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To:	Logic Technology Development, LLC
From:	Environmental Resources Management, Inc.
Date:	November 17, 2018
Subject:	**Environmental Assessment for the Logic® Vapeleaf™ Electronic Nicotine Delivery Systems (ENDS) Products**

This environmental assessment was prepared in accordance with 21 CFR 25.20 and 21 CFR 25.40, the Food and Drug Administration's (FDA's or Agency's) regulation implementing the National Environmental Policy Act of 1969 (NEPA). Under NEPA, "all applications or petitions requesting Agency action require the submission of an environmental assessment or a claim of categorical exclusion".[1]

The Logic® Vapeleaf™ Products ("New Products") are novel electronic nicotine delivery systems (ENDS) products with a tobacco component. Absent a categorical exclusion for ENDS or tobacco products, Environmental Resources Management, Inc. (ERM) respectfully submits the following environmental assessment in support of the Premarket Tobacco Applications (PMTAs) for the Logic Vapeleaf Products pursuant to 21 CFR 25.20. The environmental assessment was prepared in accordance with 21 CFR 25.40 and relevant aspects of FDA guidance including:

- *Environmental Considerations for Tobacco Product Applications Submitted to CTP, presented by Cristi Stark, M.S., Associate Director for Science Policy, Office of Science, CTP, FDA (August 2016);*
- *Environmental Considerations for Premarket Tobacco Product Applications Submitted to CTP, presented at "The Premarket Tobacco Product Application for Electronic Nicotine Delivery Systems (ENDS): A Public Seminar" by*

[1] 21 CFR 25.15(a)

Gregory Gagliano, M.S., Toxicologist, Division of Nonclinical Science, Office of Science, CTP, FDA (October, 17 2016);

- *Draft guidance: Premarket Tobacco Product Applications for Electronic Nicotine Delivery Systems. Presented by: Paul Hart, J.D. Ii-Lun Chen, M.D. Center for Tobacco Products Food and Drug Administration;*
- *Guidance for Industry: Environmental Impact Assessments (EIA's) for Veterinary Medicinal Products (VMP's) – Phase I (March 2001); and*
- *Guidance for Industry: Environmental Assessment of Drug and Biologics Applications (July 1998).*

This environmental assessment was prepared at the request of Logic Technology Development, LLC (Logic). The potential aquatic, atmospheric, and terrestrial environmental effects of marketing the New Products were considered using a conservative set of assumptions. The assessment identified no significant environmental impacts, and a Finding of No Significant Impact by FDA is warranted for this environmental assessment of the New Products.

Confidentiality Statement

This memorandum contains trade secret and confidential commercial information that Logic considers to be proprietary and highly sensitive, and which is protected from disclosure under the Food, Drug and Cosmetic Act §§ 301(j) (21 U.S.C. §§ 331(j)), the Trade Secrets Act (18 U.S.C. 1905), the Freedom of Information Act (5 U.S.C. 552), and FDA's implementing regulations, 21 CFR Part 20 and Part 40. If FDA receives a request for these records and tentatively determines that any portion of this submission is disclosable, Logic requests that FDA provide notice and opportunity for Logic to object to any disclosure in accordance with 21 CFR 20.47 and 21 CFR 20.61. Logic reserves all of its legal rights to protect against public disclosure of its trade secret and confidential commercial information and to seek legal recourse against anyone who discloses such information without legal authorization.

1. DATE

November 17, 2018

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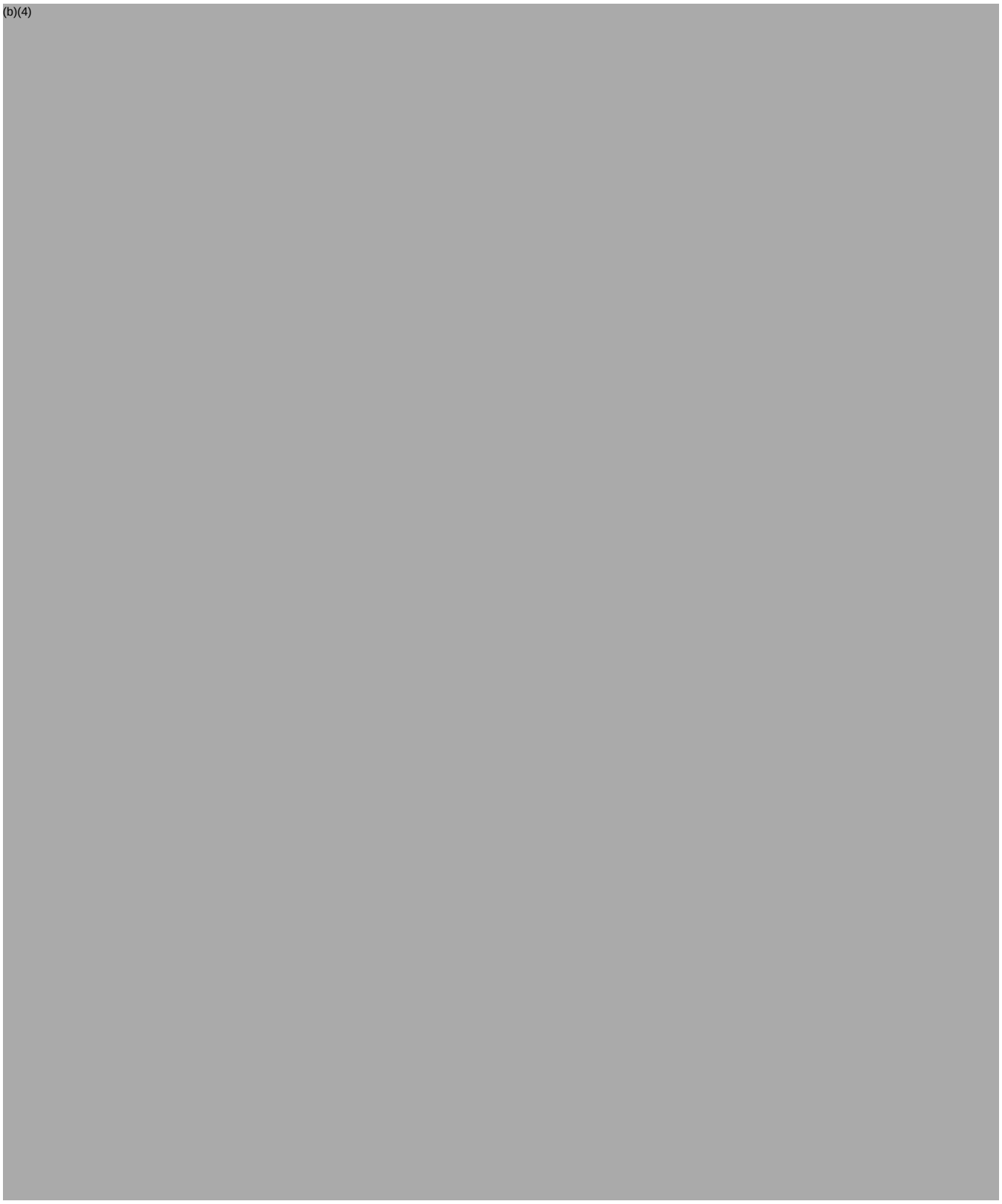

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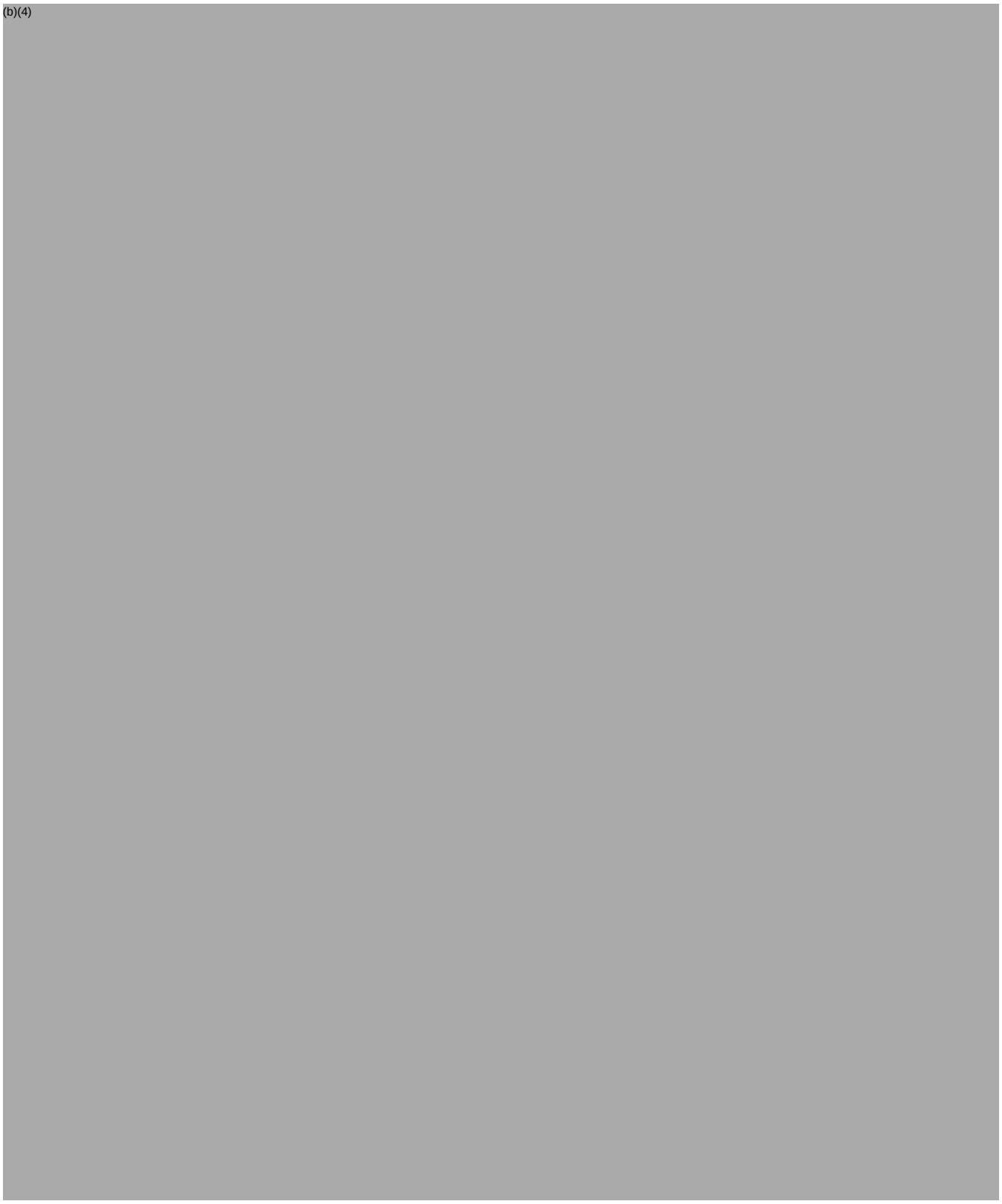

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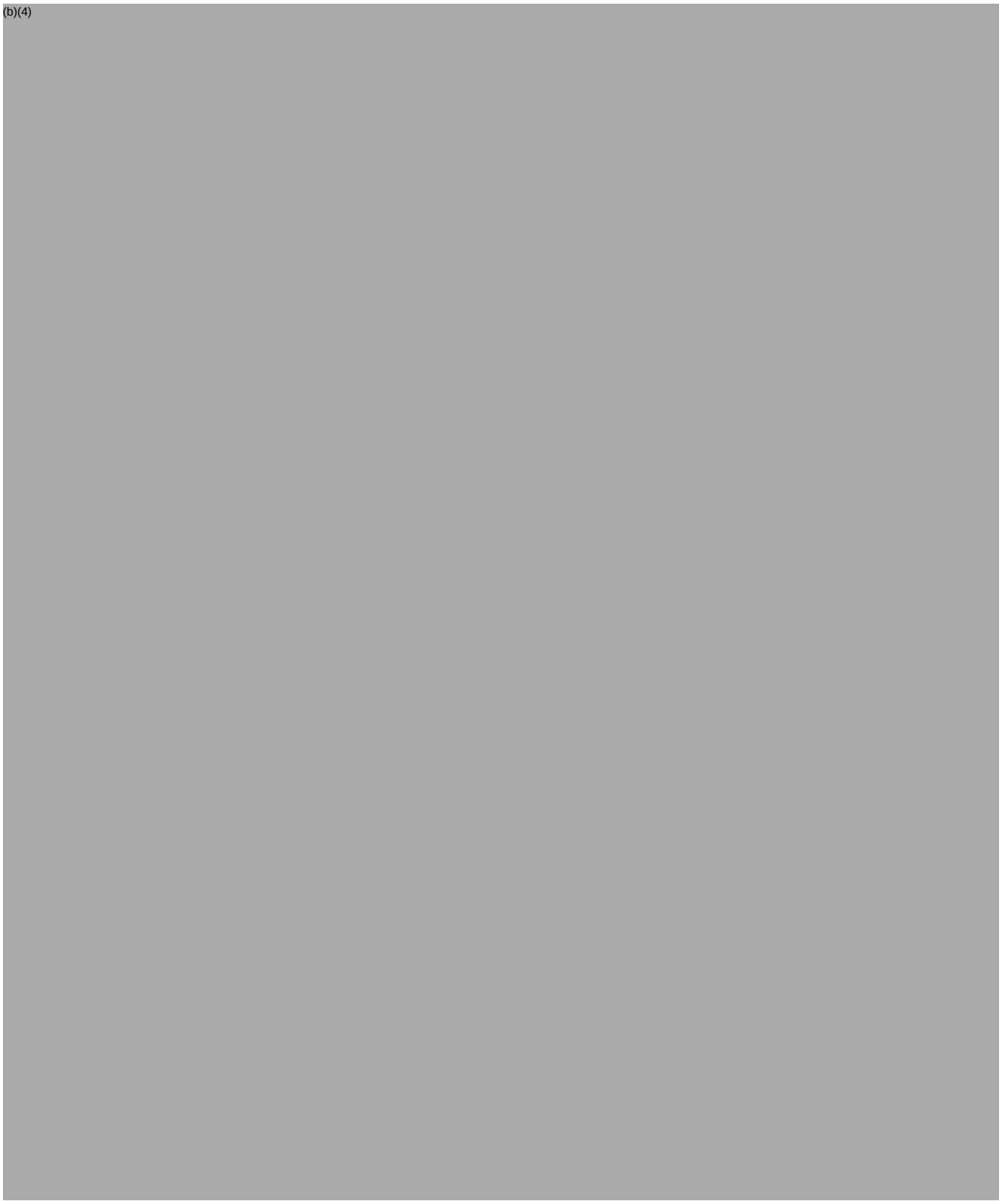

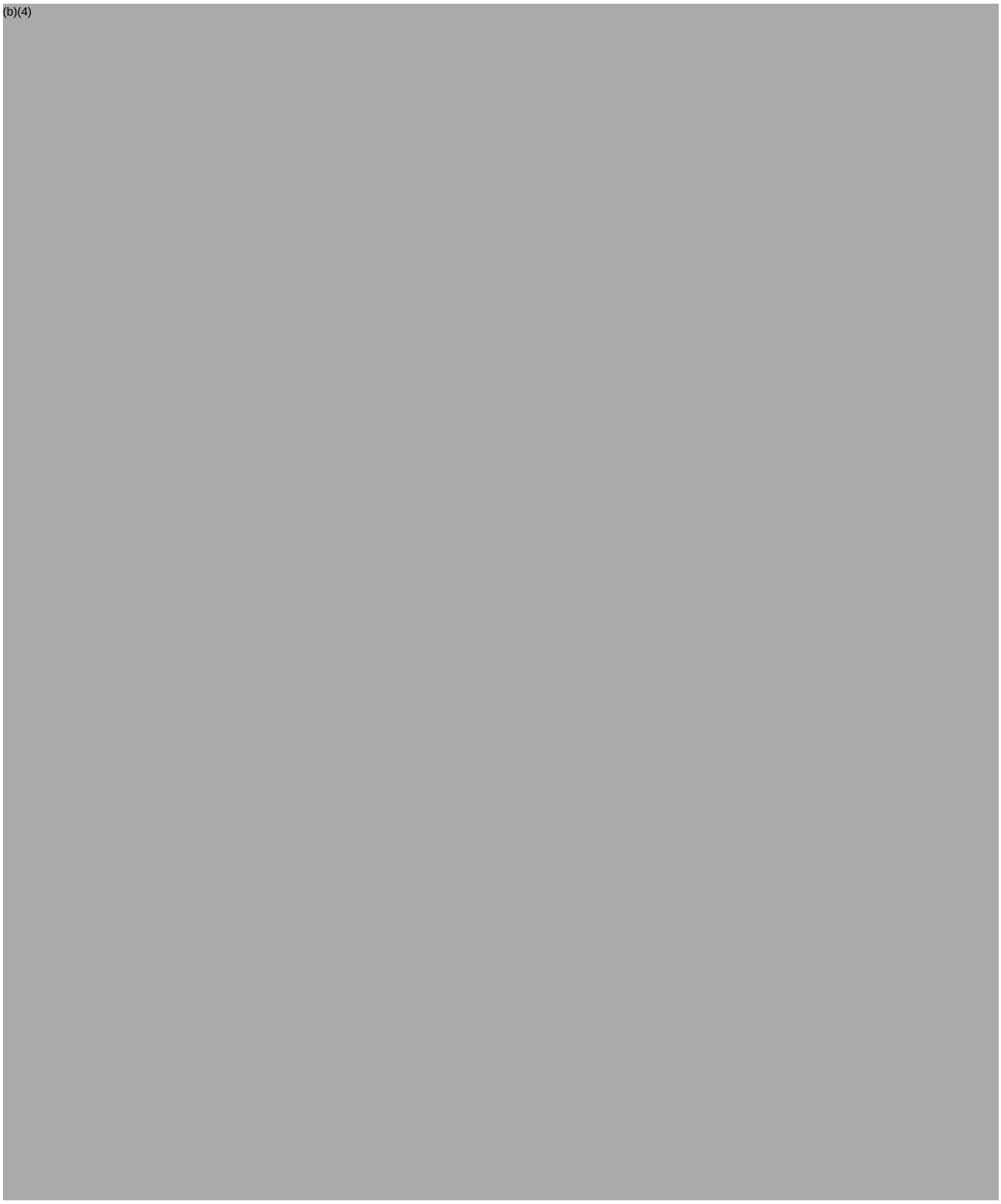
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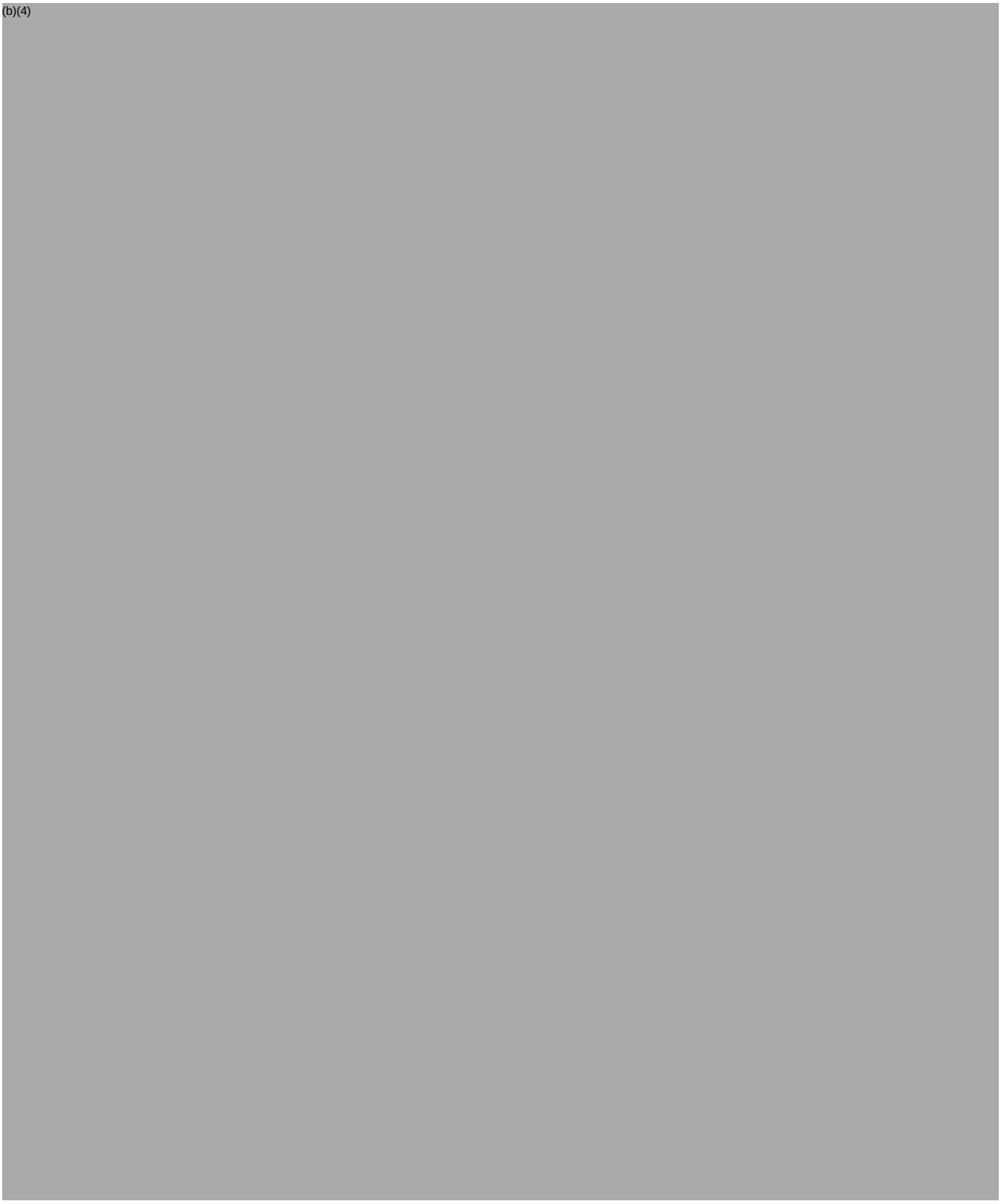

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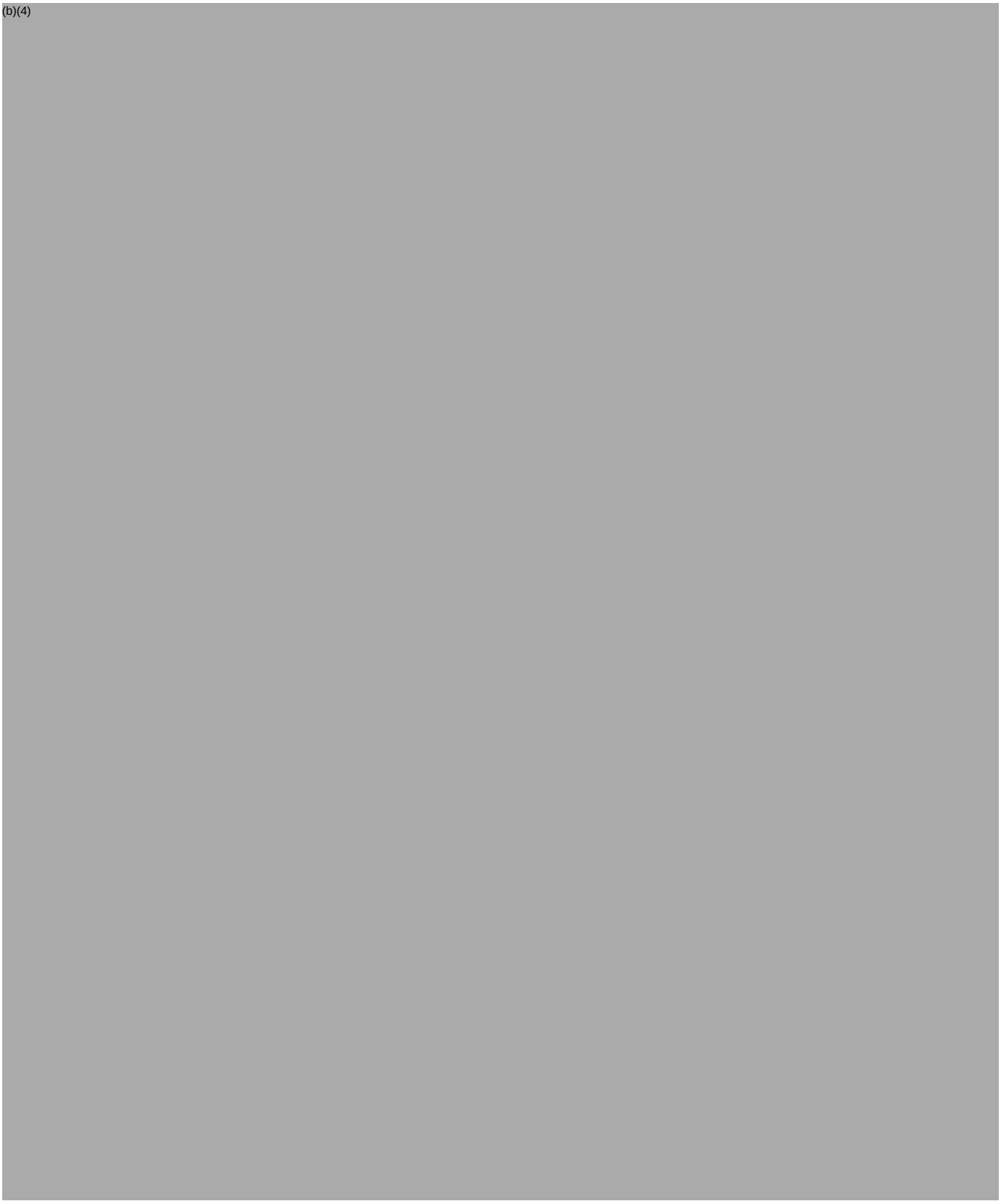

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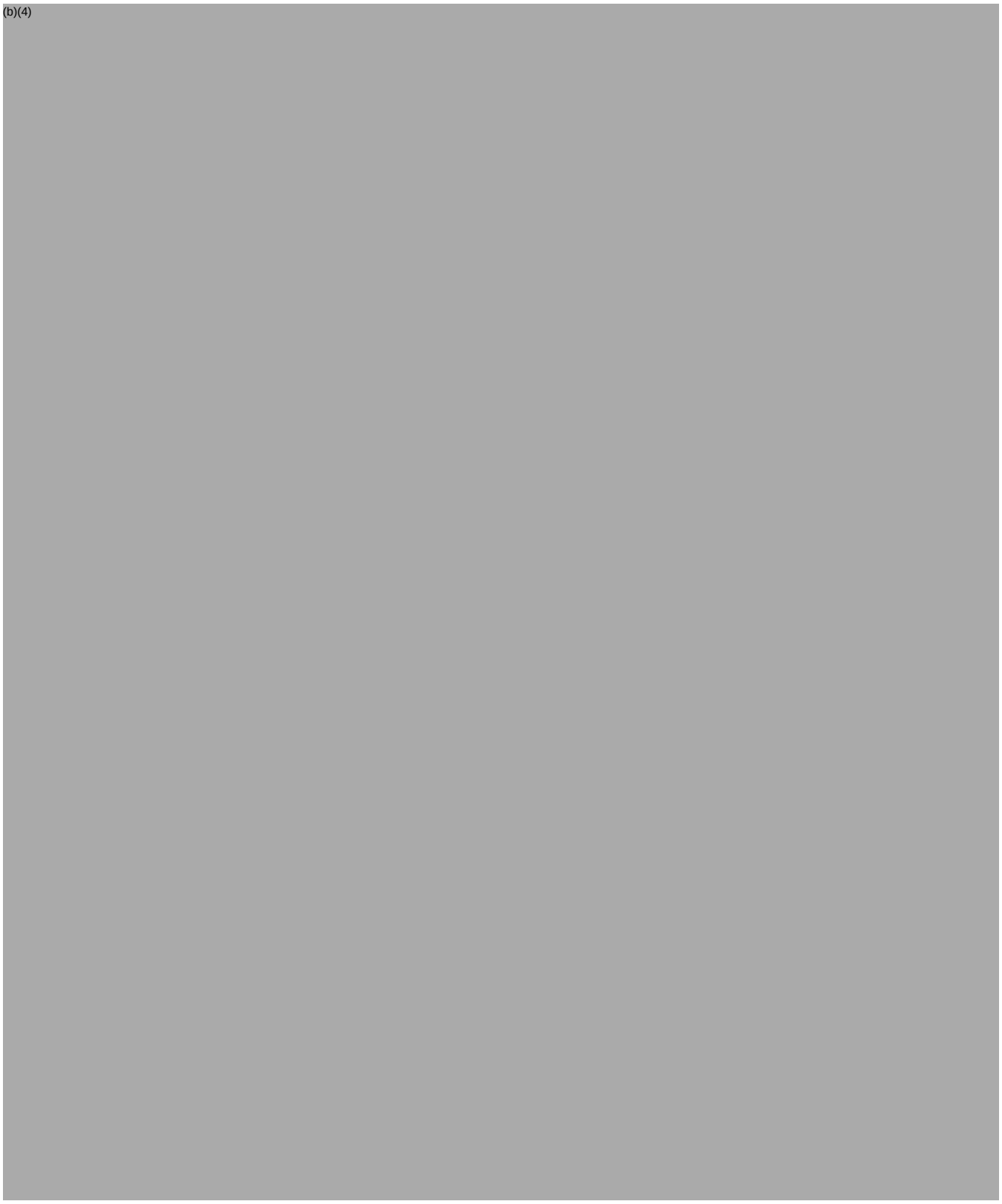

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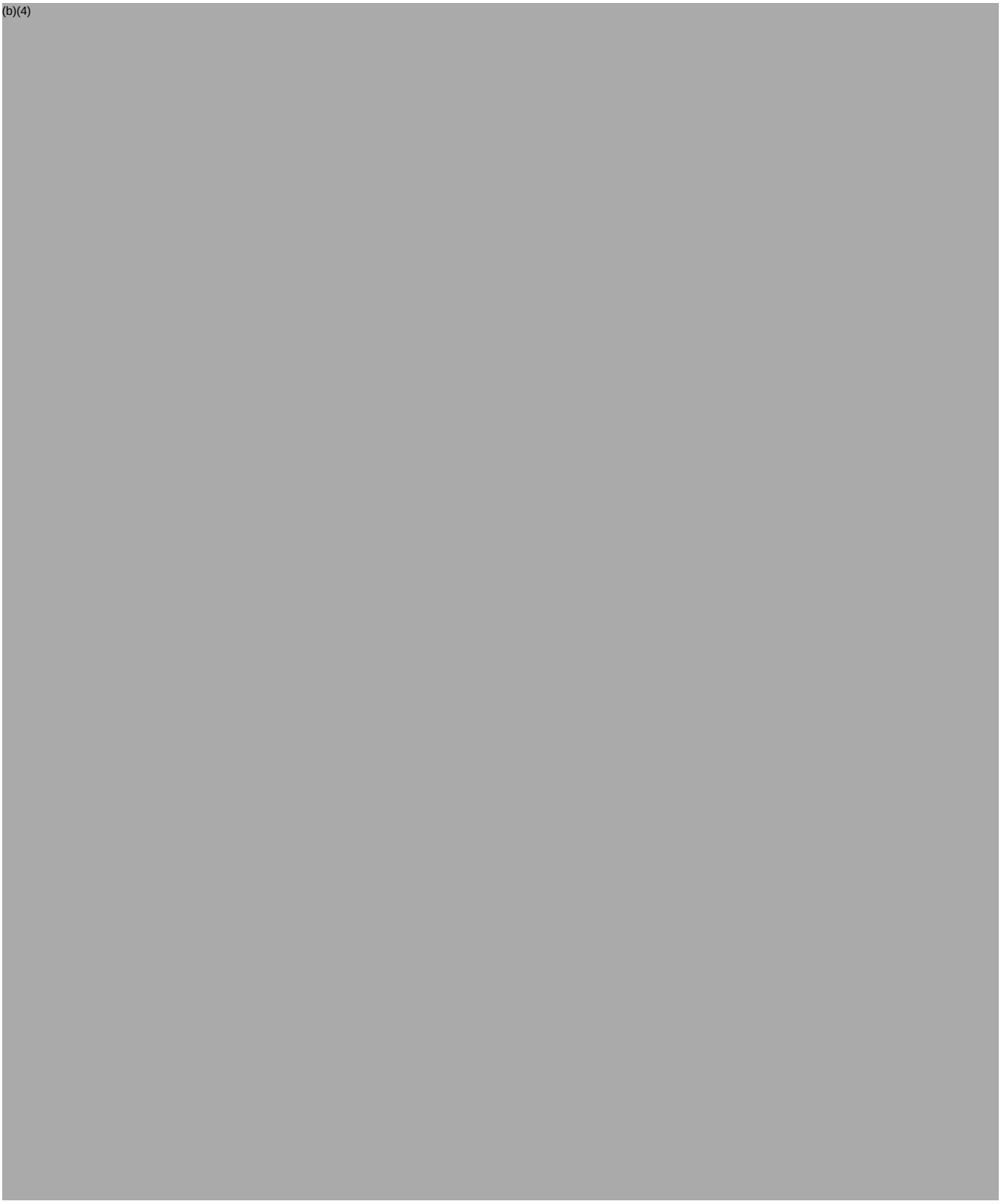

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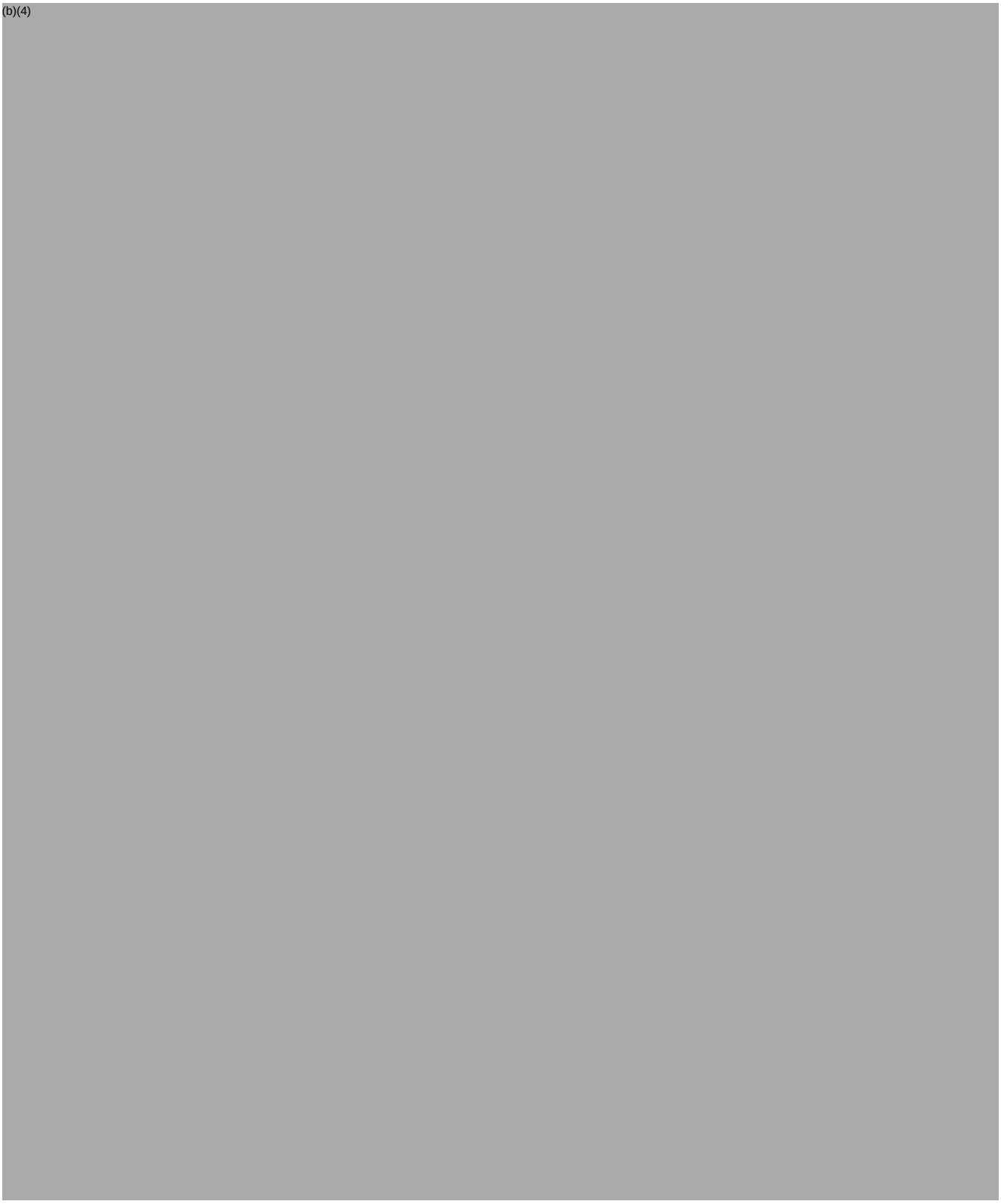

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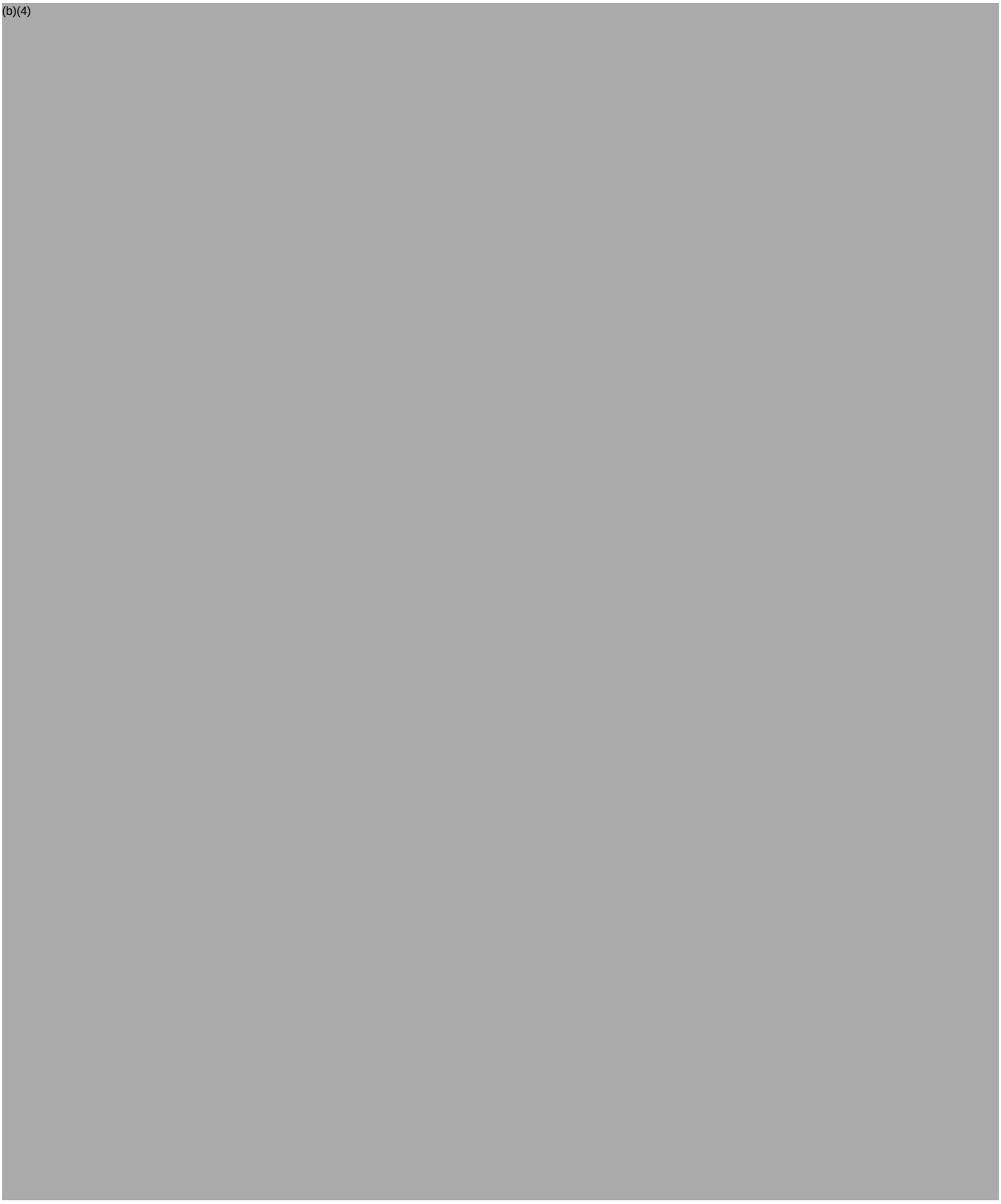

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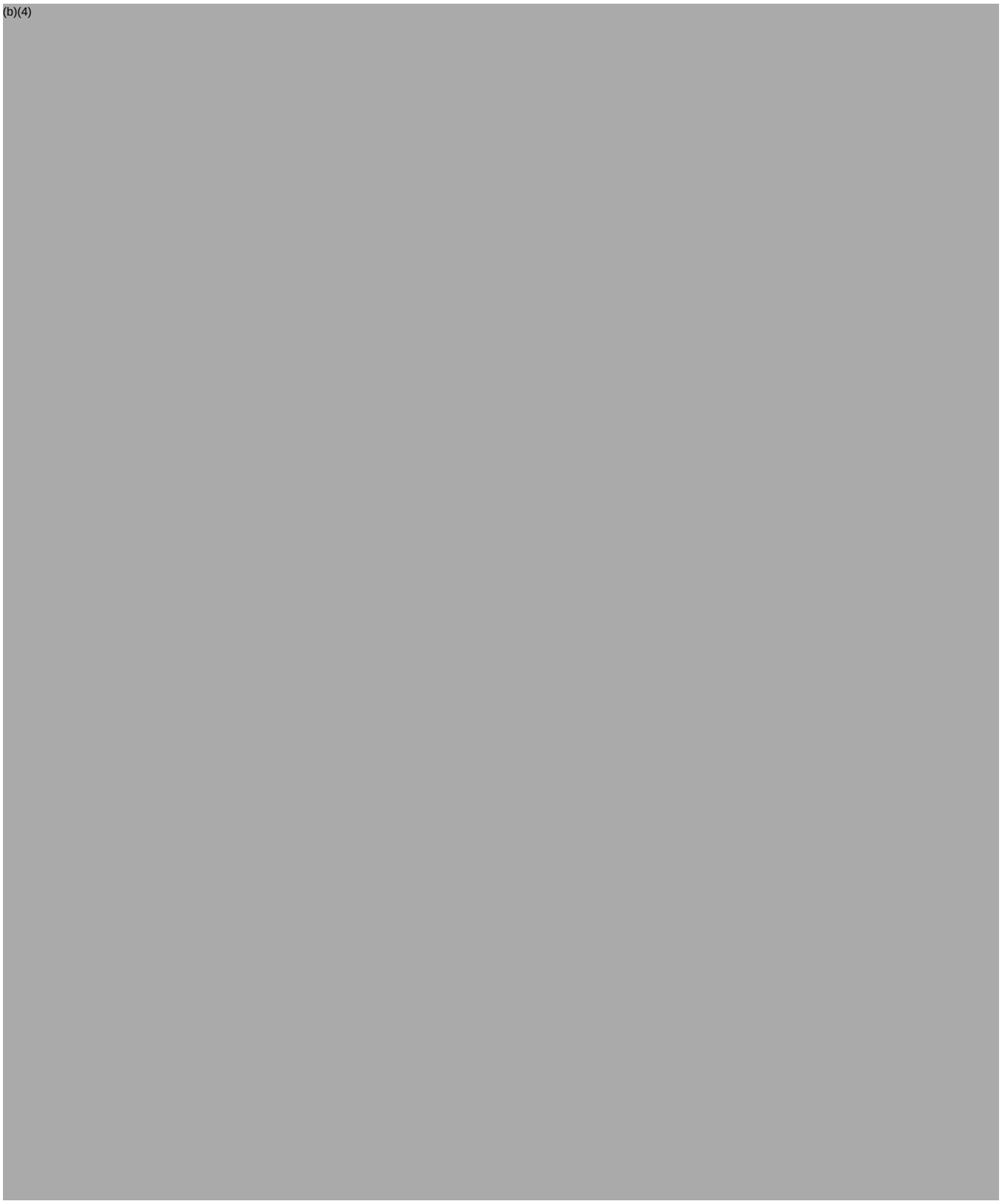

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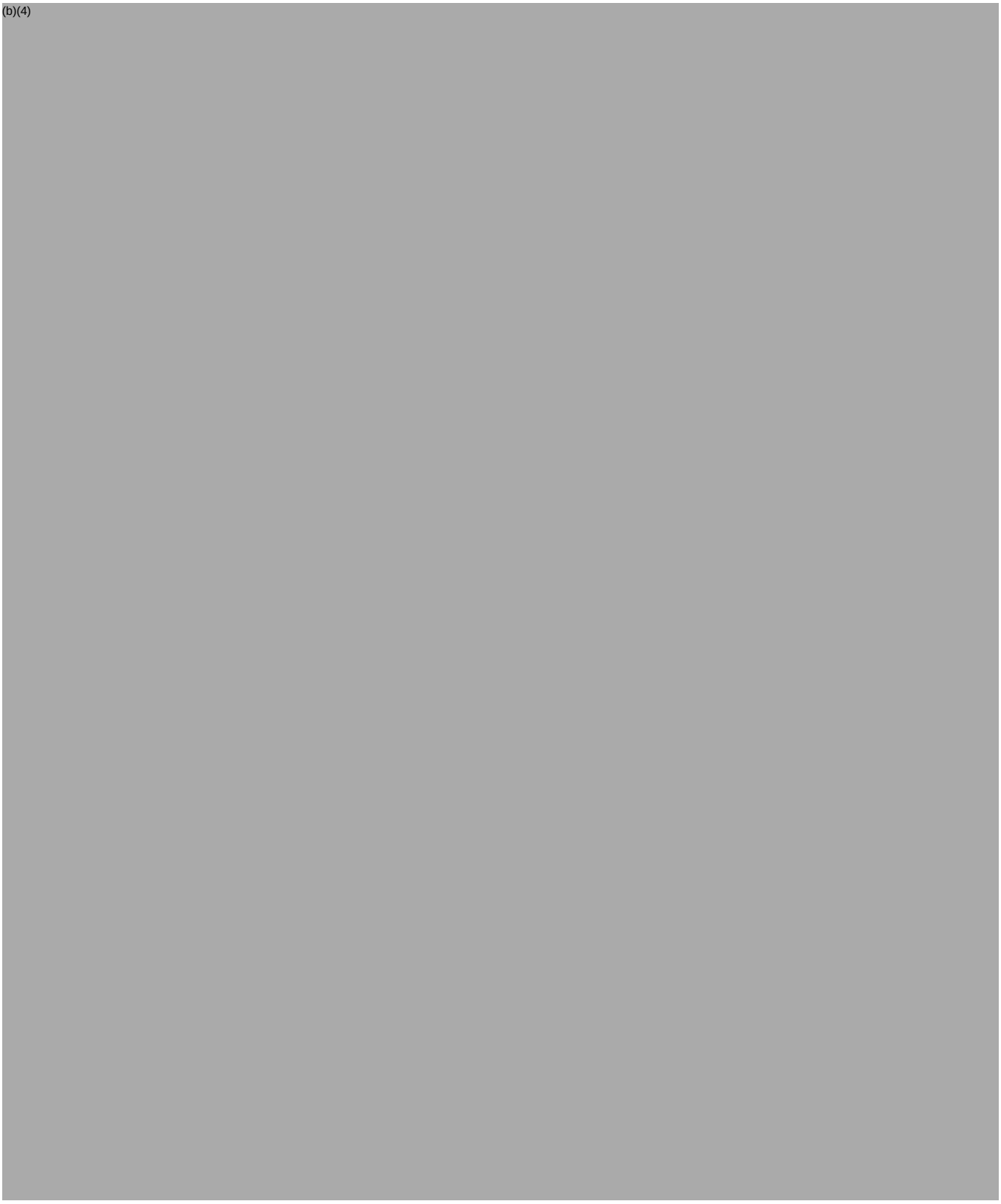

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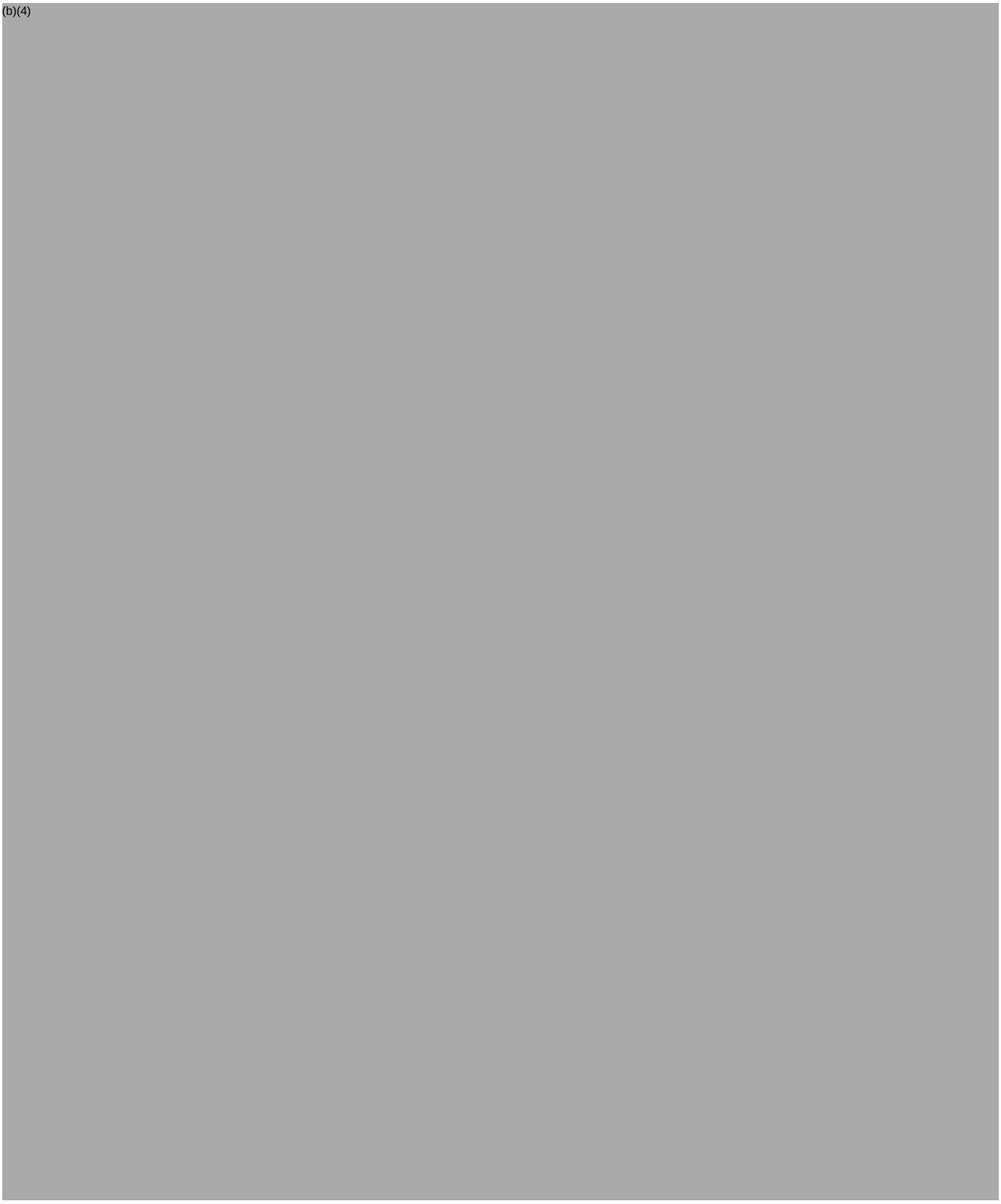

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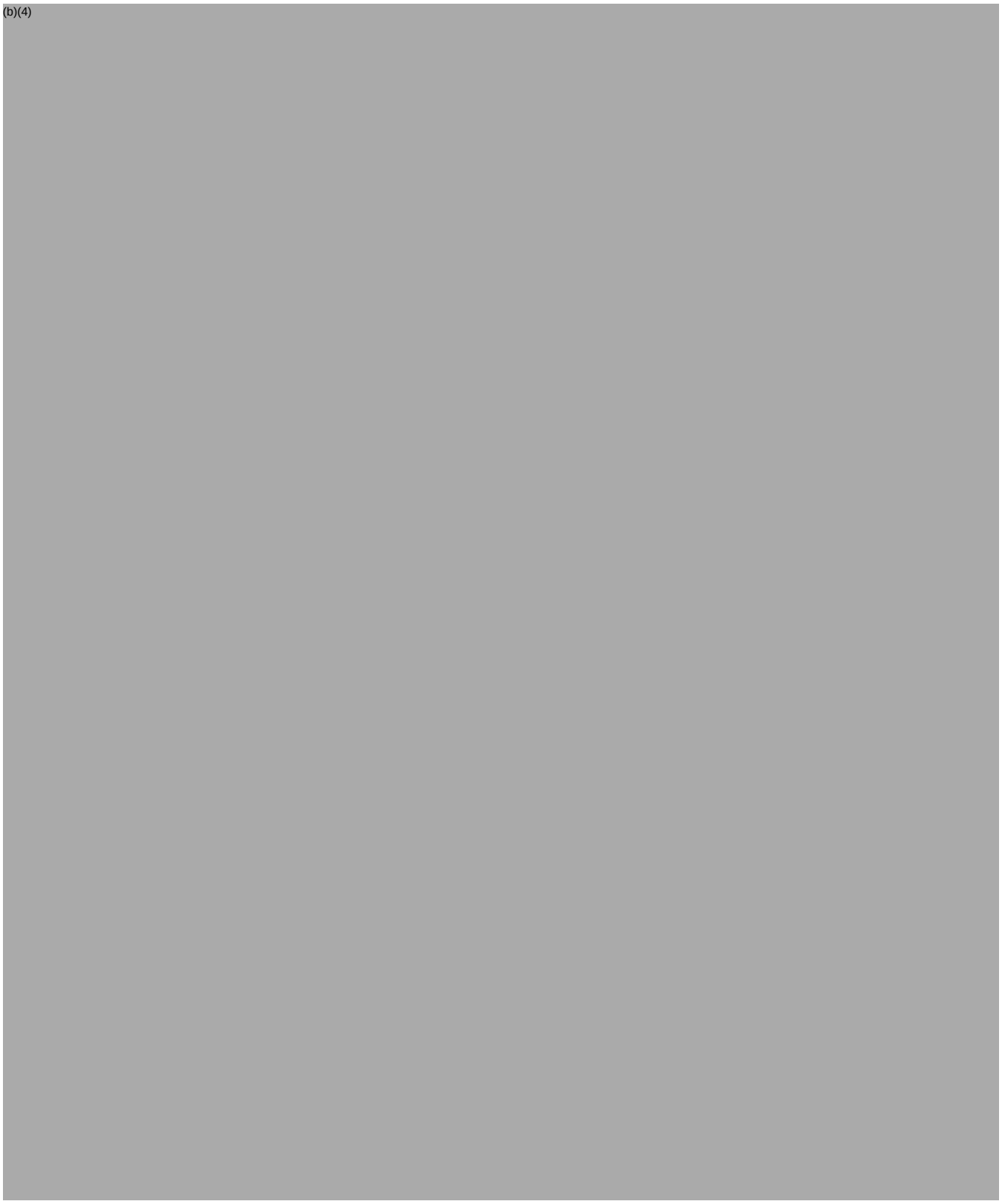

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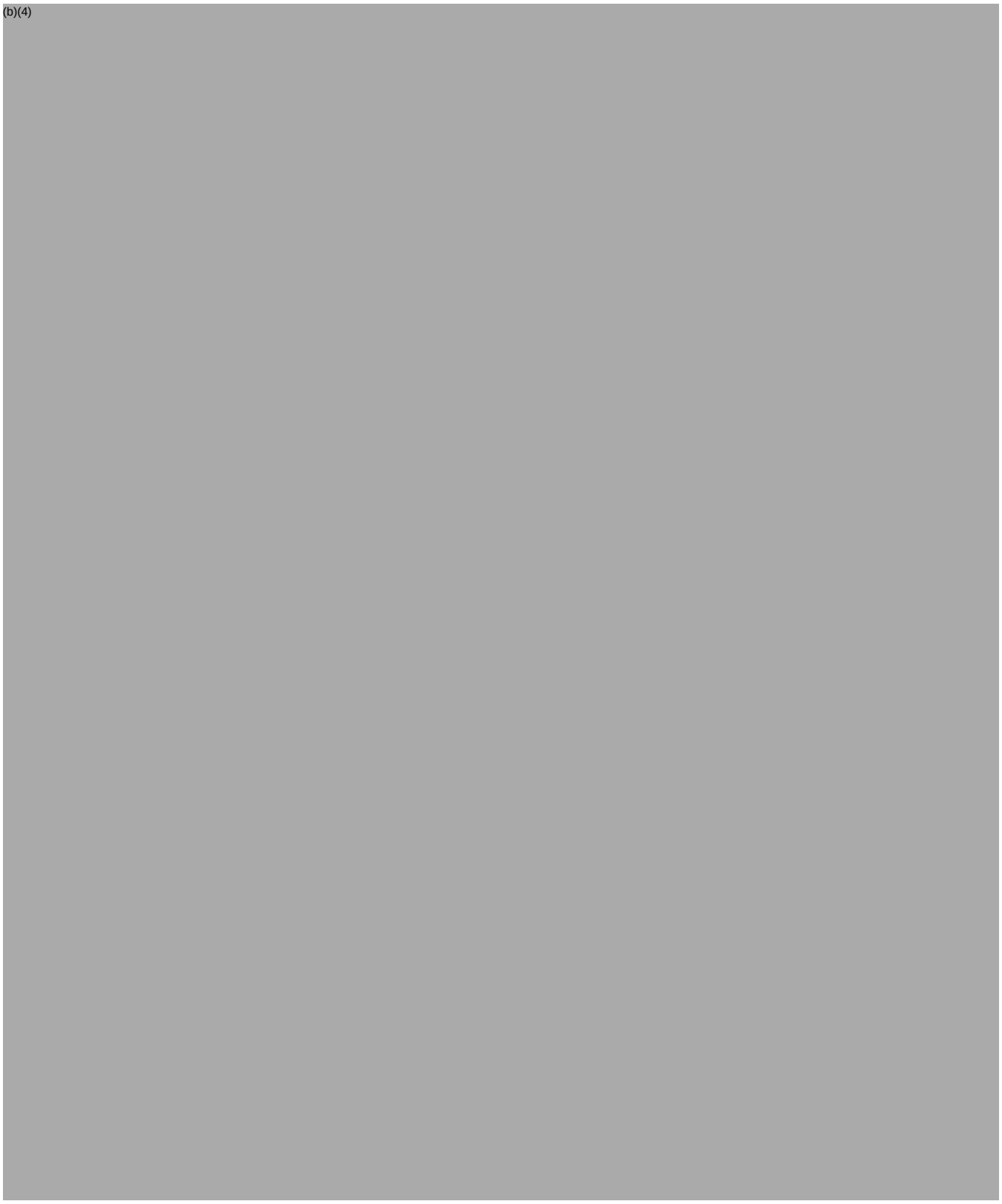

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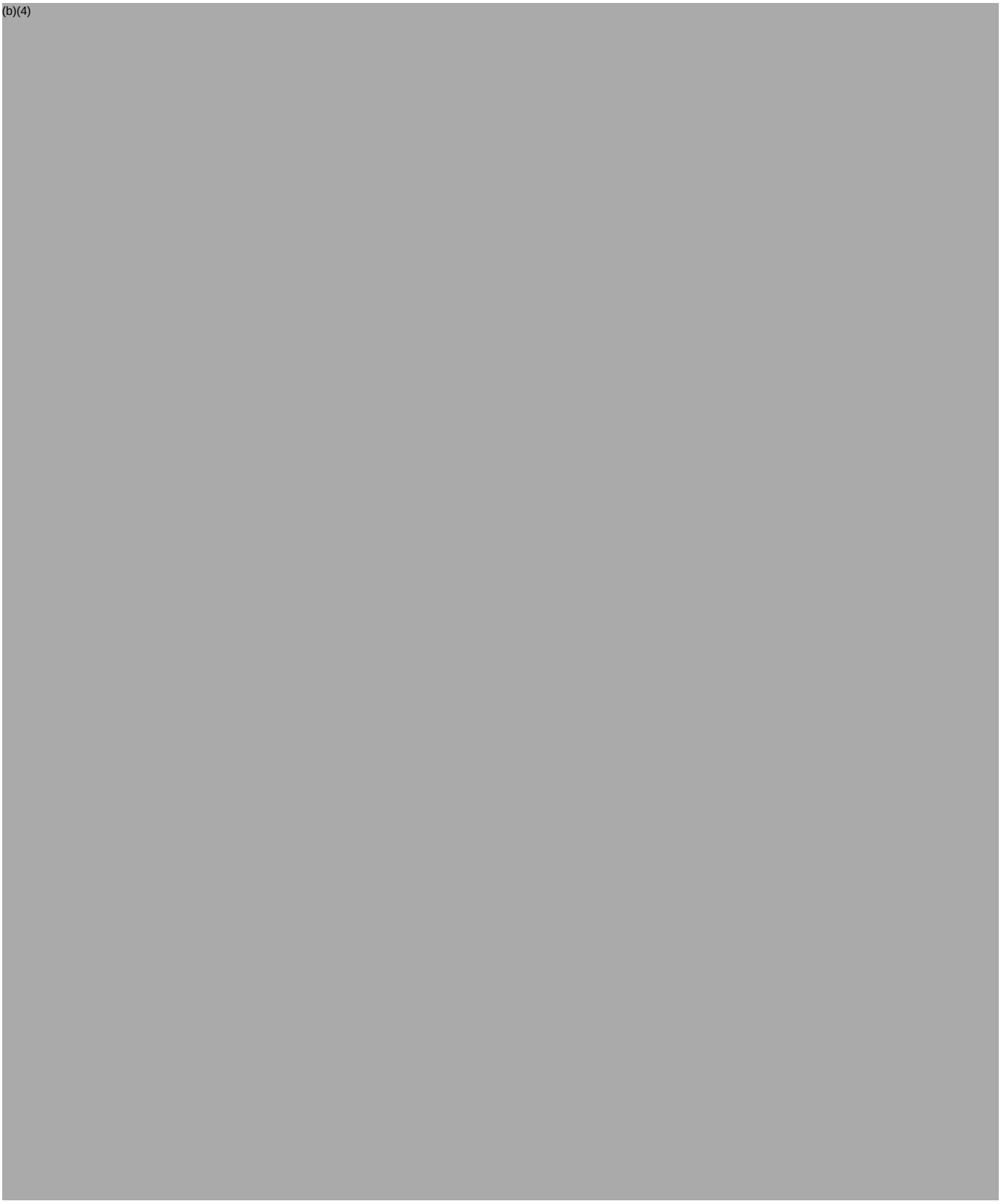

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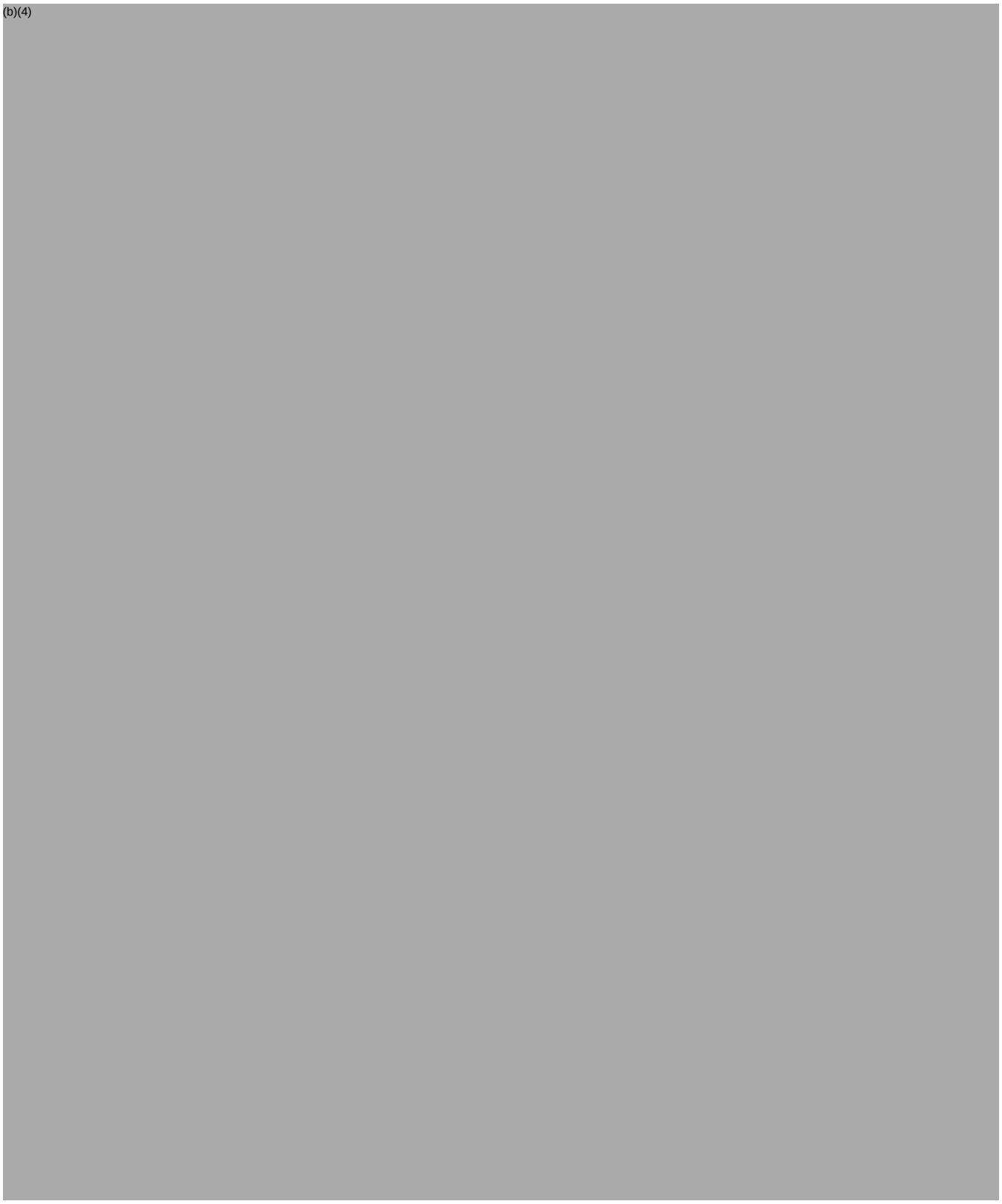

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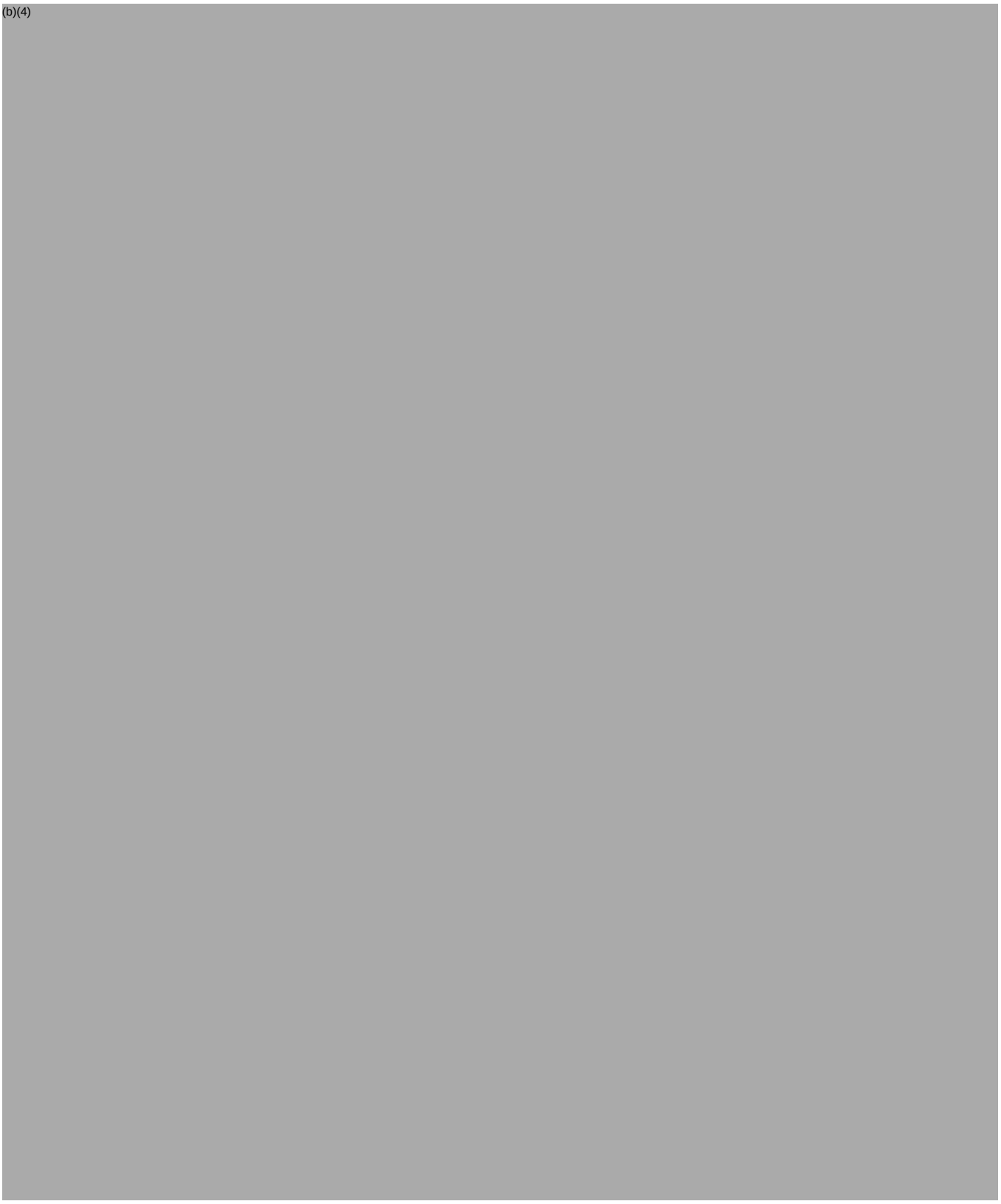

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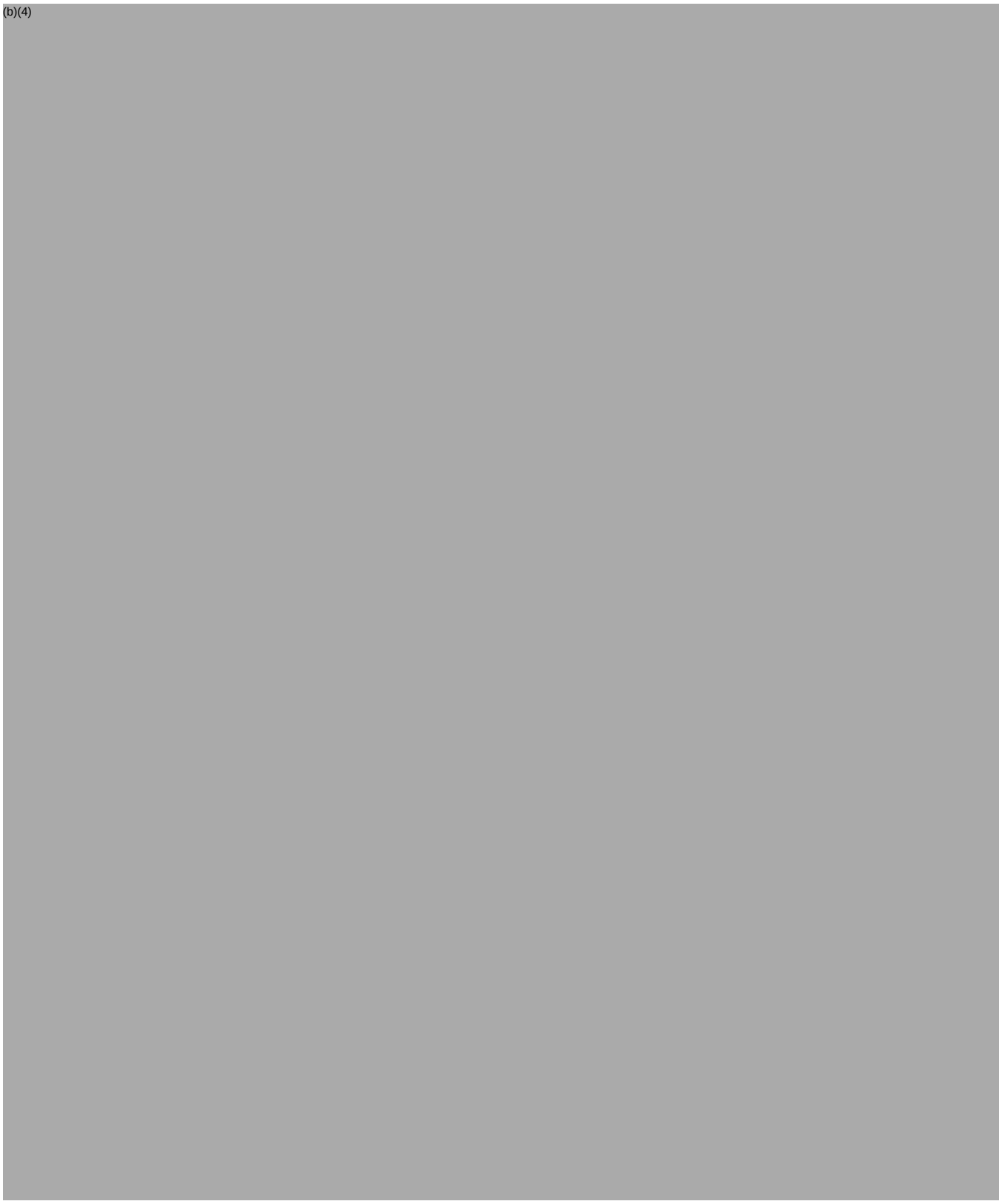

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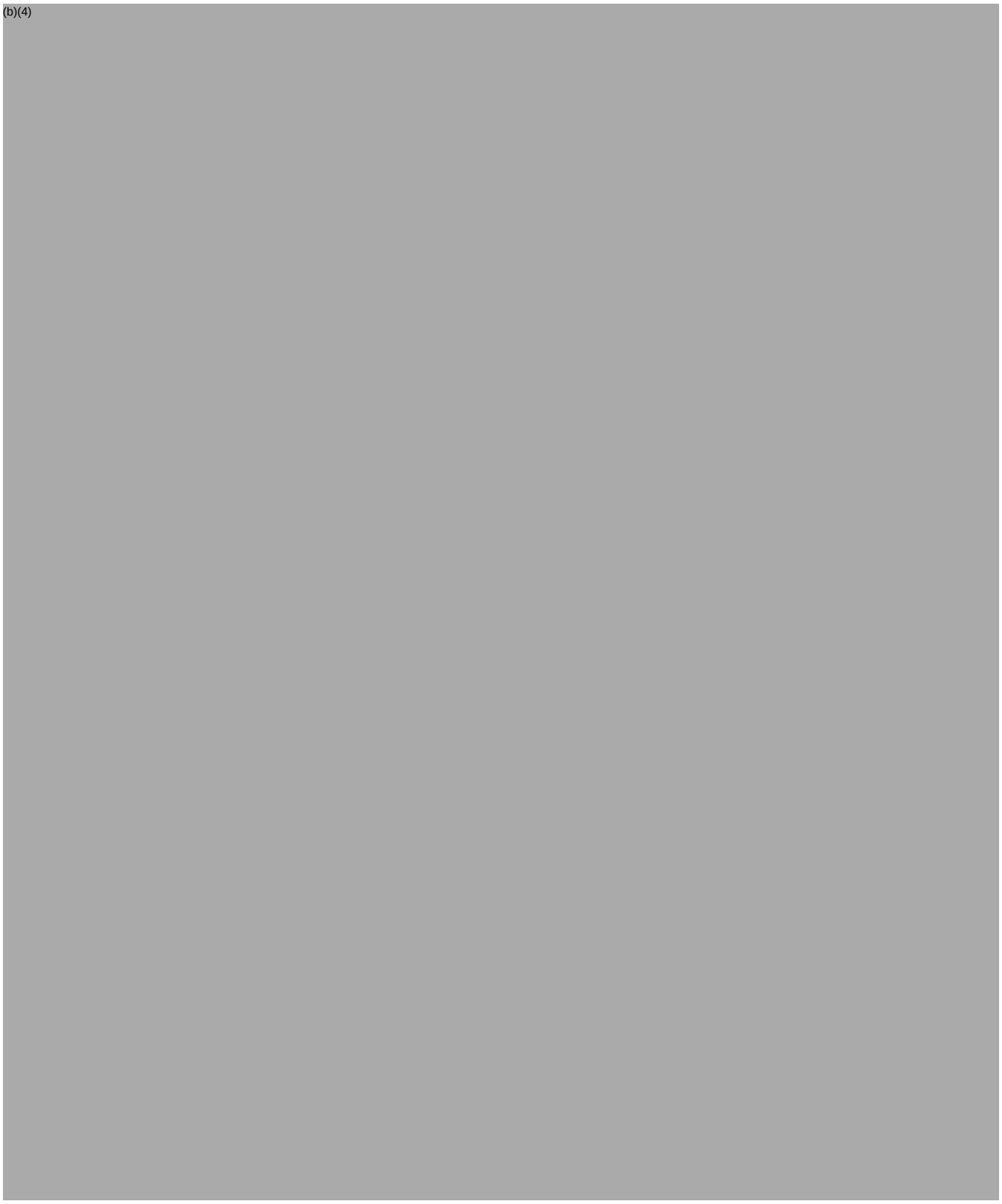

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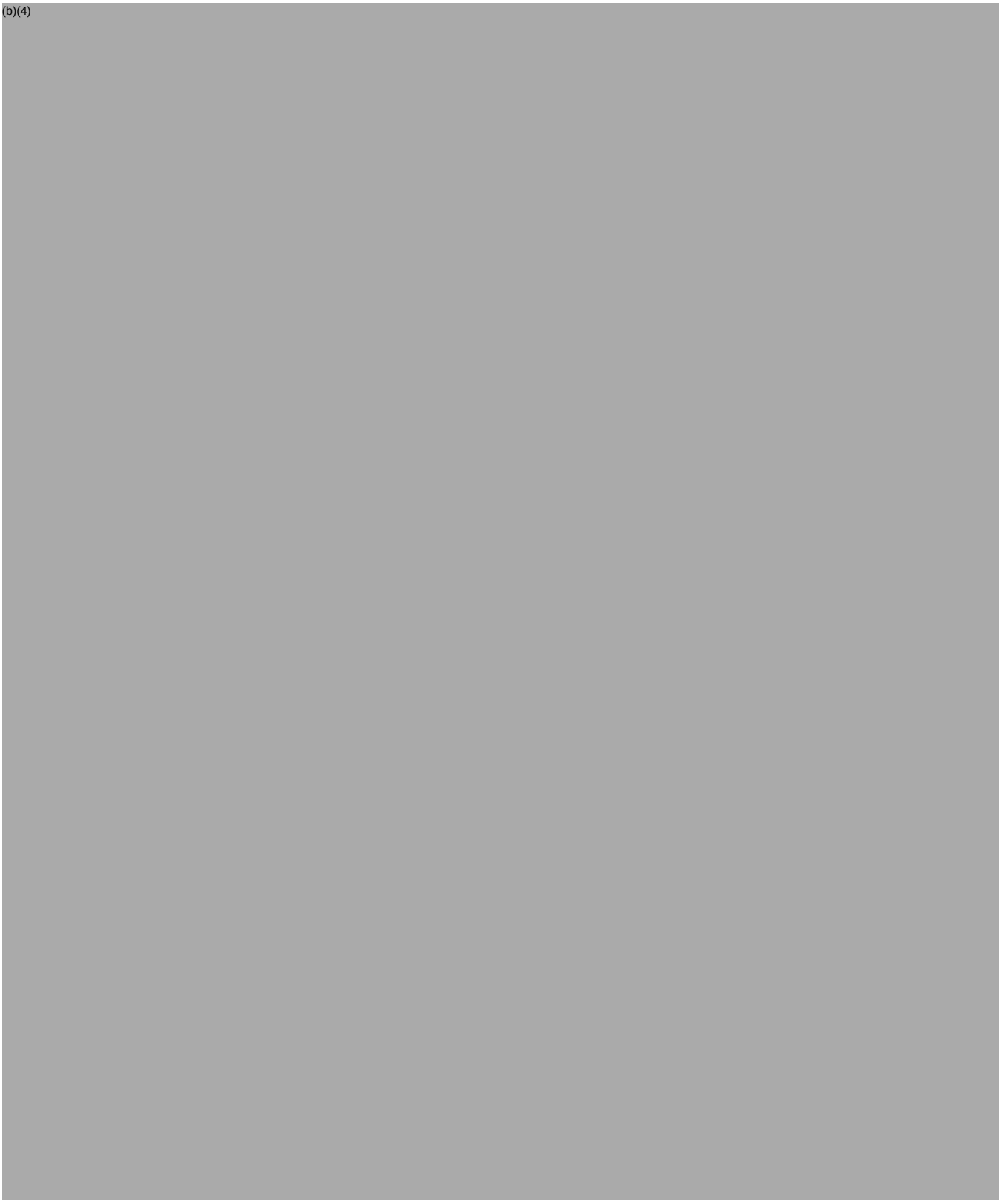

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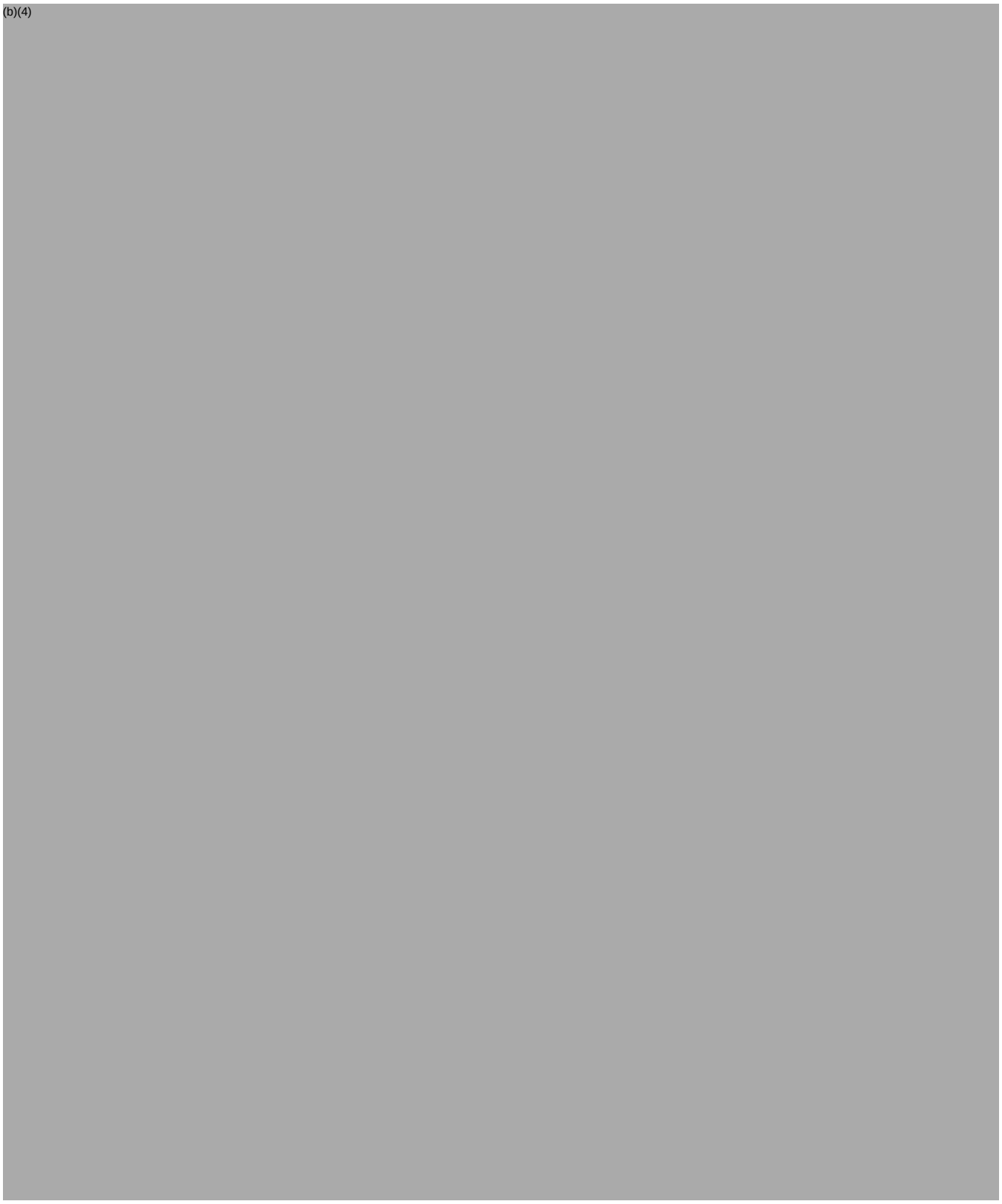

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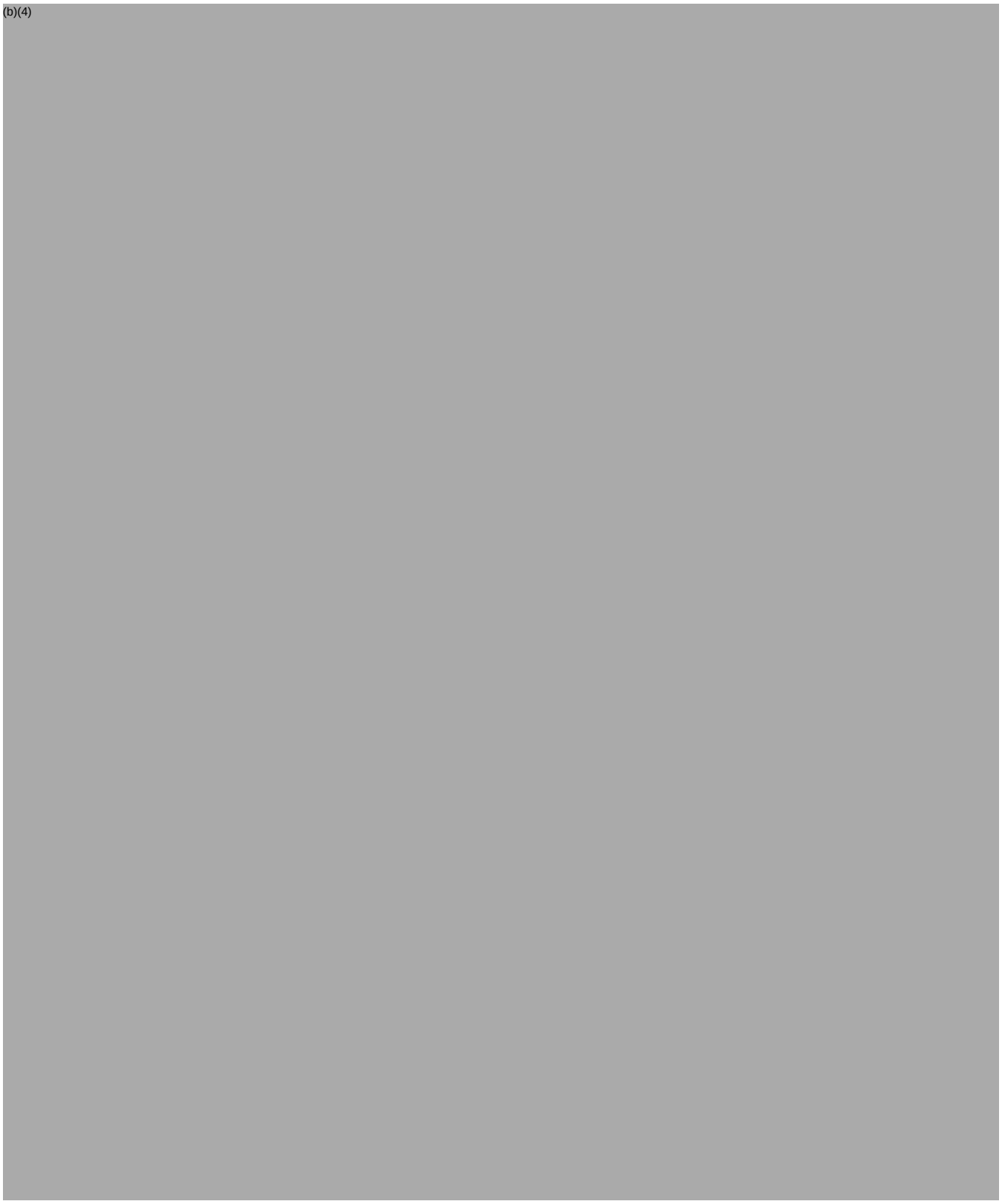

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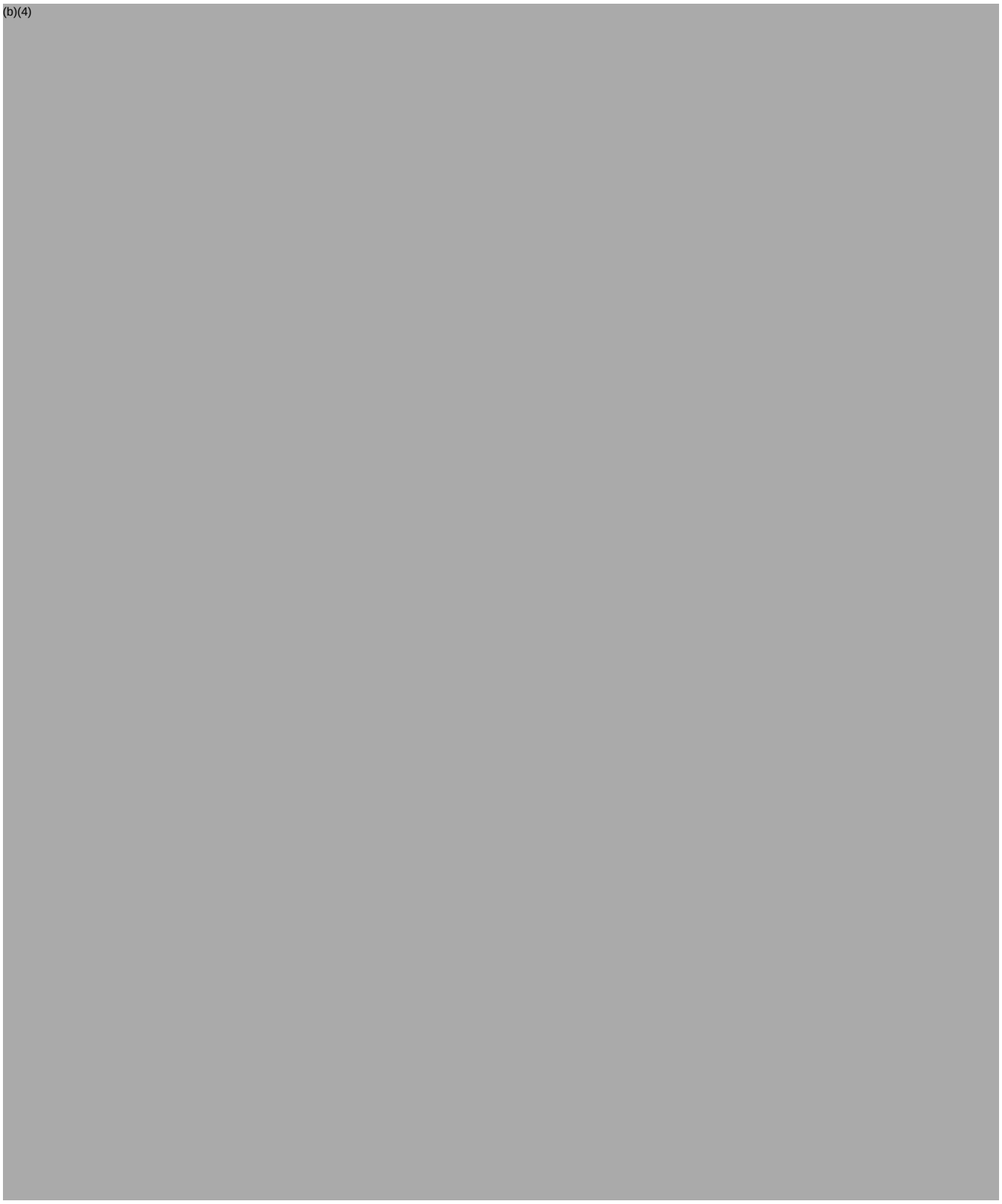

