent - Osstem - and more	X	X	X	X	X	X	X		X		X		- CE
Zimmer Dental (US)* www.zimmerdental.com				👍					X	X				X							- FDA - CE

Please note:

- Only Implant Libraries marked with an asterisk (*) are approved for use in the United States. See the full list of approved Implant Systems in the Appendix.
- The above information is solely provided by third parties, and 3Shape assumes no responsibility for its accuracy or completeness.

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Appendix: Regulatory Declaration

The following implant systems have been approved for use in the USA by the FDA. Notice, the approvals apply only for the implant systems and not for the implant libraries above. For further information please refer to the 510(k) numbers listed below with the implant systems.

AB-Dental	
A.B. Dental Implant System	K132125
Alpha - Bio Tec.	
Alpha-Bio Tec®	K063364
Anthogyr	
AXIOM® REG	K131066
AXIOM® Dental Implant System	K101913
AXIOM® 2.8	K141450
DYNA Dental	
DYNA Implant Design	K930868
AVINENT	
AVINENT Dental Implant System	K121873
ATLANTIS	
ATLANTIS ABUTMENT AND ATLANTIS ABUTMENT SCREW	K981858
BTI	
BTI Dental Implant 5.5-6.5	K091387
BTI Dental Implant Tiny® 3.0	K092112
BTI Internal Dental Implant System	K053355
BEGO Implant Systems	
BEGO Semados® S-Line	K090716
Bicon	
Bicon Dental Implant System 3.0mm	K101849
Bicon Implants with a 2.5mm Internal Connection	K092035
Bicon 5.0 x 5.0mm and 6.0 x 5.0 dental implants	K073368
Bicon the 5.0 x 6.0mm dental implant	K062044
Bicon 4.5.* 6.0mm and 6.0*6.0 mm dental implants	K050712
Bicon Orthodontic Implant System	K050408
Bicon Surface Treatment	K031568
Bicon the 5.0 x 6.0mm dental implant	K042637
Bicon Transitional Implant (bti) system	K023705
Bicon 6.0 x 5.7mm dental implant	K010185
Bicon the 4.5mm diameter bicon dental implant	K994037
Bicon bone screw system	K982488
Bicon the 6.0 x 8.0mm dental implant system	K972417
Bicon Dental Implants II part abutment system	K972029
Biodenta	
Biodenta Dental Implant System - Bone Level Tapered D 3.0	K133884
Biodenta Dental Implant System - Bone Level D 3.0 to 6.0 mm	K123512
Biodenta Dental Implant System - Bone Level Tapered	K123415
Biodenta Dental Implant System - Bone Level	K111003
Biodenta Dental Implant System	K093630
BioHorizons	
Biohorizons Tapered Internal Implants	K143022
BioHorizons Tapered Internal Plus Implants	K121787
BioHorizons Laser-Lok 3.0 Implant System	K093321
BioLok Micro-Lok Implant System	K081818
BioHorizons Single-stage Implant System	K073282
BioHorizons Internal Implant System	K073268
BioHorizons Tapered Internal Implant System	K071638
BioHorizons Single-stage Implant	K053152
Maximus™ 3.0mm and OS Implants	K052419
Prodigy System™ Dental Implants	K042429

Biomet 3i	
3i T3® External Hex Dental Implants	K133049
CP4 OSSEOTITE® Certain Dental Implants	K130949
3i T3 Dental Implant	K122300
OSSEOTITE® 2 Dental Implants	K111216
Full OSSEOTITE® Certain® II Dental Implant	K100724
BIOMET 3i NanoTite™ Dental Implants	K072363
Certain™ PREVAIL™ Implants	K061629
OSSEOTITE NT™ Implant System	K014235
Biomet 3i OSSEOTITE®	K980549
Blue Sky Bio	
Blue Sky Bio Dental Taper Hex Implant systems	K112875
Blue Sky Bio Dental Implant System	K102034
Blue Sky Bio Dental Implant System	K073713
Drill for Blue Sky Bio Dental Implant Systems	K063874
Modification to Blue Sky Bio Dental Implant System	K060957
Modification to Blue Sky Bio Dental Implant System	K051507
Modification to Blue Sky Dental Implant System	K021833
Blue Sky Bio Dental Implant System	K010882
CAMLOG	
CAMLOG SCREW-LINE	K083496
CAMLOG ROOT-LINE (J-Line)	K000100
CONELOG SCREW-LINE	K113779
iSy	K133991
CAMLOG CYLINDER	K000065
CAMLOG SCREW	K000099
Cortex Dental Implants	
SATURN Dental Implant System	K131258
CORTEX Dental Implant System	K090709
Creodent	
Creodent Solidex Customized Abutment	K150012
Creodent Solidex Custom Abutment	K113738
Dentium	
Dentium Slim Onebody System	K111162
Dentium Simpleline II Model Sofx483408r, Sofx483	K102308
Dentium Speedy Orthodontic Screw	K060500
Dentium Implantium II	K060501
Dentium Co., Ltd. Implantium	K041368
DENTSPLY - Astra Tech	
OsseoSpeed™ Profile EV	K130999
OsseoSpeed™ Plus	K120414
Astra Tech Implant System Plus	K111287
Astra Tech Implant System	K101732
Astra Tech Implant System	K091239
OsseoSpeed™ Profile System	K080156
OsseoSpeed™ Narrow	K080396
OsseoSpeed™ 4.0S-6mm	K063779
Astra Tech Implants-Dental System	K041492
DENTSPLY - Friadent	
ANKYLOS® C/X Implant System	K140347
ANKYLOS® C/X Dental Implant System	K083805
FRIALIT® plus Dental Implant System, XiVE® S plus Dental Implant System,	K073075
ANKYLOS® Dental Implant System /Claims	K073067
ANKYLOS® Dental Implant System	K041509
FRIADENT plus Dental Implant Systems	K040170
ANKYLOS® Dental Implant System	K040946
XiVE® Dental Implant System	K013867
ANKYLOS® Dental Implant System	K012681

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DIO	
DIO UP HSA Internal Sub-Merged Implant System	K122519
Dioslimon Implant System	K112746
DIO STEADY External Implant System	K100100
Secure Implant System (2.5/3.0 mm)	K080129
SM-Extra Wide (RBM) Implant System	K080128
DIO Protein Implant System	K080126
DIO Biotite-H Implant System	K073070
DIO Implant System	K070570
SM® Internal/External Implant System	K070569
DIO Protem Implant System	K070568
SM® Implant Systems	K061797
Eurotek/Ika	
UNIVERSAL, AESTHETICA, NATEA, NATURA Obi	K083670 K083669
GC America	
GC Aadva Implant System	K093749
JNE Implant System	K072425
Green Den Tech	
DENRACLE DENTAL ABUTMENT	K131468
implantDirect	
Spectra System	K061319
Intractive/ SwishPlus2 Implant System	K130572
Spectra System Dental Implants 2008	K090234
Swissplant Dental Implant System	K081396
Intra-lock	
Intra-lock® OP Dental Implants	K130140
Intra-lock® Dental Implants	K133613
Intra-lock Dental Implant System with Blossom	K103194
Mini Drive-lock™ Dental Implant System	K070601
Intra-lock MILO™ Dental Implant System	K050970
Intra-lock Hydroxyapatite Coated Implants	K031322
Intra-lock Translational Implant System	K021915
Intra-Lock Dental Implant System	K021322
Keystone Dental	
Genesis Implant System	K101545
Olympus Dental Implant System	K071070
LifeCore Biomedical	
Lifecore FrimoConnex™ Internal Connection Implant System	K051614
Lifecore Frimo5olo™ One-Piece Implant System	K050506
RENOVA™ Internal Hex Implant System	K032774
Restore® RBM Self-Tapping Regular Diameter Dental Implant	K002037
Lifecore Stage-1 Single Stage RBM Dental Implant System	K003226
Single Stage Dental Implant	K991114
Stage-1™ RDS TPS Dental Implant System	K994205
MIS Implants	
Conical Connection Implants	K112162
SEVEN Implants, BioCom Implants, LANCE Implants	K103089
UNO Narrow Implant	K092555
UNO -One Piece Screw-Type Dental Implant	K080162
Mistral One Stage Screw-type Dental Implant	K070022
MIS Dental Implant System	K040807
Megagen	
AnyOne™ Internal Implant System	K123988
Xpeed Anyridge Internal Implant System	K122231
Xpeed Anyridge Internal Implant System	K123870
RESCUE® External Implant System	K081302
RESCUE® Internal Dental Implant System	K073058
RESCUE® Internal Dental Implant System	K063216
RESCUE® Implant Systems	K053353
Intermezzo™ Plus	K053354
Exfeel® Implant Systems	K052369
Intermezzo™ Implant Systems	K051018
Neoss	
Neoss Proactive Tapered Implant	K113376
Neoss Implant System 3.25	K090452
Neoss Proactive Implant	K083561
Neo Implant System	K043195
Neoss Tibase, Neoss Cocr Abutments	K150669
Neoss Ti Reinforced Membrane	K143327
Neoss Access Abutments	K081851
Neoss Various Titanium Abutments	K071838

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Nobel Biocare	
NobelActive Wide Platform (WP)	K133731
NobelActive 3.0	K102436
NobelActive 8.5mm & 18.0mm	K083205
NobelReplace Hexagonal Implant	K073142
NobelPerfect Conical Connection Hexagonal	K072980
NobelActive Internal Connection Implant	K071370
NobelReplace Tapered Conical Connection	K062566
NobelBranemark	K022562
NobelReplace	K020646
Osstem	
MS SA Implant System	K122171
TS Fixture System	K121995
TS Implant System	K121585
ET/SS Implant System	K120847
HG II Short Fixture System	K091678
GS III System	K091208
MS System	K083067
HS II Short Fixture System	K083633
GS III Fixture System	K082213
NT-IT System	K081078
HG II Fixture System	K080744
MS System (Narrow Ridge)	K080594
HU II - HS II Fixture System	K080387
US-SS-GS System	K073247
US-GS Ultra Wide System	K073465
MS System (Denture)	K072959
GS Fixture System	K072896
GS System	K063861
US System	K062030
SS System	K062051
AVANA Dental Implant System	K051576
Prismatik DentalCraft	
Inclusive® Tapered Implant System	K121406
Inclusive® Mini Implant	K100932
Ritter Implants	
Ritter Implant System	K131557
Straumann	
Straumann SLActive® and Roxolid®	K130222
SLA®, SLActive® and Roxolid® Product Families	K123784
Straumann Tissue Level 0.1 mm and 0.8 mm Roxolid	K122855
Straumann Bone Level (BL) 0.1 mm and 0.8 mm Regular Connection (RC) Roxolid	K121131
Straumann Narrow Neck CrossFit® (NNC) 03.3 mm Dental Implant System	K111357
Straumann Dental Implant System	K083550
Straumann Dental Implant System	K081419
Straumann® Bone Level	K062129
Straumann synOcta®	K061176
Straumann Narrow Neck Implants	K060958
Straumann SLActive® Implants	K053088
ITI Dental Implant System	K033984
Straumann® Bone Level	K030007
Straumann® Bone Level	K010291
SYBRON	
Pitt-Easy Dental Implant System	K083297
Thommen Medical	
SPI® Dental Implant, ELEMENT	K093615
SPI® Dental Implant, INICELL®	K090154
SPI® System Dental Implants	K072649
SPI® CONTACT Platform 4.0 mm	K072933
SPI® ELEMENT Platform 4.0 mm	K070007
SPI® Dental Implant	K051502
SPI® CONTACT Dental Implant	K034014

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Zimmer Dental	
Zimmer Dental Tapered Screw-Vent® T Implant, HA Coated; Zimmer Dental Tapered	K133339
Zimmer Dental Tradecular Metal Implant System	K132258
Zimmer Dental Tapered Screw-Vent® X Implant	K113753
Zimmer Dental Tapered Screw-Vent® X Implant	K112160
Zimmer Dental Tapered Screw-Vent® M Implant	K111889
Zimmer Dental Tapered Screw-Vent® T Implant;	K101880
Zimmer Dental Tapered Screw-Vent® T Implant	K101977
3.25mm Spline® Twist™ Implant, HA Coated	K093164
Zimmer Dental Tapered SwissPlus® Implants	K082639
Zimmer Dental Tapered Screw-Vent® Implant 4.1mm	K072589
Zimmer® One-Piece Implant, 3.0mm, Angled	K071235
Zimmer® One-Piece Implant, 3.7mm and 4.7mm	K063523
Zimmer Dental Tapered Screw-Vent® Implant System 5V; Zimmer Dental Screw-Vent®	K061410
Zimmer® One-Piece Implant 3.7mm Angled	K061717
Zimmer® One-Piece Implant 4.7mm Straight	K062281
Zimmer® One-Piece Implant	K052997
Zimmer 3.1mm Dental Implant 2.9mm Angled	K142082

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List of Implant Providers and Implant Library information as included on the 3Shape US Server

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Implant libraries for the 3Shape Dental System™

June, 2016

Implant systems / Providers of implant solutions	Implant systems								Implant Solutions					Manu-facturing		Consumables (for local use)						Additional Info
	Nobel Biocare	Biomet 3i	Straumann	Zimmer Dental	DENTSPLY - Astra Tech	DENTSPLY - Friadent	CAMLOG	Other systems	1- Piece (Titanium)	1- Piece (Zirconia)	2- Piece (Ti base + Zr abutment)	Implant Bars & Bridges	Digital implant models	Providers milling center	Local milling by 3rd party	Blanks with pre-milled interface (for 1-piece abutment)	Titanium bases (for 2-piece abutments)	Intraoral Scan bodies	Digital model analogs	Multi-unit abutments	Cleared for use in US	Comments
Argen (US) 3shape reseller www.argen.com	👍	👍	👍	👍	👍	👍			x		x			x		x	x	x	x		x	- CE
ATLANTIS™ (SE) 3shape reseller - FDA cleared only www.dentsplyimplants.com	Information not available				👍	👍	Information not available														x	- CE
Bicon (US) www.bicon.com								- Bicon			x	x			x			x			x	- CE, Health Canada
Biodenta (CH) 3shape reseller - FDA cleared only www.biodenta.com	👍	👍	👍	👍	👍			Straumann Bone Level (no Tissue Level) BioHorizons Internal Osstem (Hiossen) TSIII Biodenta Bone Level and Tapered	x		x	x	x	x	x	x	x	x	x	x	x	x	- Implant Bridges only available for Abutment Level, not implant level. - 3rd party milling center must become Biodenta Contract Manufacturer and comply to QSR
Biomet (US) 3shape reseller - FDA cleared only www.biomet.com	Information not available	👍	Information not available																		x	- CE - encode healing abutments
BlueSkyBio (US) blueskybio.com	👍		👍	👍	👍			- BlueSkyBio	x		x				x	x	x			x	x	- CE, Health Canada
CAMLOG (CH) - FDA cleared only www.camlog.com							👍	- CONELOG - iSy									x	x			x	
CAP (US) 3shape reseller www.cap-us.com	👍	👍	👍	👍	👍	👍			x		x	x	x	x	x	x	x		x		x	
CMC (US) 3shape reseller - FDA cleared only www.custom-milling.com	👍	👍	👍	👍	👍	👍	👍	- BioHorizons - Osstem - LifeCore - Intra-Lock, - Neoss	x	x	x	x		x				x			x	- CE
Core3D International (NL) 3shape reseller - FDA cleared only www.core3dcenters.com	Information not available								Information not available												x	- CE, Health Canada, TGA (AUS), Taiwan regulatory - MHLW: Ministry of Health, Labour and Welfare (JP)
Cortex Dental (IL) www.cortex-dental.com				👍				- Cortex Dental			x	x			x	x	x	x	x		x	- CE
Creodent (US) www.Creomc.com	👍	👍	👍	👍	👍			- Hiossen	x		x	x		x			x				x	
Dentium (KR) www.dentium.com								- Implantium - SuperLine - SimpleLine II NR Line Custom Abutment	x	x	x	x		x	x						x	- CE, CFDA, PMDA, TFDA, GOST
Euroteknika (FR) www.euroteknika.com	👍	👍	👍	👍	👍			- Anthogyr, - Biotech - Easy Implant - MIS Implants - and more	x		x	x	x	x		x	x	x	x	x	x	- CE
Glidewell (US) 3shape reseller www.glidewelldental.com	👍	👍	👍	👍	👍	👍	👍	- Prismatik - DentalCraft - Keystone Dental - Neoss	x	x	x	x	x	x			x	x	x		x	- CE pending
Hiossen (US) www.hiossen.com	Information not available																				x	
Implant Direct (US) www.implantdirect.com/custom-direct	👍		👍	👍				- Biohorizons	x			x	x	x					x		x	- CE, Health Canada
Intra-Lock International (US) www.intra-lock.com								- INTRA-LOCK	x		x	x				x	x	x	x	x	x	- CE, Health Canada
Medentika (DE) www.medentika.de	👍	👍	👍	👍	👍	👍	👍	- Medentika M-Implant	x		x	x		x	x	x	x	x			x	- CE
Megagen Implant (KR) www.imegagen.com								- AnyRidge Internal - AnyOne Internal - MINI Internal - Octa Level			x		x	x	x		x	x	x	x	- CE - KFDA

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MIS Implants Technologies Ltd. (IL) - FDA cleared only www.mis-implants.com								- MIS Implants			X	X		X	X	X	X	X		X	X	- CE
Neodent (BR) www.neodent.com.br	👍		👍					- Neodent Implant Systems	X	X	X	X			X			X			X	
Neoss (UK) - all libraries www.neoss.com	👍	👍	👍	👍	👍			- Neoss	X		X	X	X	X	X	X	X	X	X	X	X	- CE
Nobel Biocare (CH) www.nobelbiocare.com	👍	👍	👍	👍	👍				X	X	X			X							X	- CE
NT Trading (DE) www.nt-trading.com	👍	👍	👍	👍	👍	👍	👍	- Thommen - Sweden & Martina - BEGO	X		X	X		X	X	X	X	X	X		X	- CE, CMDCAS, GOST R, TGC - Mexico Certification
Paltop (IL) paltopdental.com	Information not available																				X	
Straumann (CH) - FDA cleared only www.straumann.com			👍						X	X	X			X							X	- CE
Sweden&Martina S.p.A (IT) www.sweden-martina.com								- Sweden&Martina	X	X	X	X	X	X			X	X	X		X	
T.F.I. System srl (IT) www.tfisystem.it								- Easy Grip			X	X			X		X	X	X	X	X	- CE
Thommen Medical (CH) www.thommenmedical.com								- Thommen			X	X					X	X			X	- CE
TruCrown (US) www.trucrown.com	Information not available																				X	
Vulcan Custom Dental (US) www.vulcandental.com				👍				- BioHorizons	X		X	X	X	X	X	X	X	X	X	X	X	
Zimmer Dental (US) www.zimmerdental.com				👍					X	X				X							X	- CE
Zahn (Zirlux) (US) www.zahndental.com	Information not available																				X	

Please note:

- The above information is solely provided by third parties, and 3Shape assumes no responsibility for its accuracy or completeness.

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Silver Spring, MD 20993-0002

K151455
3Shape A/S
Device Trade Name: 3Shape Abutment Designer Software
Contact Name: Hanne Nielsen

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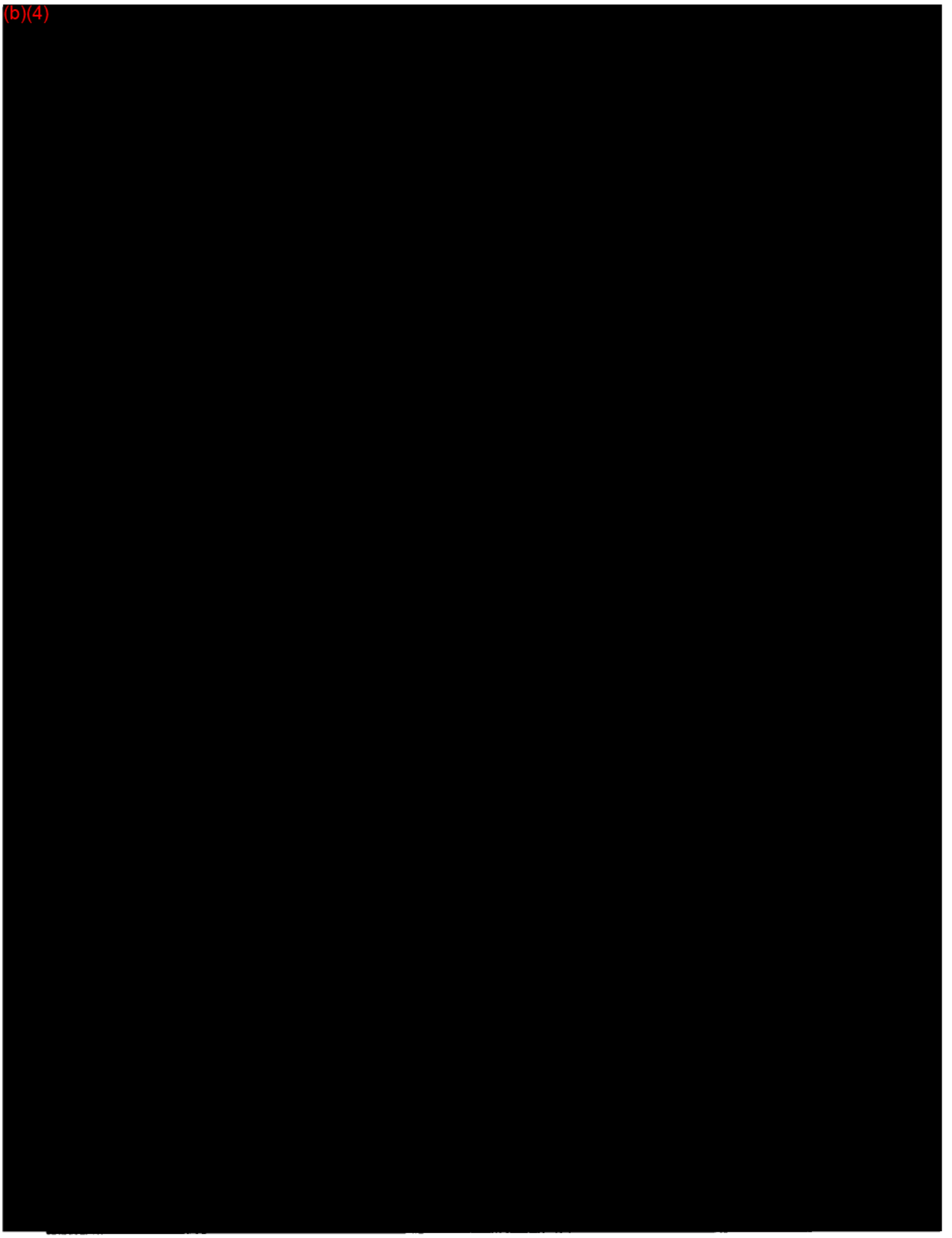

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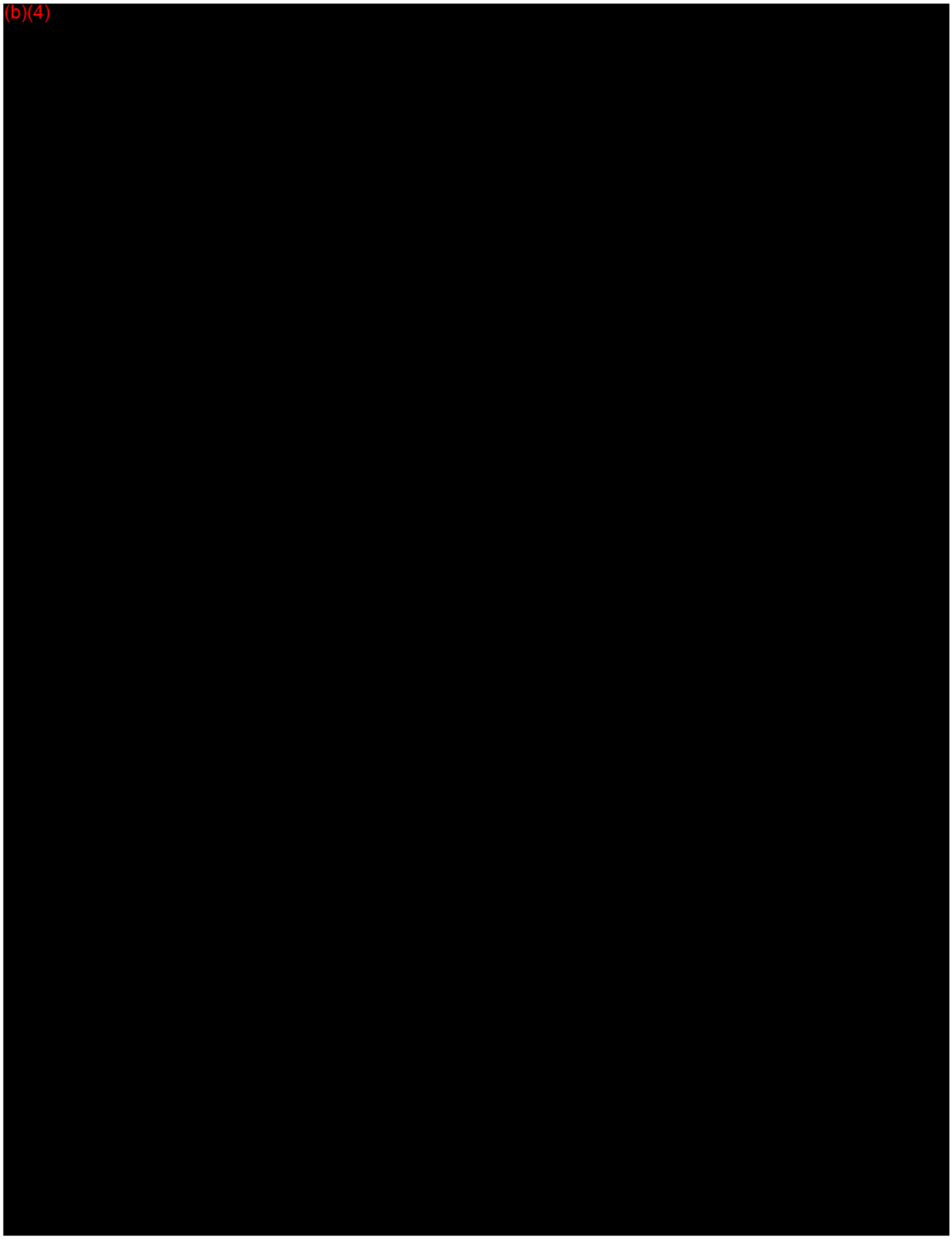

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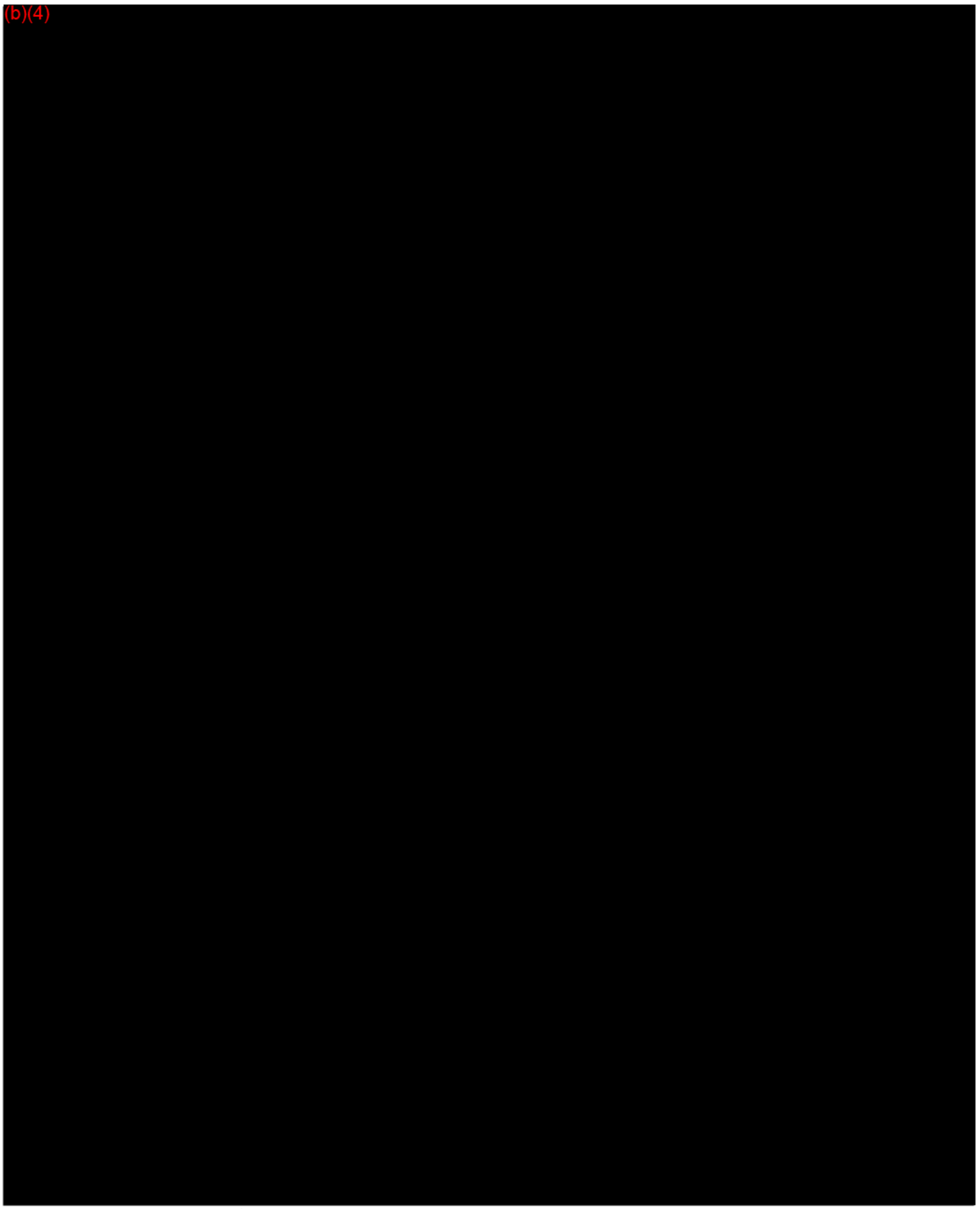

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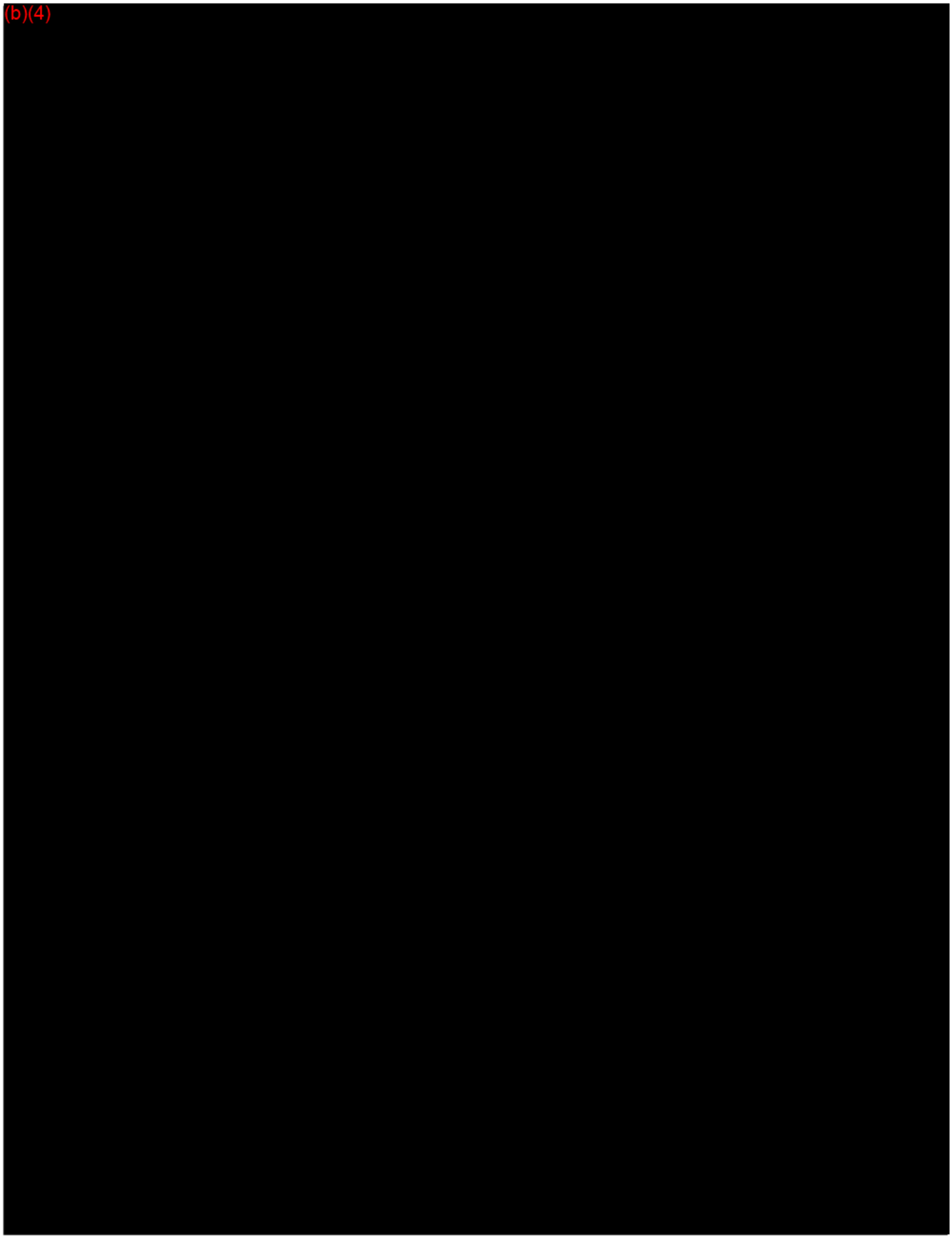