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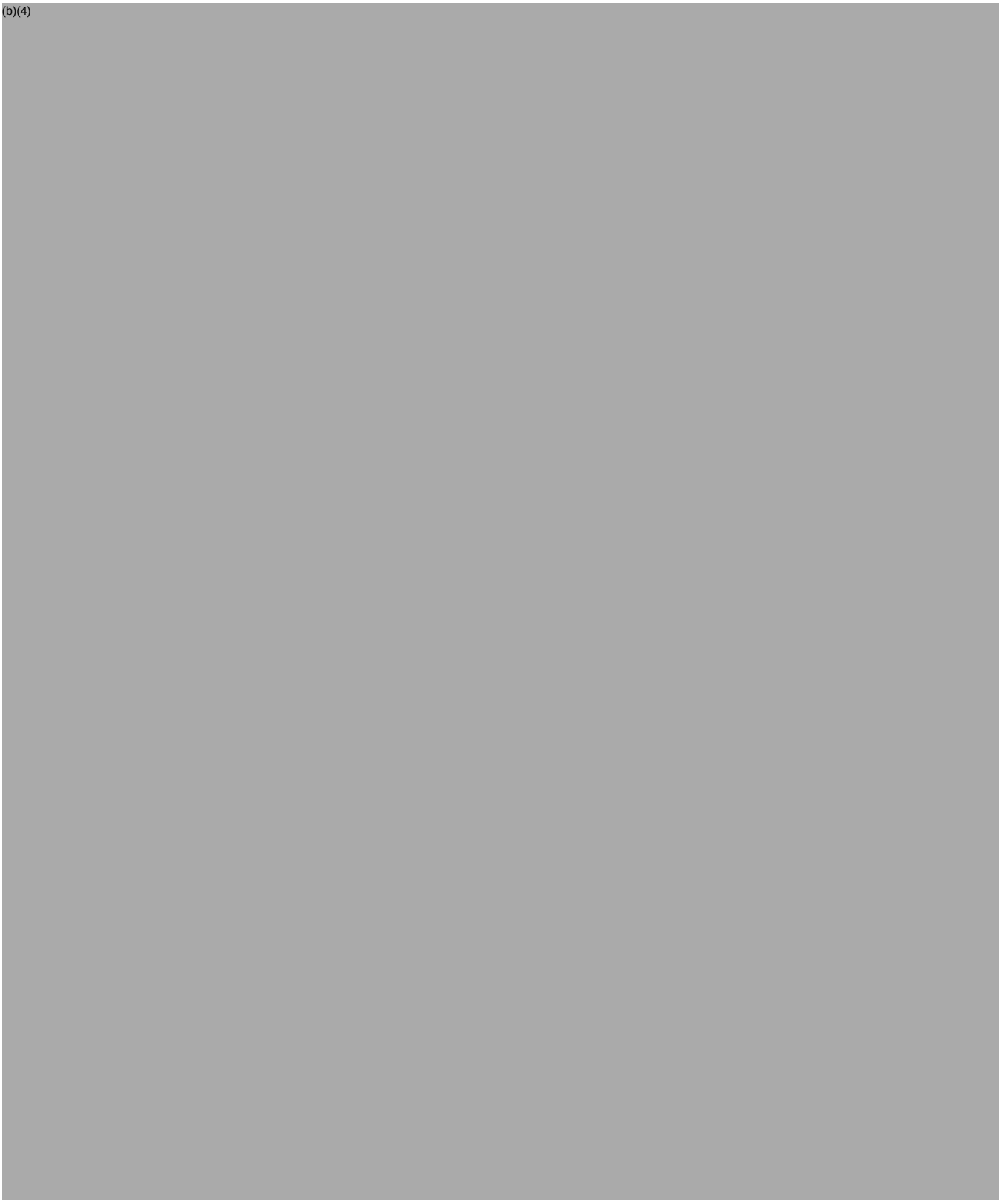

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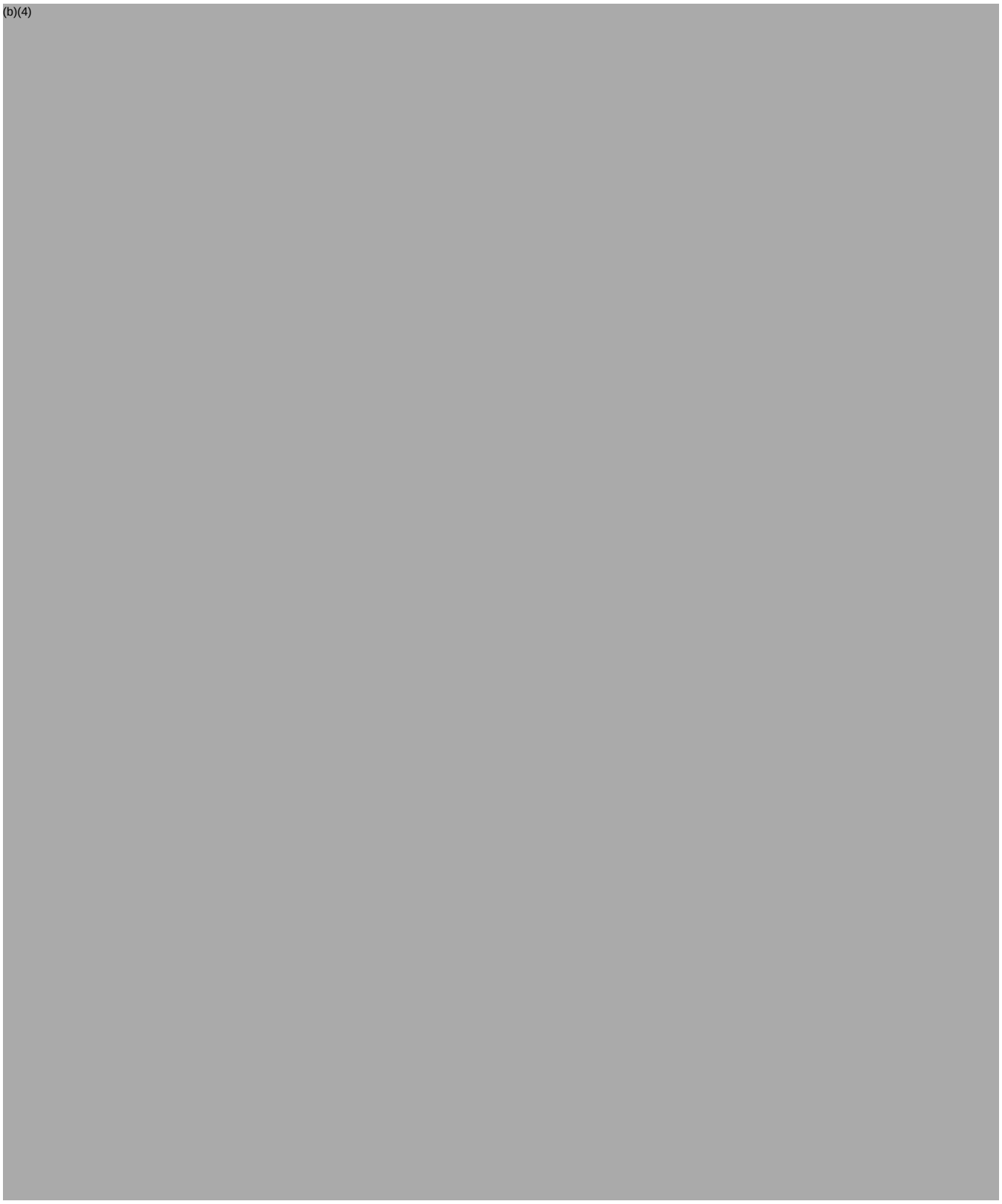

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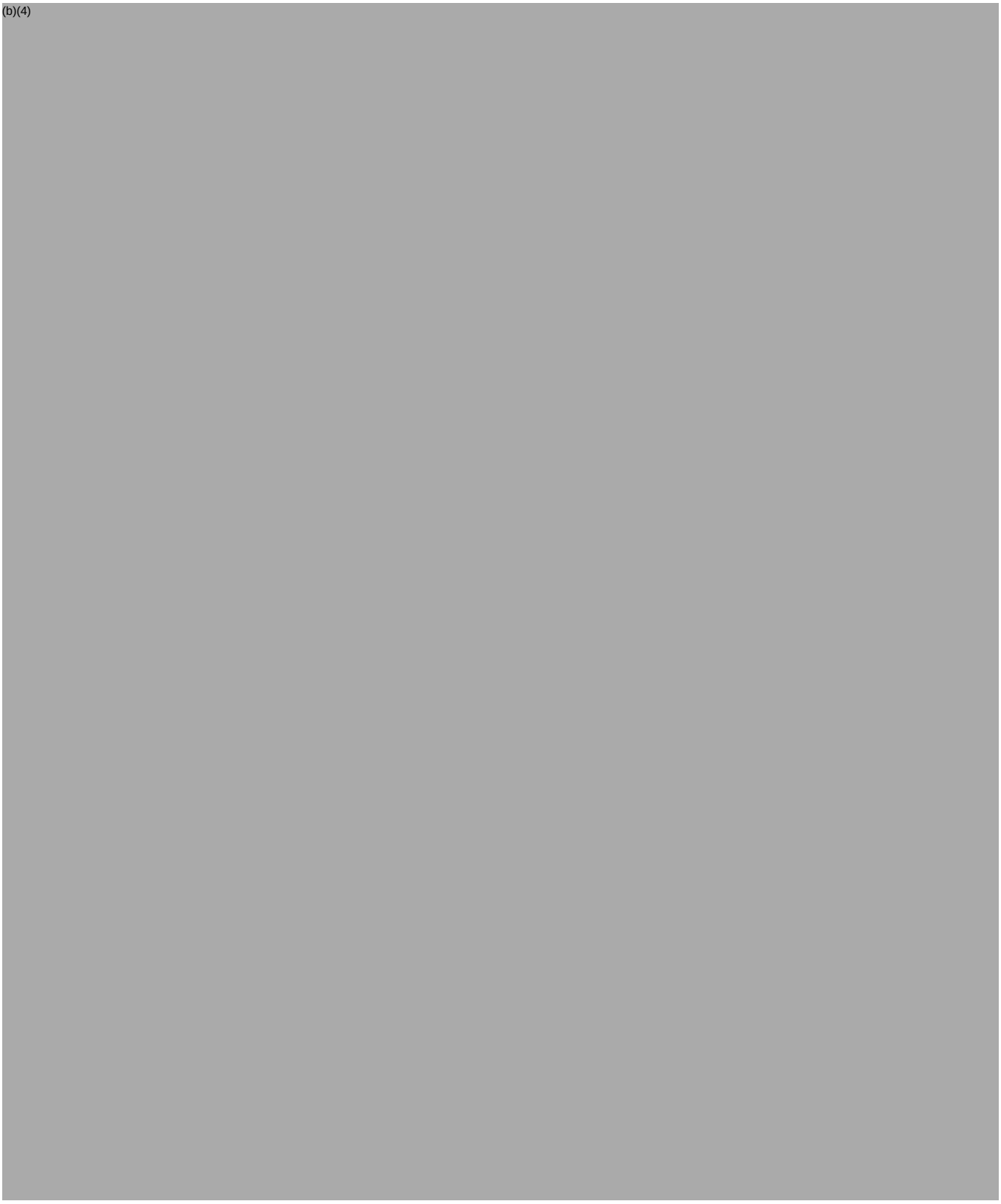

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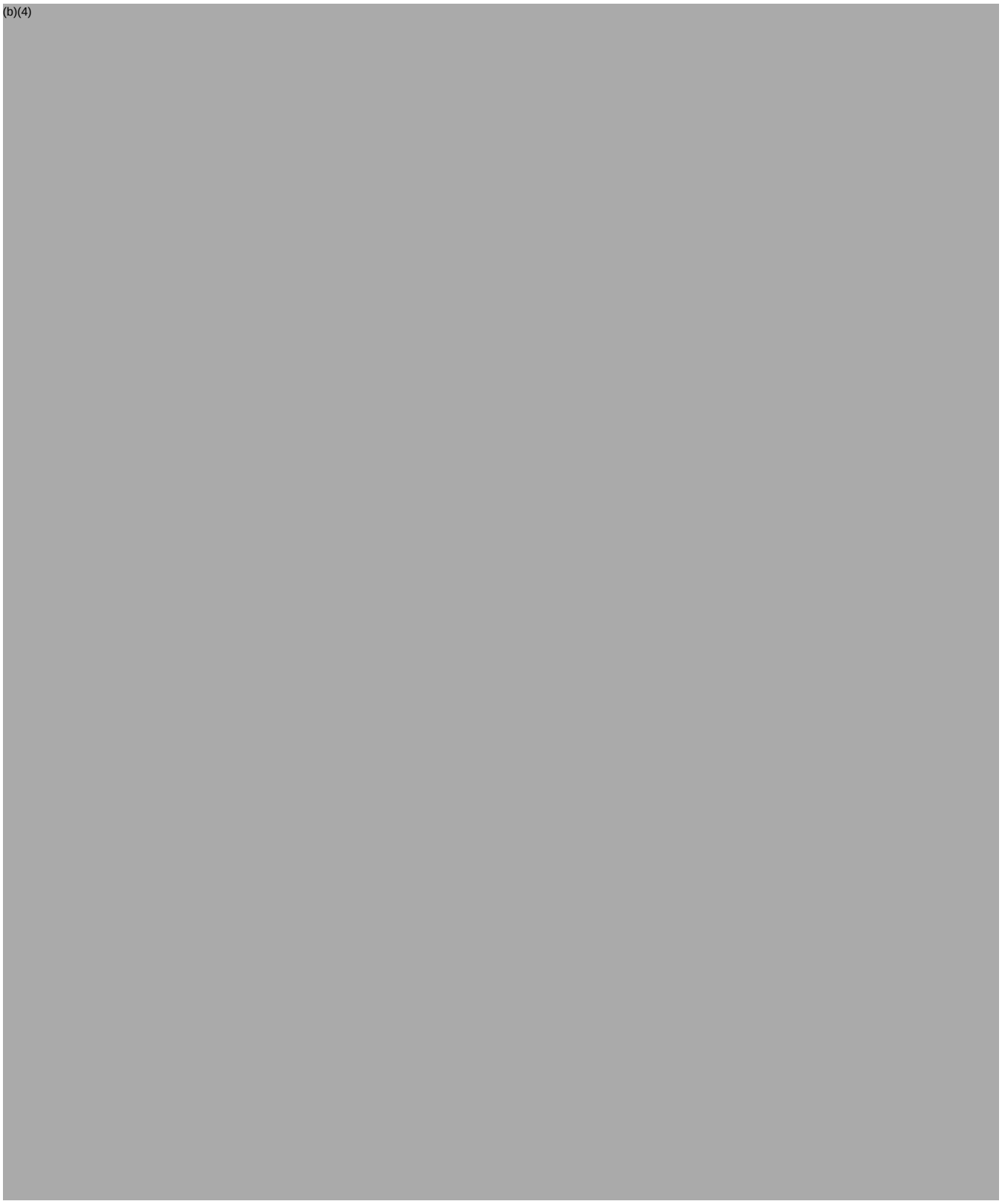

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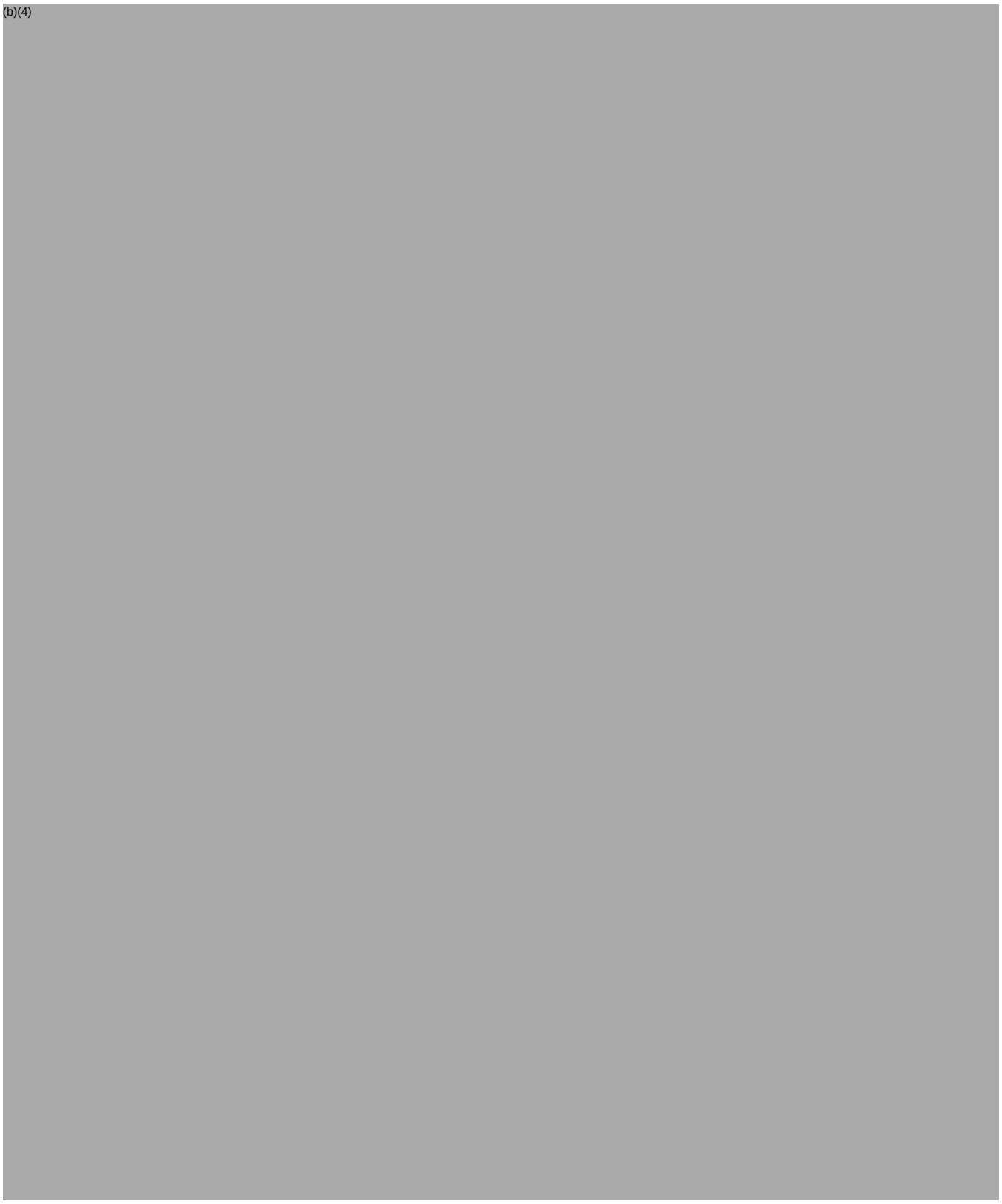

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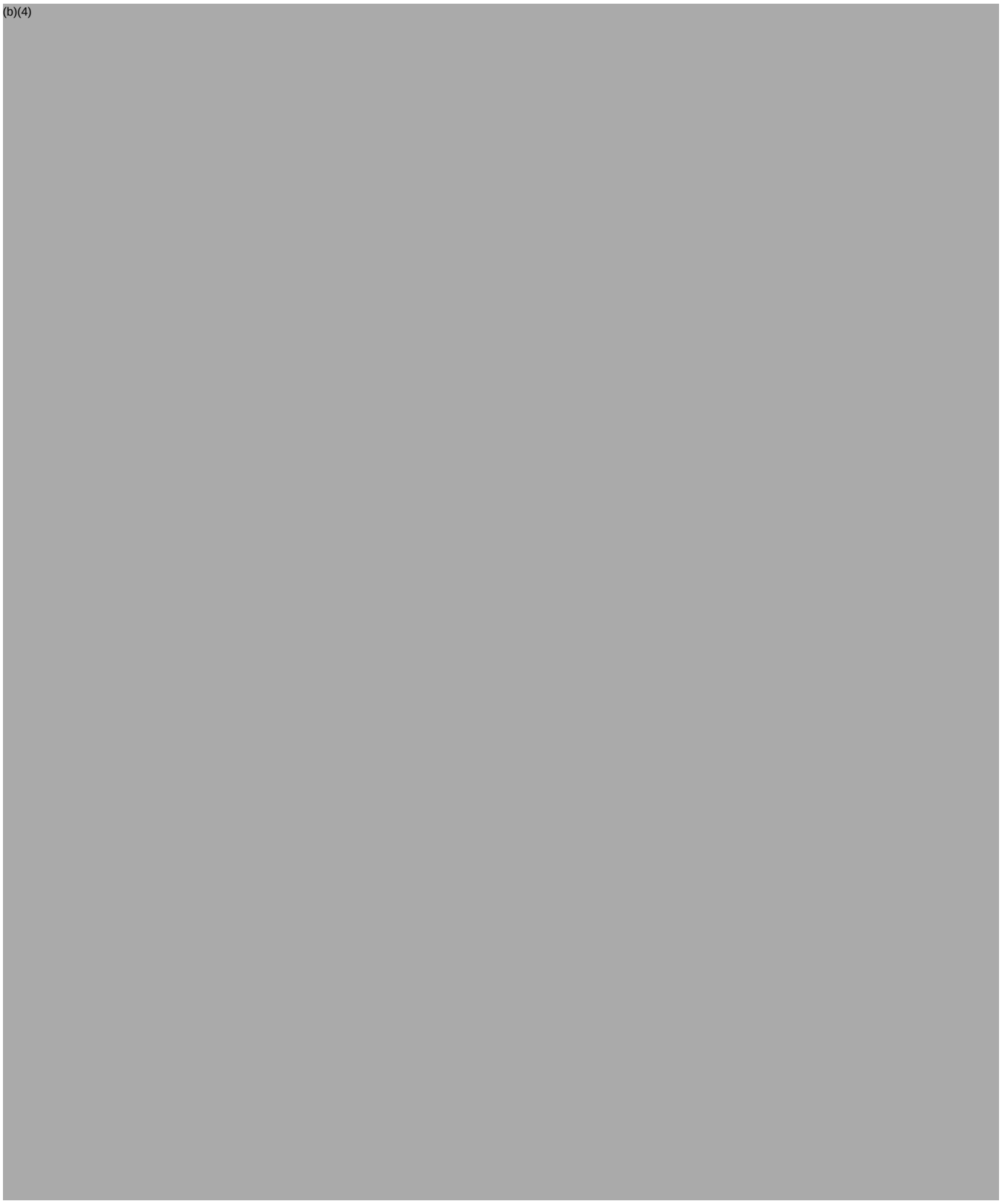

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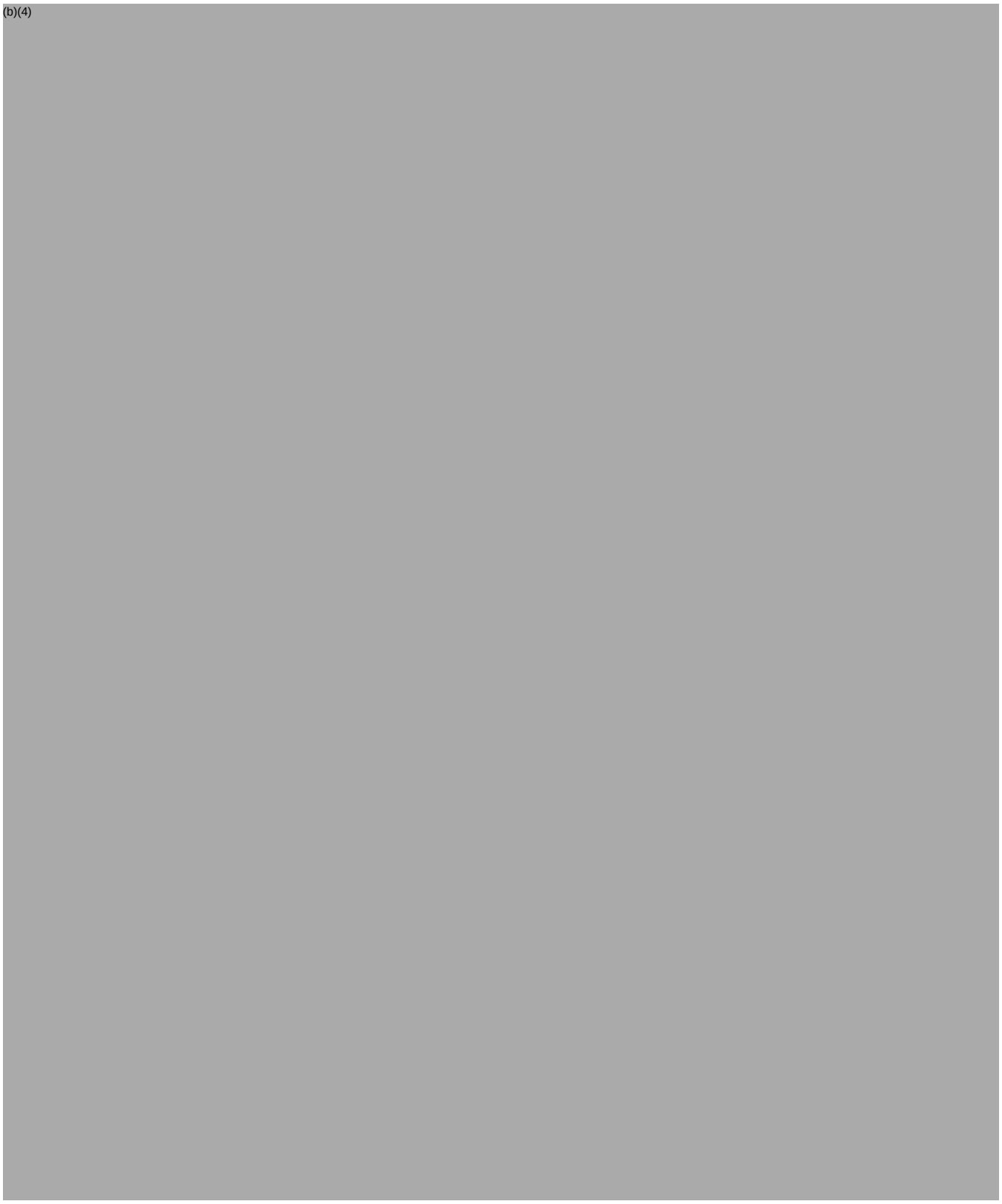

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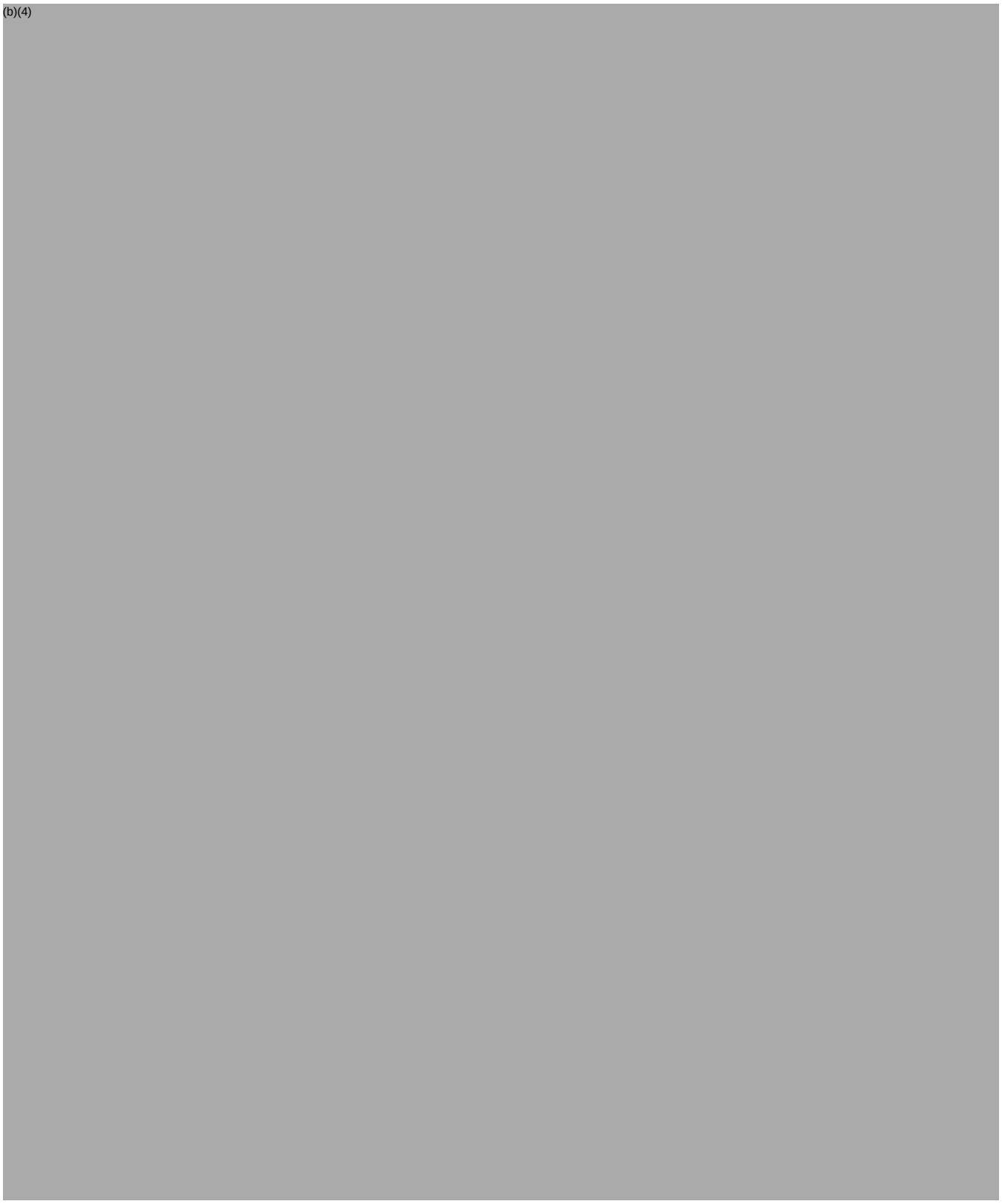

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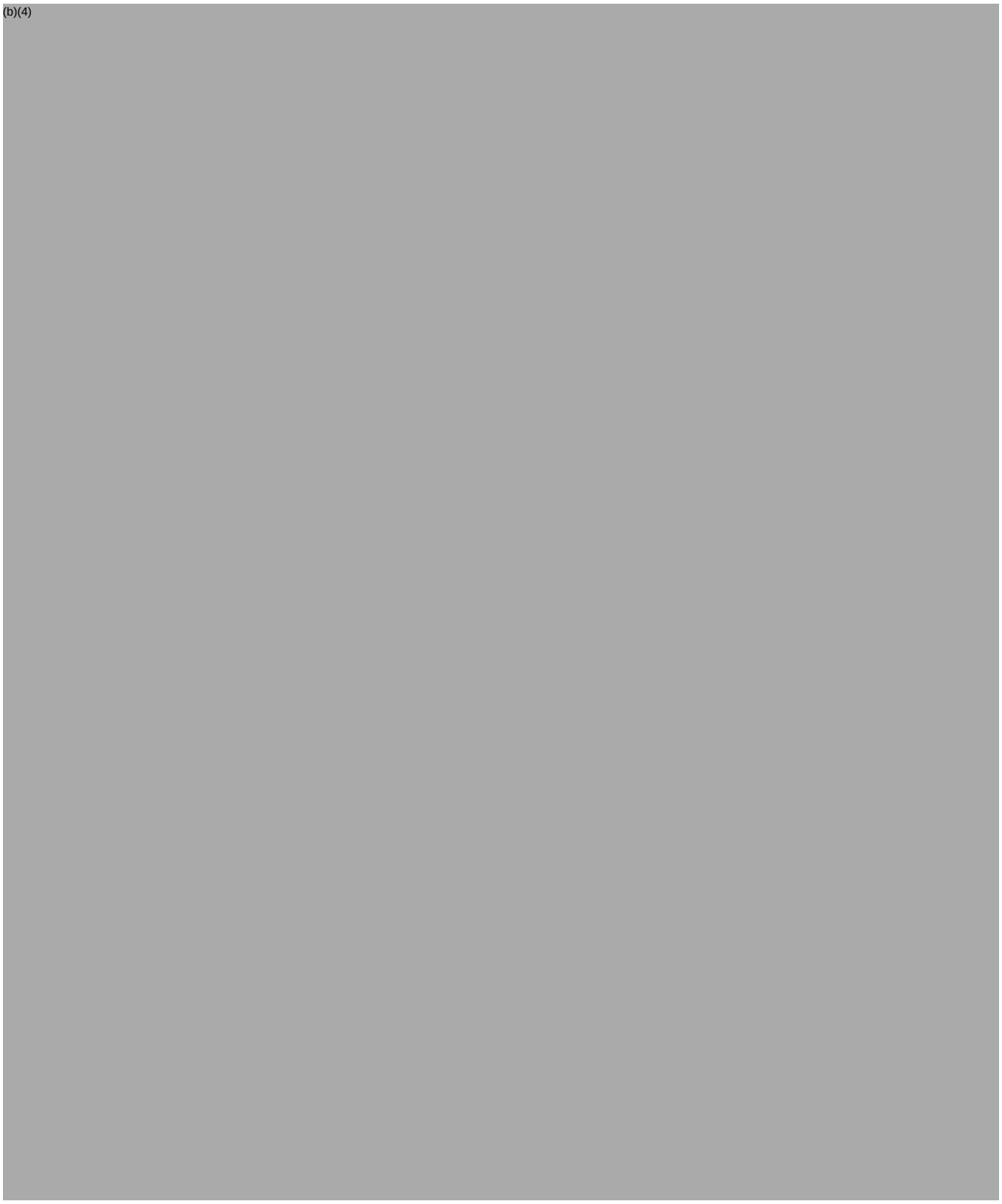

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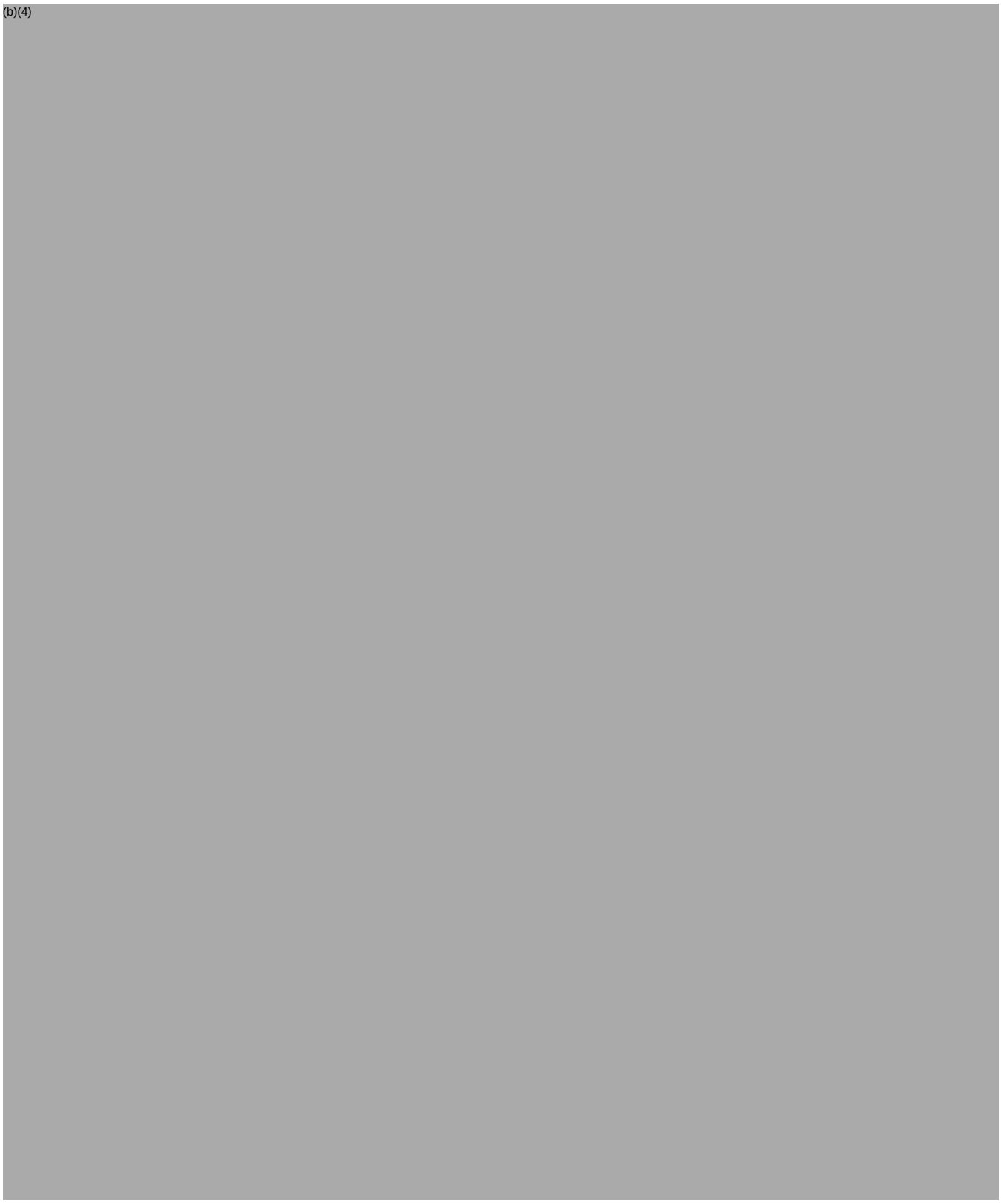

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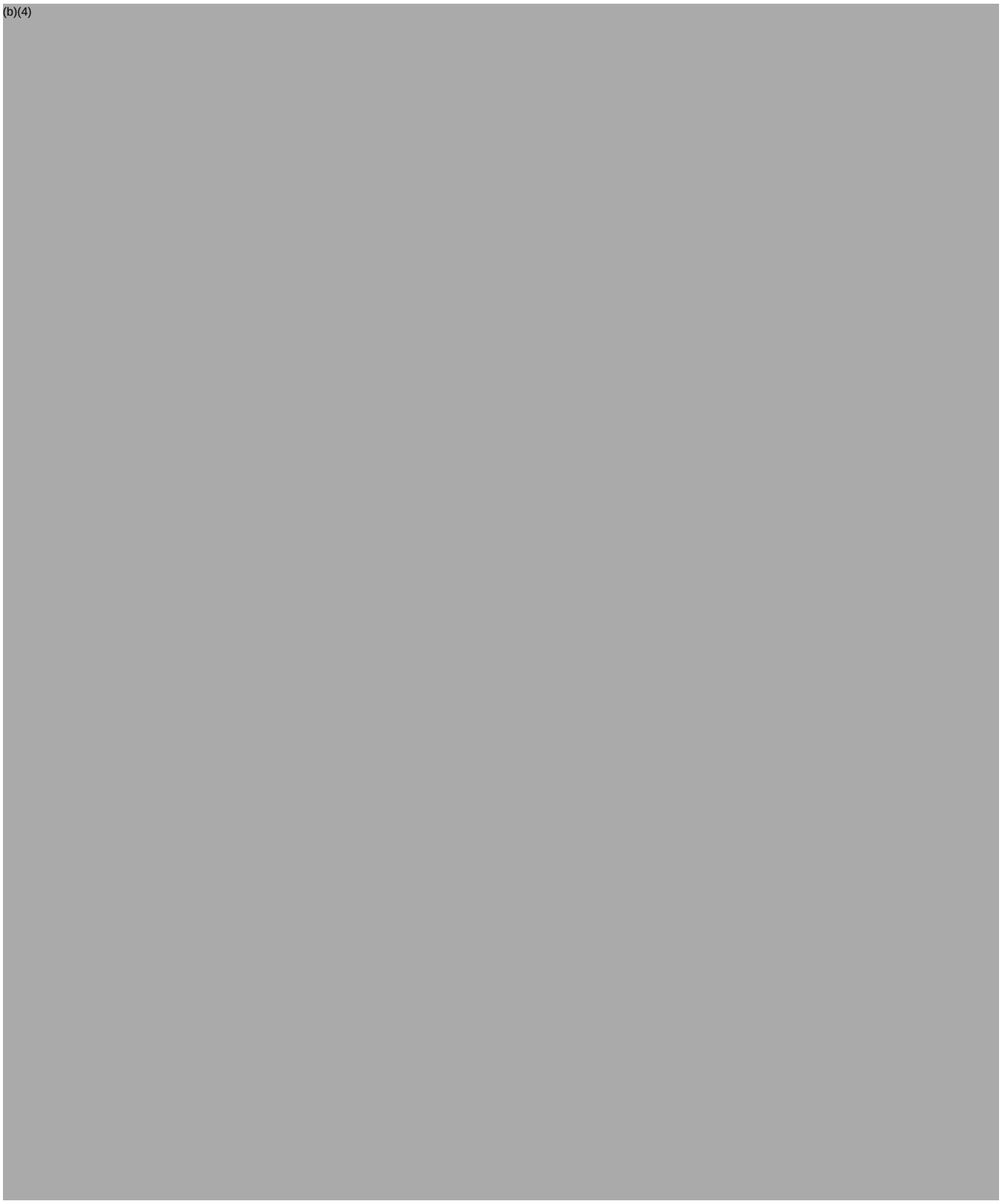

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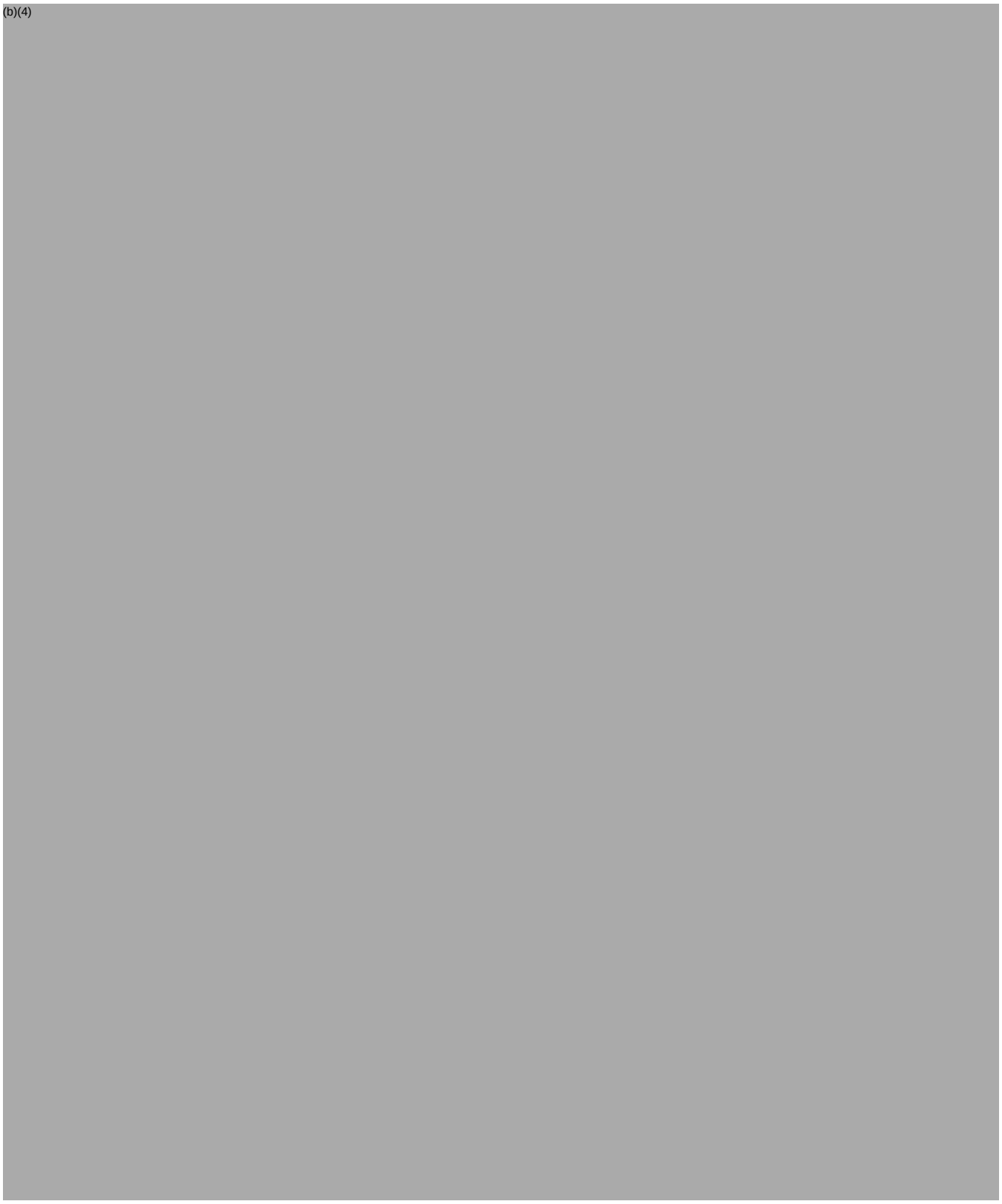

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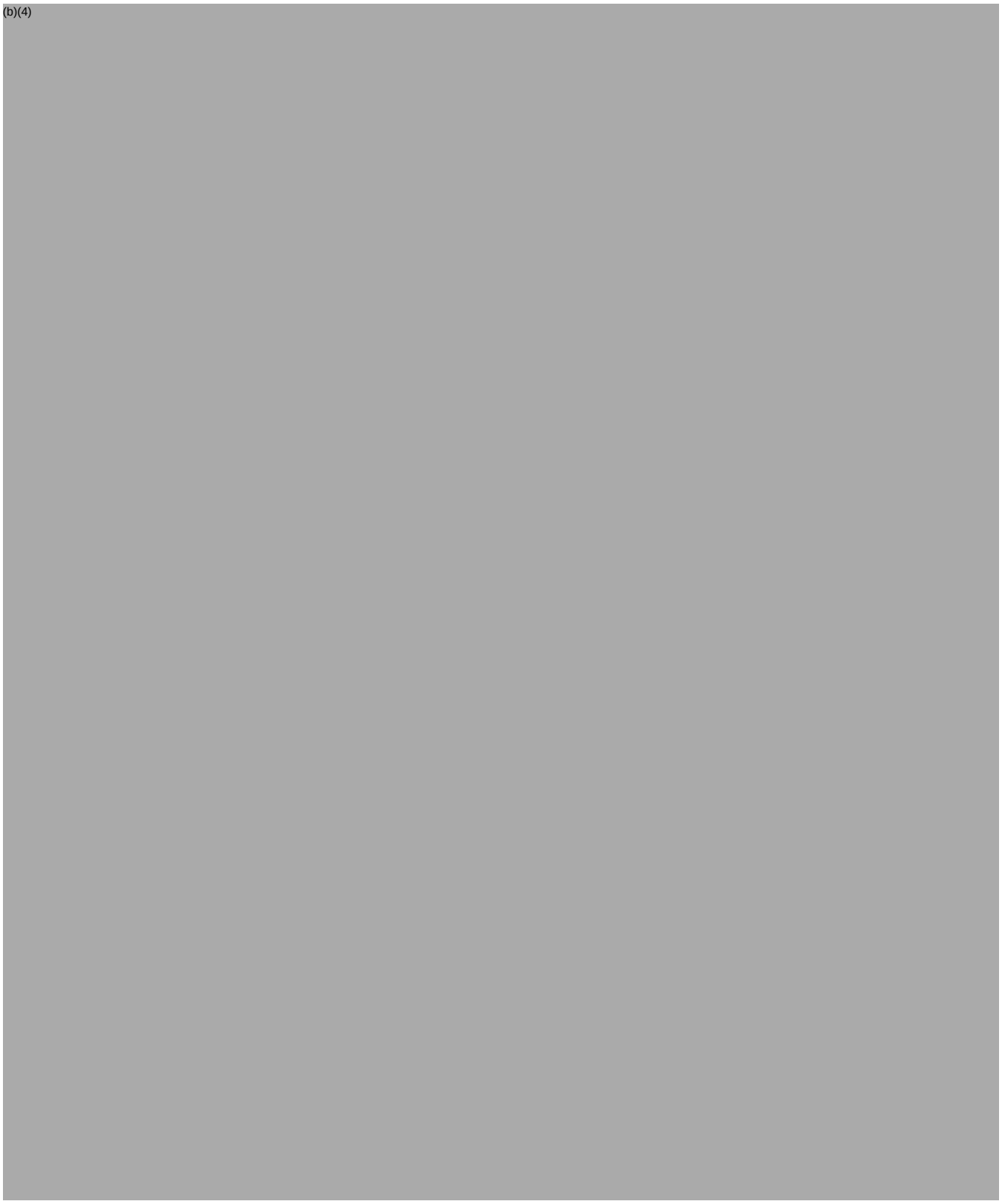

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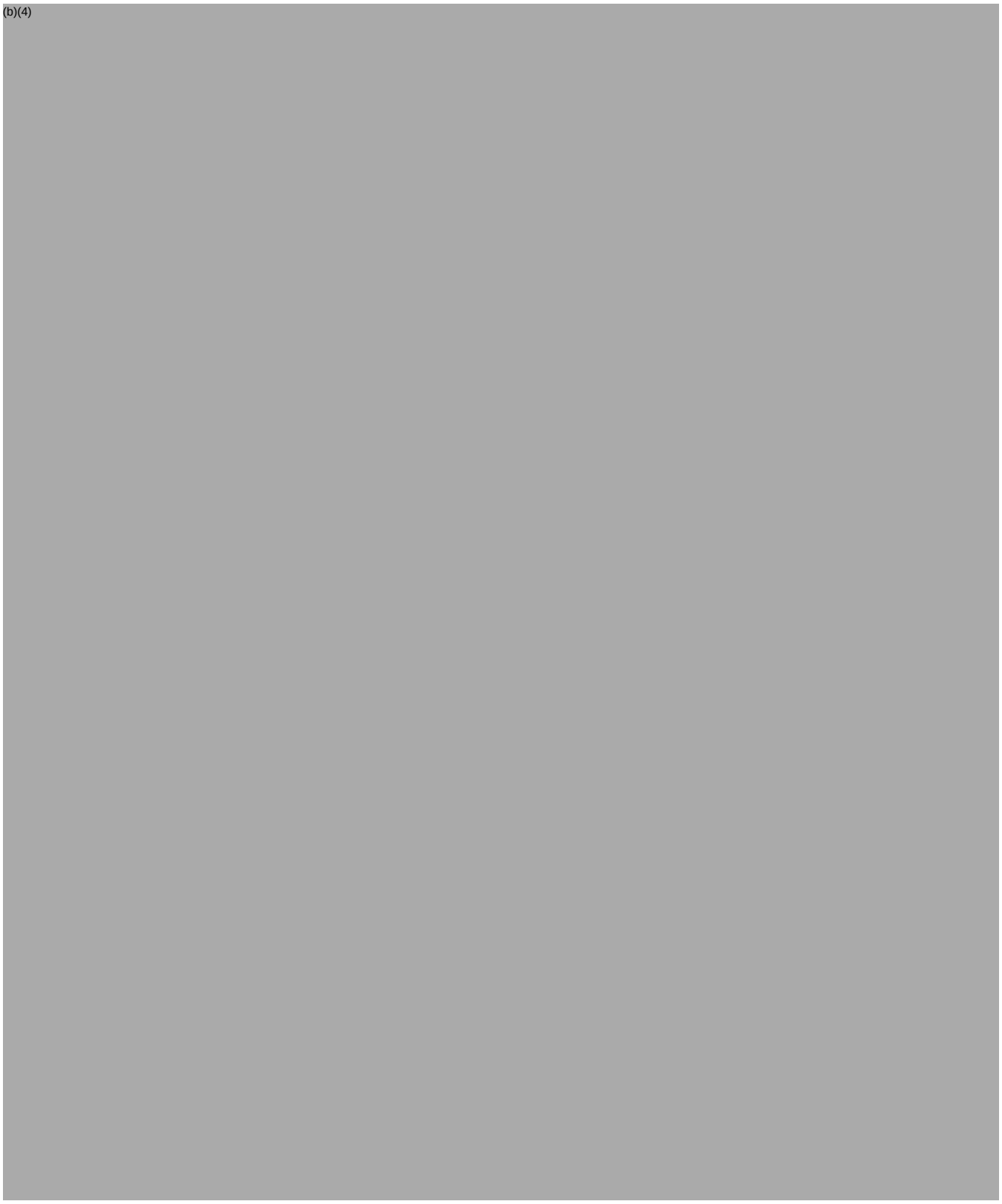

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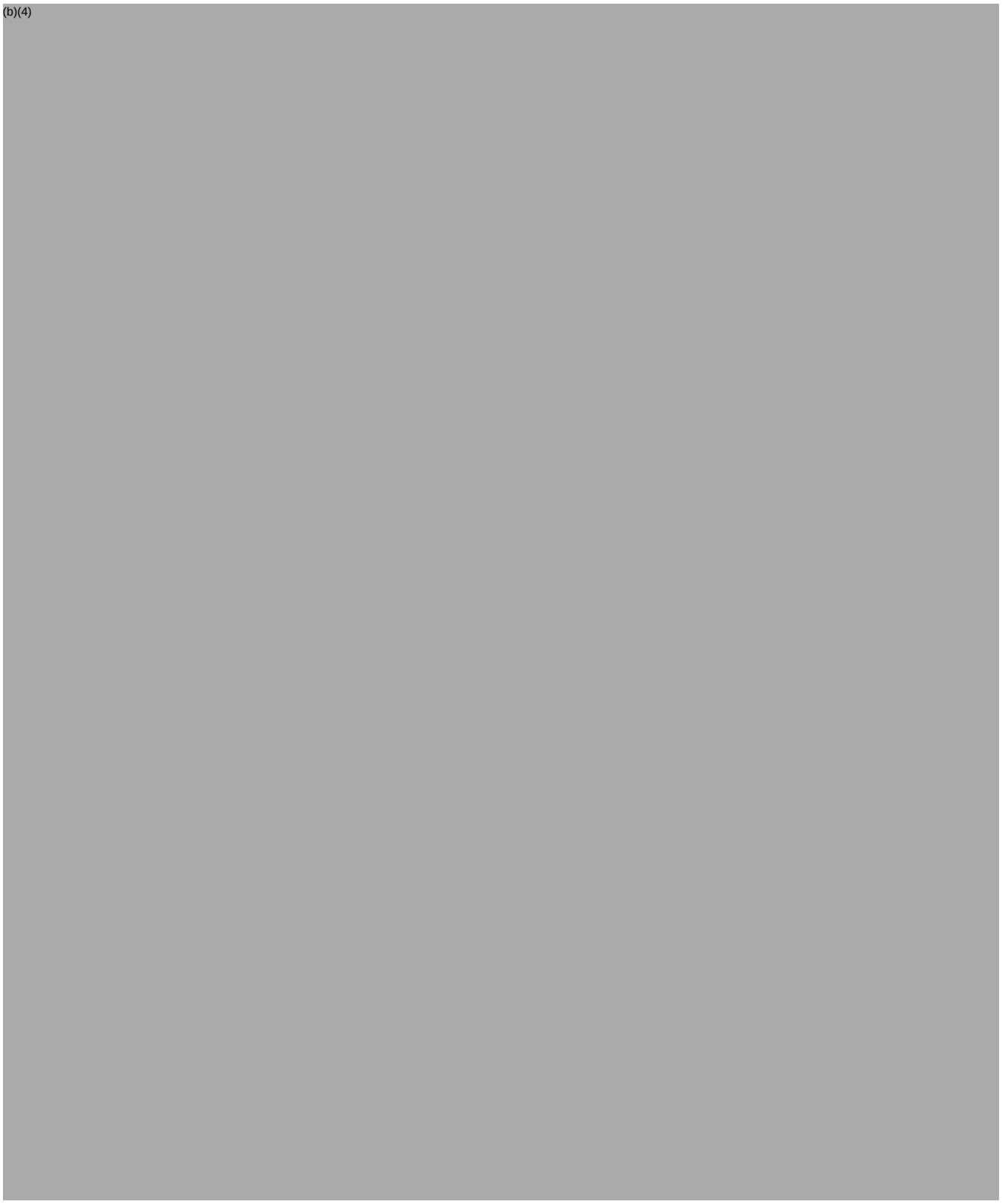

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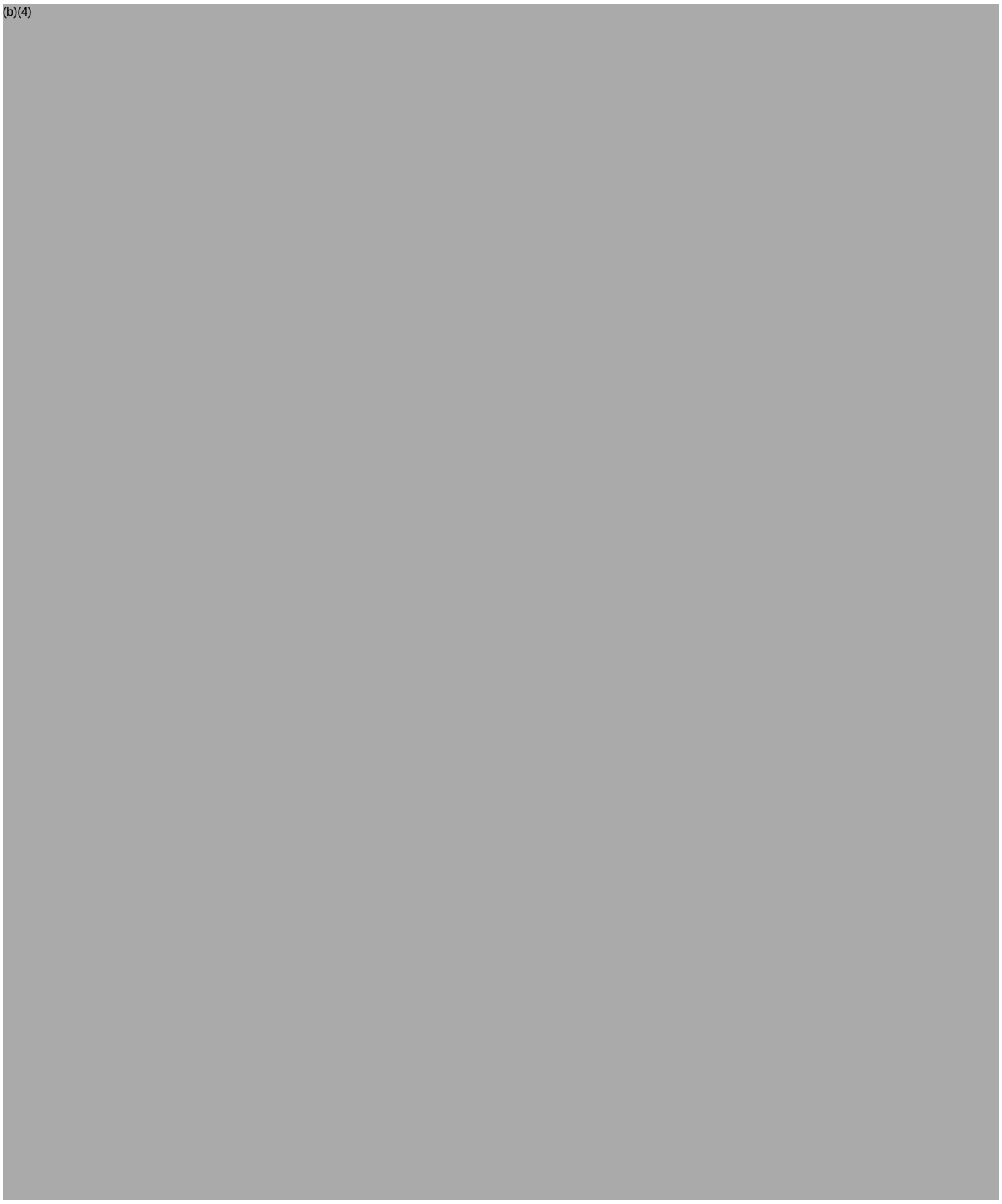

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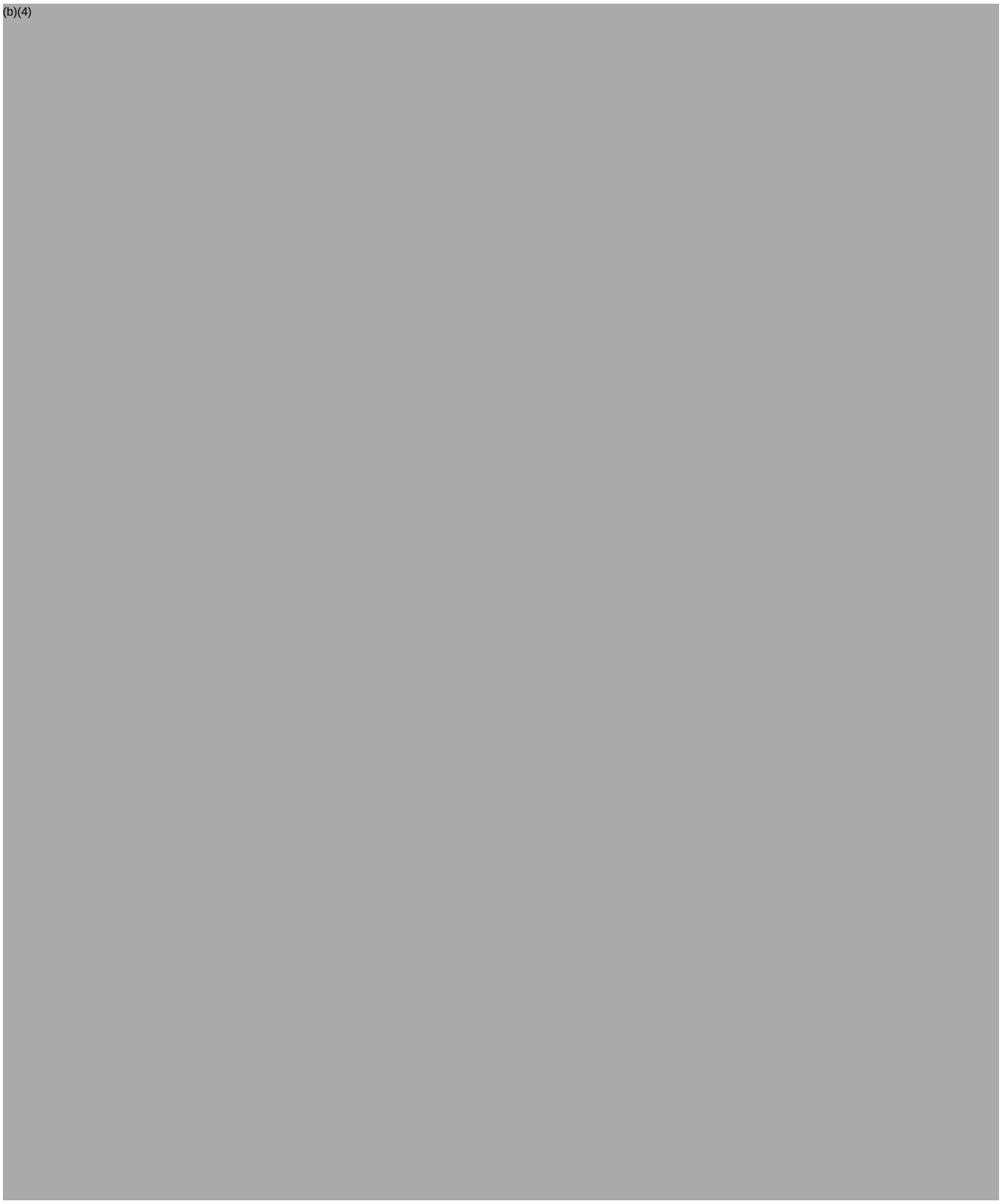

Under either scenario, we expect that the number of ENDS products sold in the United States will be similar. The difference between the environmental impacts of these two alternatives is considered negligible, or non-existent.

10. LIST OF PREPARERS

In accordance with 40 CFR 1502.17, this section includes a list of names and qualifications (including position/title, education, experience, and expertise) of individuals who were primarily responsible for preparing and reviewing this environmental assessment. No Agencies or persons besides subject matter experts within ERM and Logic were consulted.

(b)(6) ERM, Inc.

Education: M.S. in Chemical Engineering; MBA

Years of Experience: > 25 years in environmental consulting

Qualifications: Environmental assessments and audits, environmental risk assessment, environmental compliance & assurance activities, air quality, and product stewardship and sustainability.

(b)(6) ERM, Inc.

Education: B.S. in Chemistry; M.S. in Environmental Engineering

Years of Experience: > 25 years in environmental management and regulatory activities

Qualifications: Environmental assessments, environmental risk assessment, environmental compliance & assurance activities, life cycle assessment, engineering design of pollution control measures, and product stewardship and sustainability.

(b)(6) ERM, Inc.

Education: B.S. in Mechanical Engineering

Years of Experience: > 25 years in environmental management and regulatory activities

Qualifications: Environmental assessments and audits, environmental risk assessment, environmental compliance & assurance activities, air quality,

Toxic Substances Control Act (TSCA) compliance, and product stewardship and sustainability.

(b)(6) ERM, Inc.

Education: B.S. in Environmental Toxicology; Registered Environmental Assessor

Years of Experience: 22 years in risk assessment and toxicology

Qualifications: Environmental exposure assessments, human and environmental risk assessments, toxicological research, fate and transport assessments, data evaluations, and risk communication.

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ERM, Inc.

(b)(6)

ERM, Inc.

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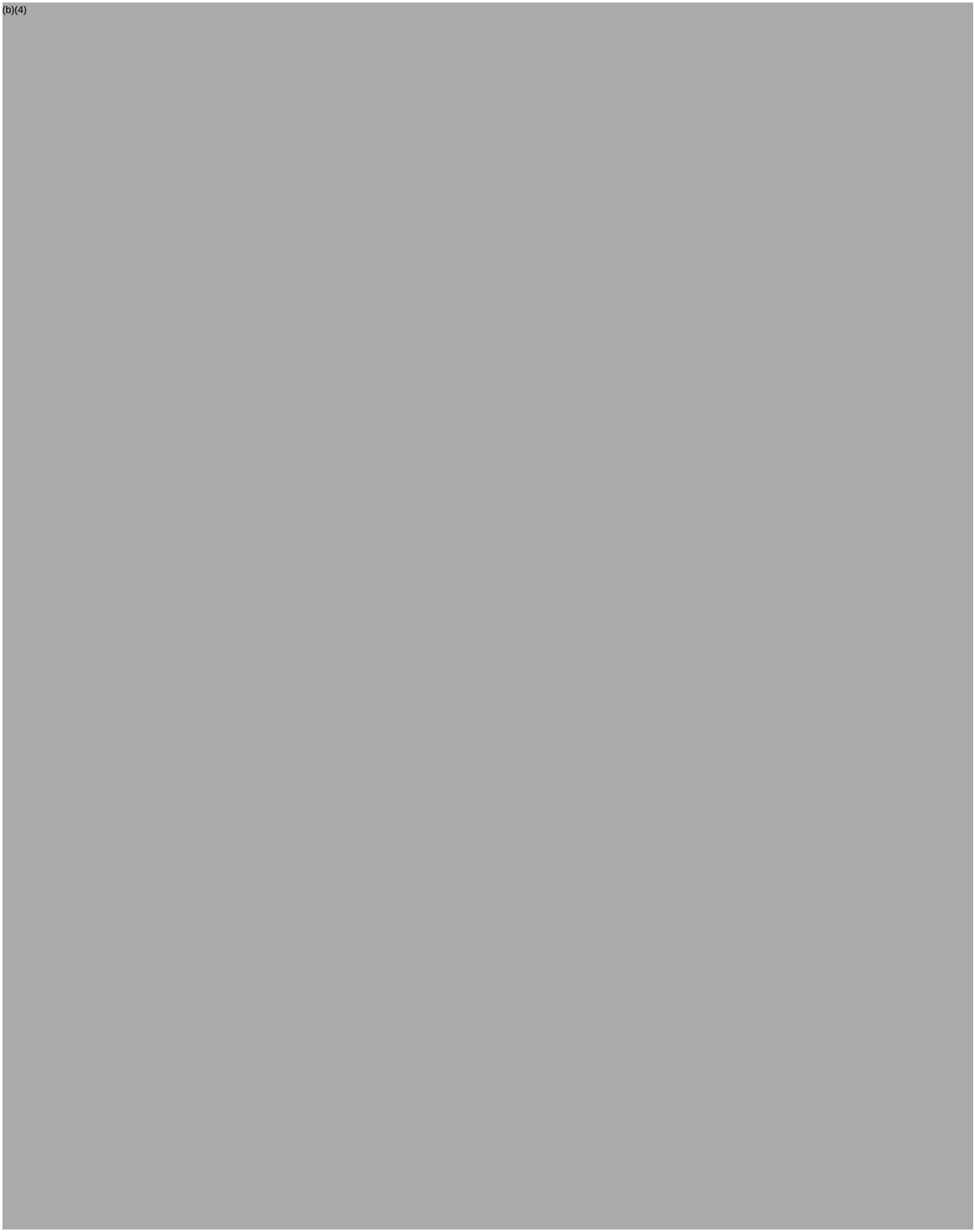
12. APPENDICES

As a final measure of substantiation for the minimal environmental risk associated with the use of the New Products, ERM has included the following Confidential Appendices.

Additional information on the components of the New Products (cartridge, tobacco capsule, battery unit, and USB charger) and the packaging materials is included within Confidential Appendix 1.

Data summaries provide a brief summation of the available physico-chemical properties, toxicology and ecotoxicology data for the e-liquid ingredients and are included in Confidential Appendix 2. Data contained in the attached summaries are from publicly available compilations from sources including the USEPA and the European Chemicals Agency (ECHA). Specific references are noted as appropriate.

Additional information regarding the regulatory status of the e-liquid ingredients in order to further substantiate FDA's acceptance of these substances from an environmental perspective are provided in Confidential Appendix 3.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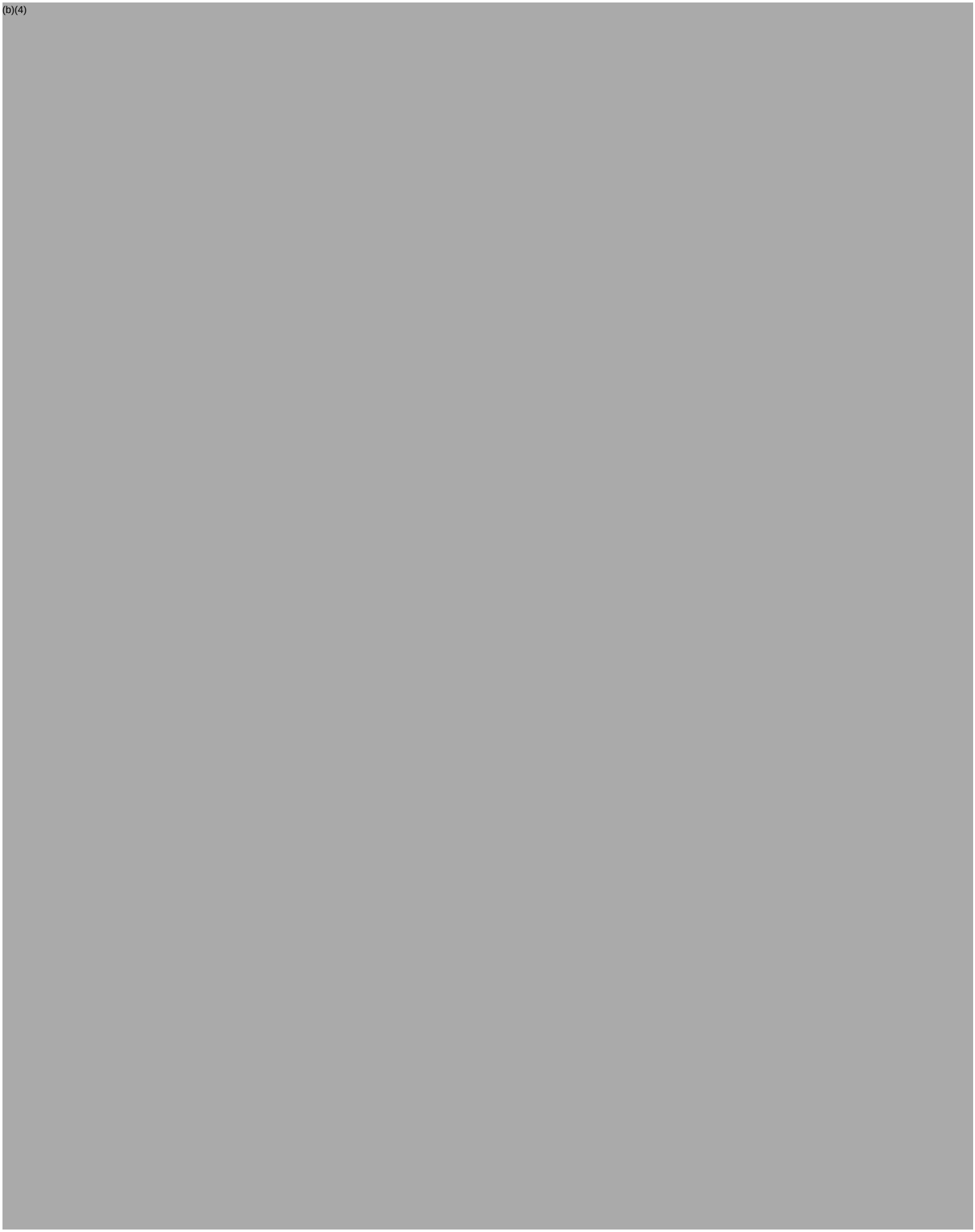
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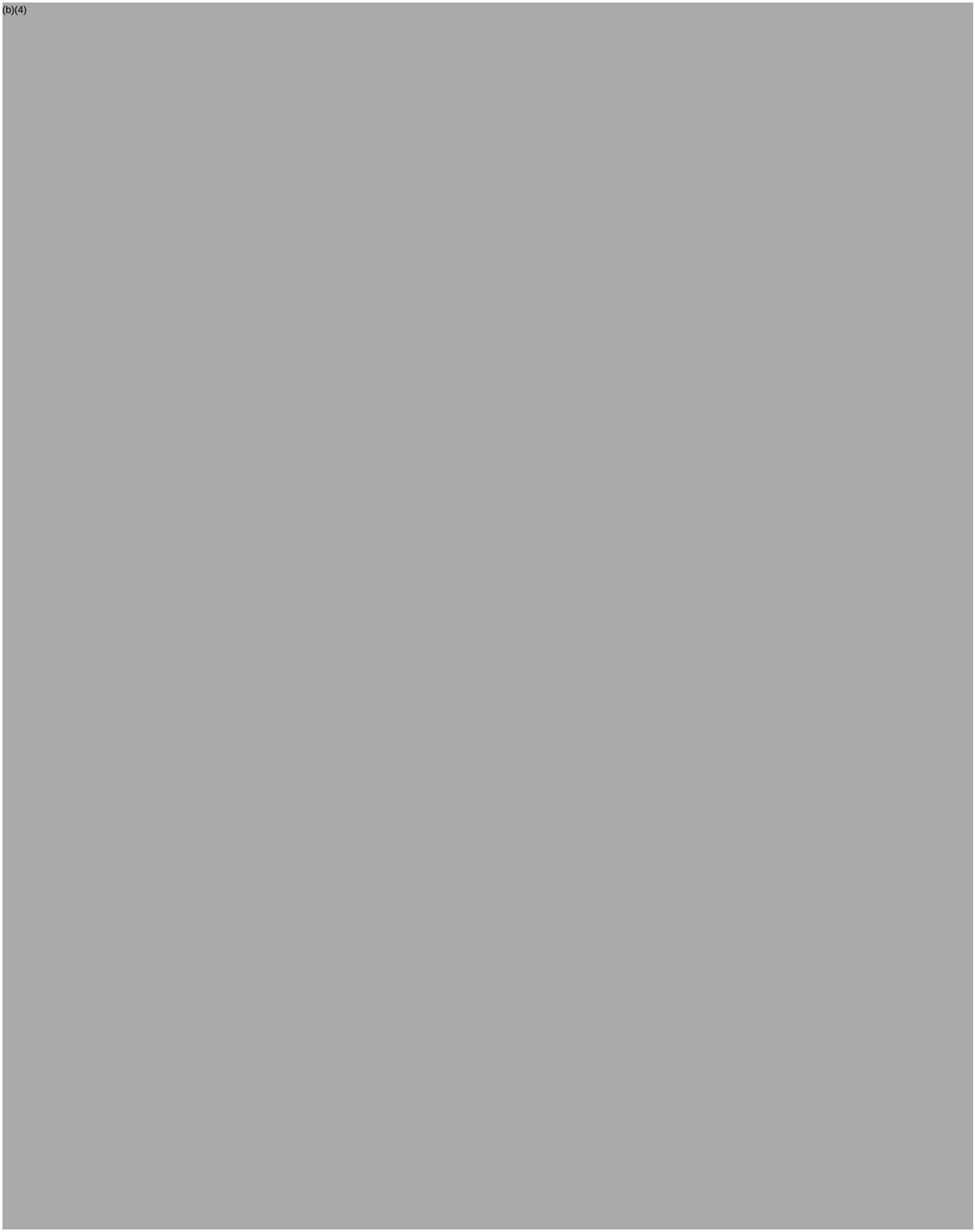
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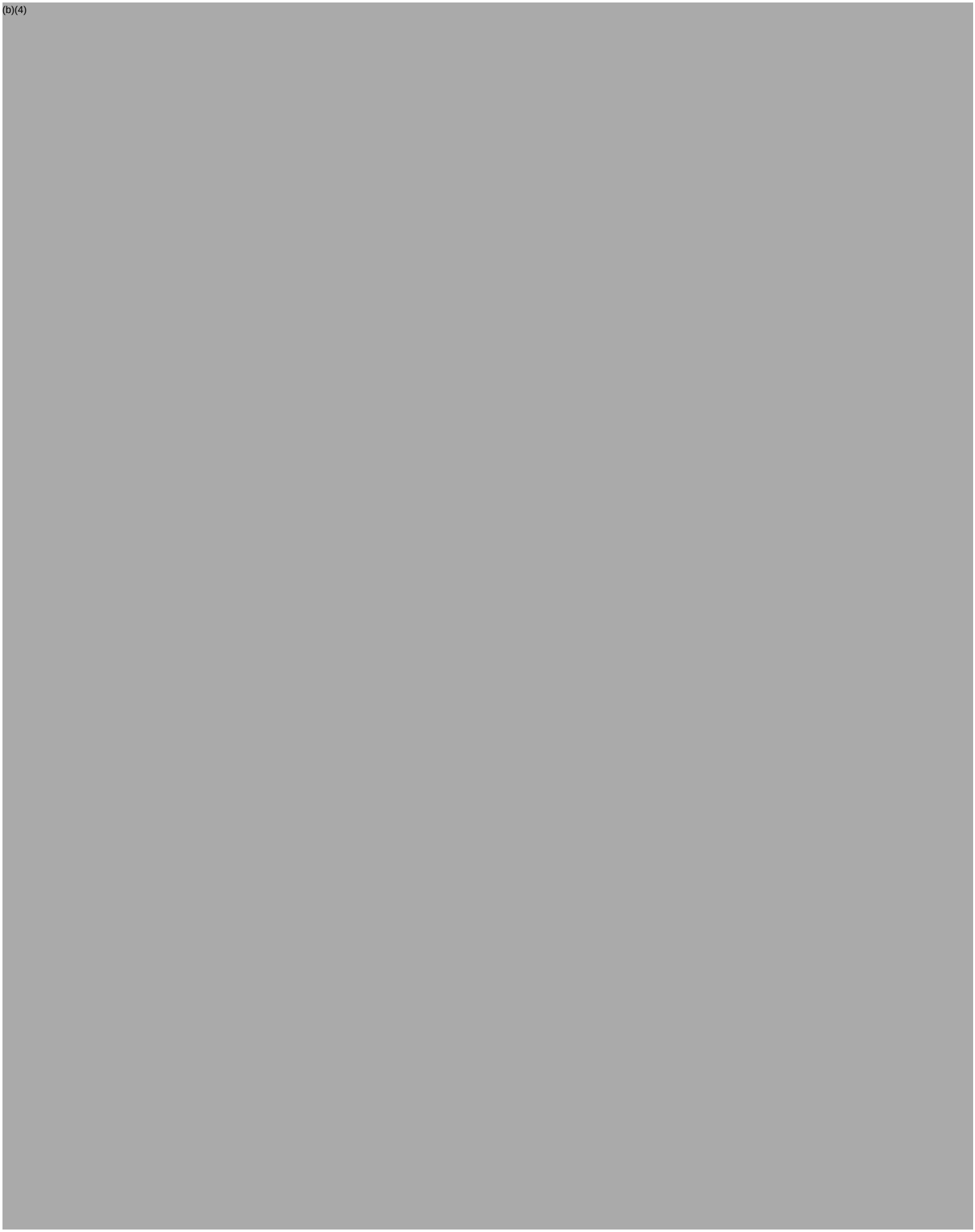
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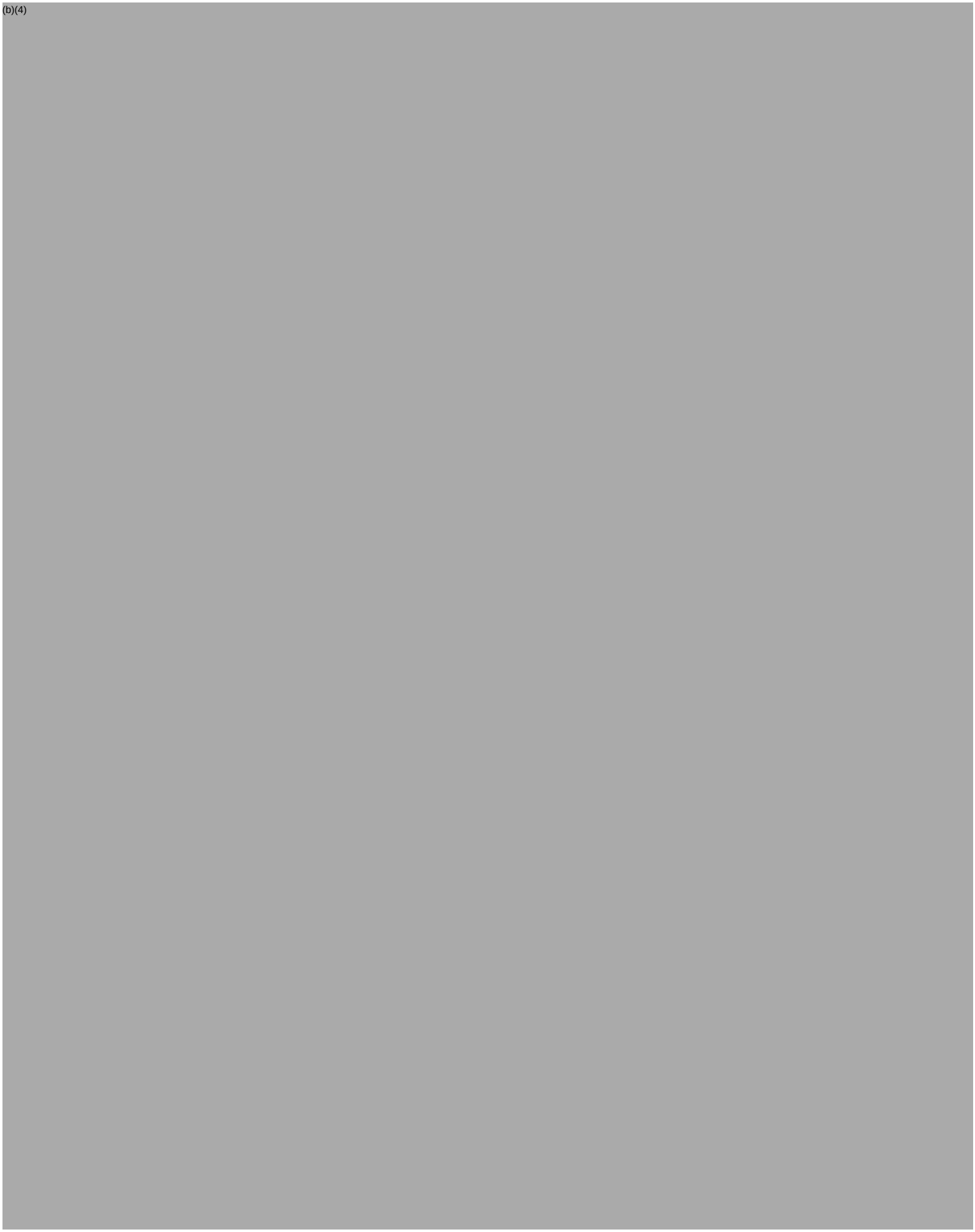
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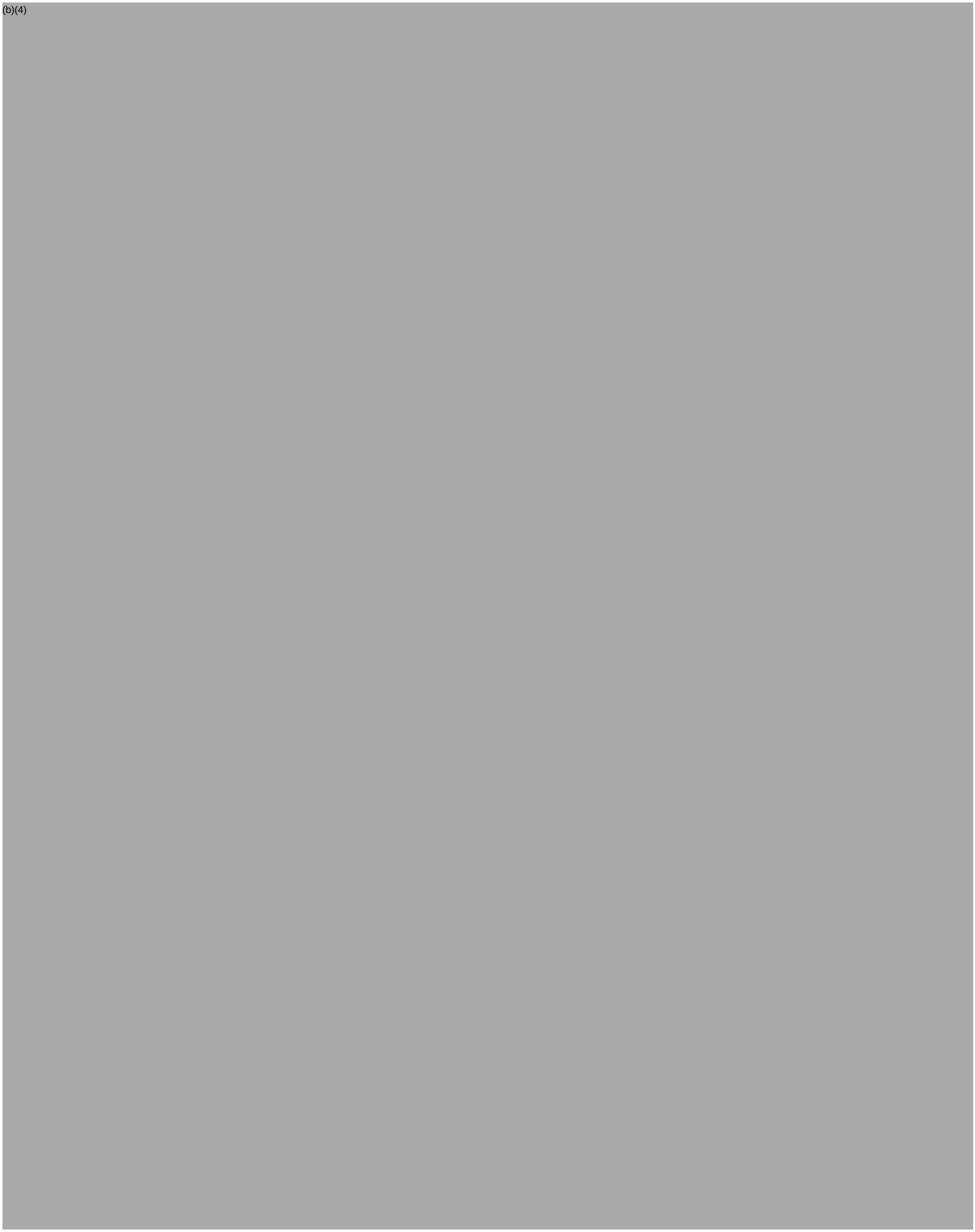

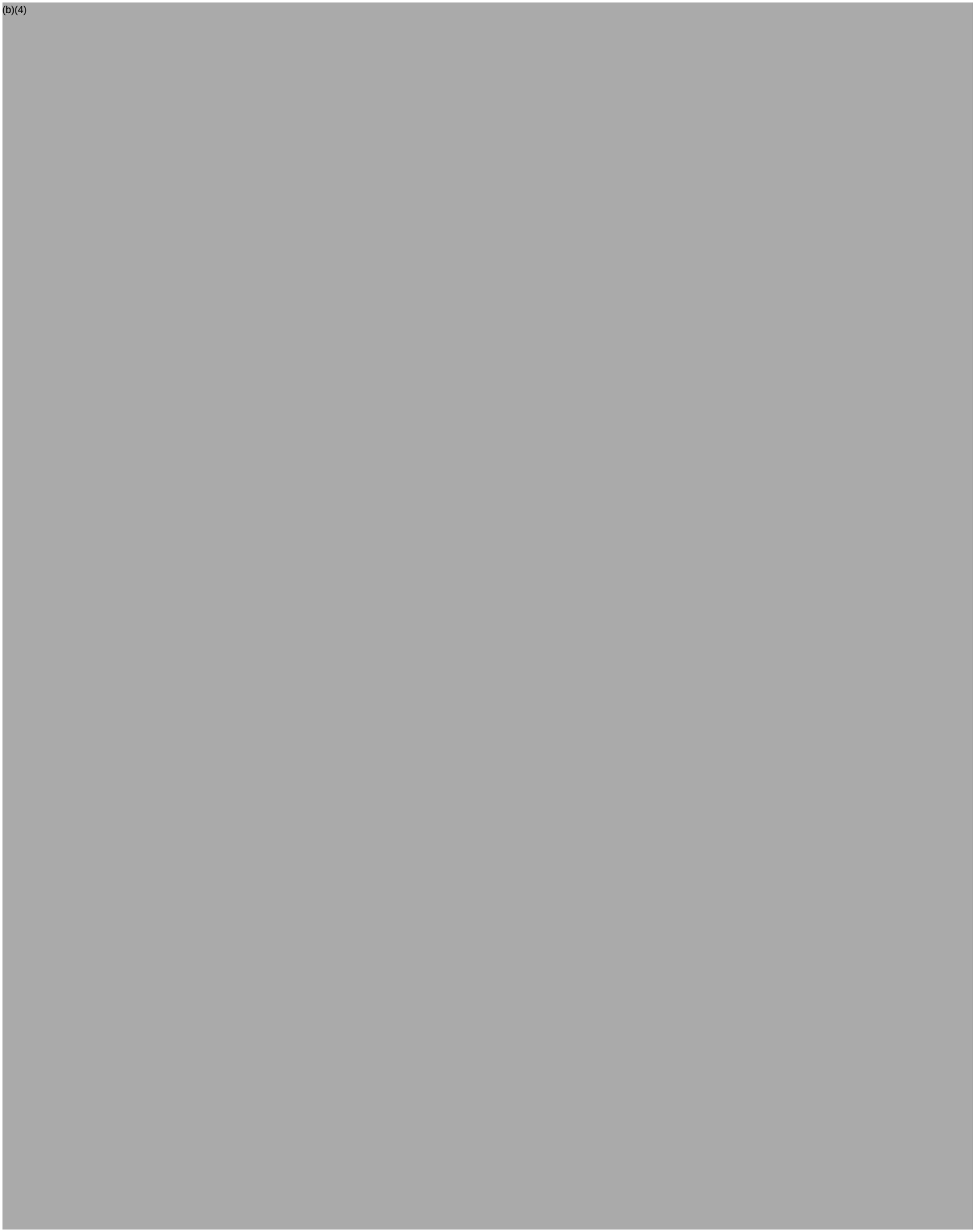
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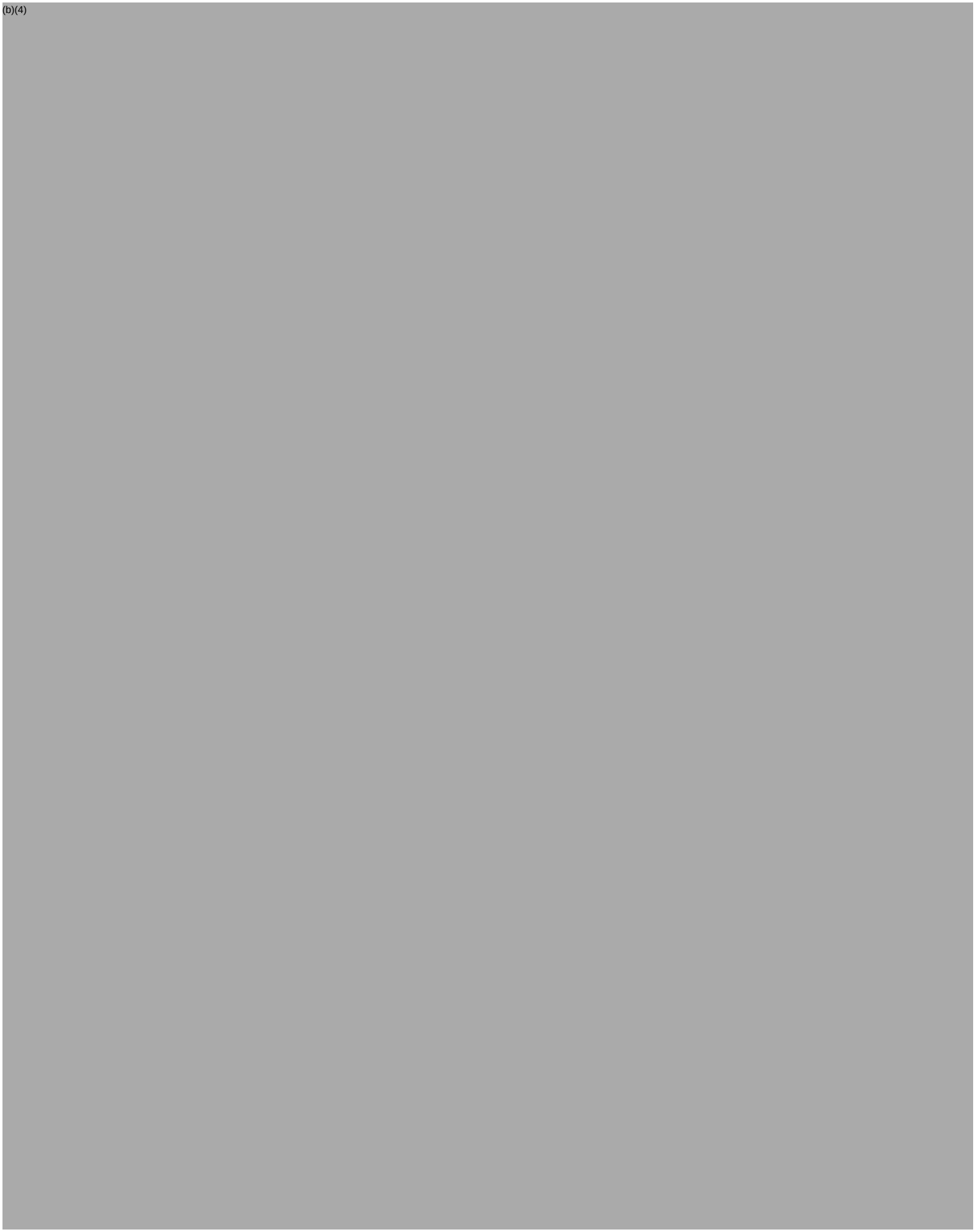