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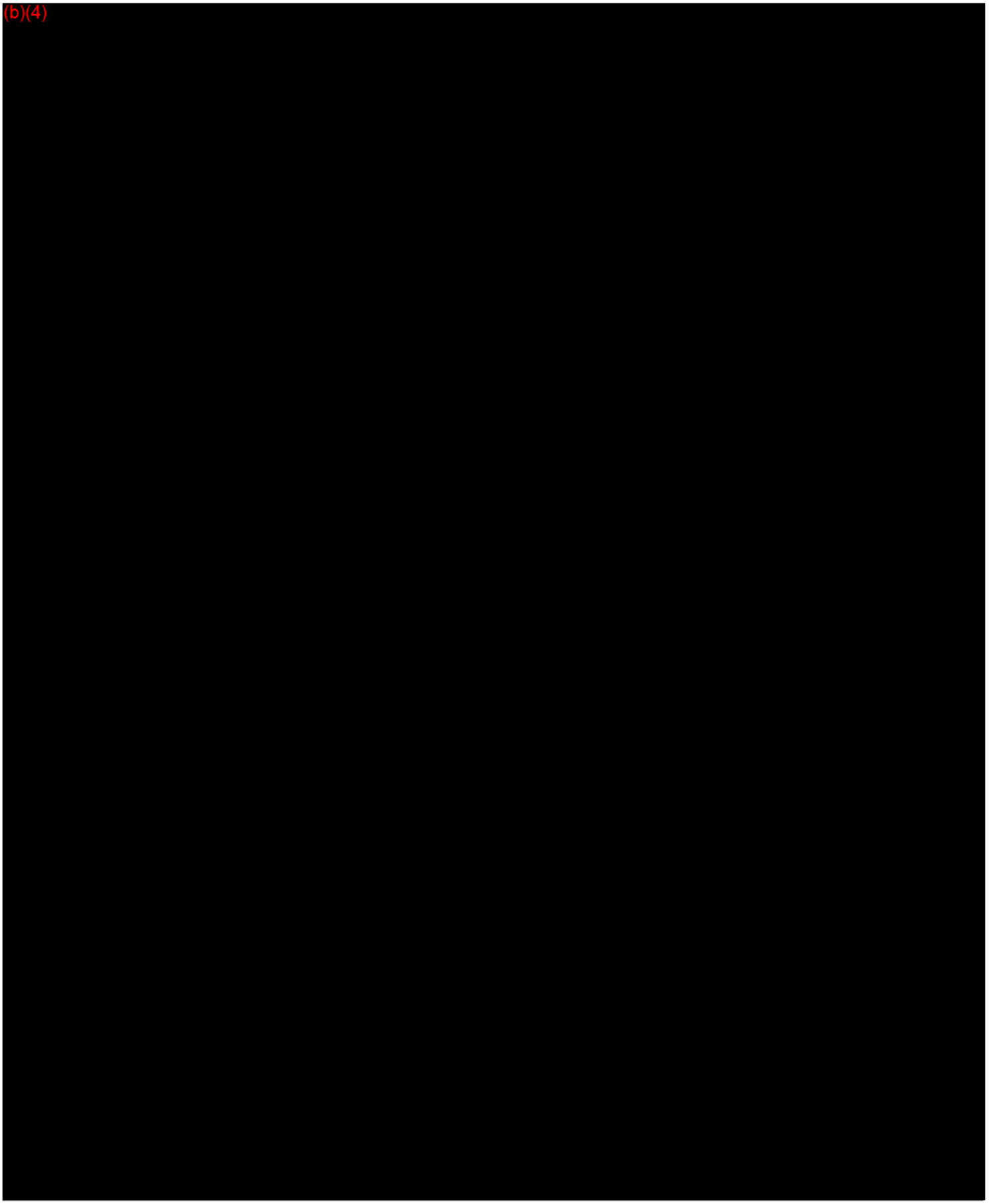

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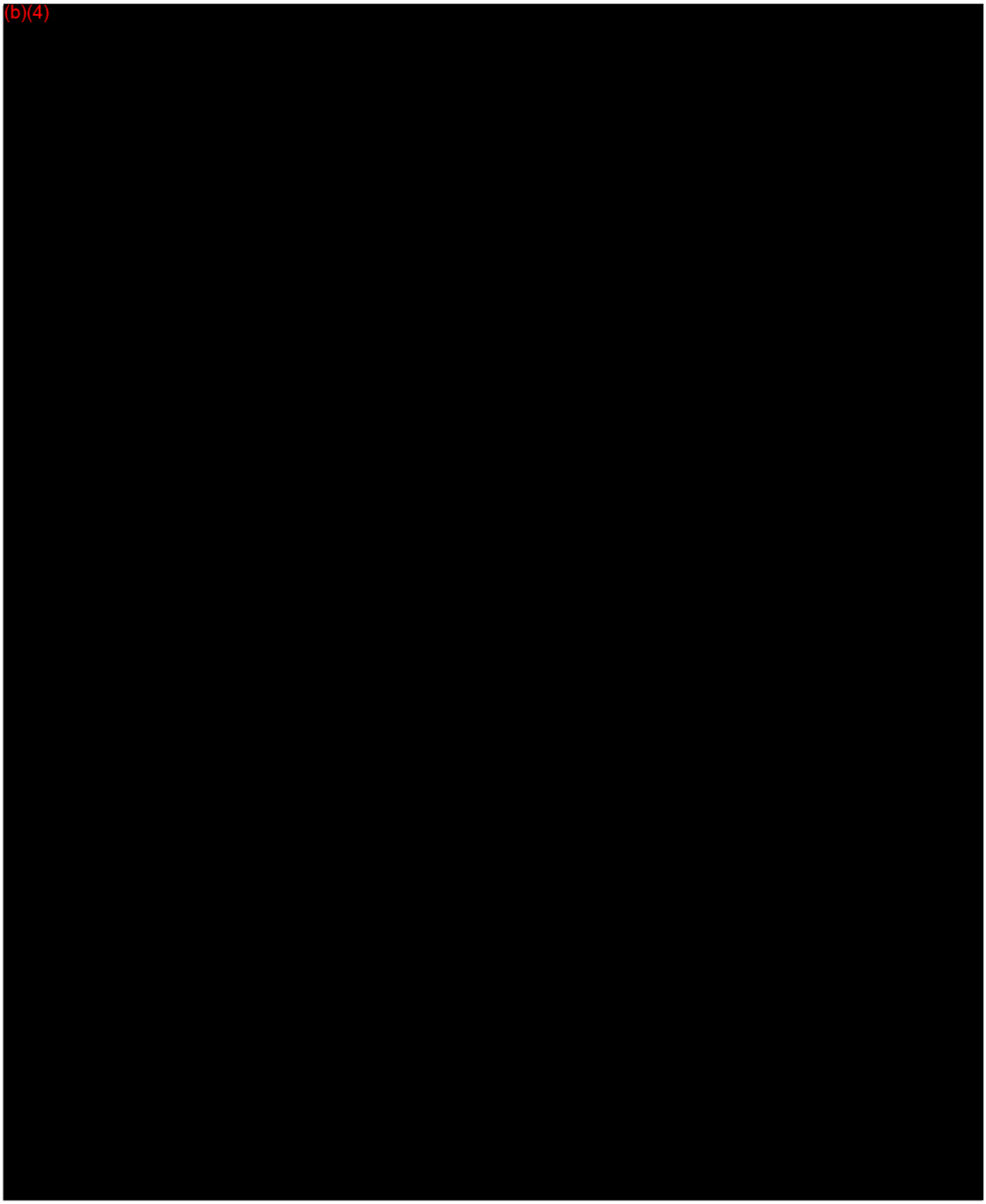

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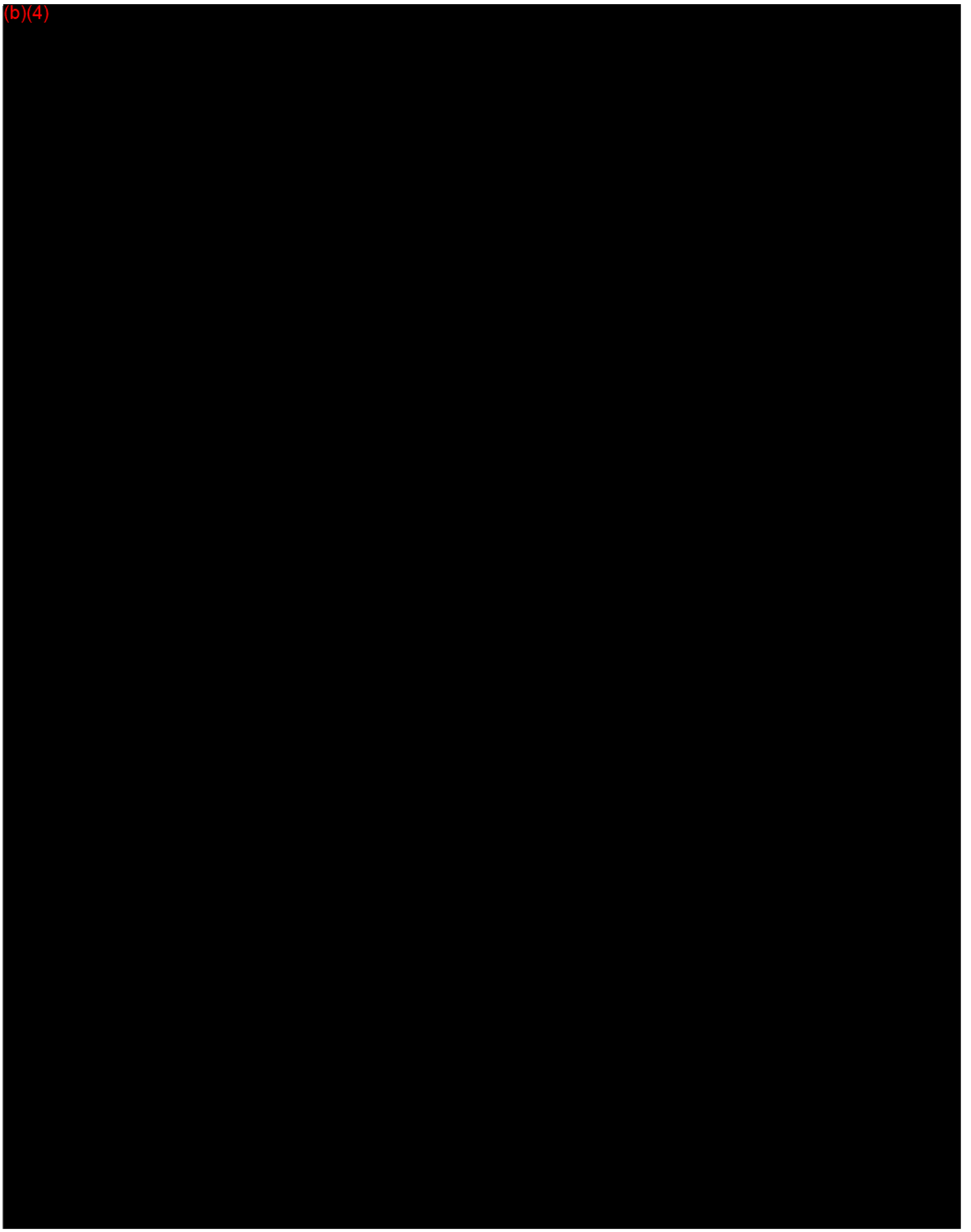

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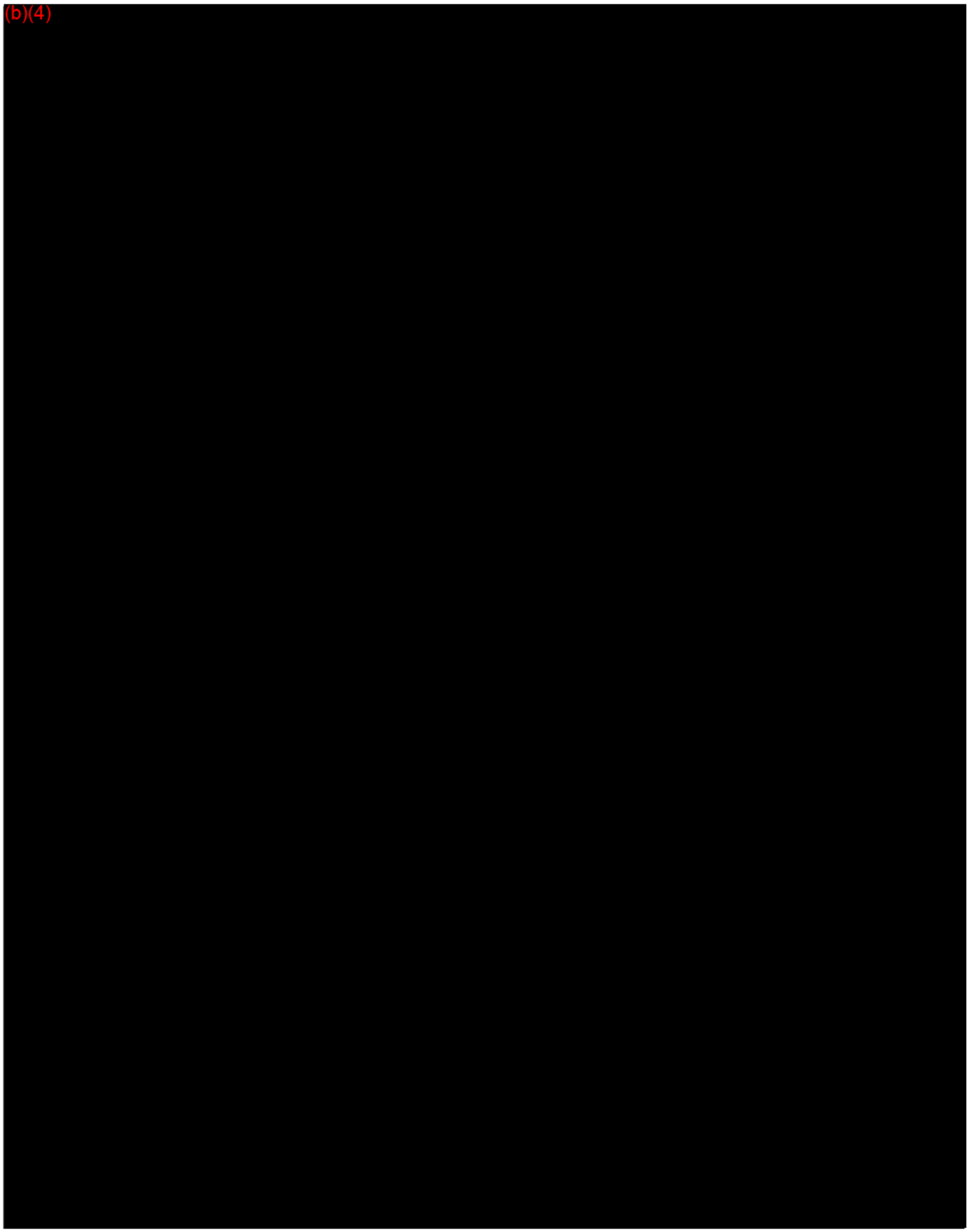

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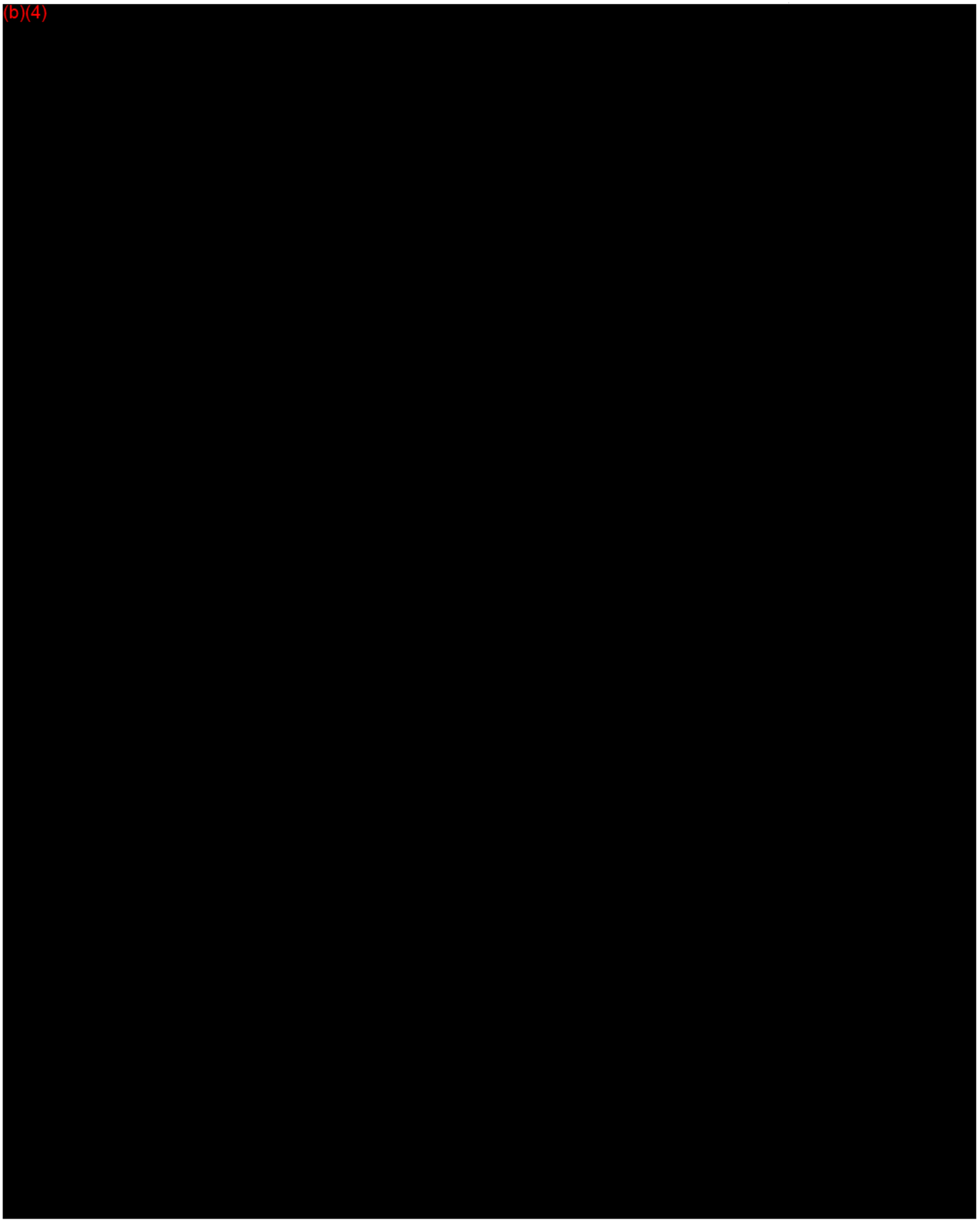

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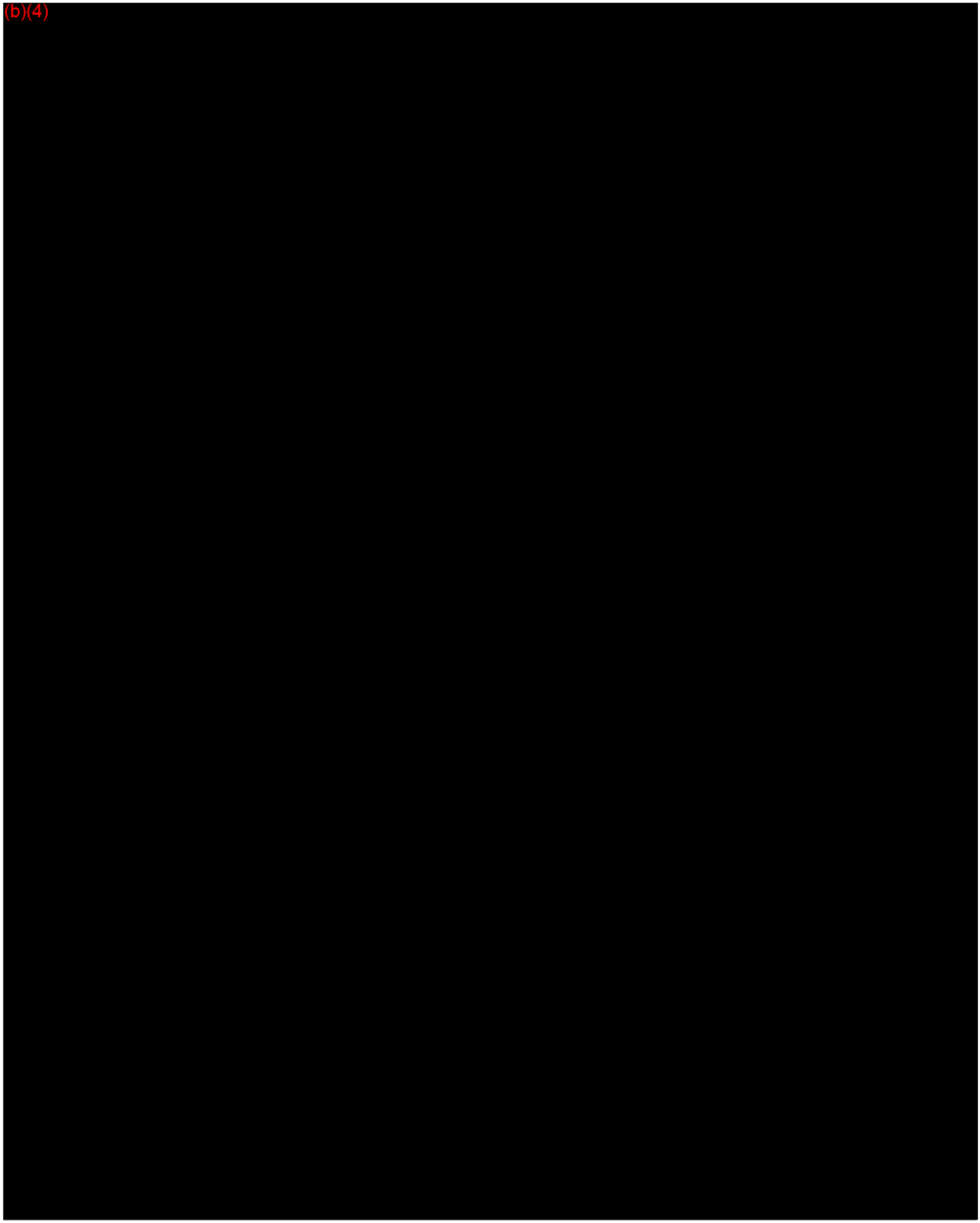

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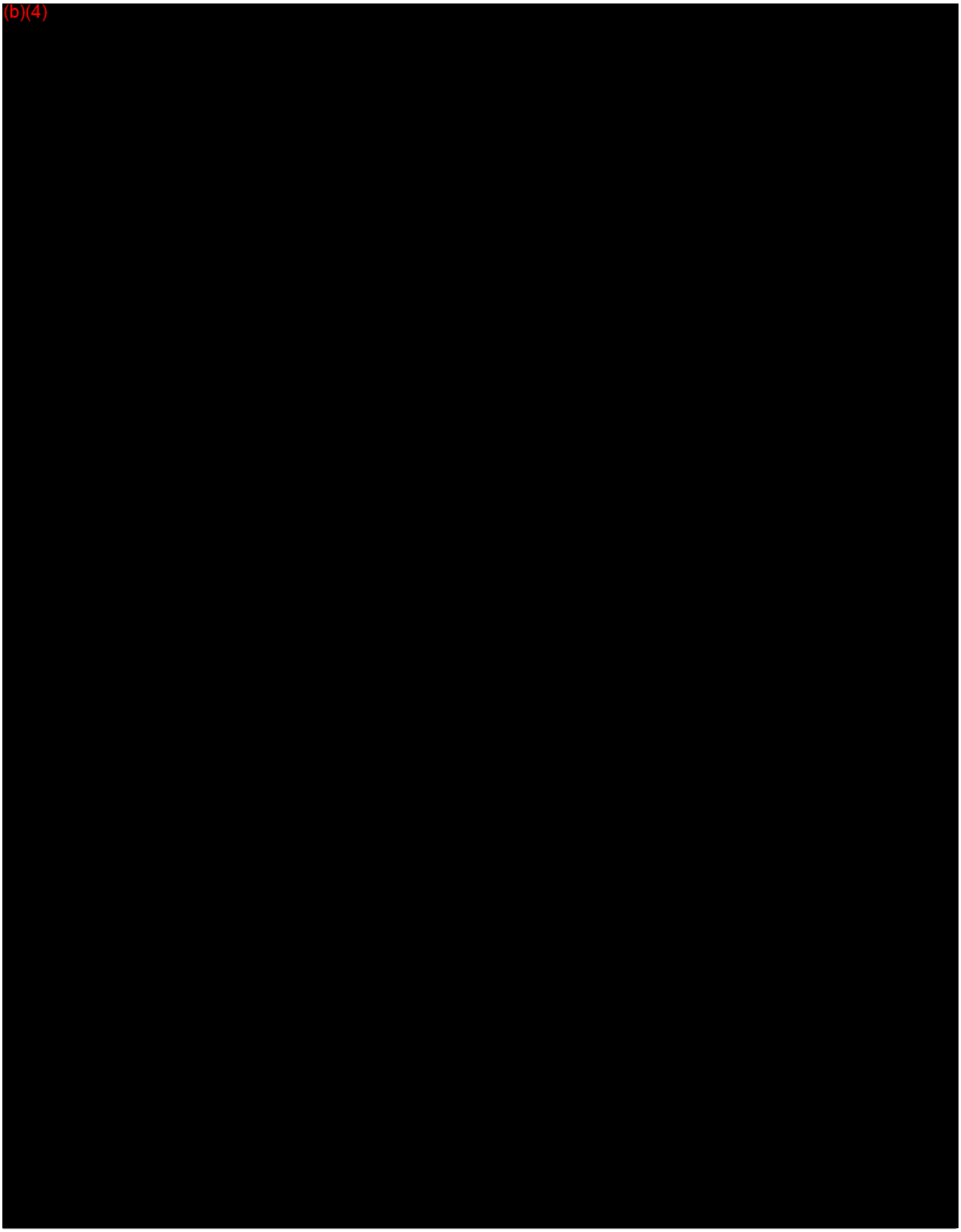

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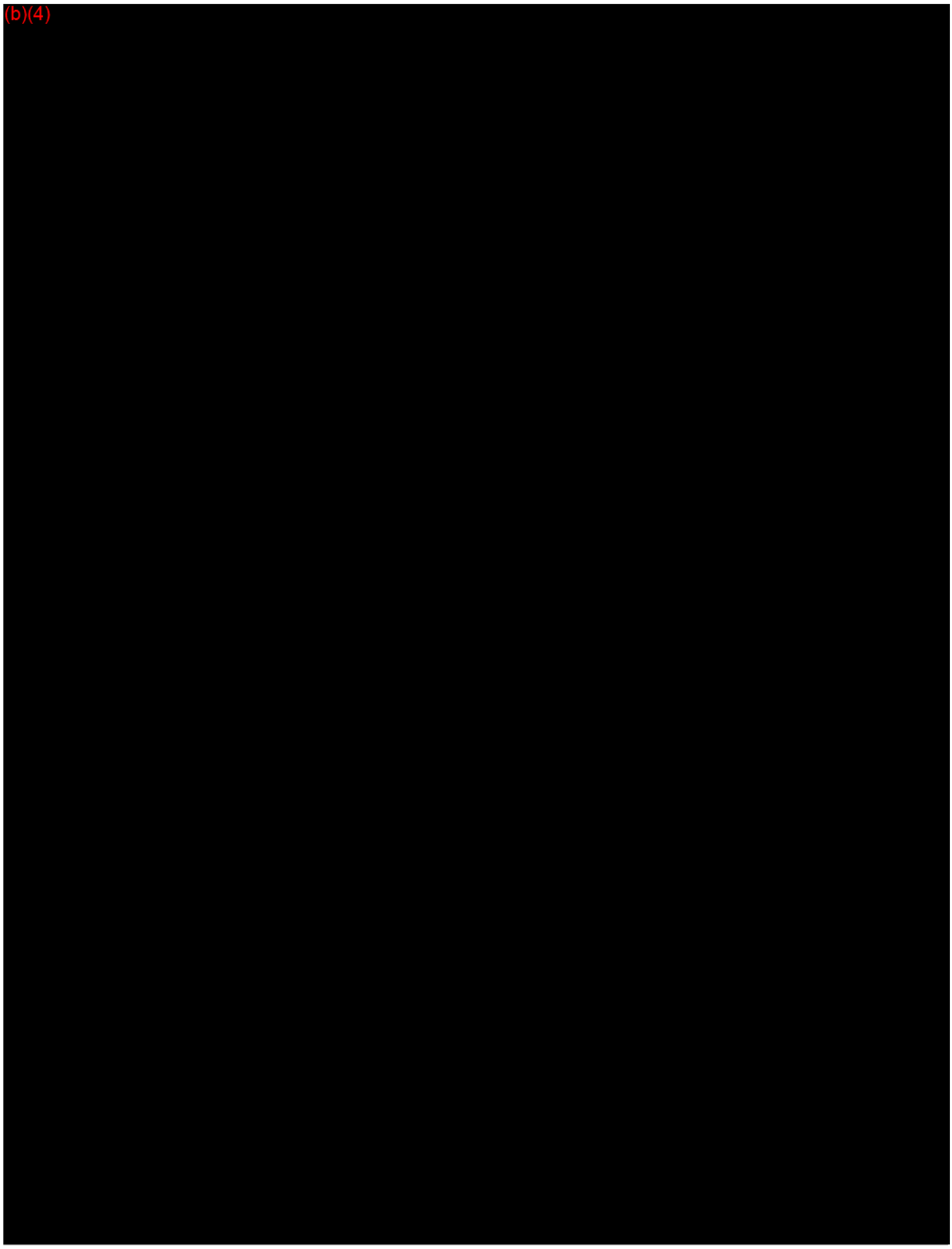

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Ms. Nielsen,

Following our March 8, 2016, phone conference to discuss the January 11, 2016, additional information you provided, the FDA has worked to develop the following interactive deficiencies which we believe as necessary to adequately describe the submission device, demonstrate the verification and validation of the software system, and ensure substantial equivalence of the submission device with respect to other previously cleared dental implant abutment and dental implant system devices. Some of the following questions are a request to provide the information discussed in our March 8 phone conference in written form for the record. The FDA respectfully requests the following information be provided by May 9, 2016.