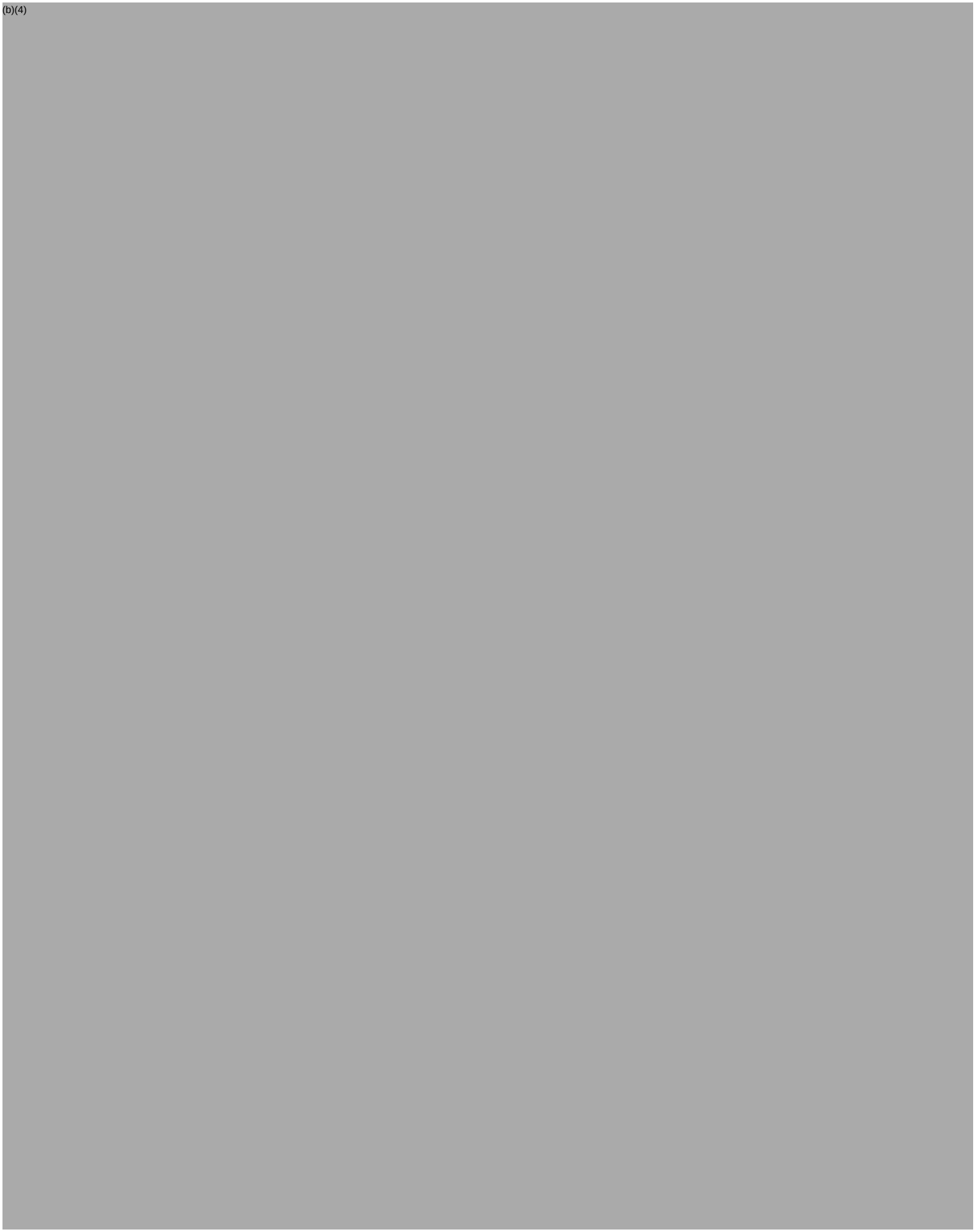
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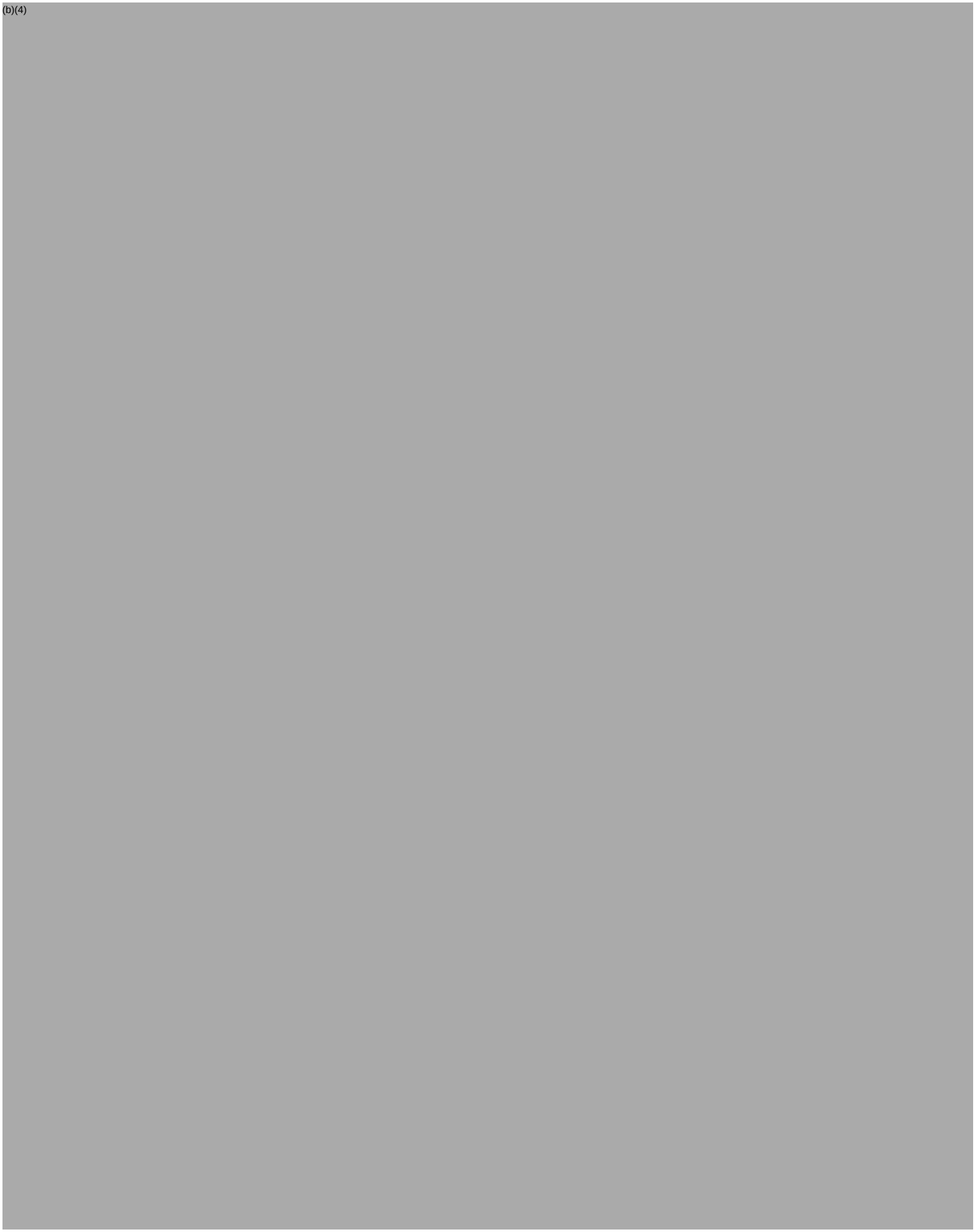

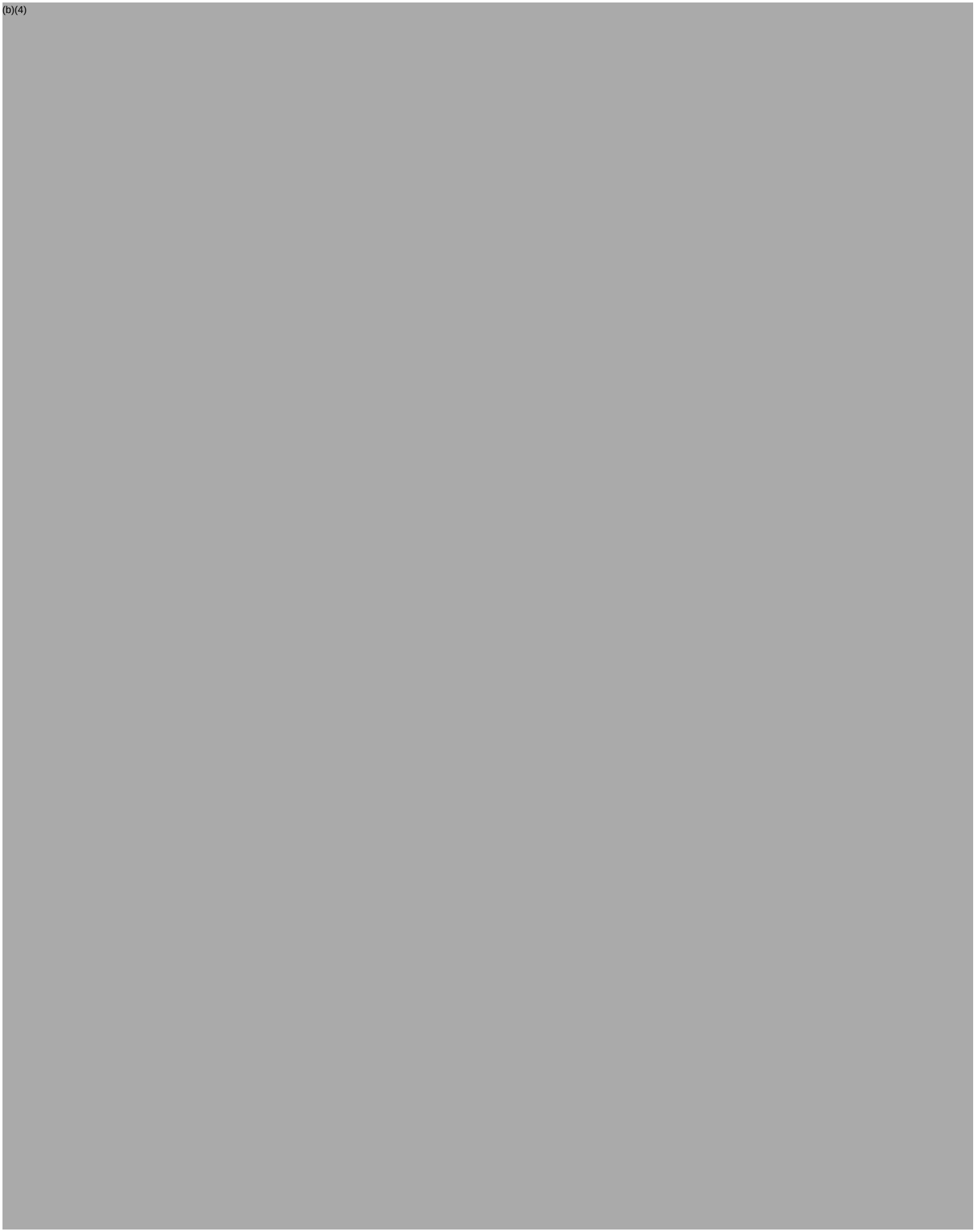
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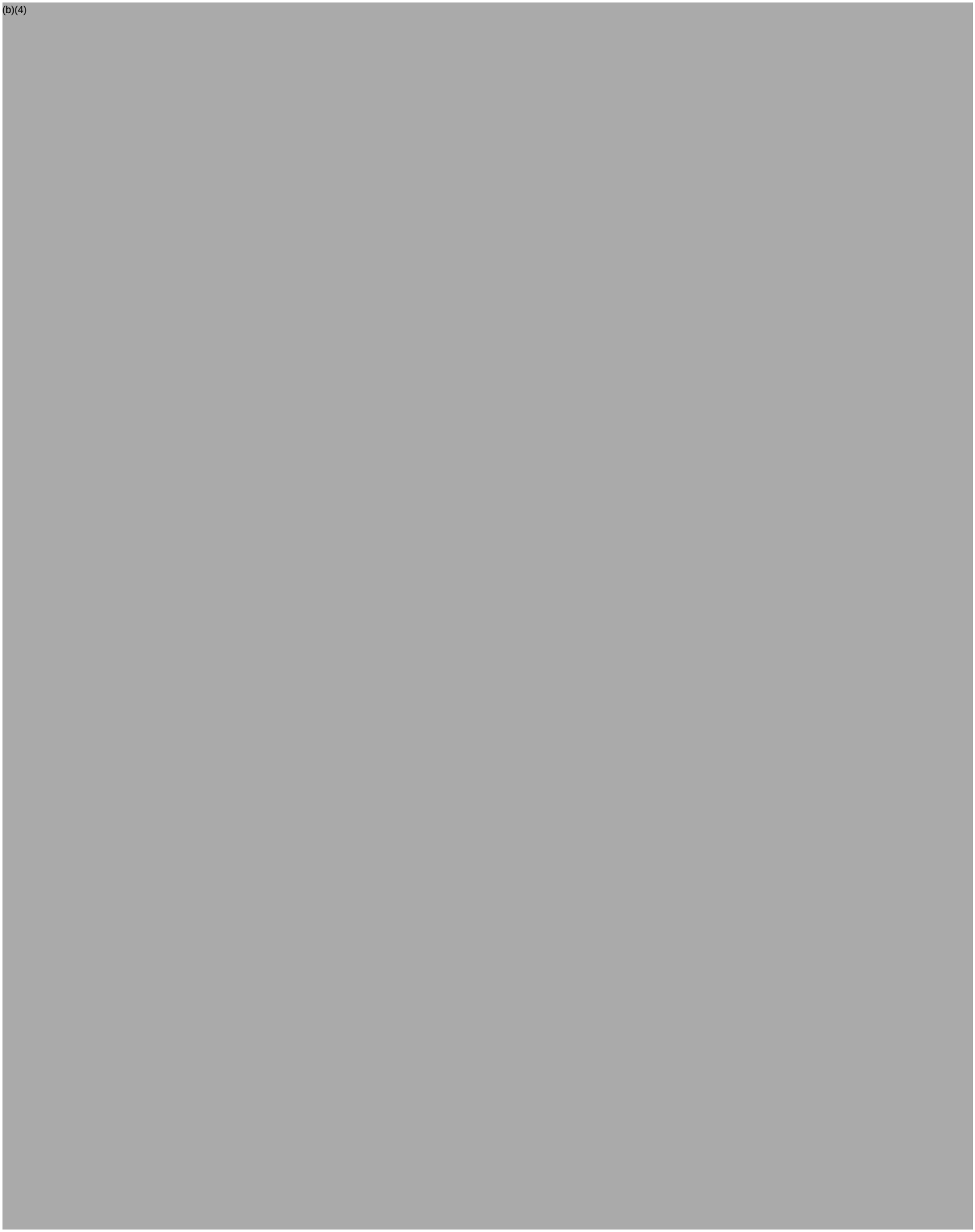

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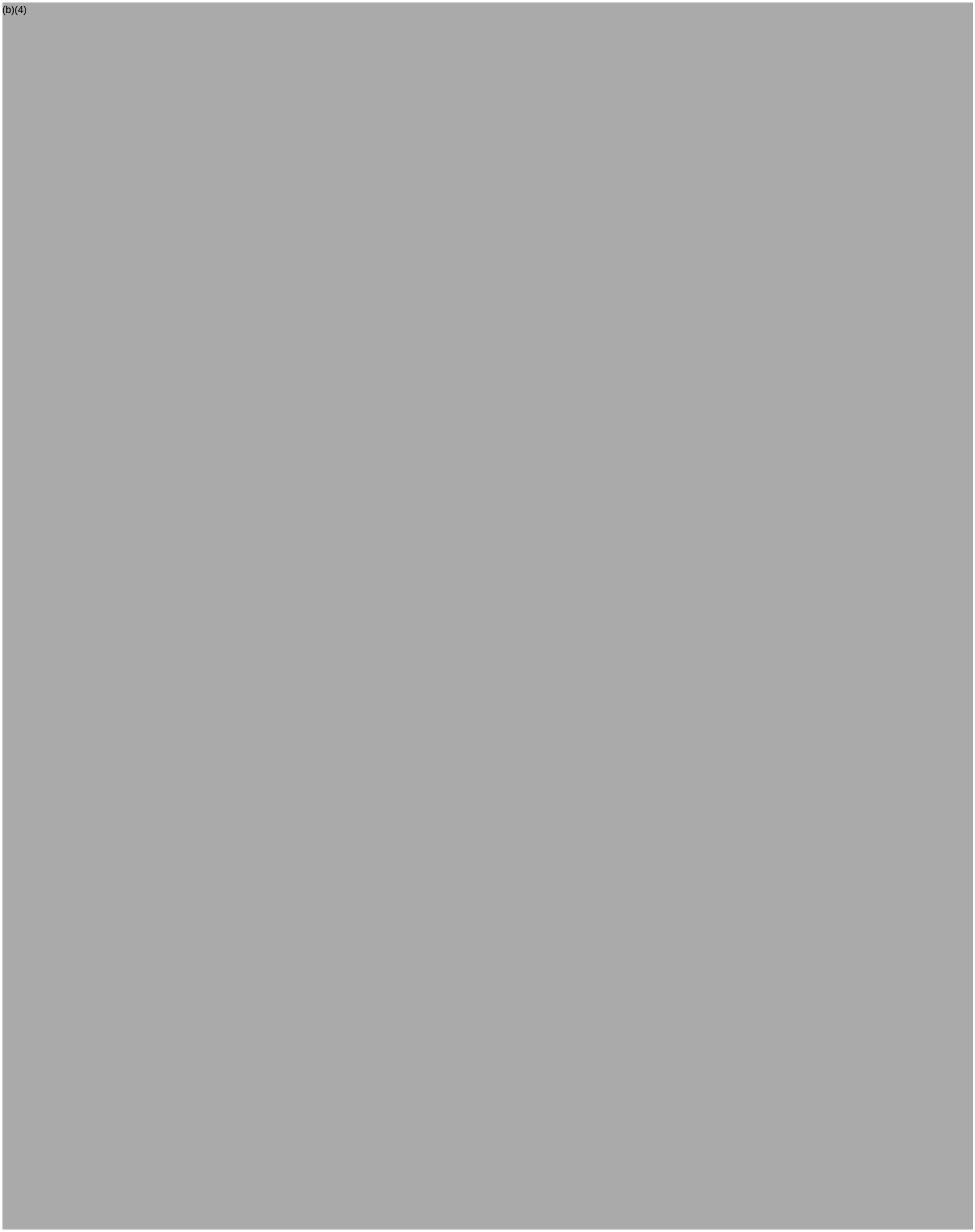

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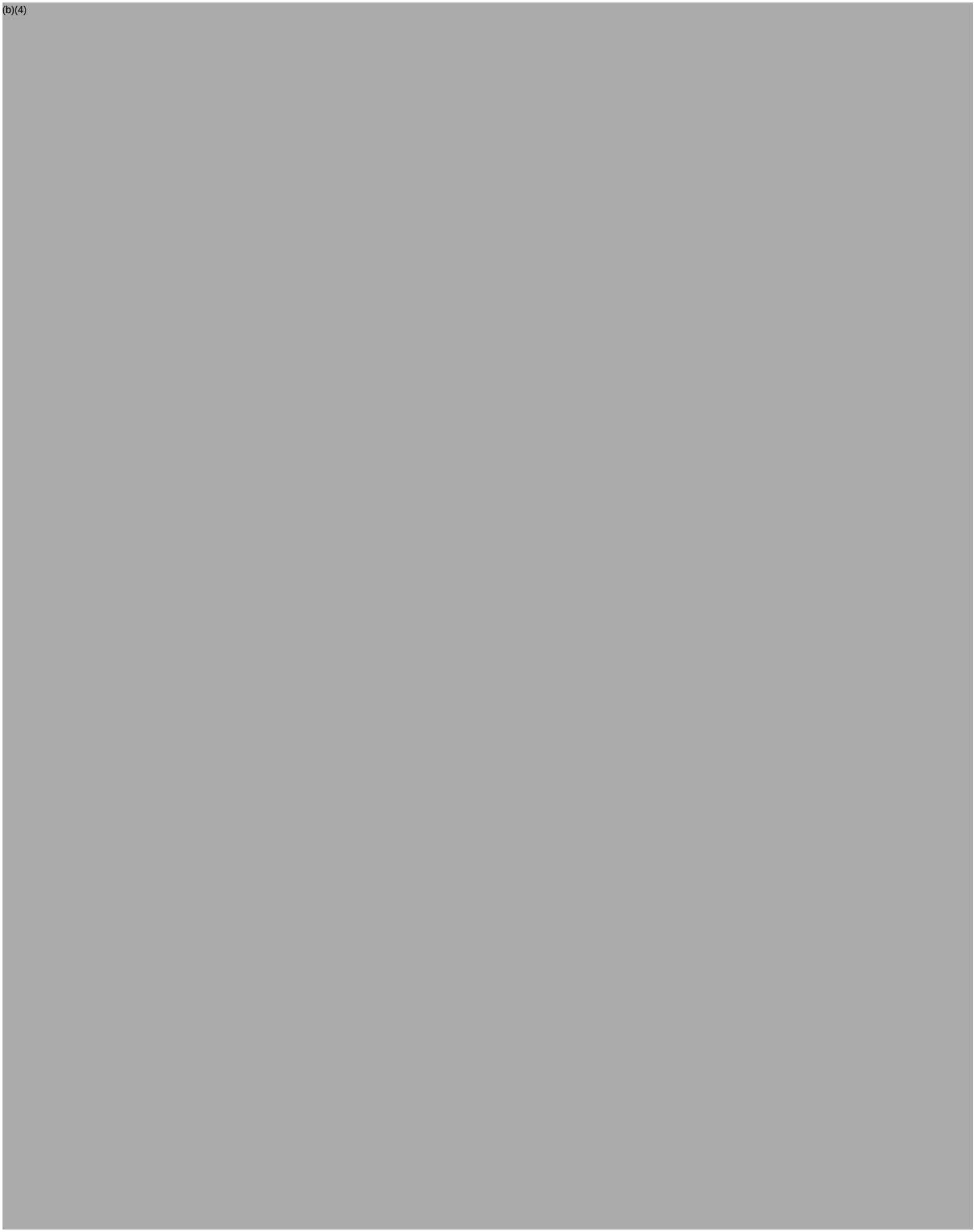

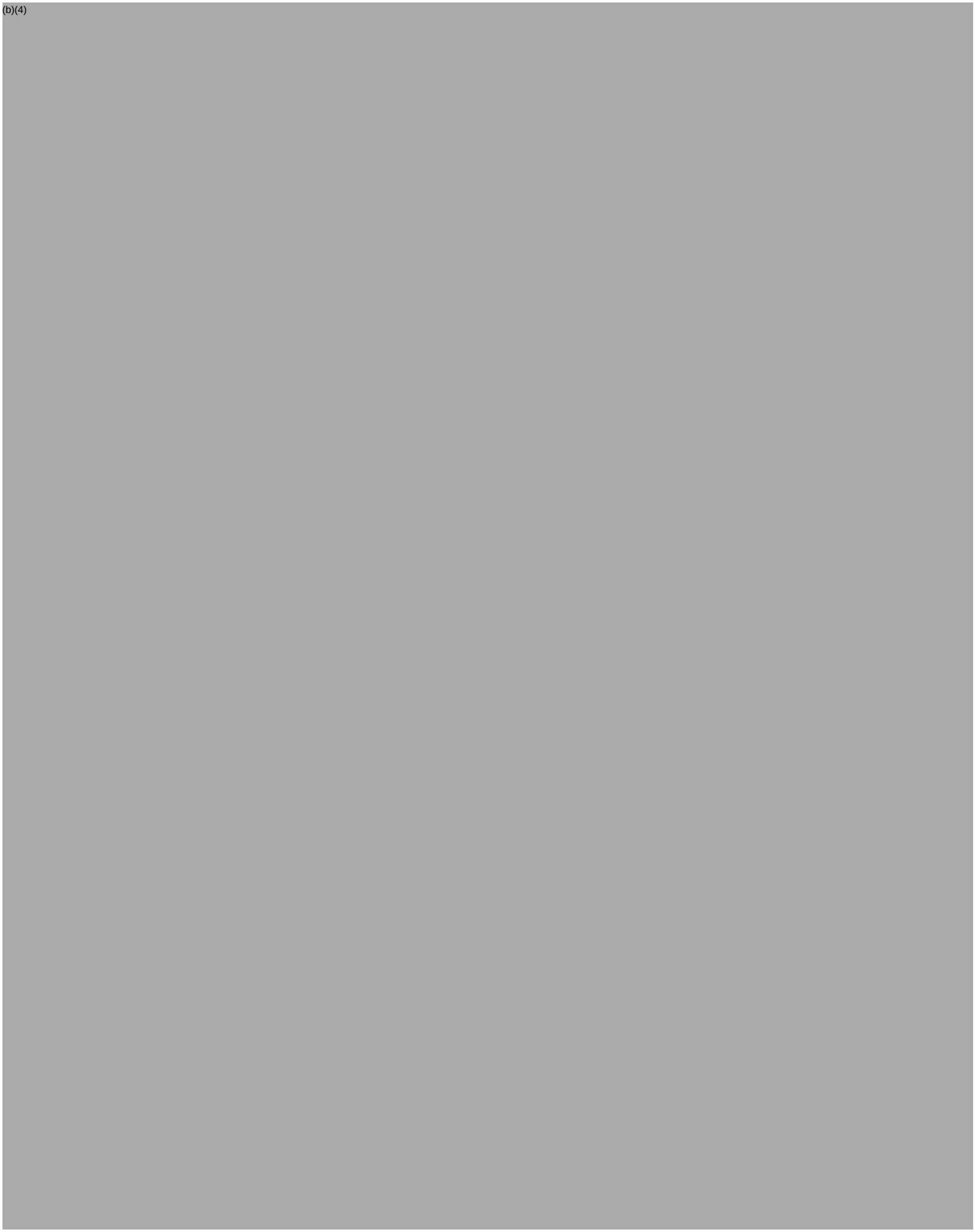
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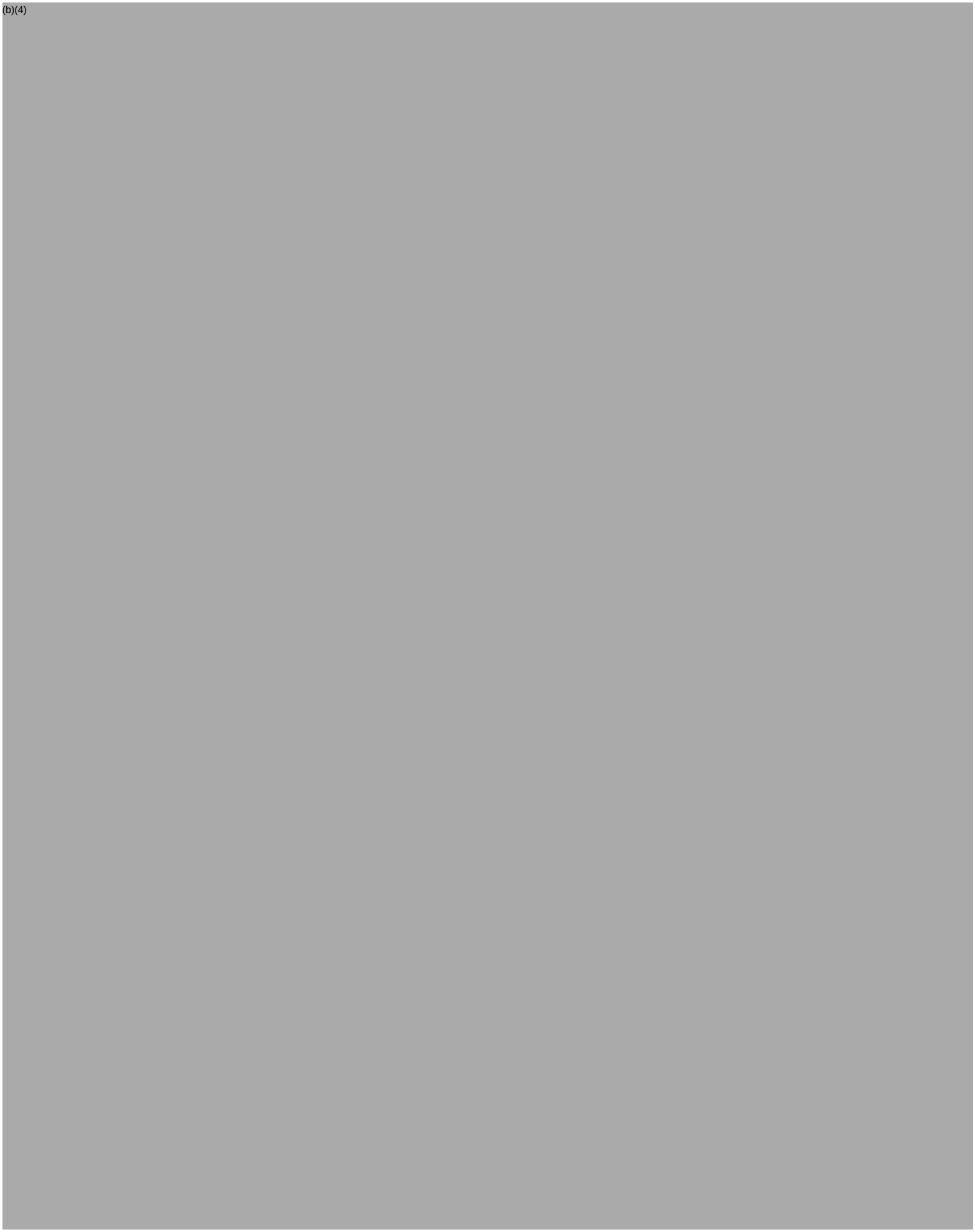
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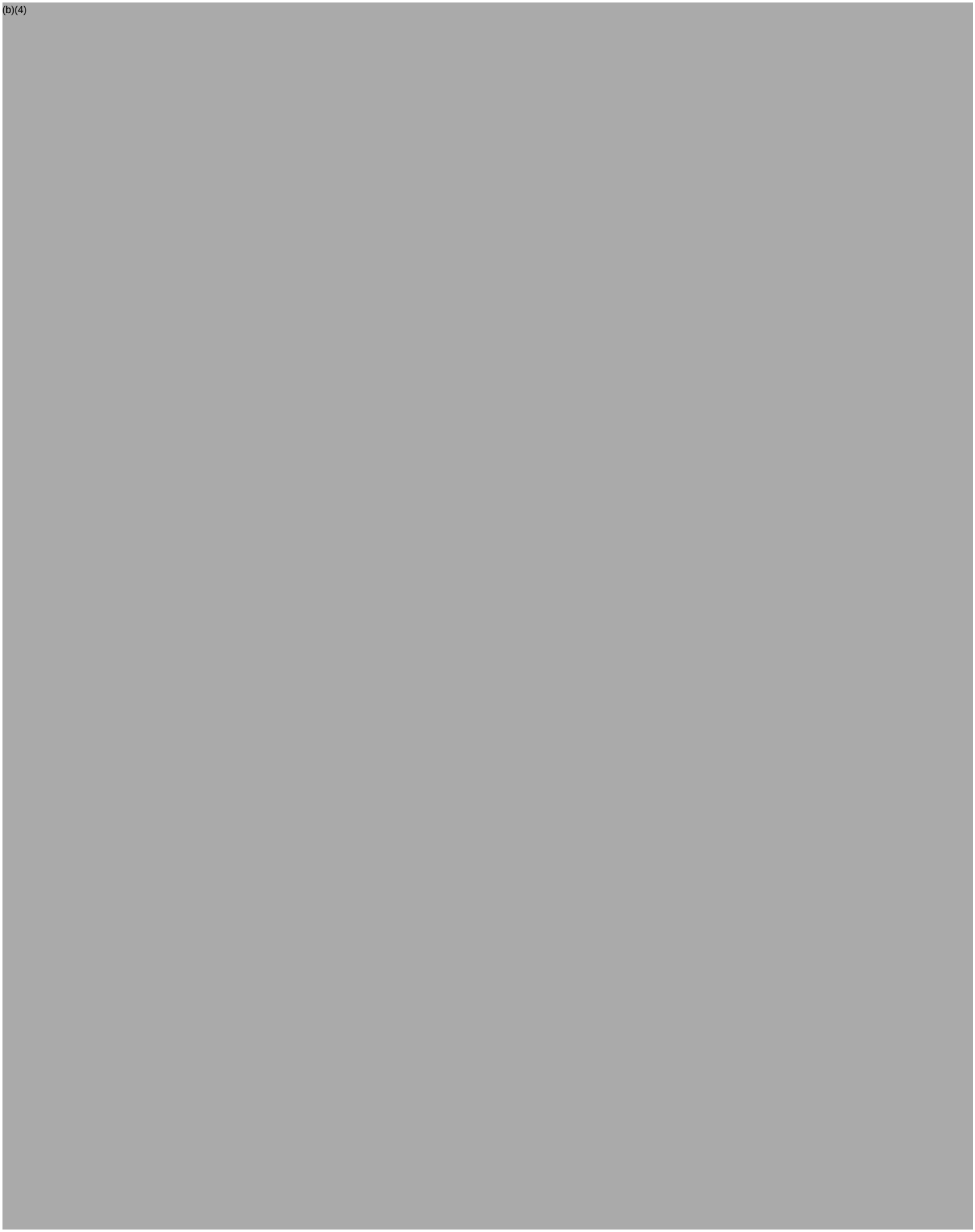
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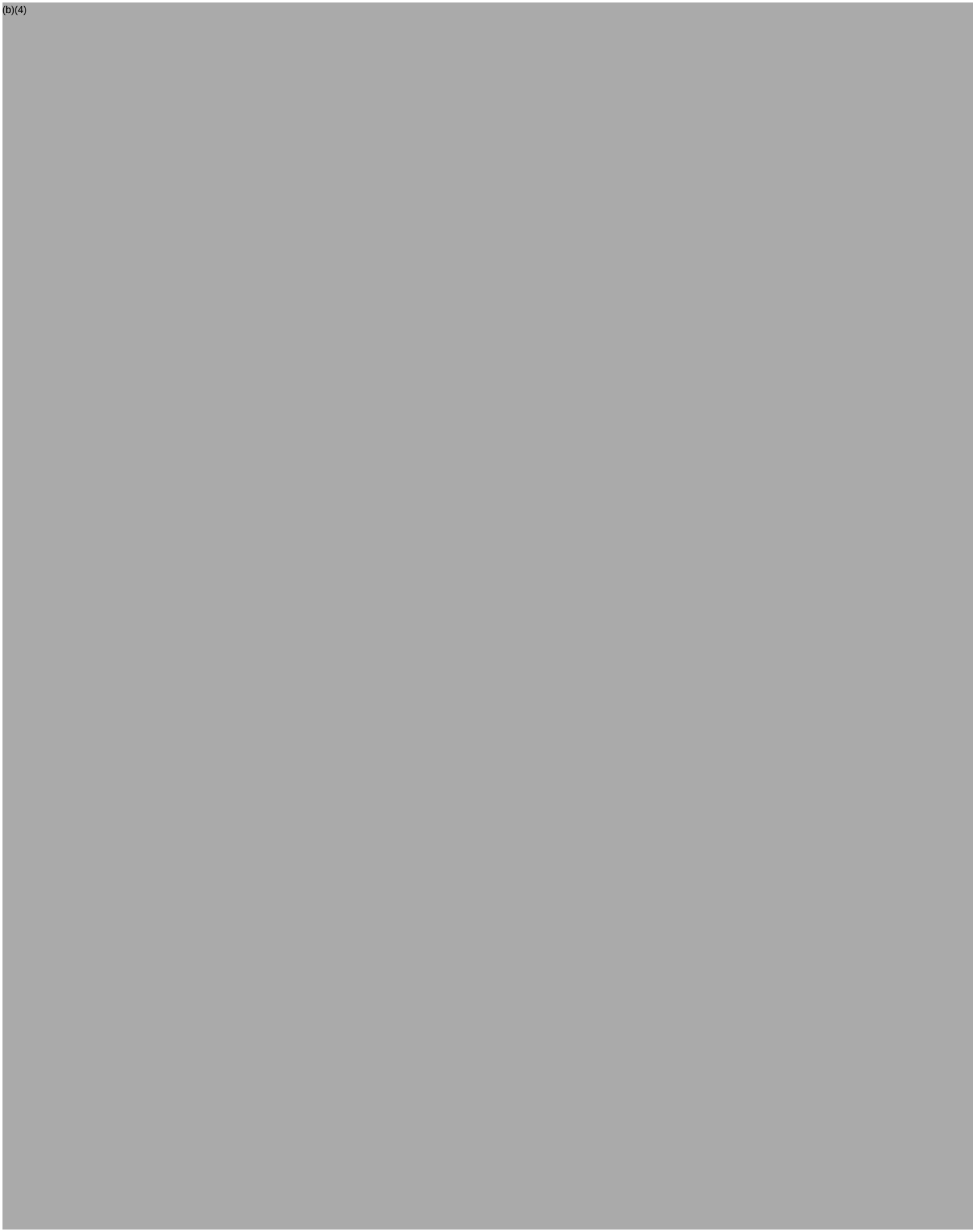
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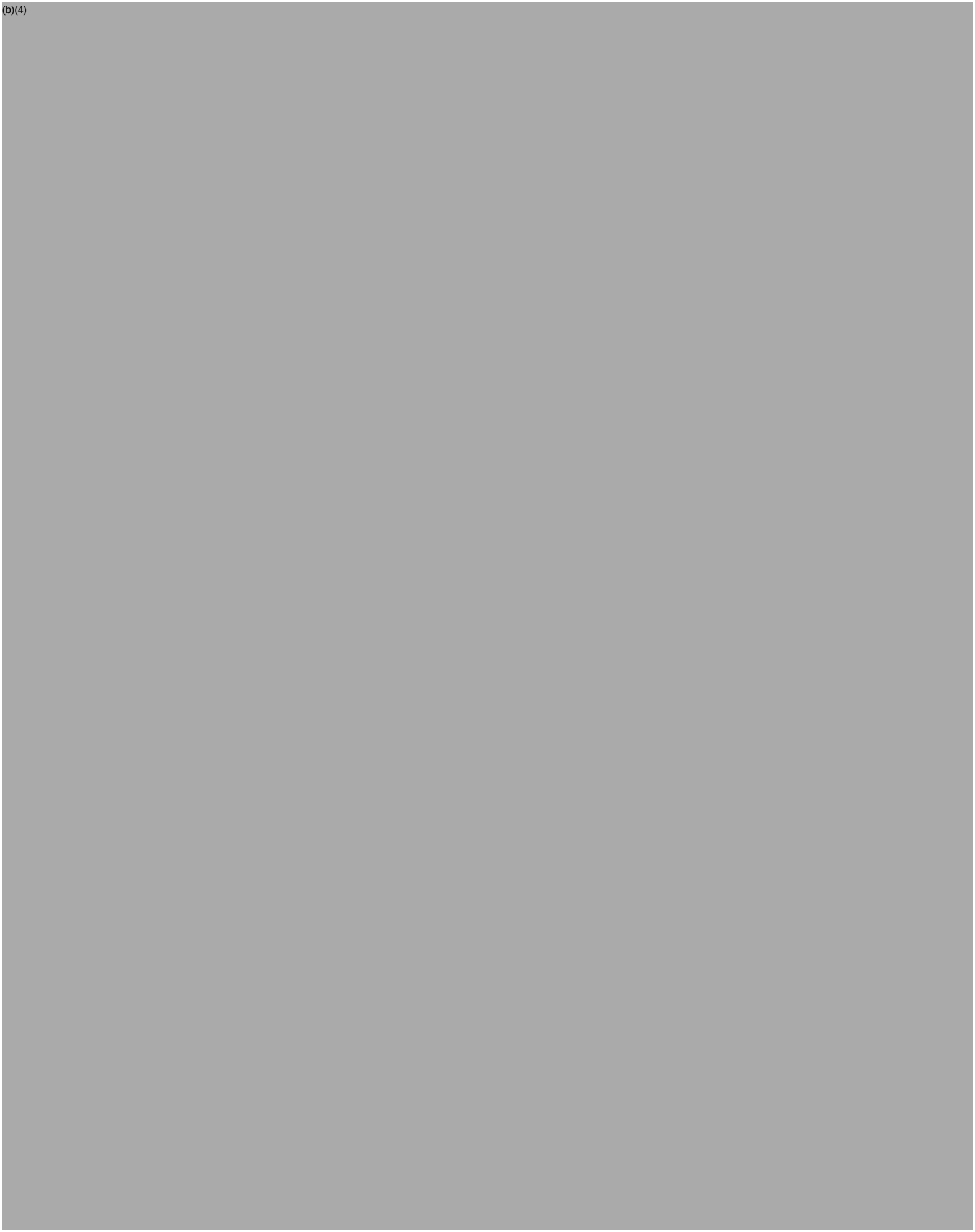
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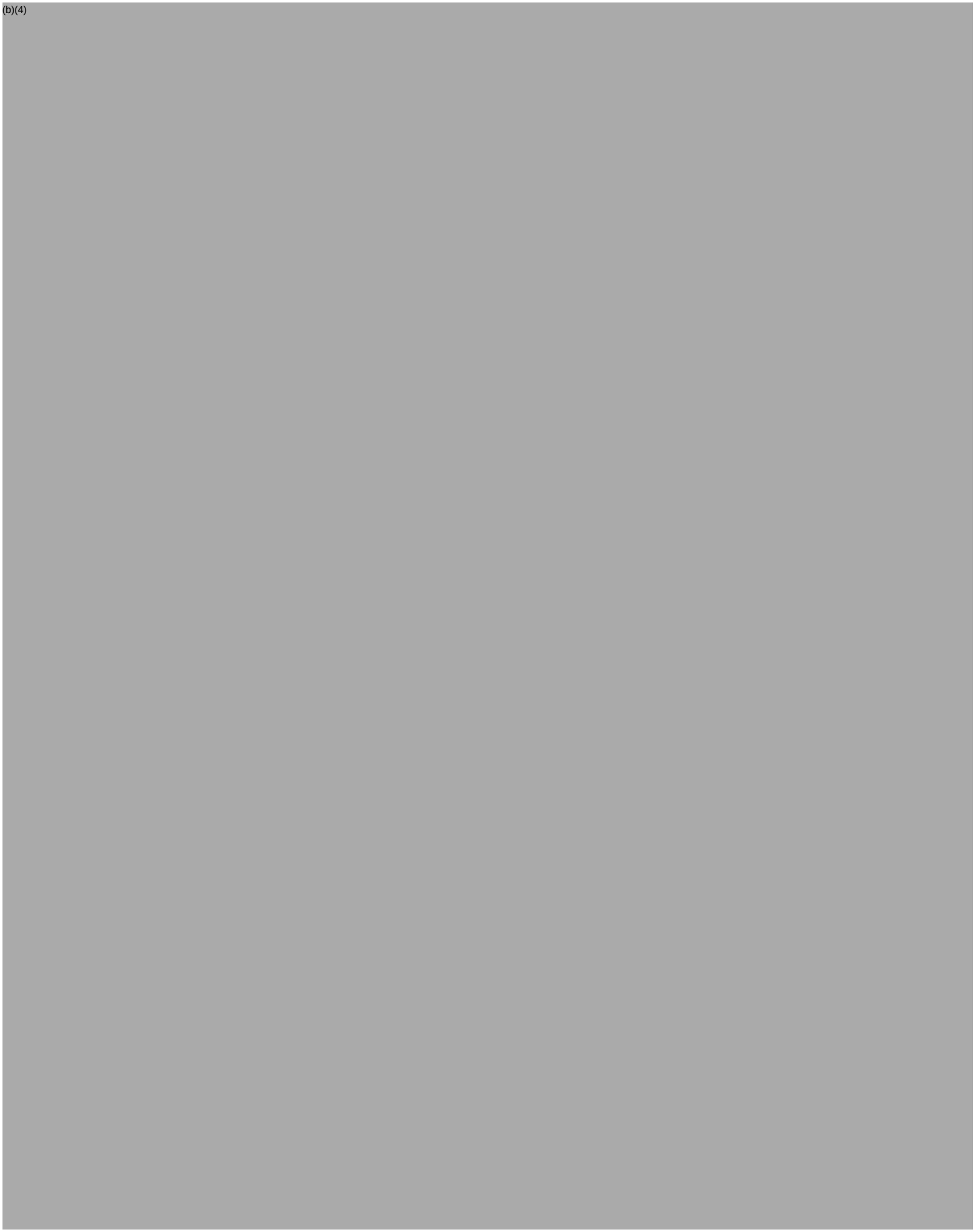
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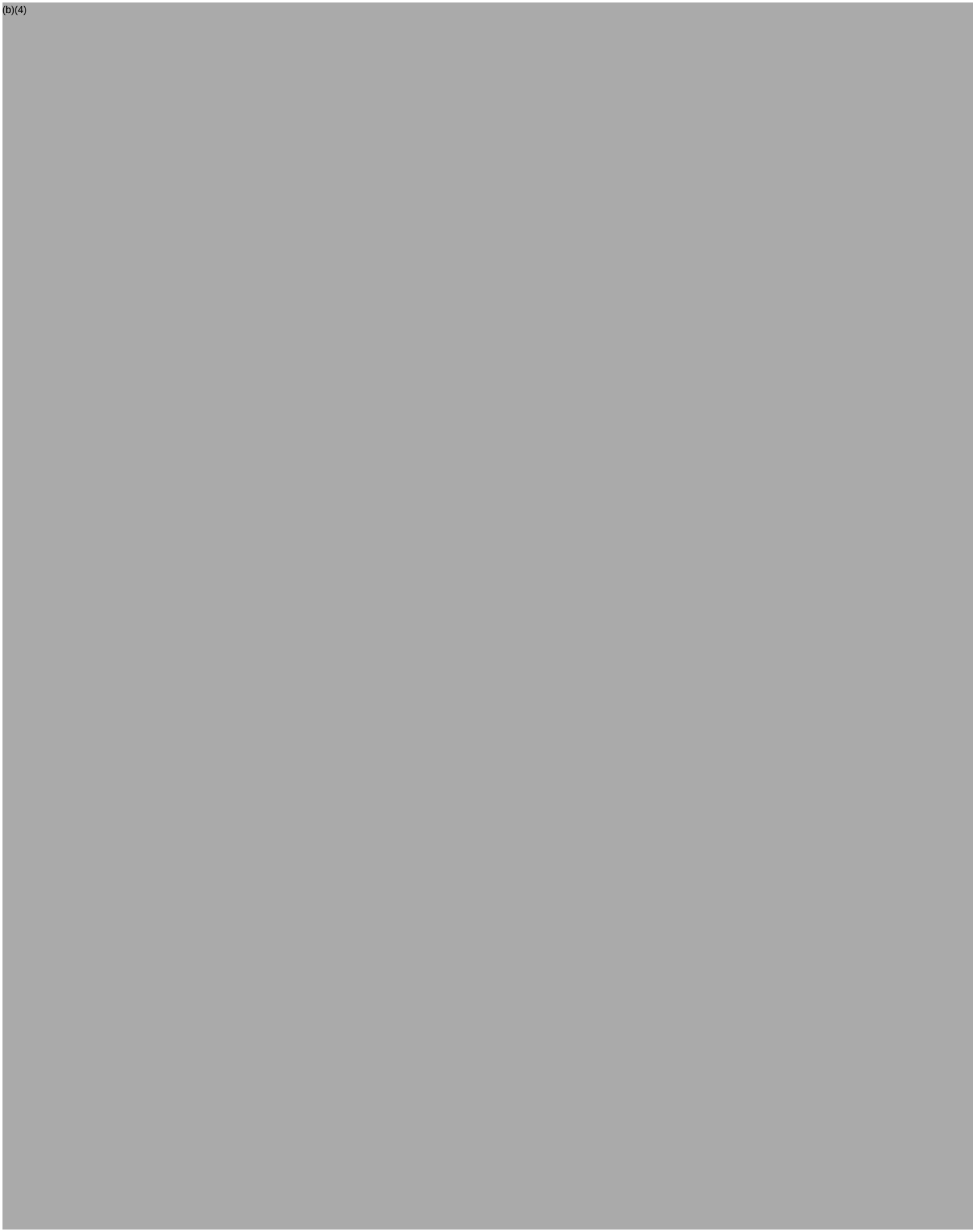
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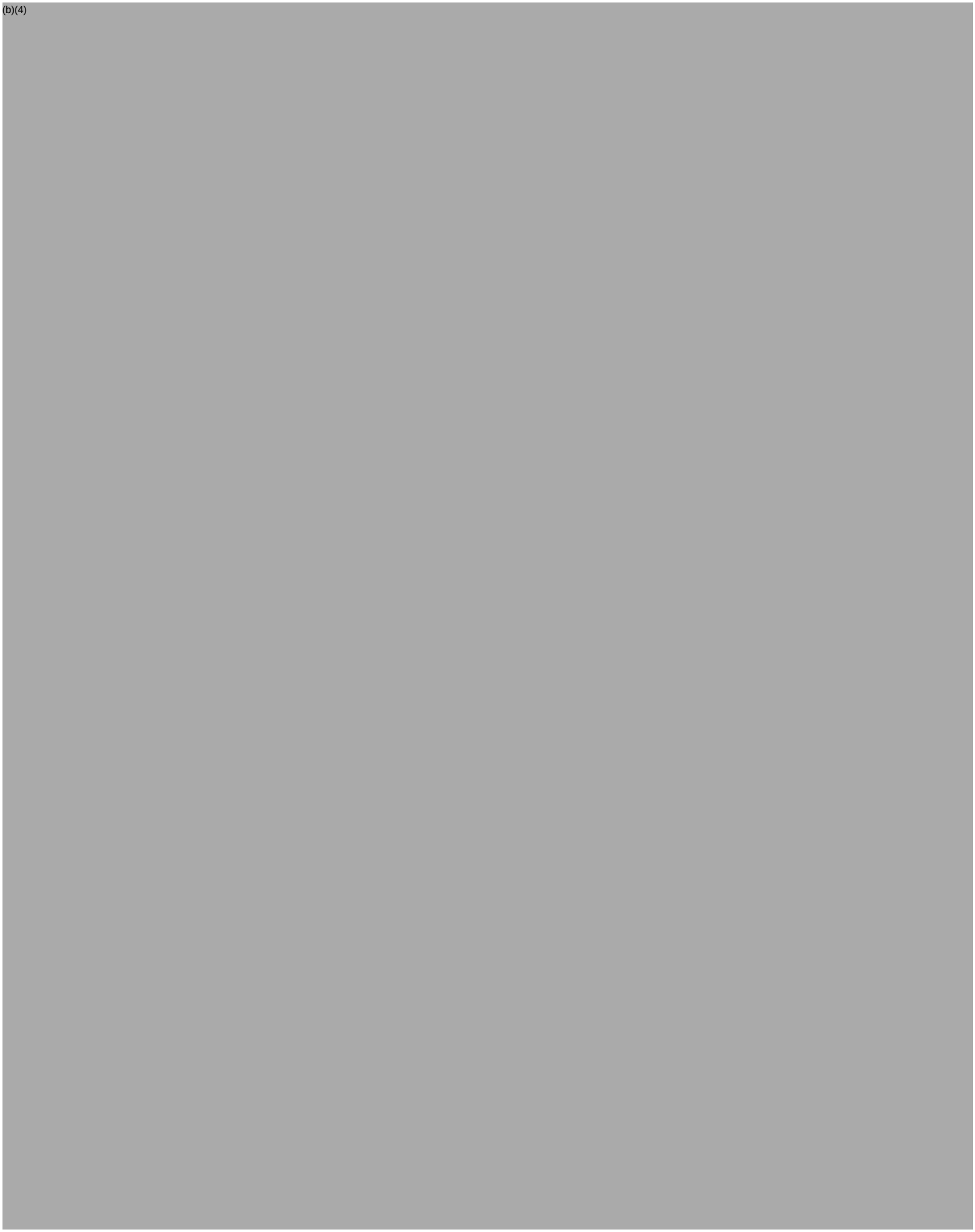
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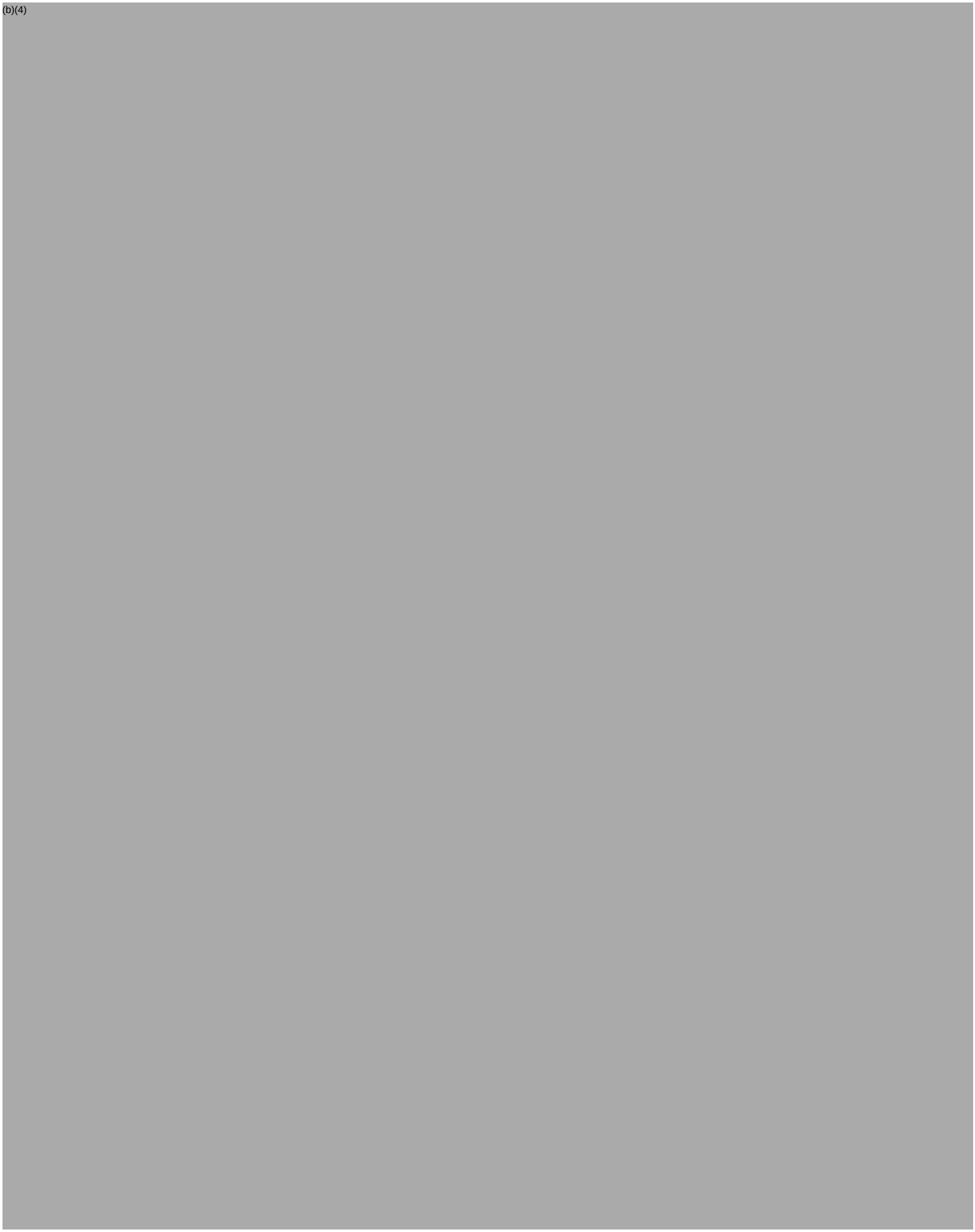
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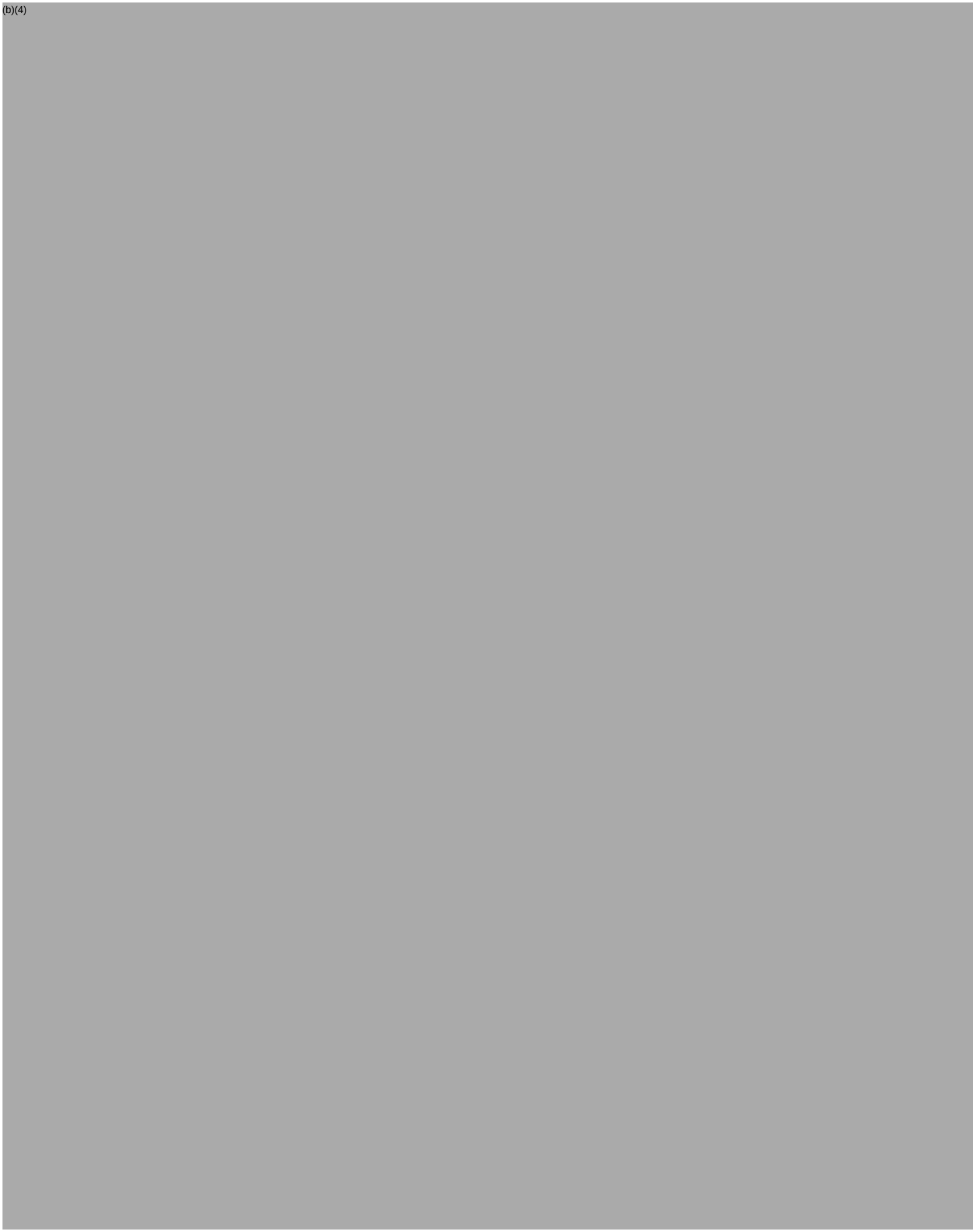
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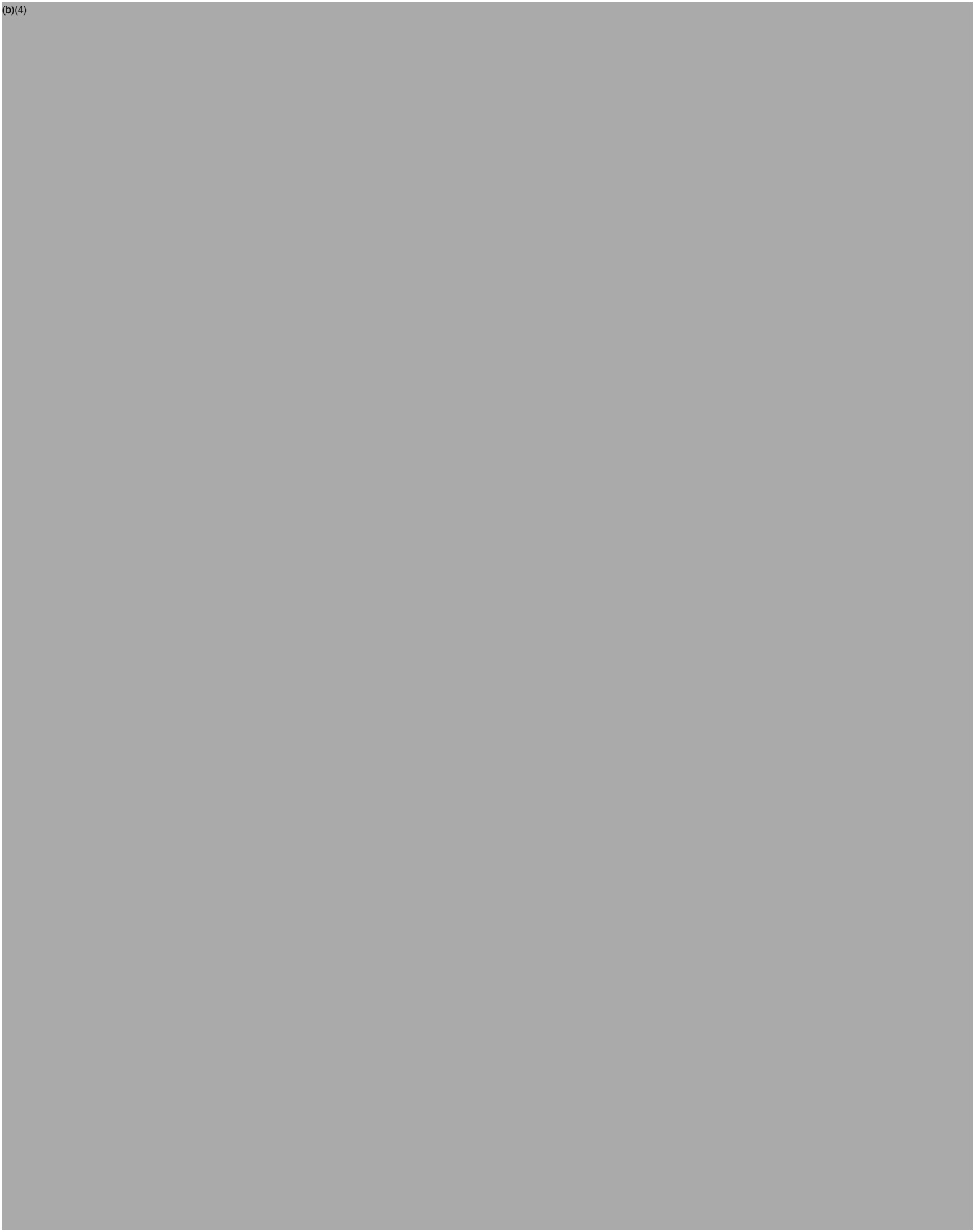
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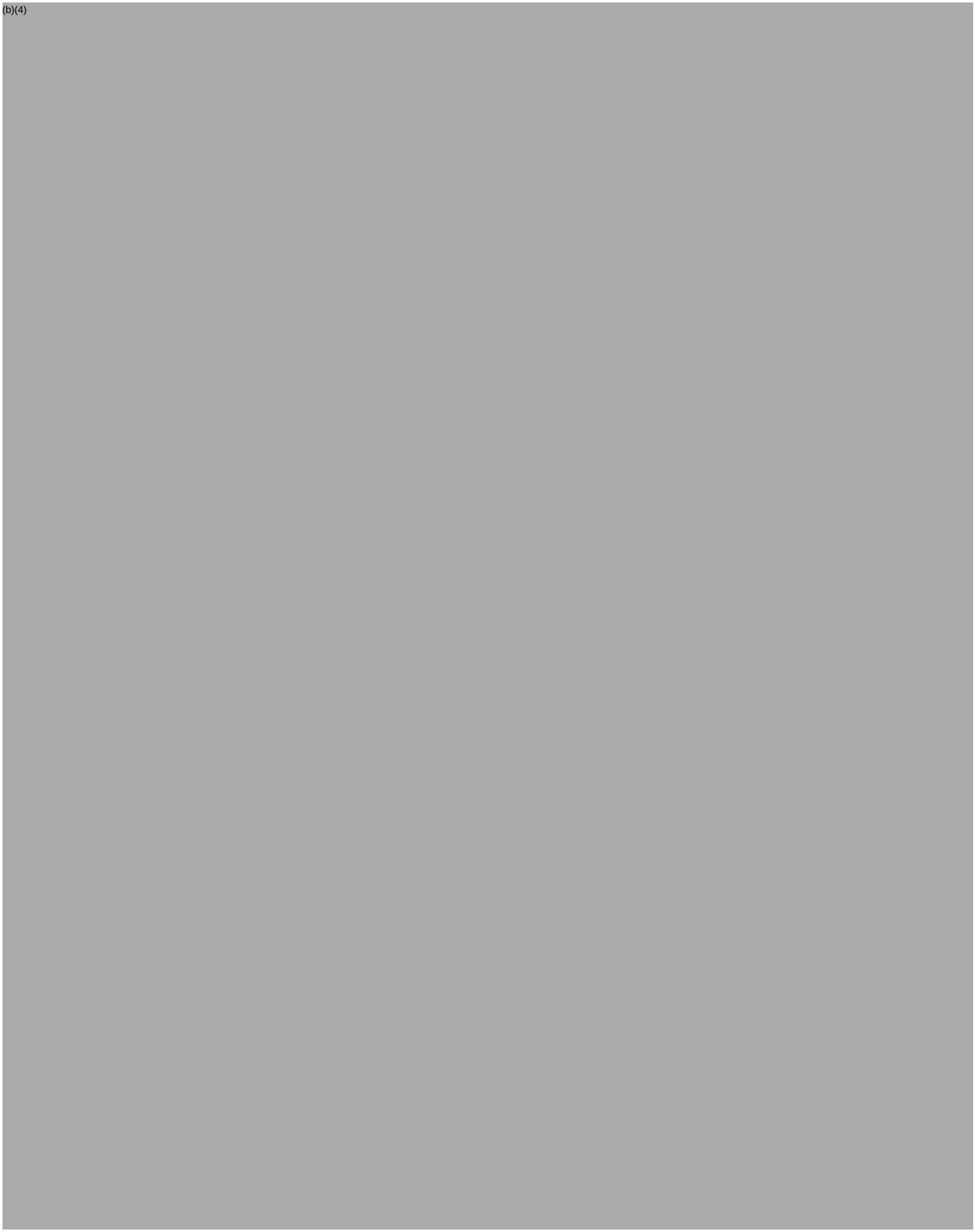
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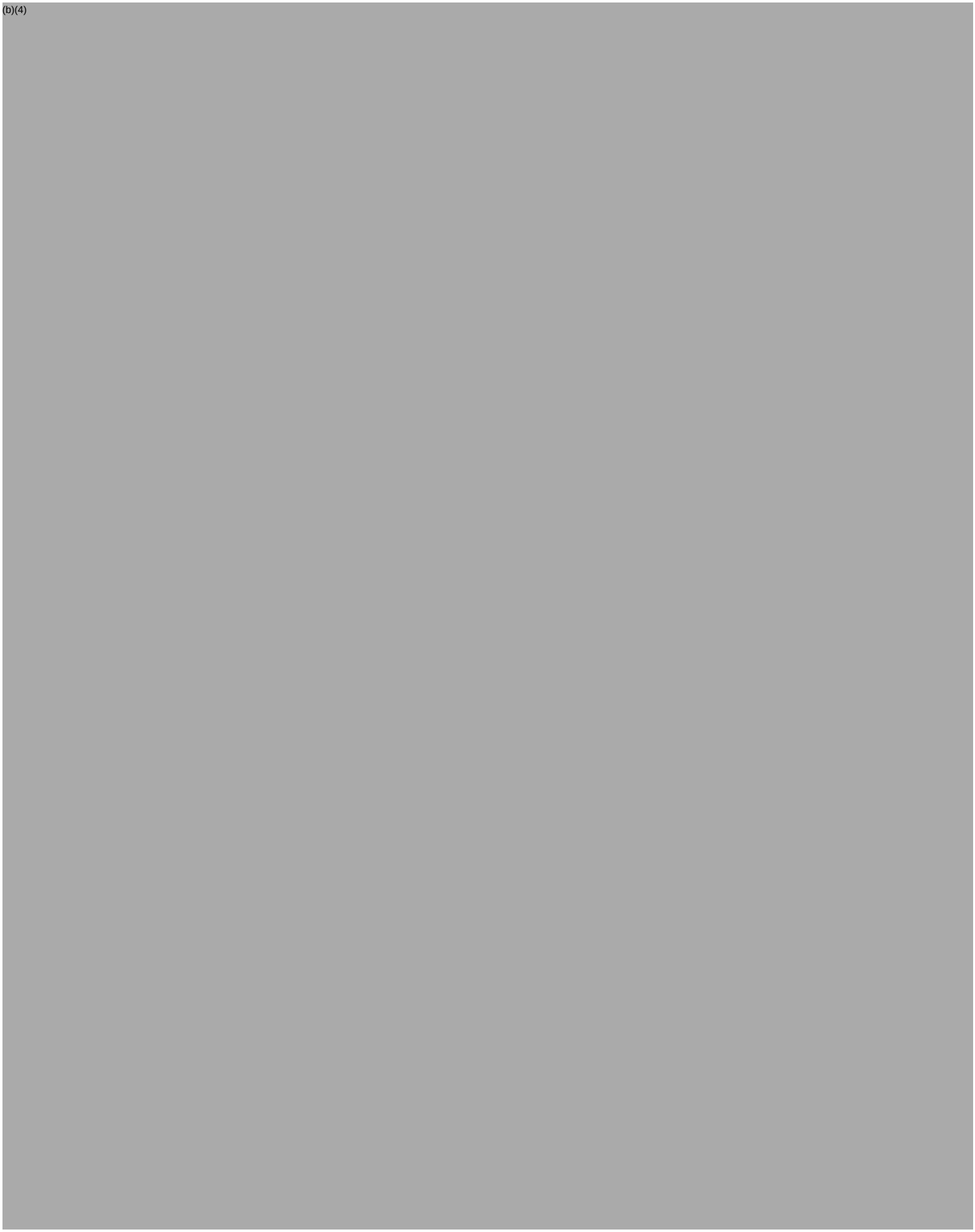
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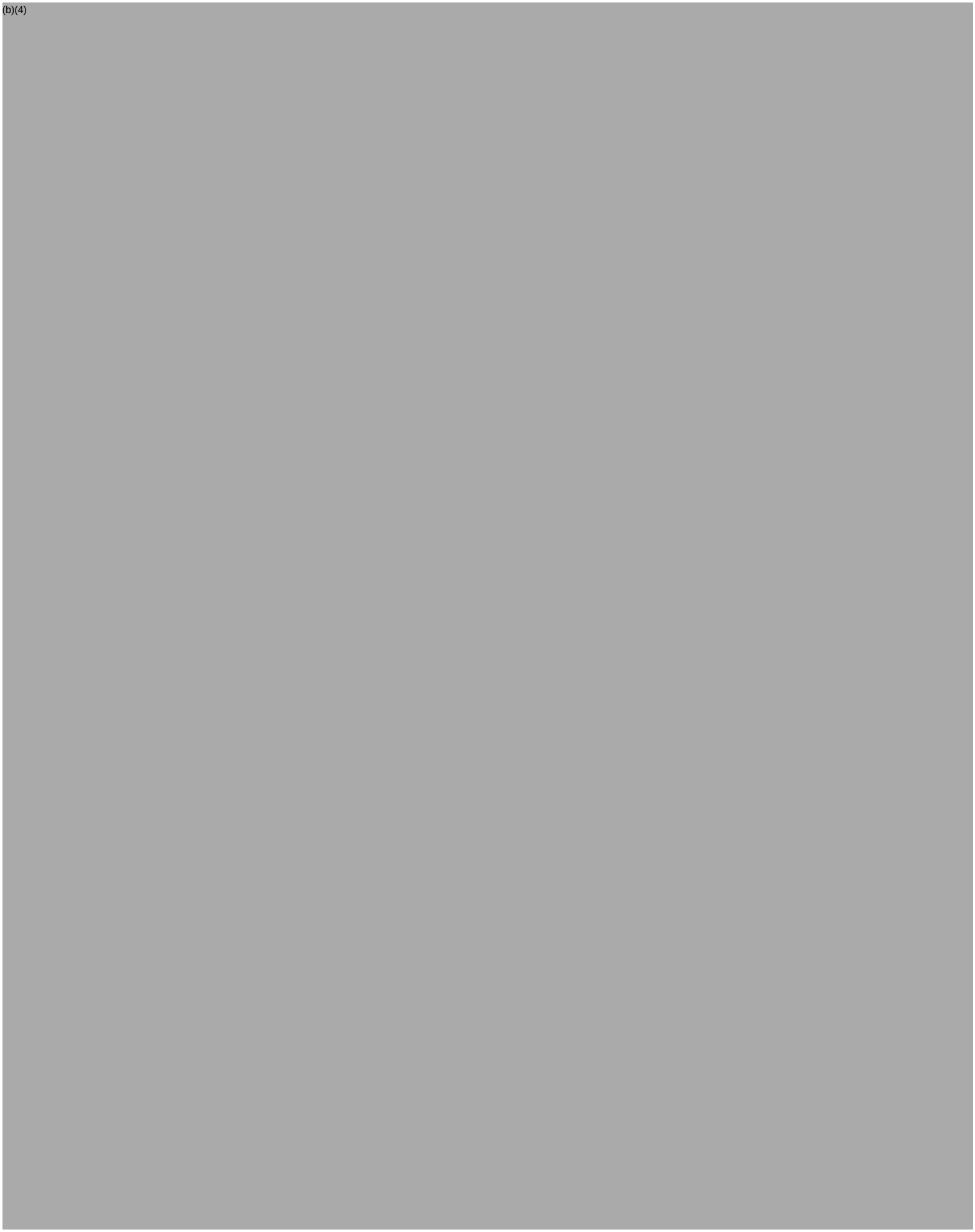
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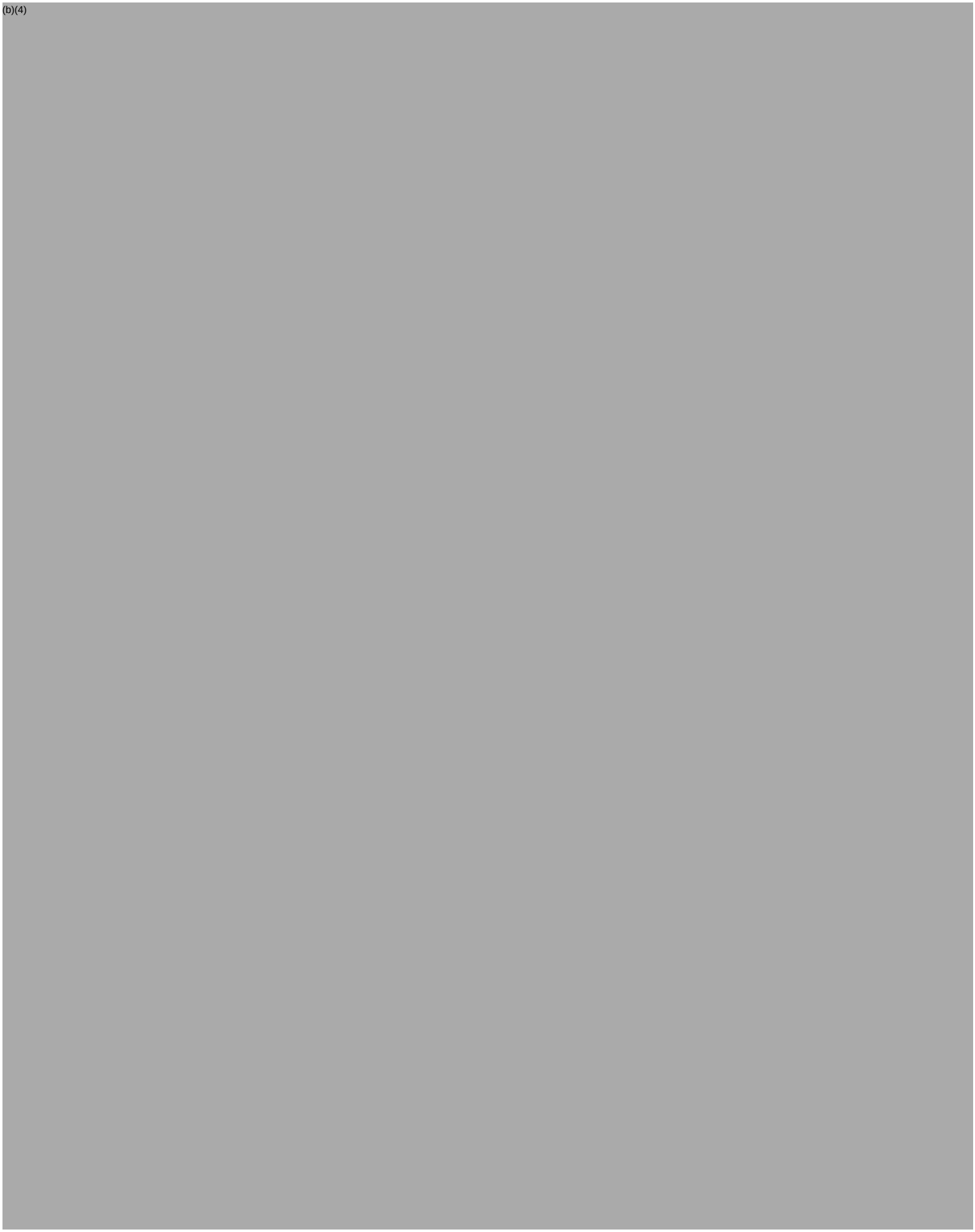

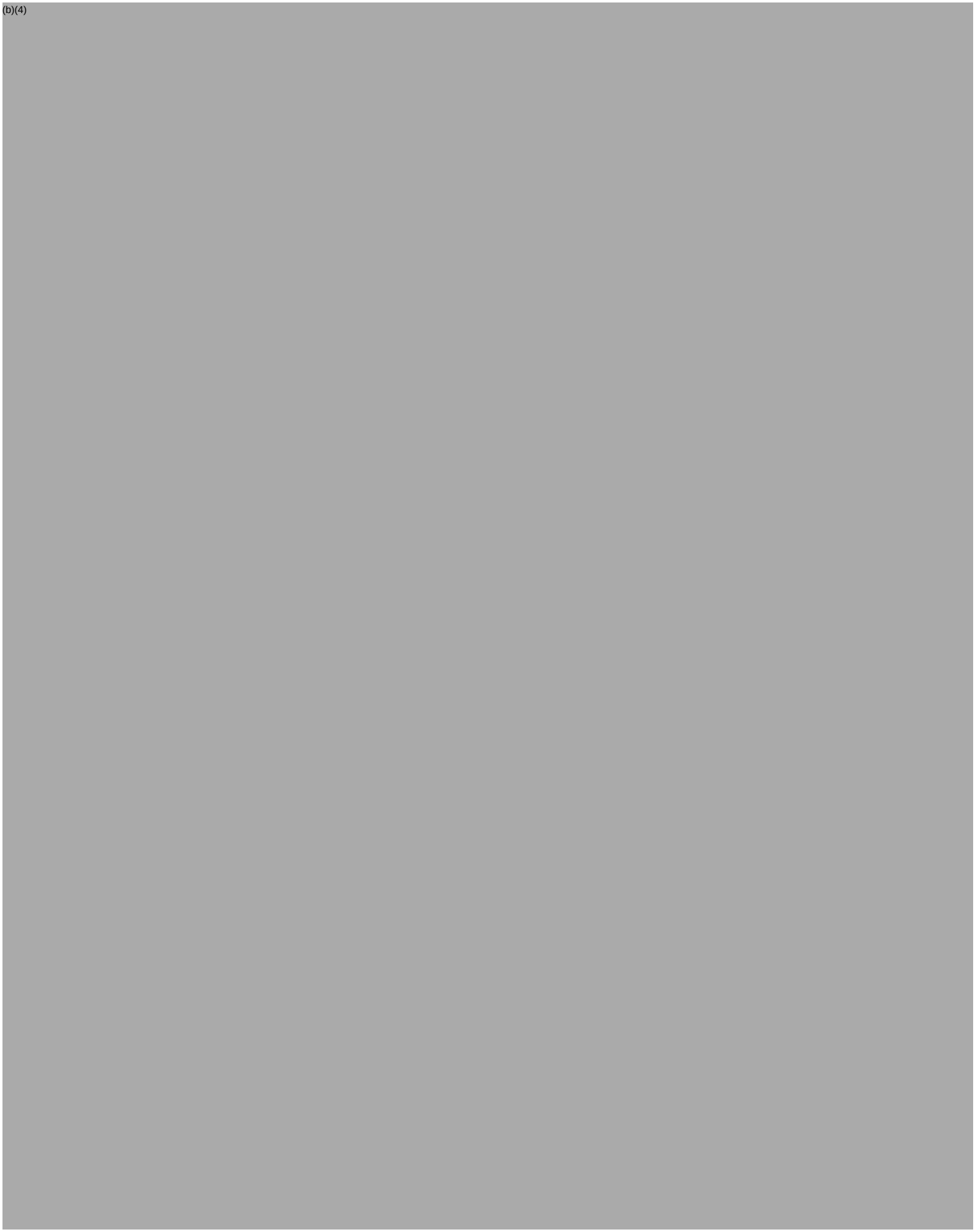
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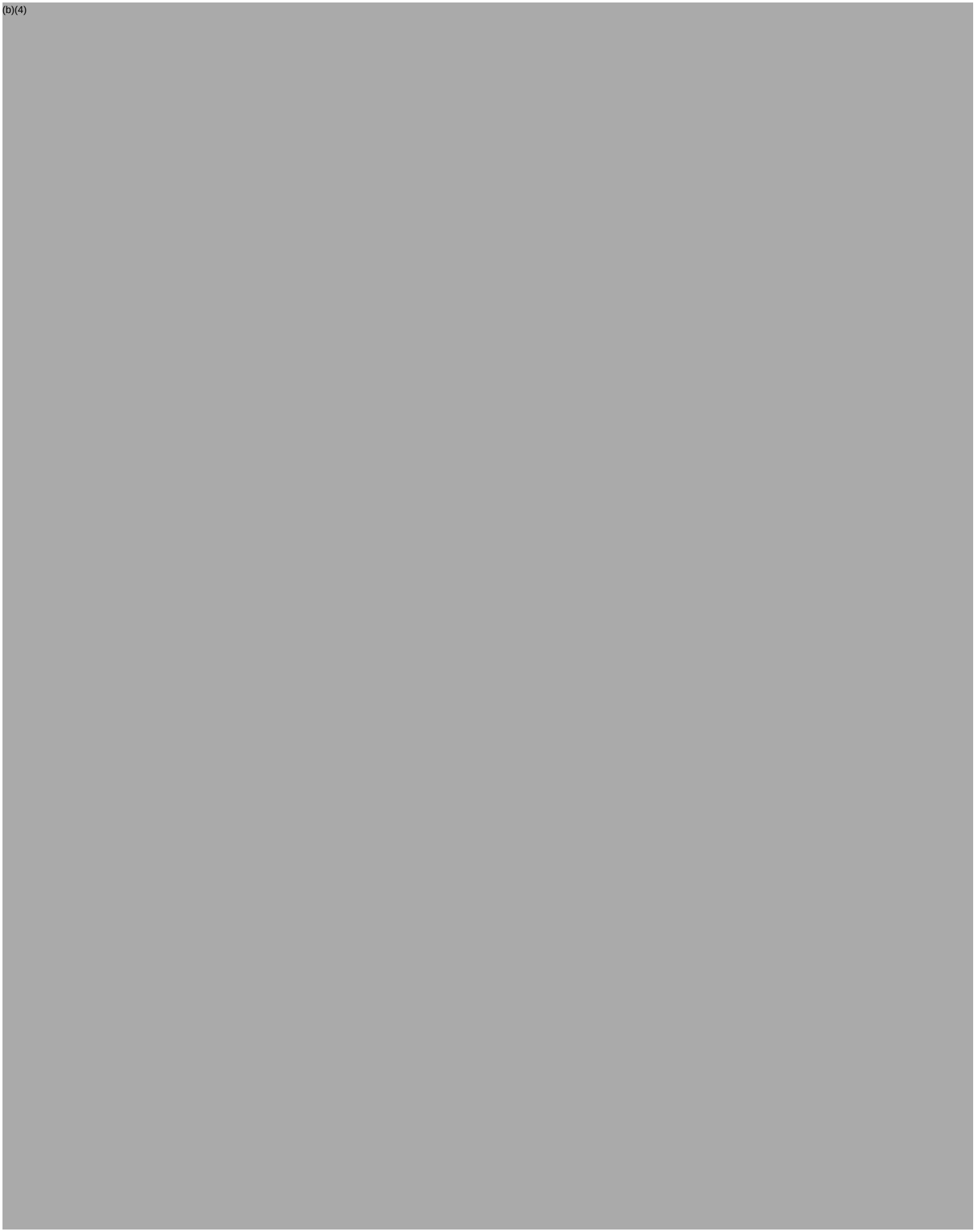
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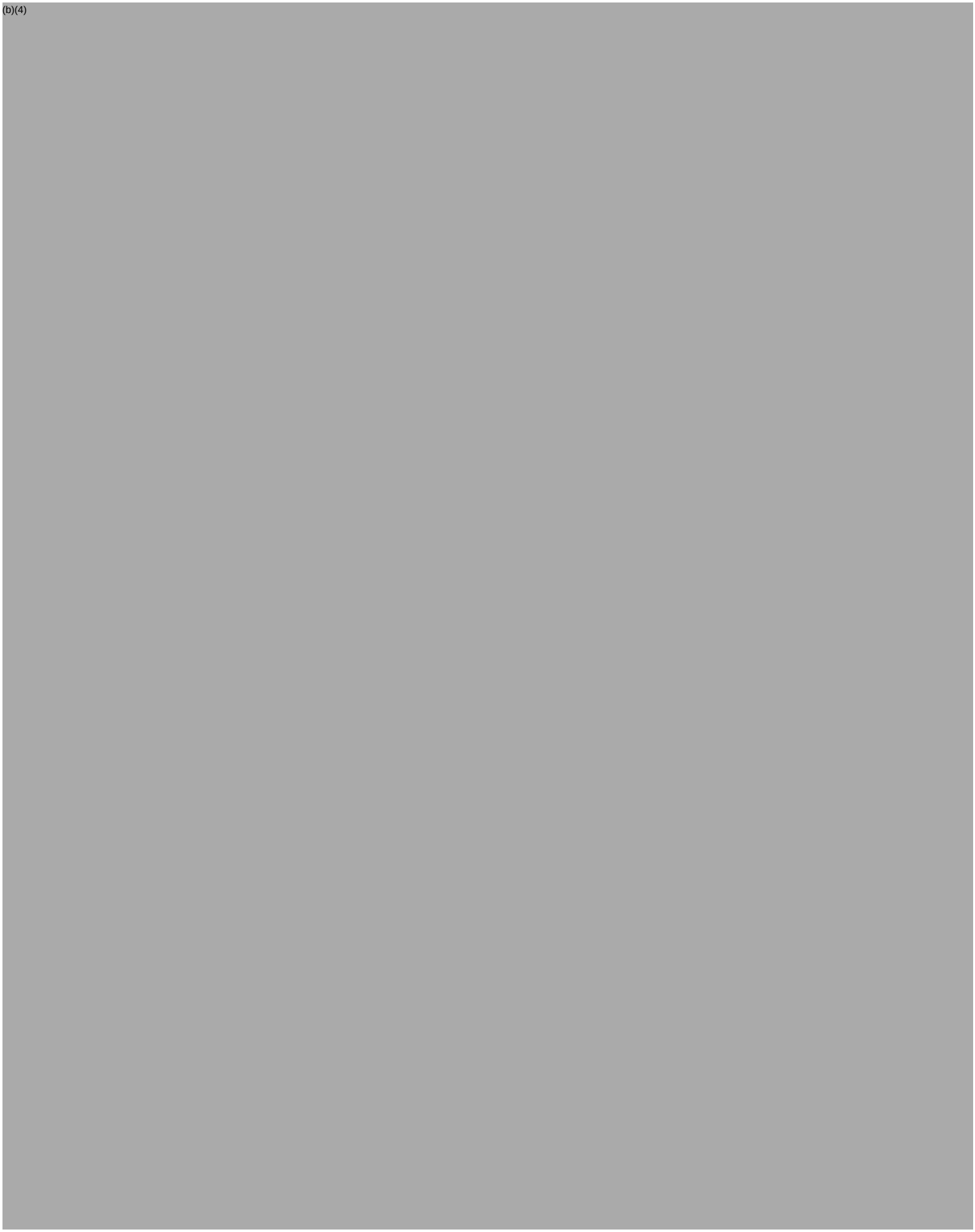
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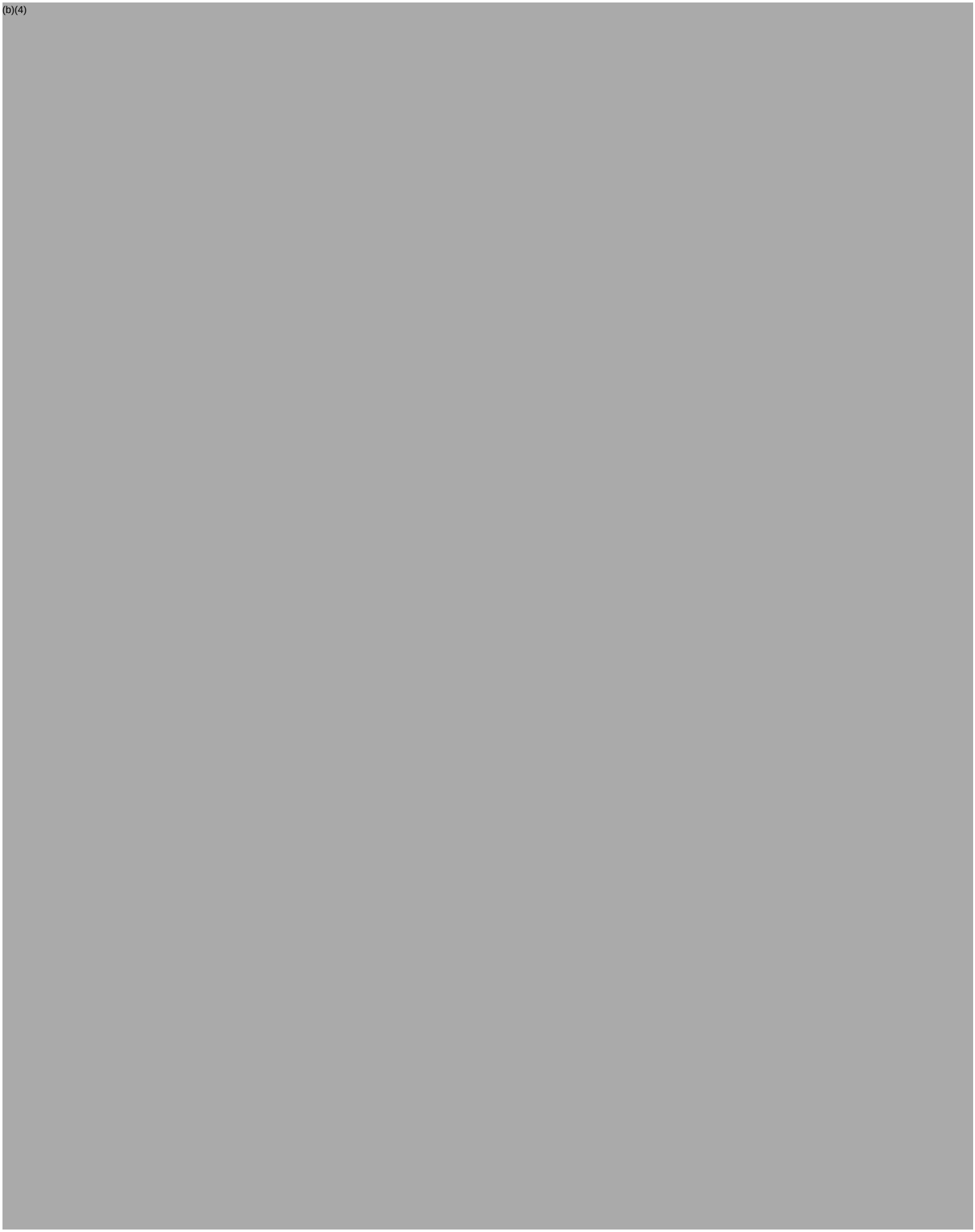
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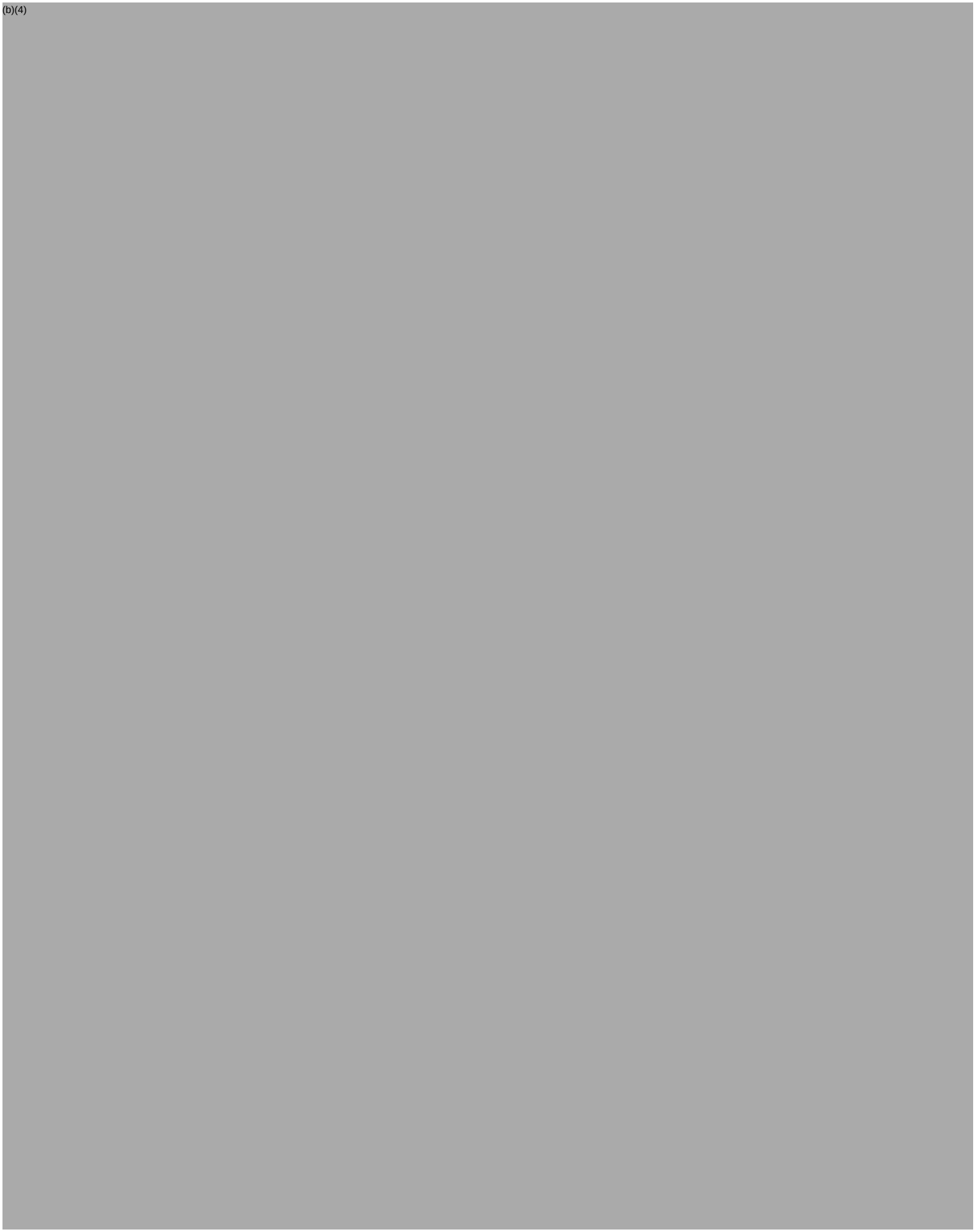
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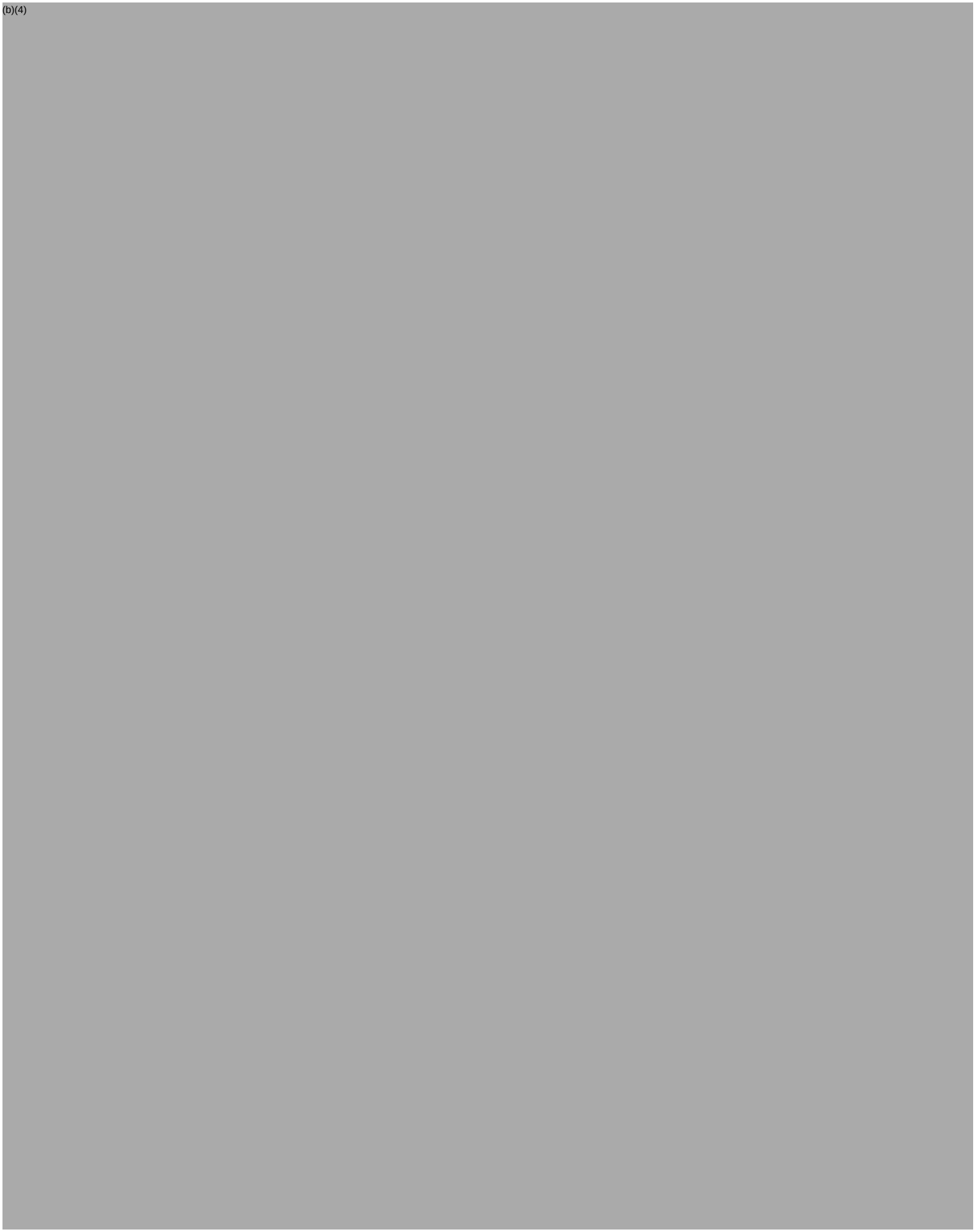
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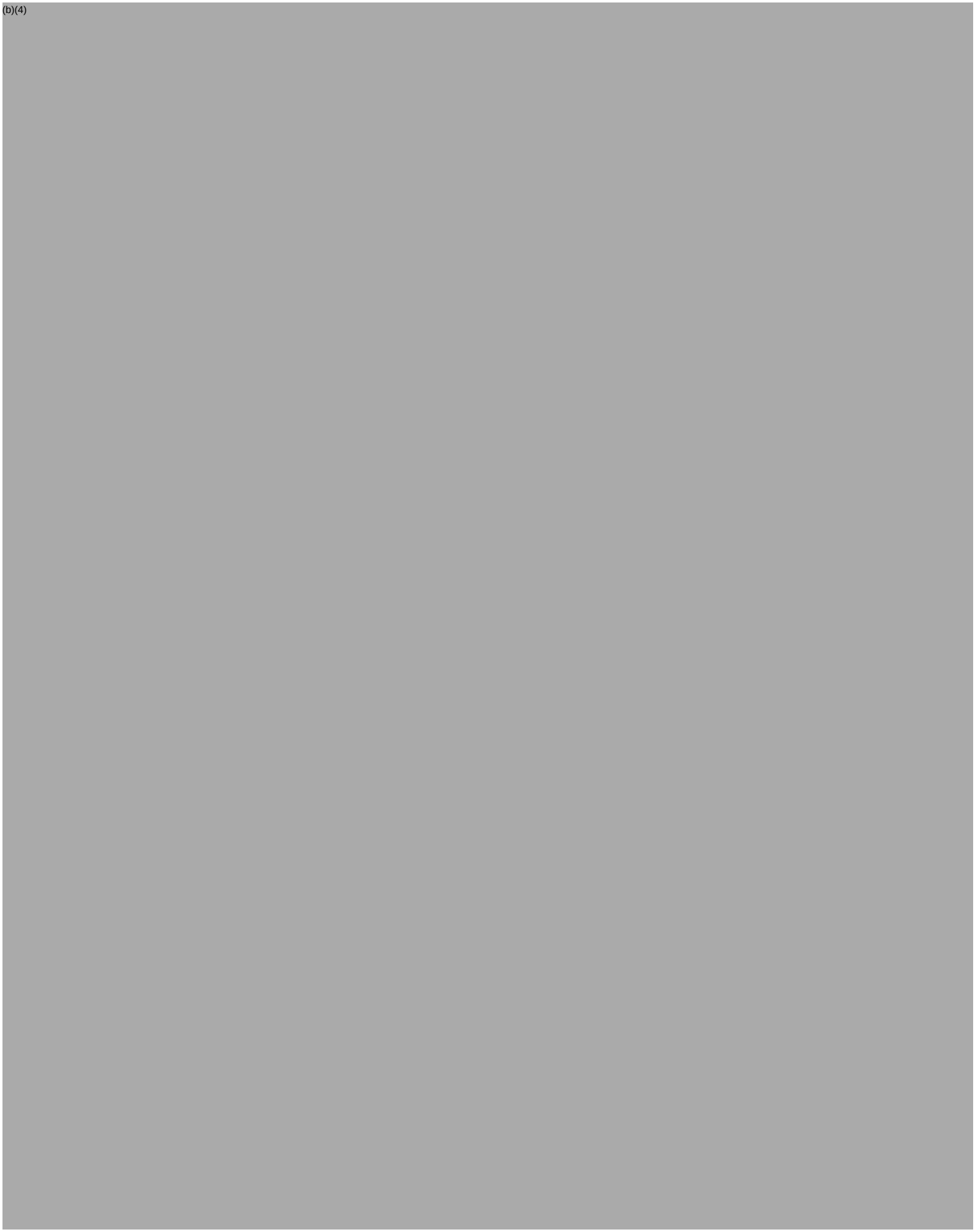
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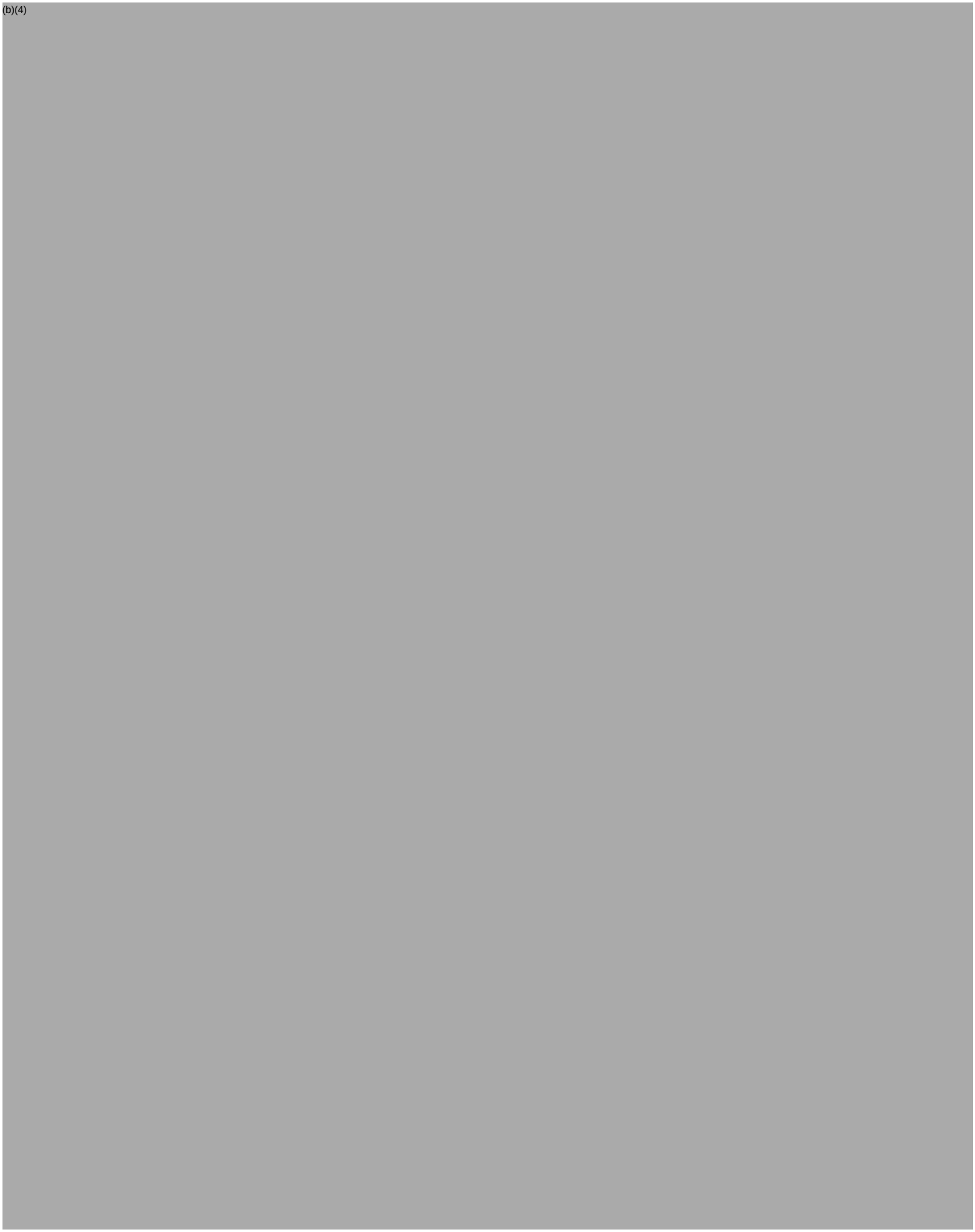
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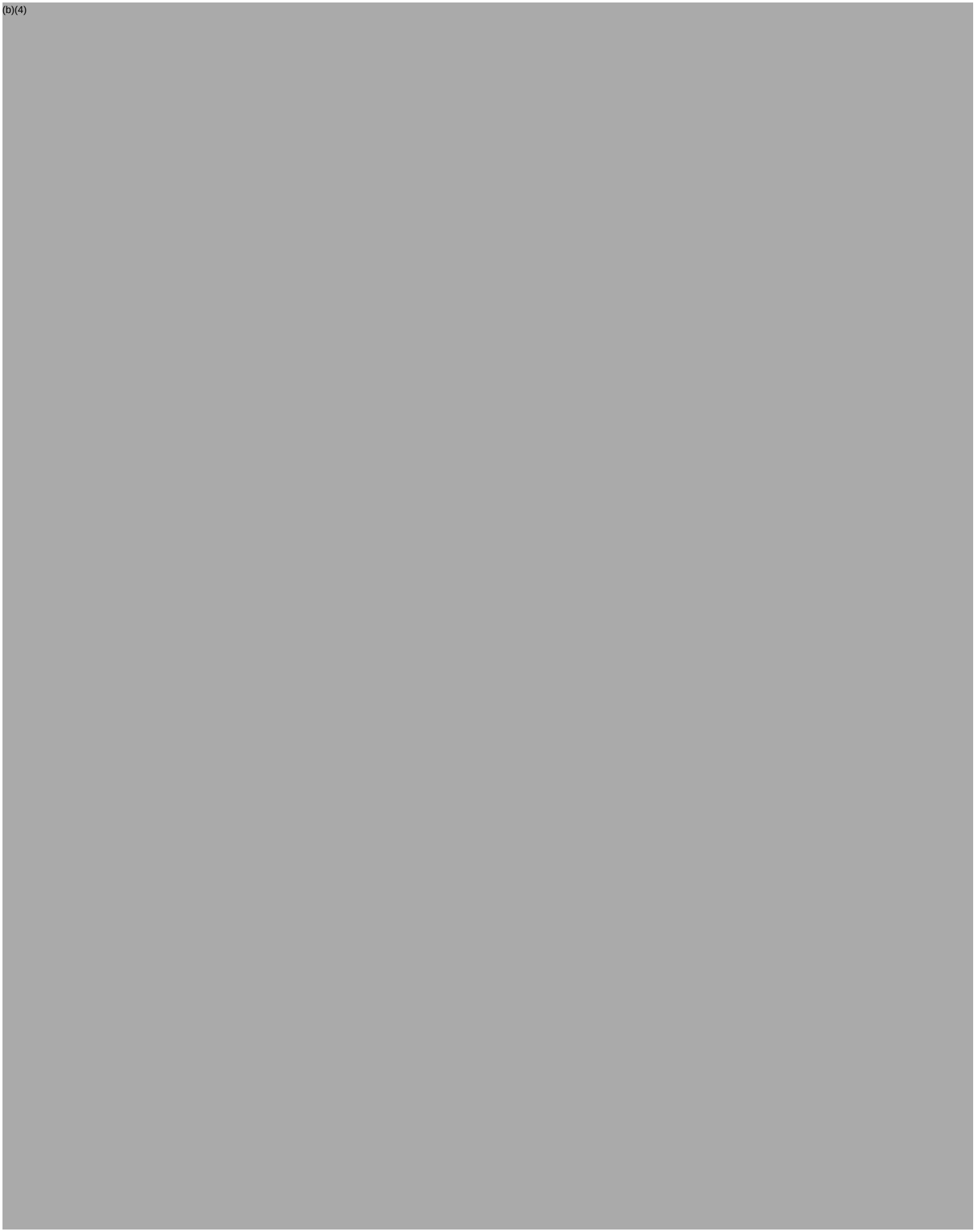