(b)(4)

[redacted]

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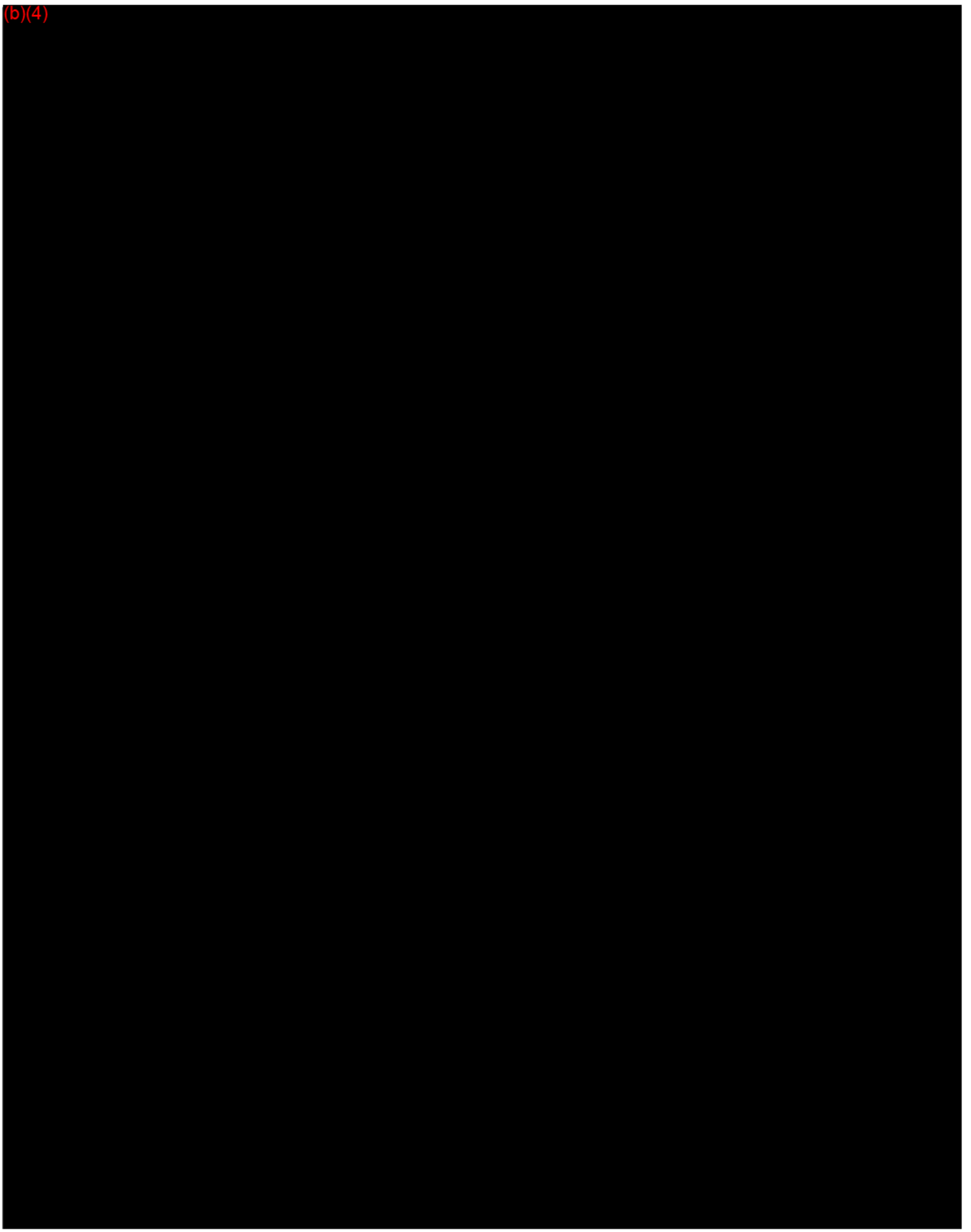

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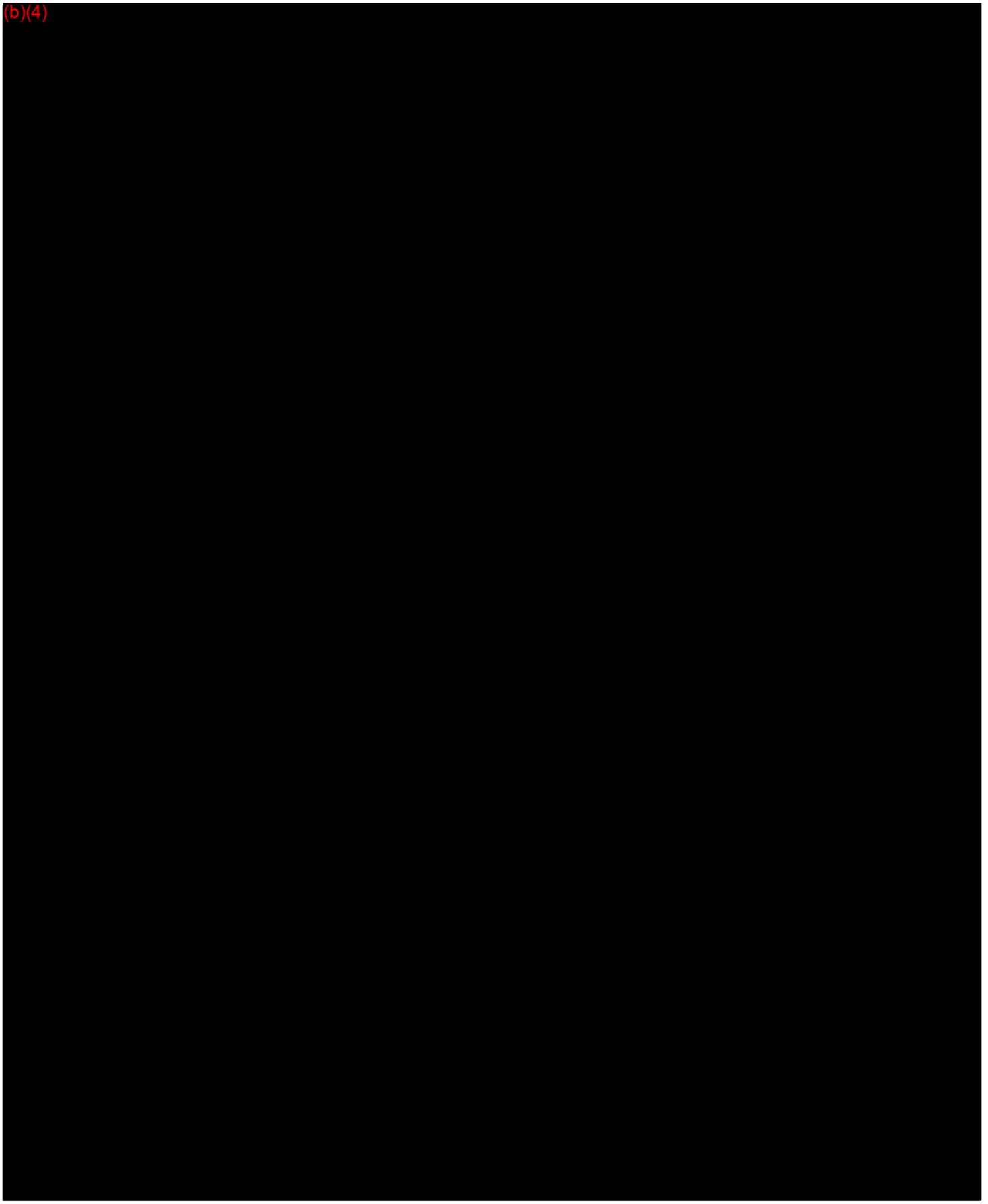

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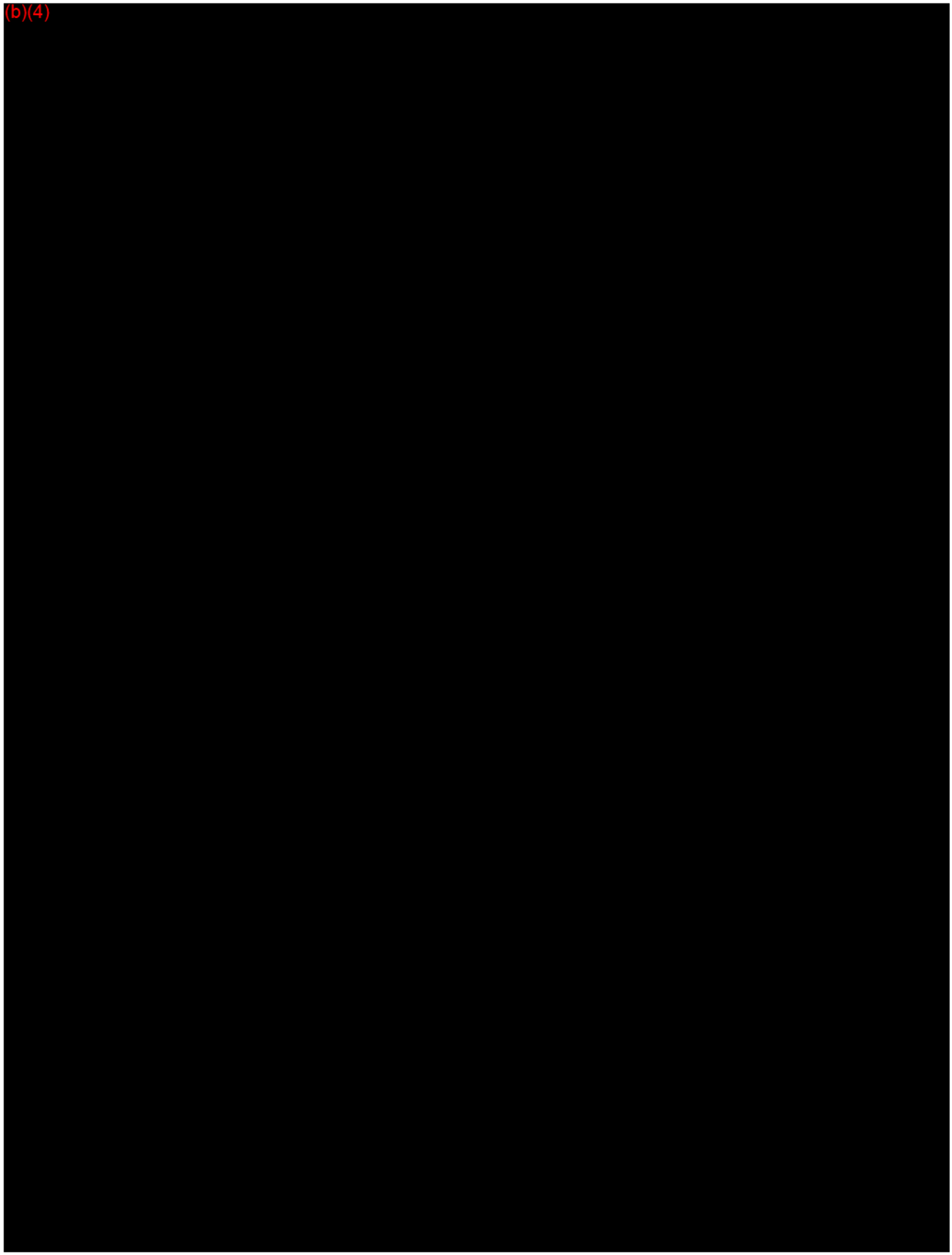

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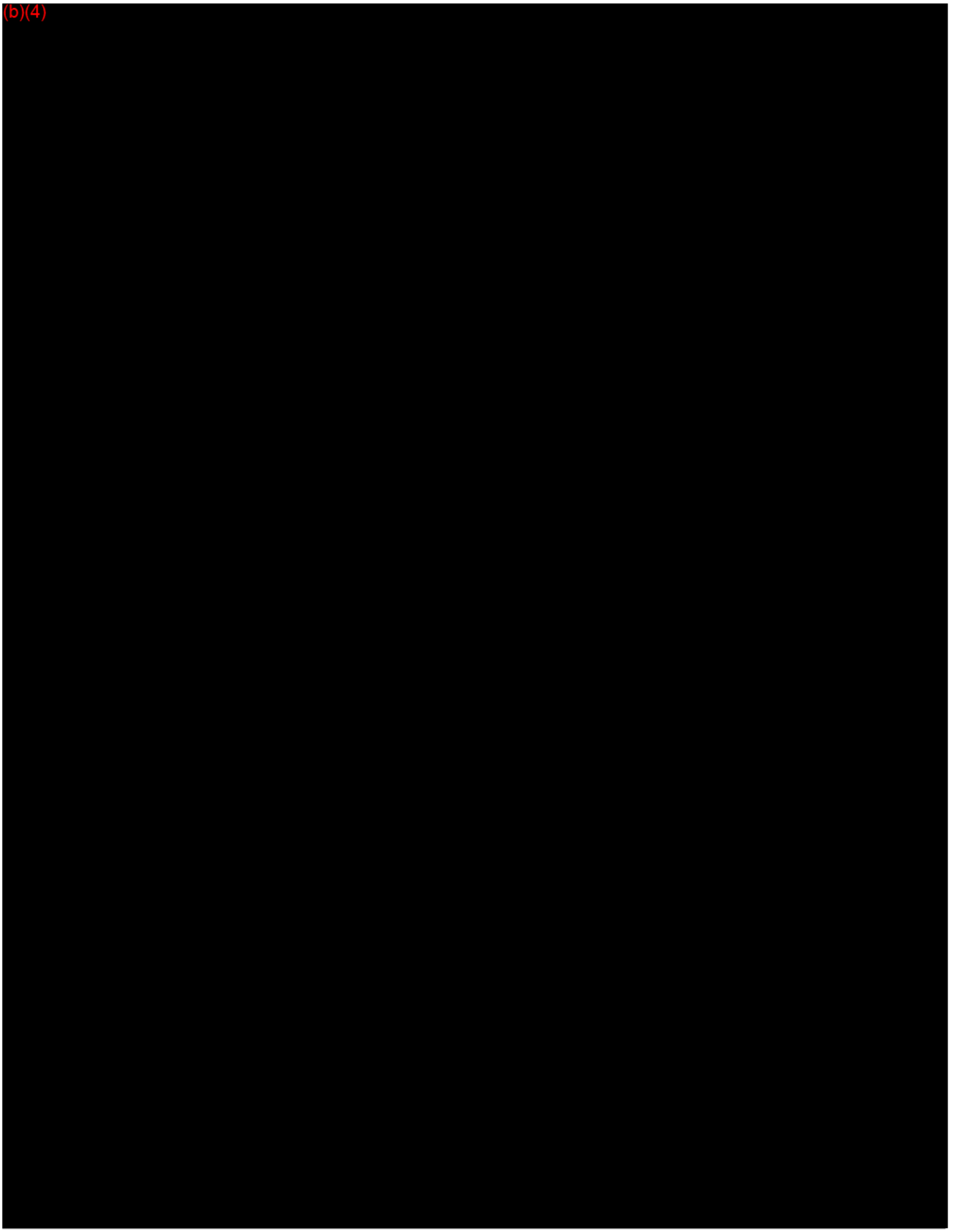

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(b)(4)

[redacted]

Respectfully,

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Mechanical Engineer
Senior Lead Reviewer - Endosseous Dental Implant Systems
FDA/ODE/DAGRID/Dental Devices Branch
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WO66 - G312 (NEW OFFICE)
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phone: 301-796-6284
fax: 301-847-8109
[cid:image001.gif@01CD32AC.53BB7410]

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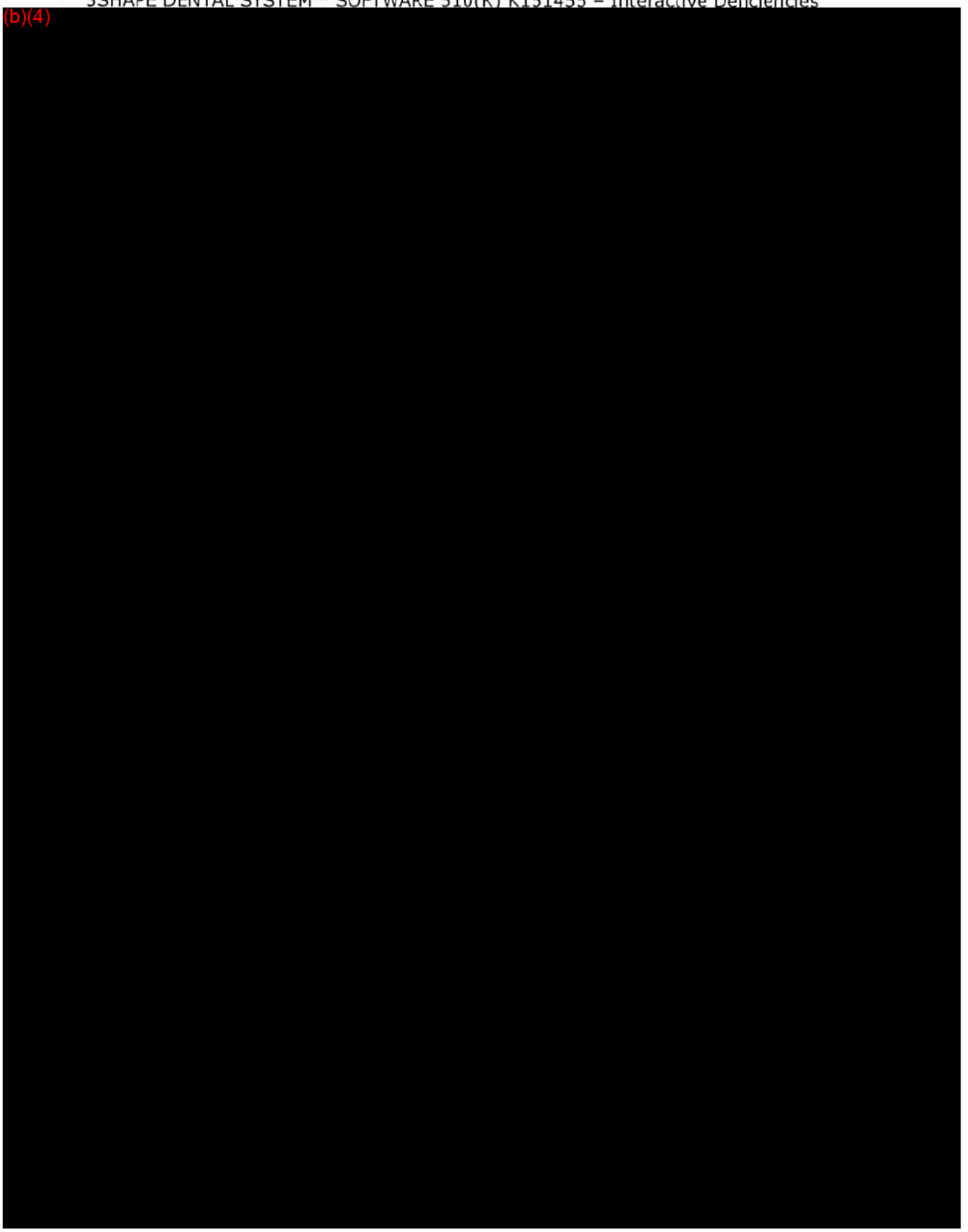