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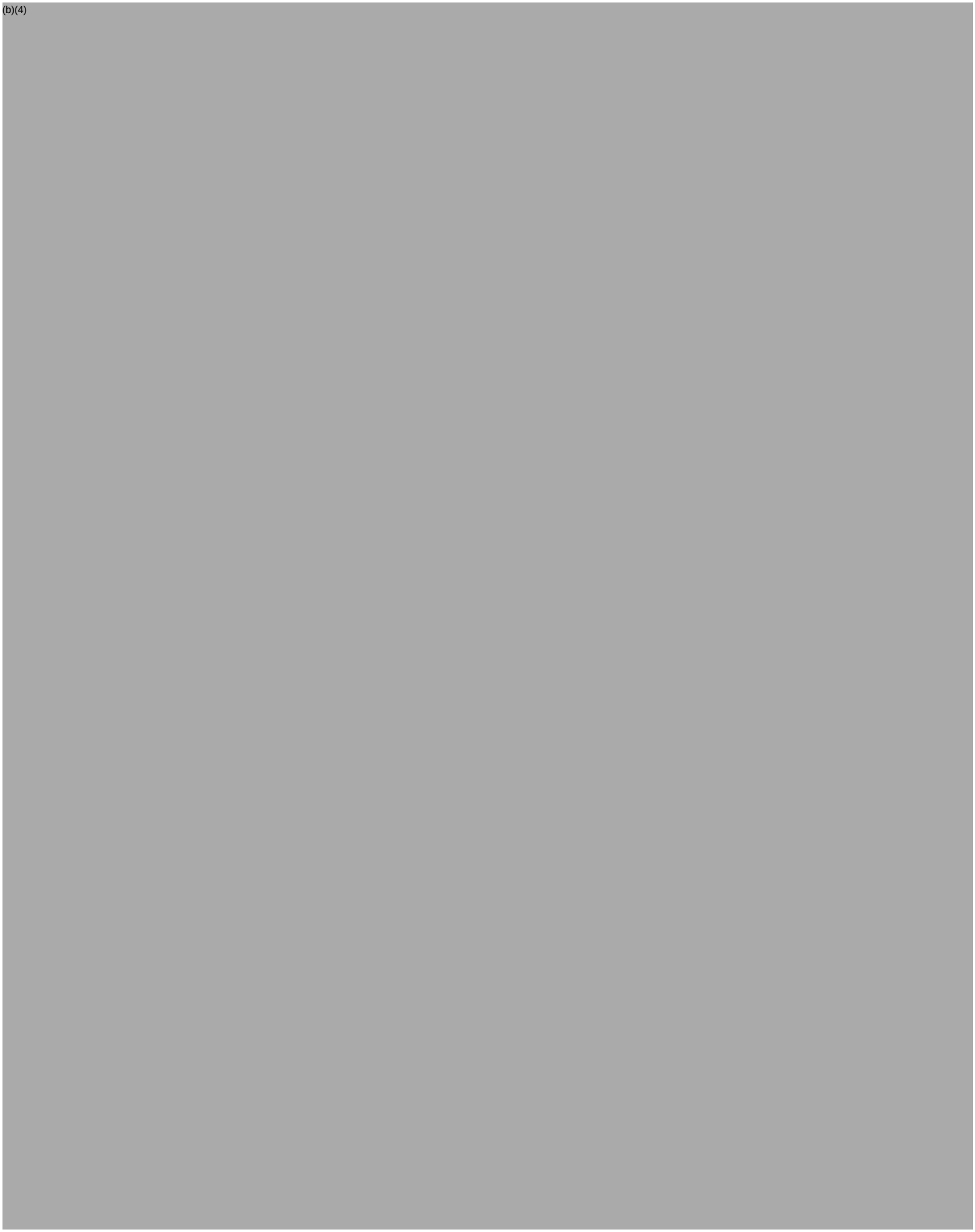

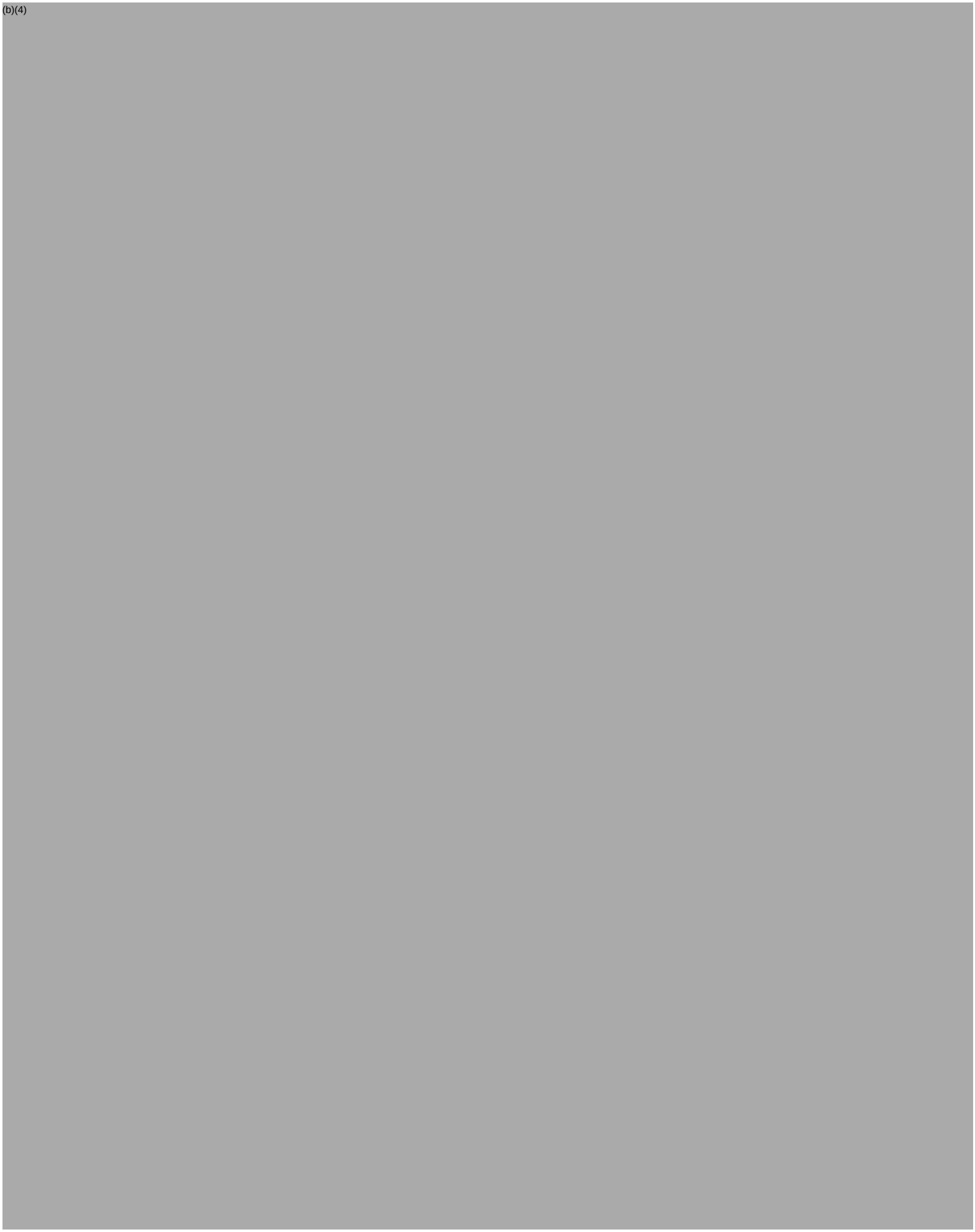
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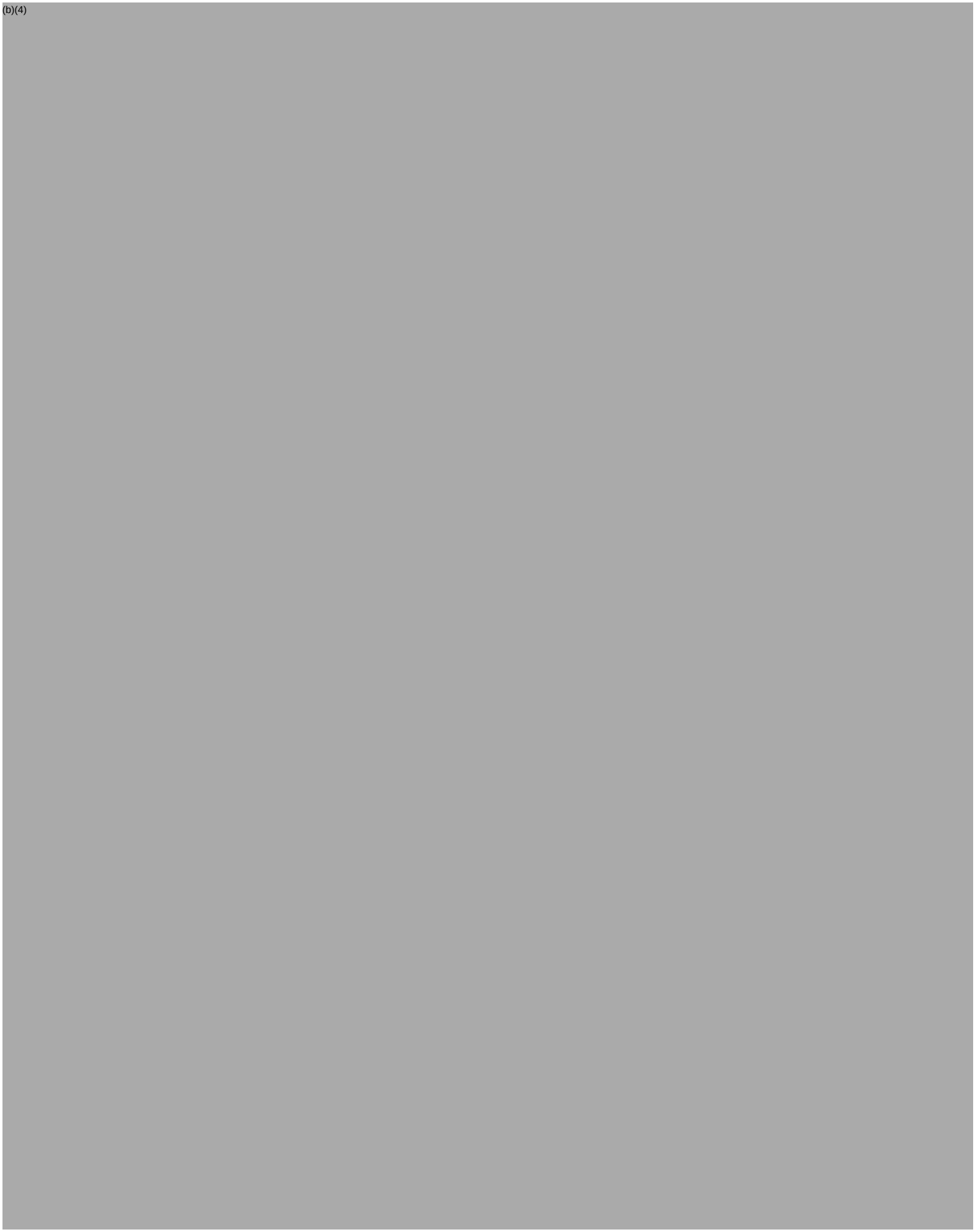
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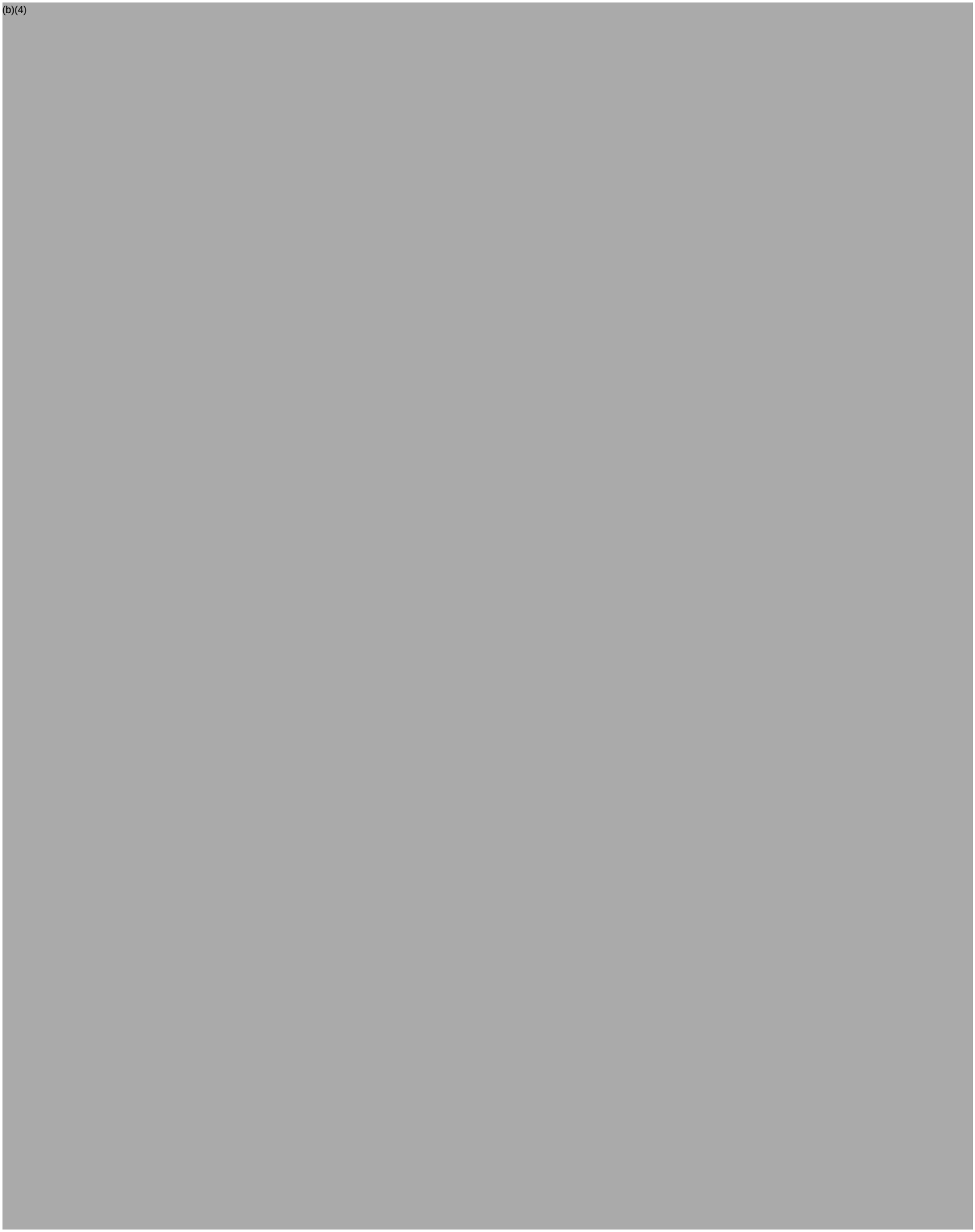
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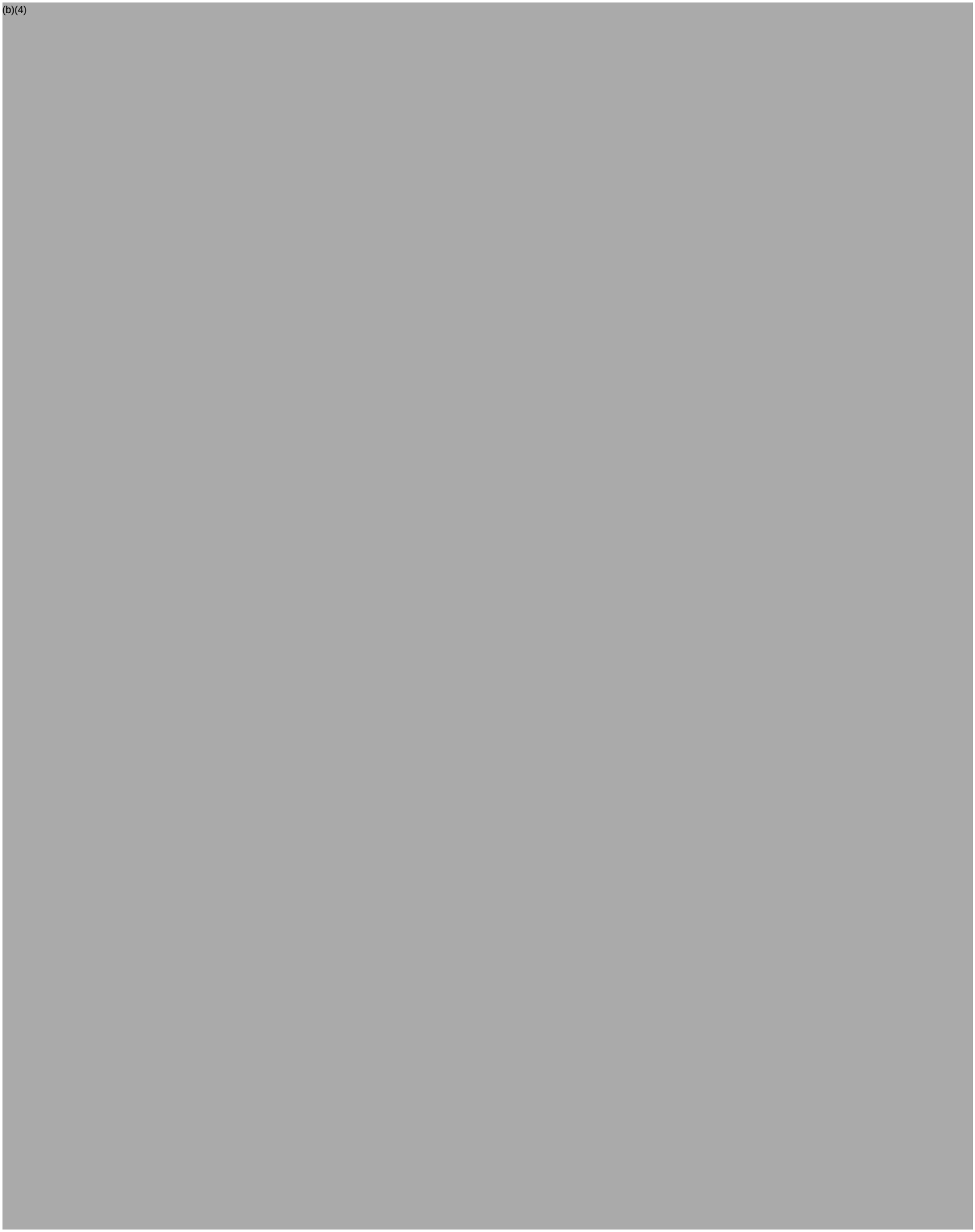

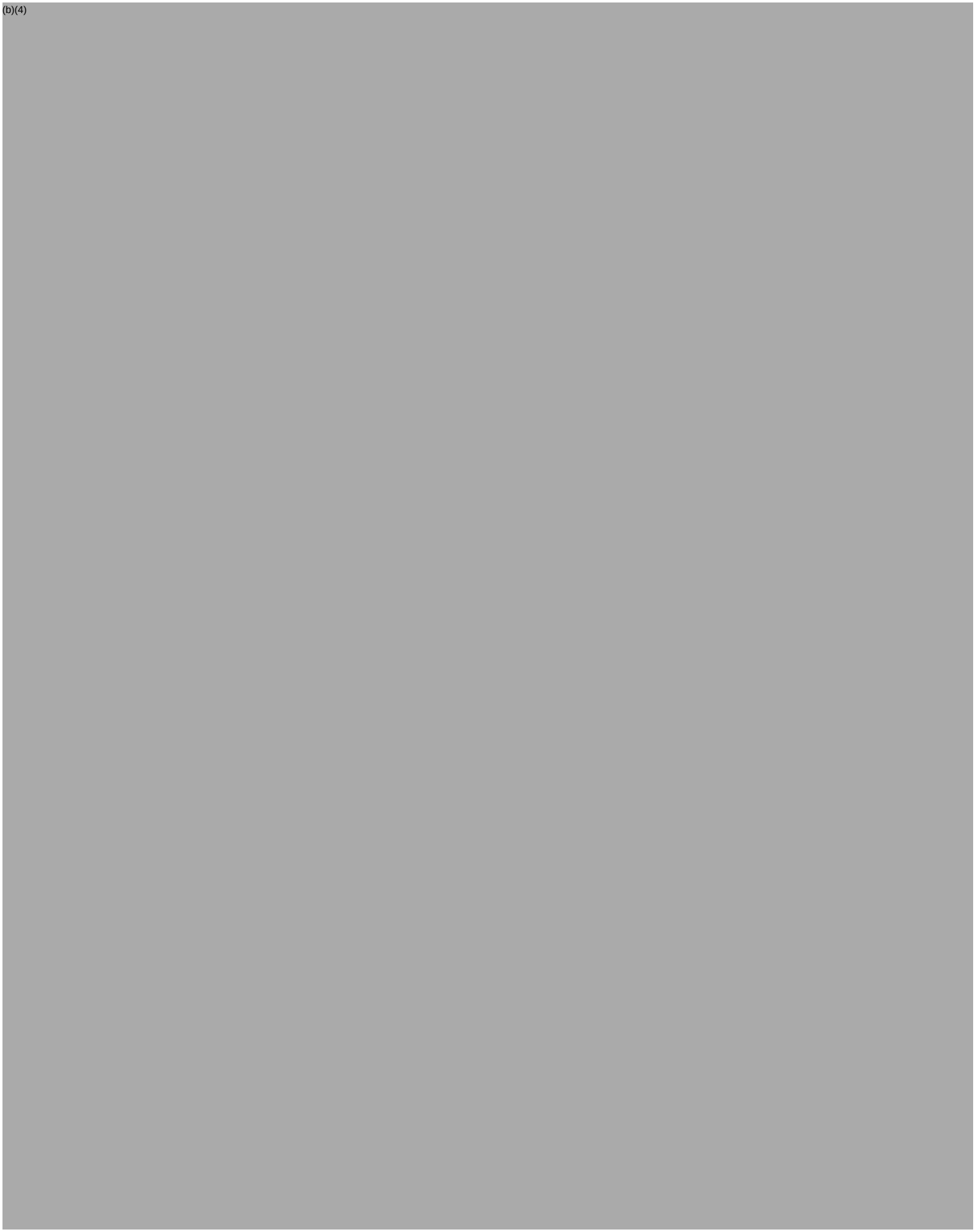
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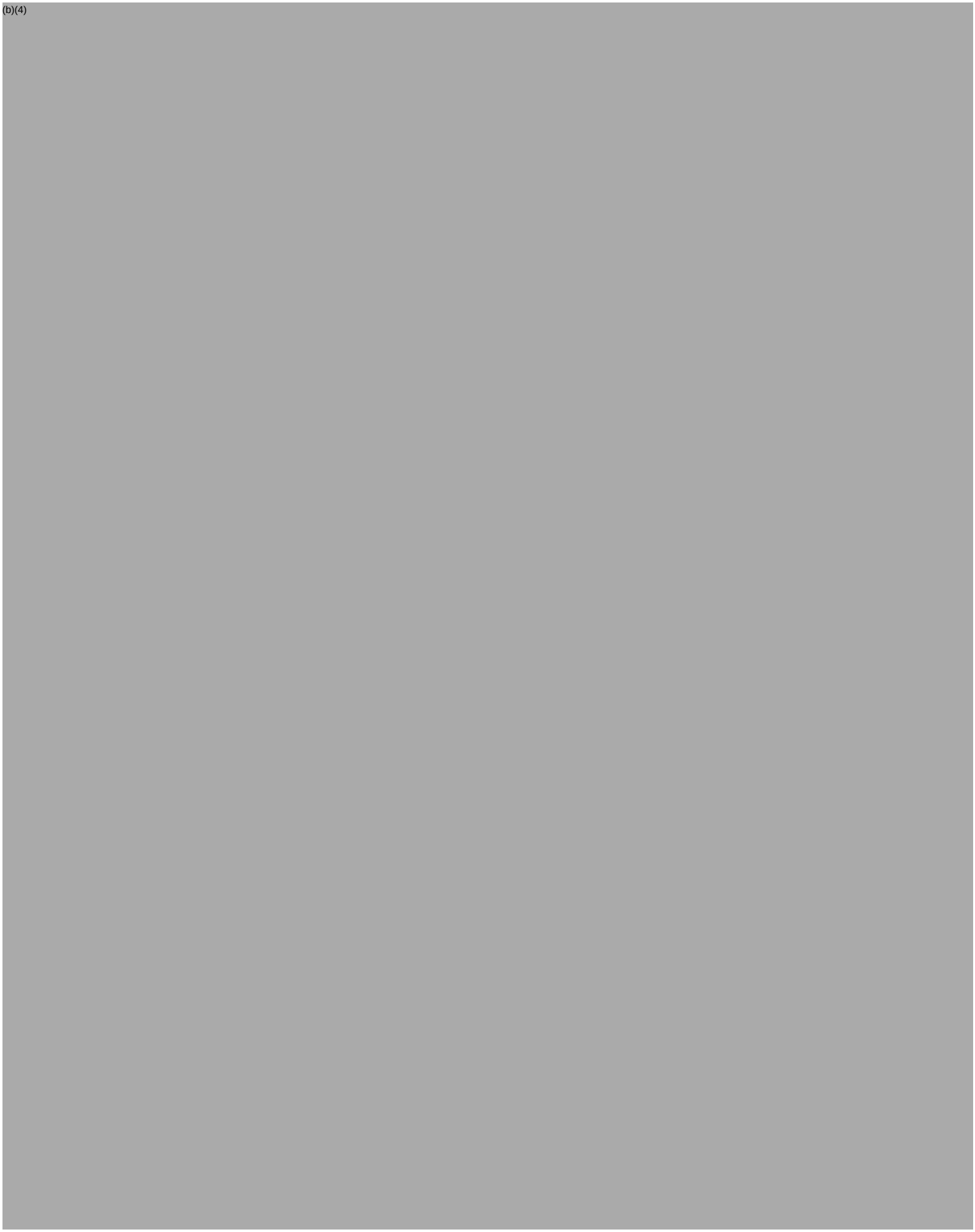
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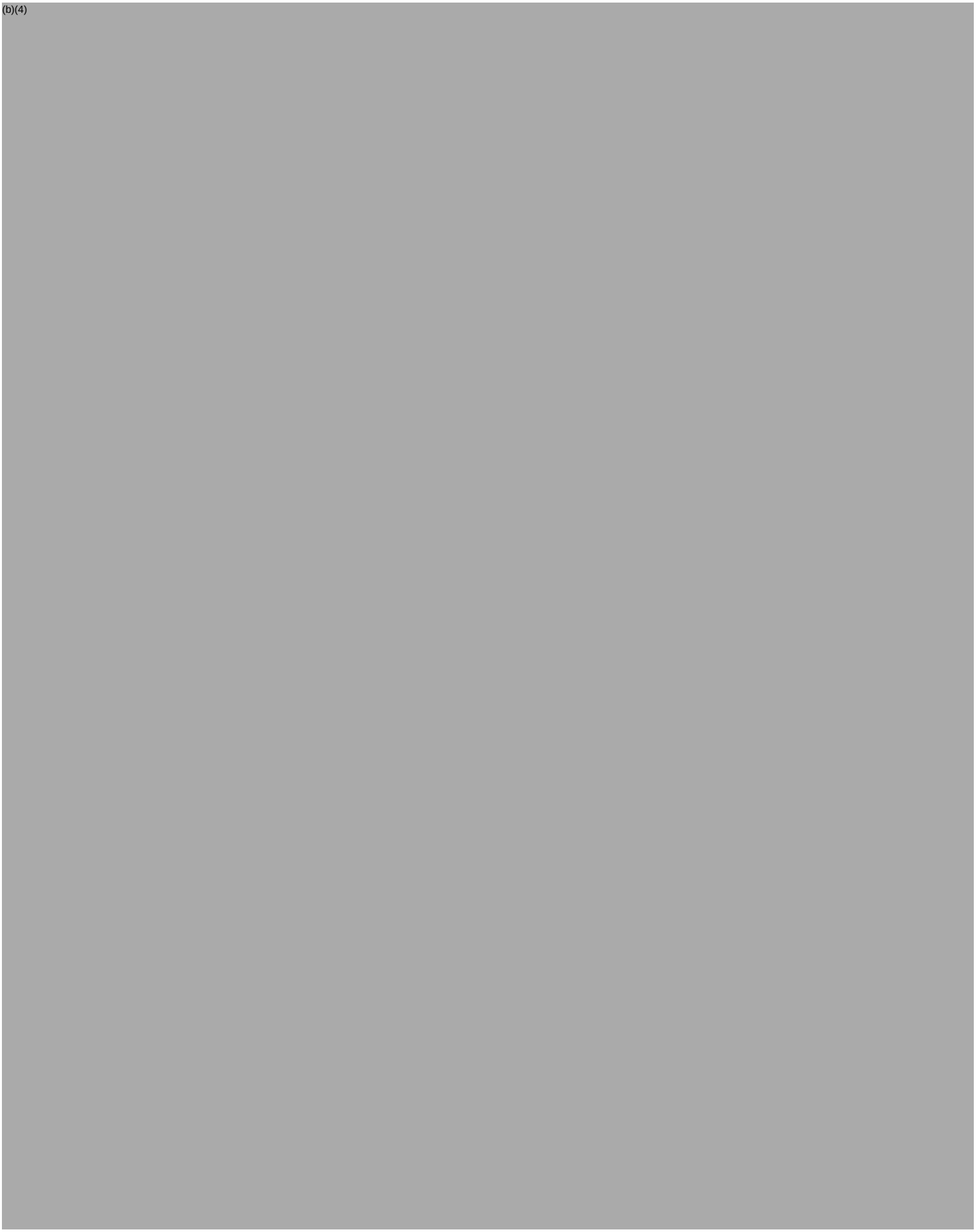
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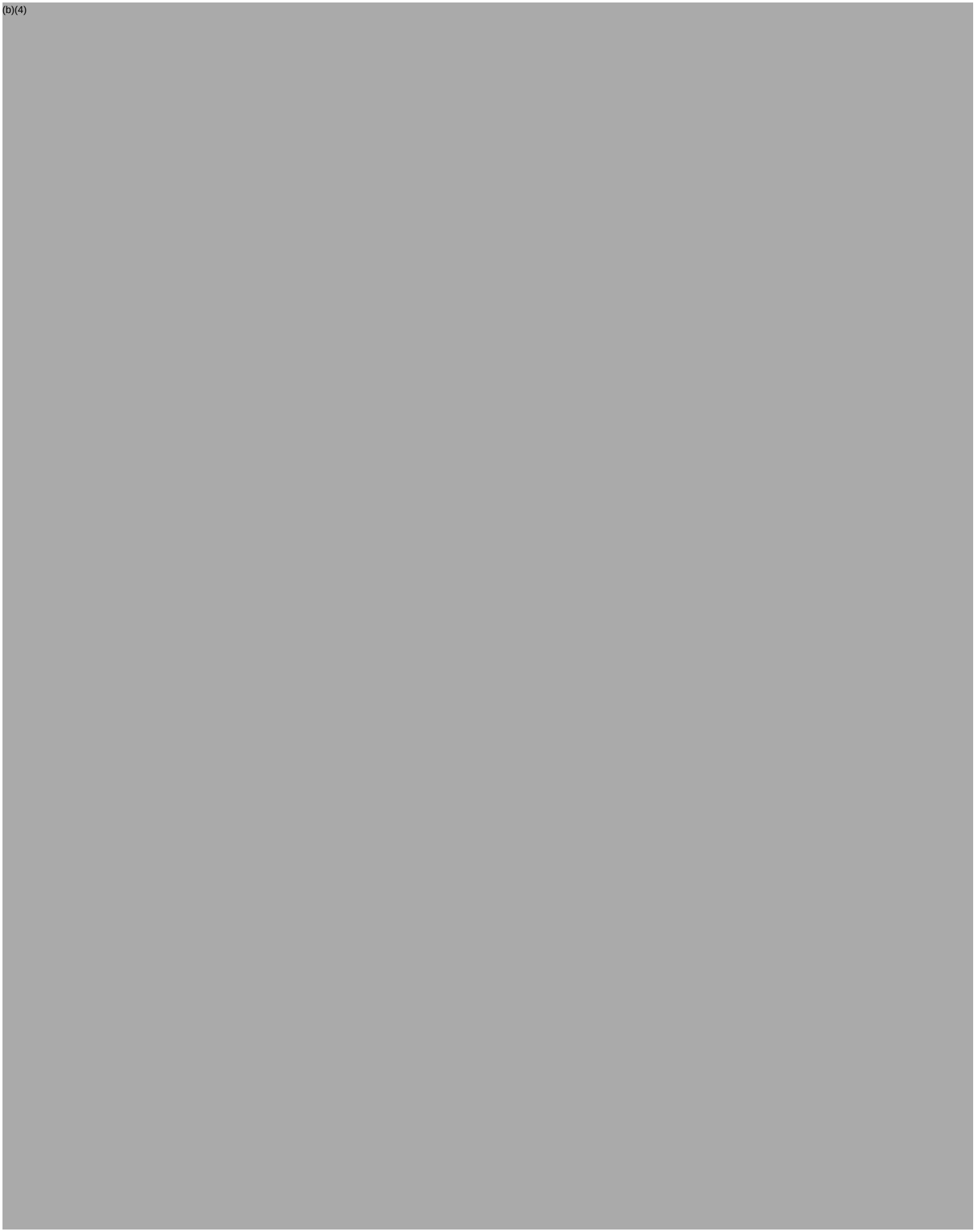
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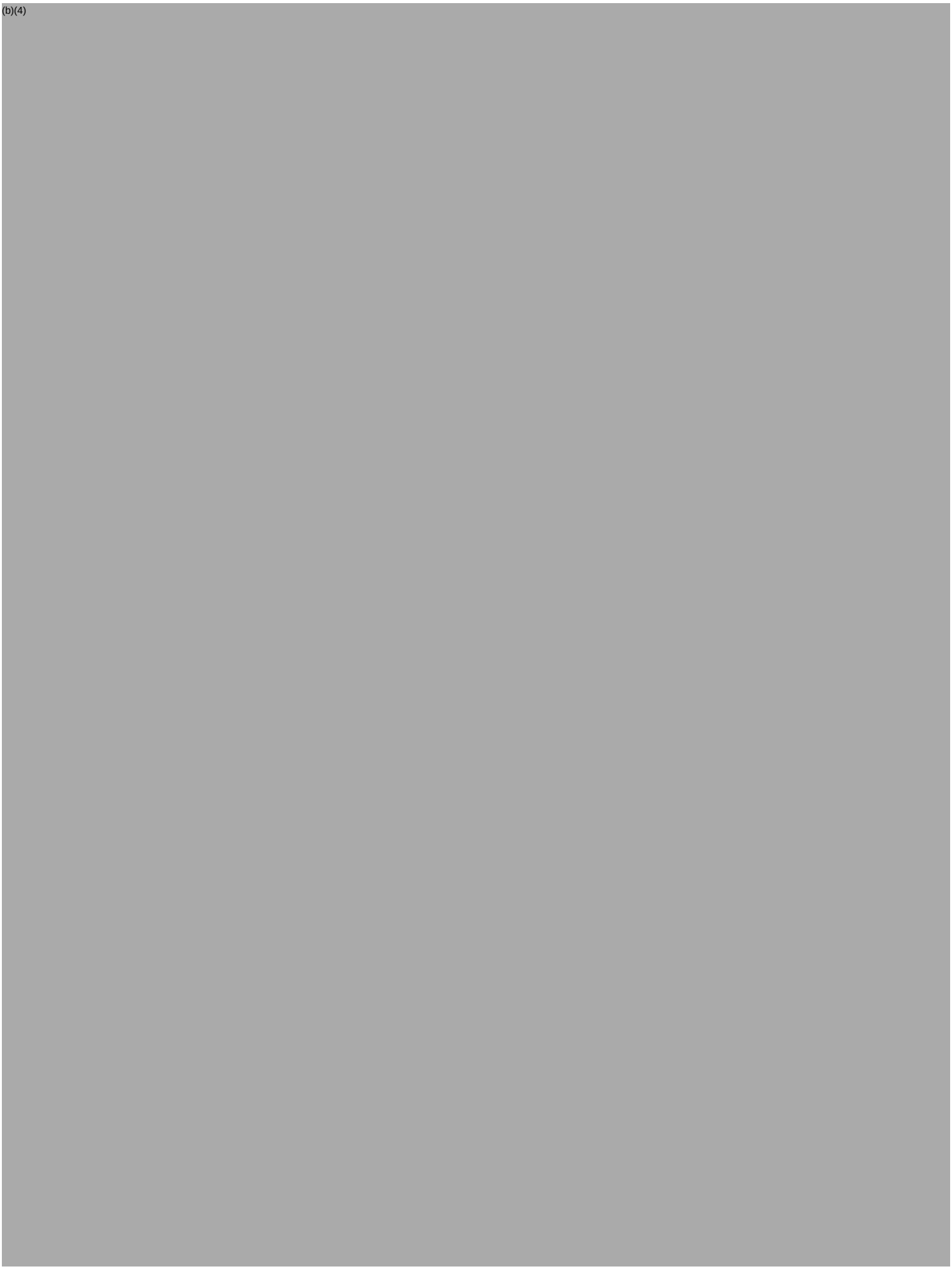
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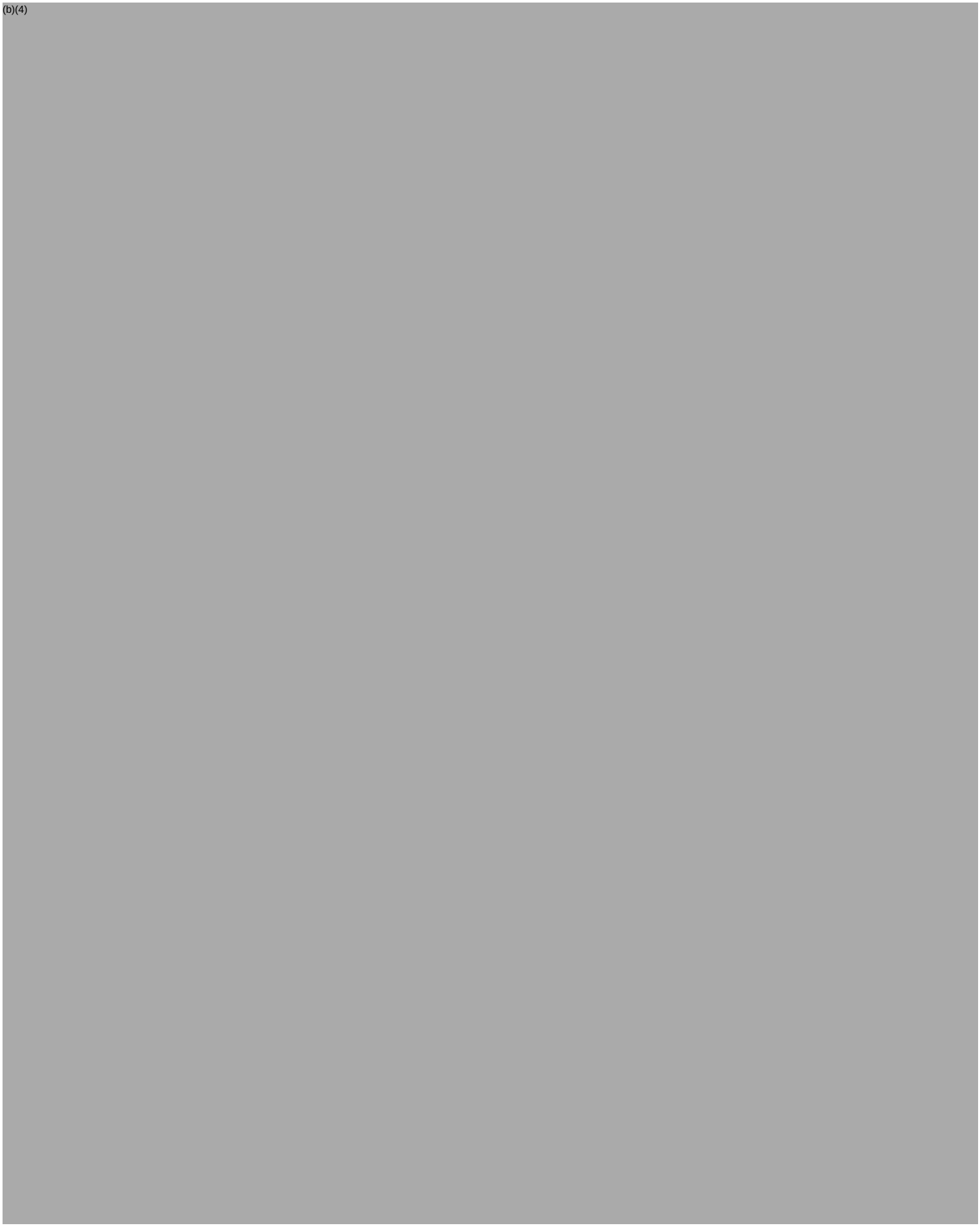
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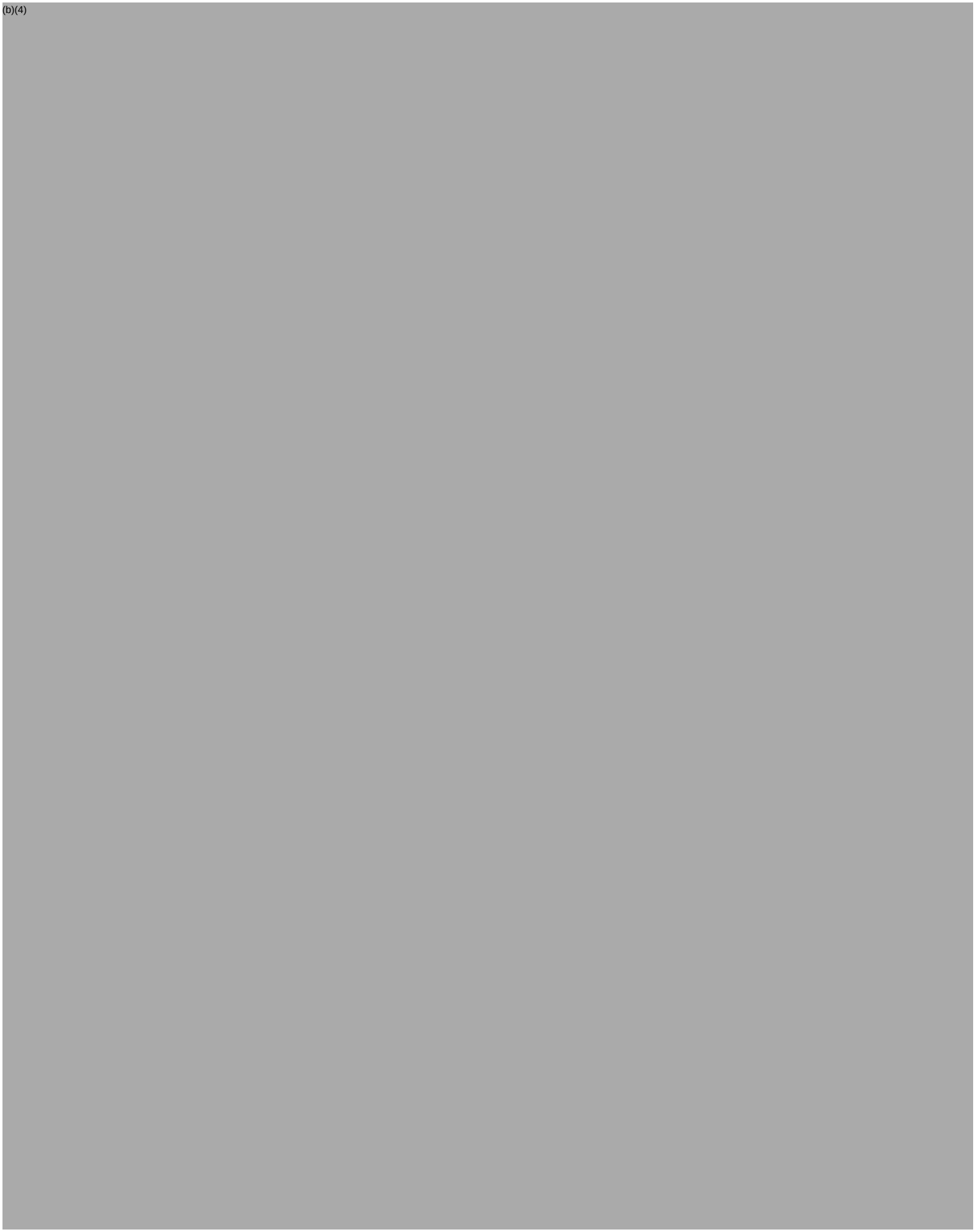
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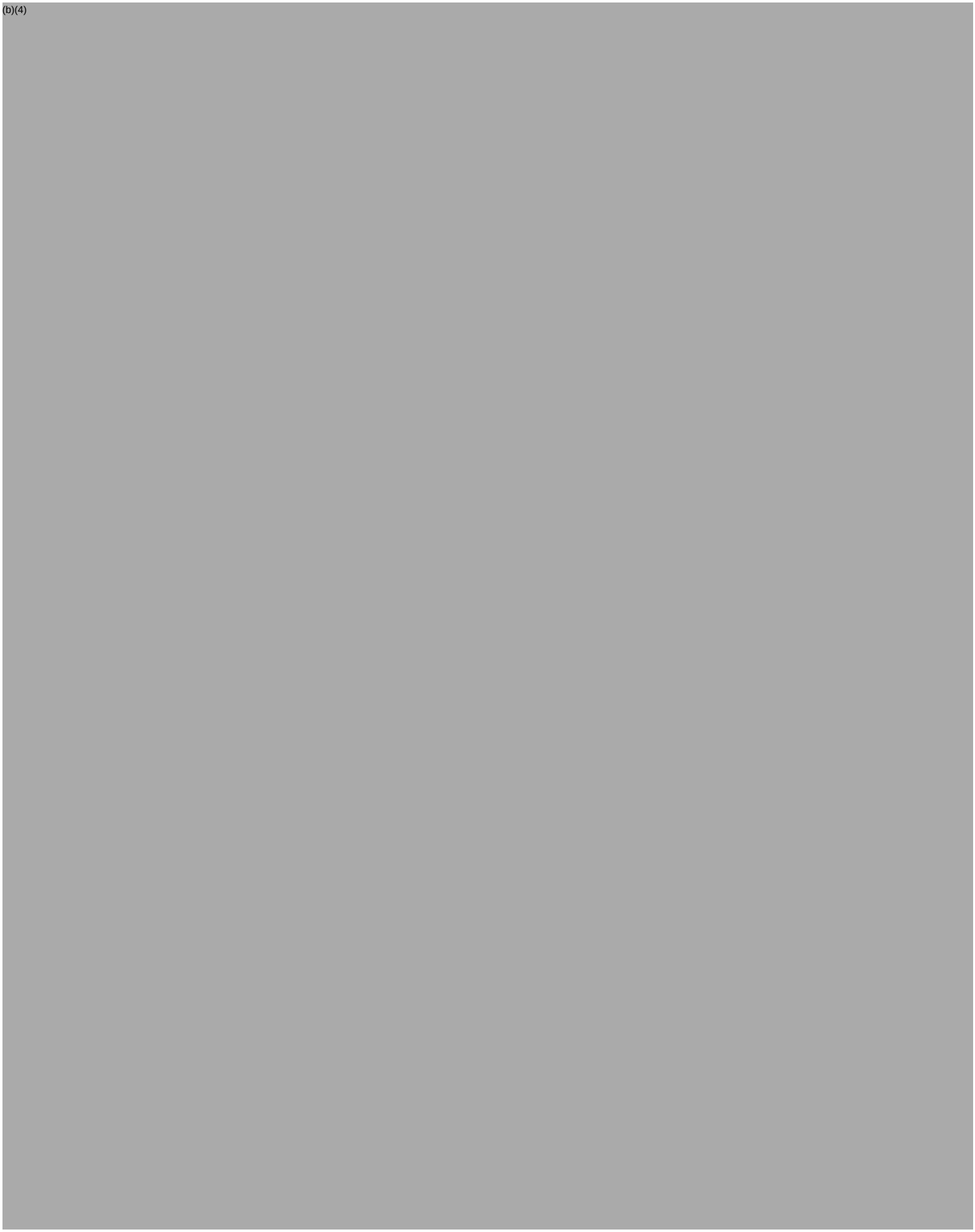
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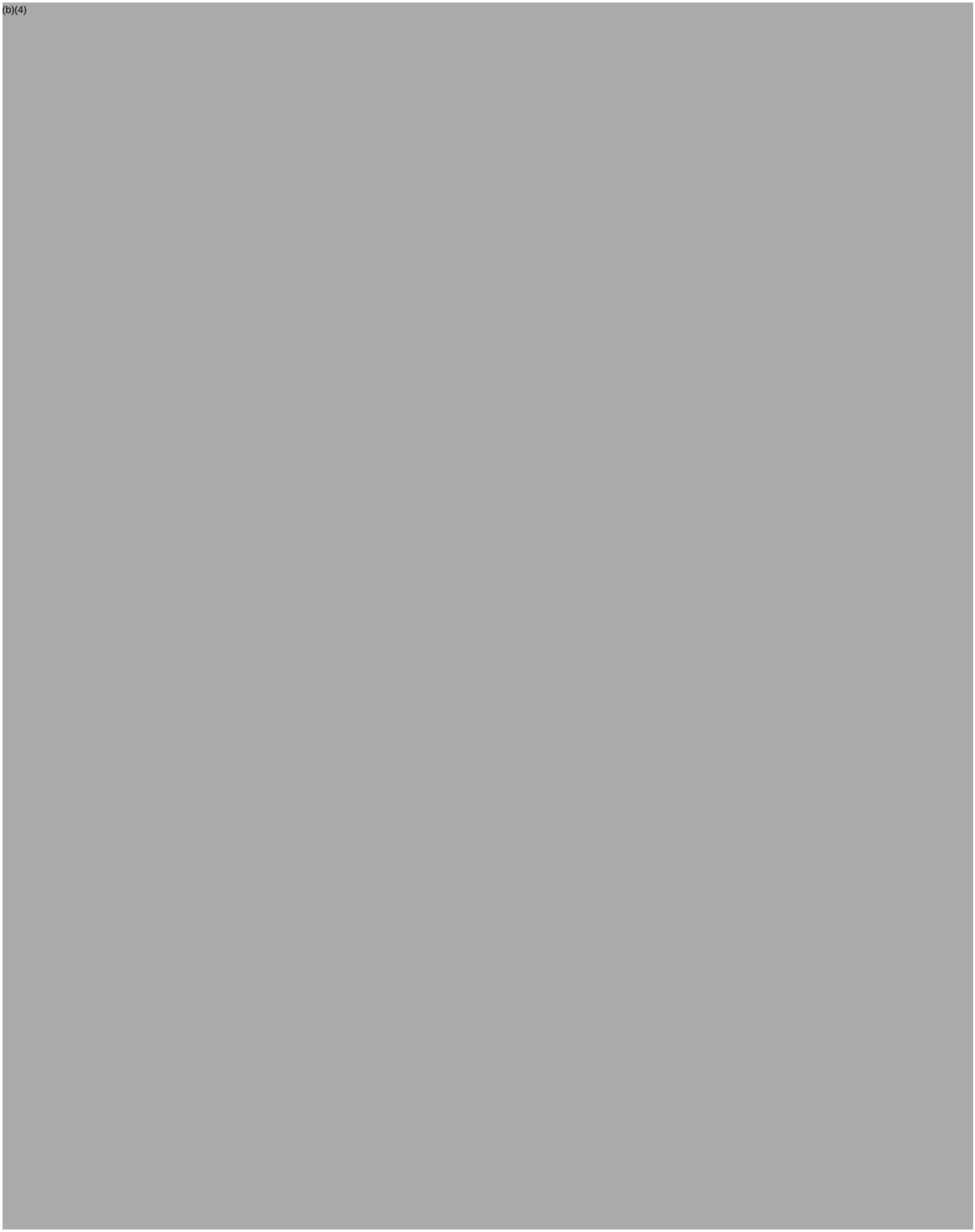

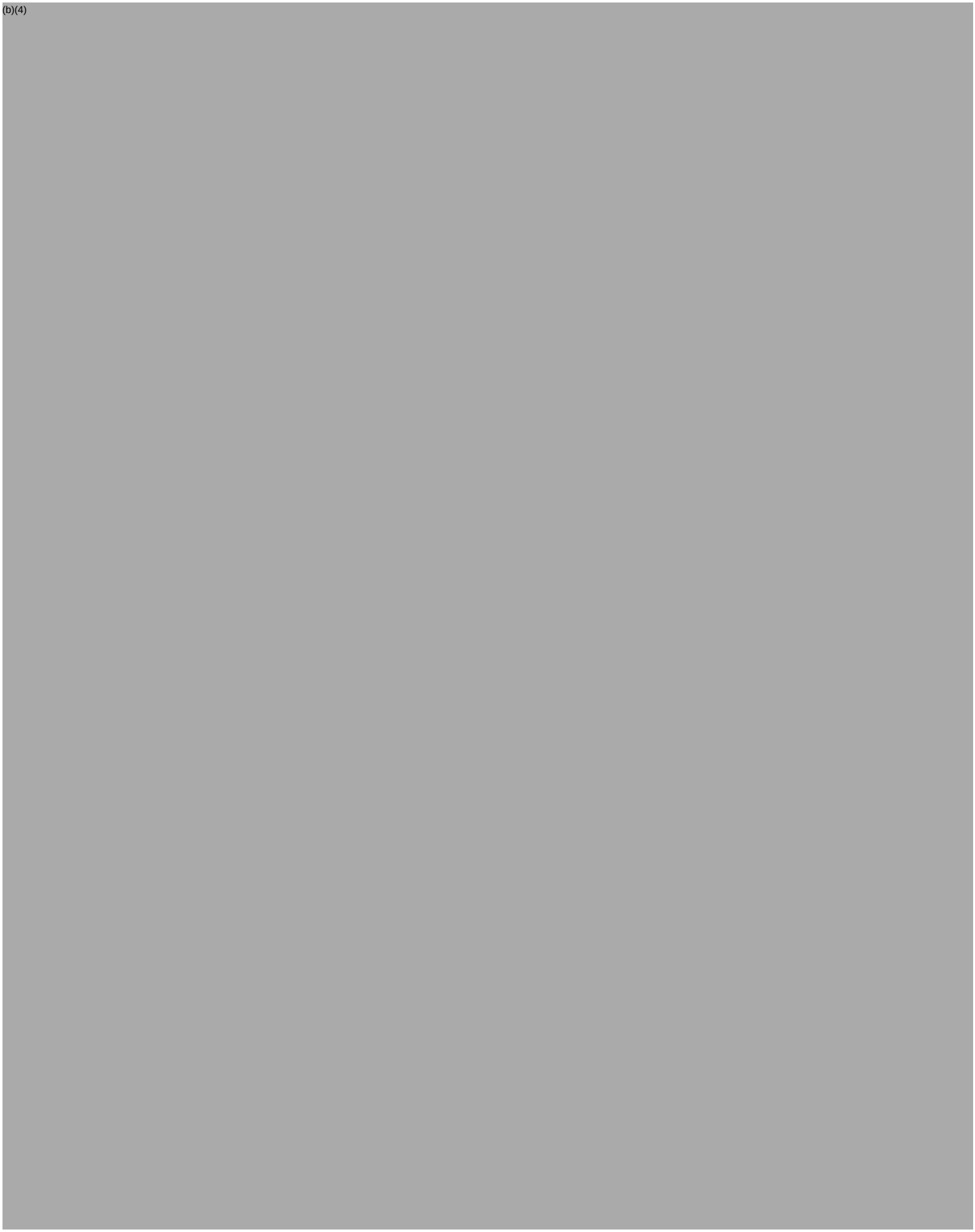
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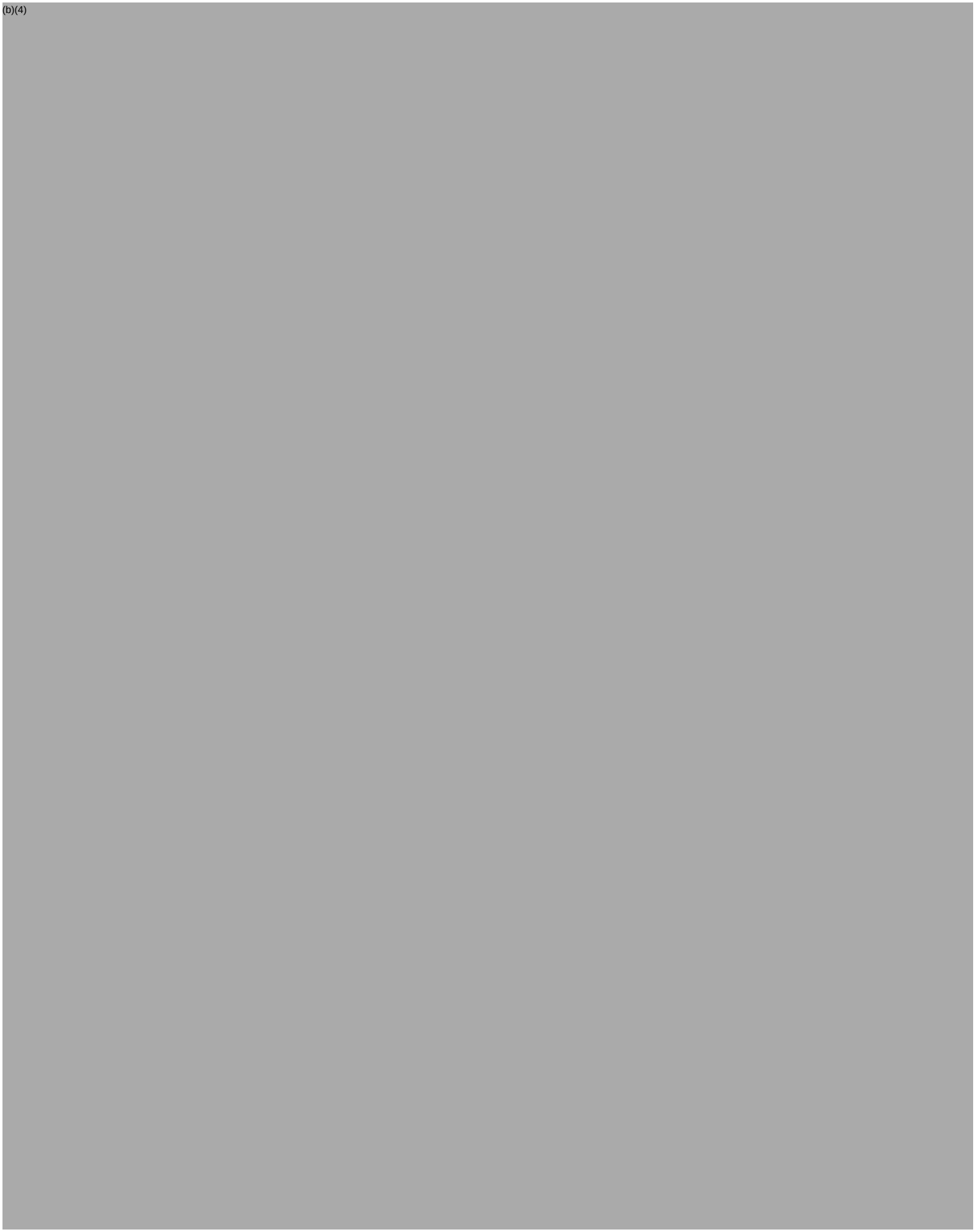
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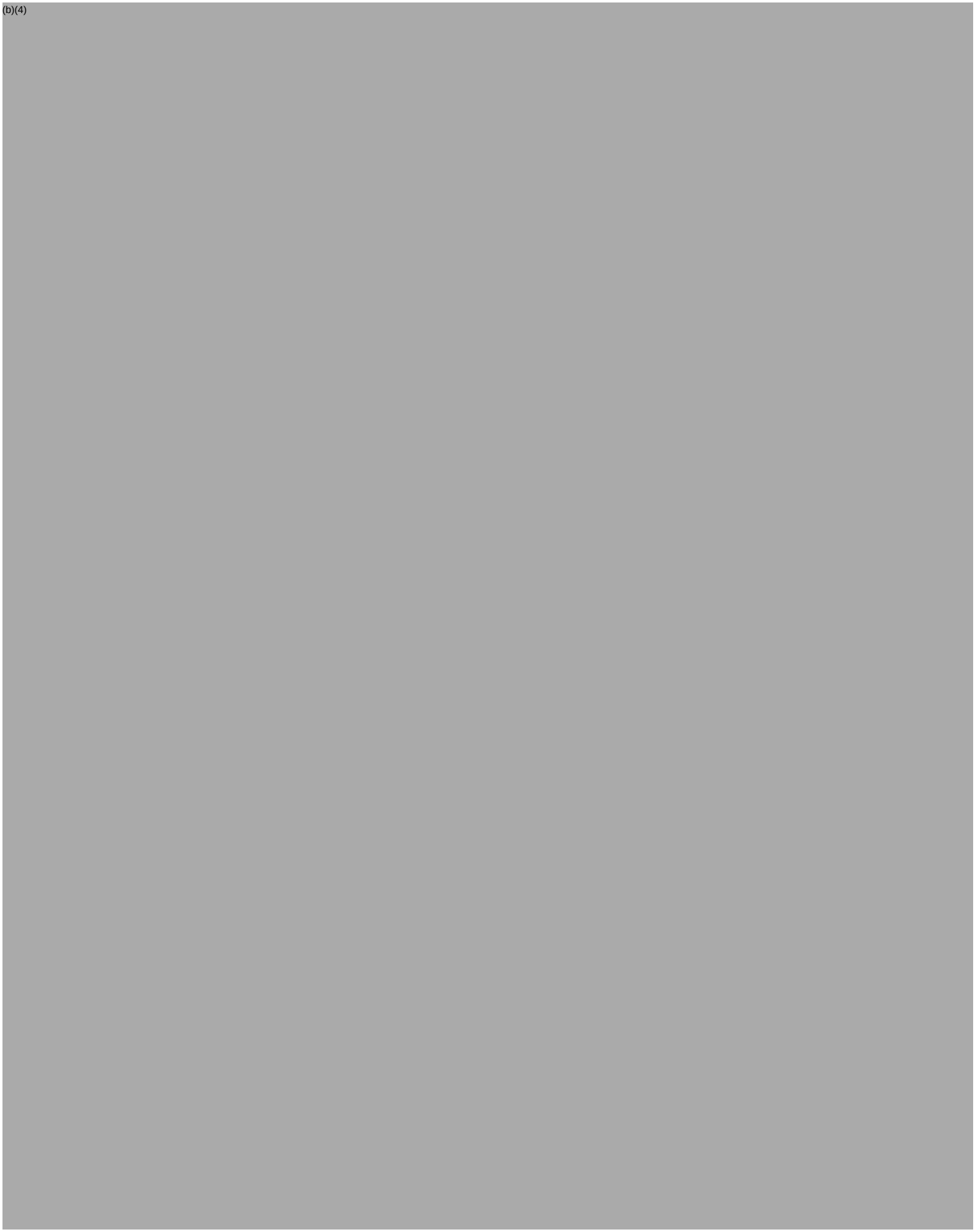

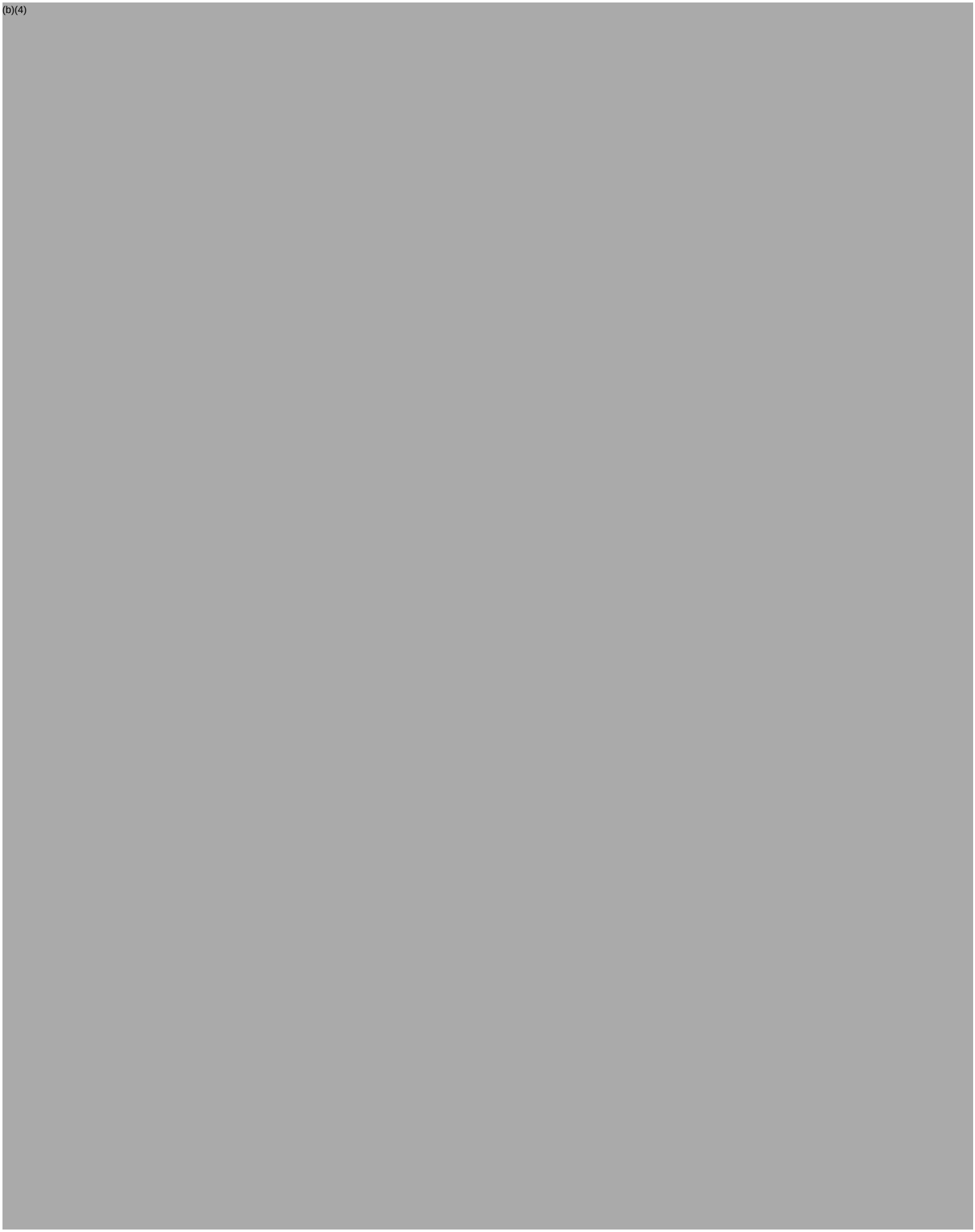
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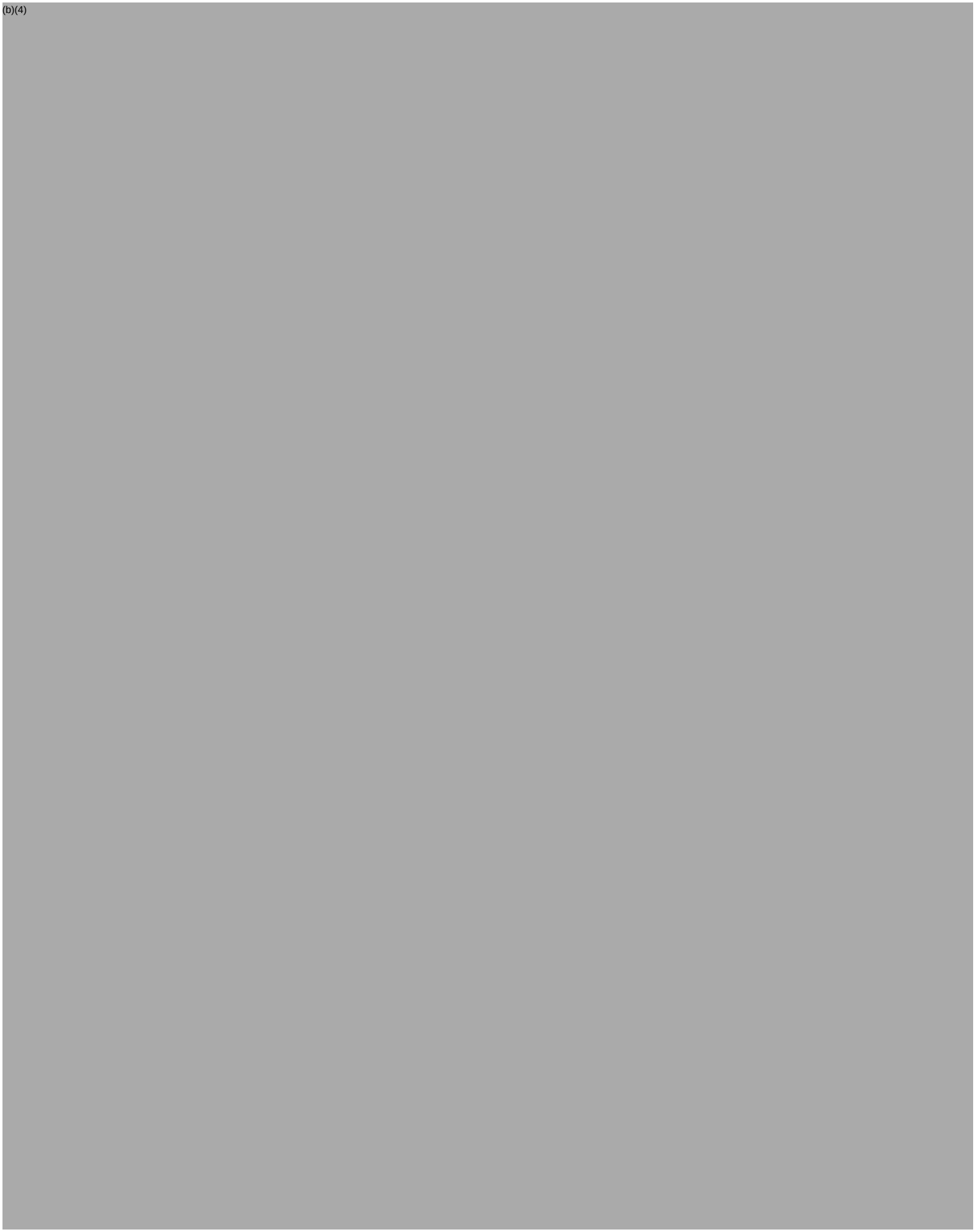
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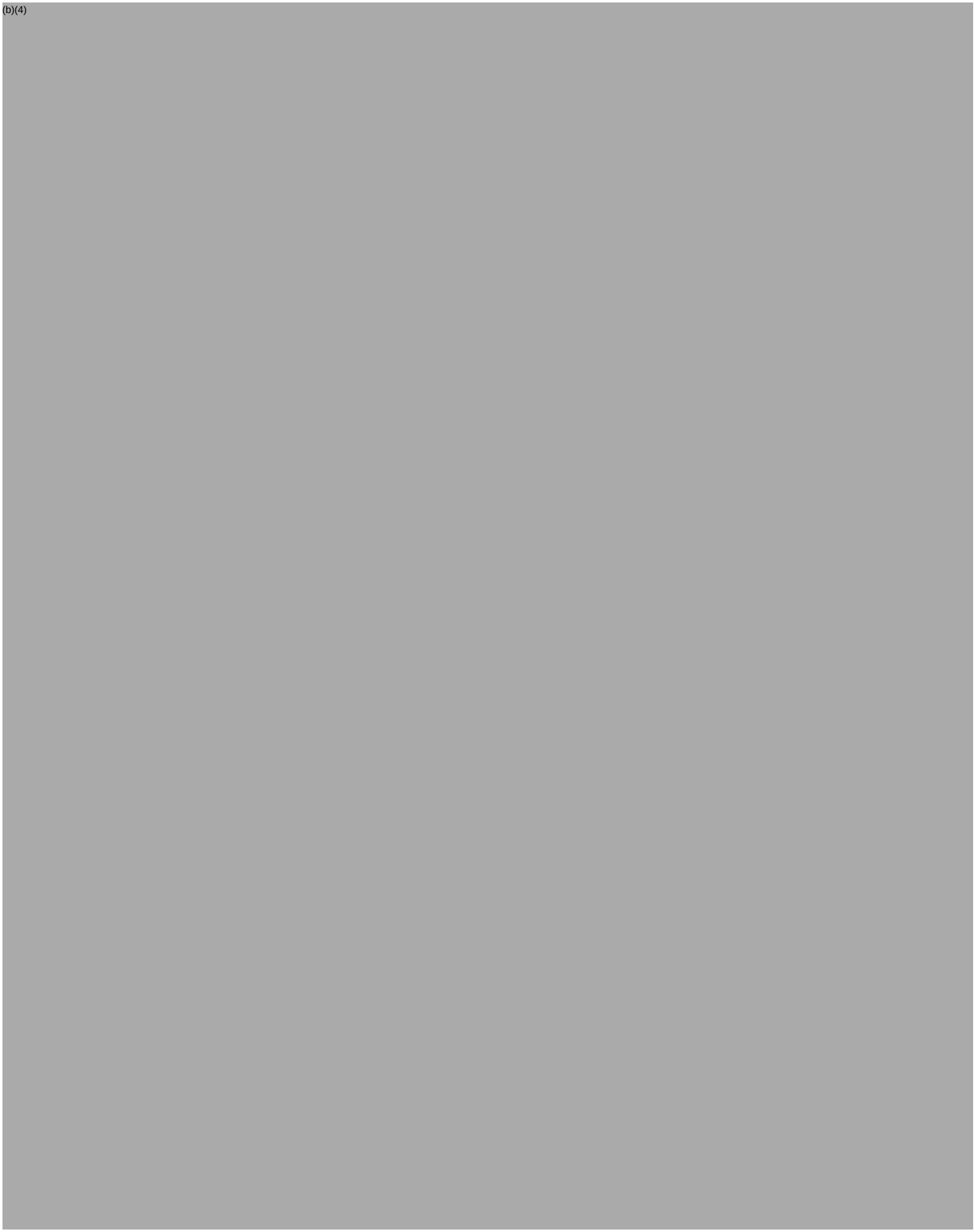

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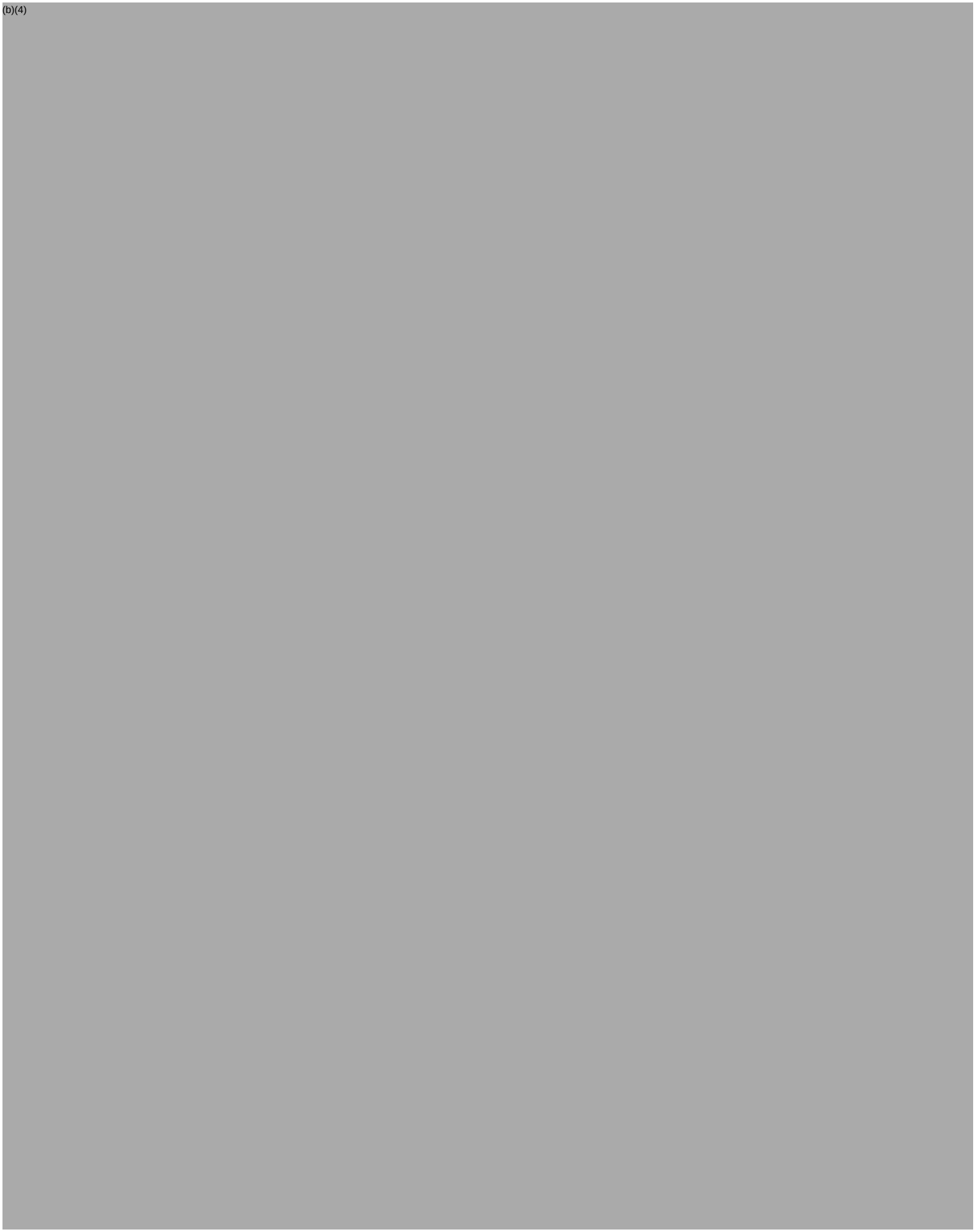