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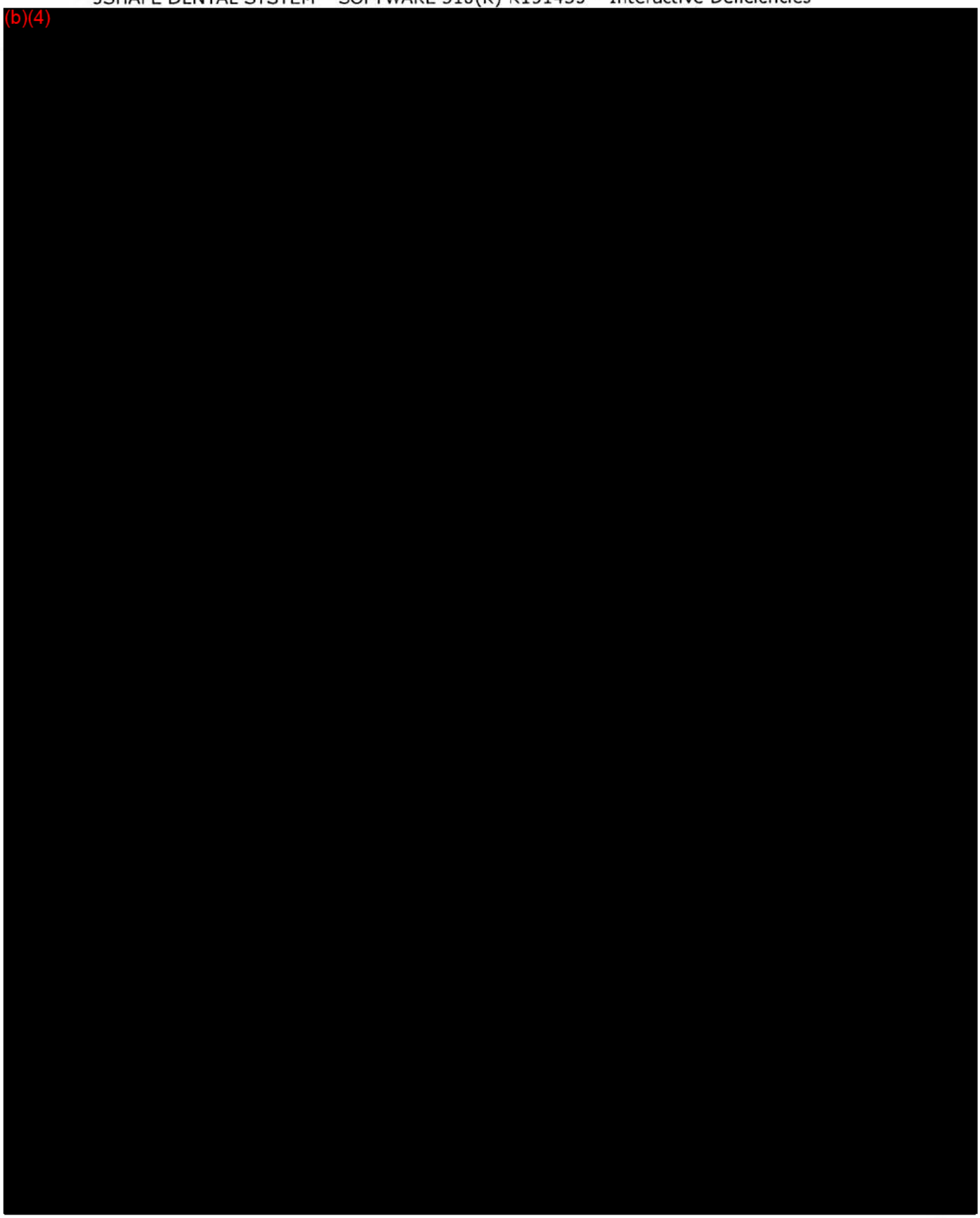

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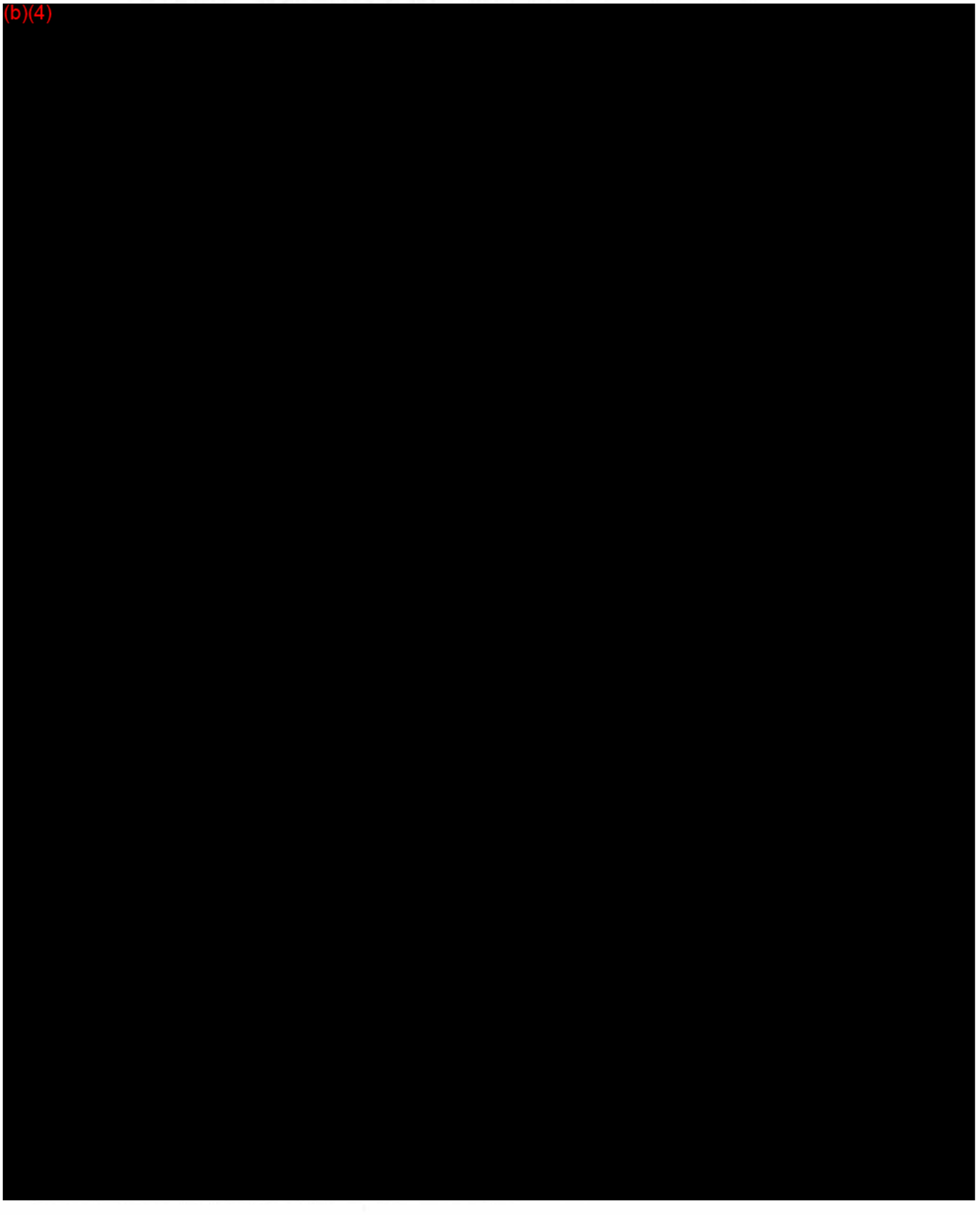

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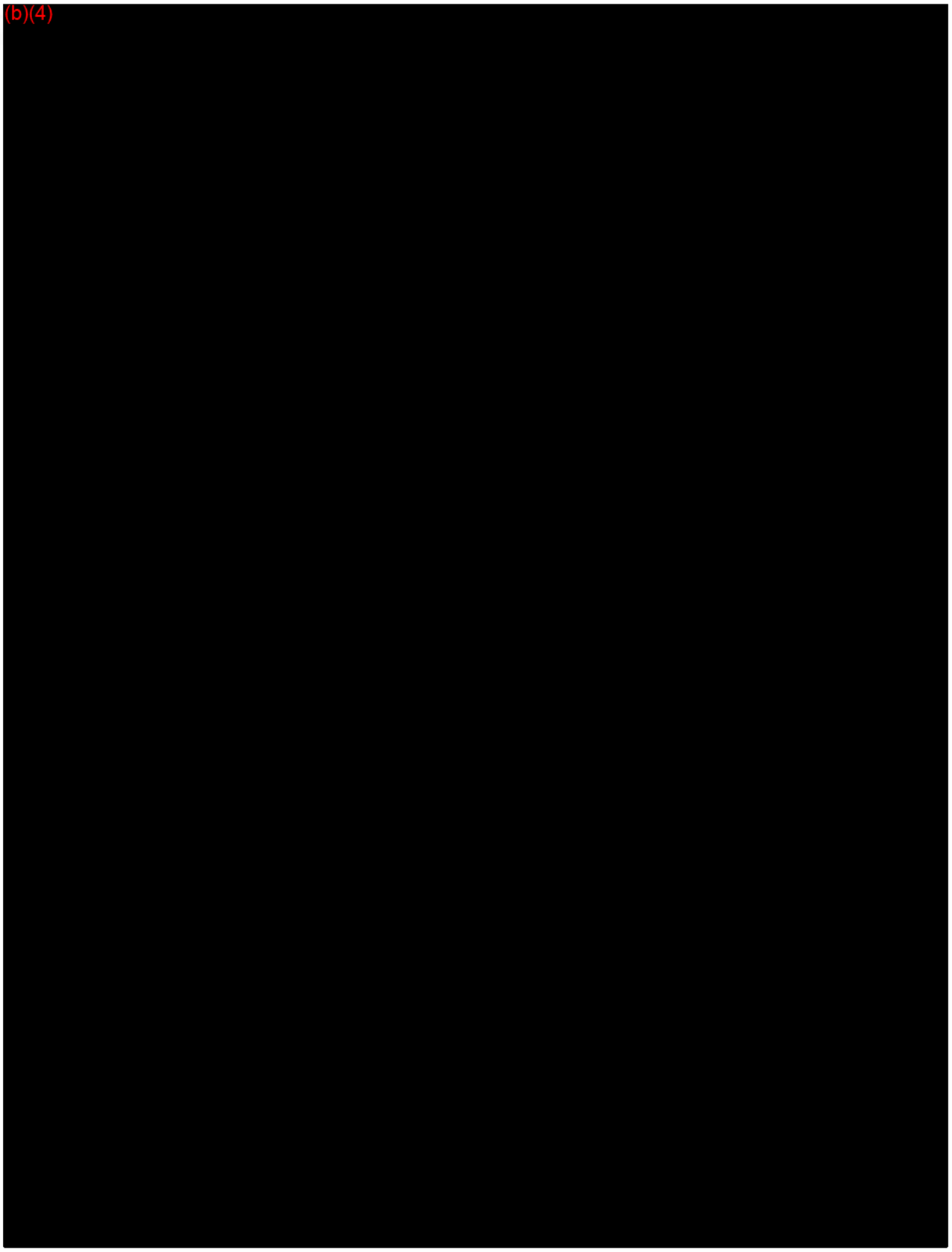

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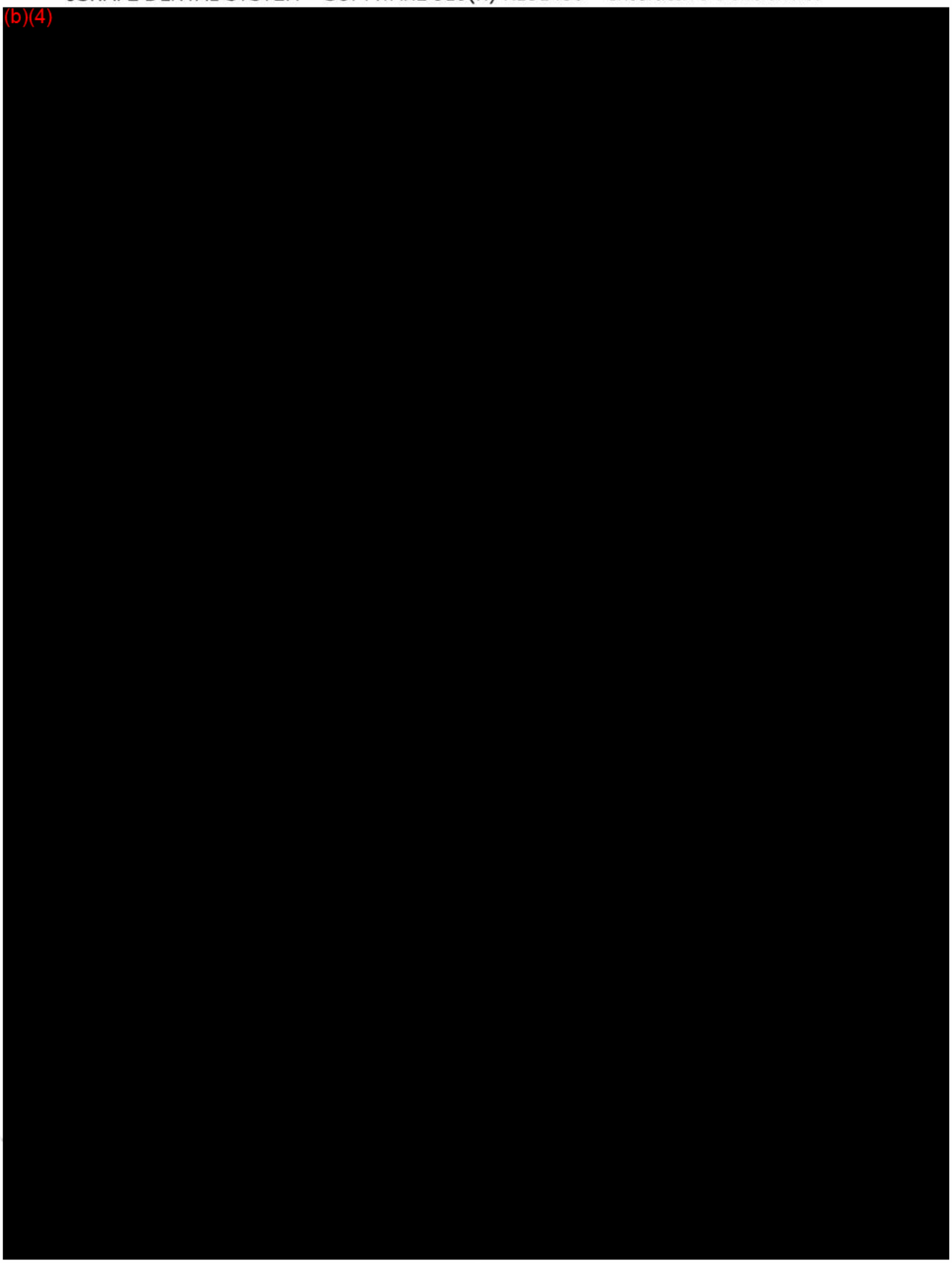