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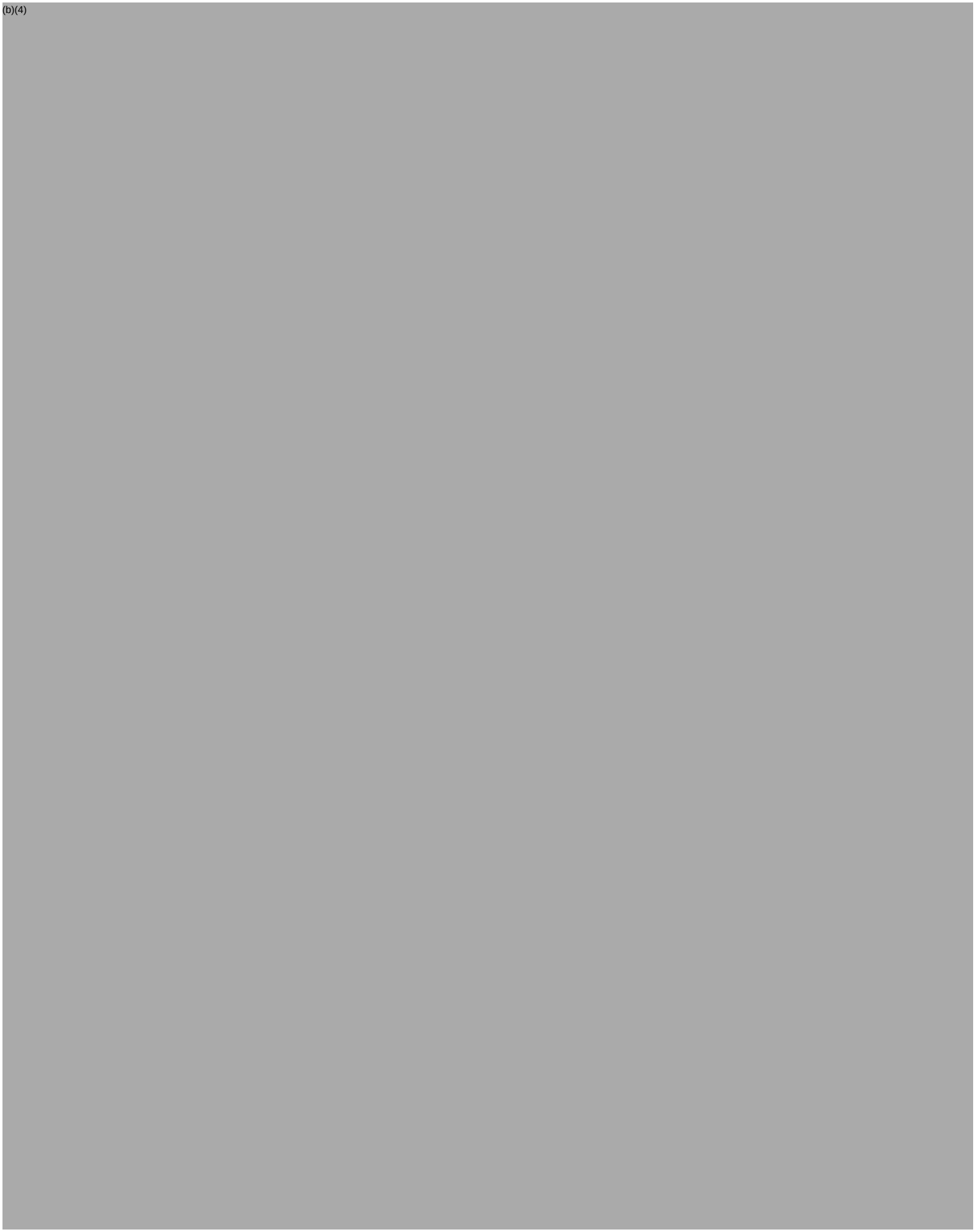

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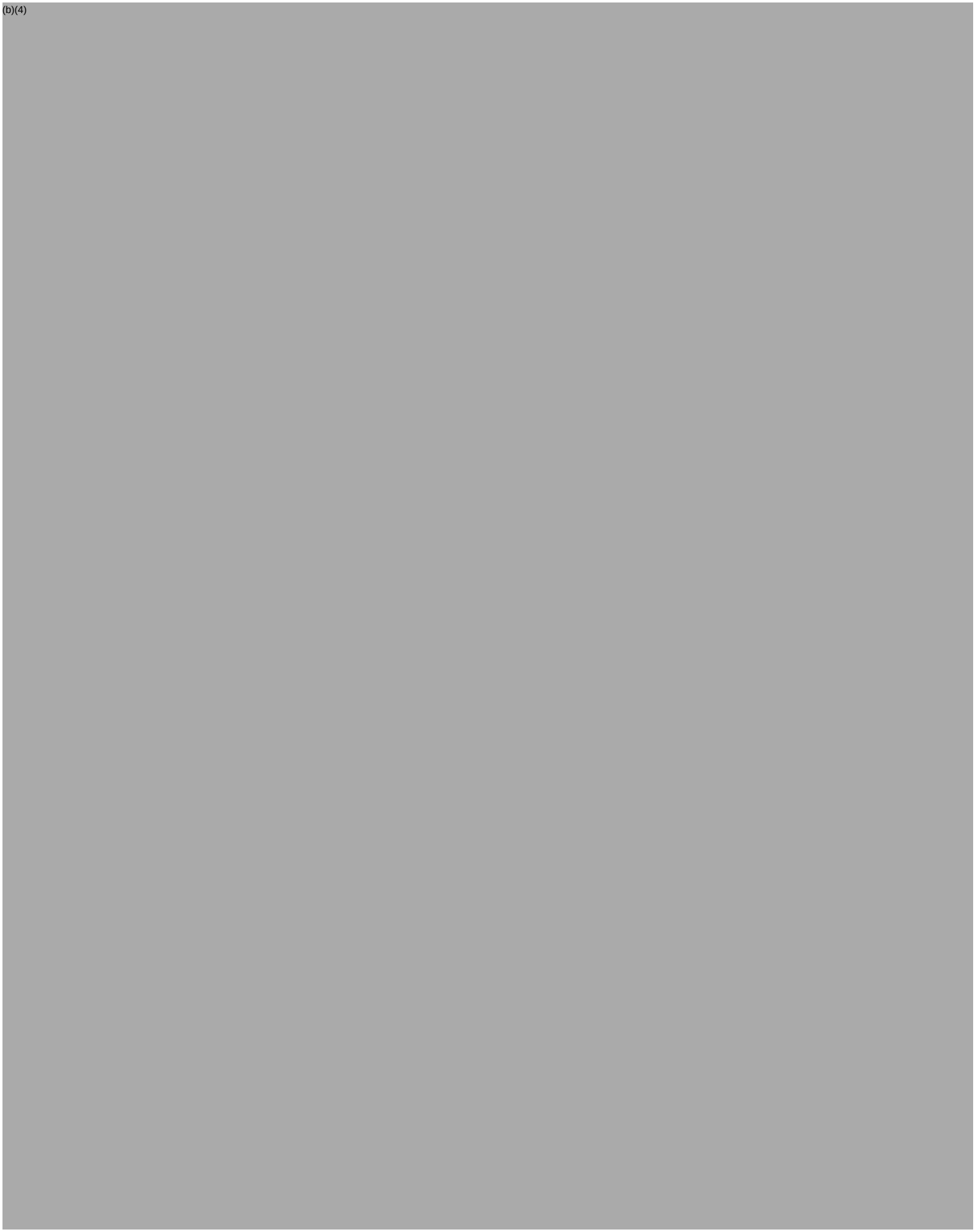

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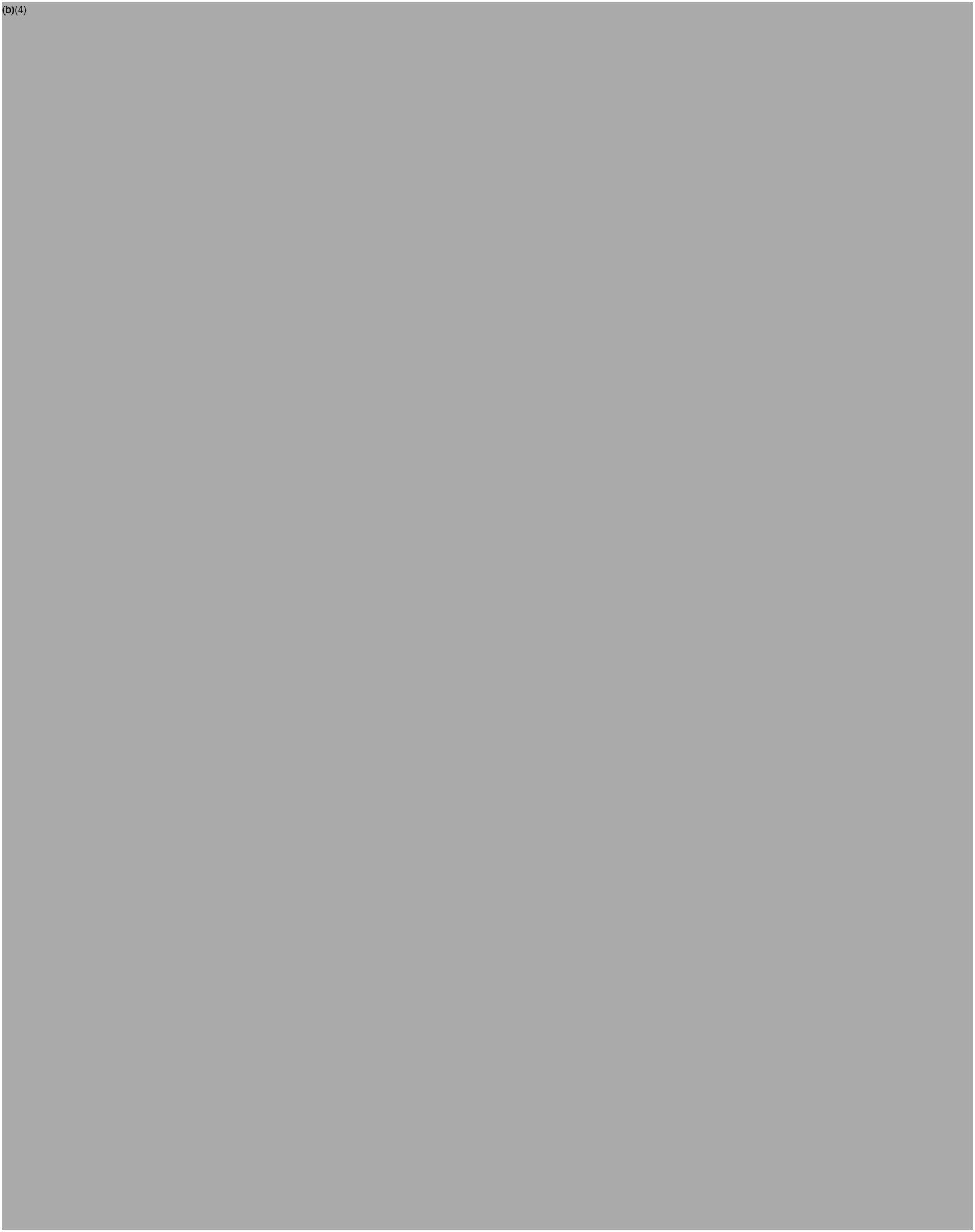

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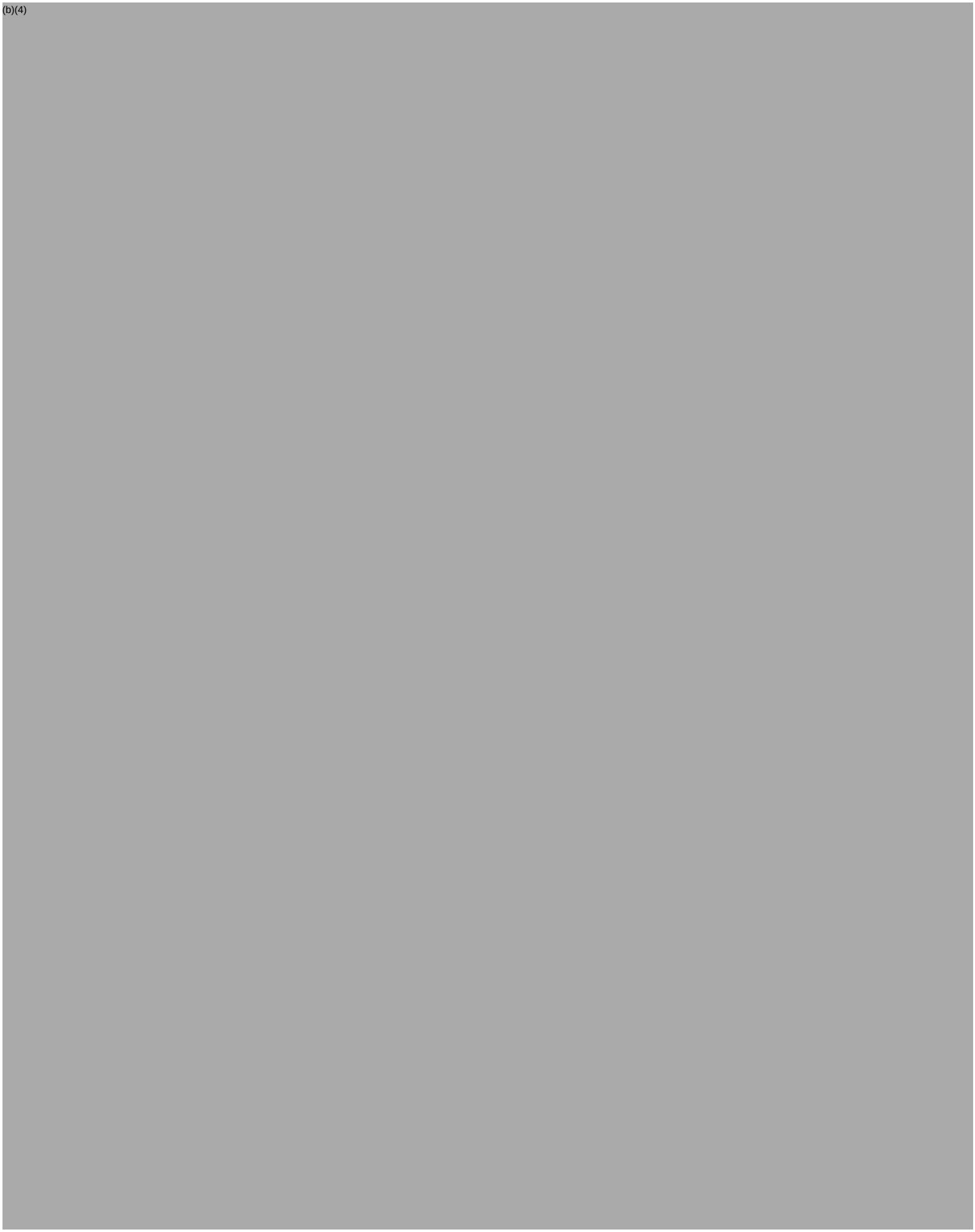

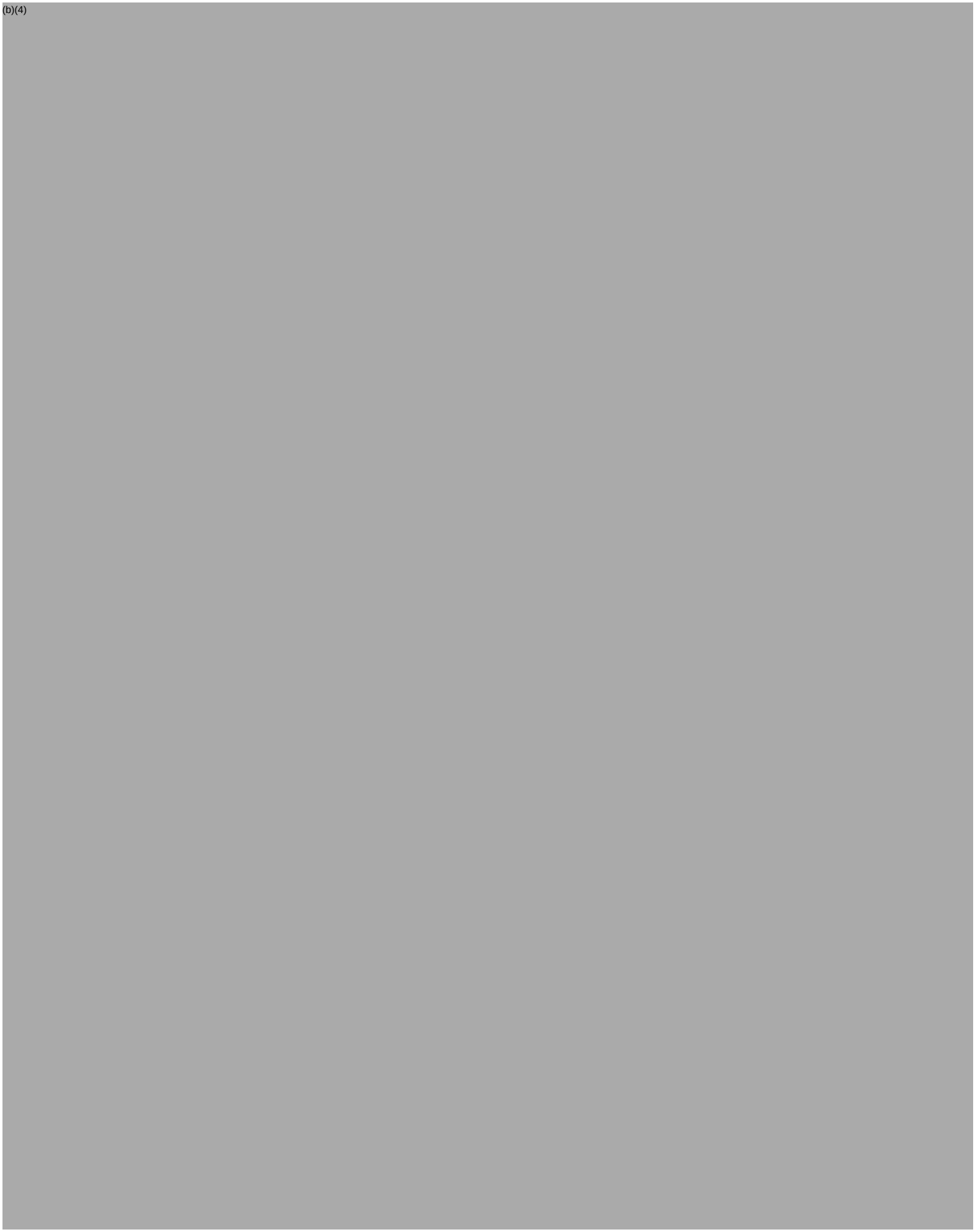
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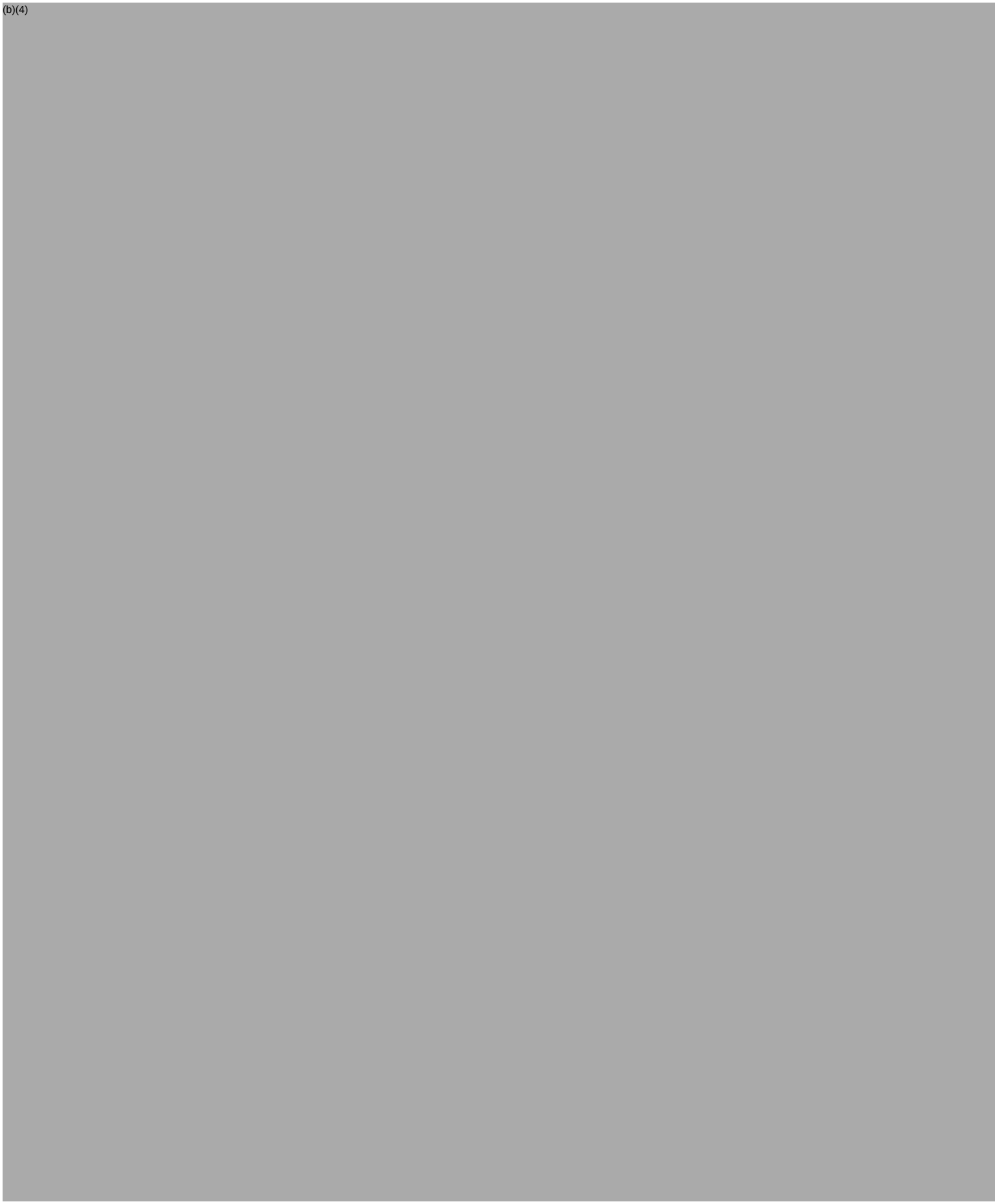

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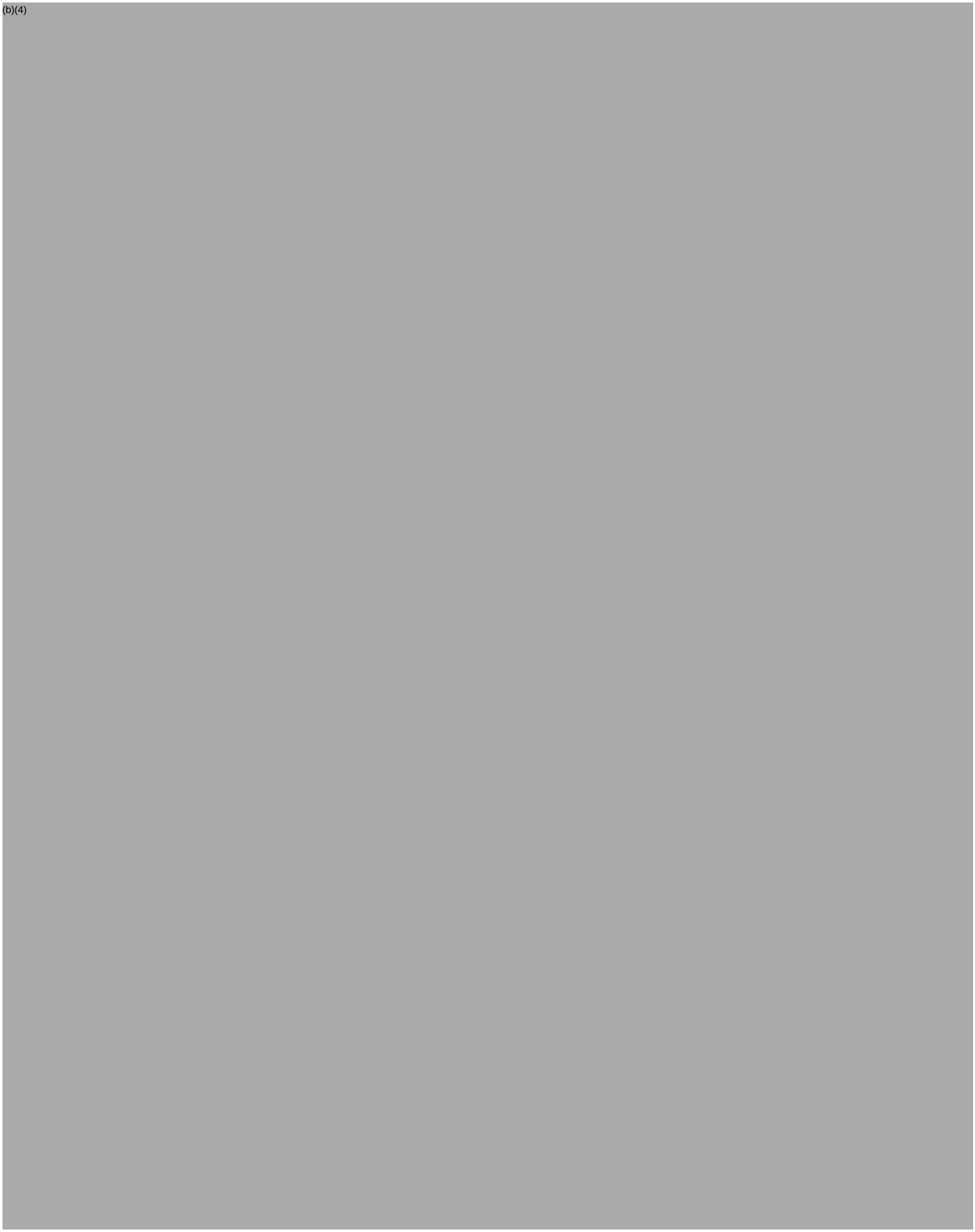

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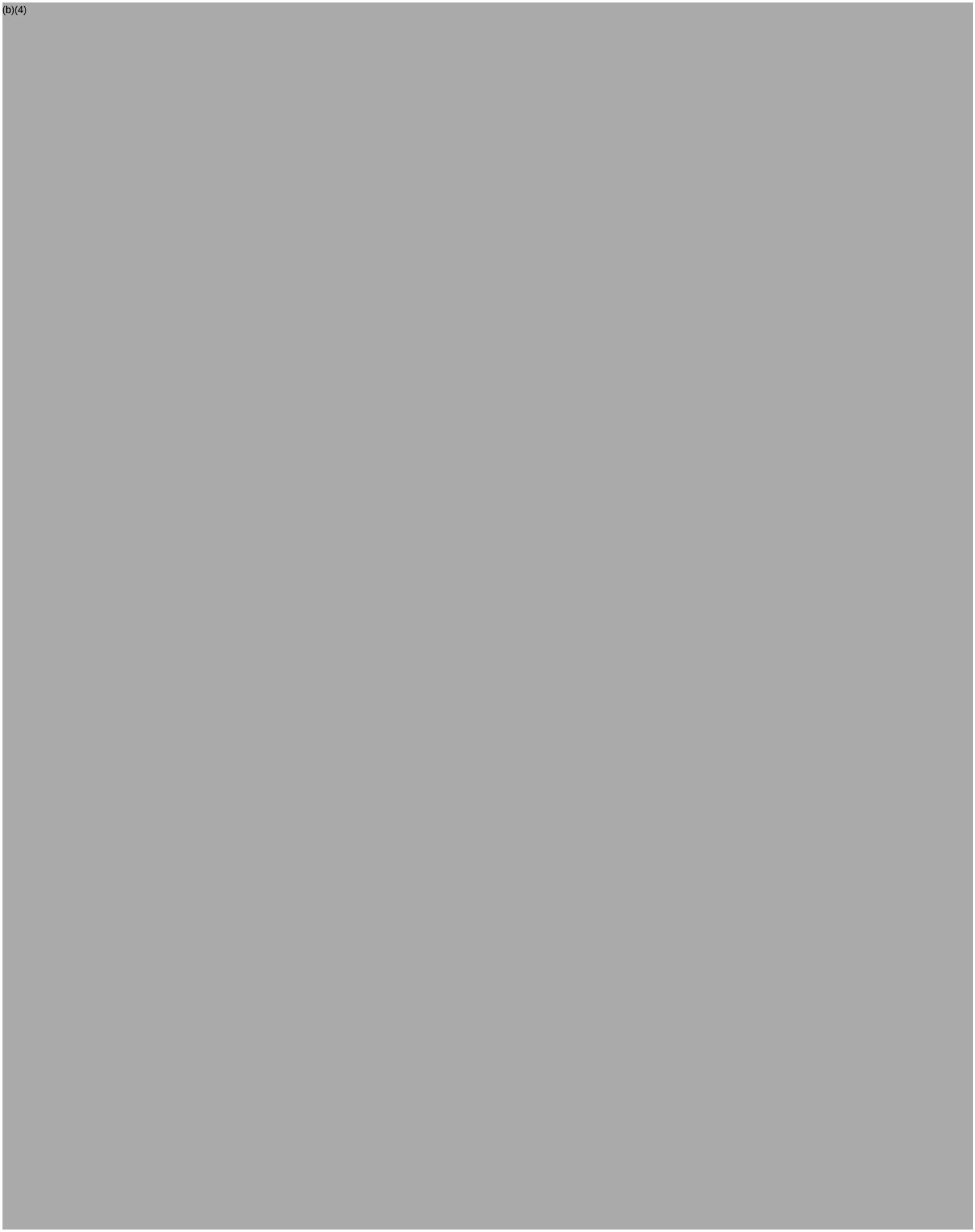

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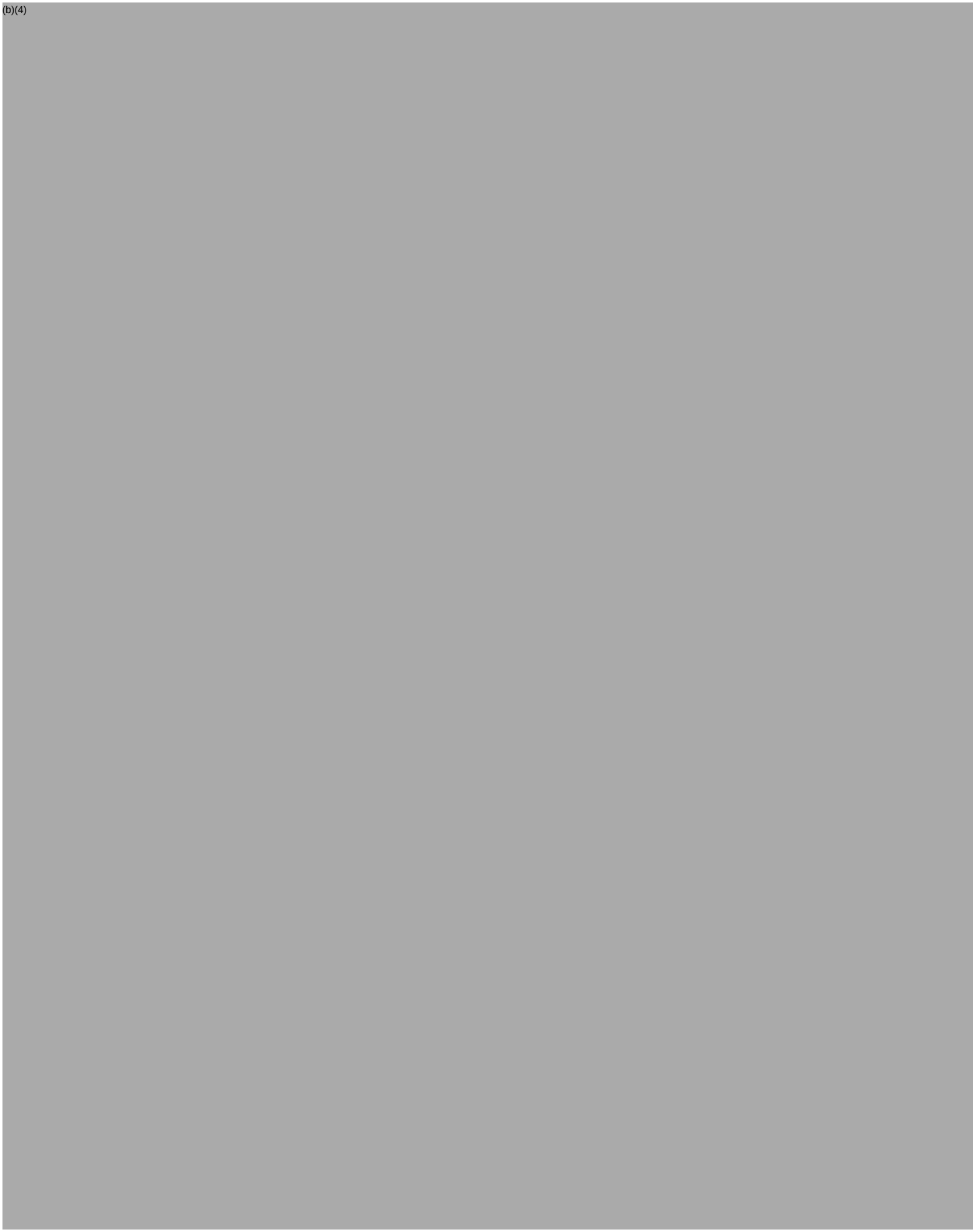

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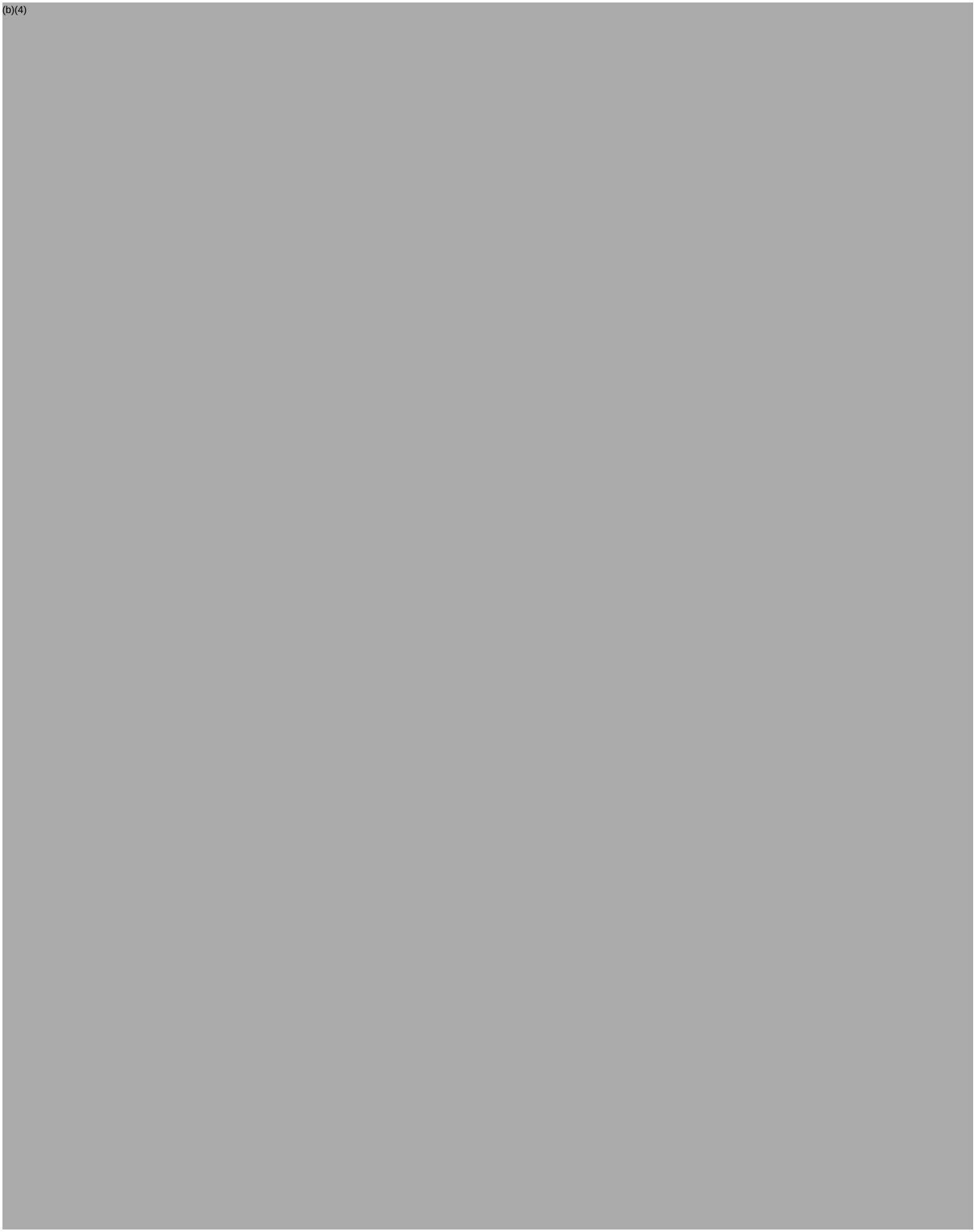

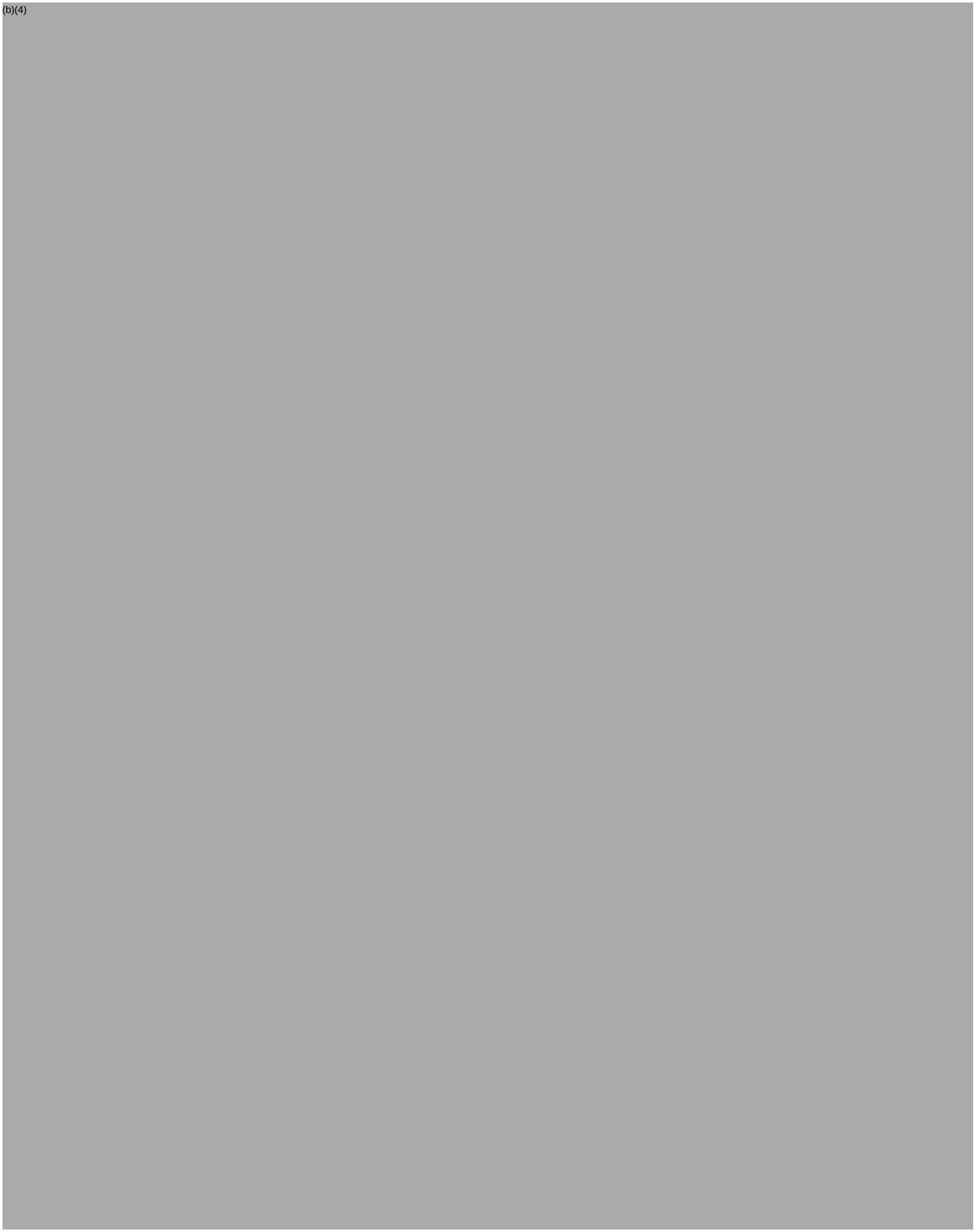
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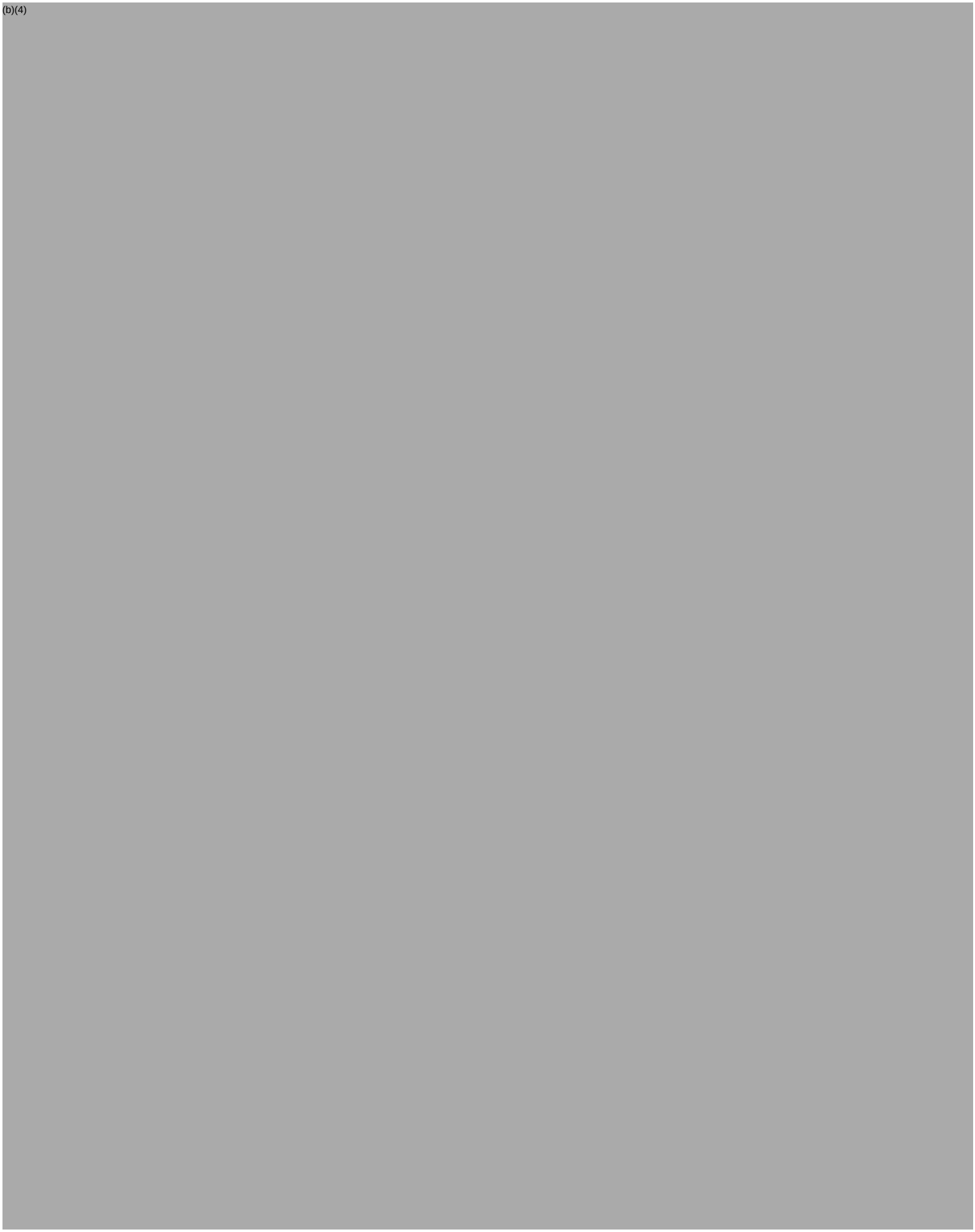
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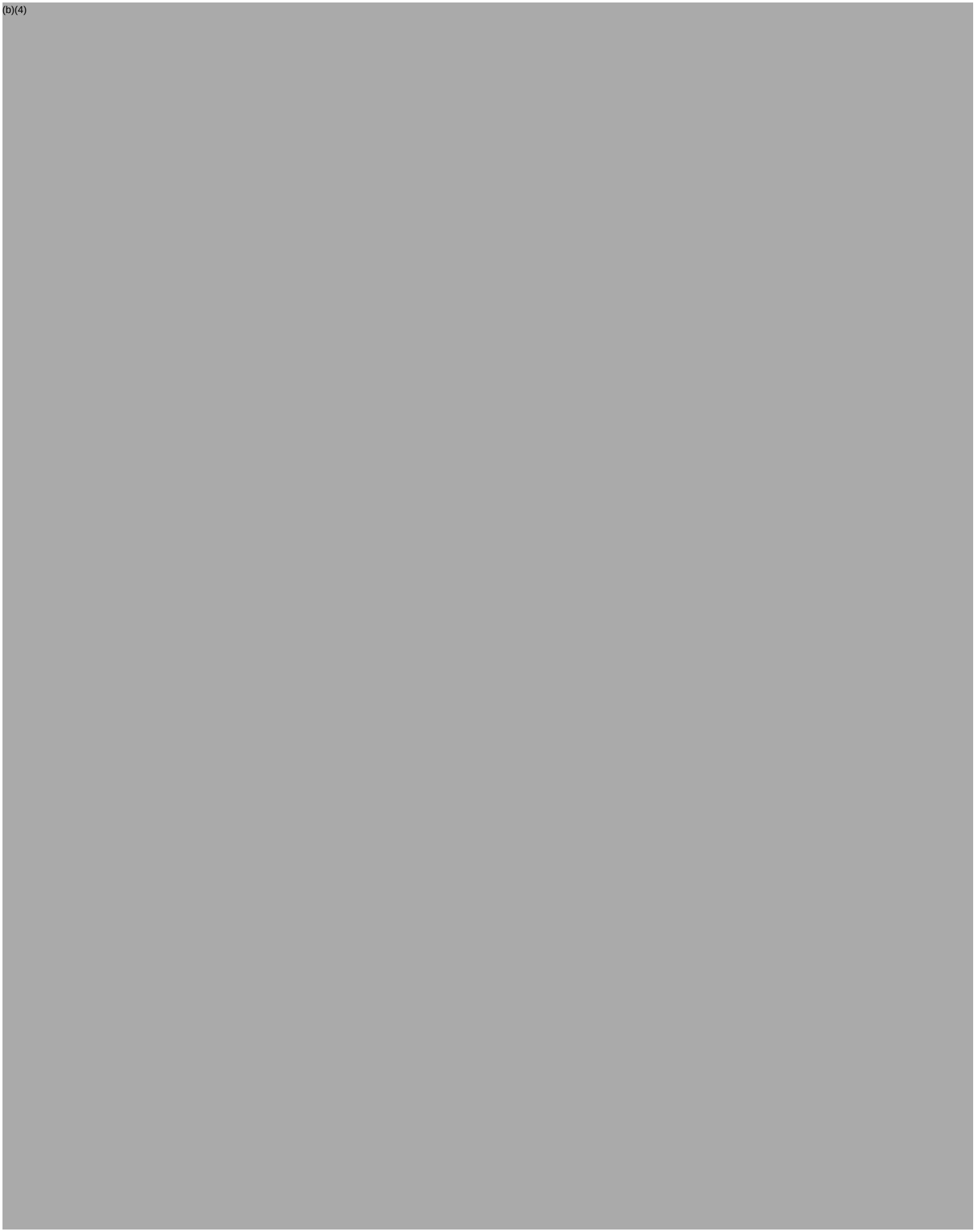
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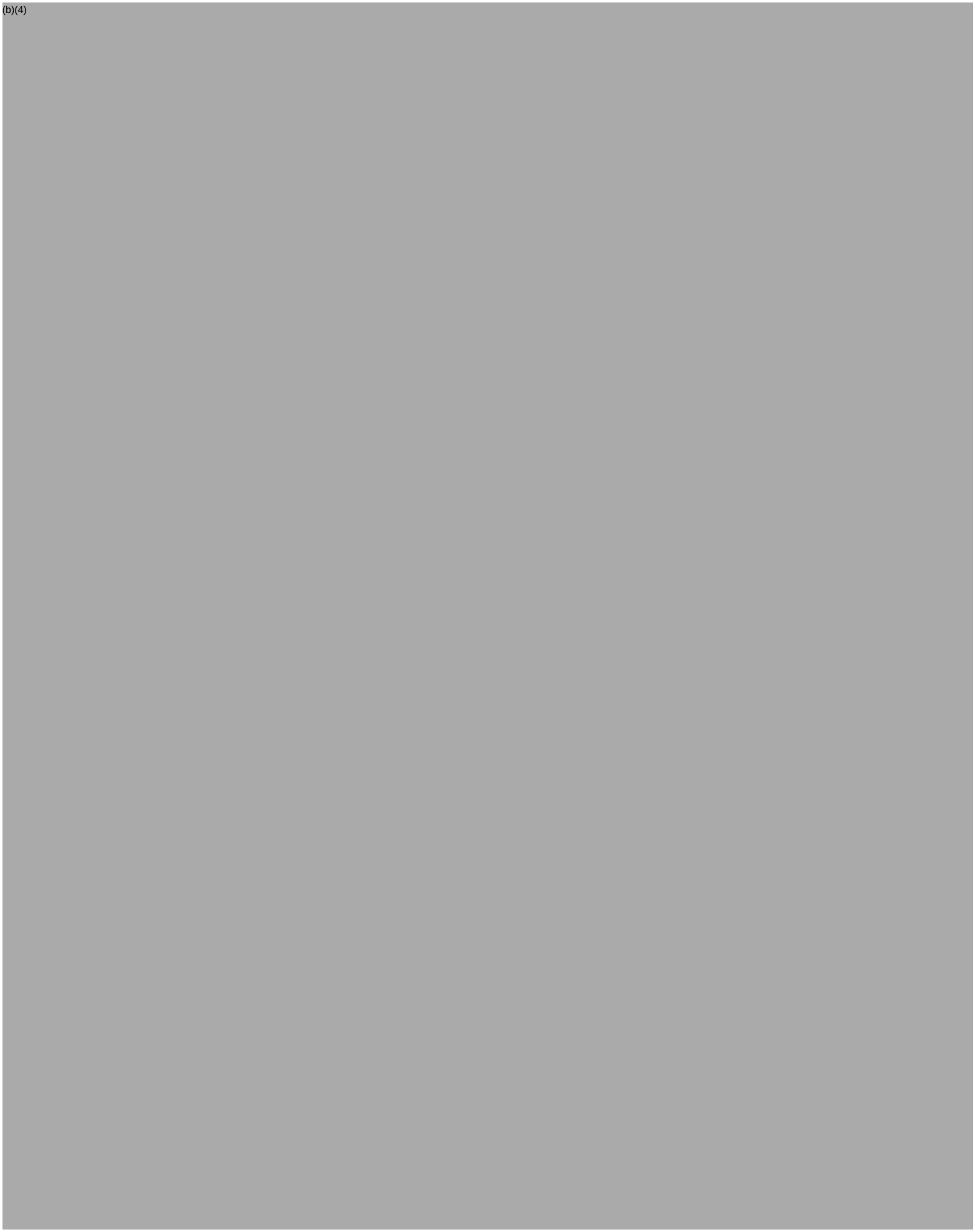
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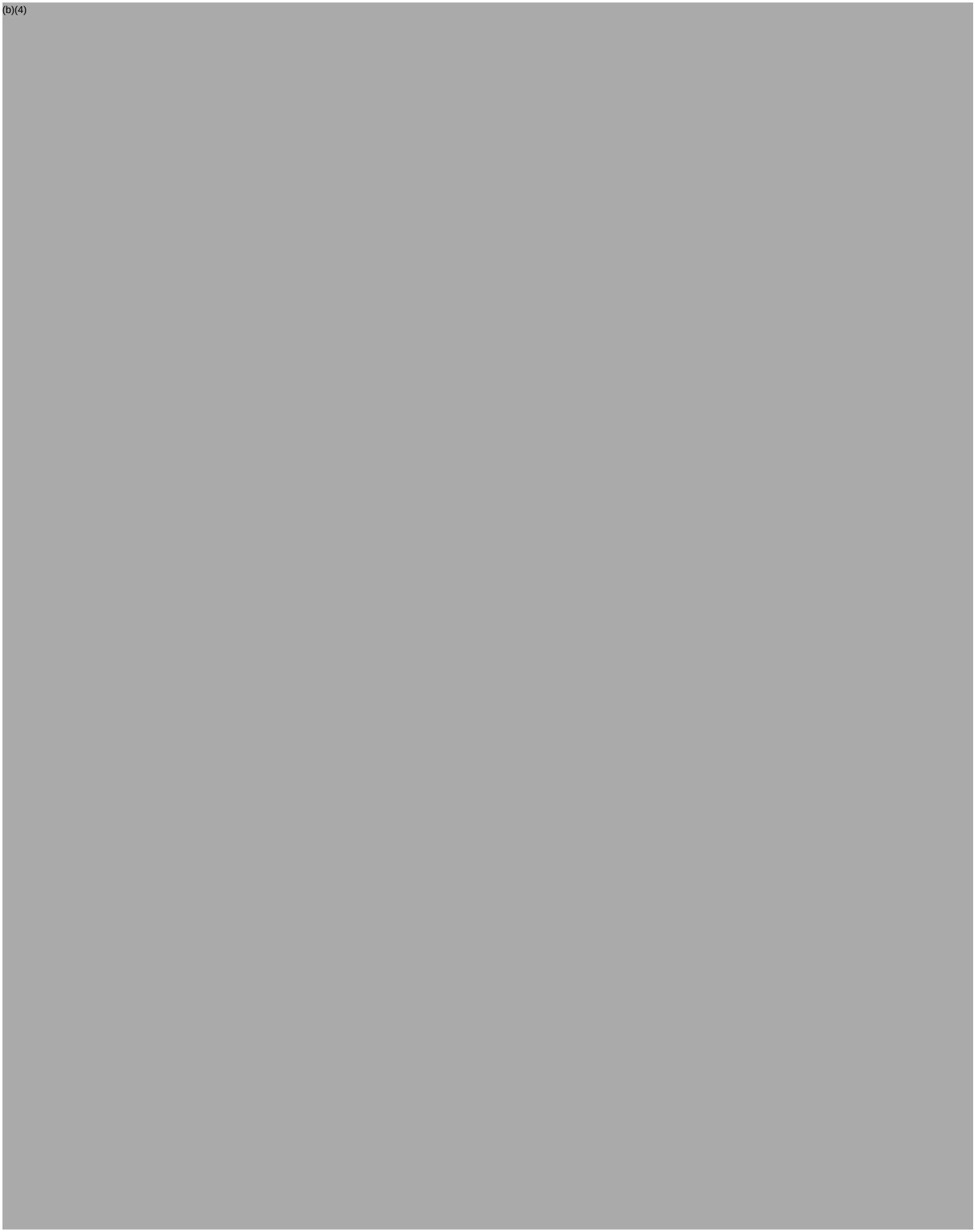

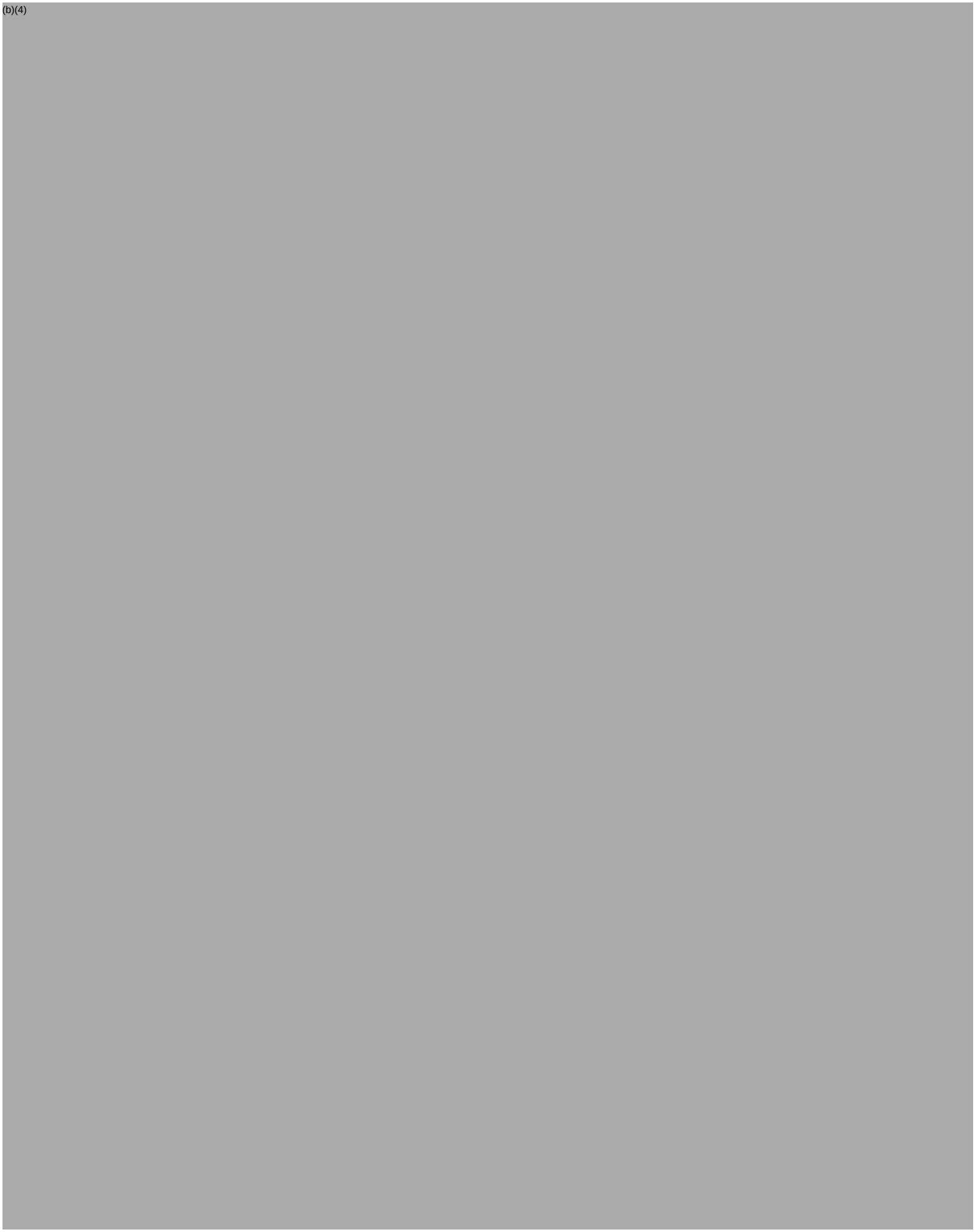
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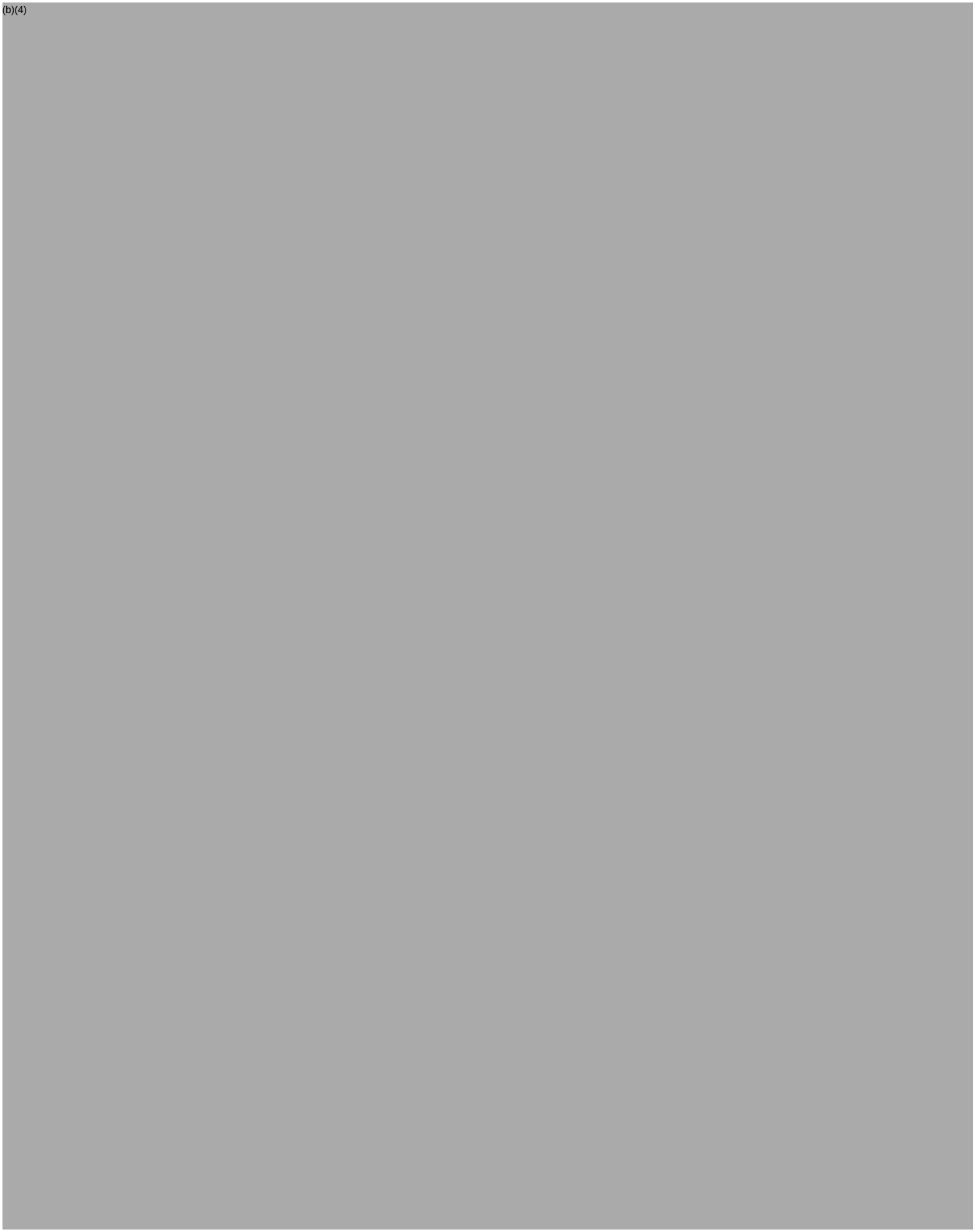

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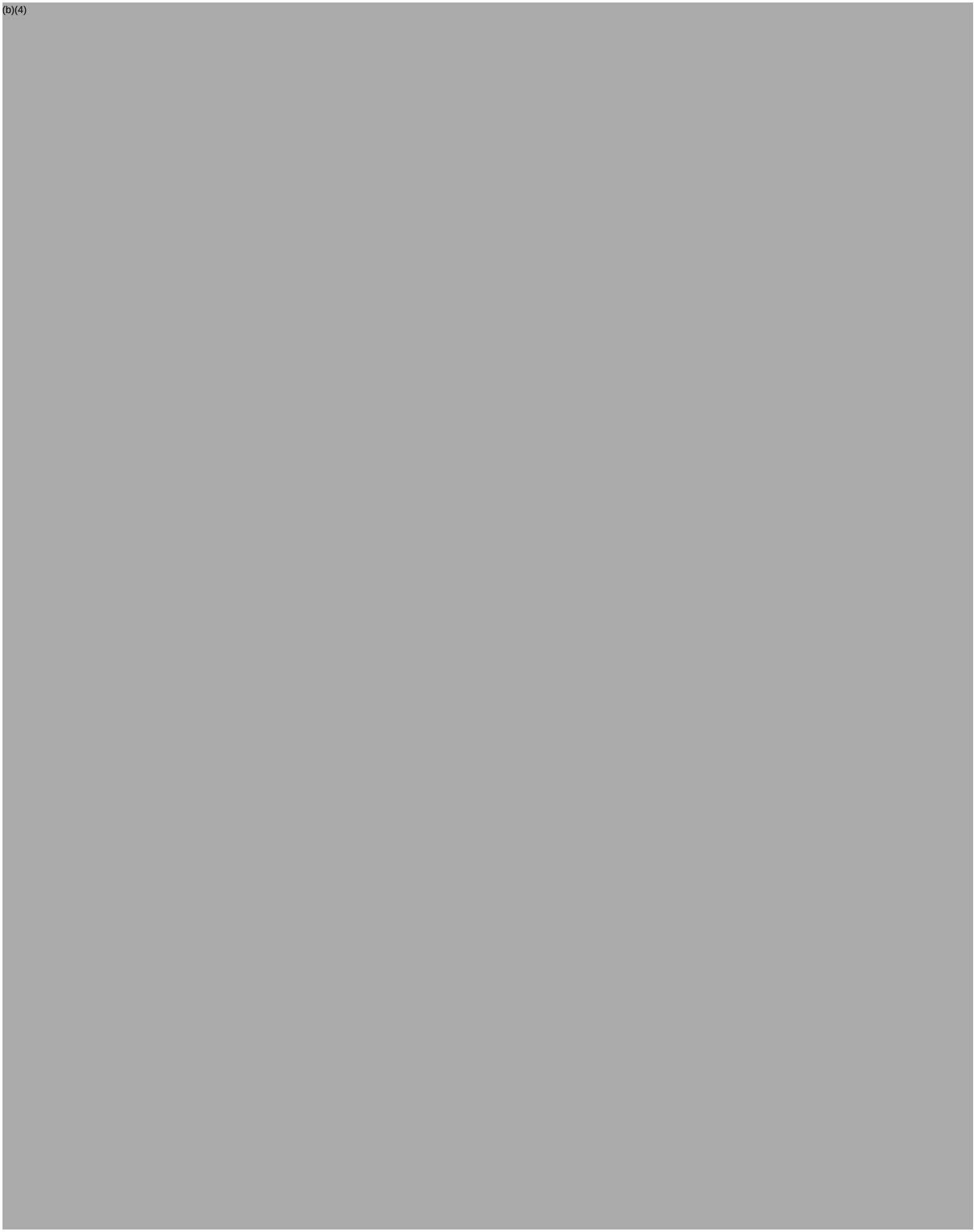

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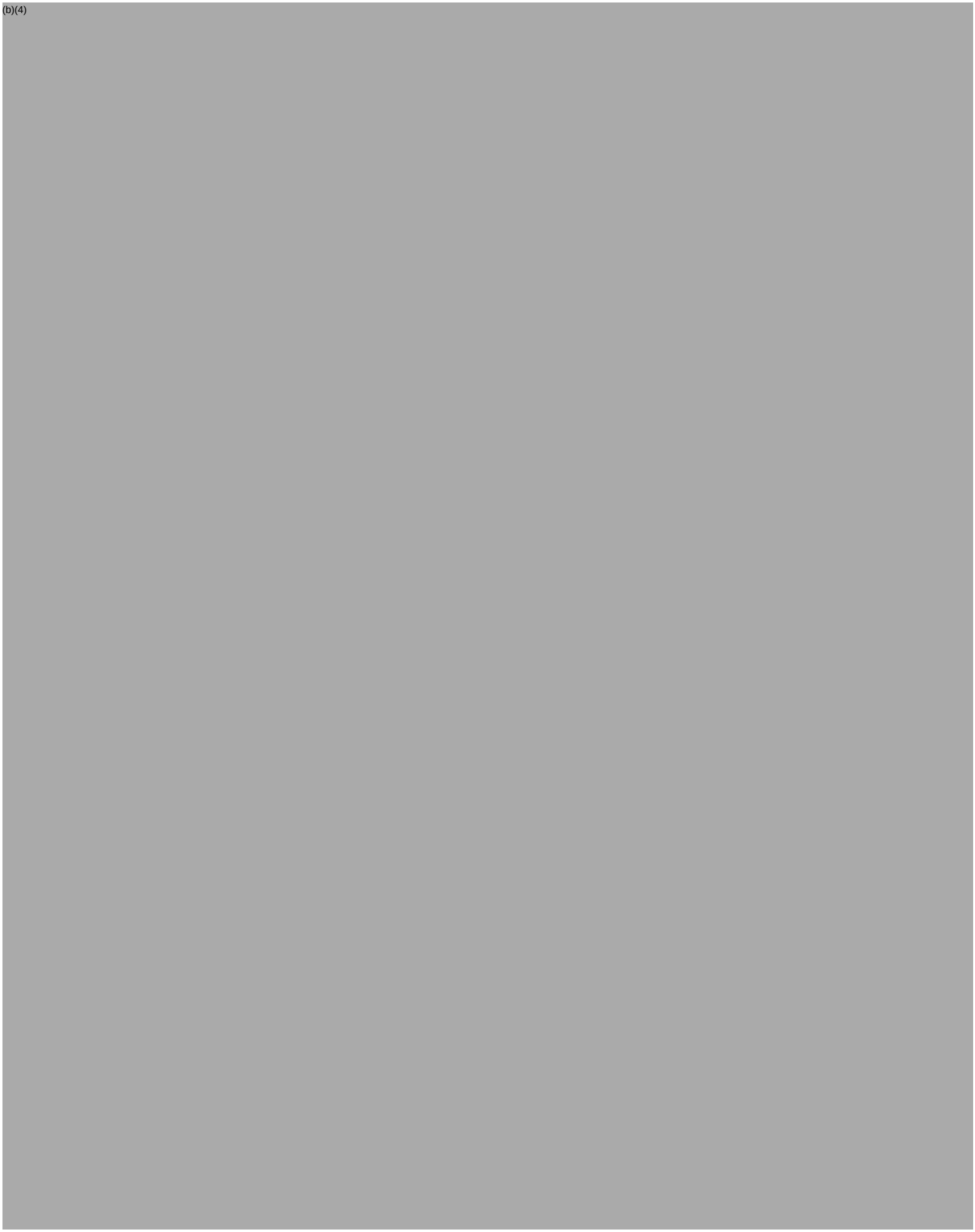

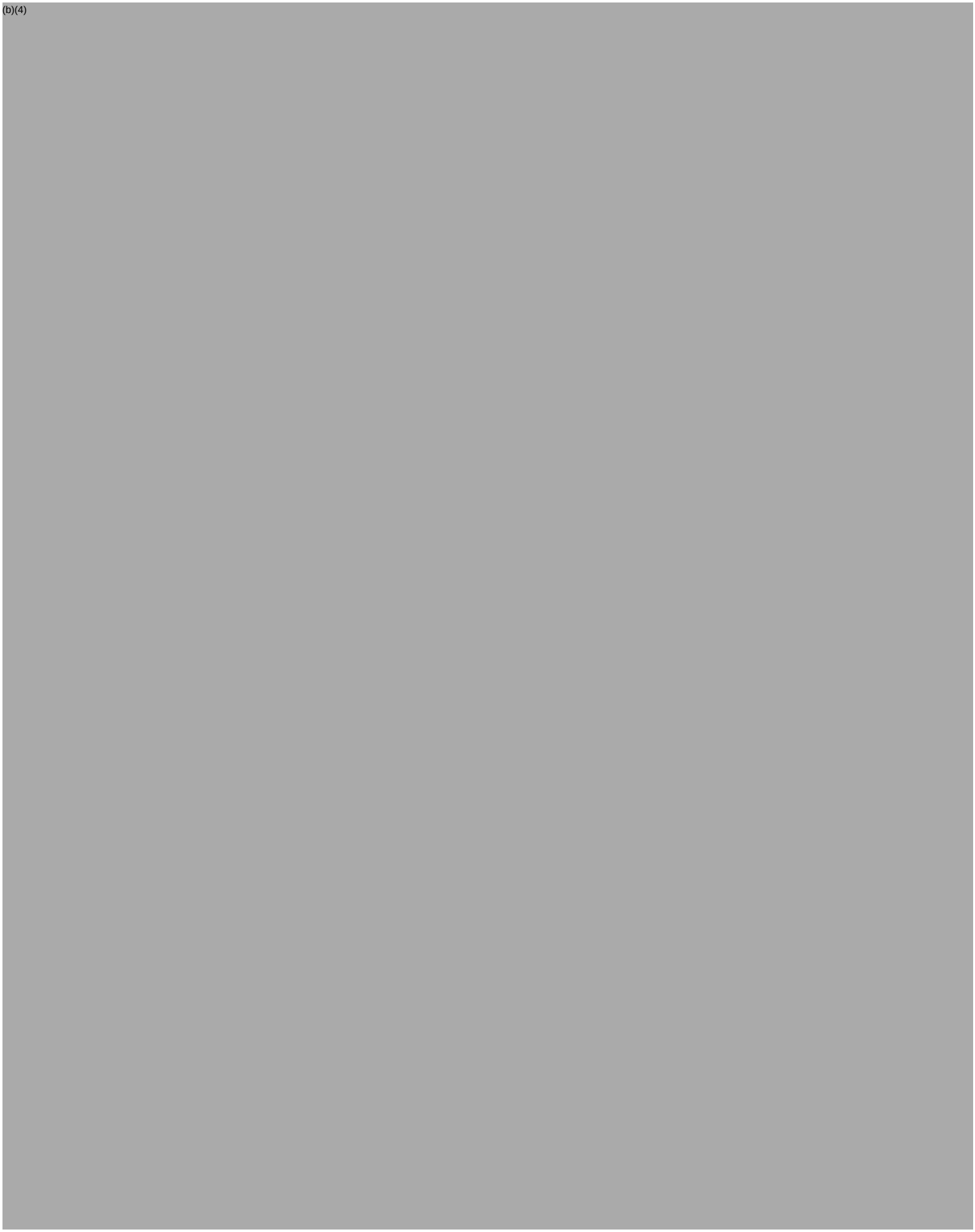
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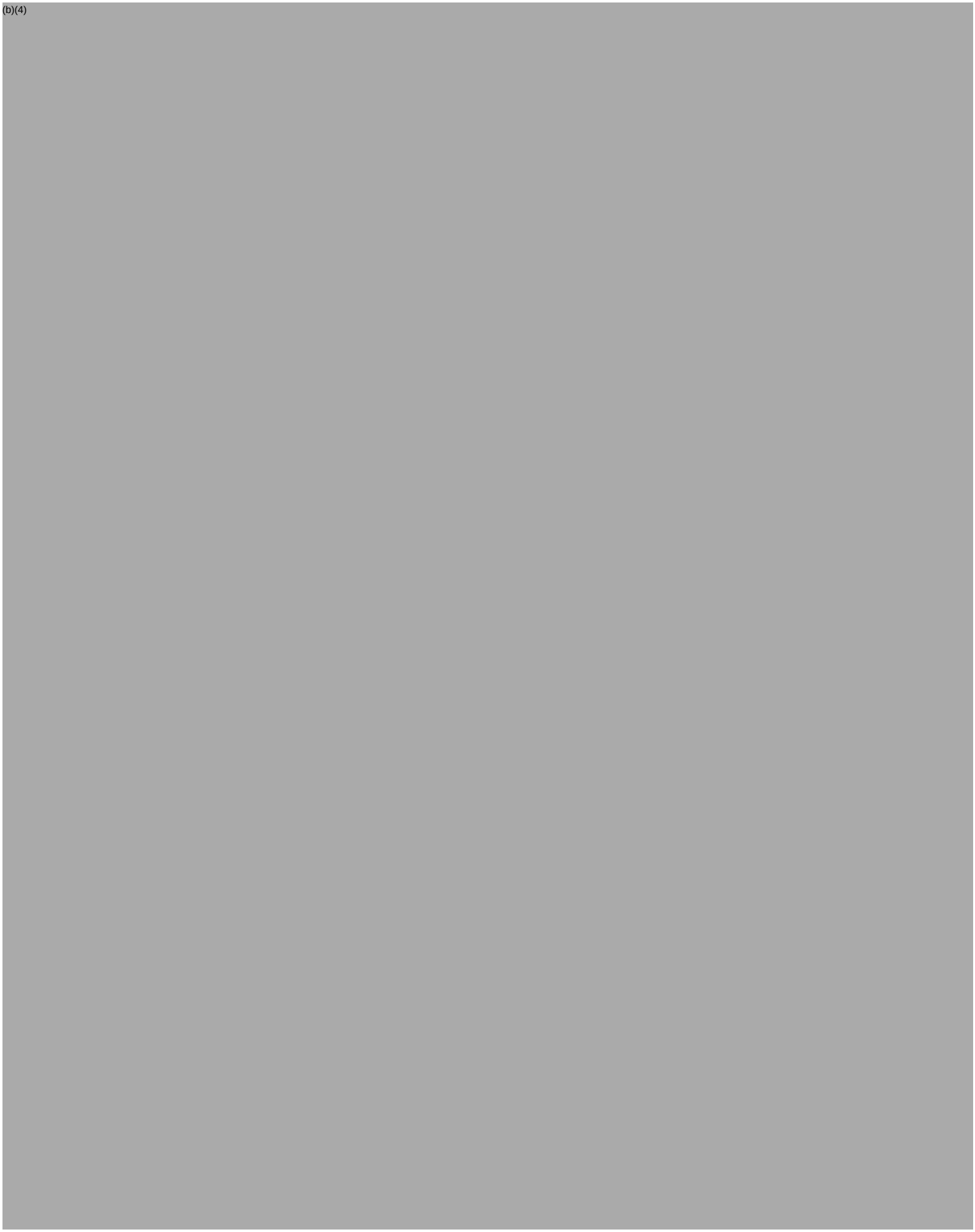
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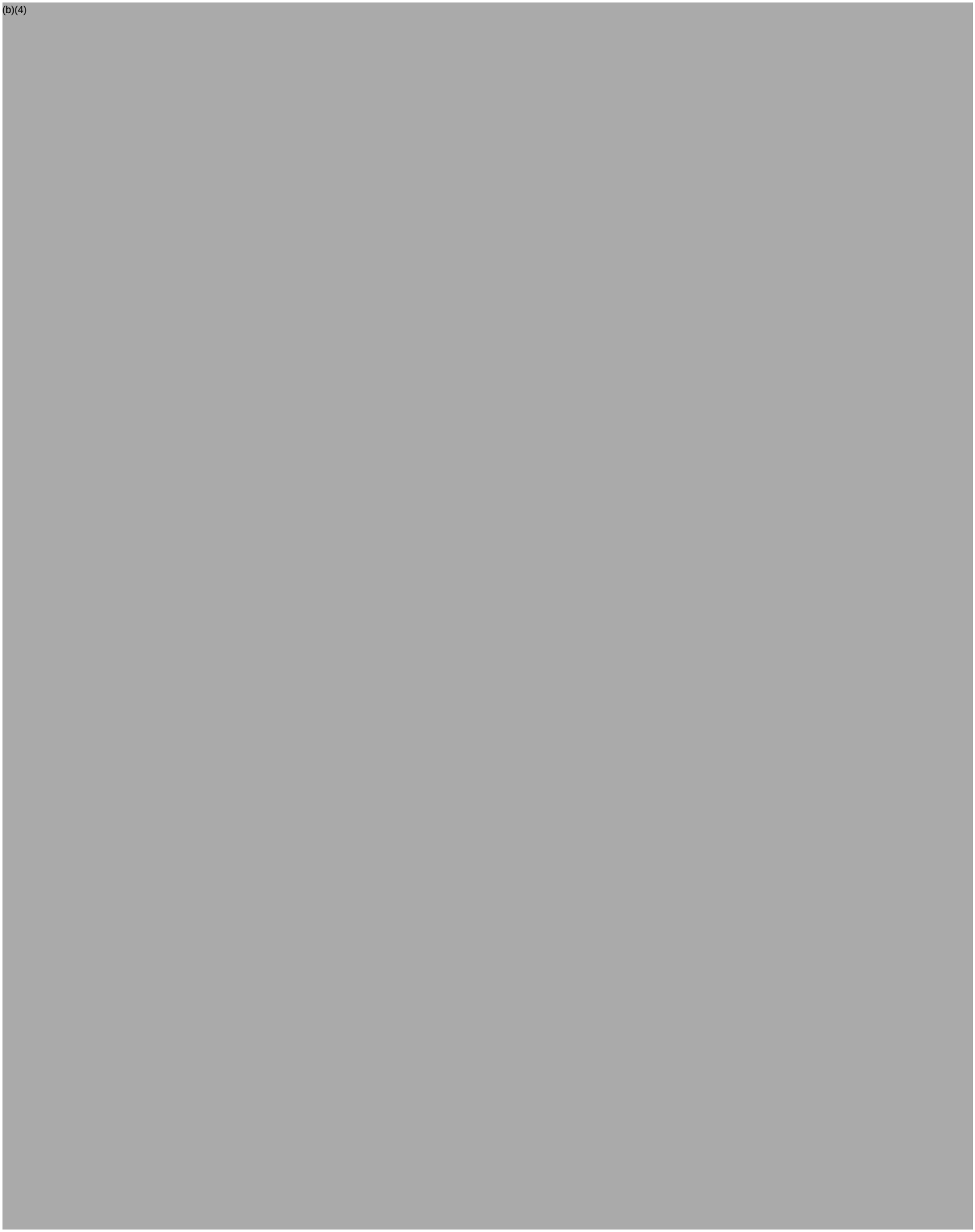

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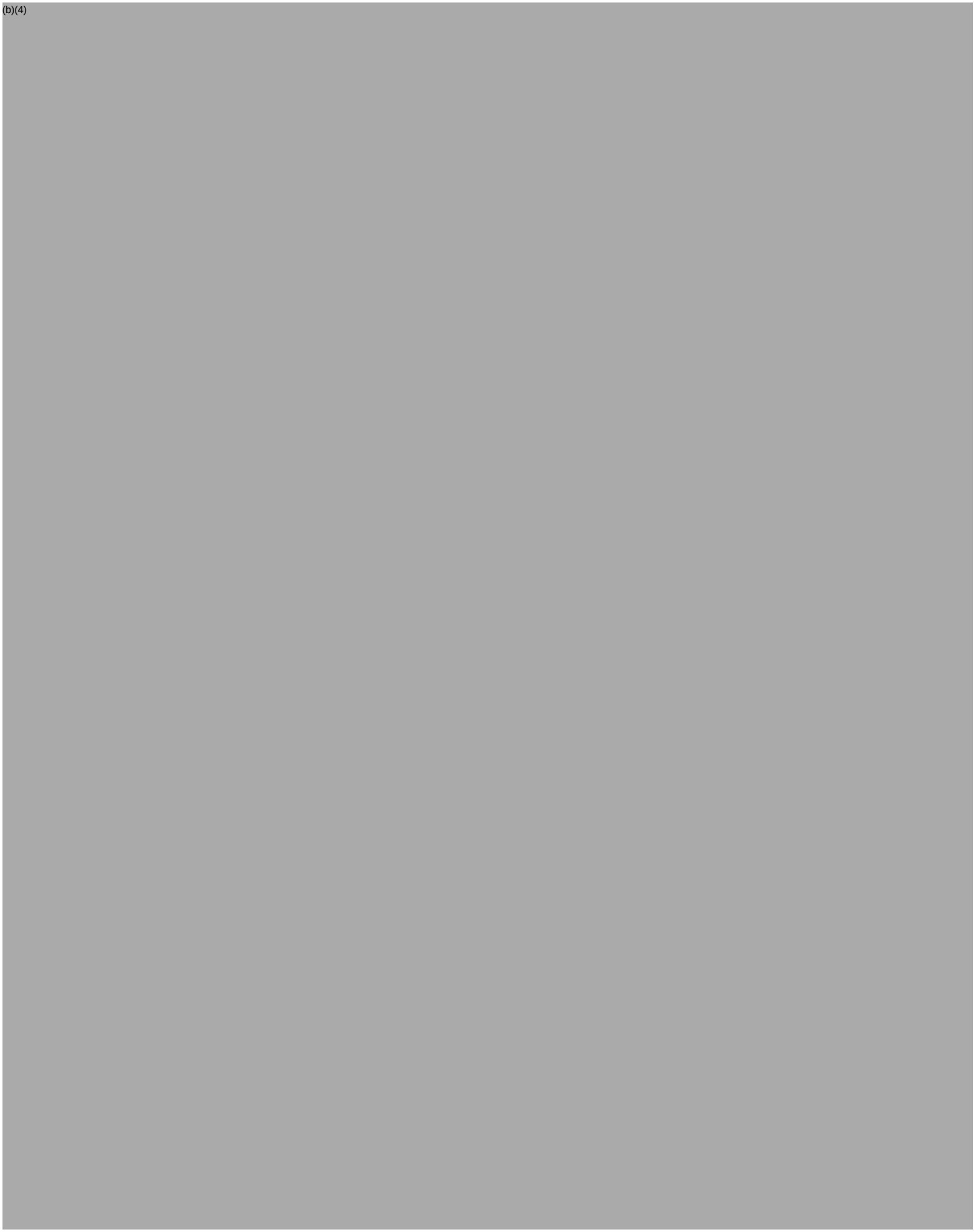

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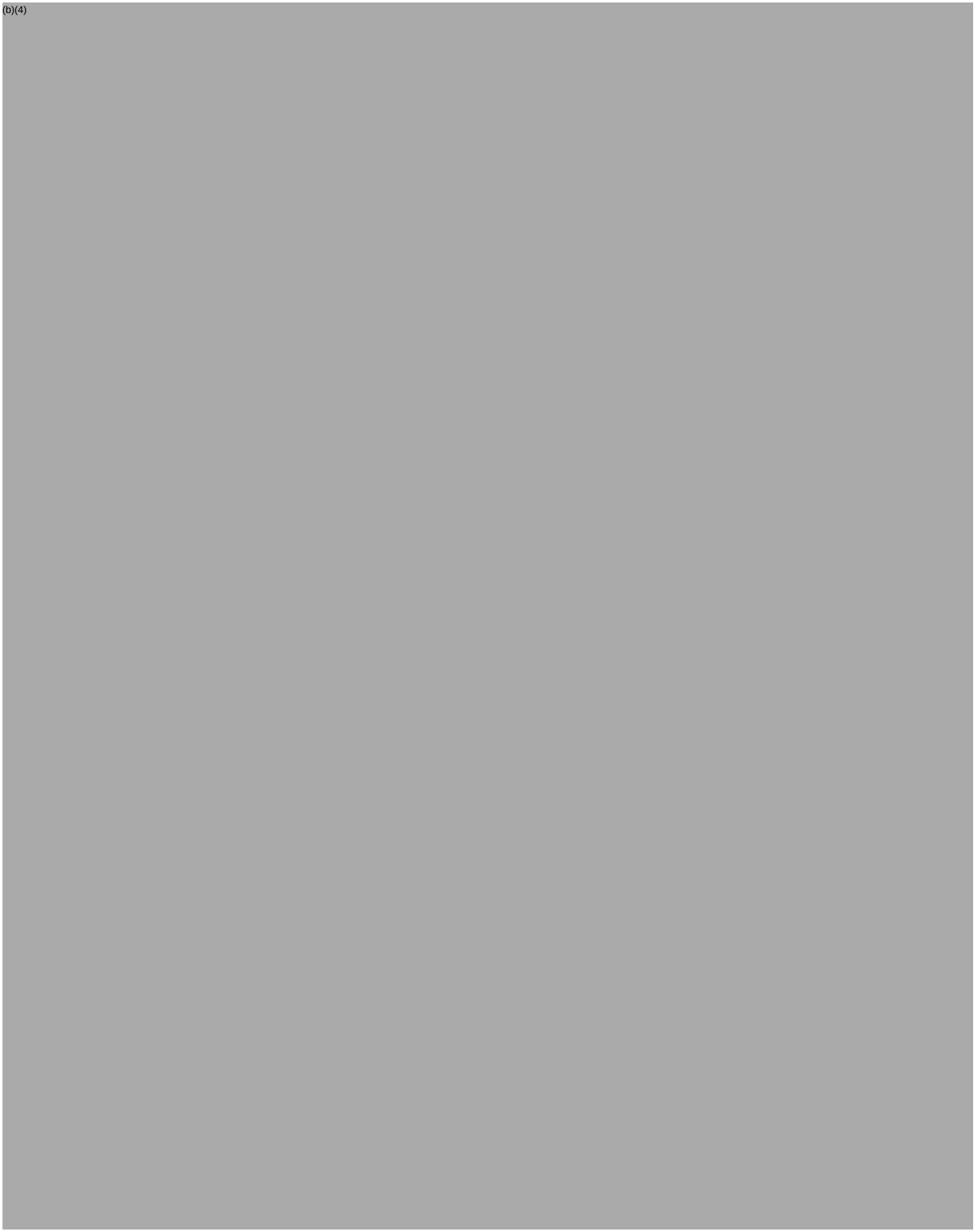

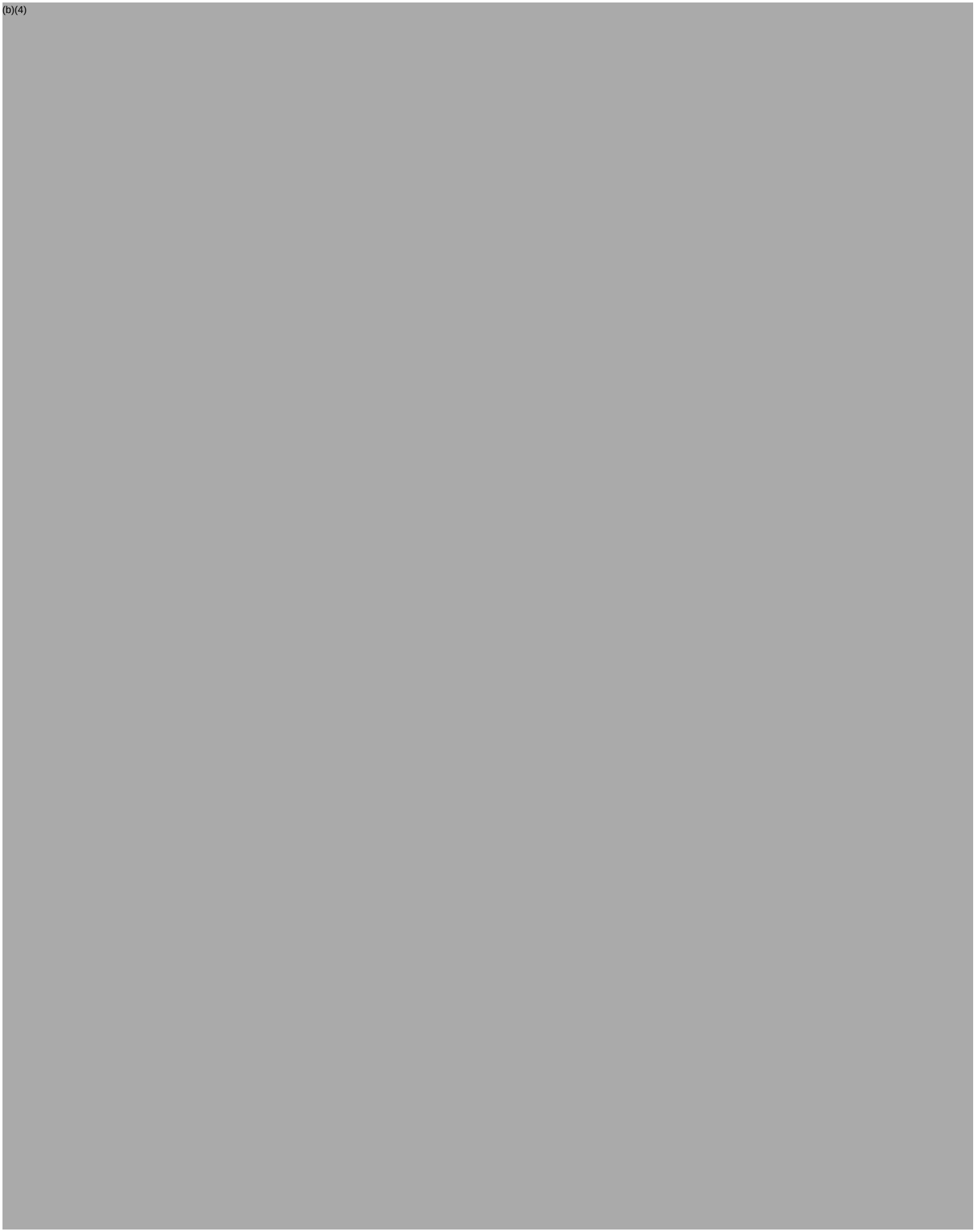
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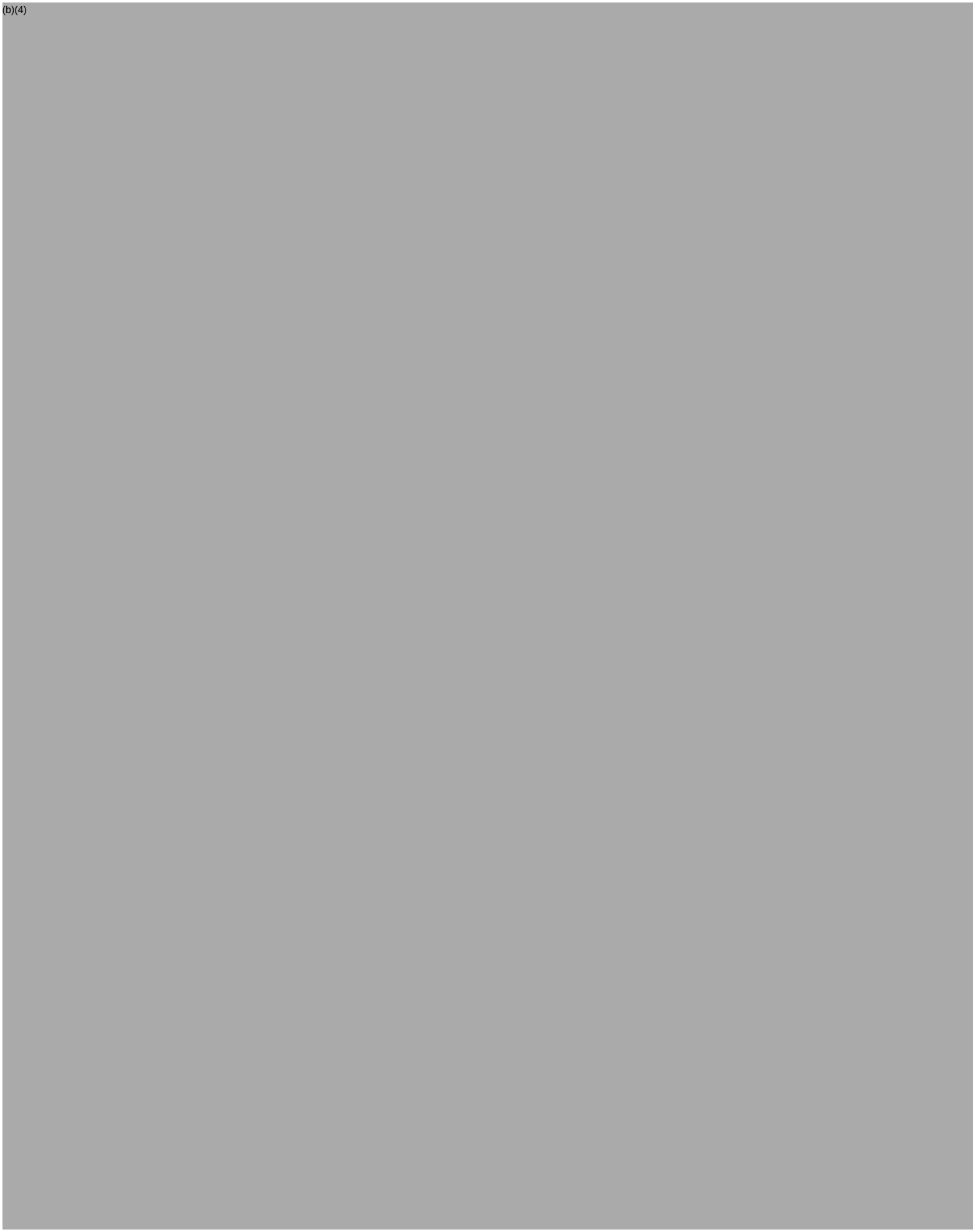
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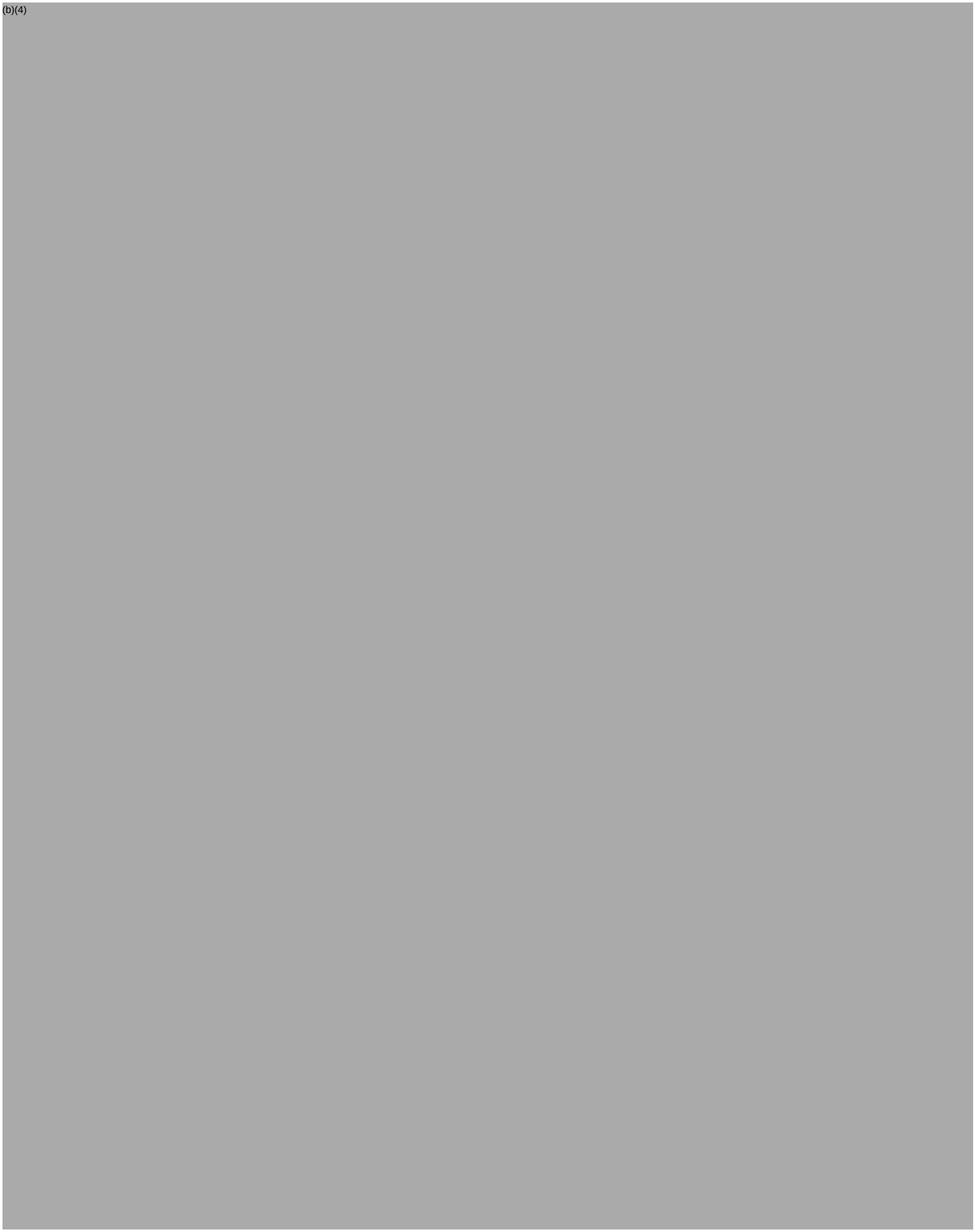
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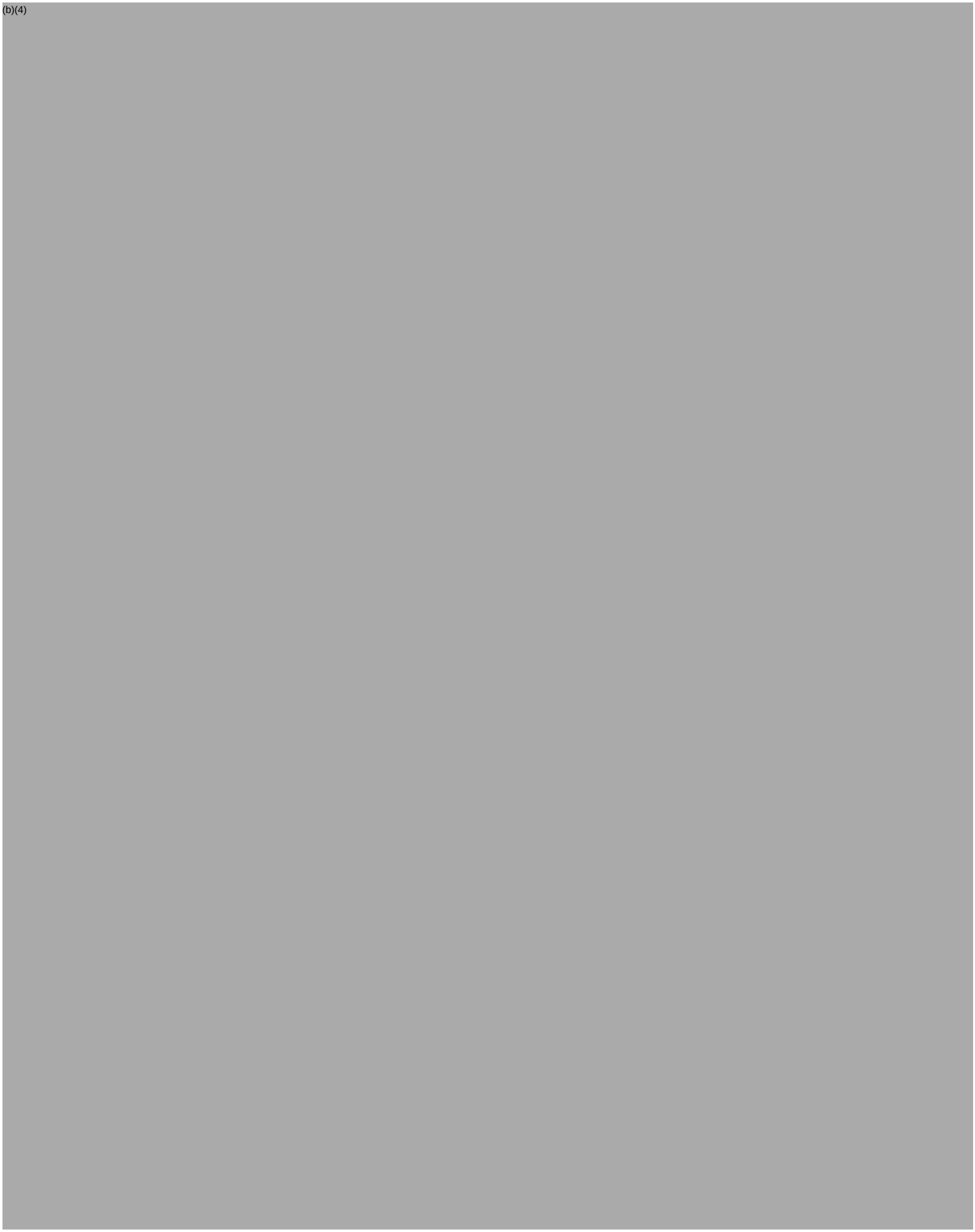

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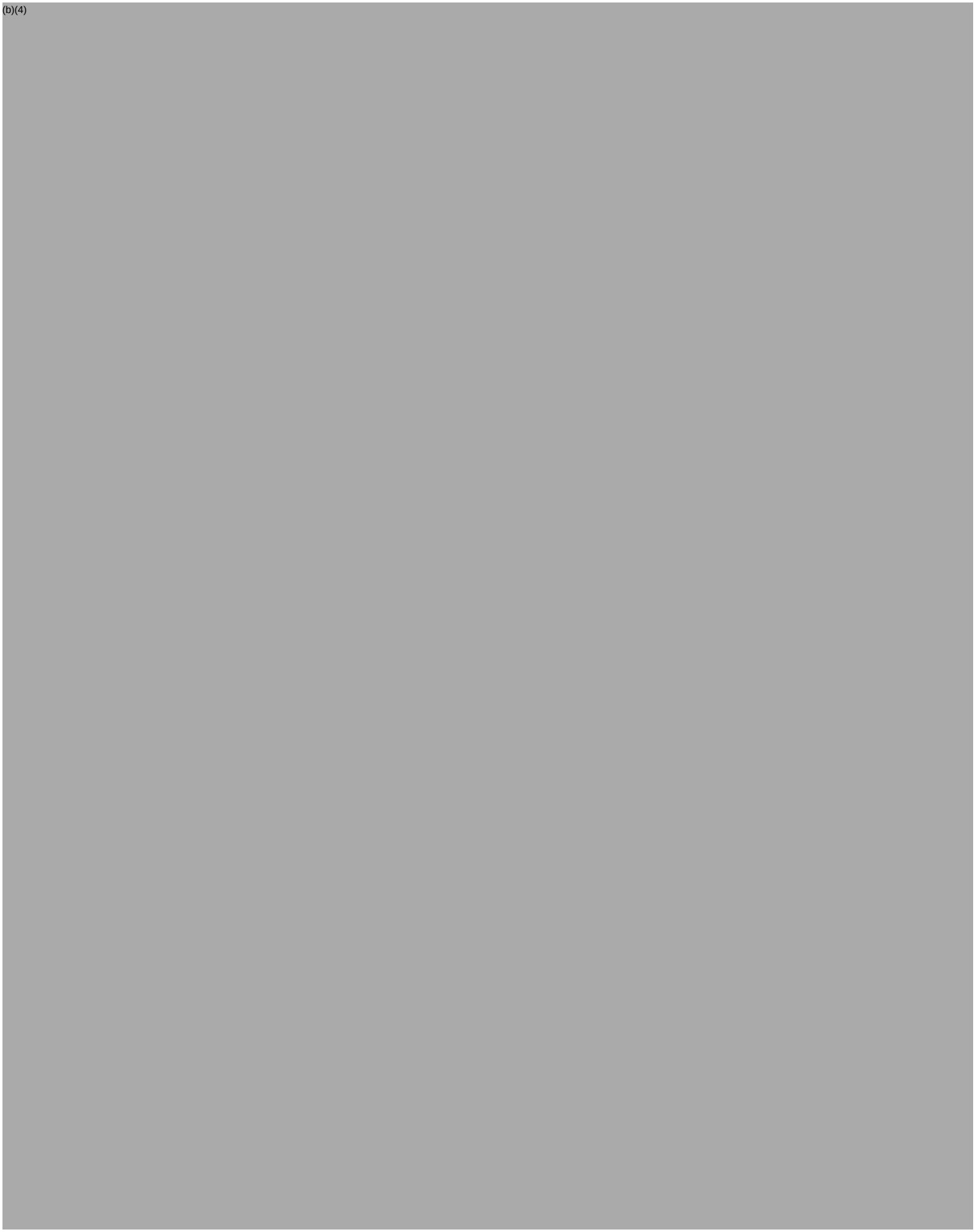

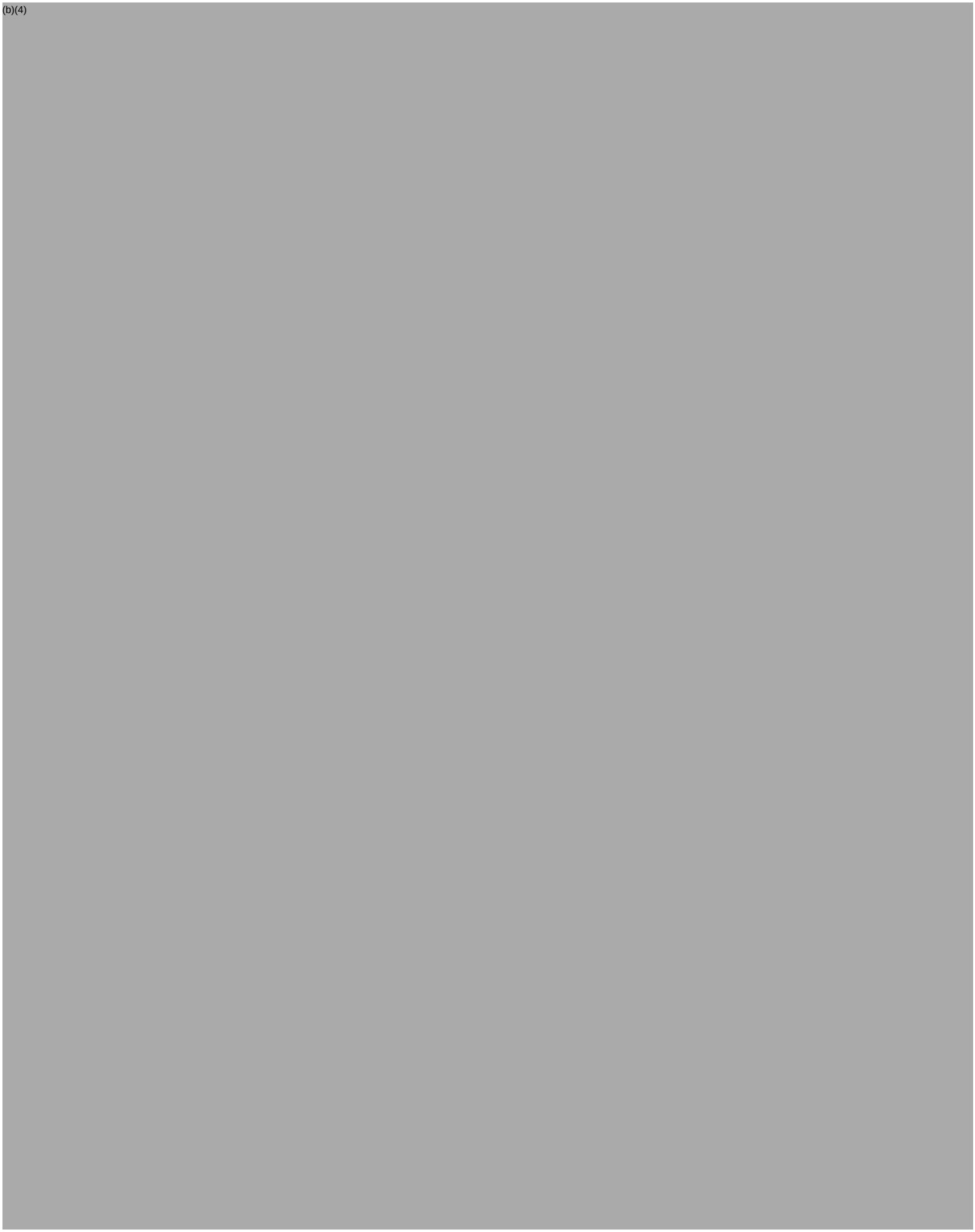
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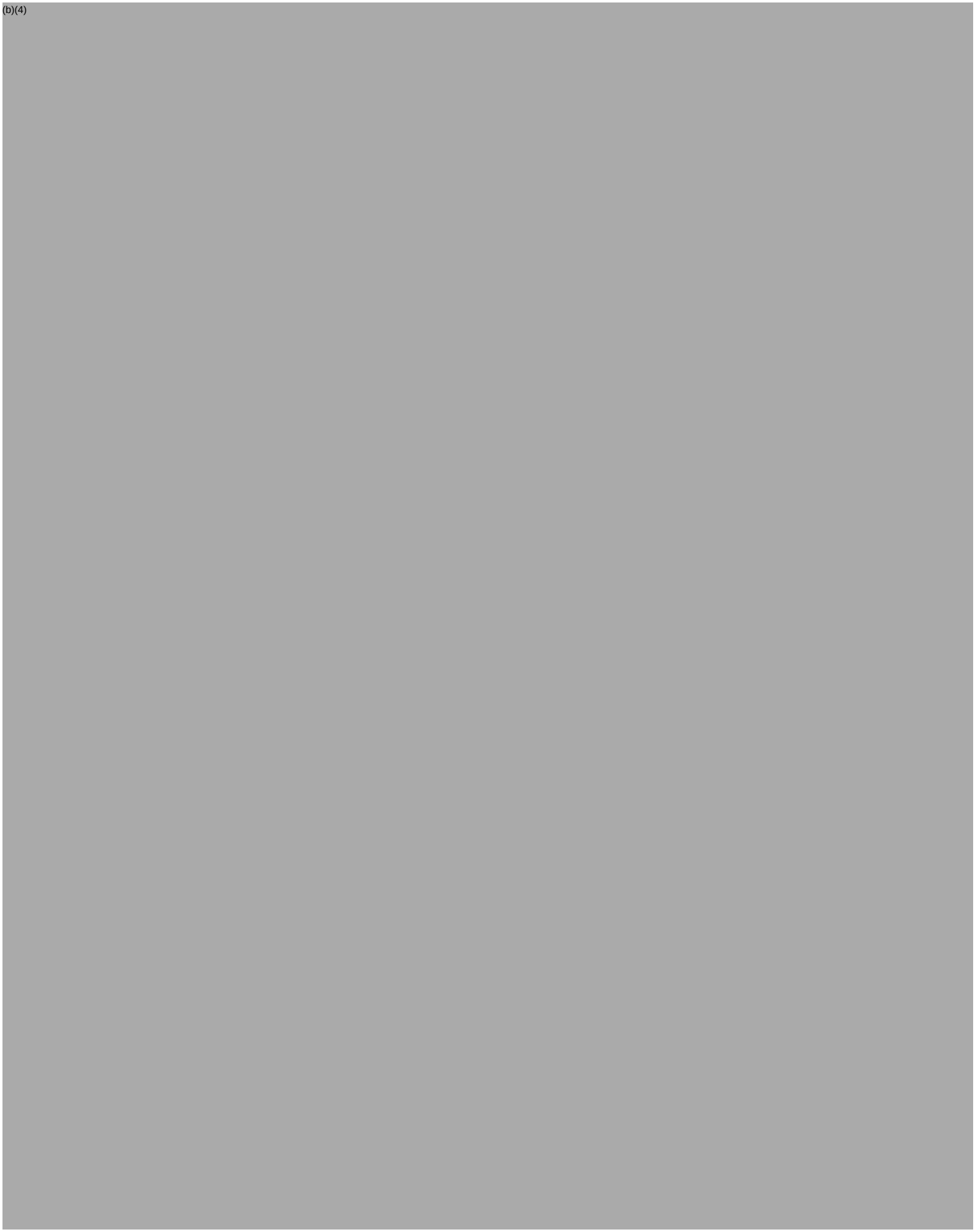

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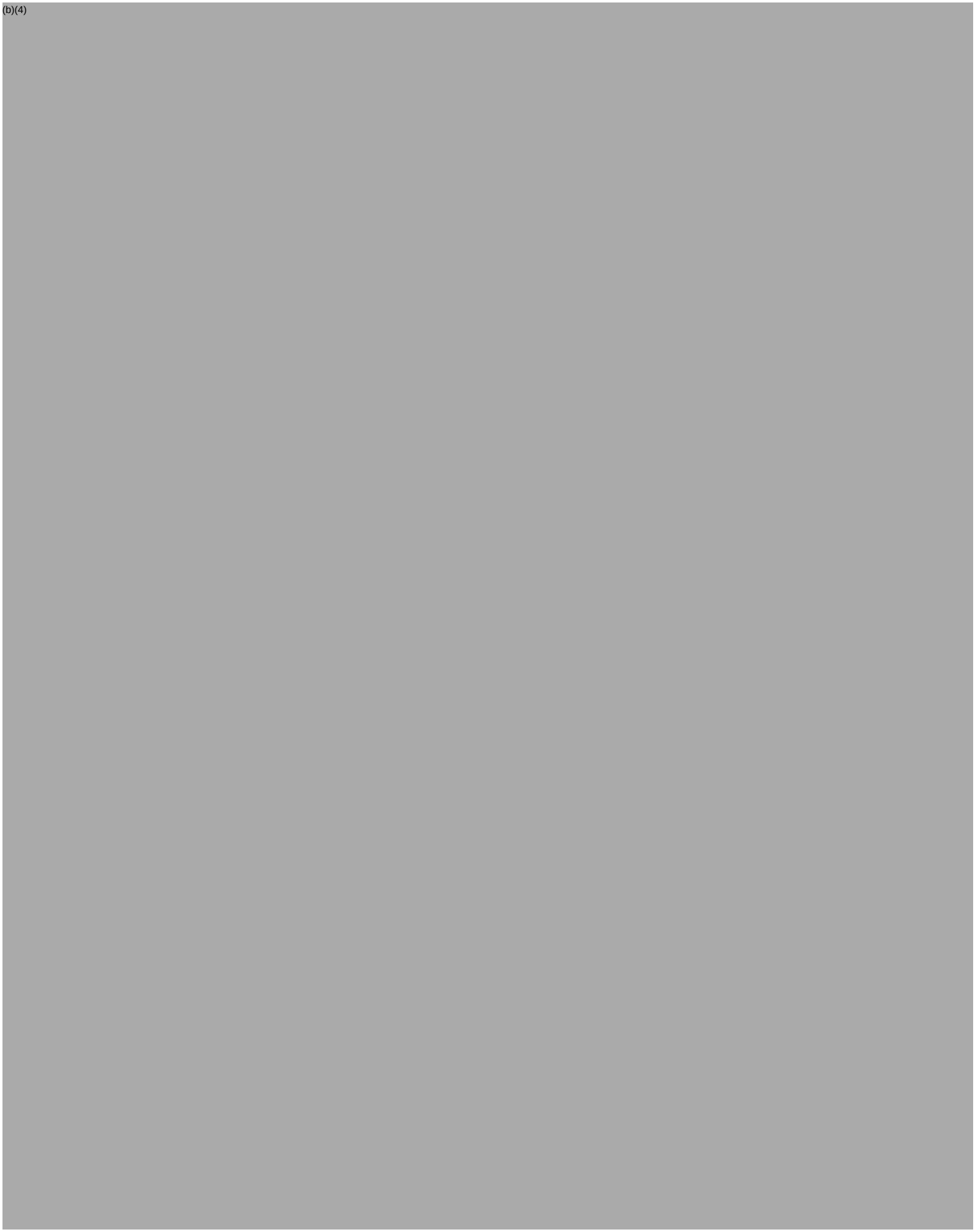

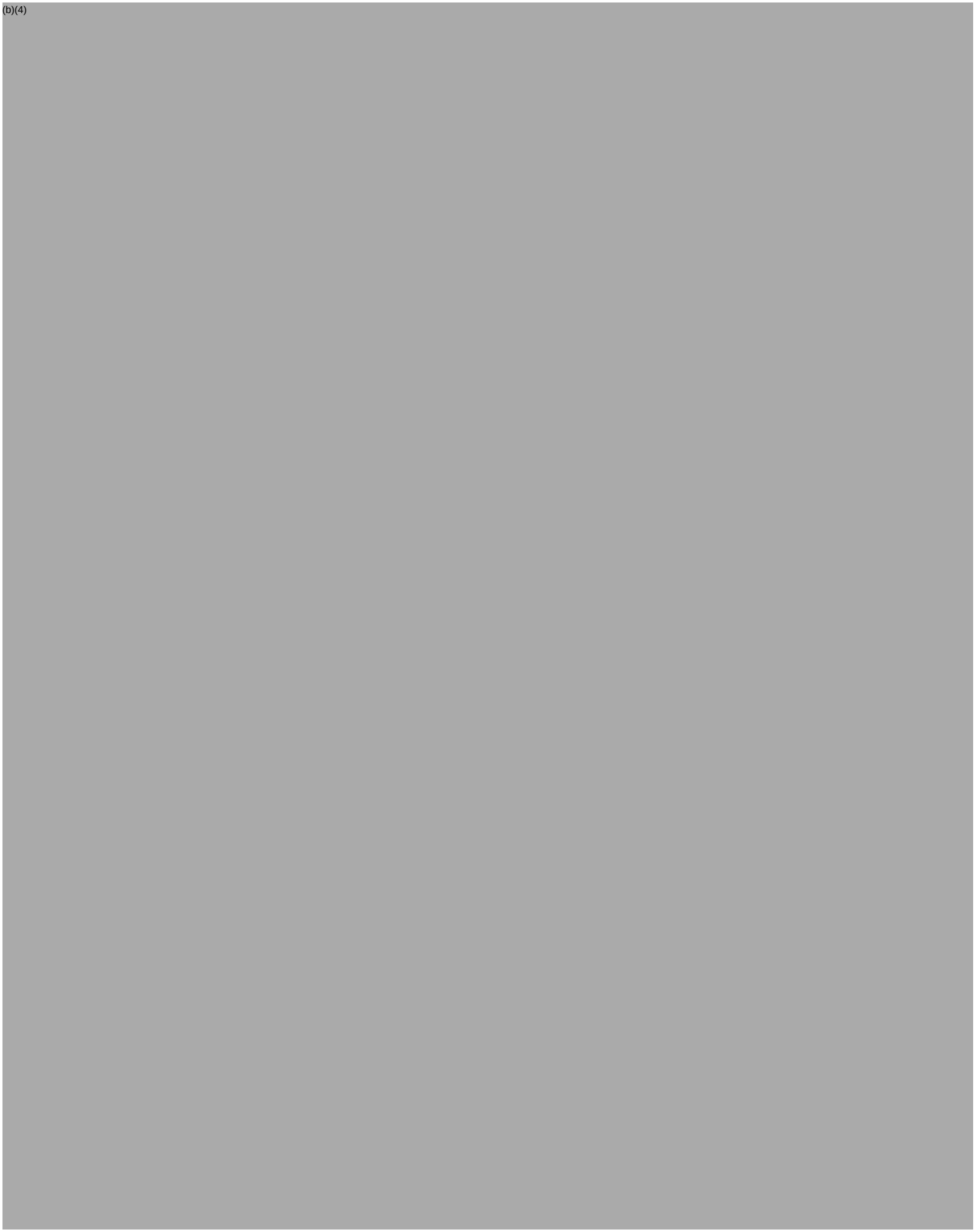
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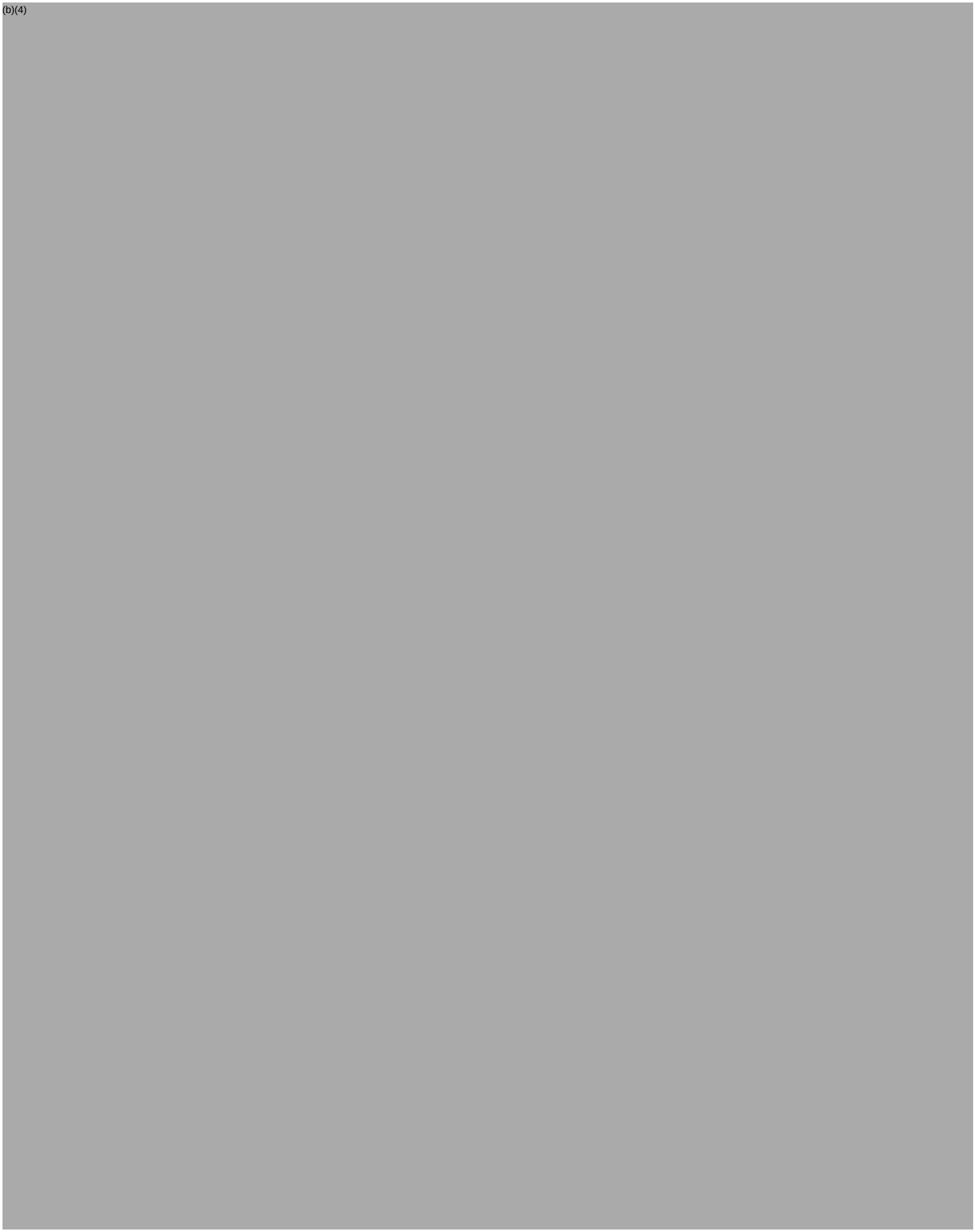
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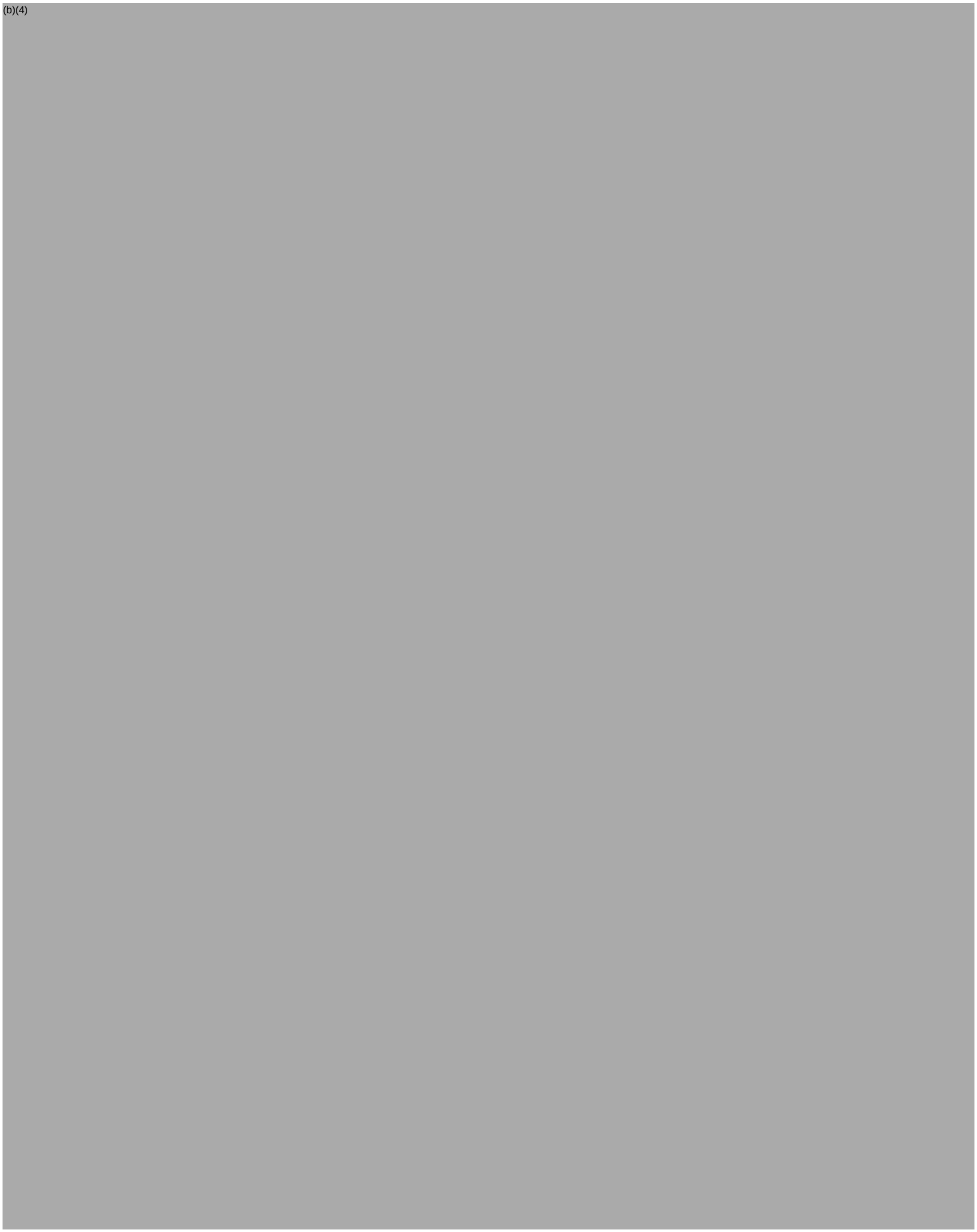
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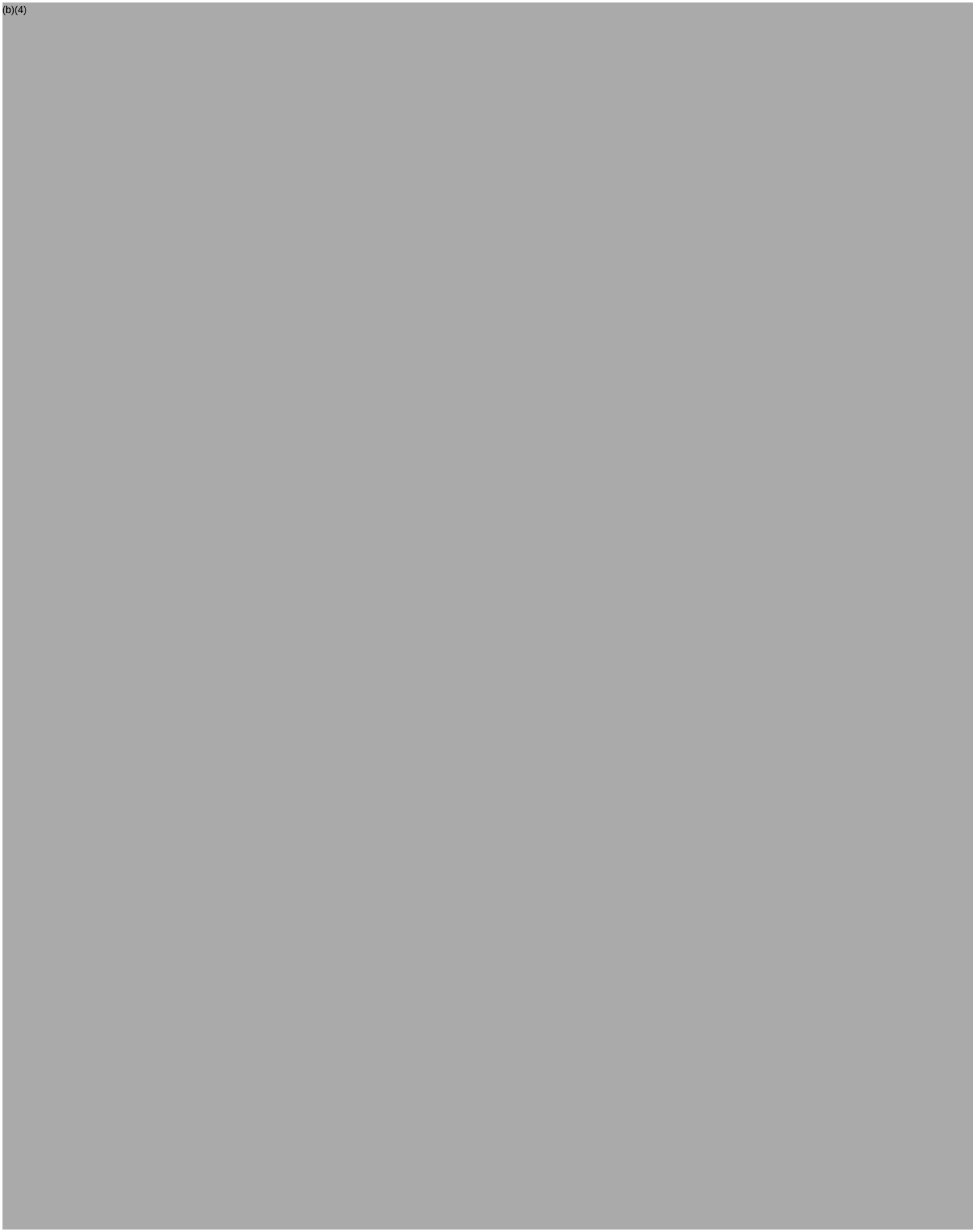

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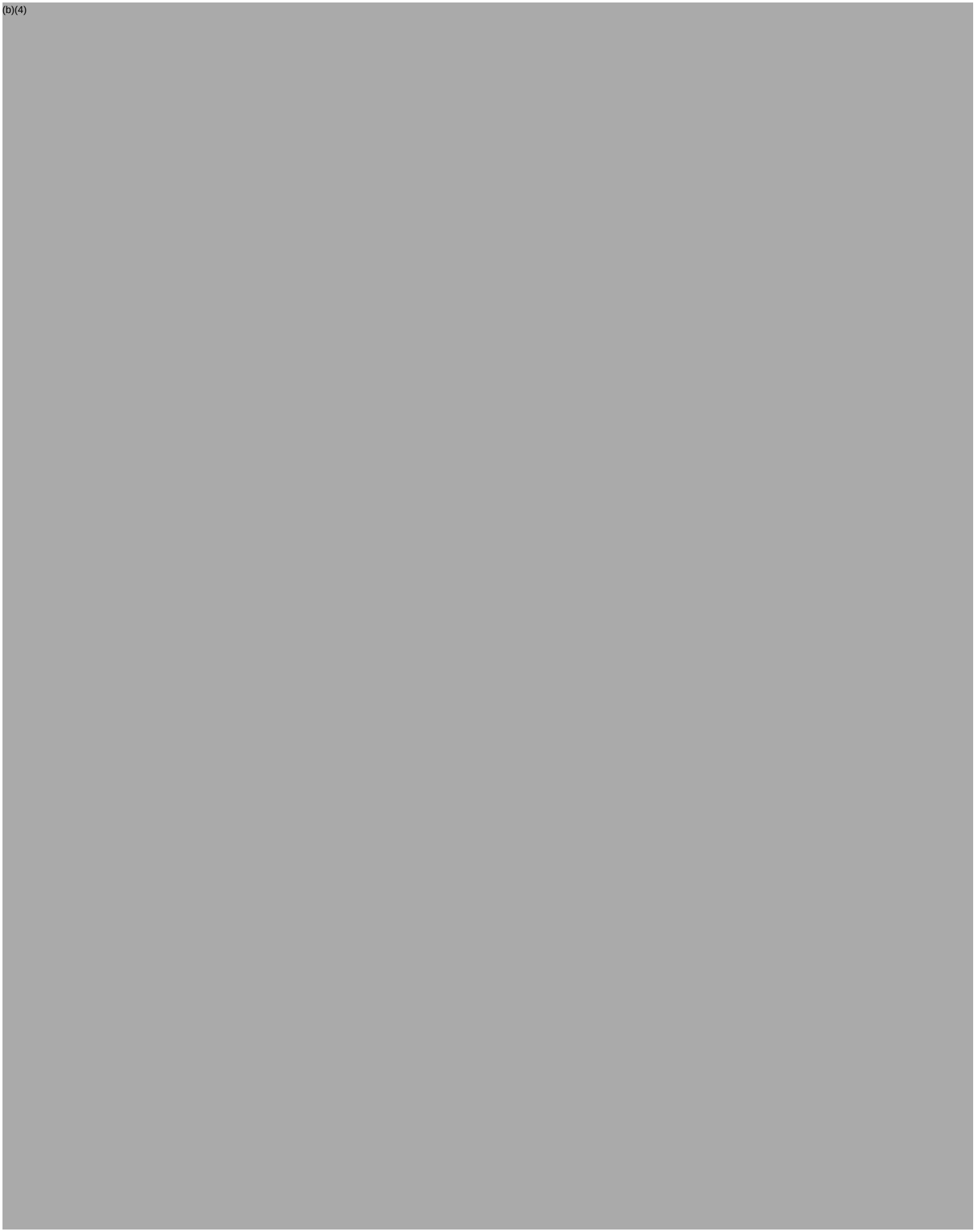

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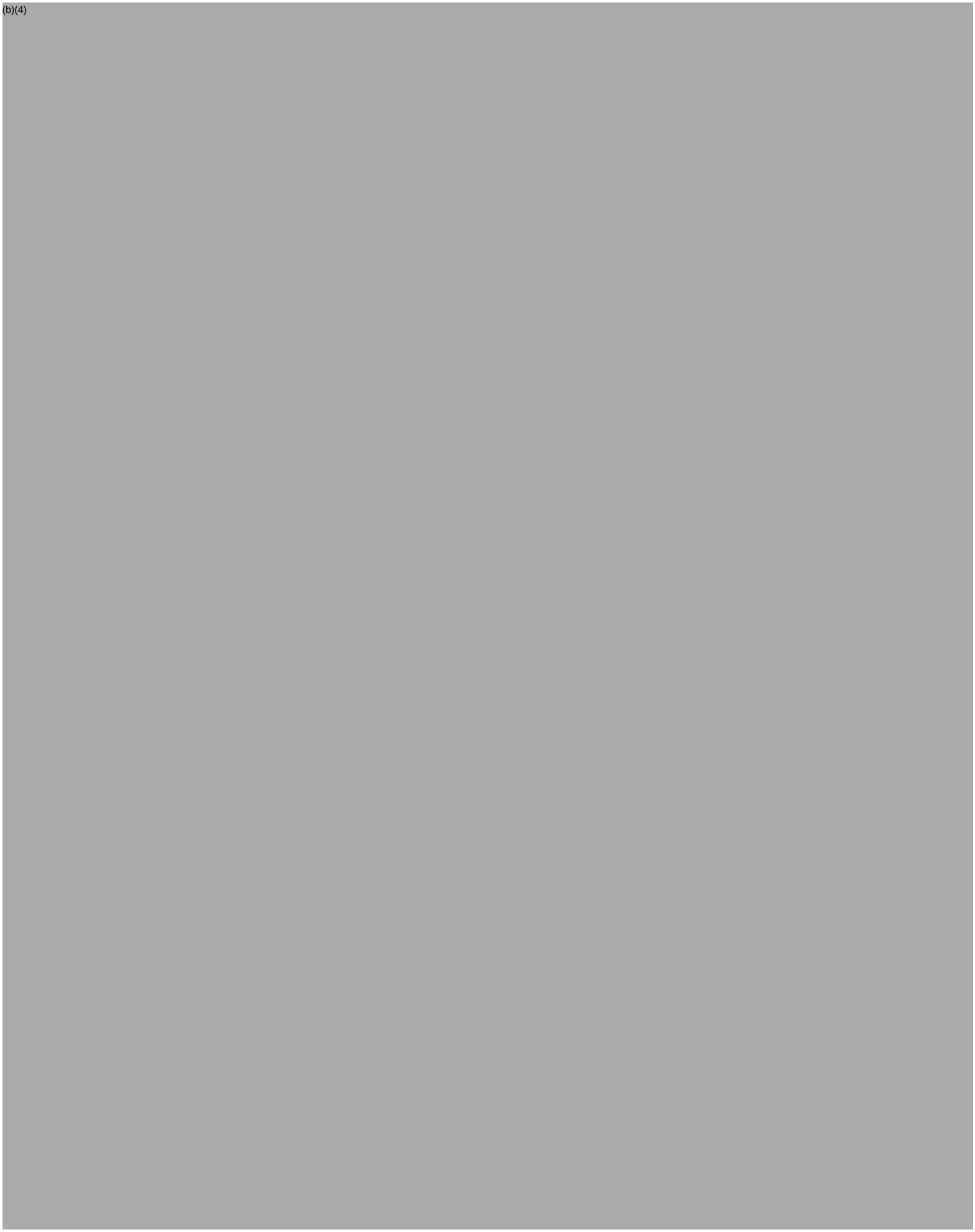

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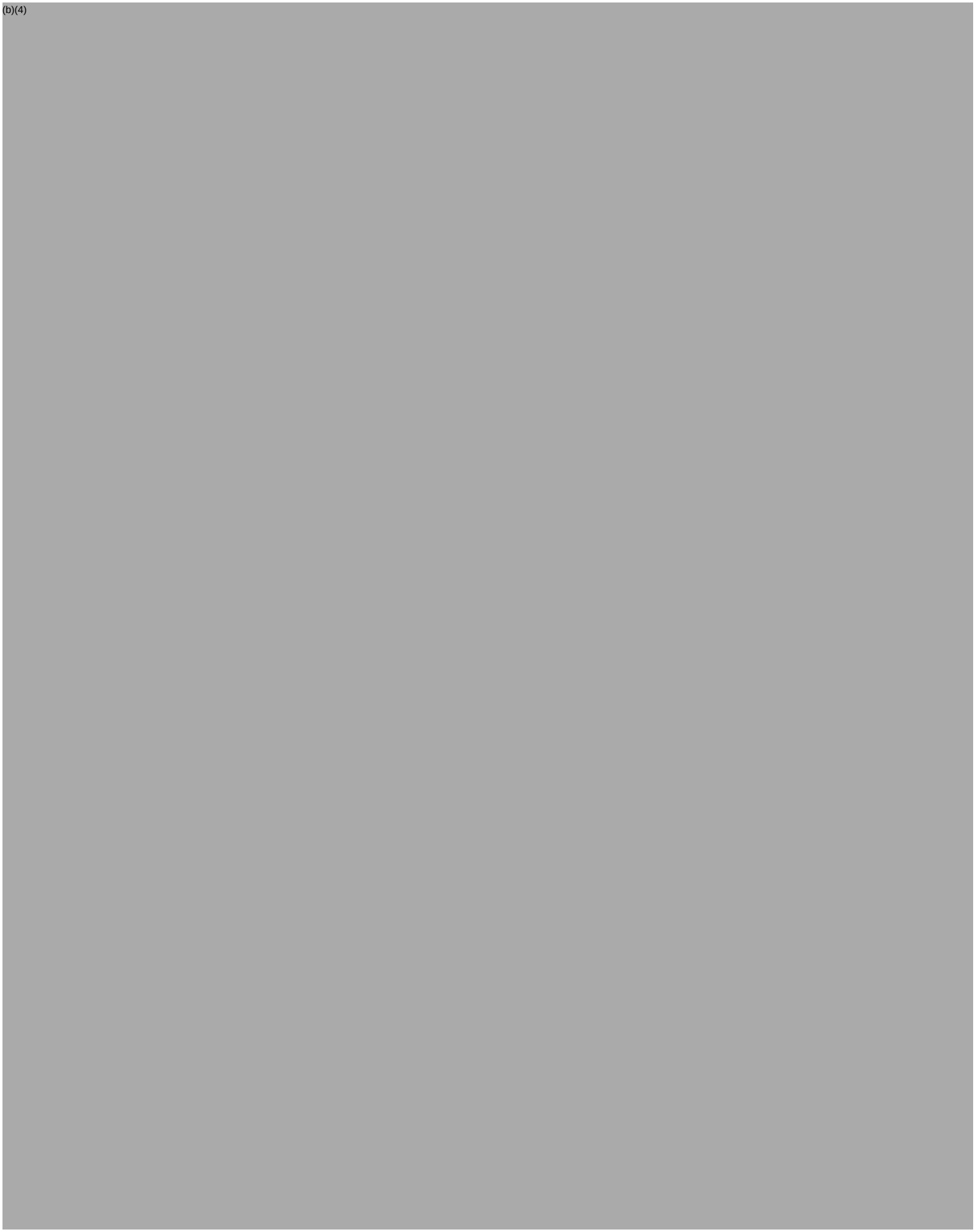

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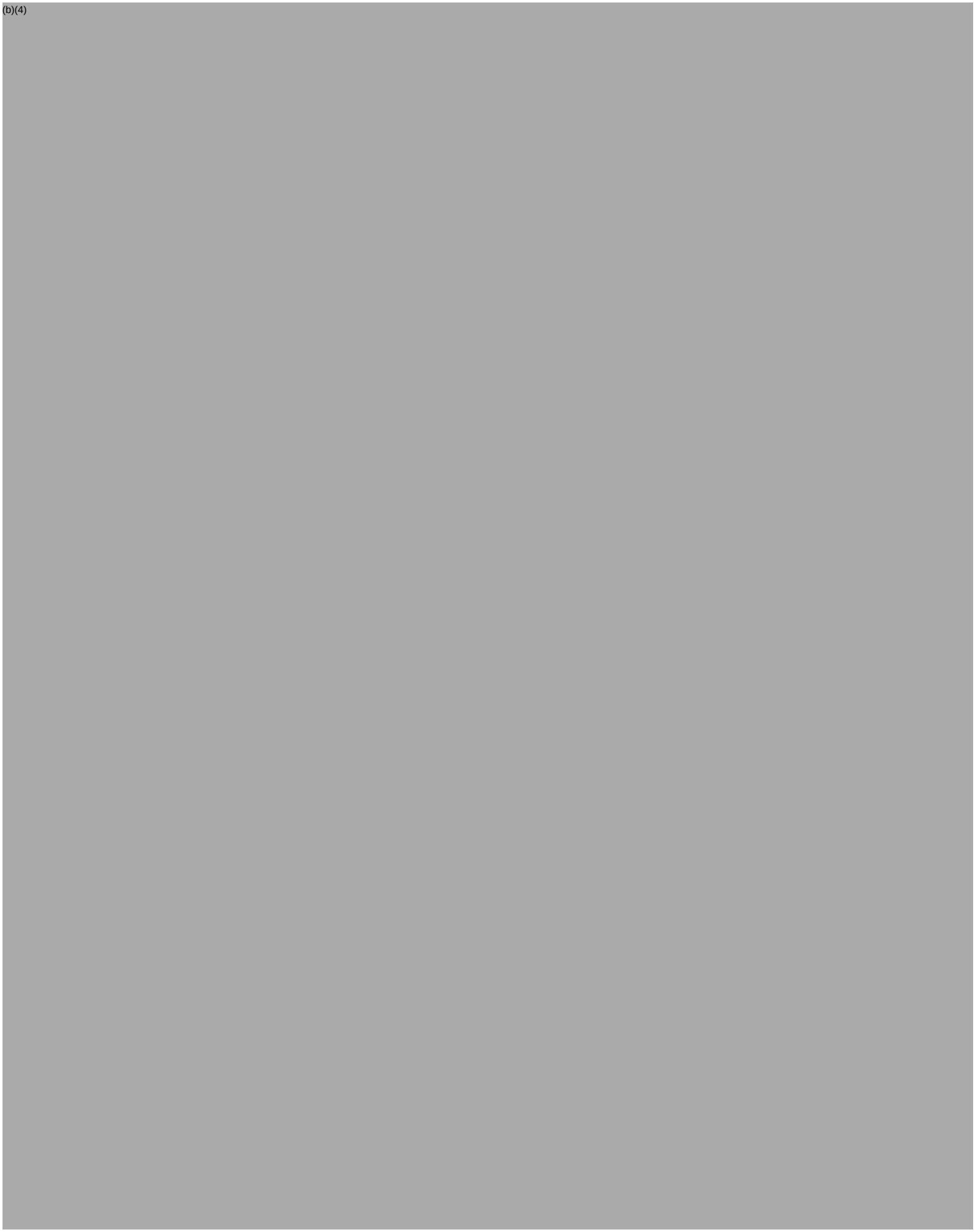

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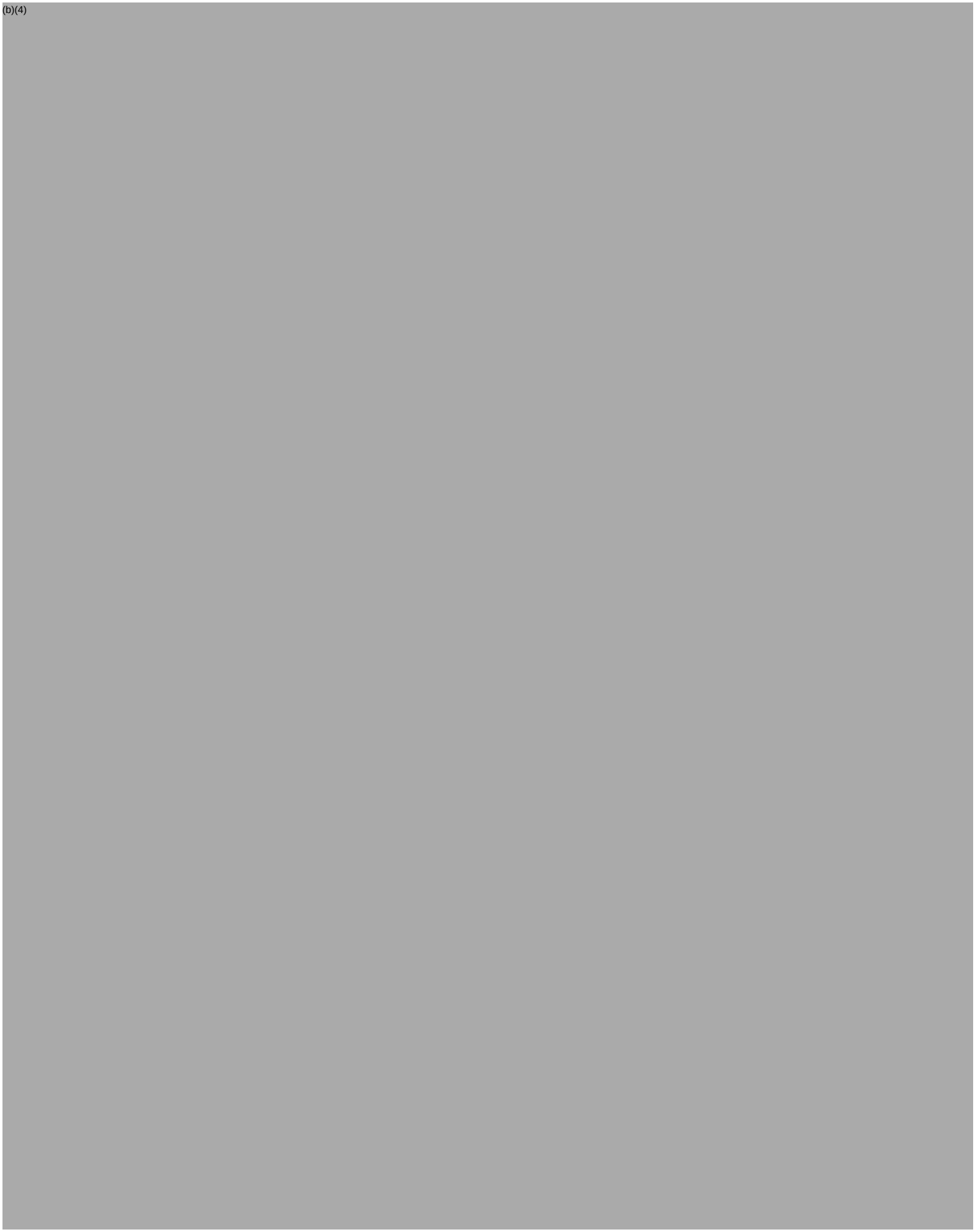

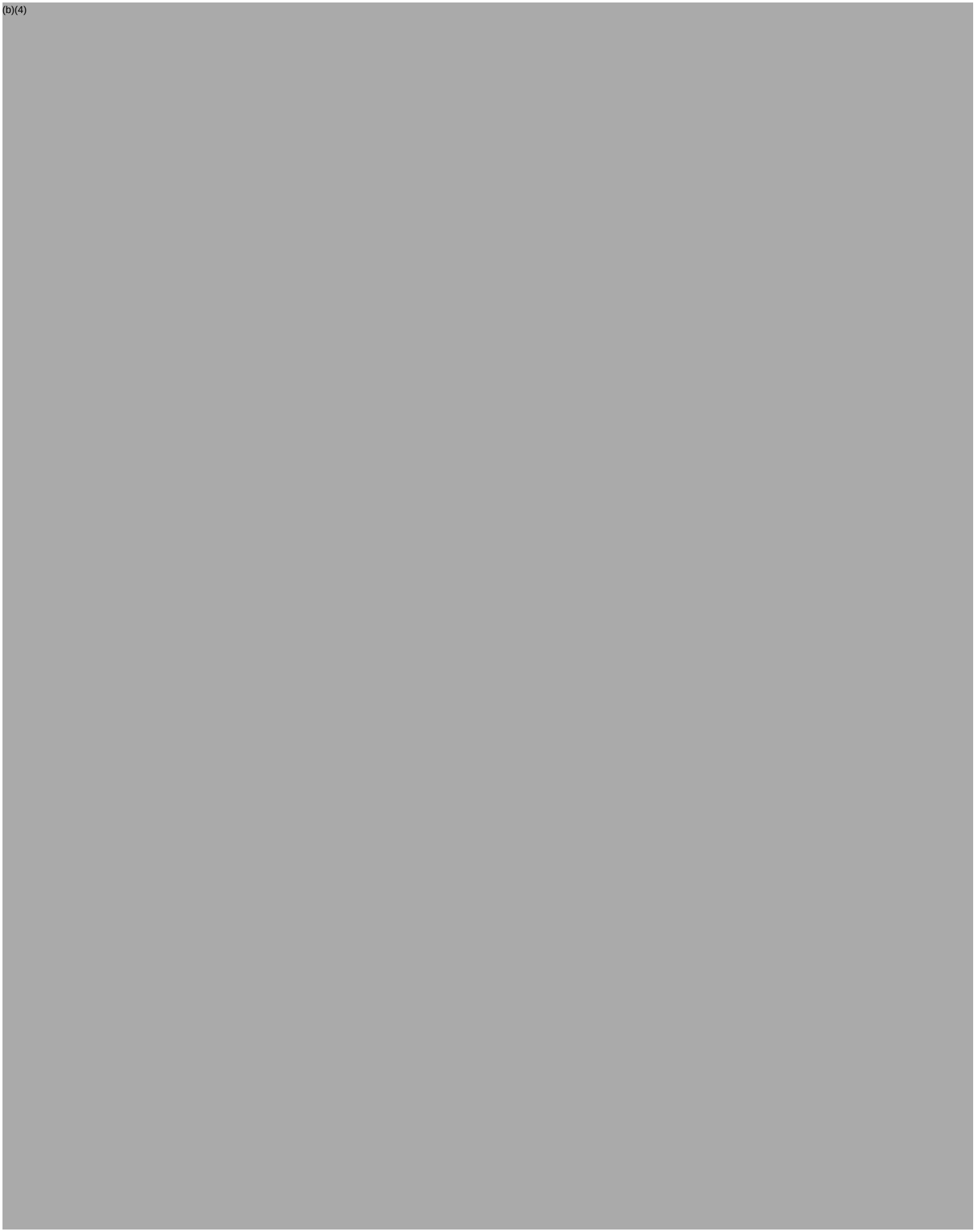
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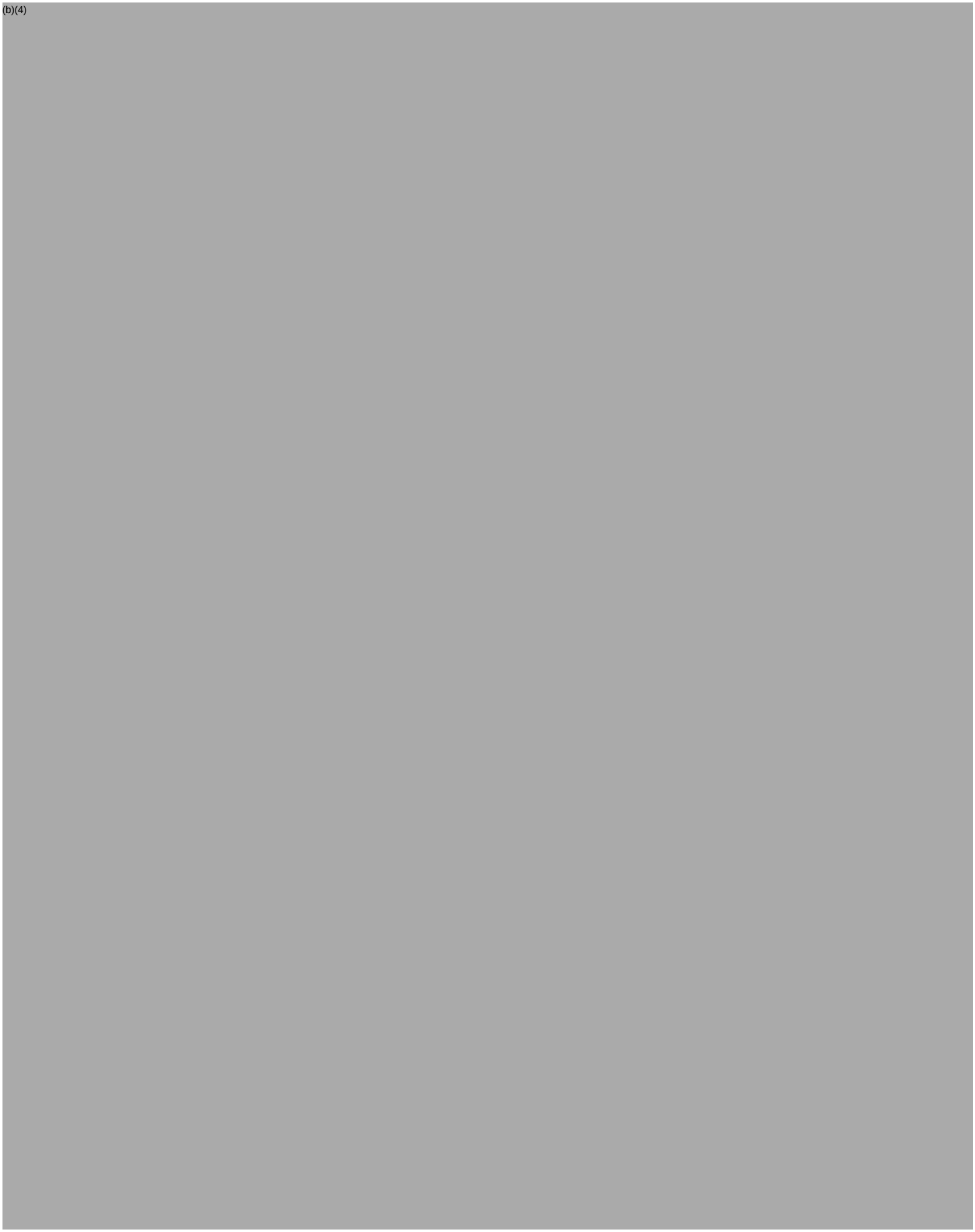

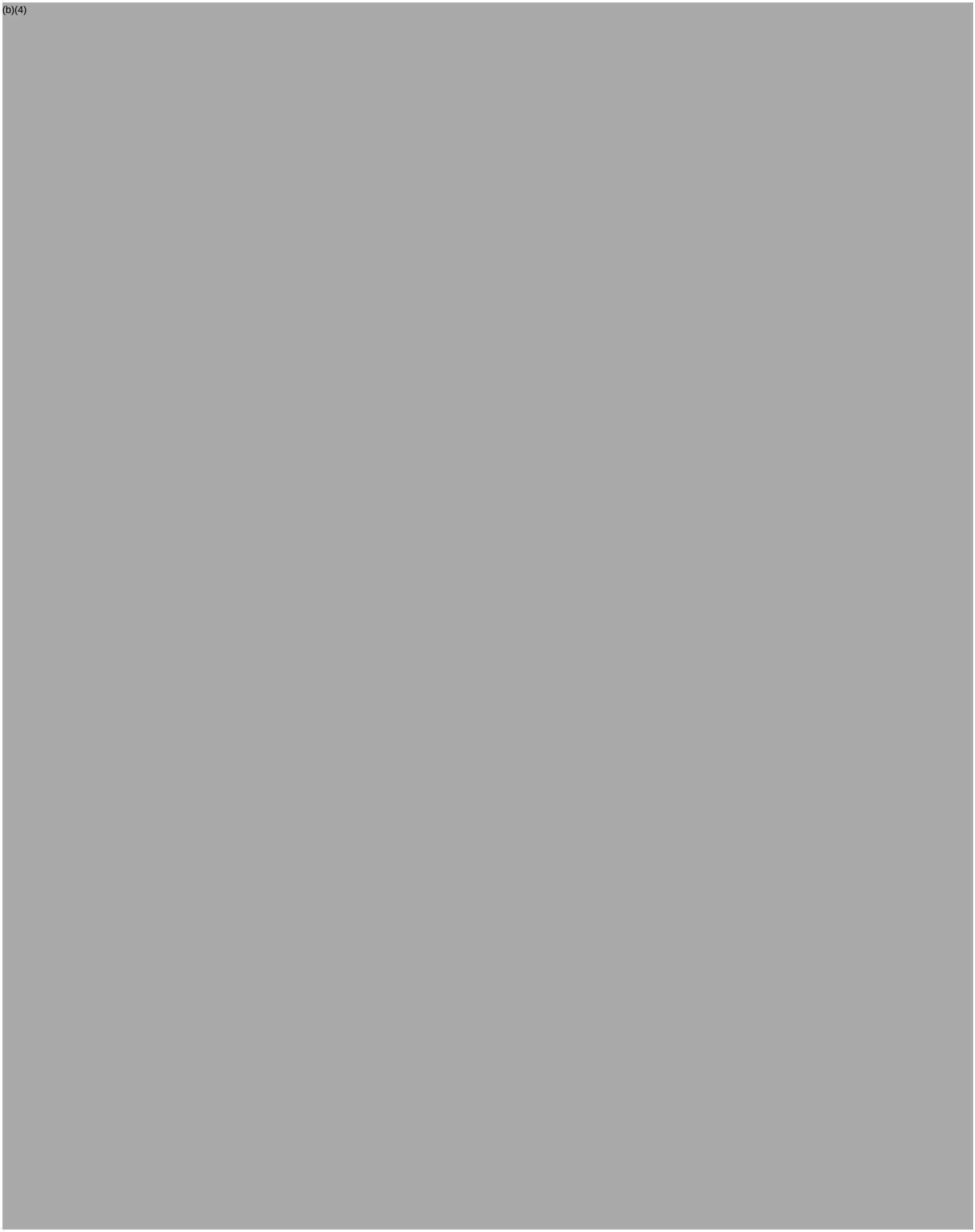
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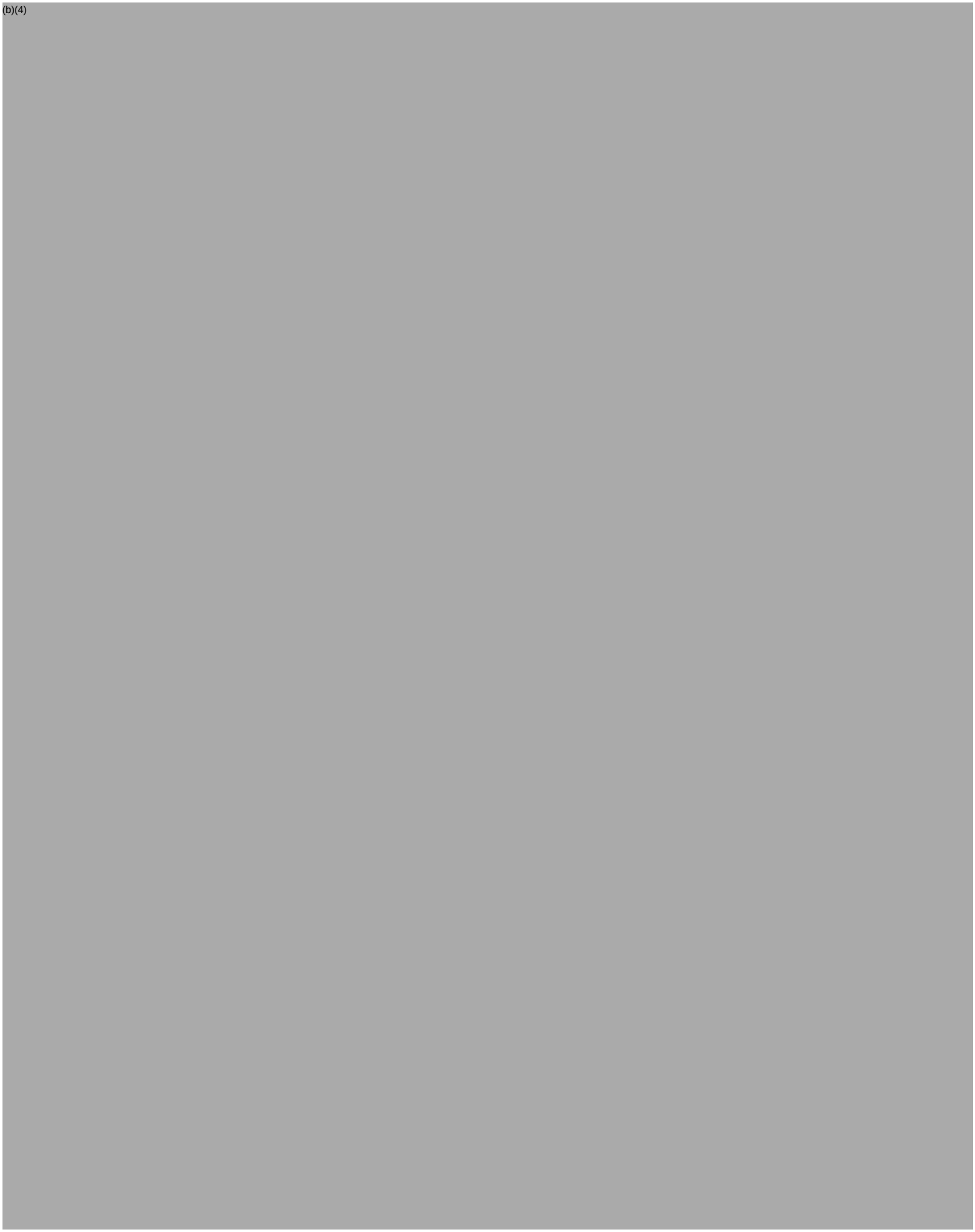

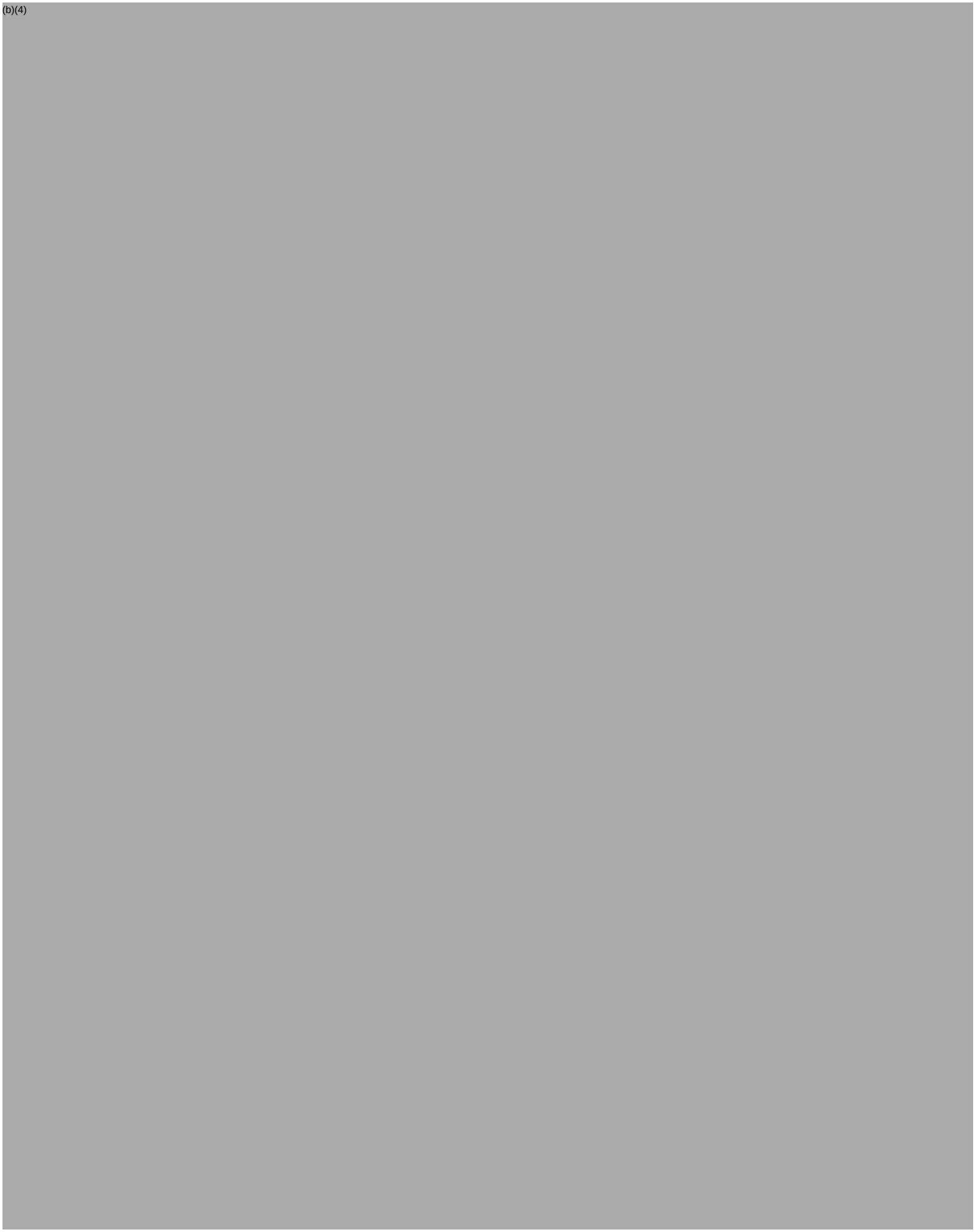
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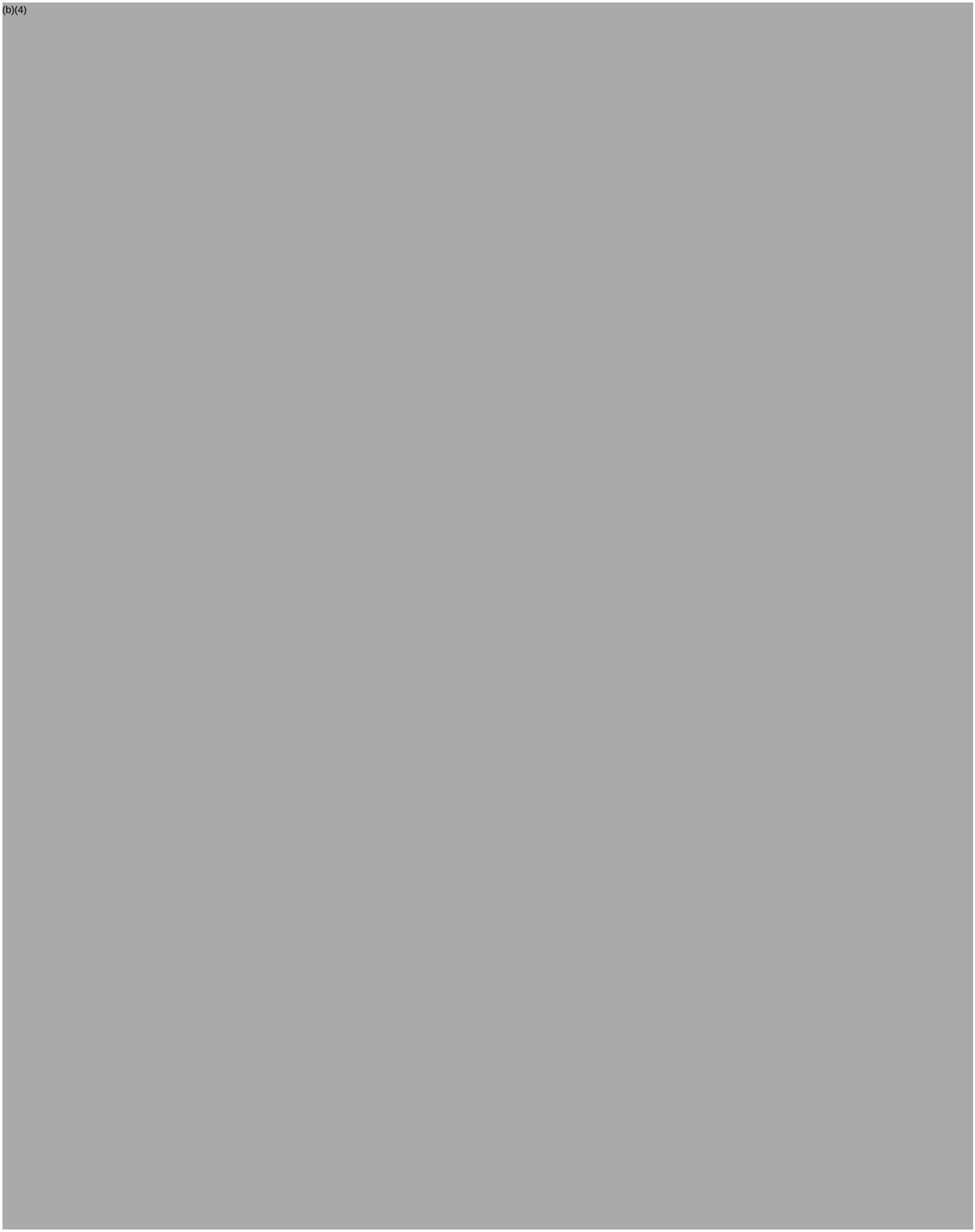

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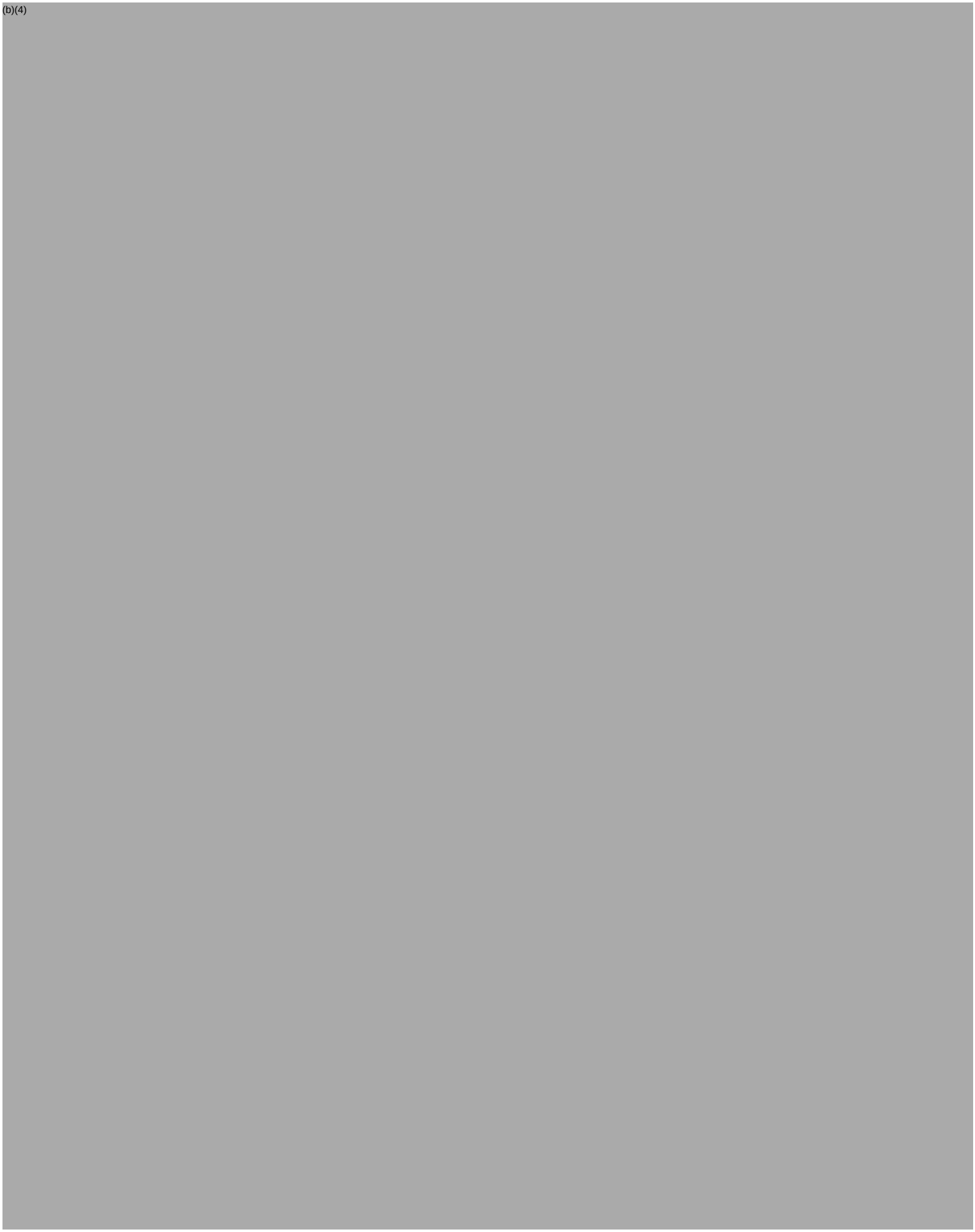

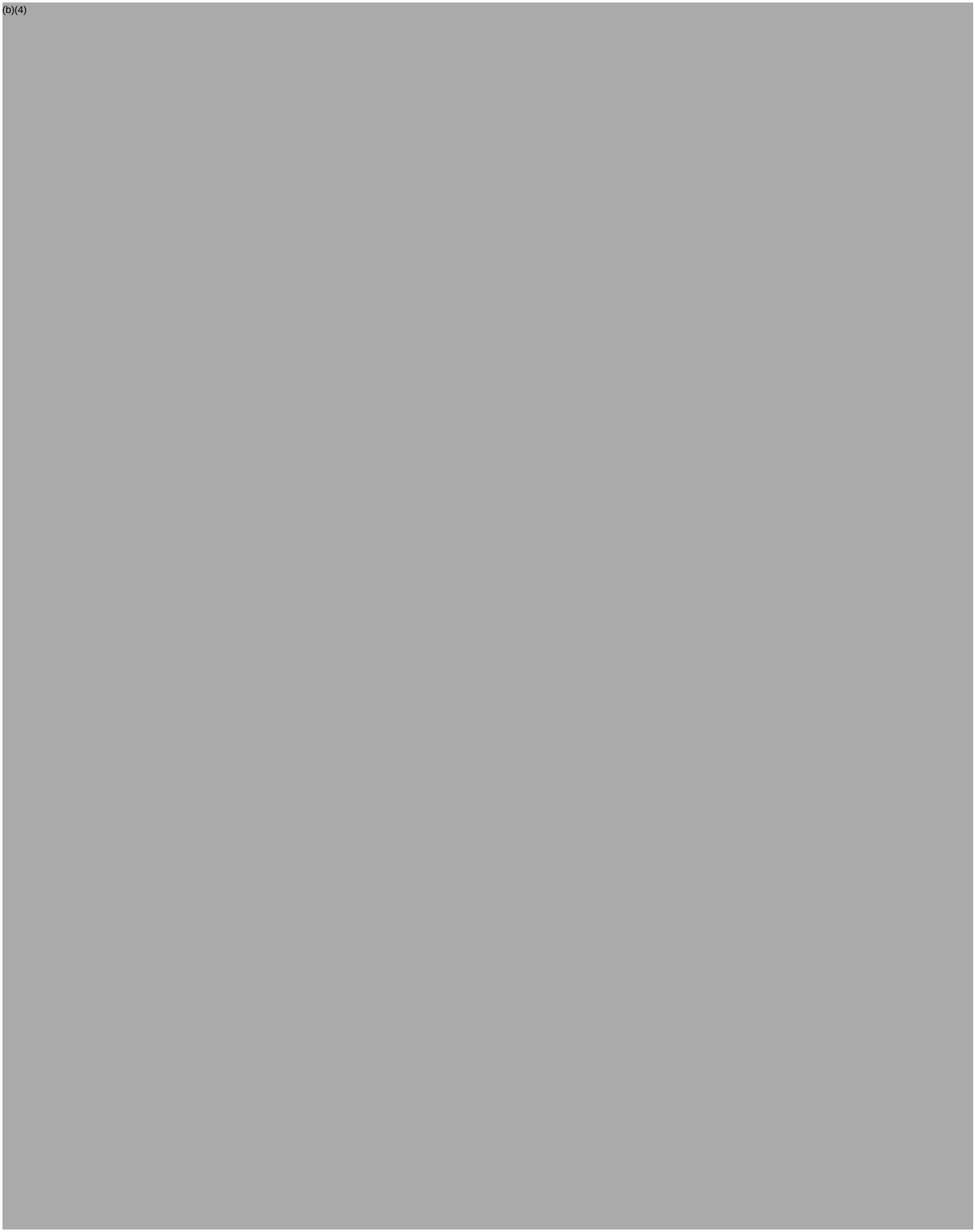
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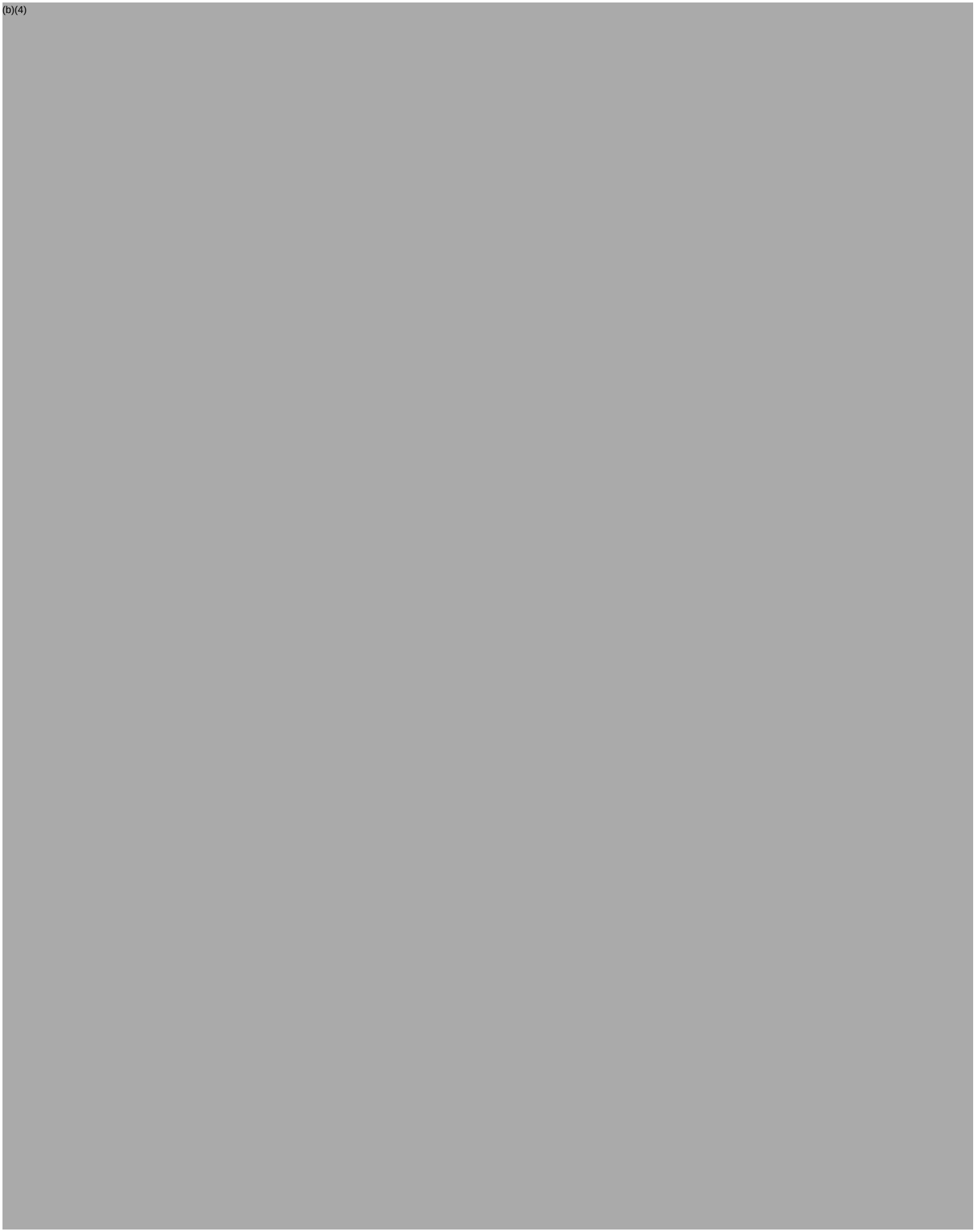