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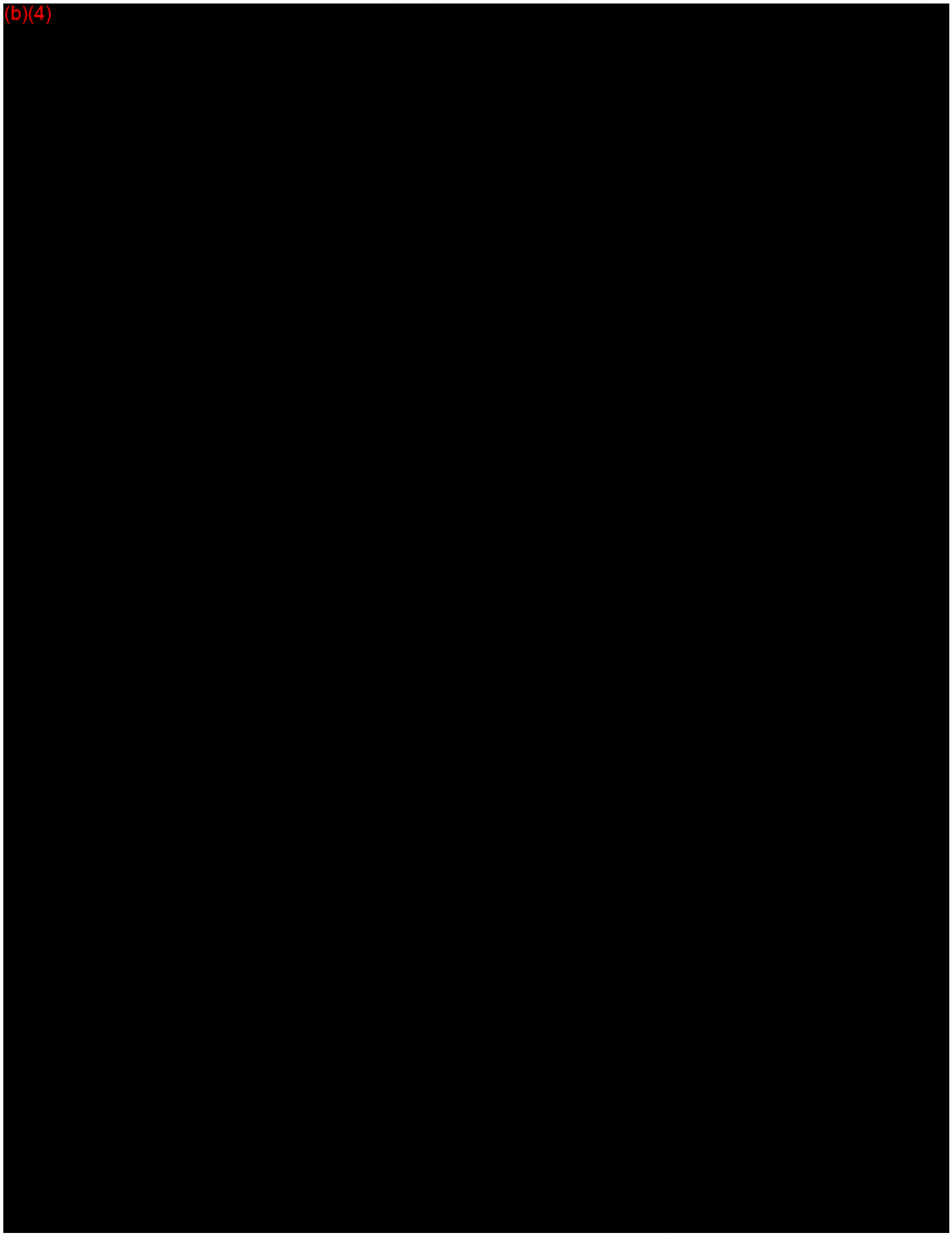

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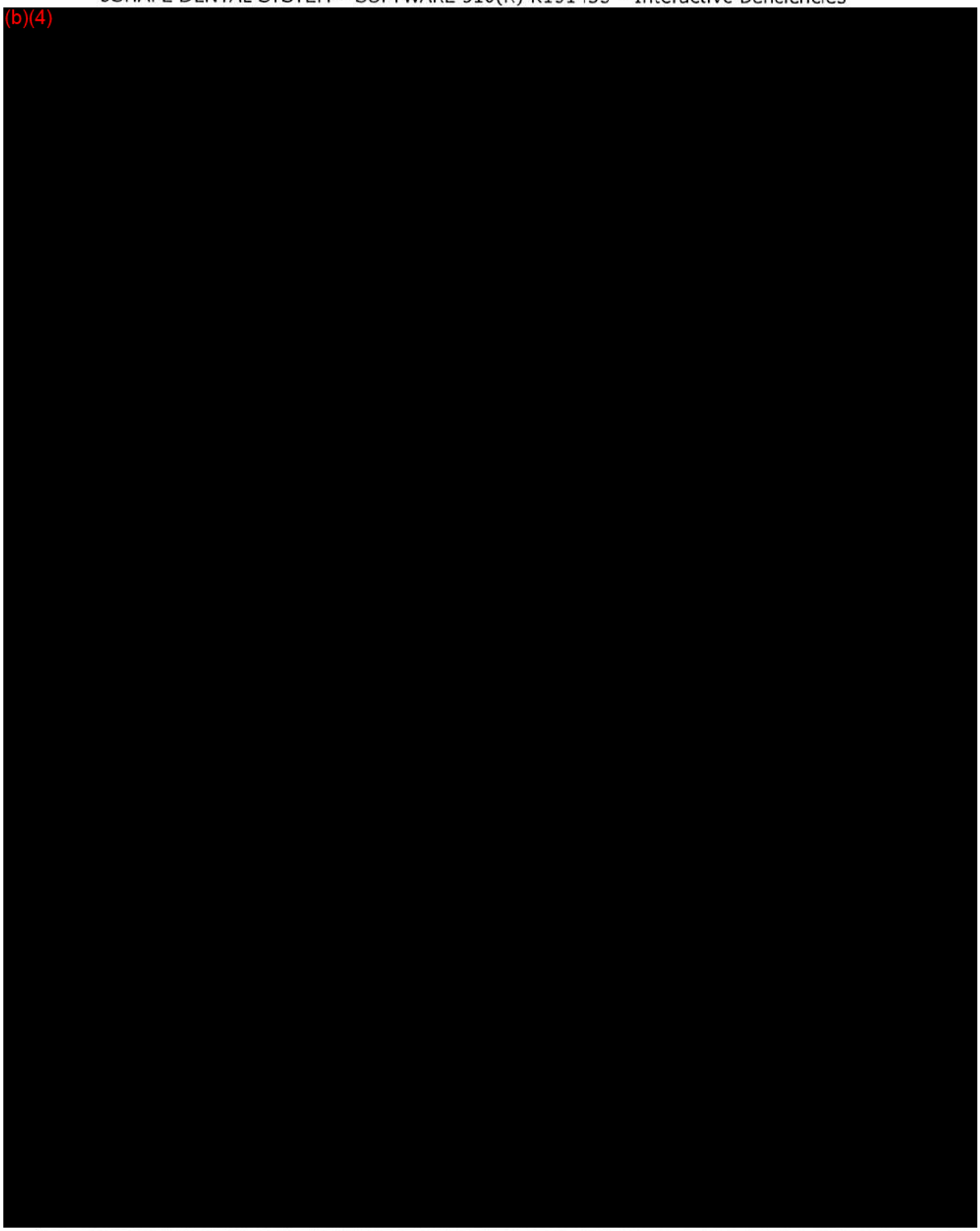

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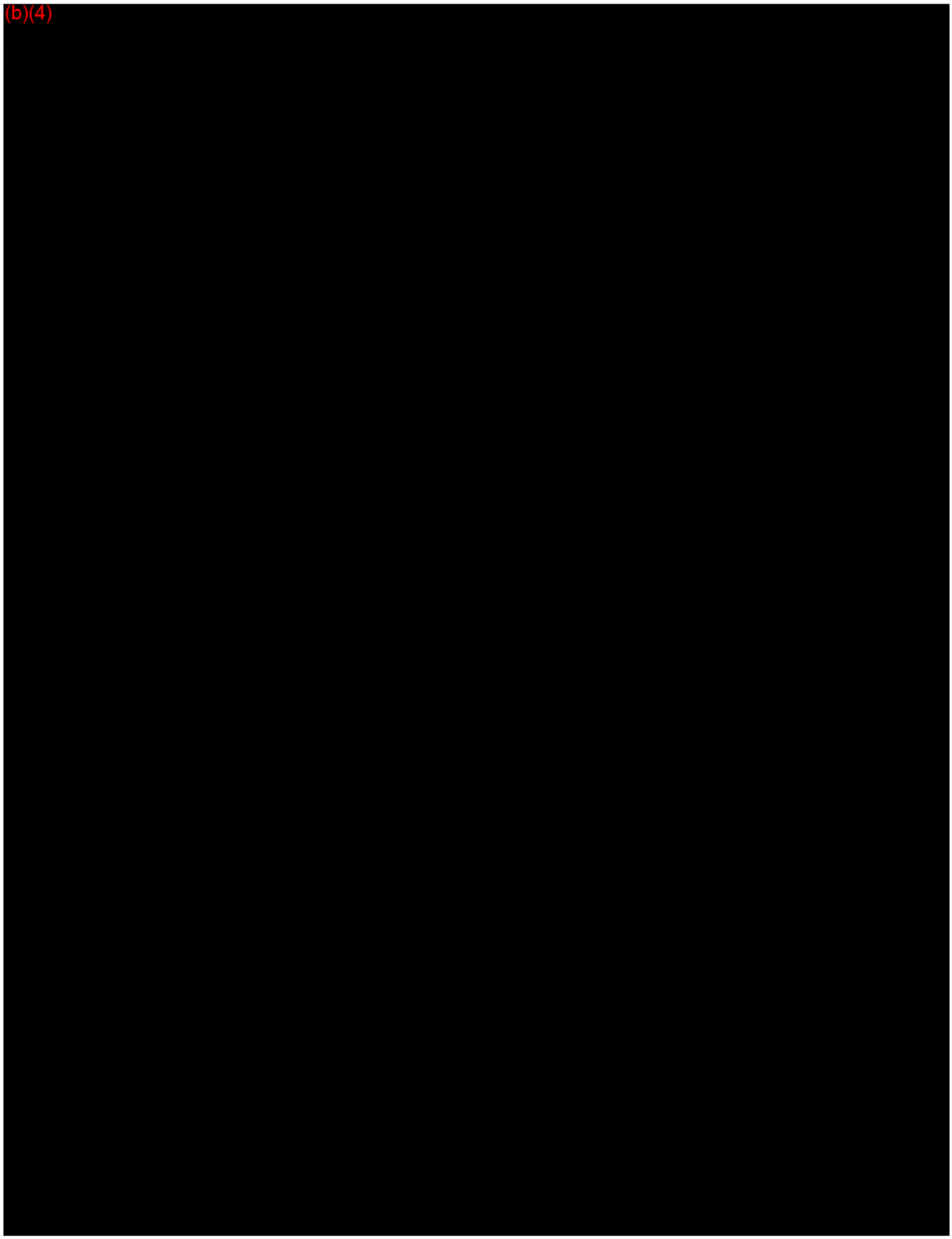

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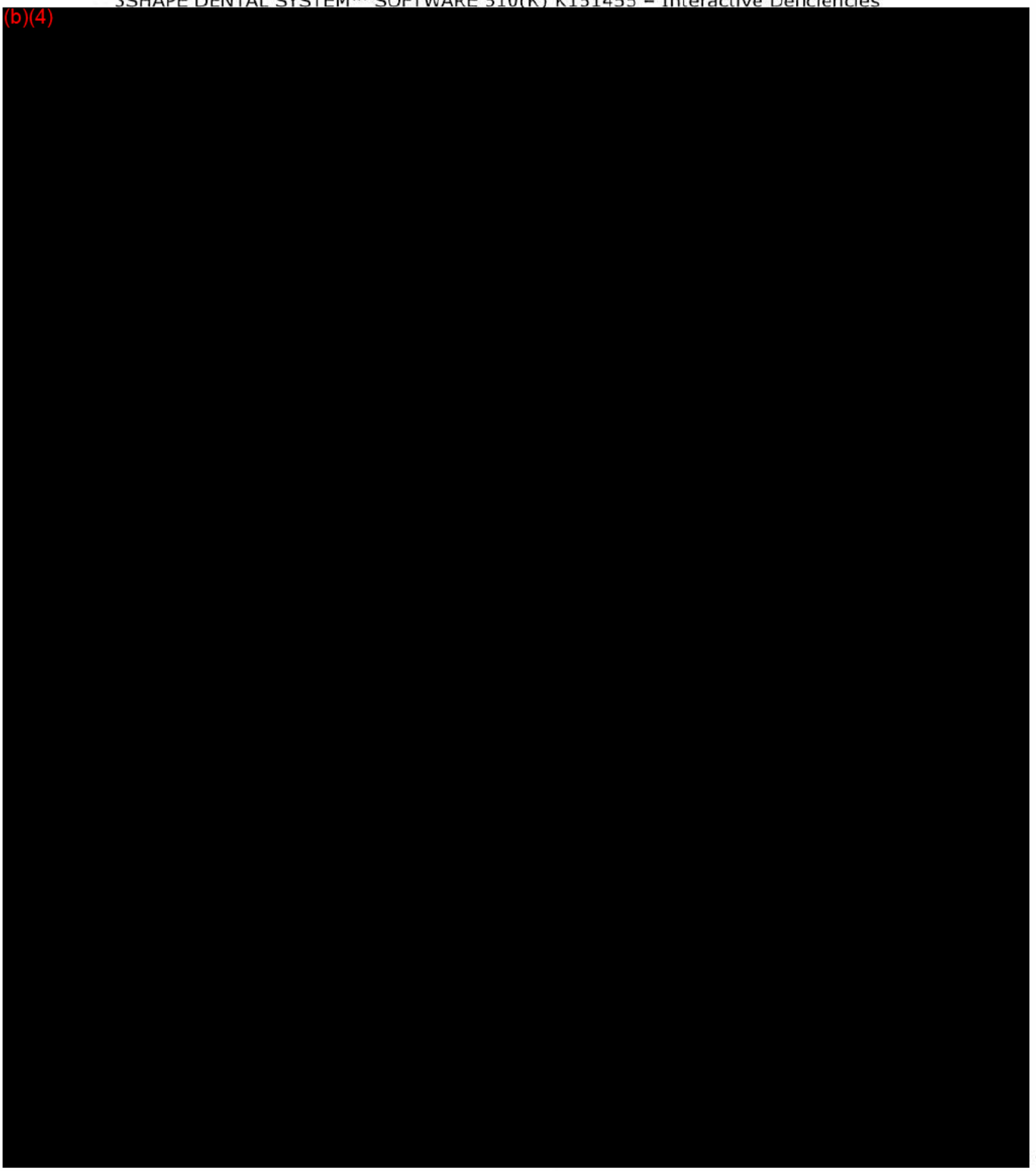

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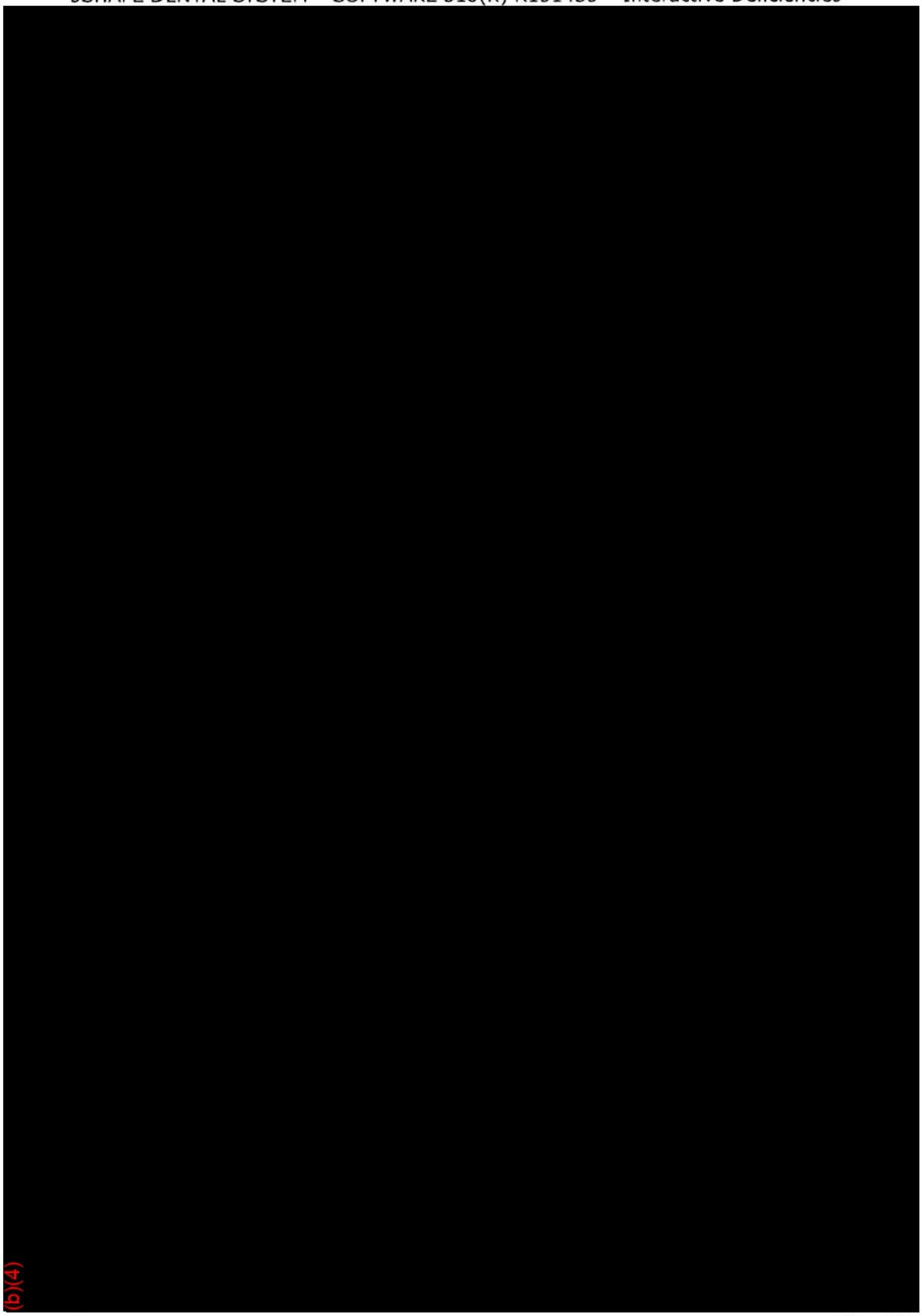