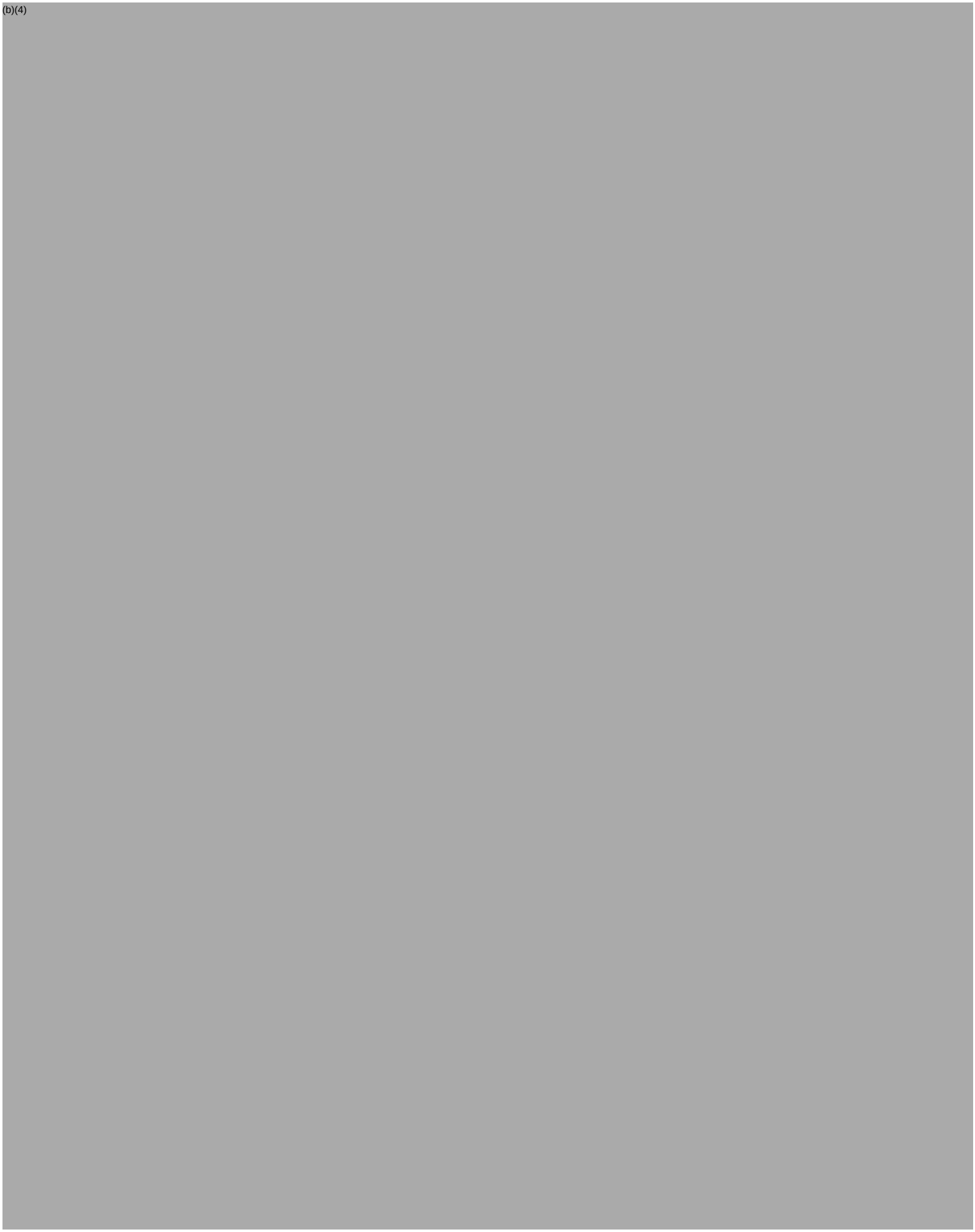
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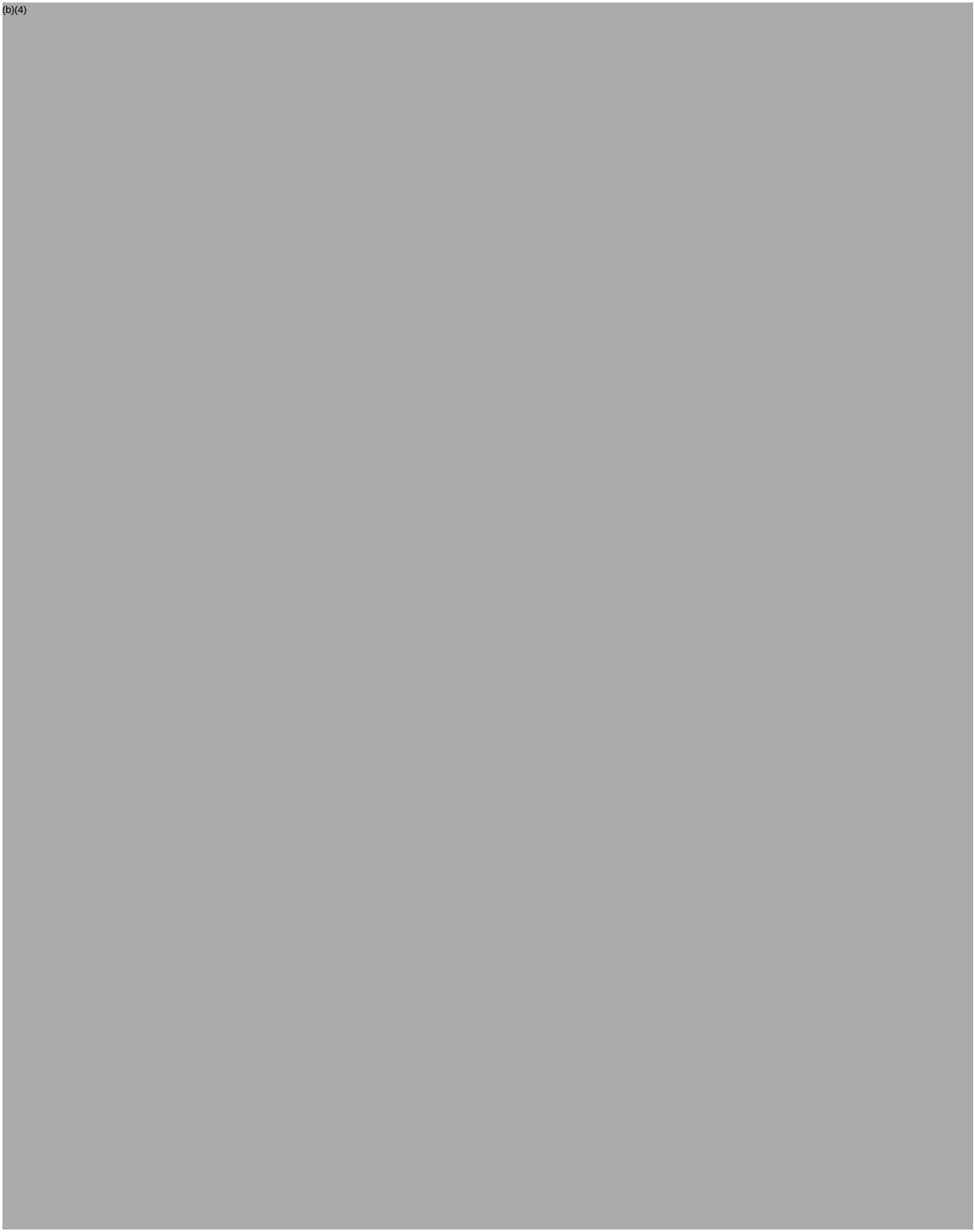
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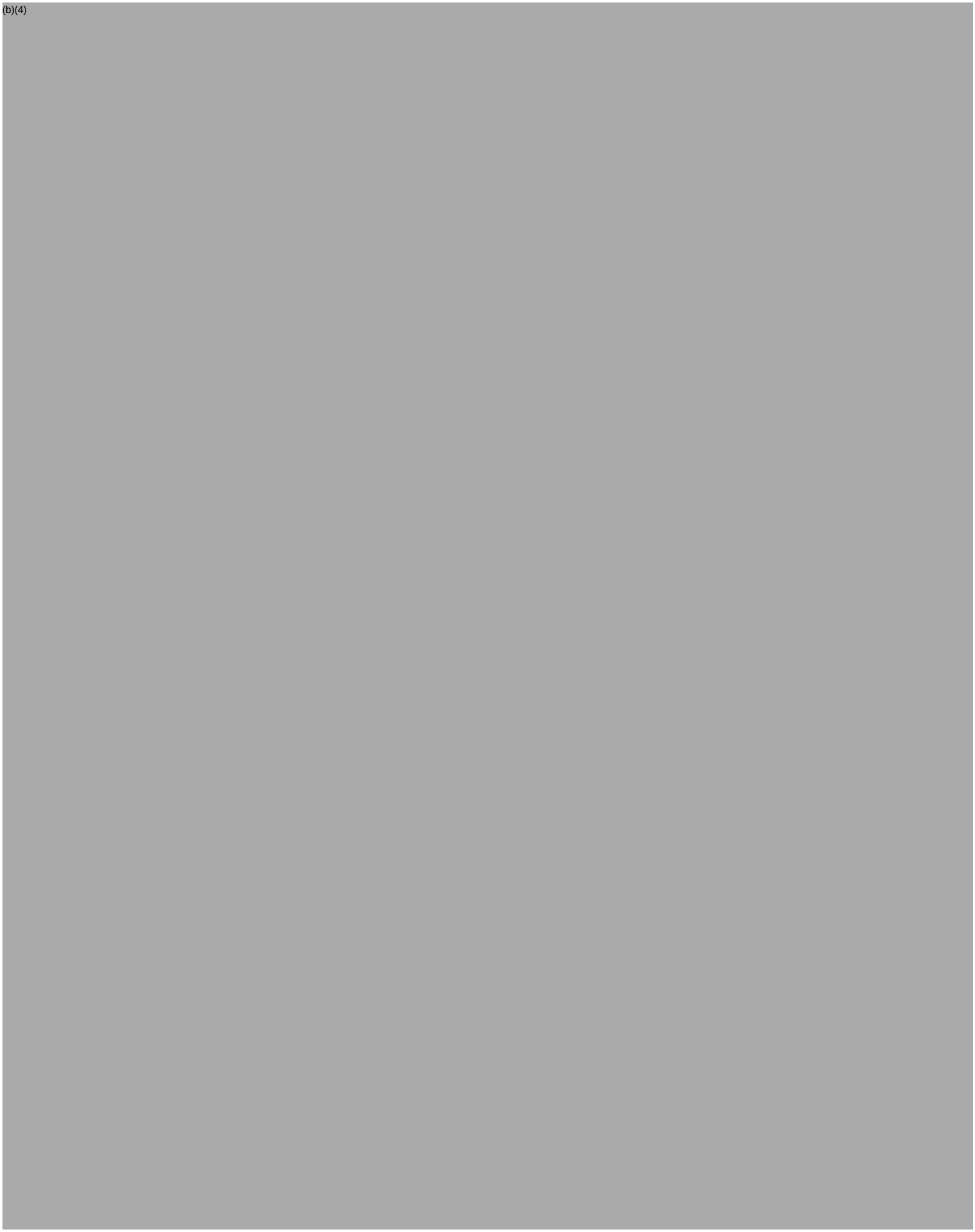

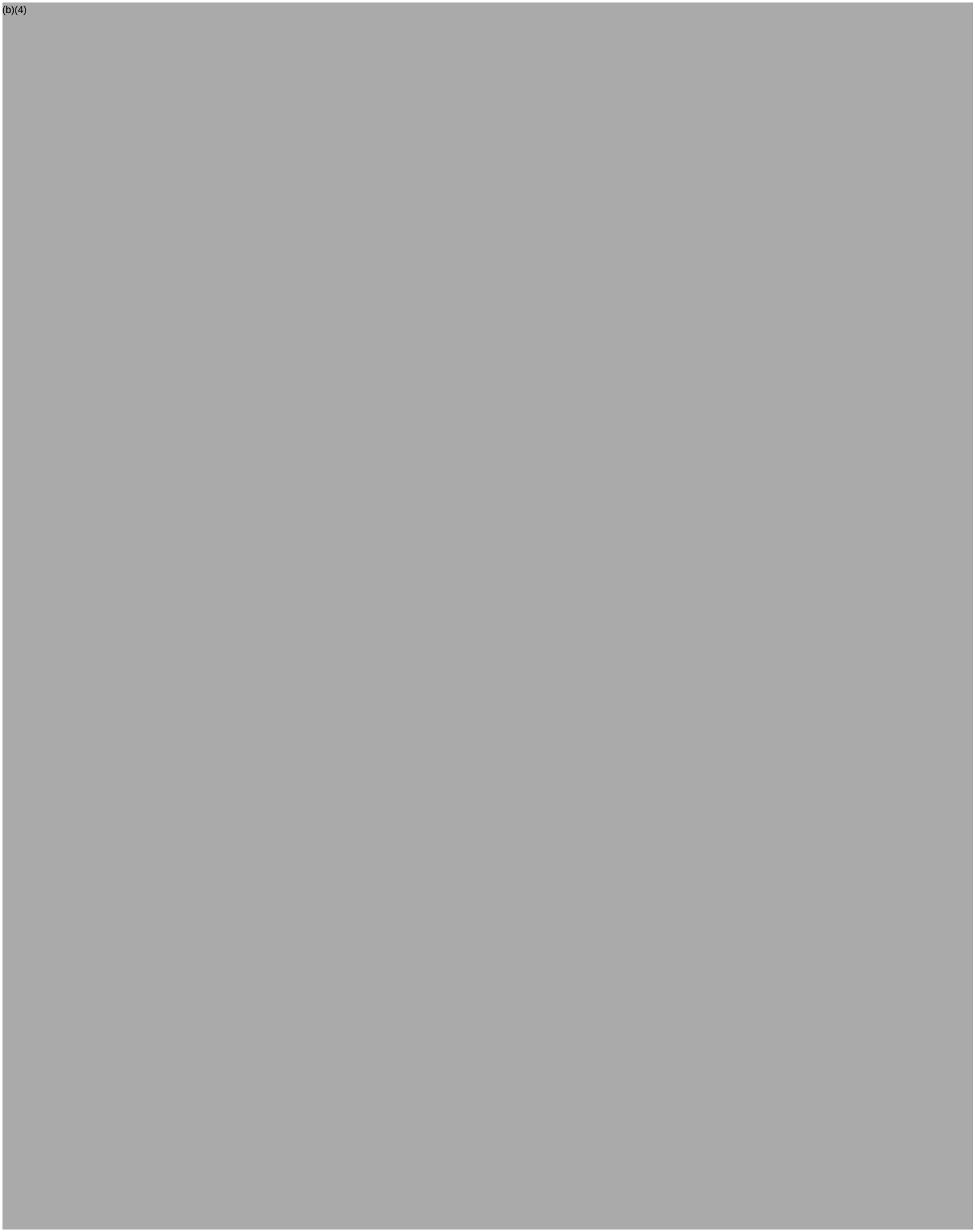
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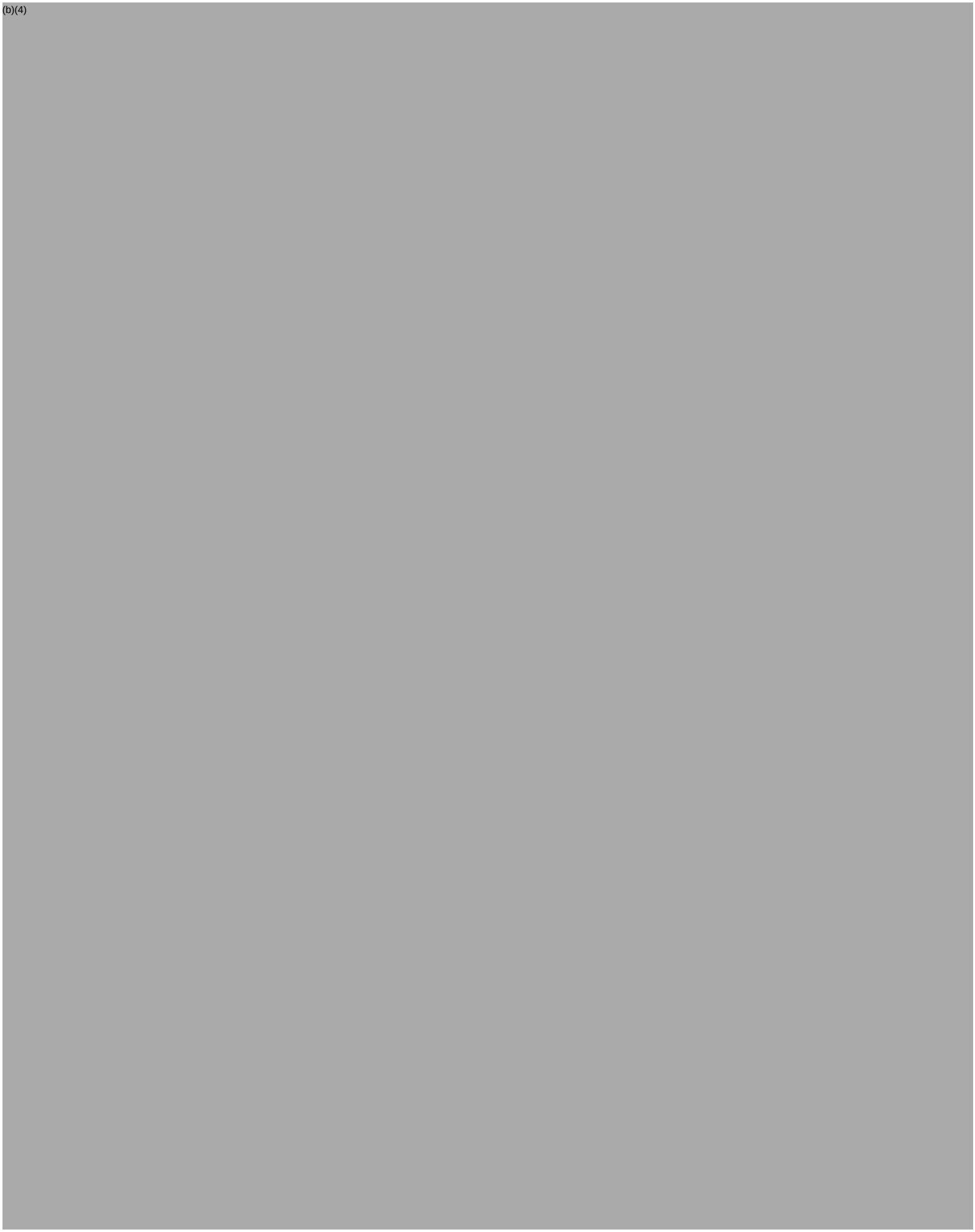
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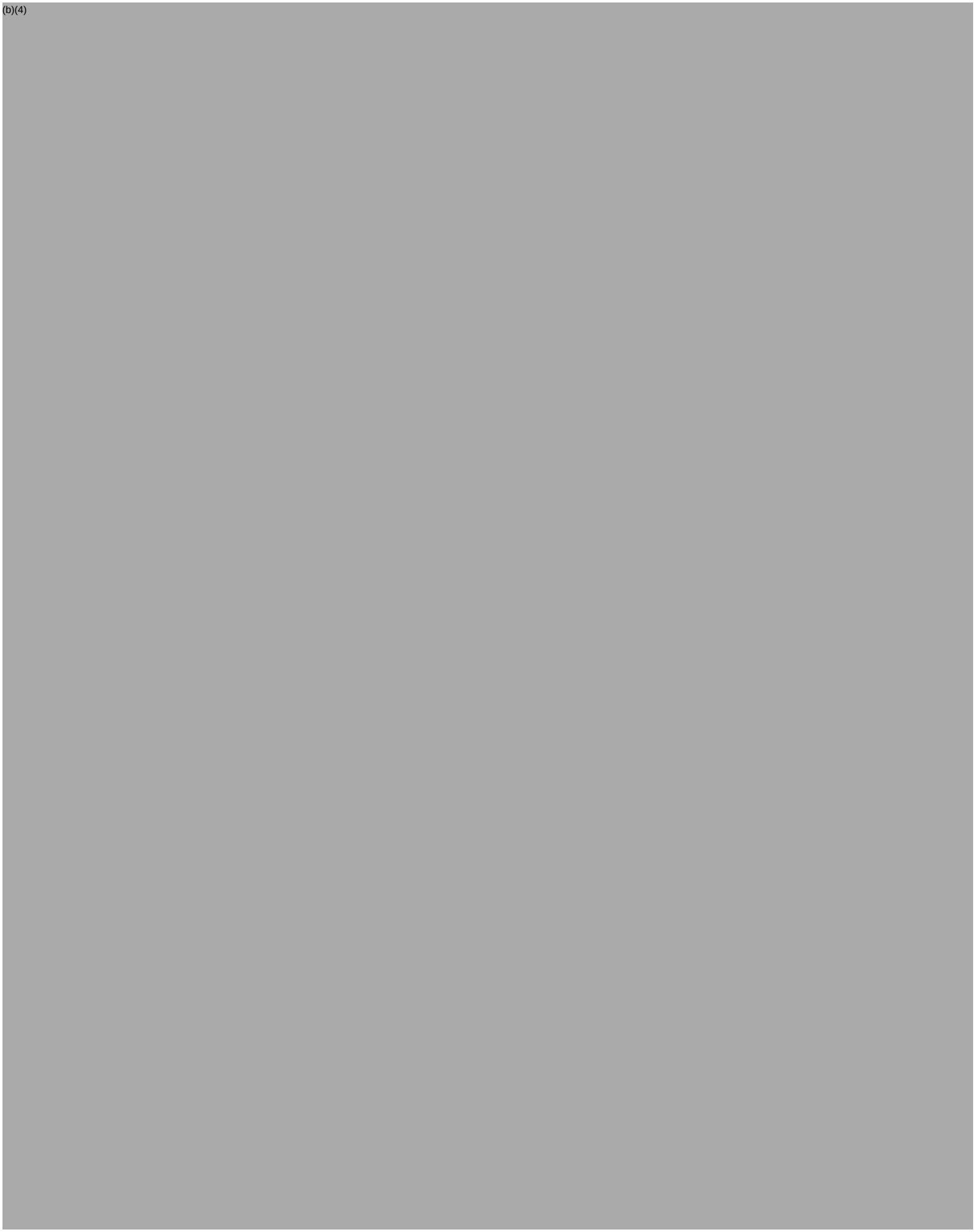
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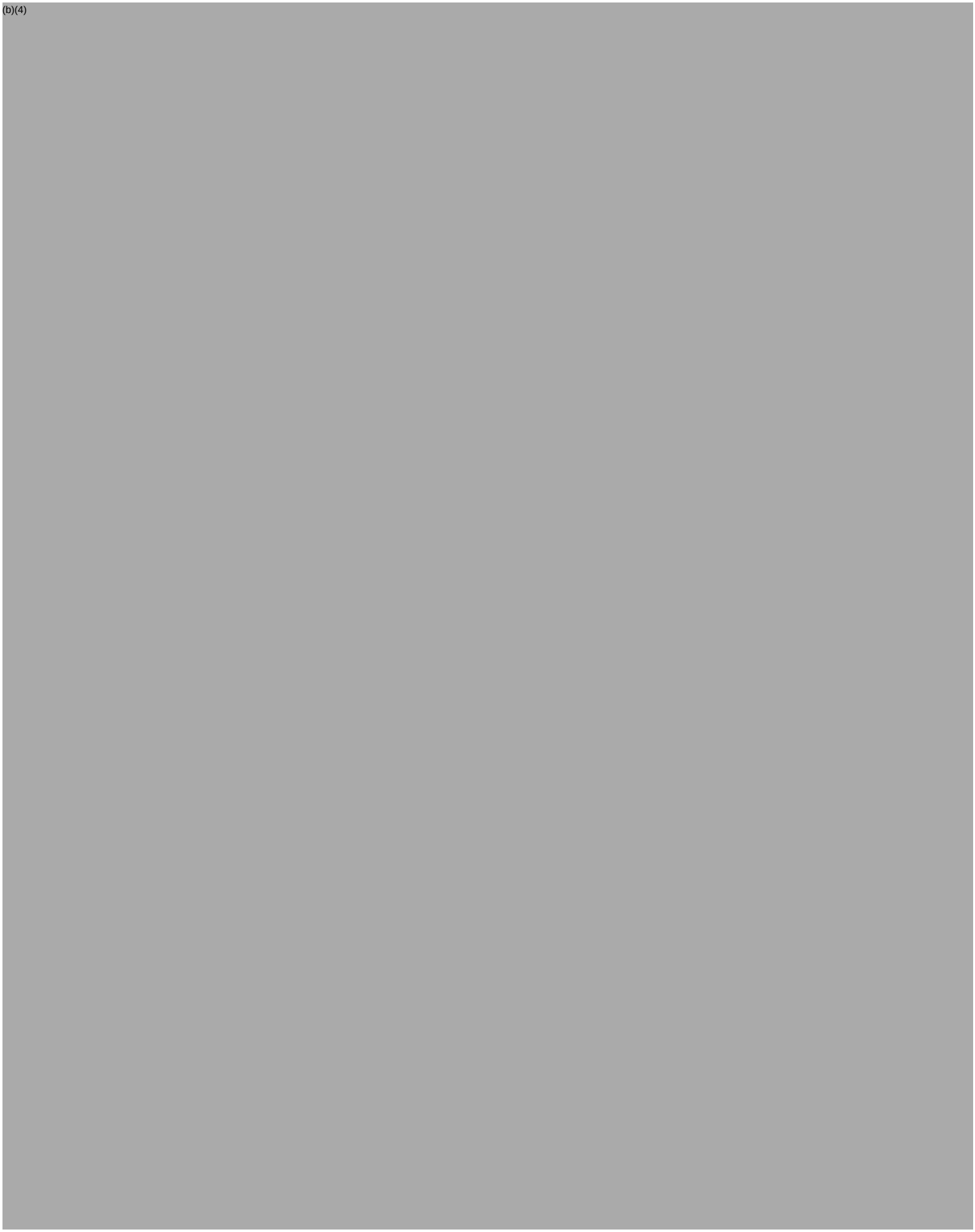

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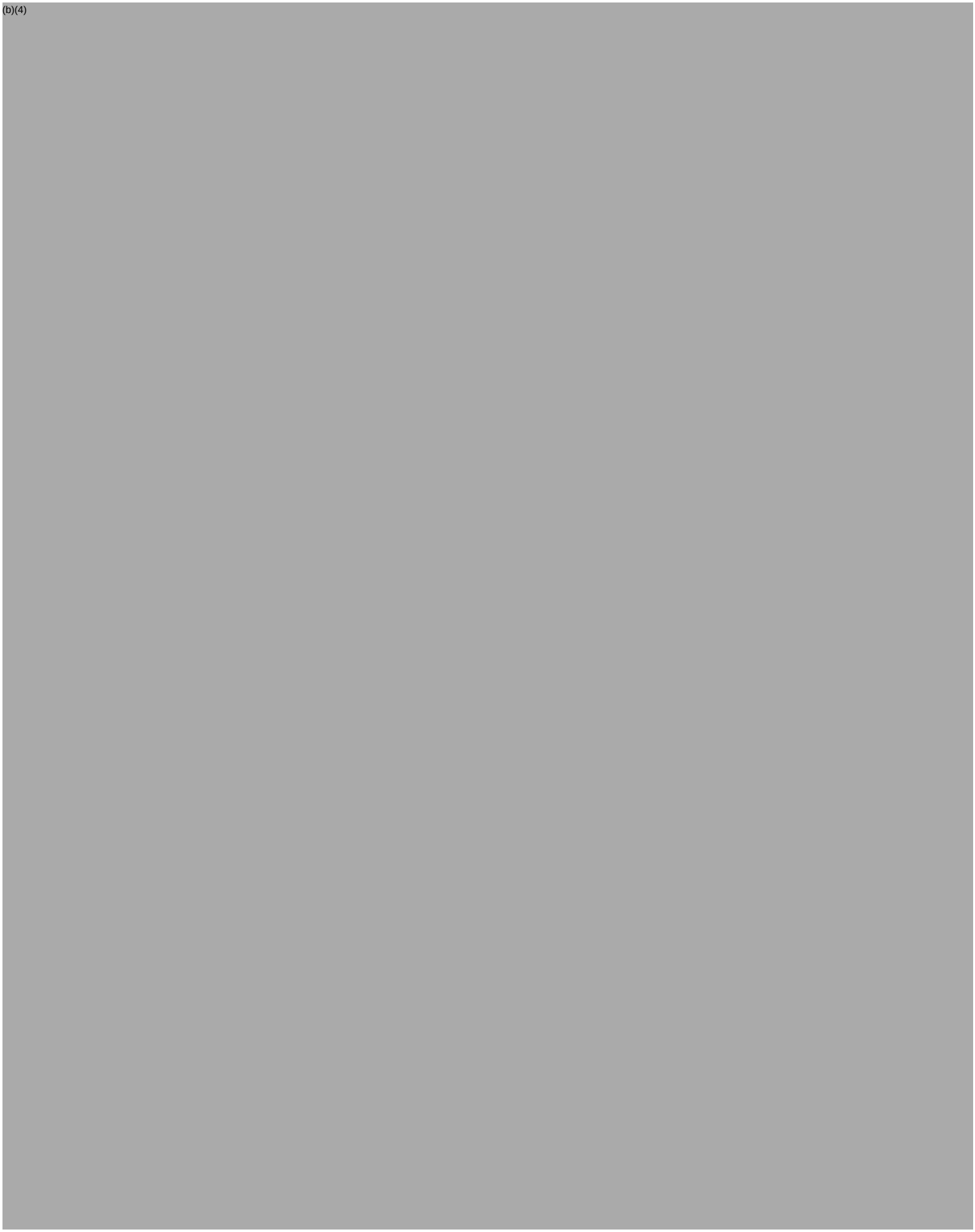

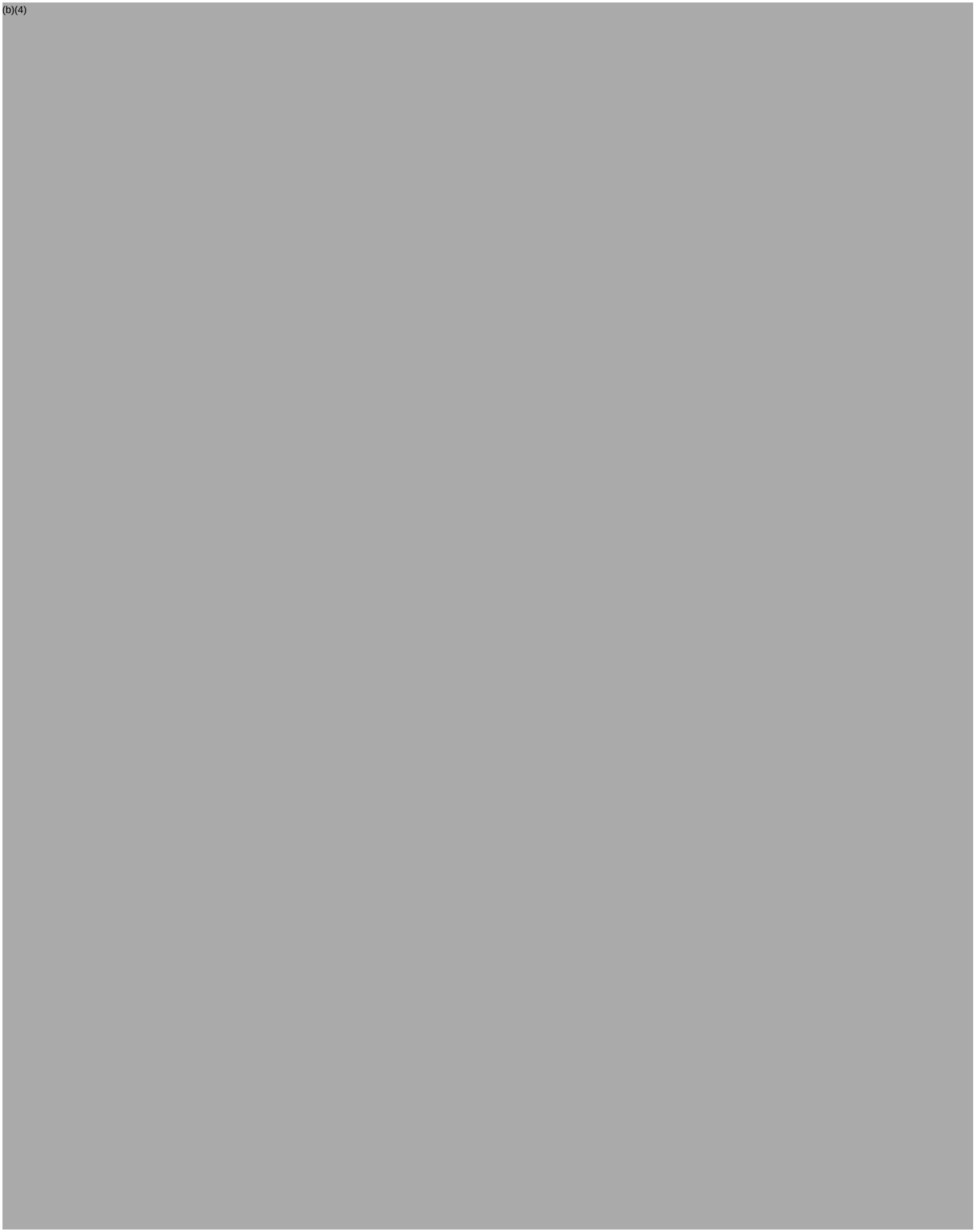
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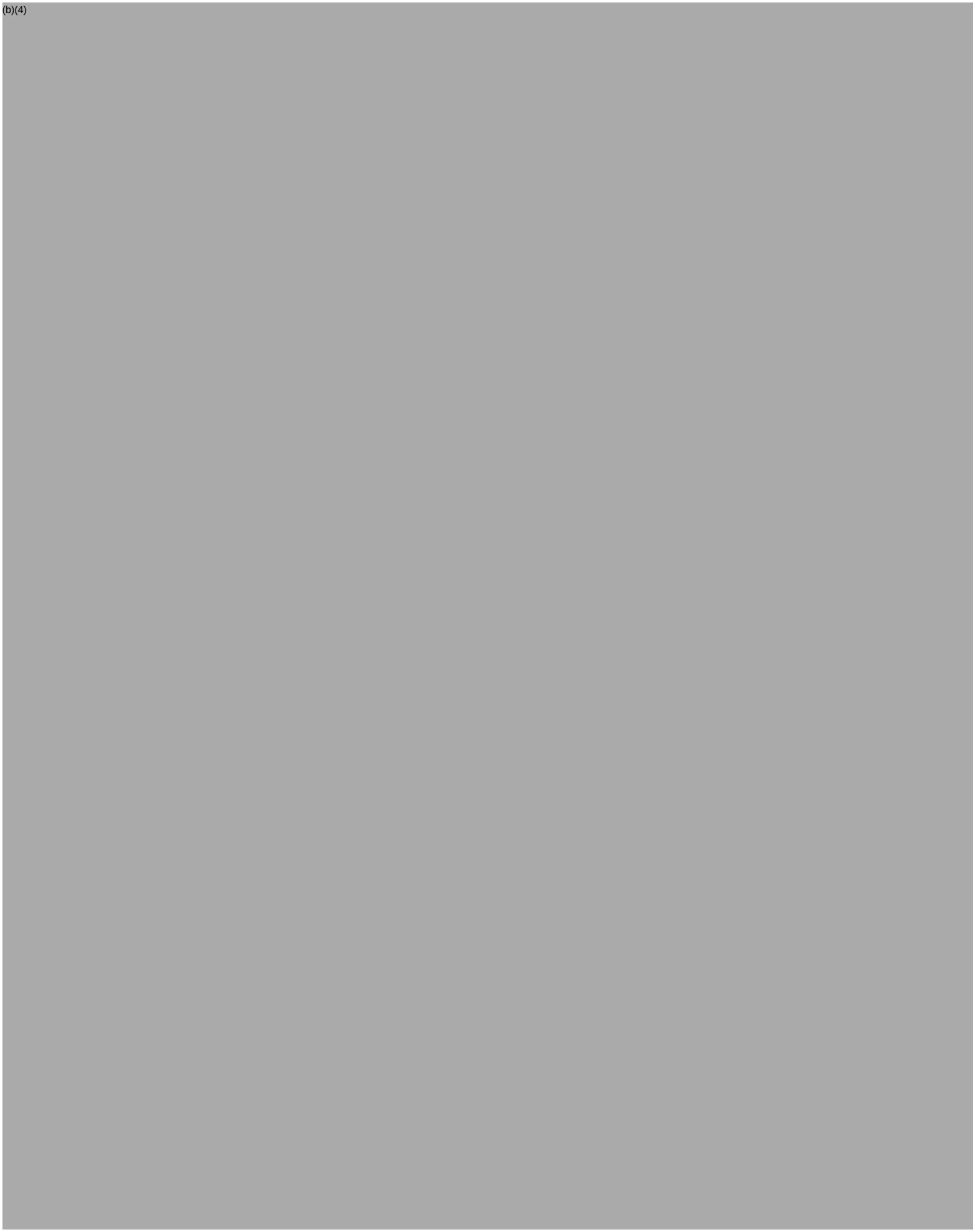
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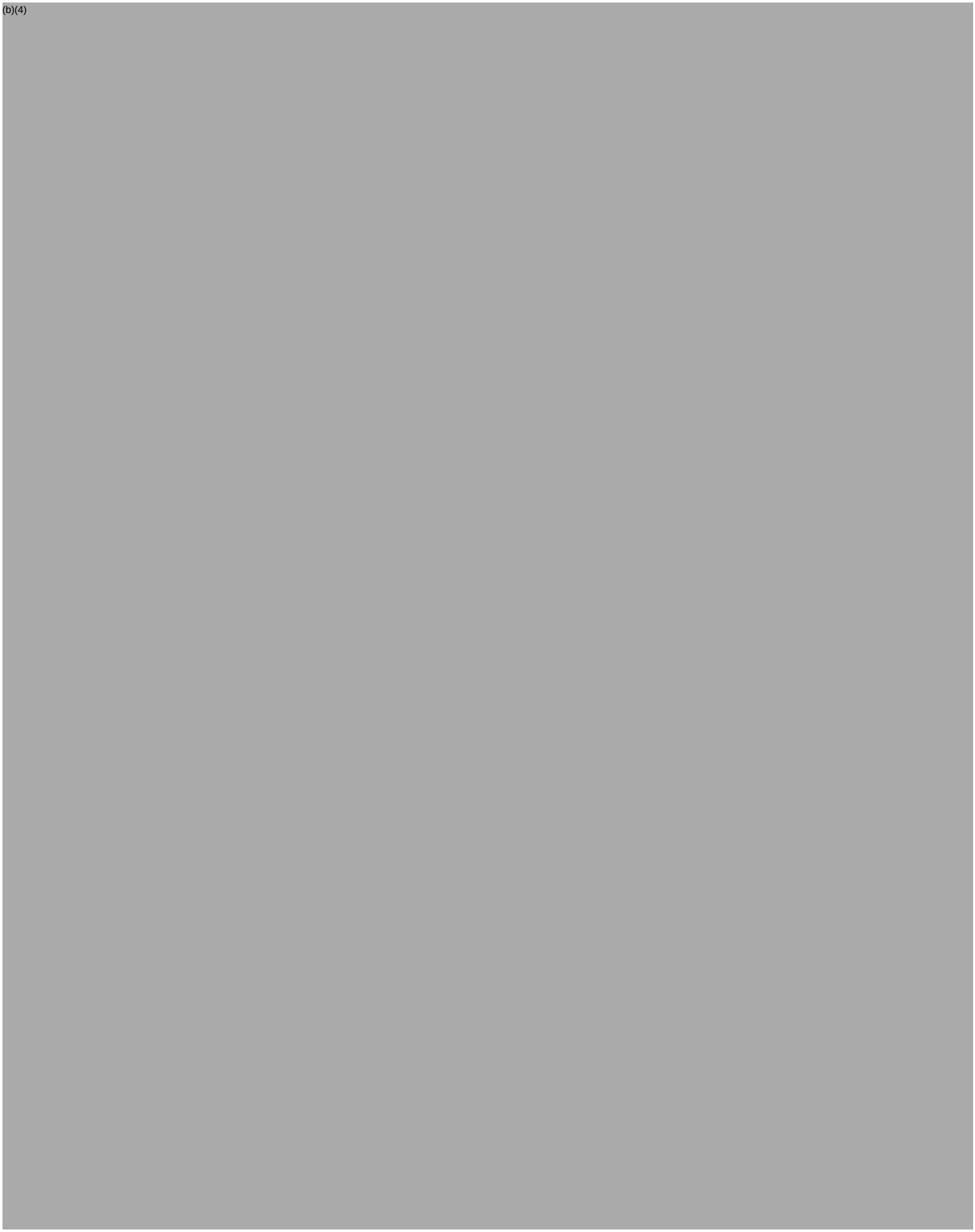
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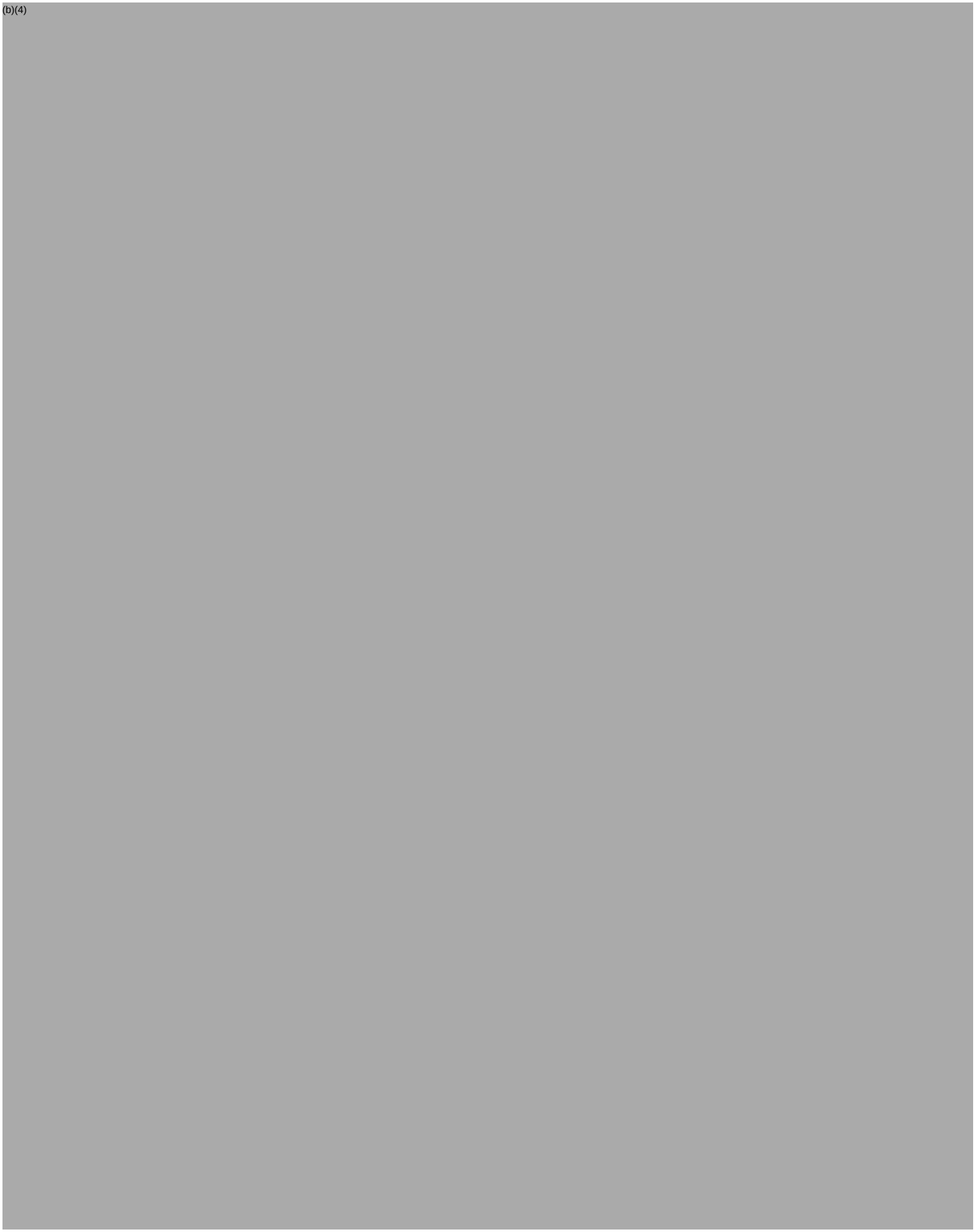
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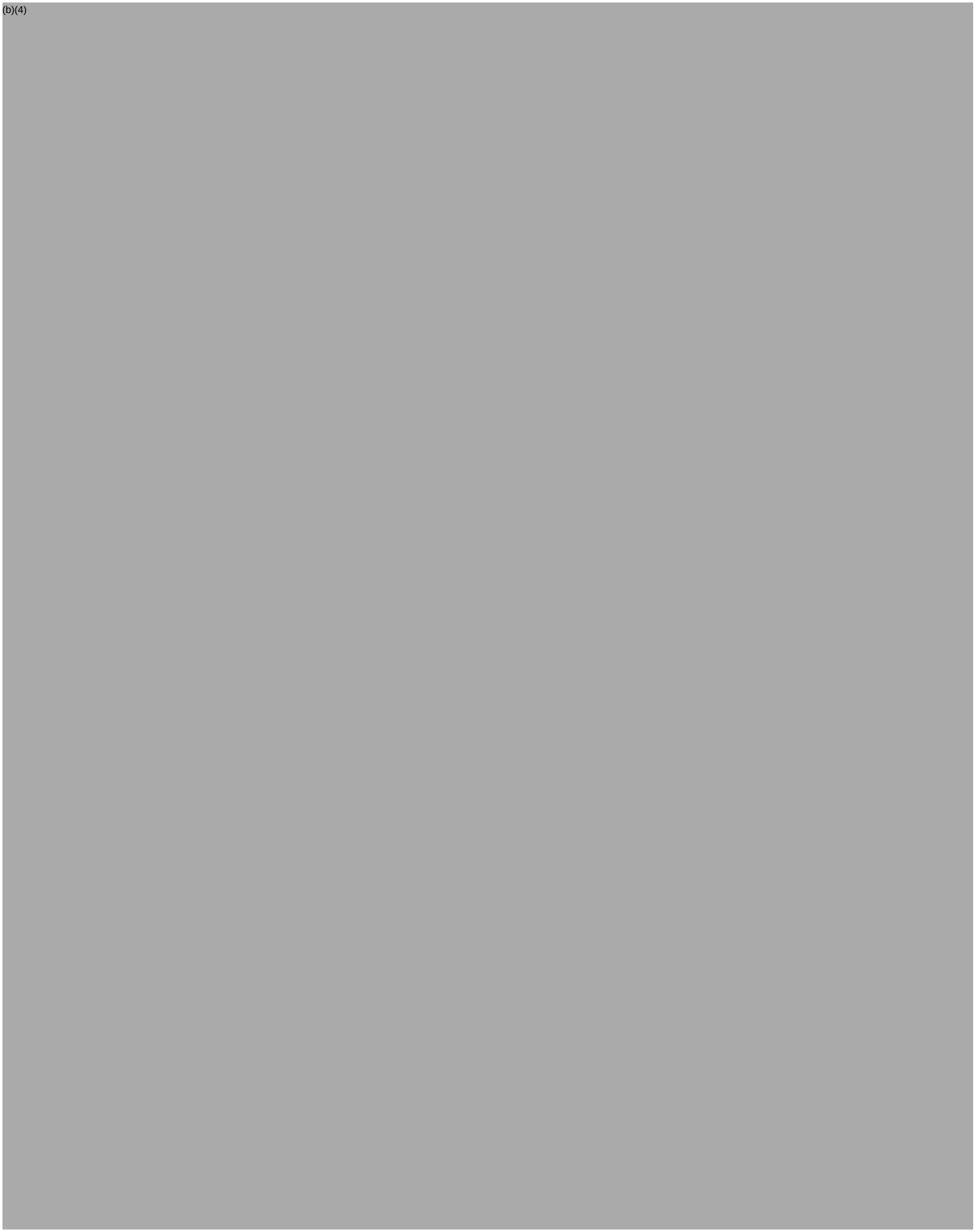
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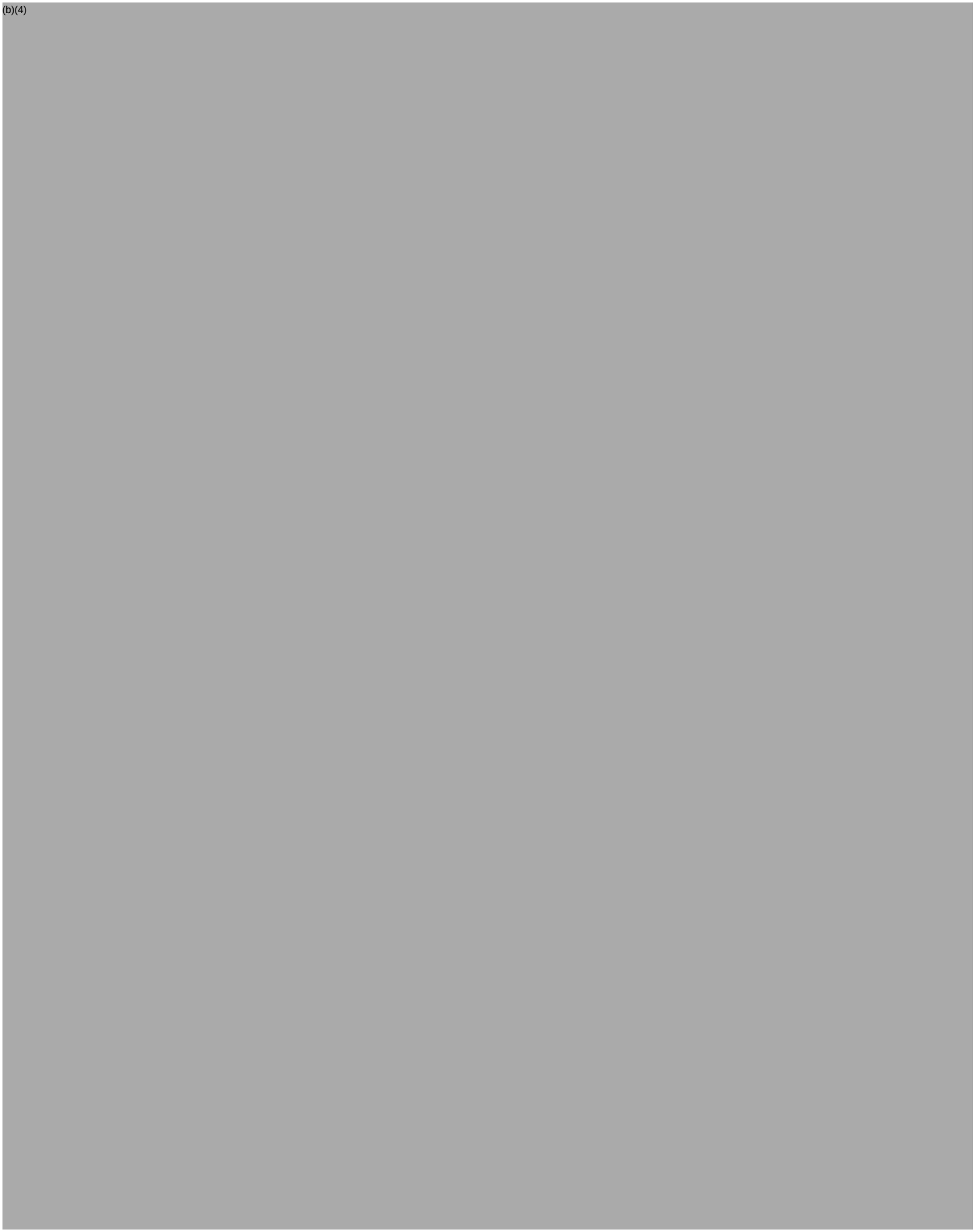

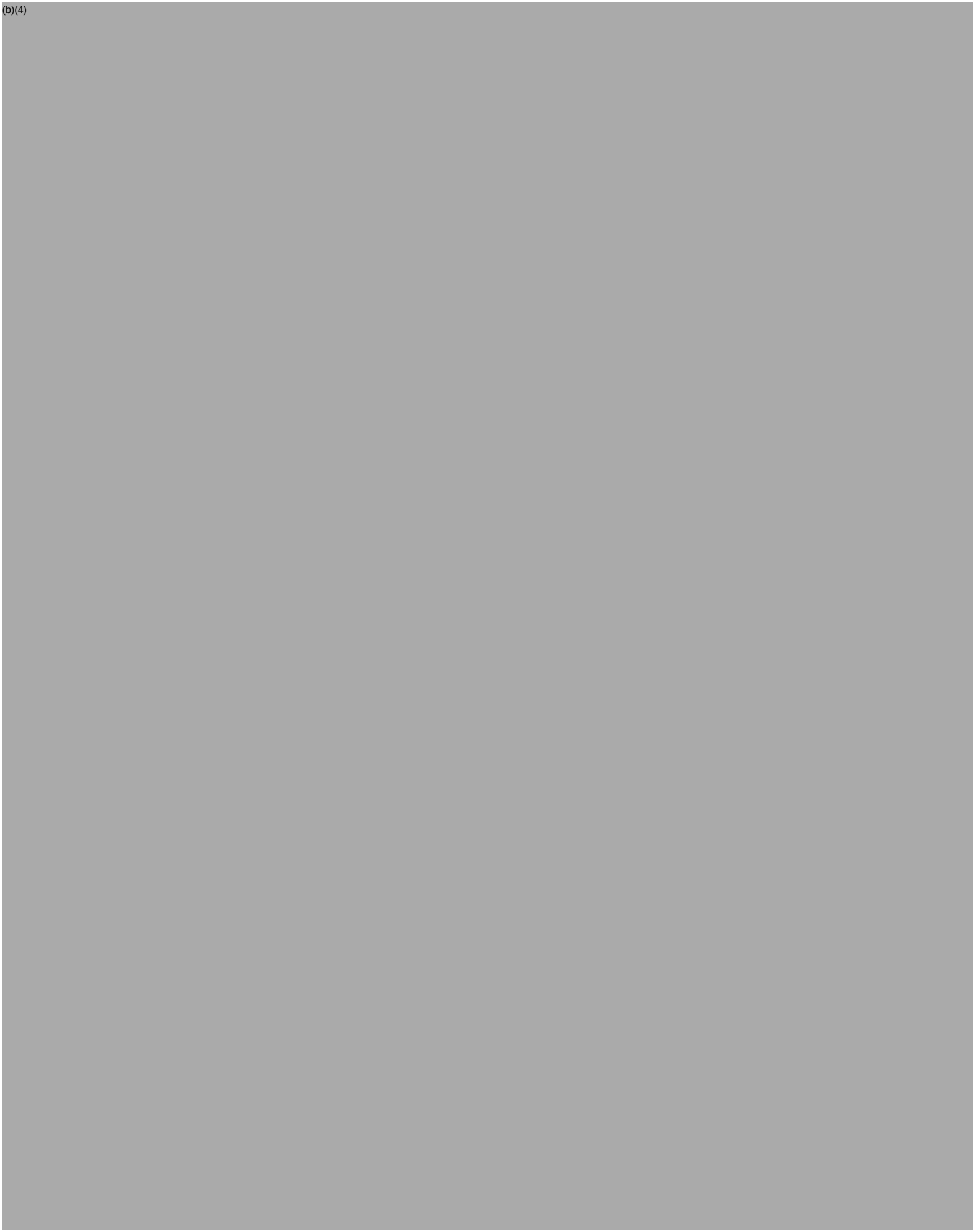
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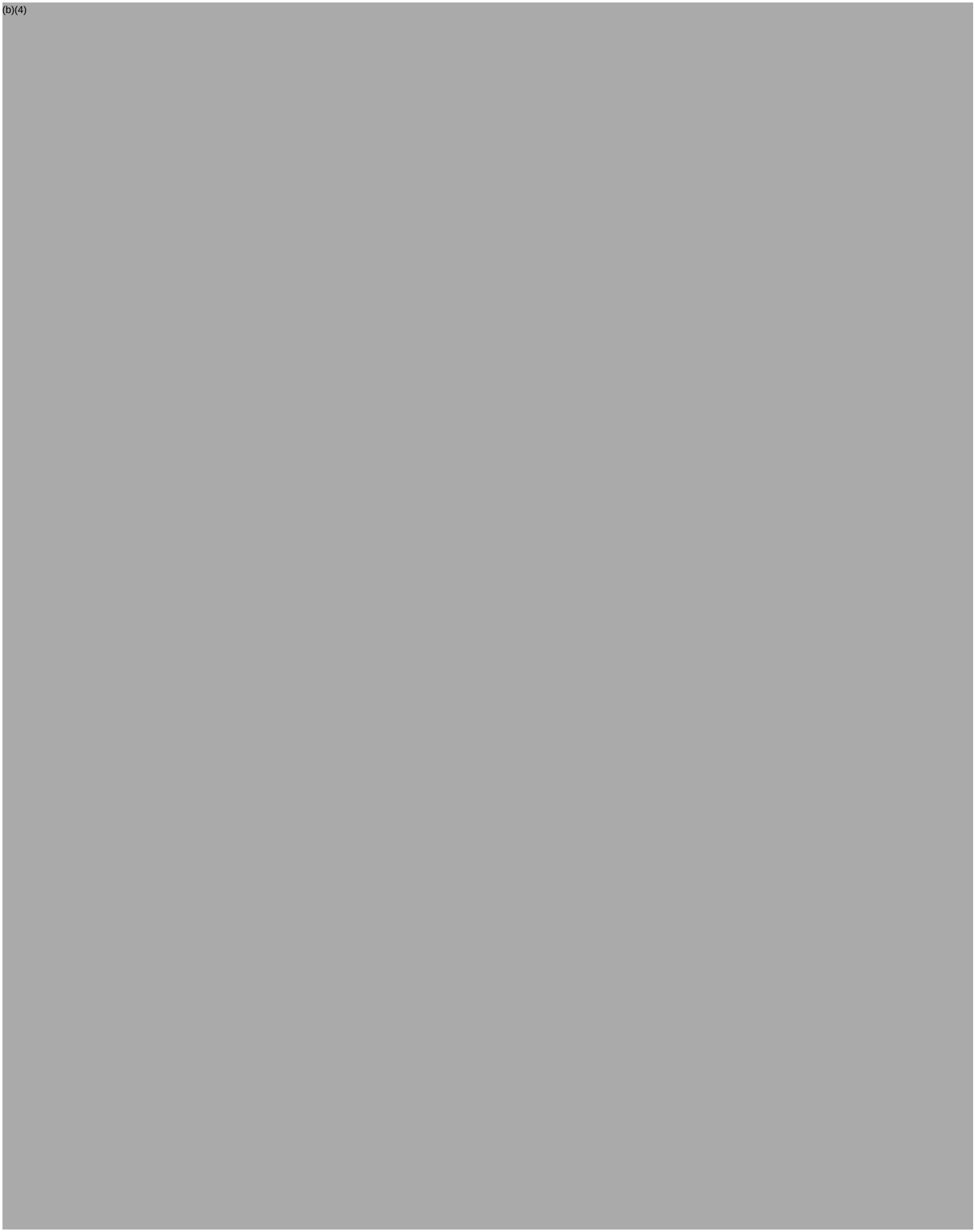
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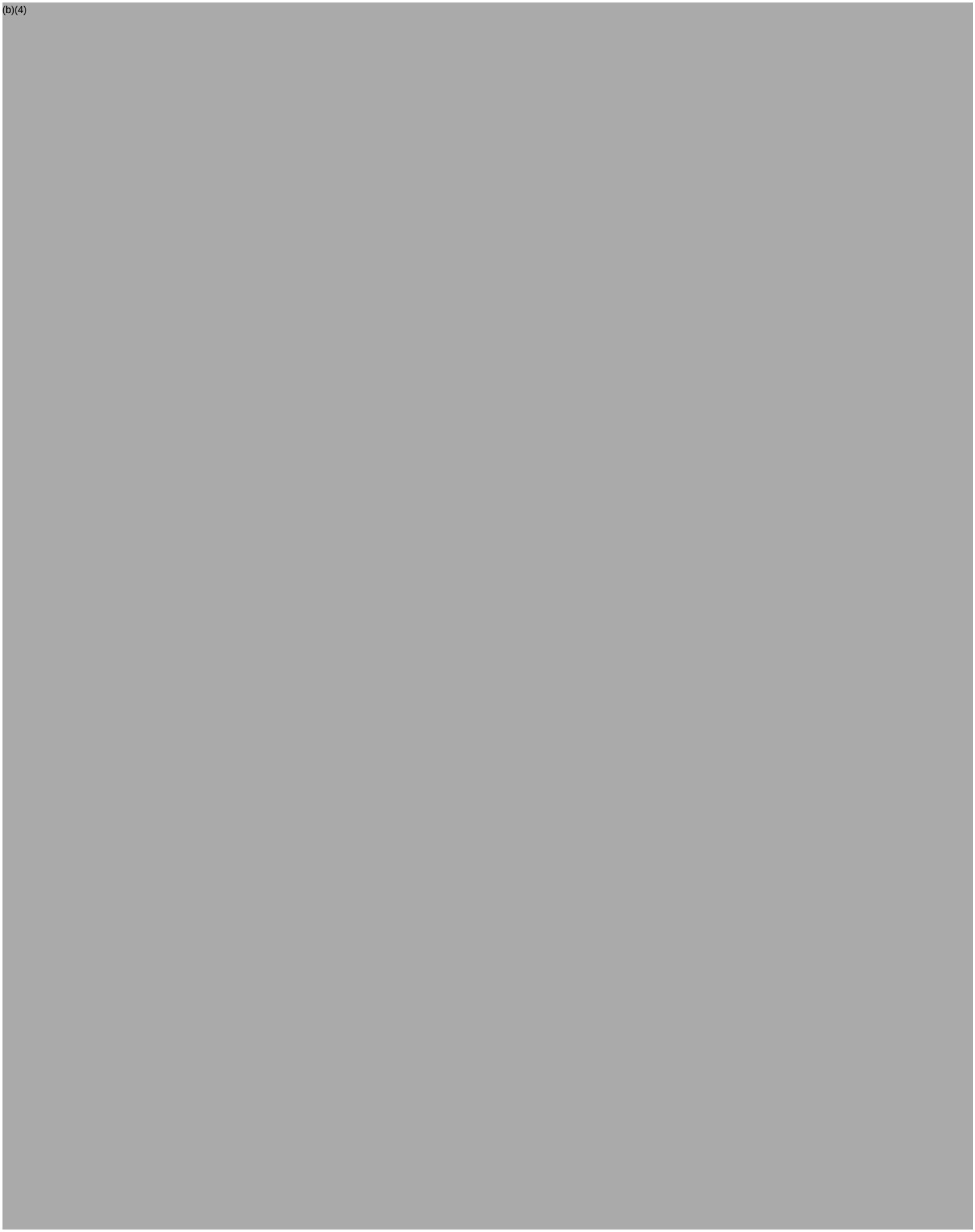
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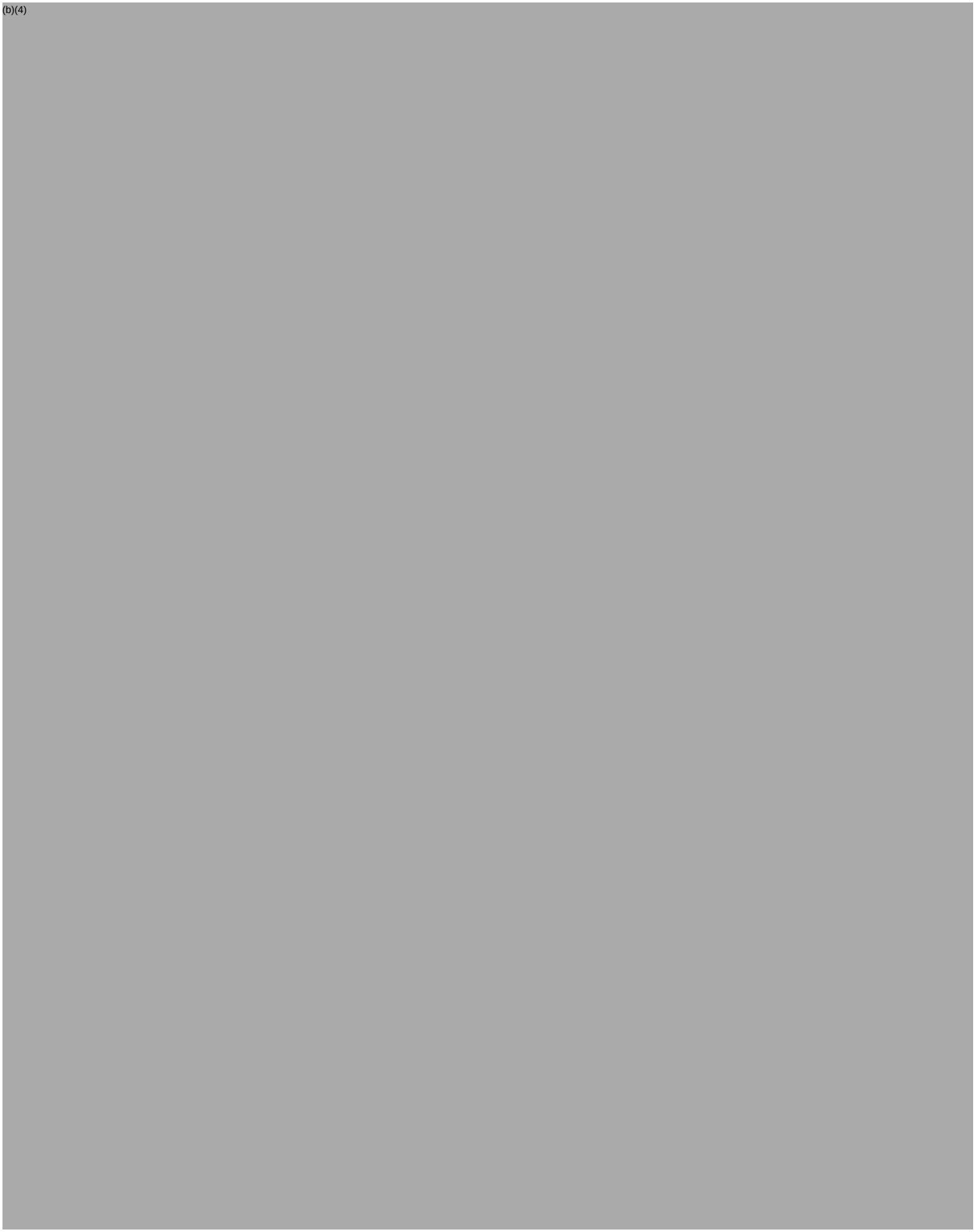

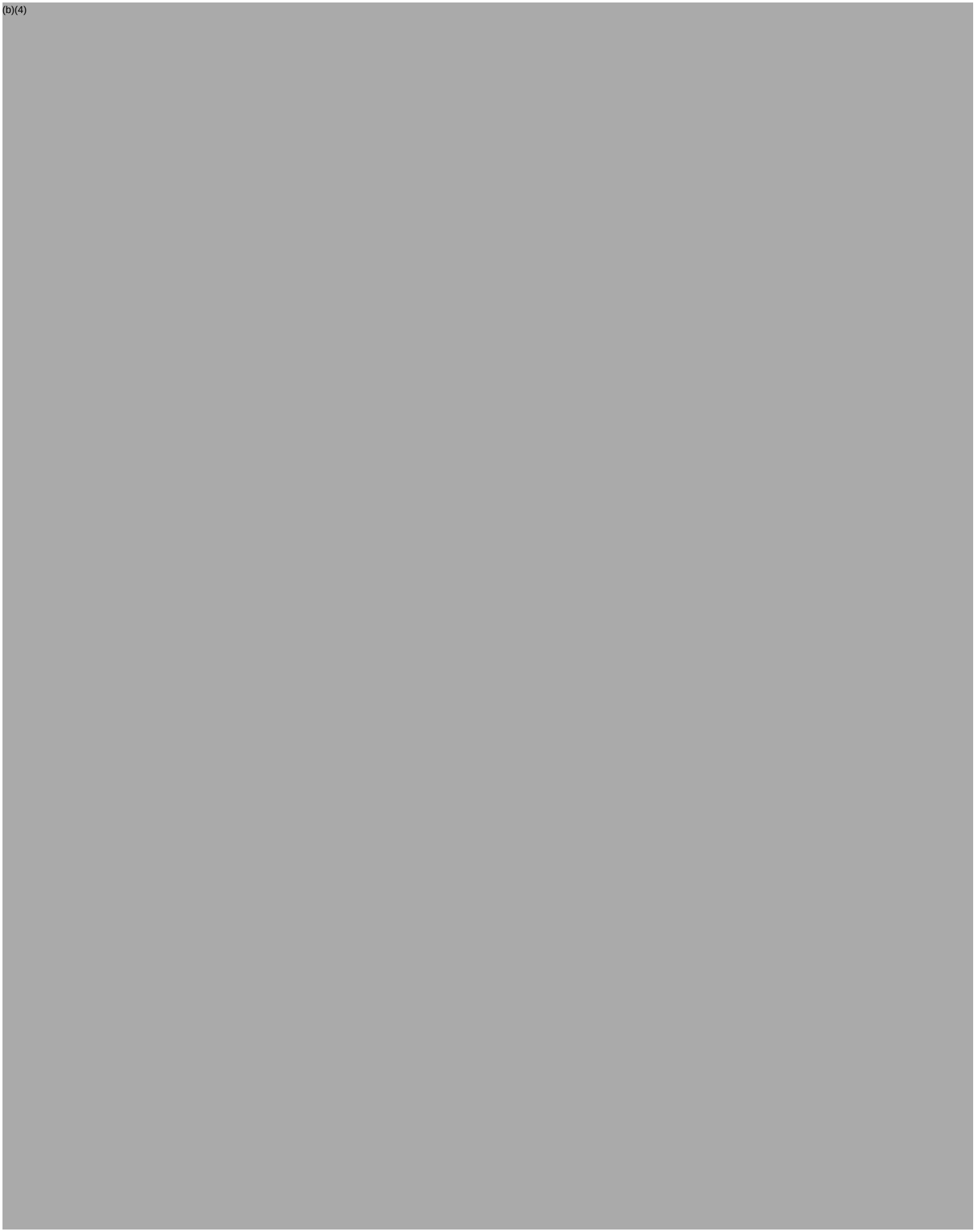
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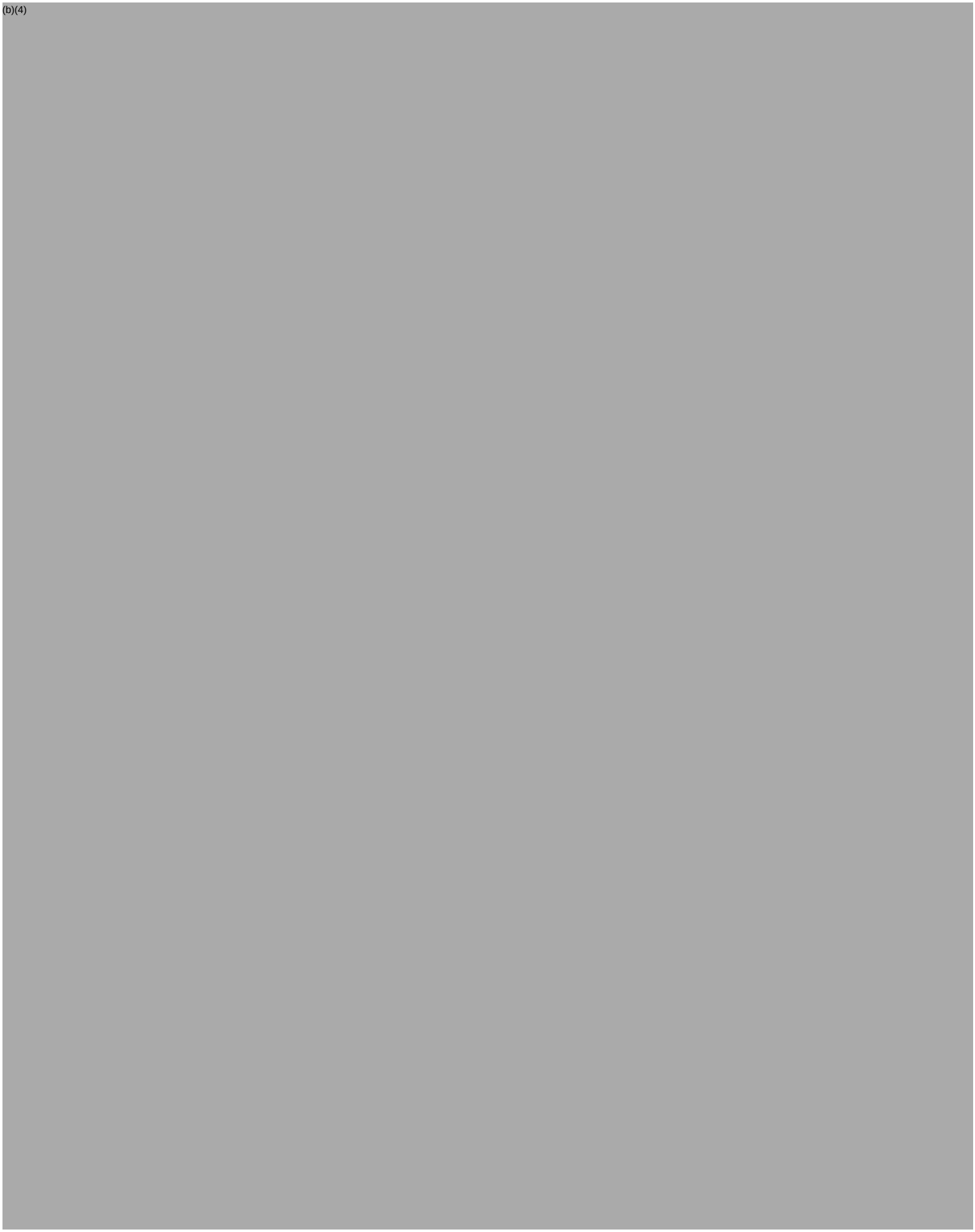

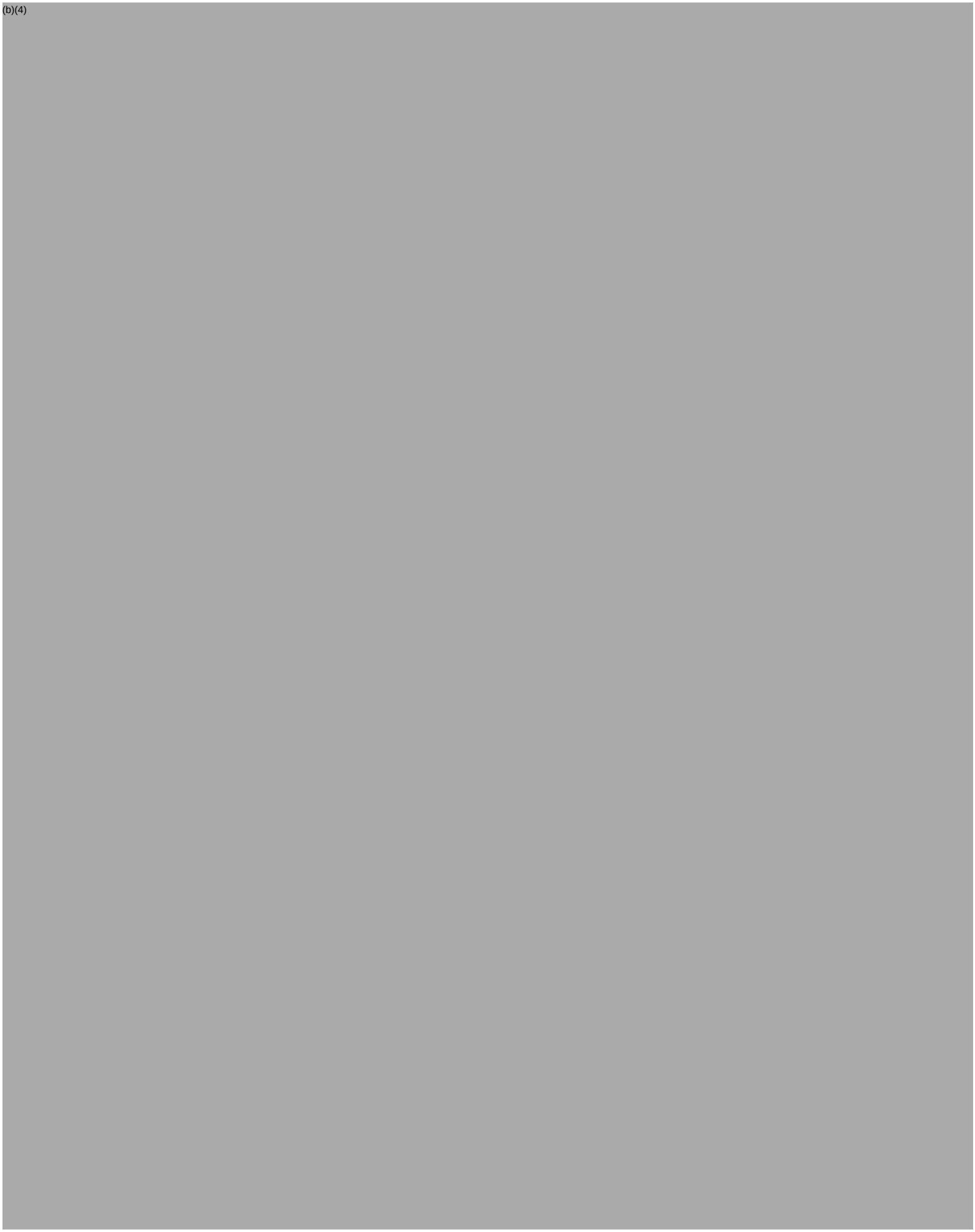
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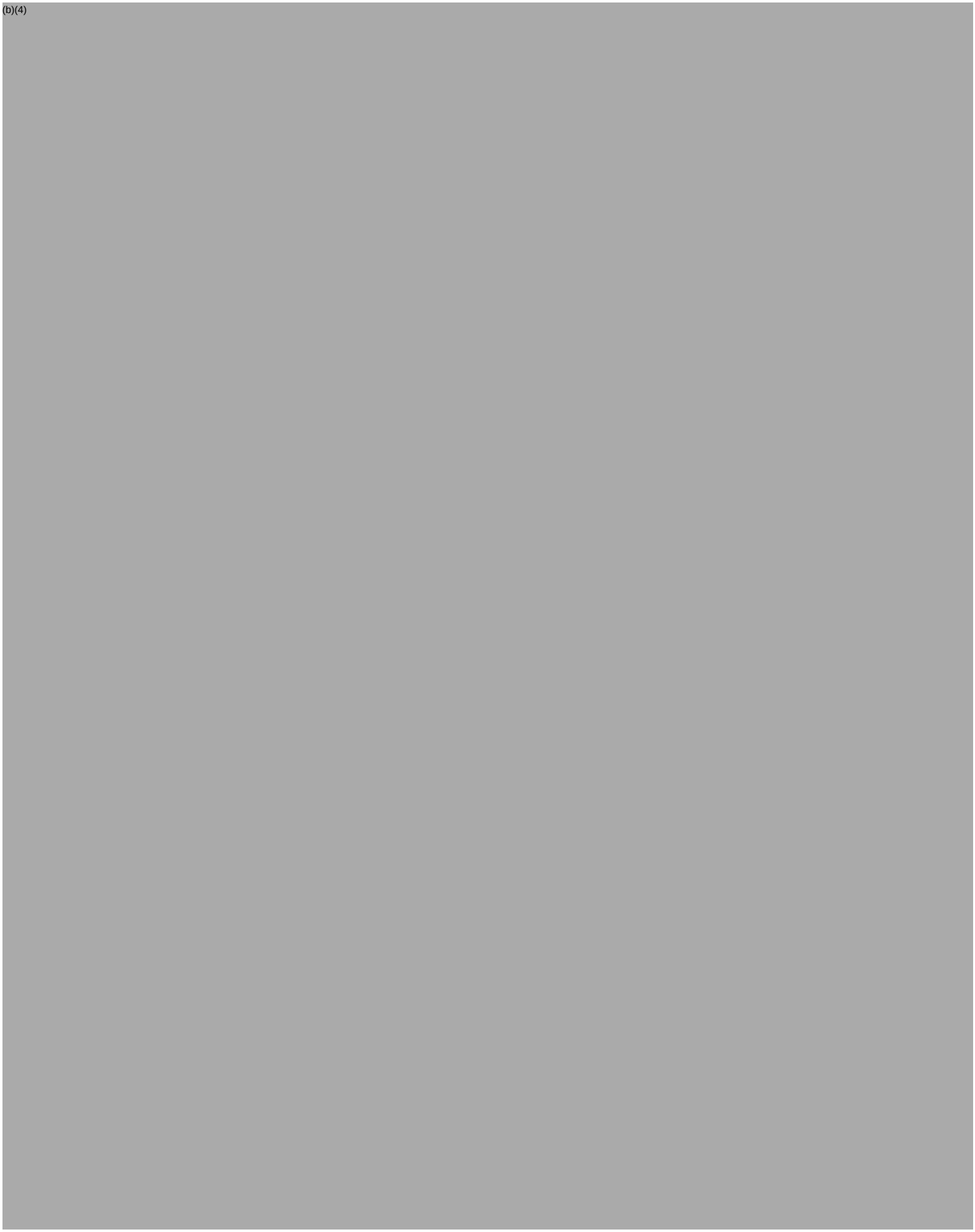
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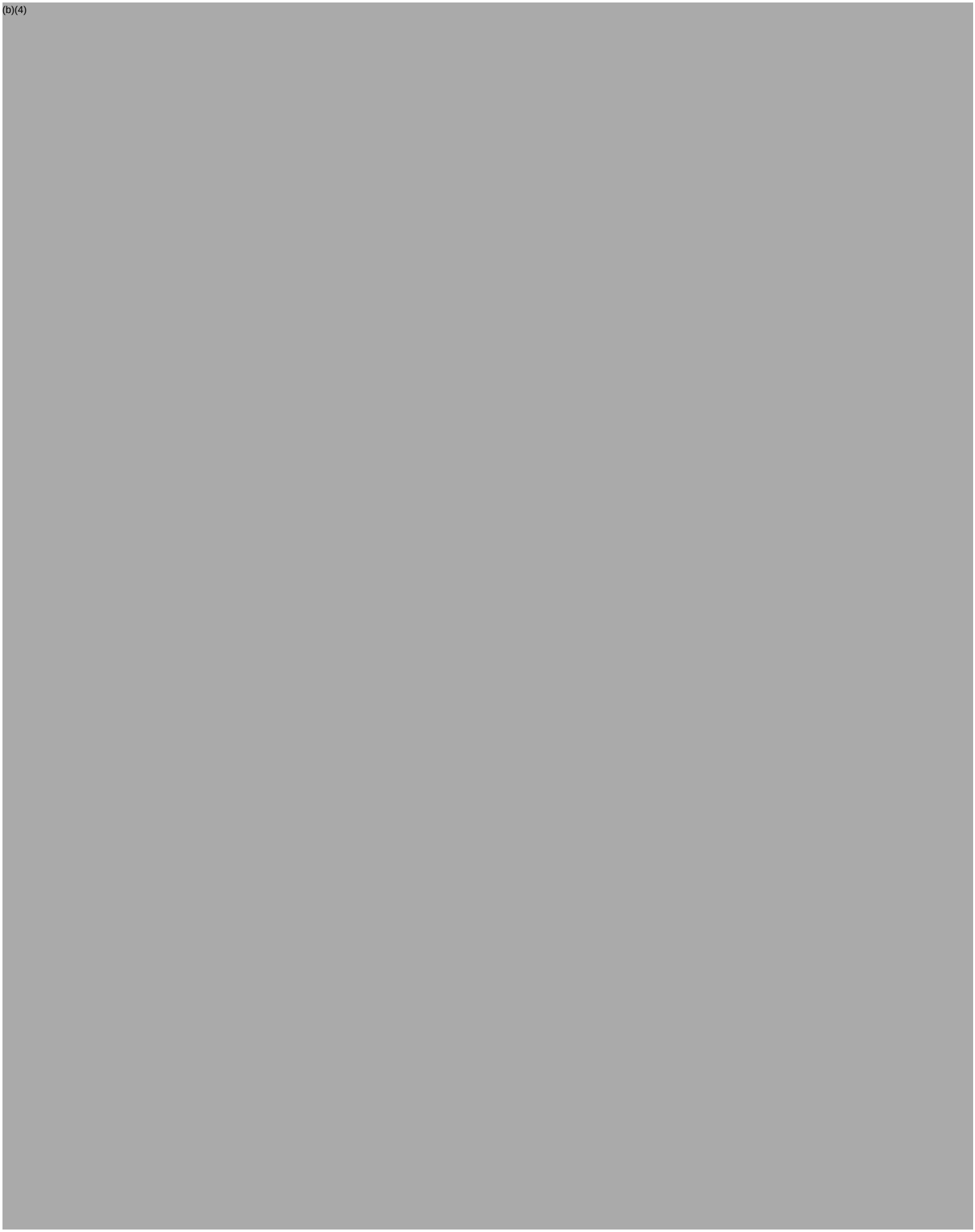

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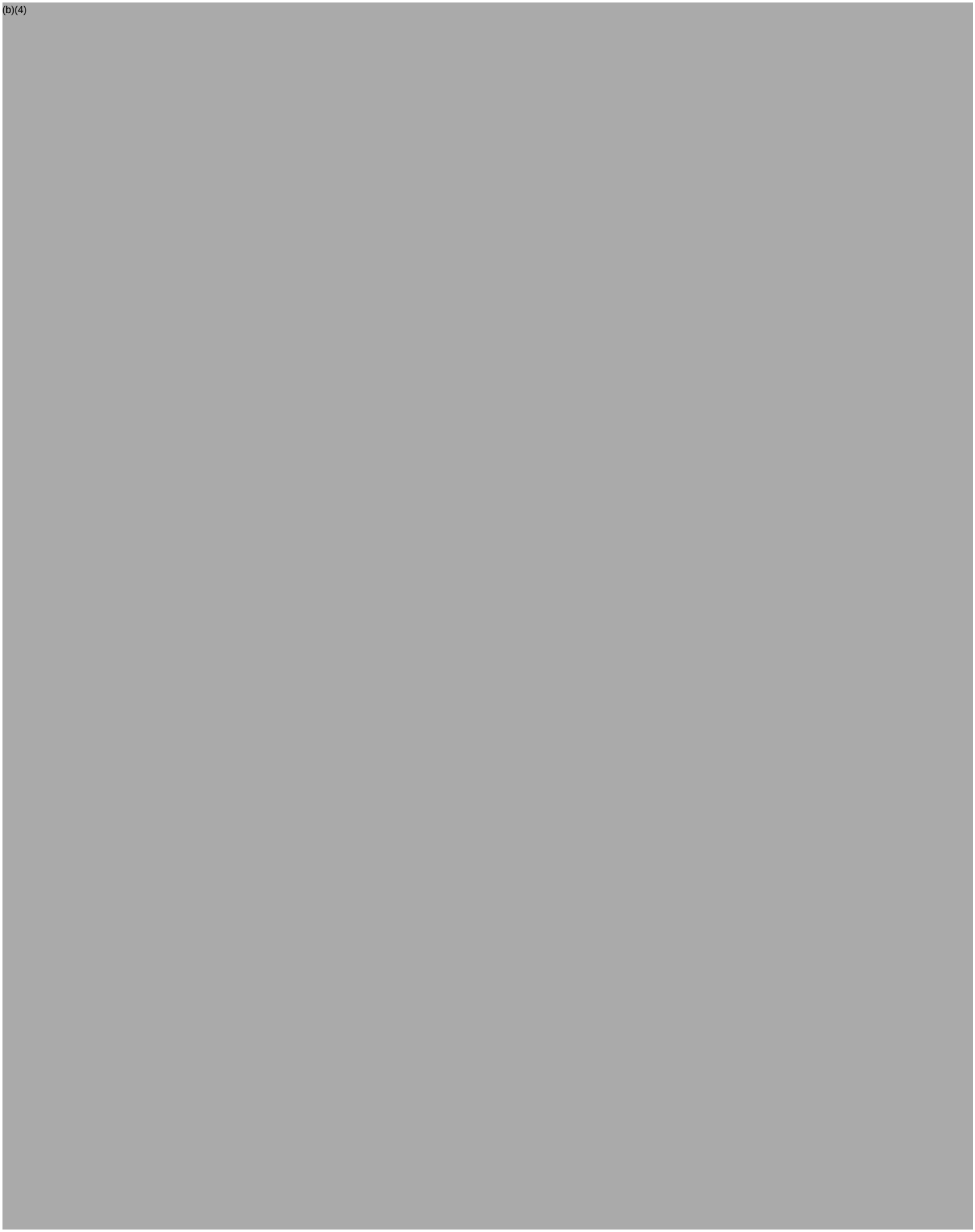

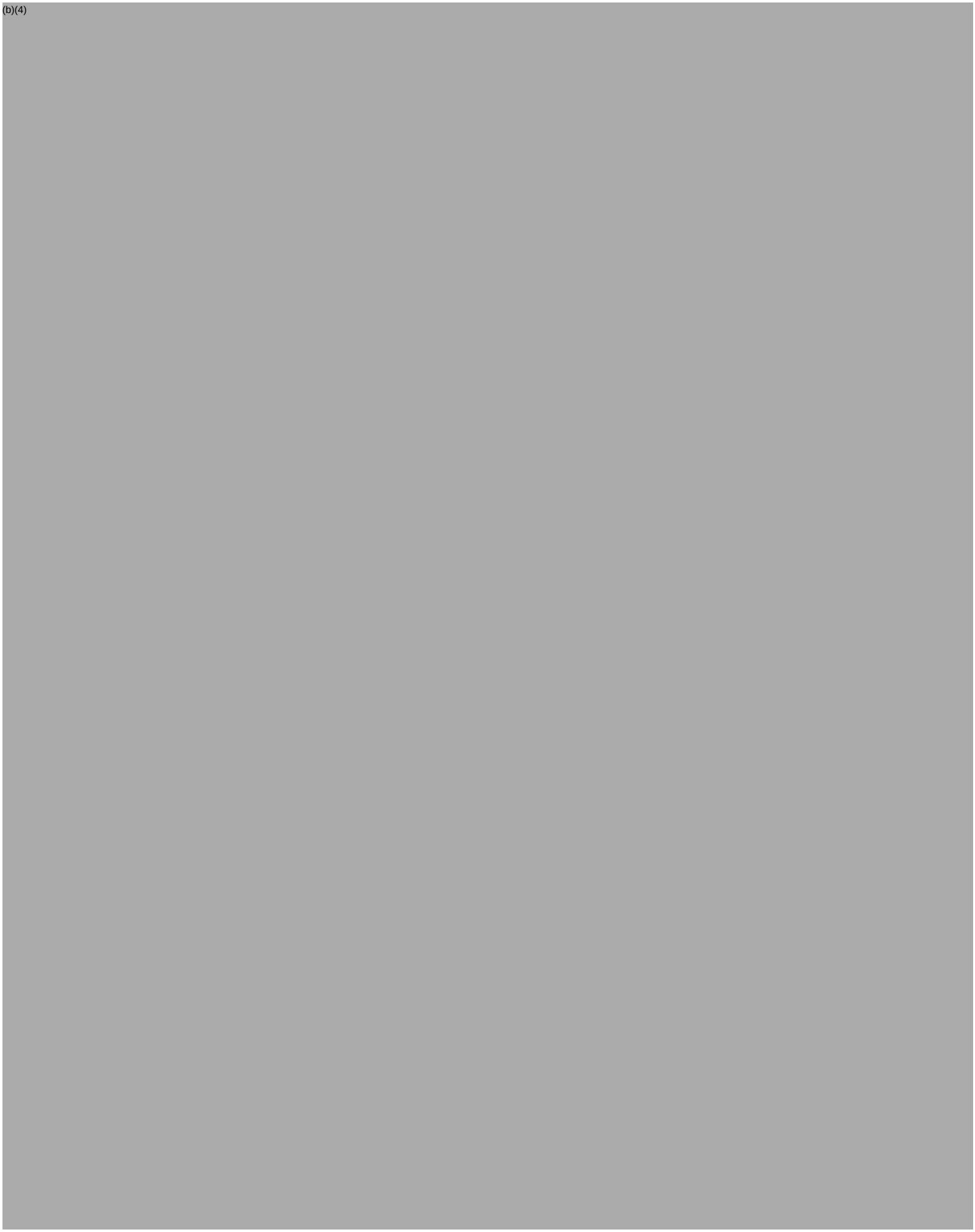
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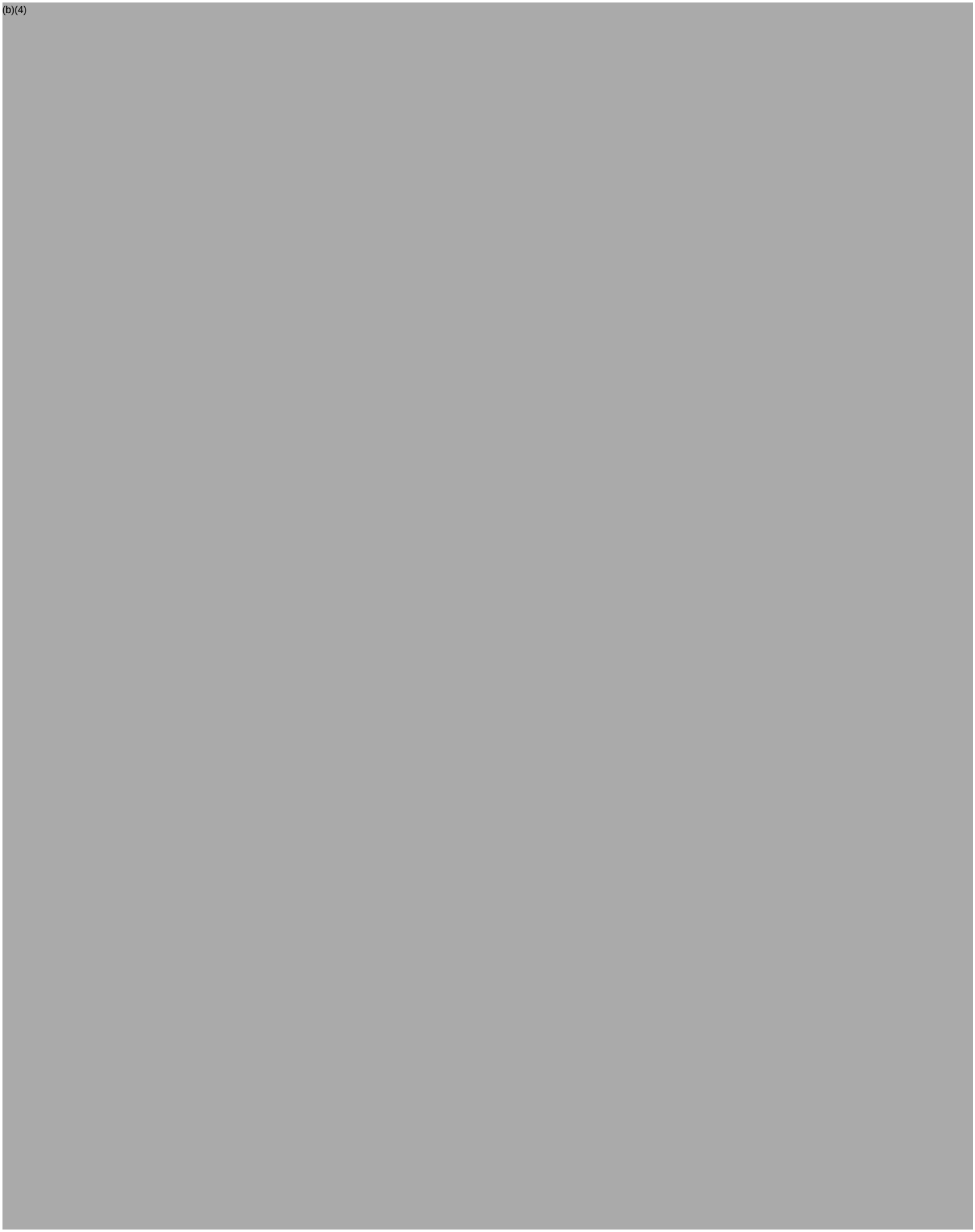