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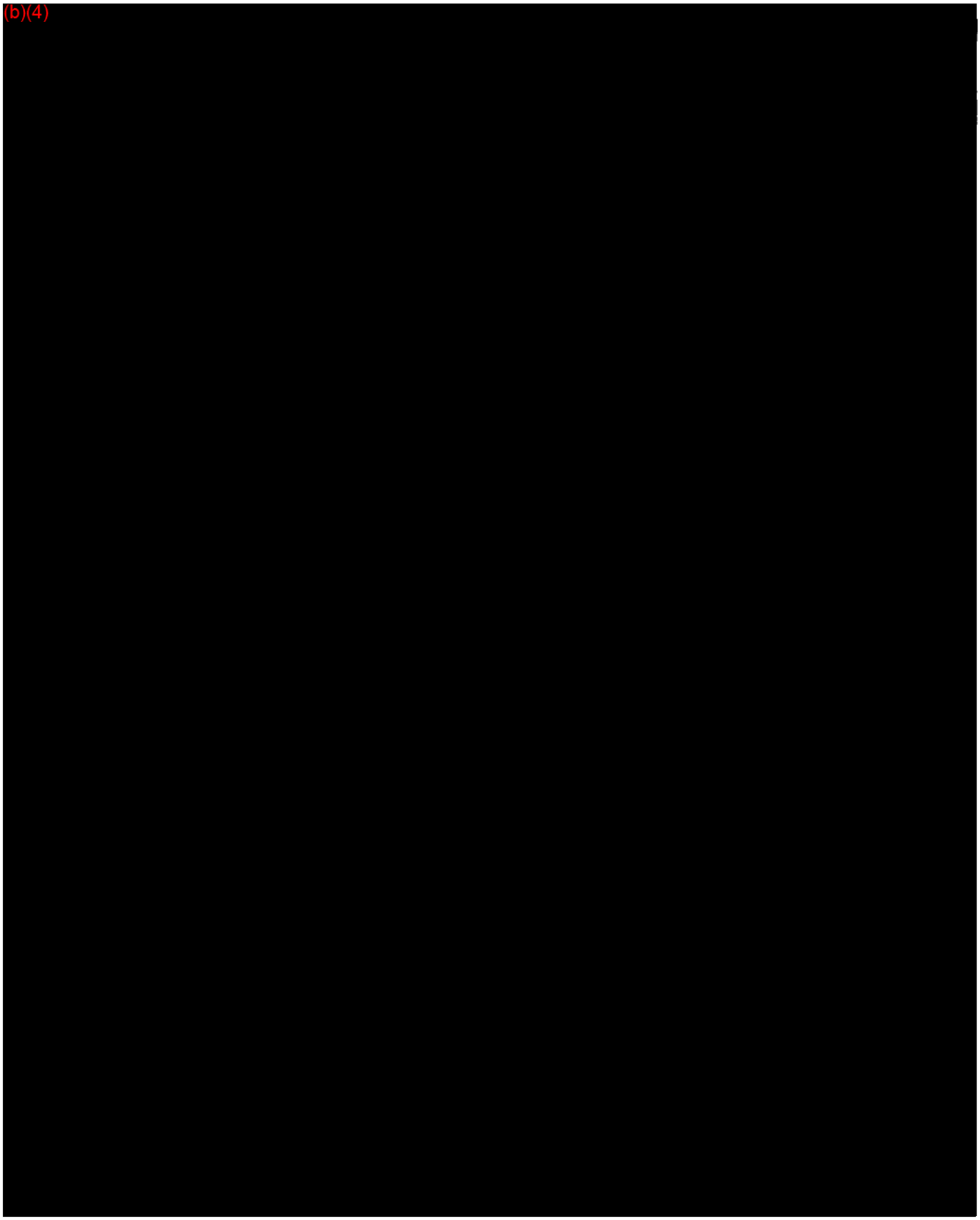

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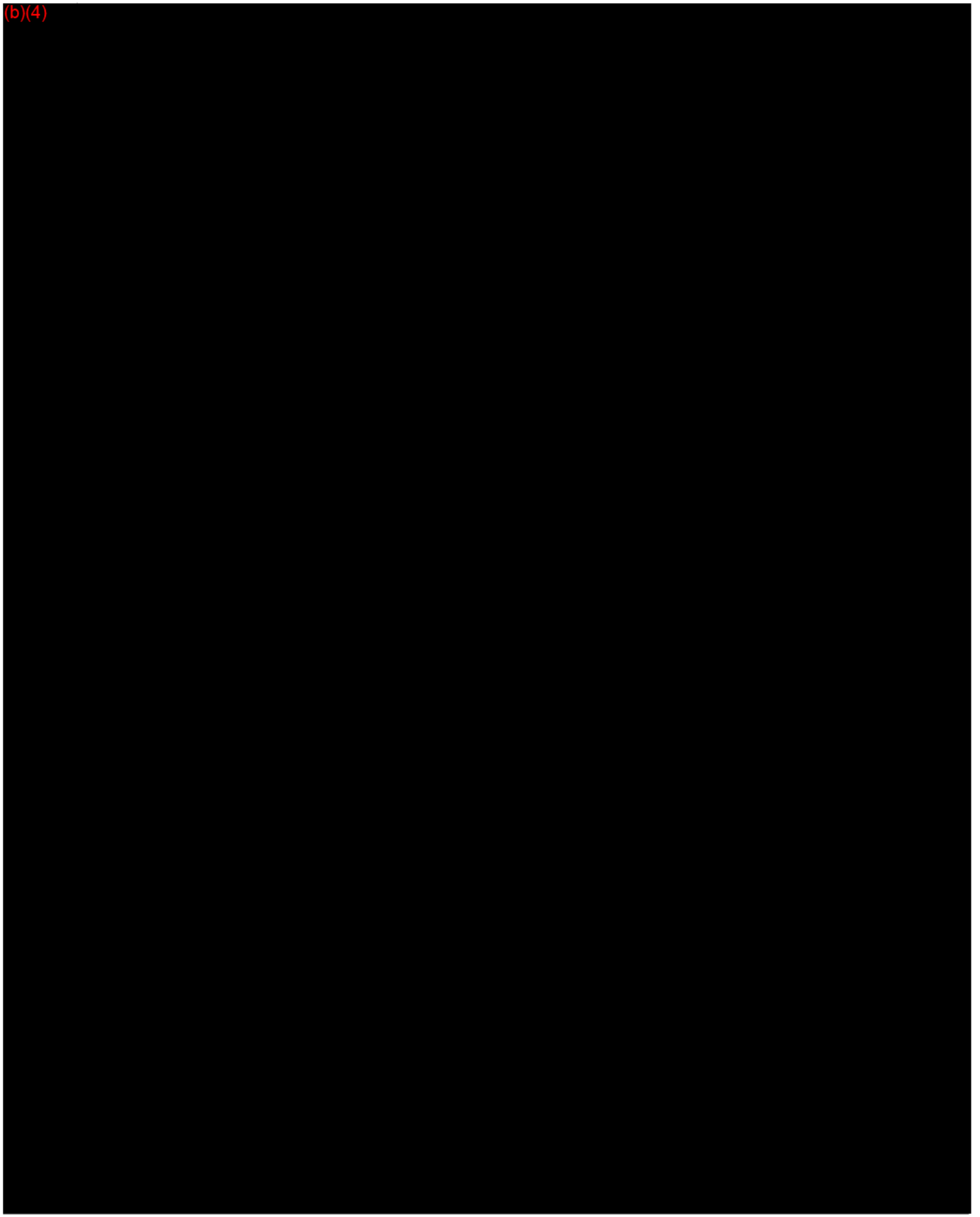

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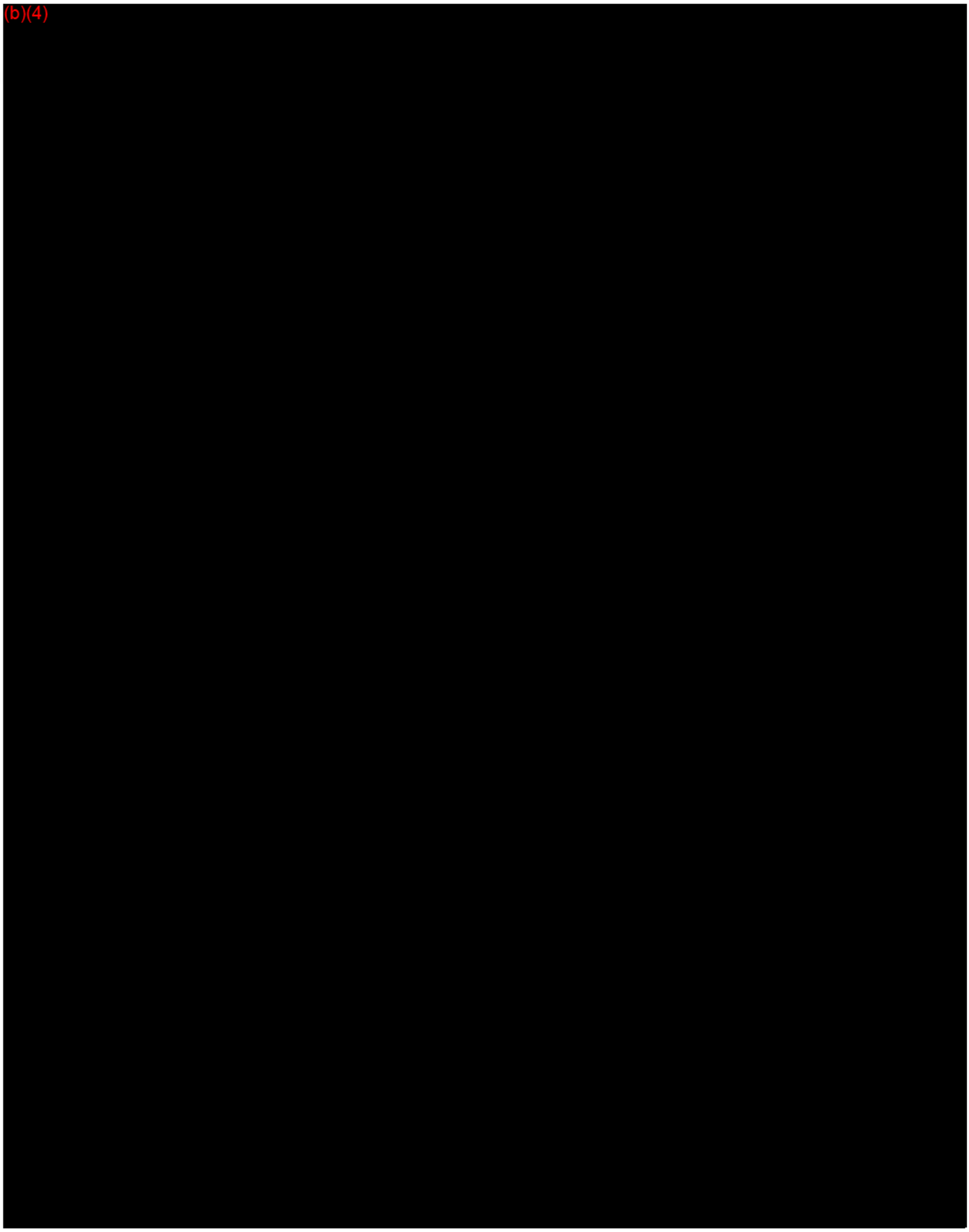

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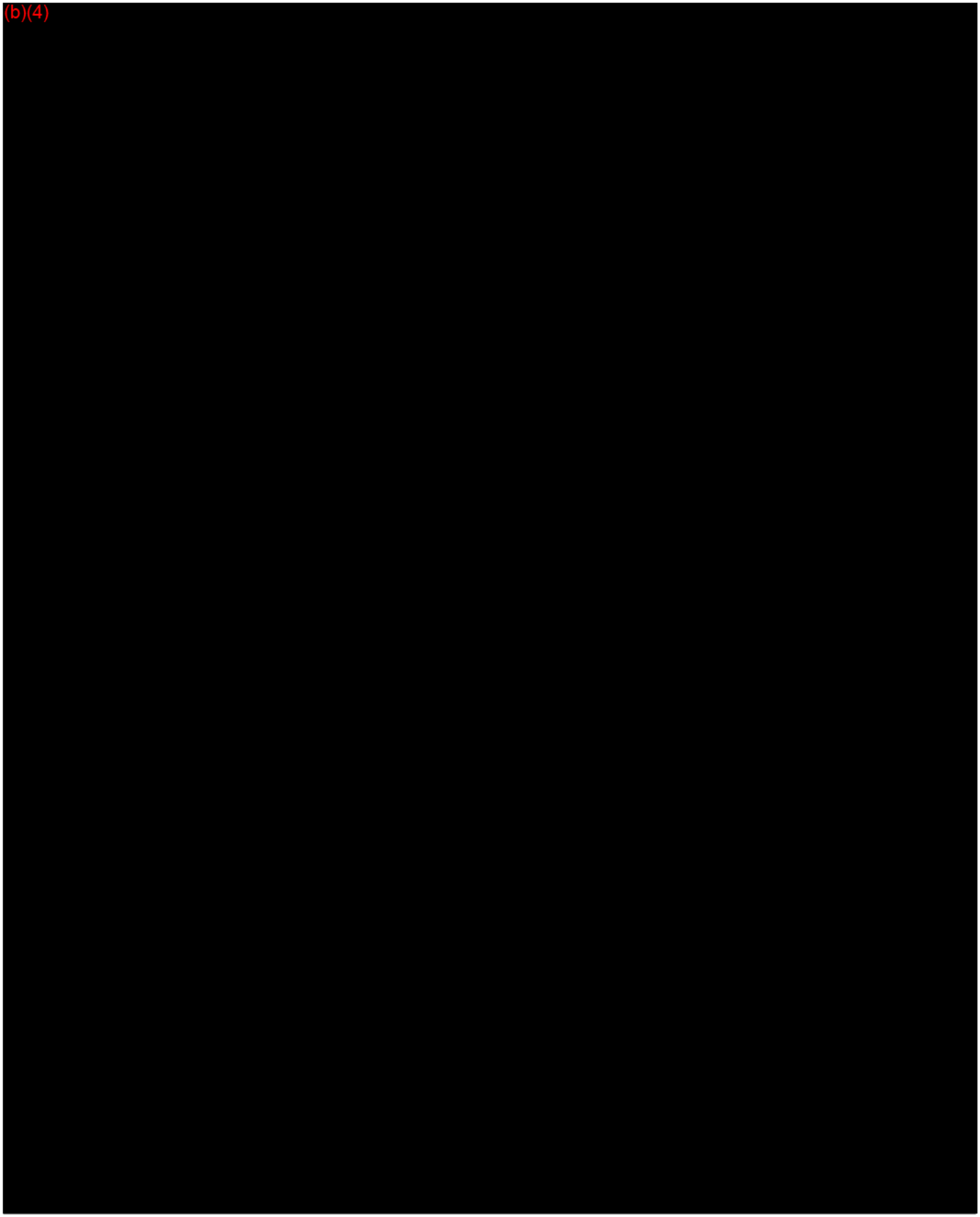

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