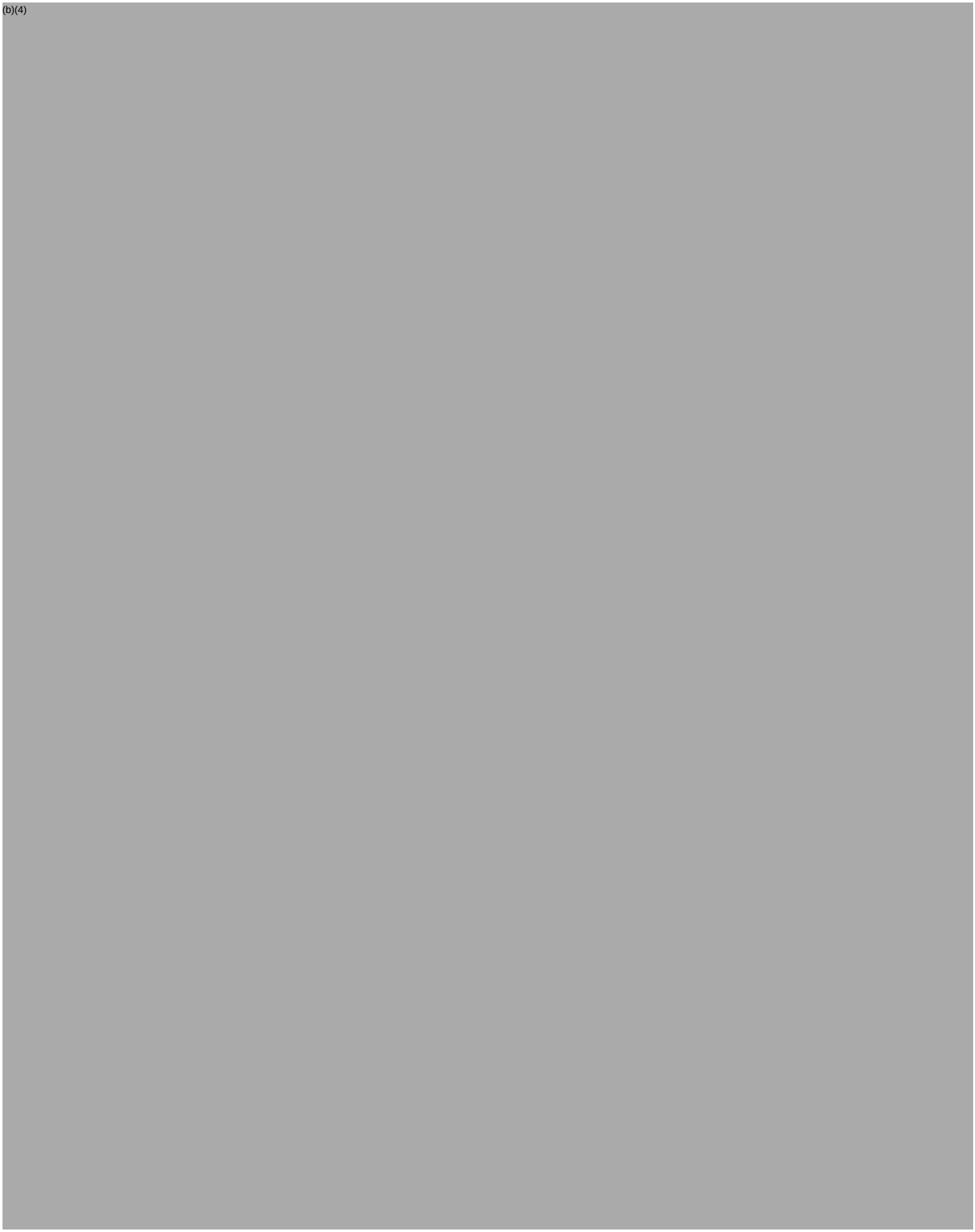
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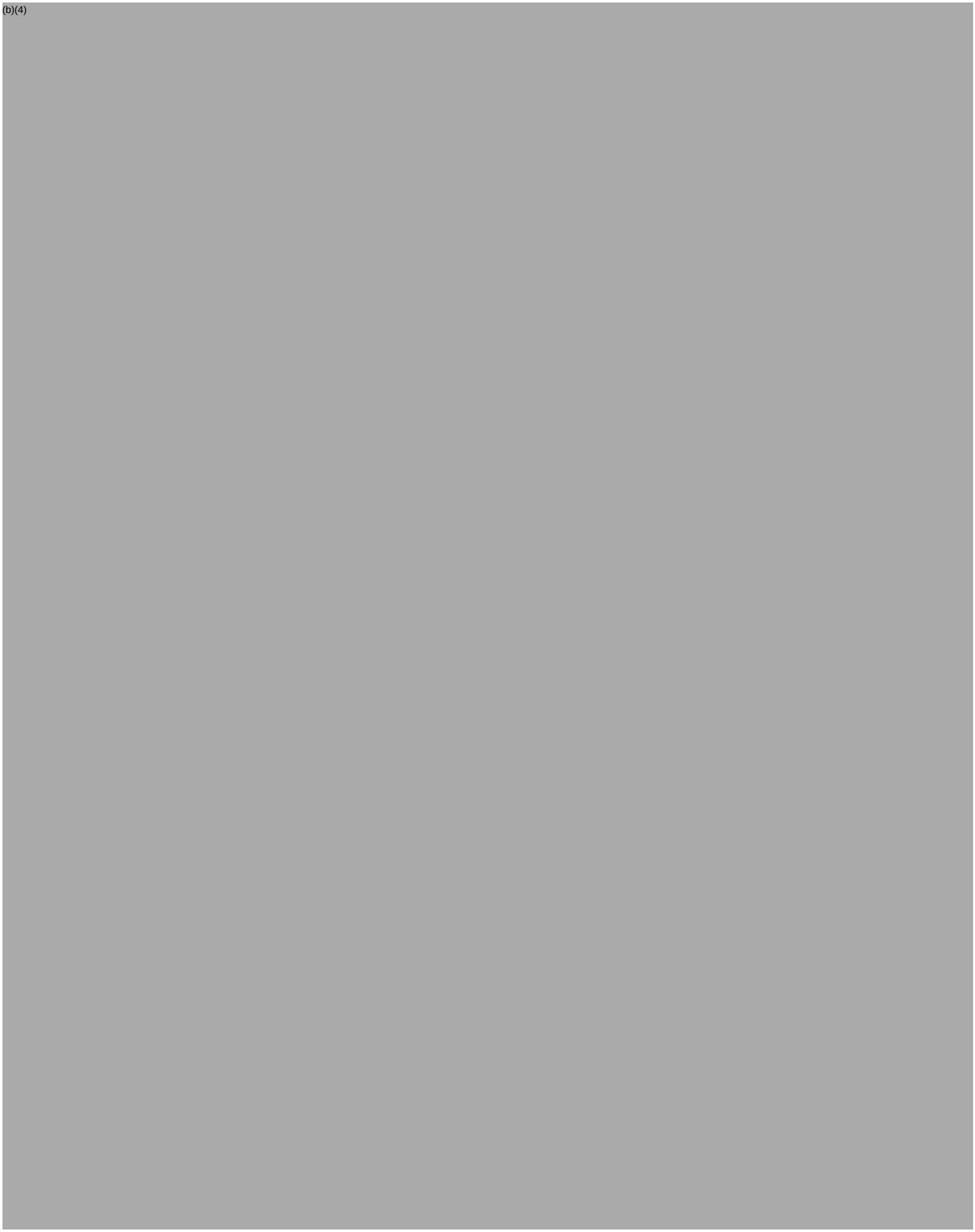
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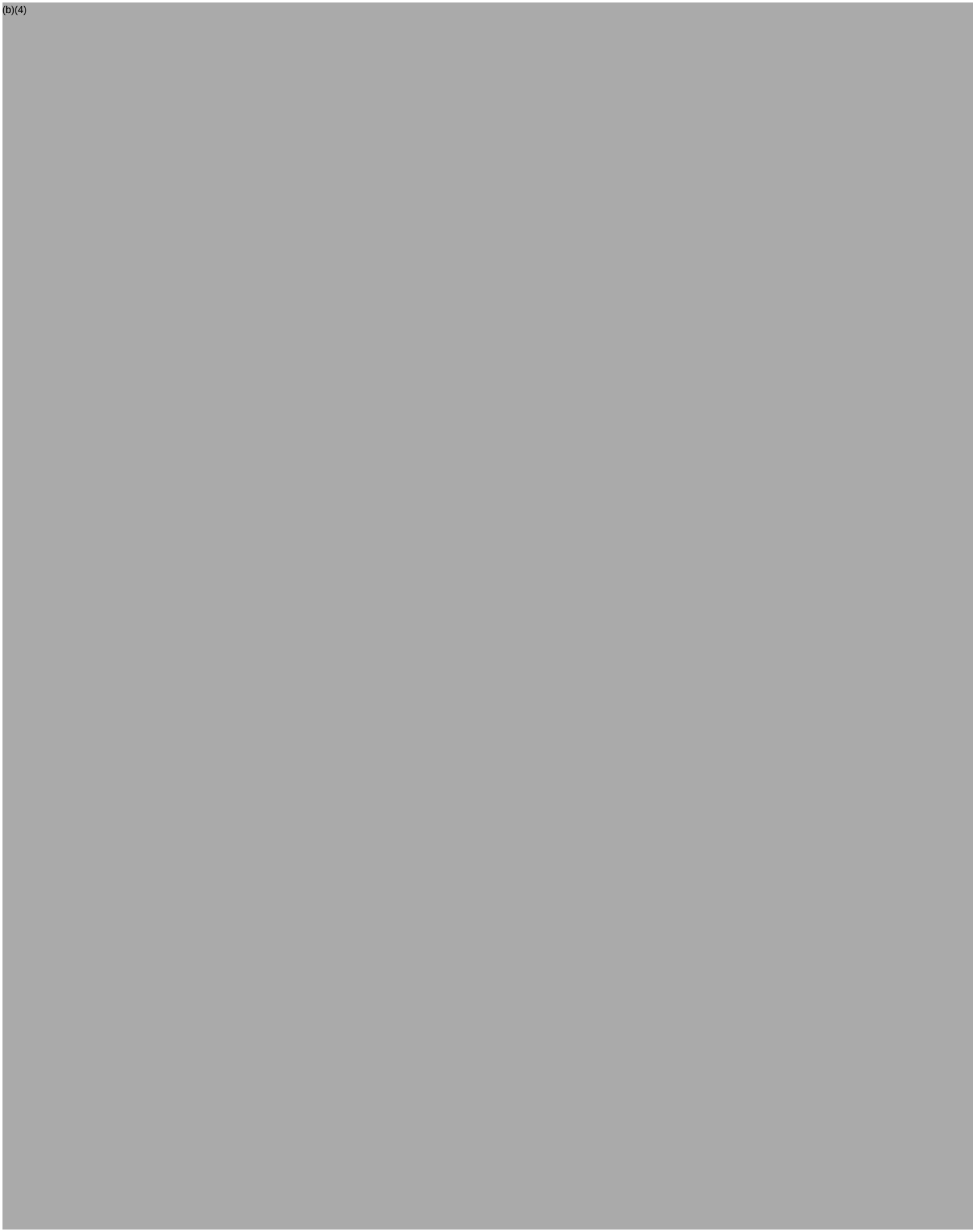
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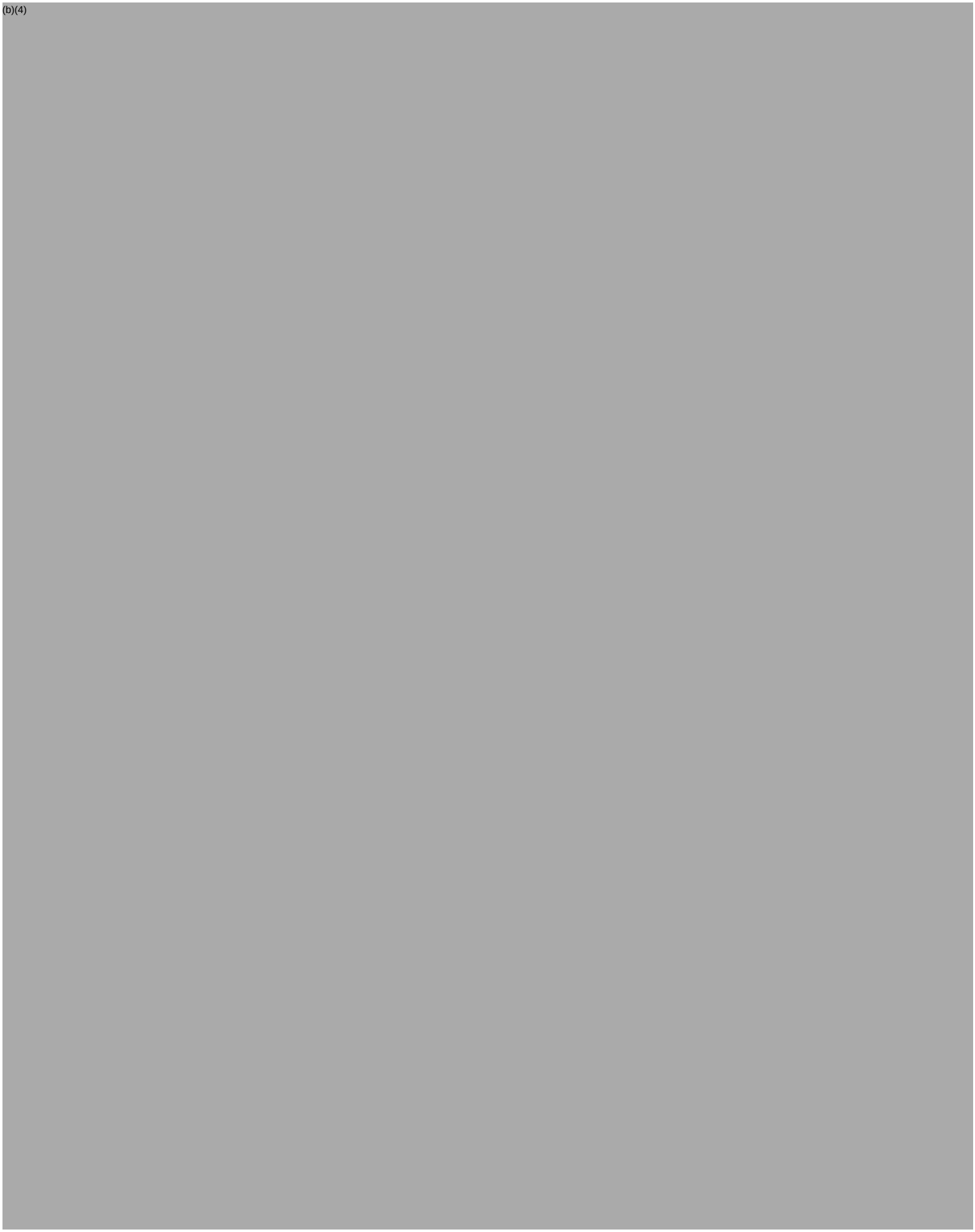

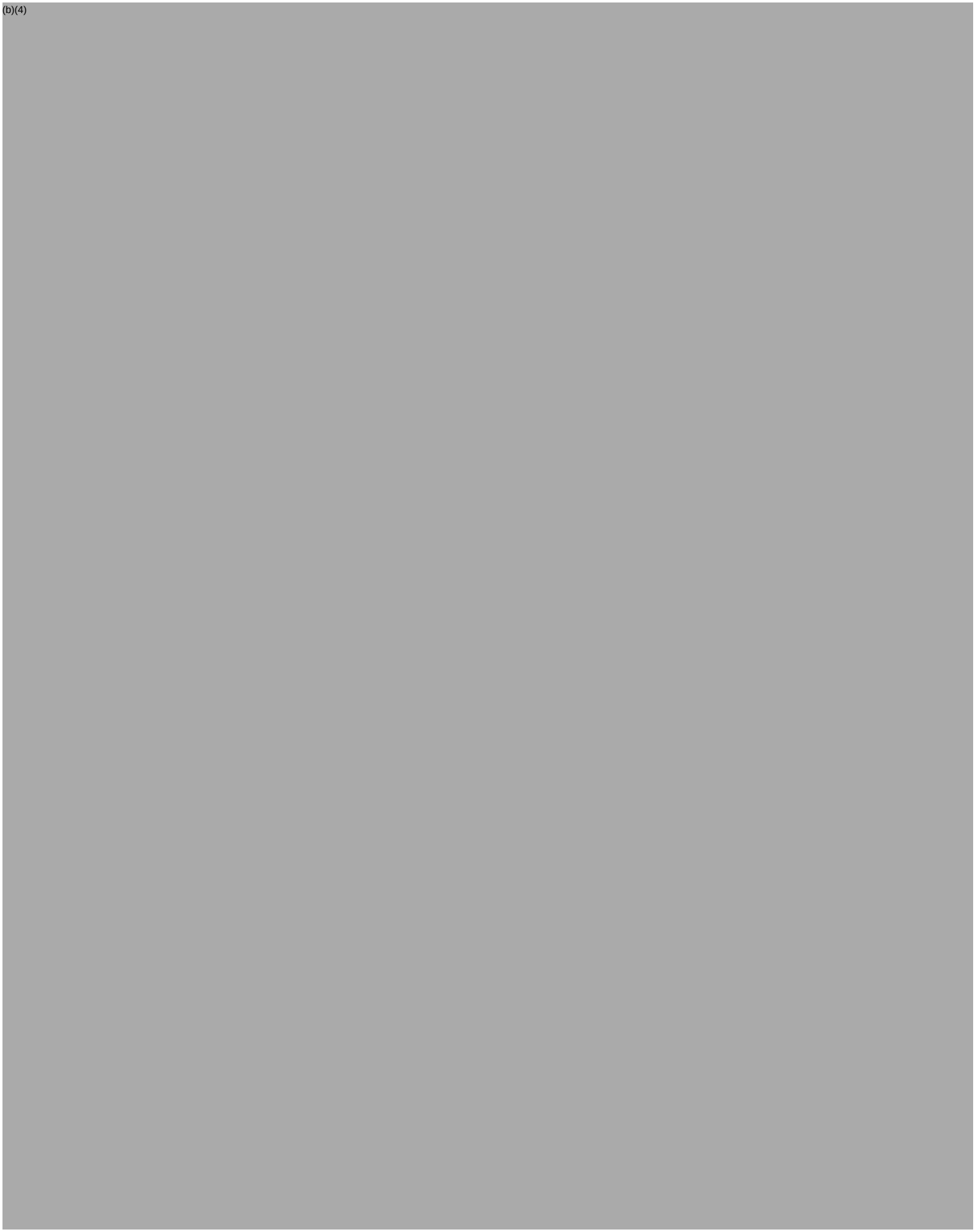
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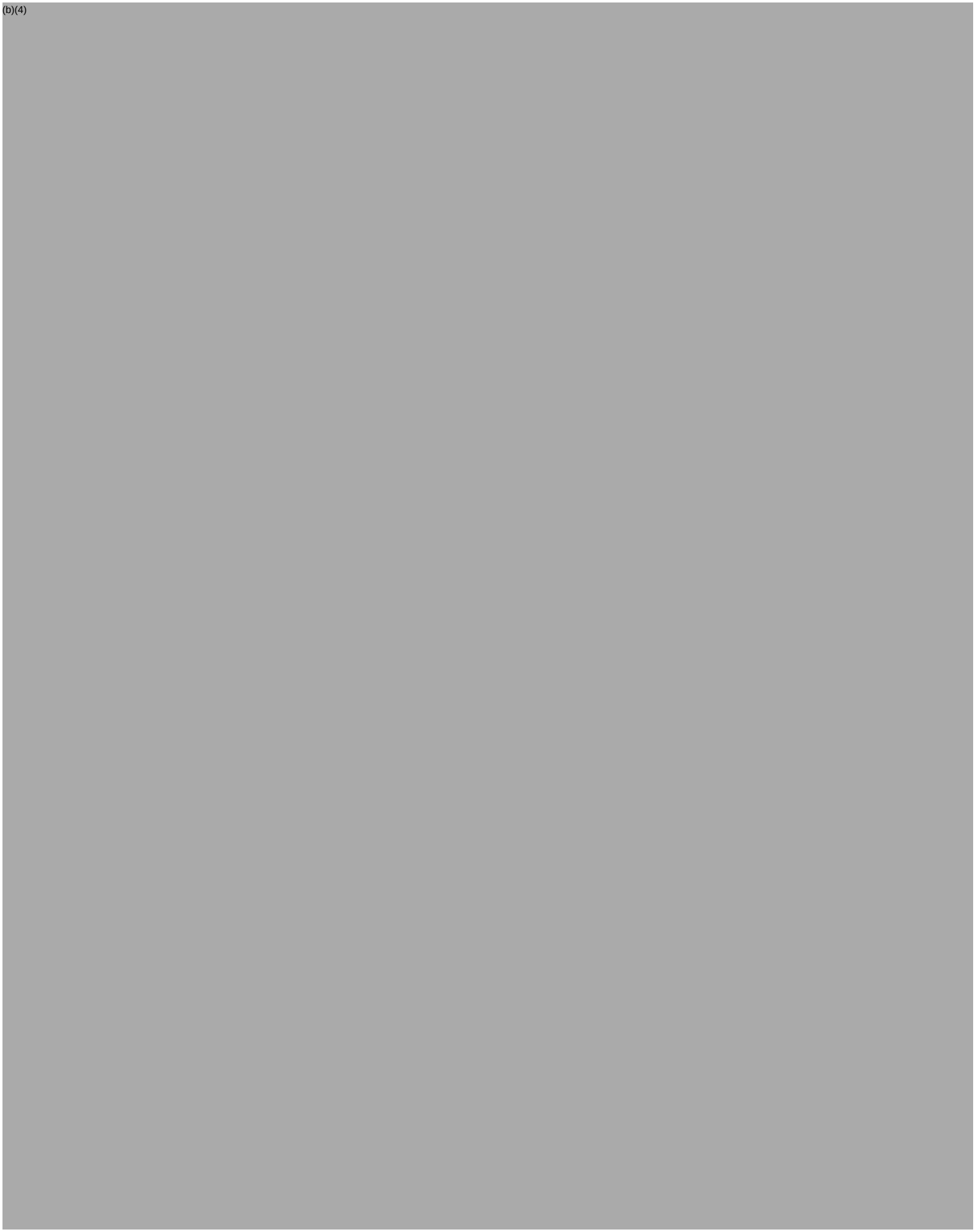
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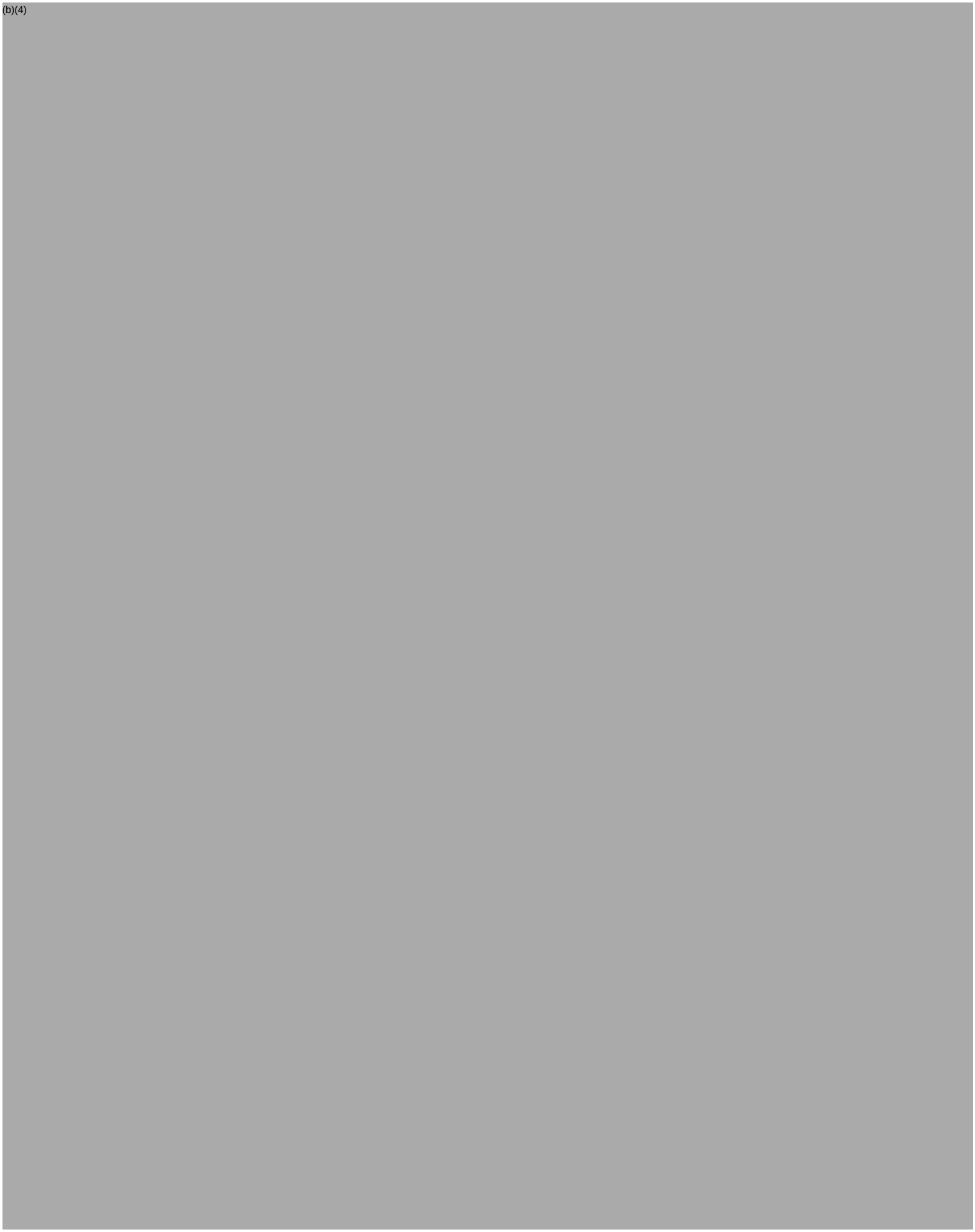
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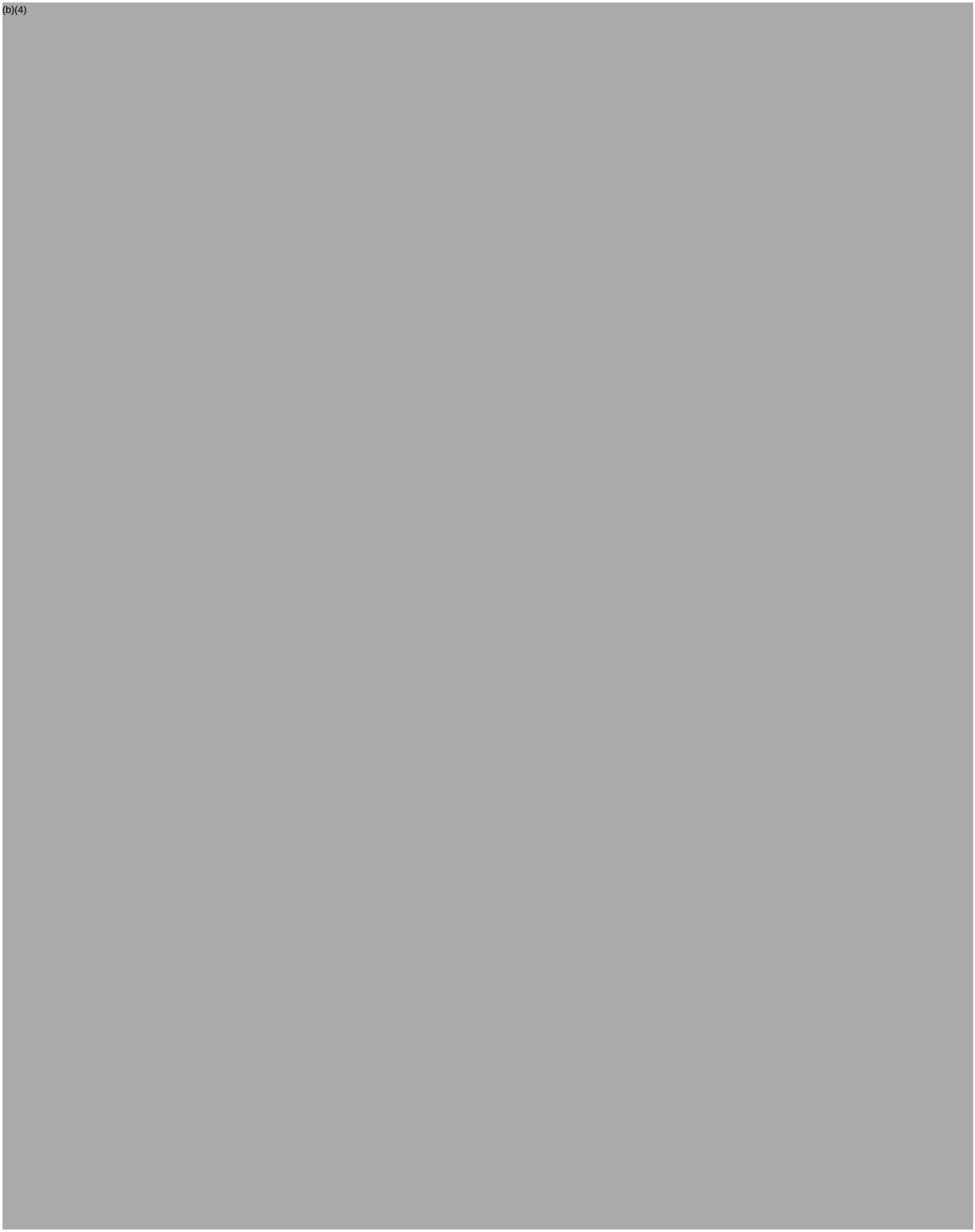
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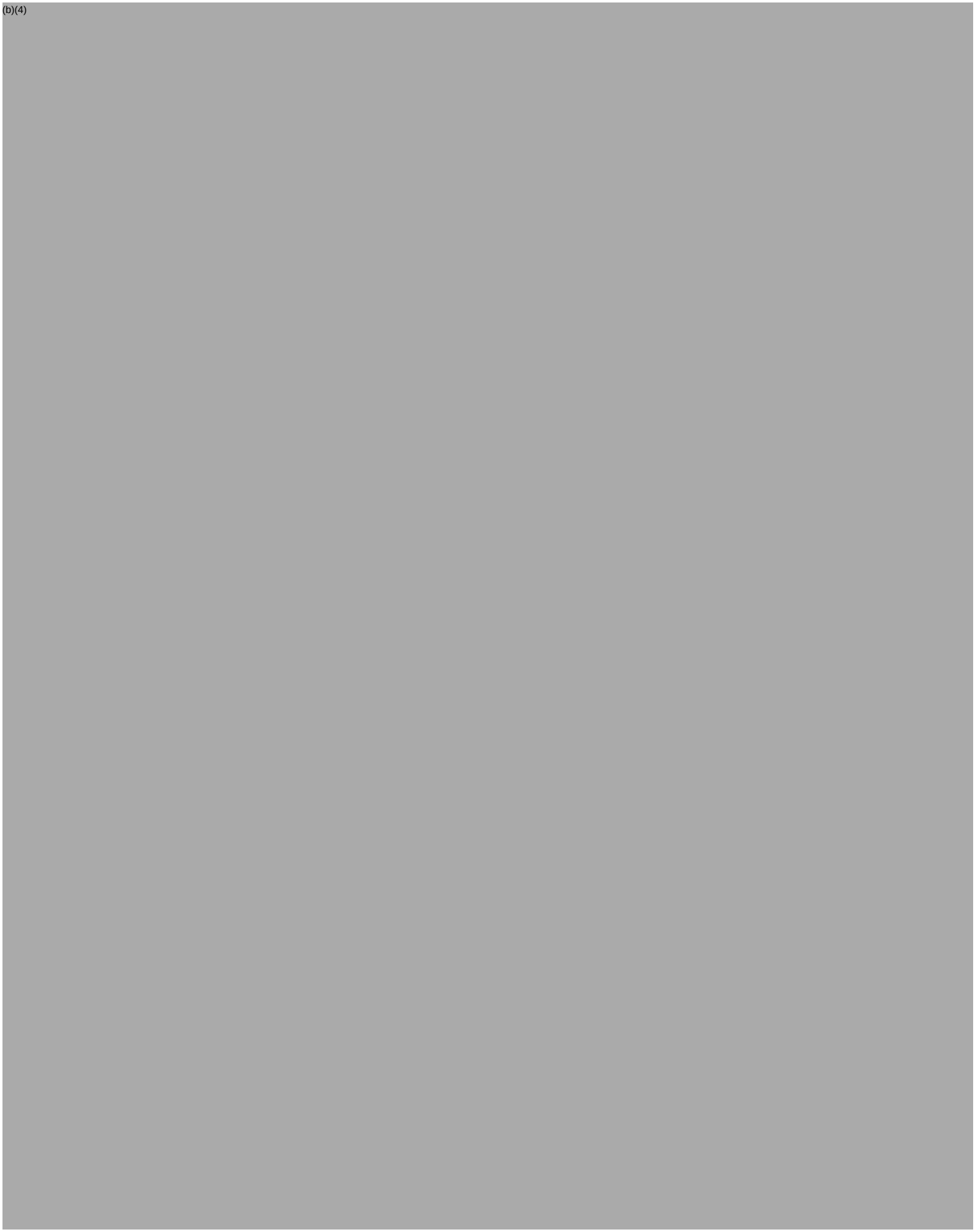
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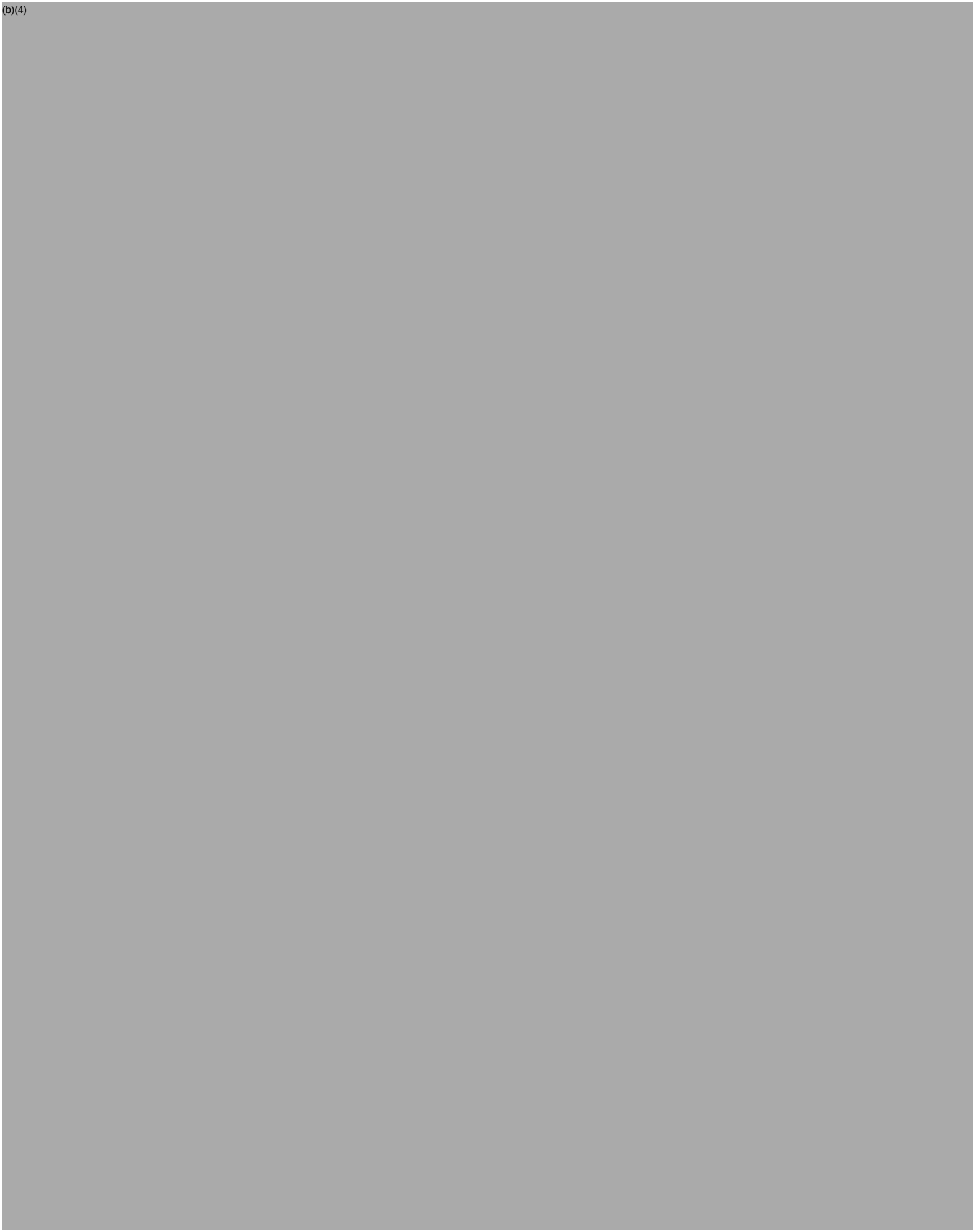
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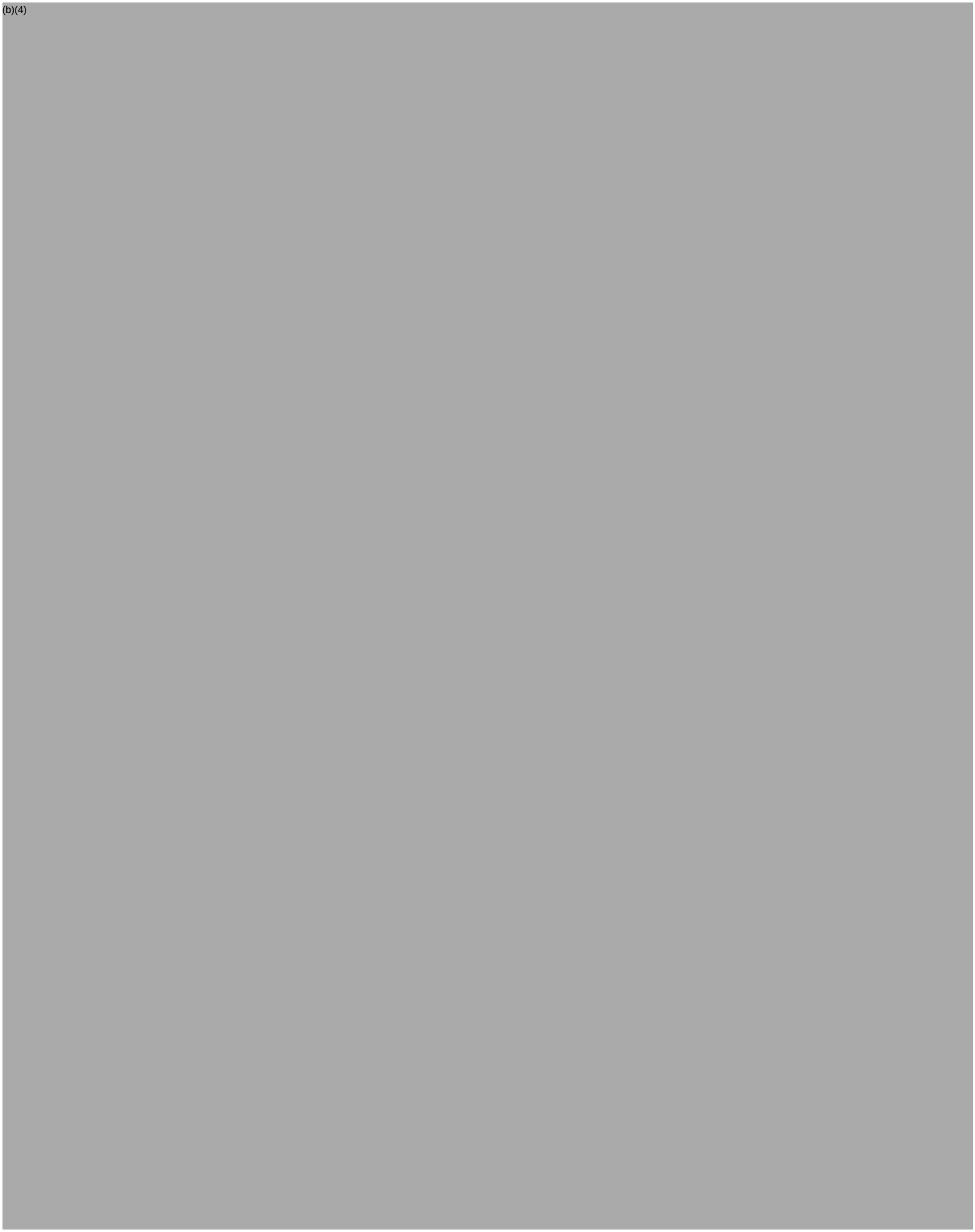
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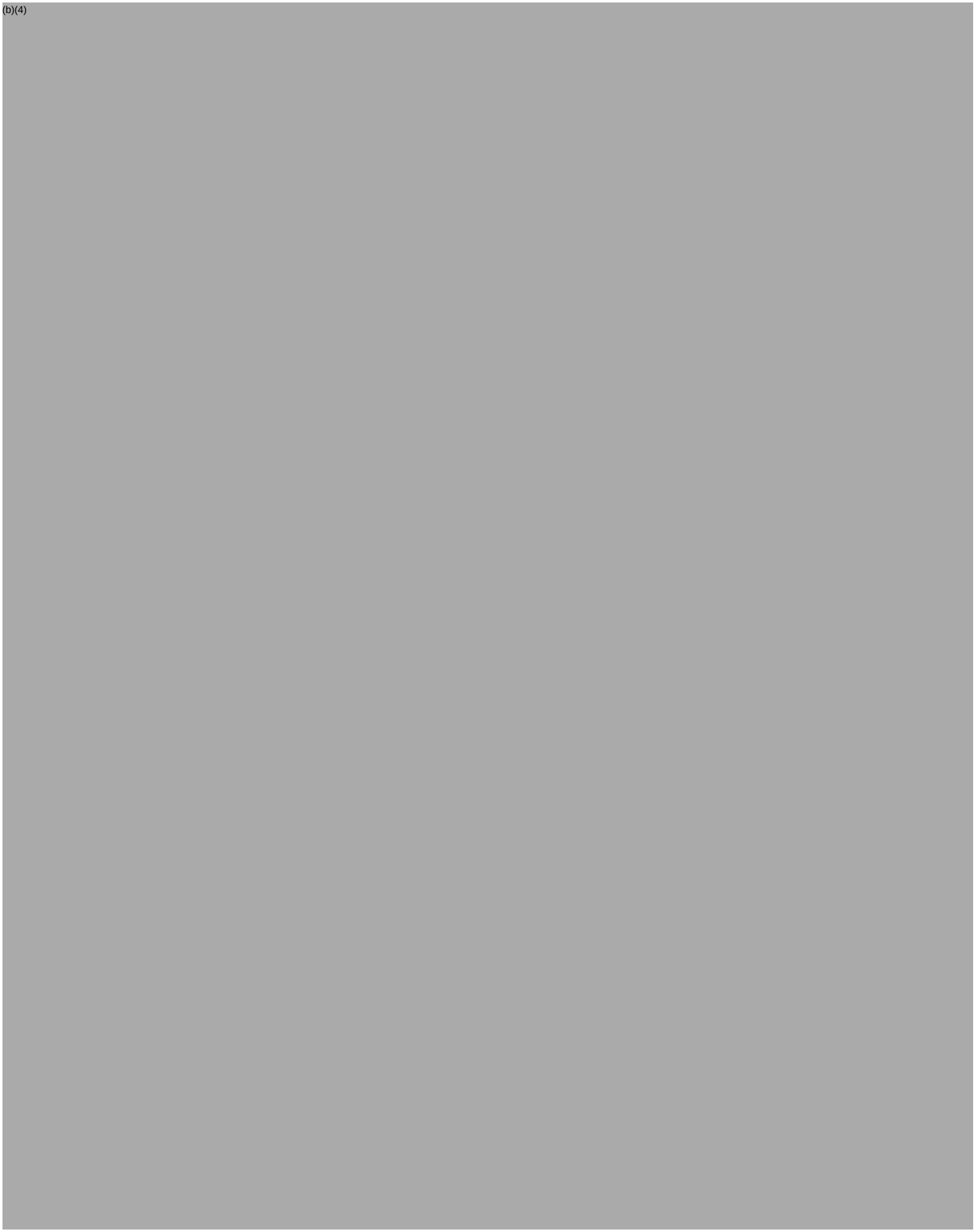
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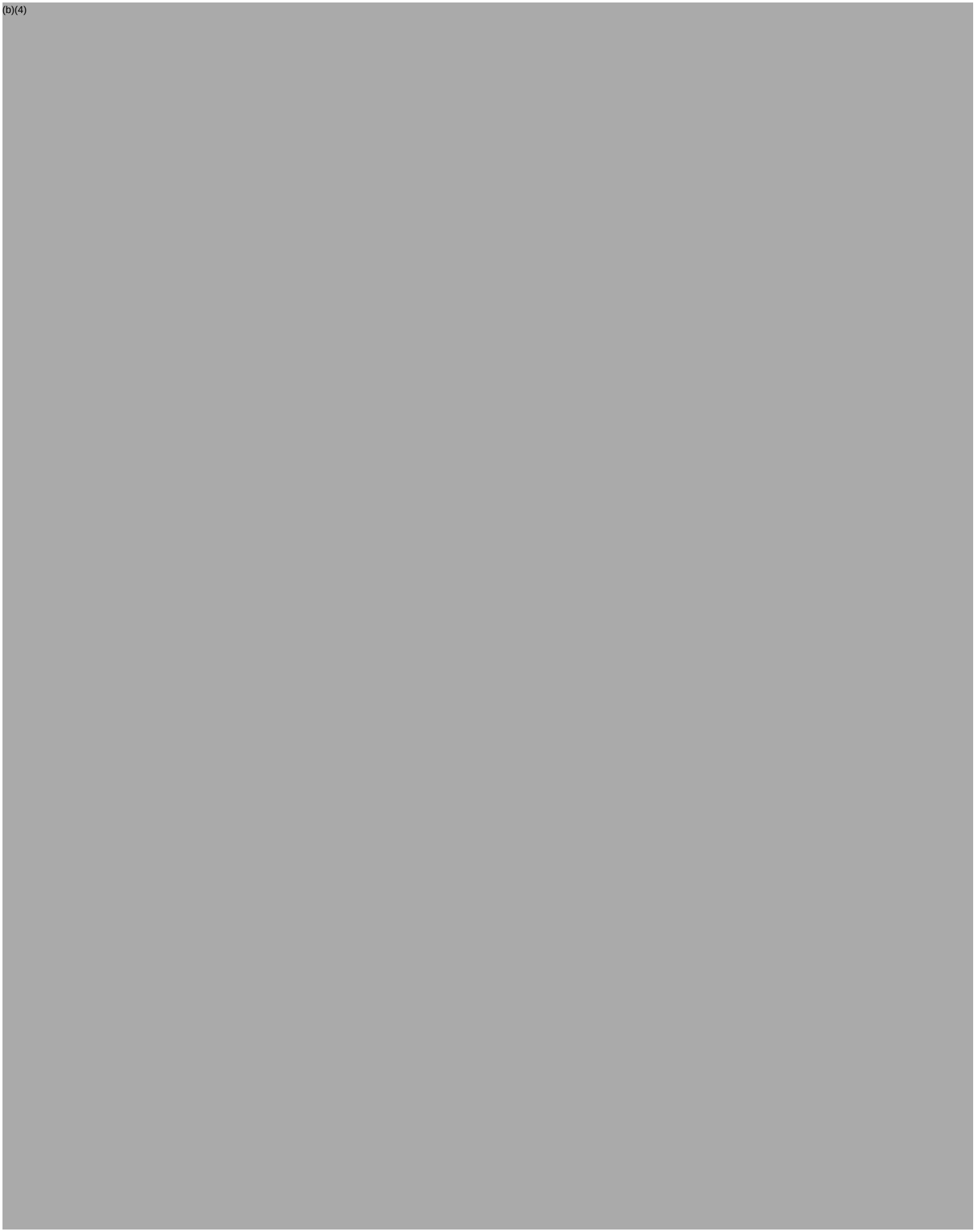
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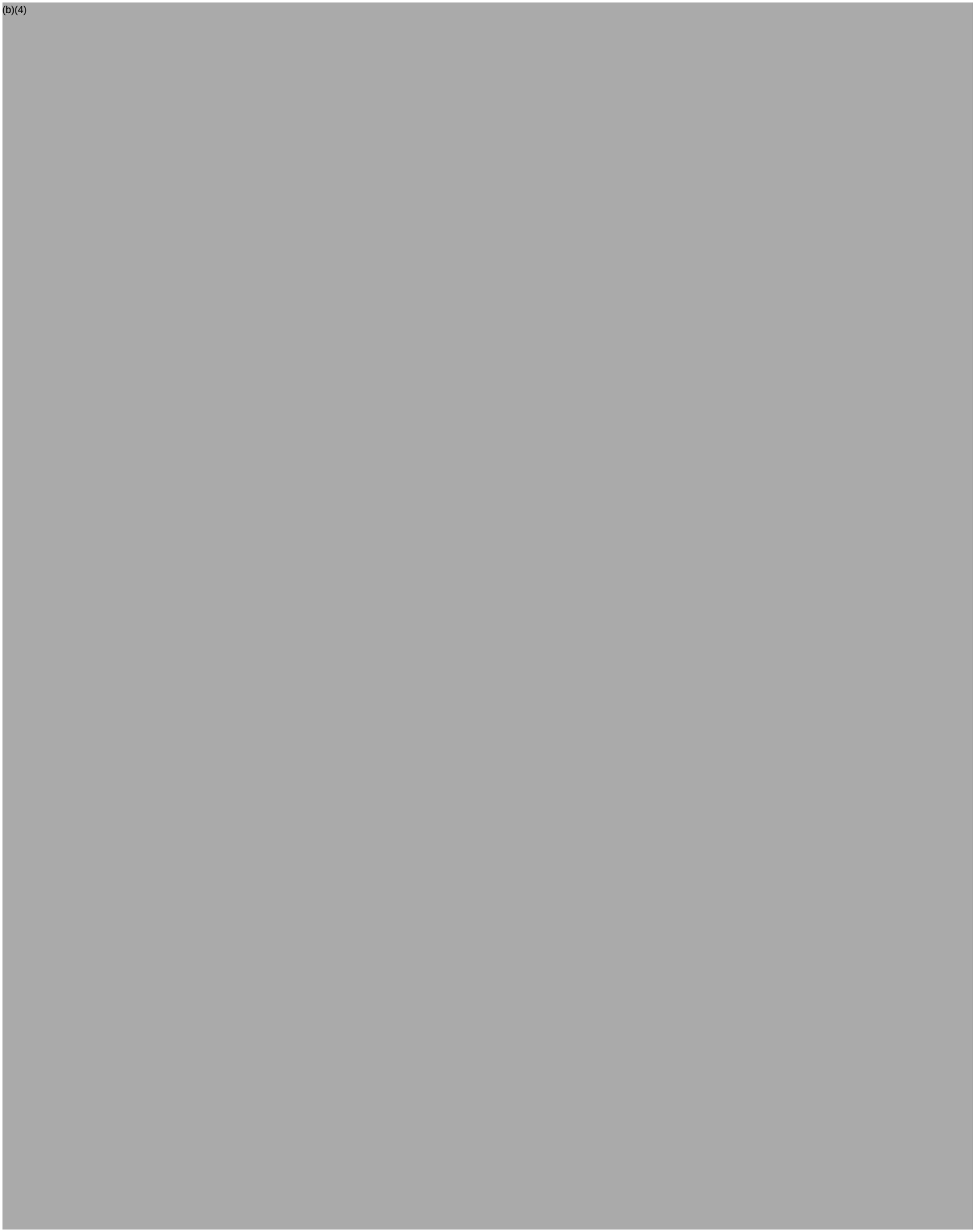
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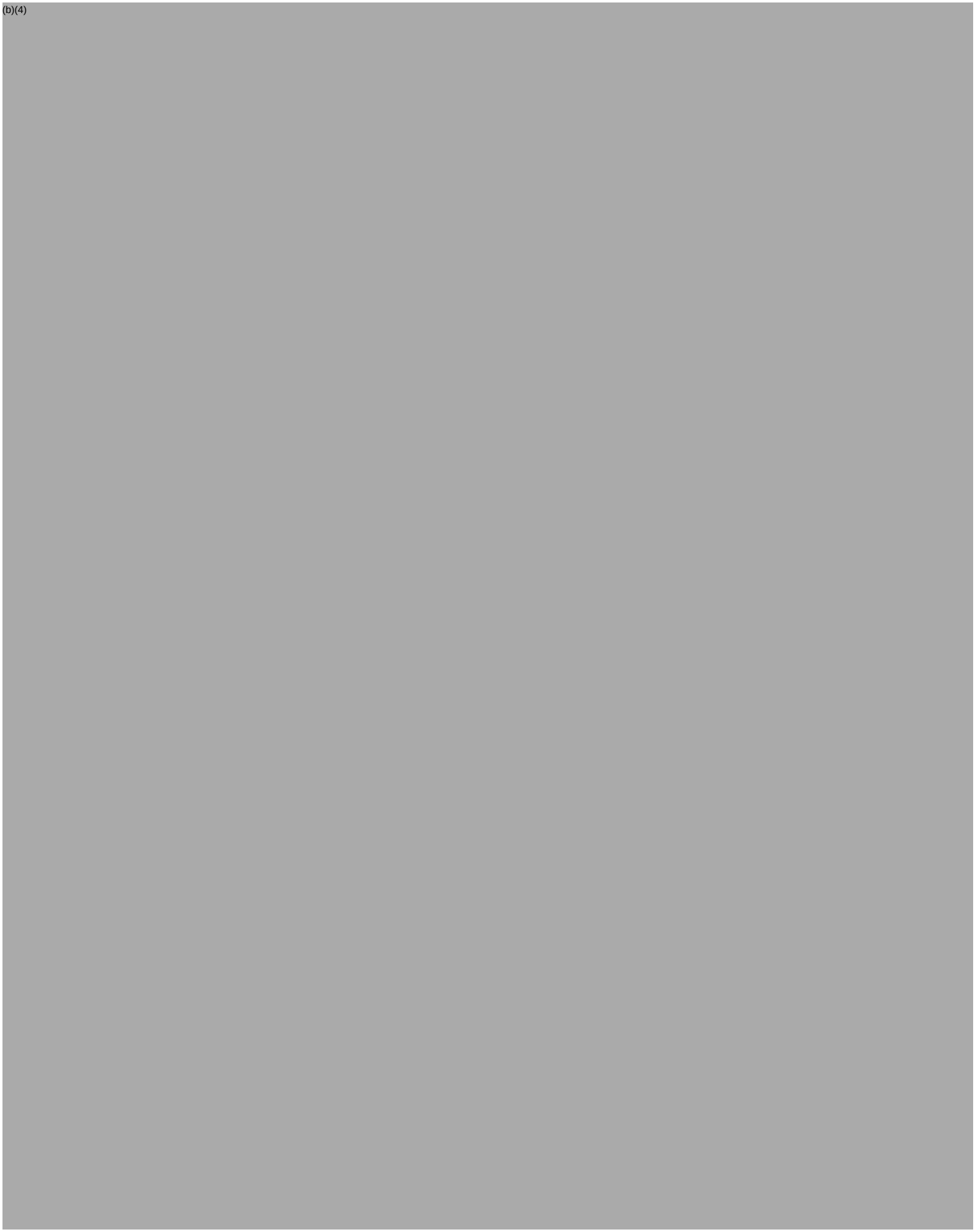
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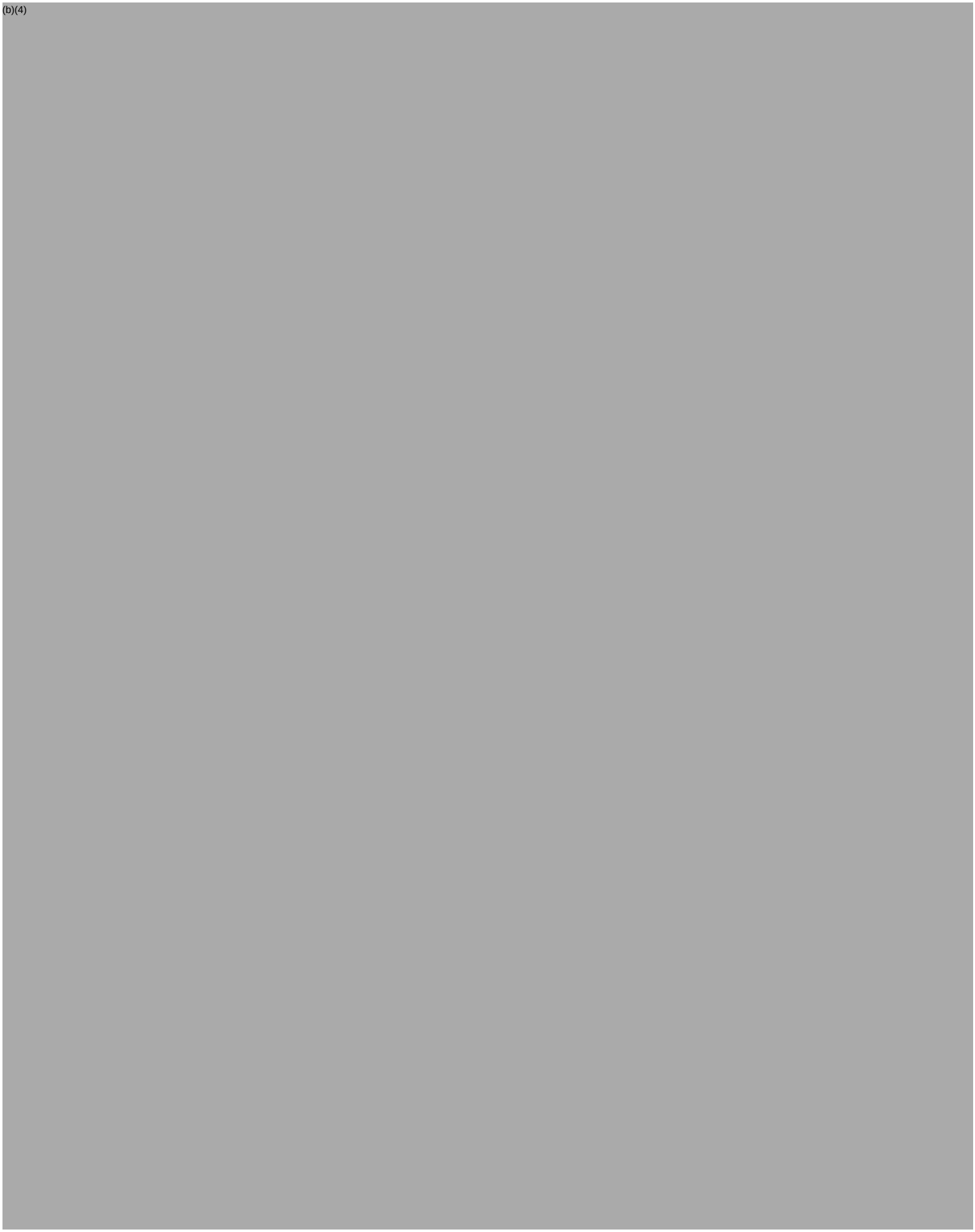
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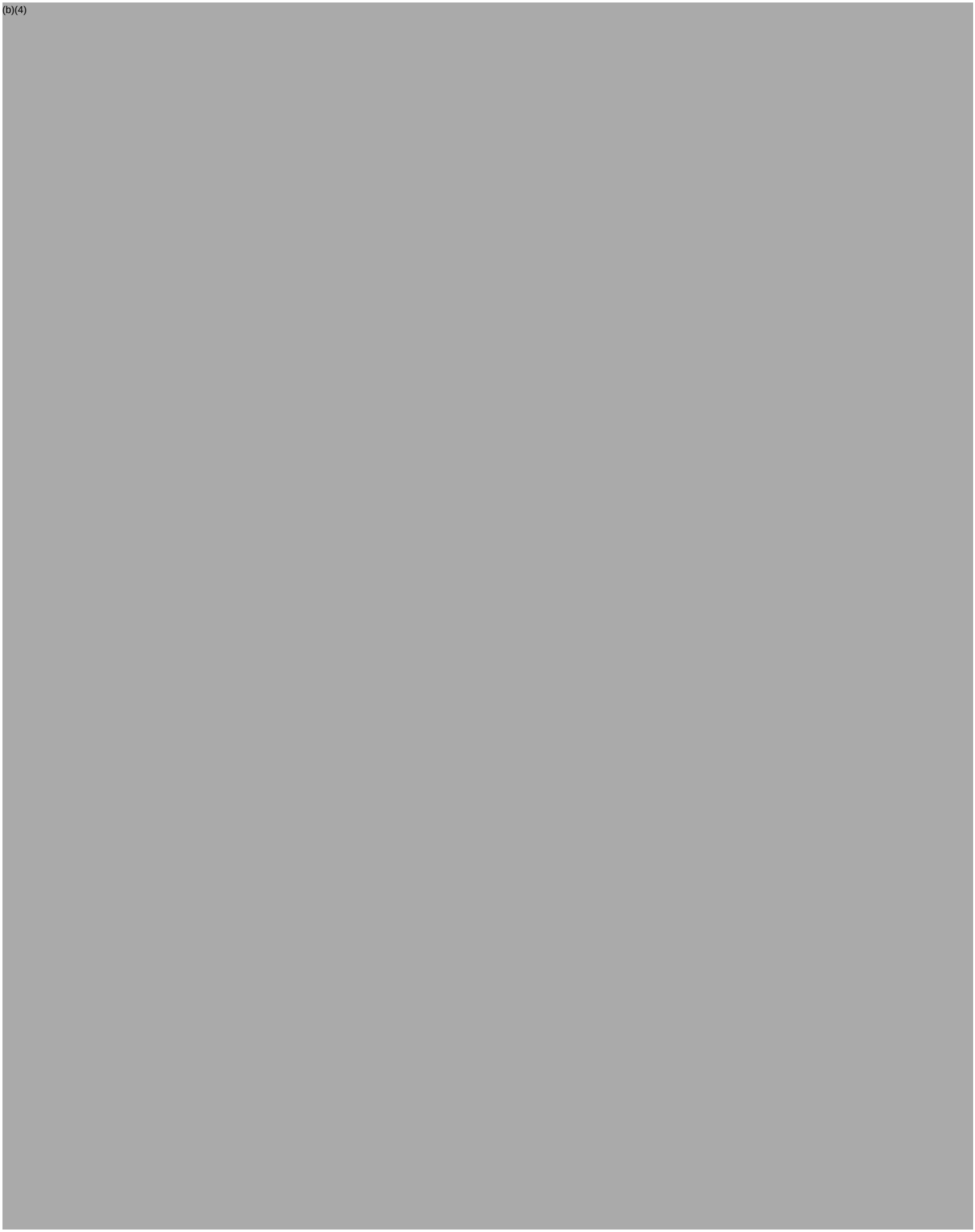
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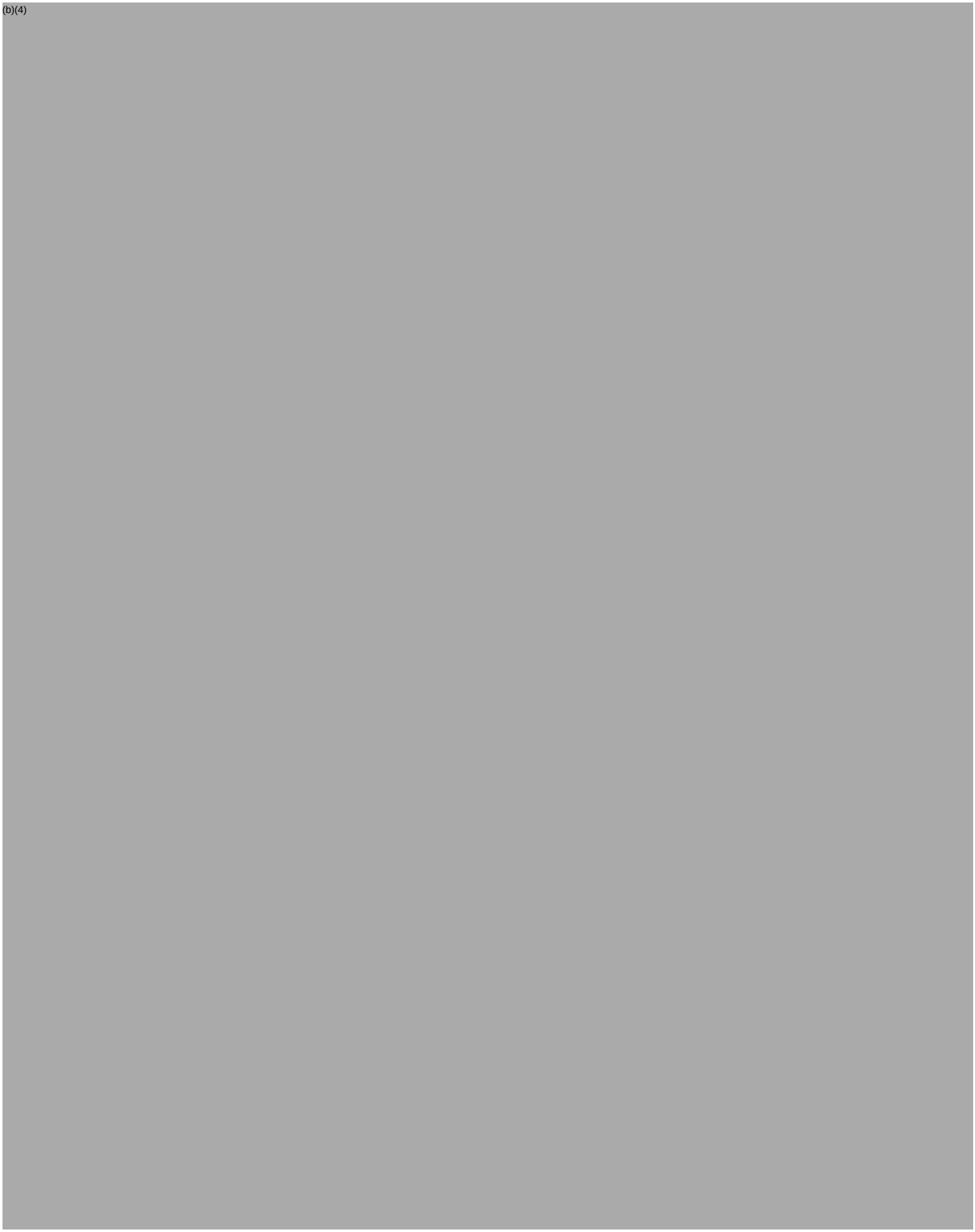
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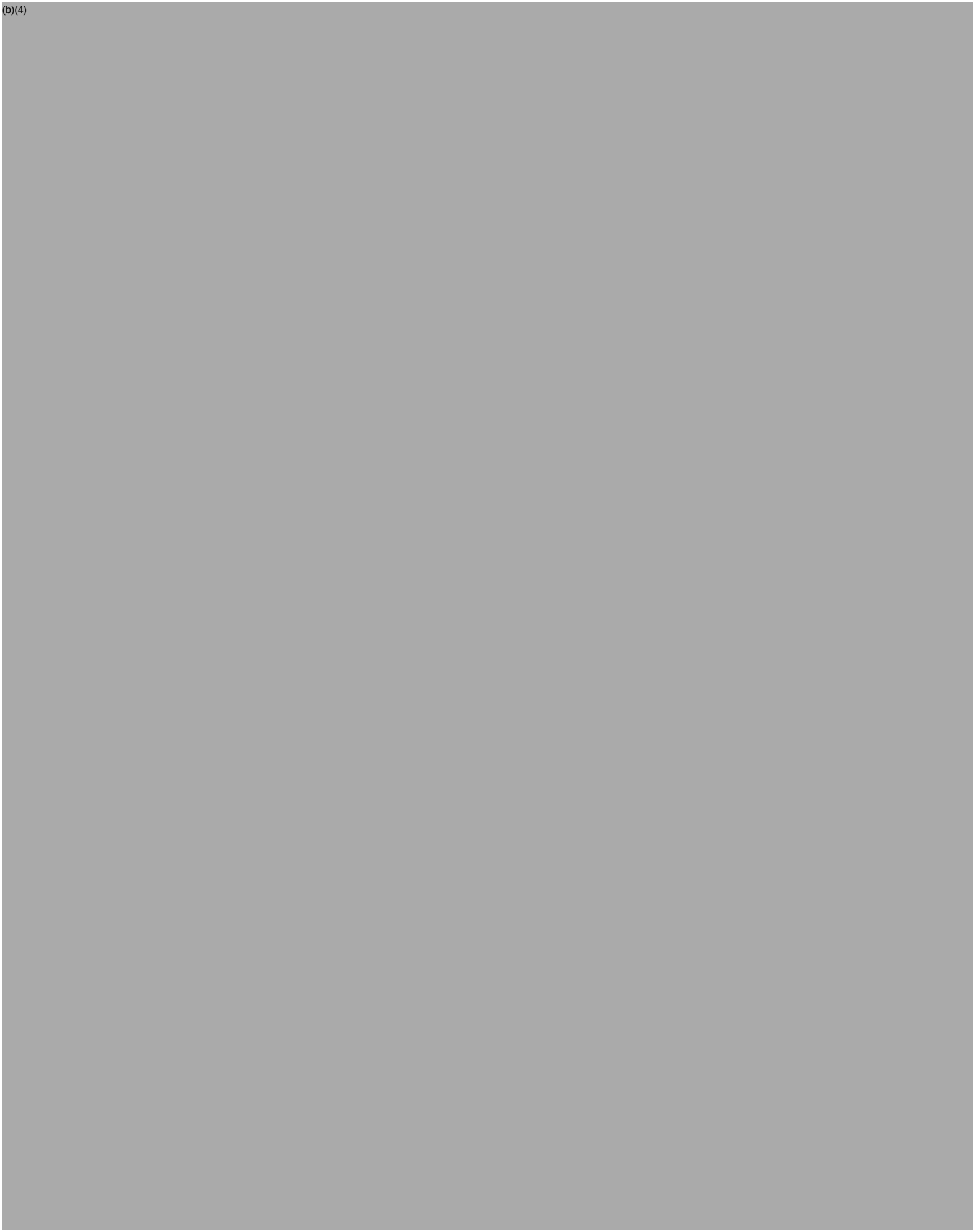
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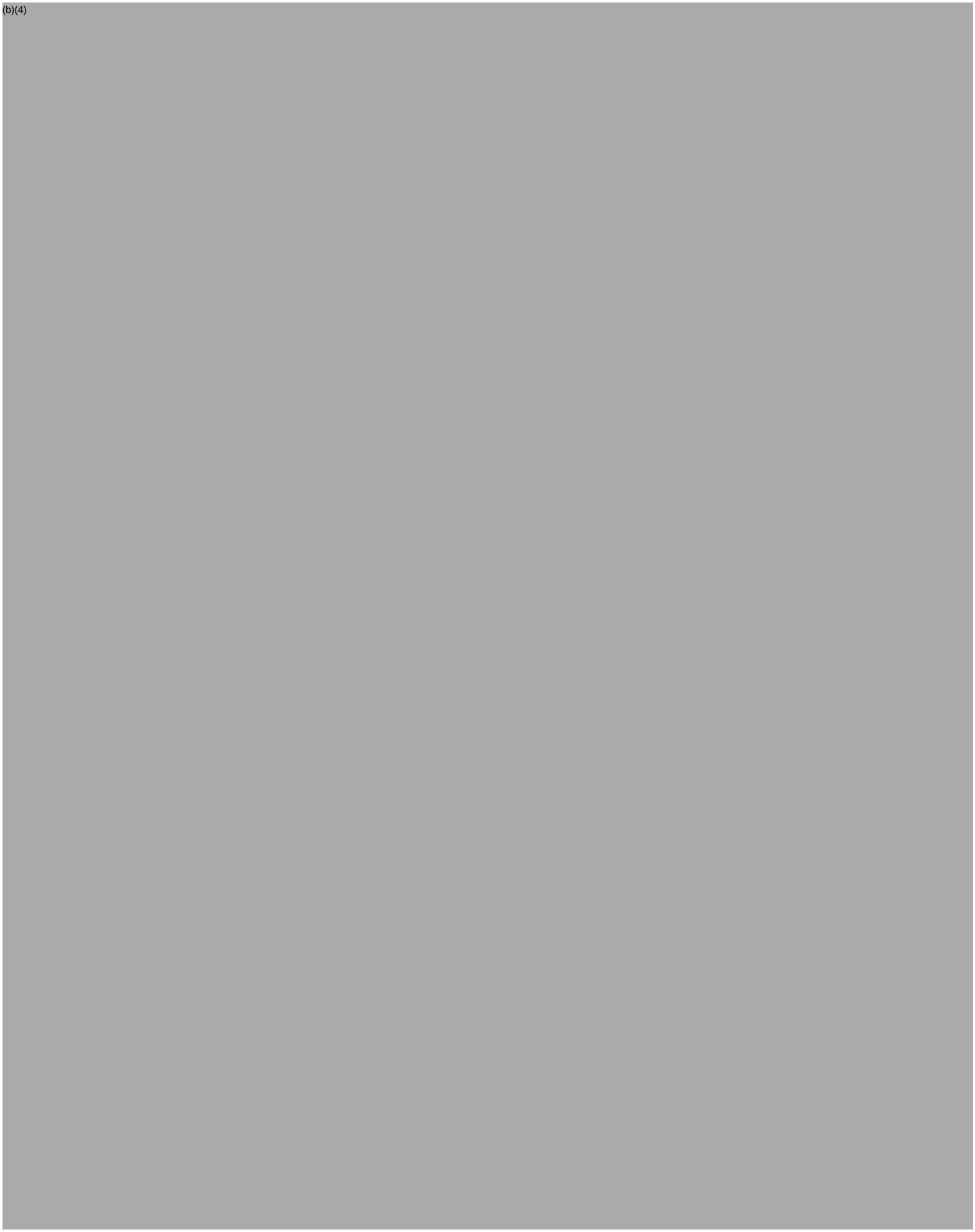
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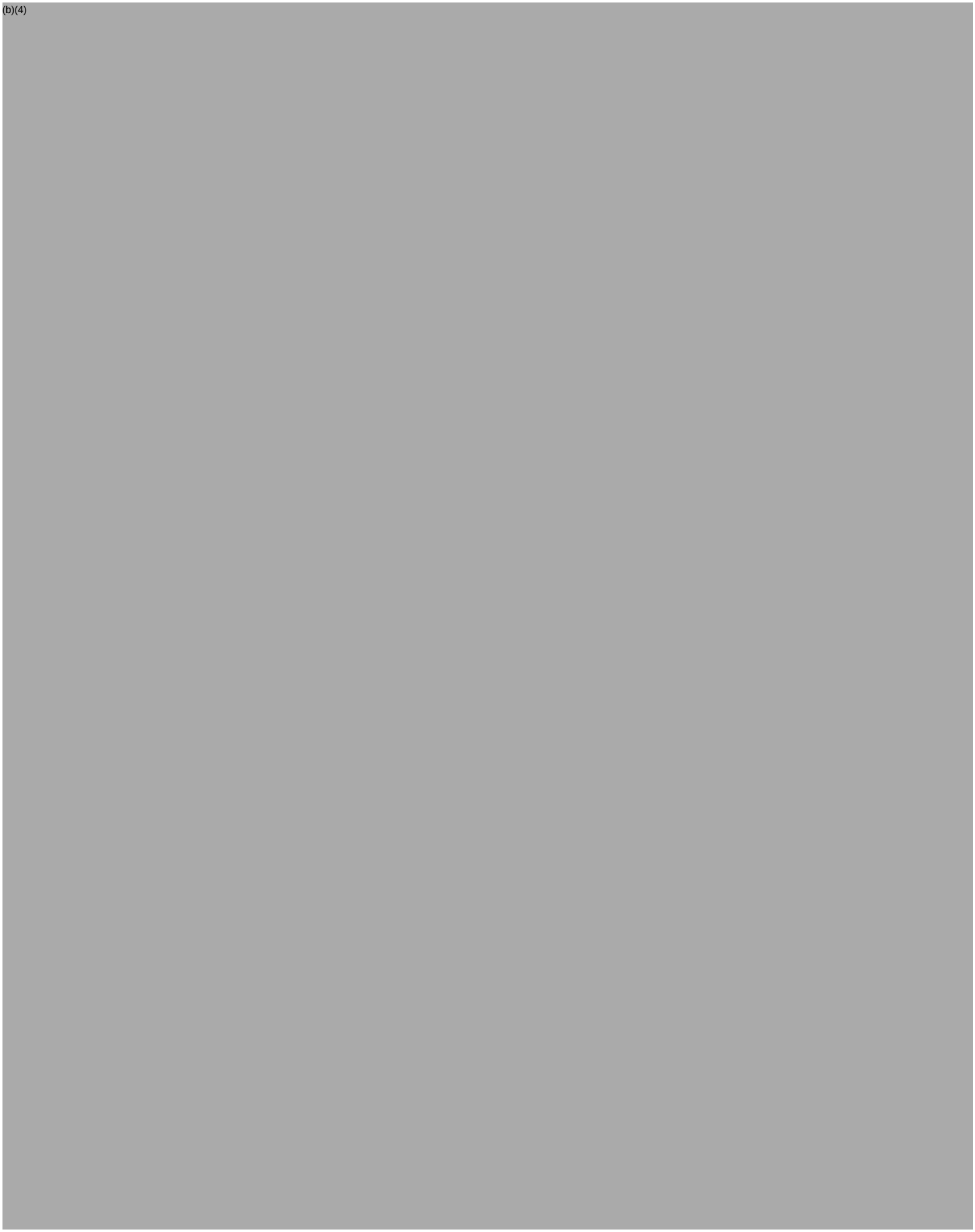

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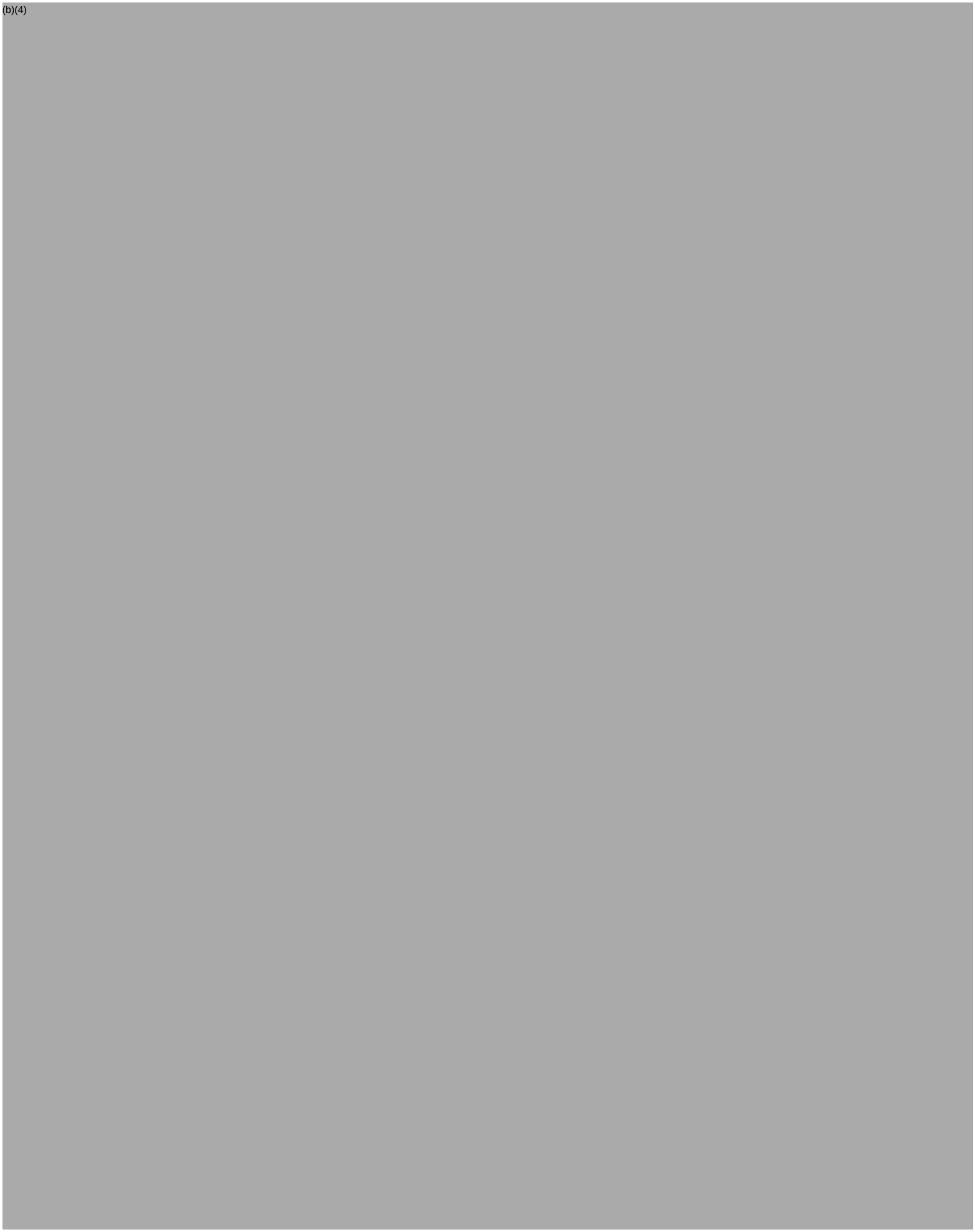

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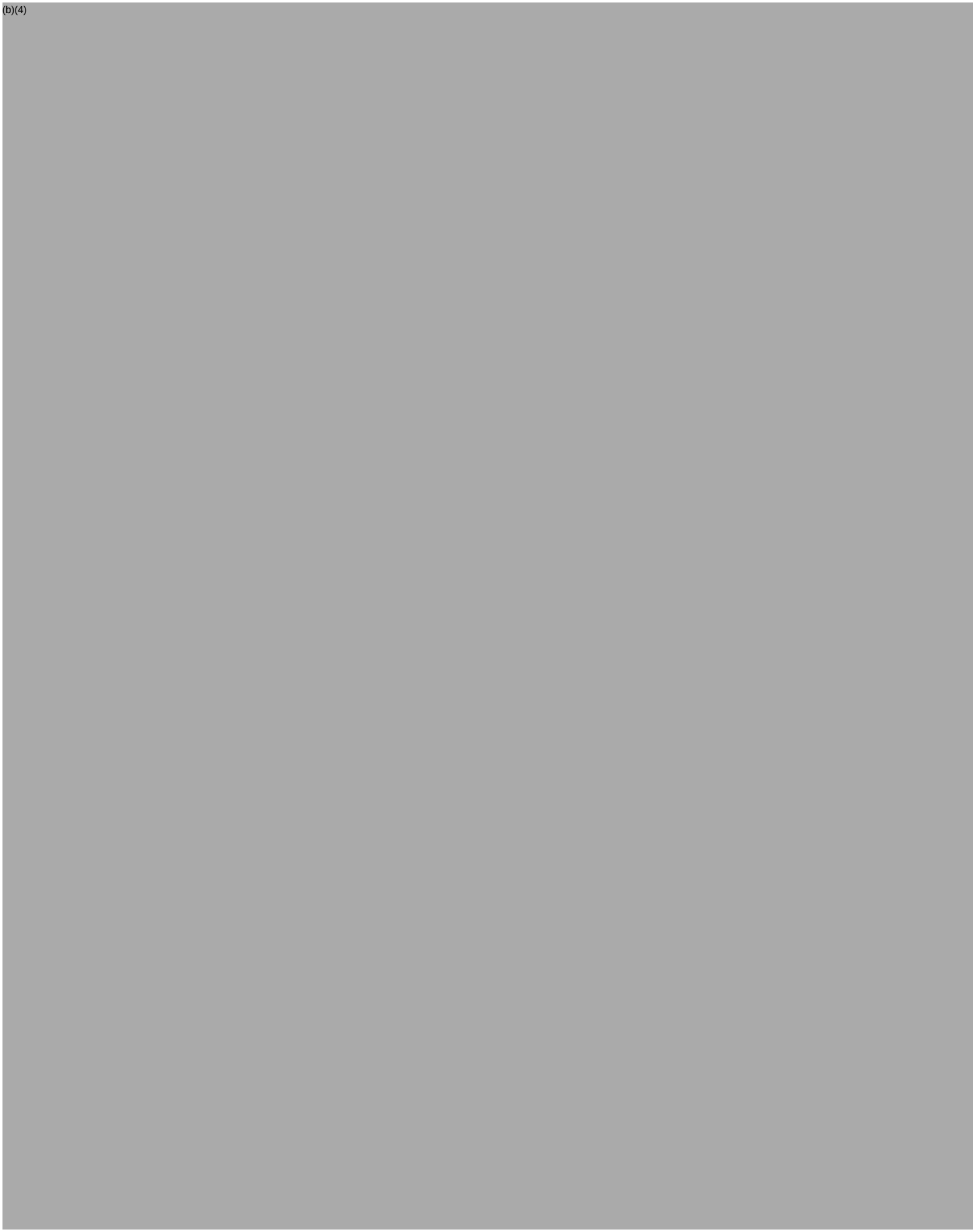

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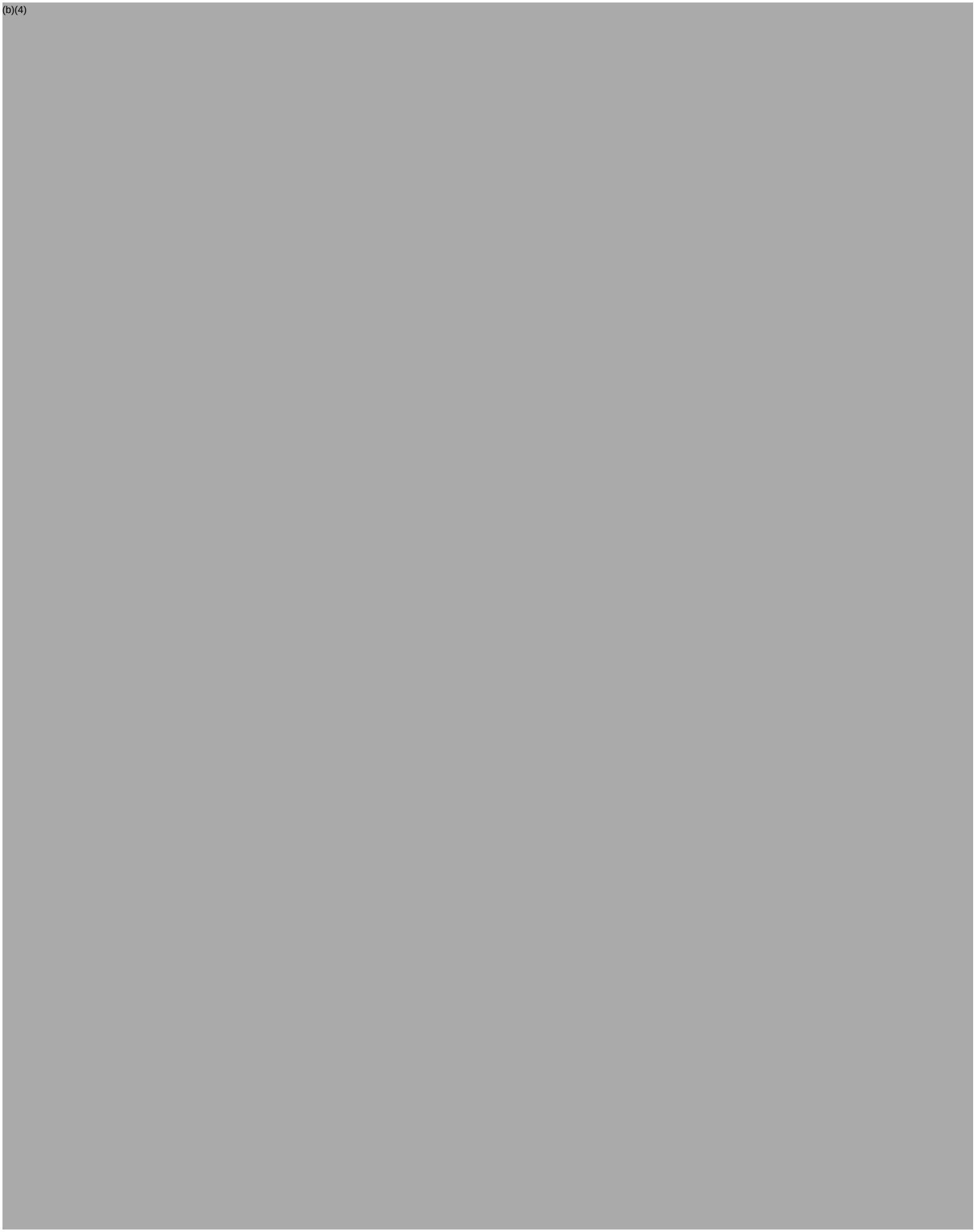

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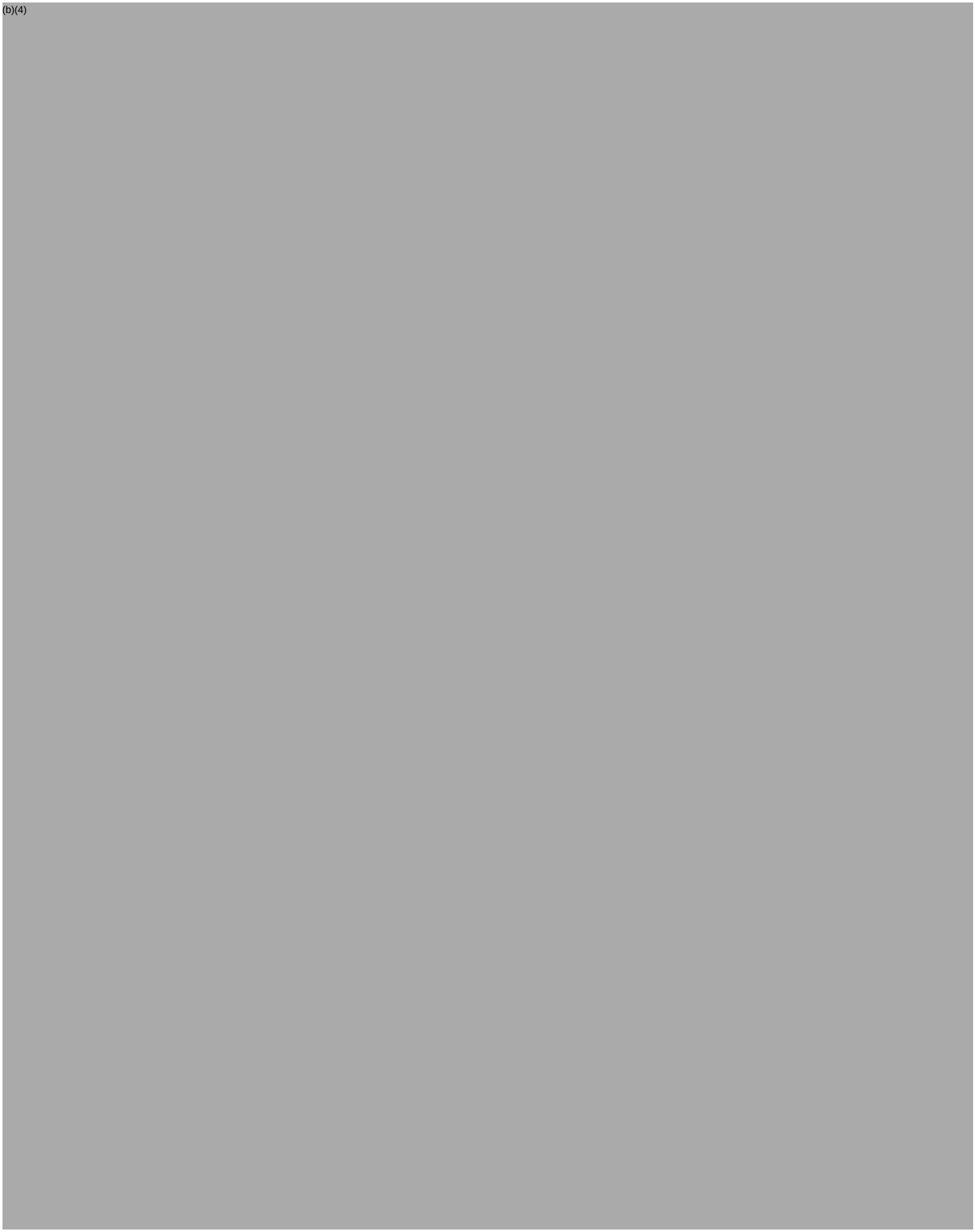

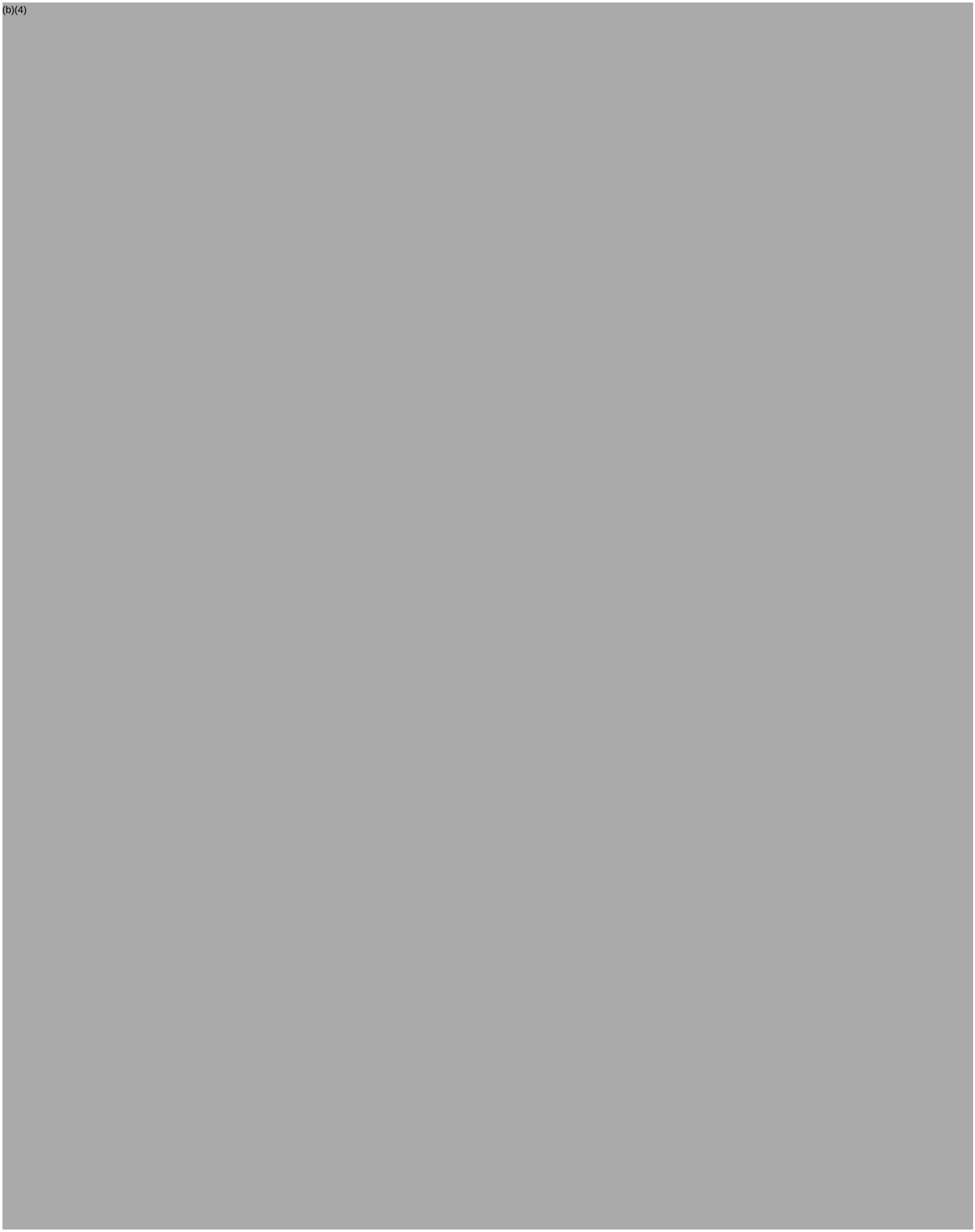
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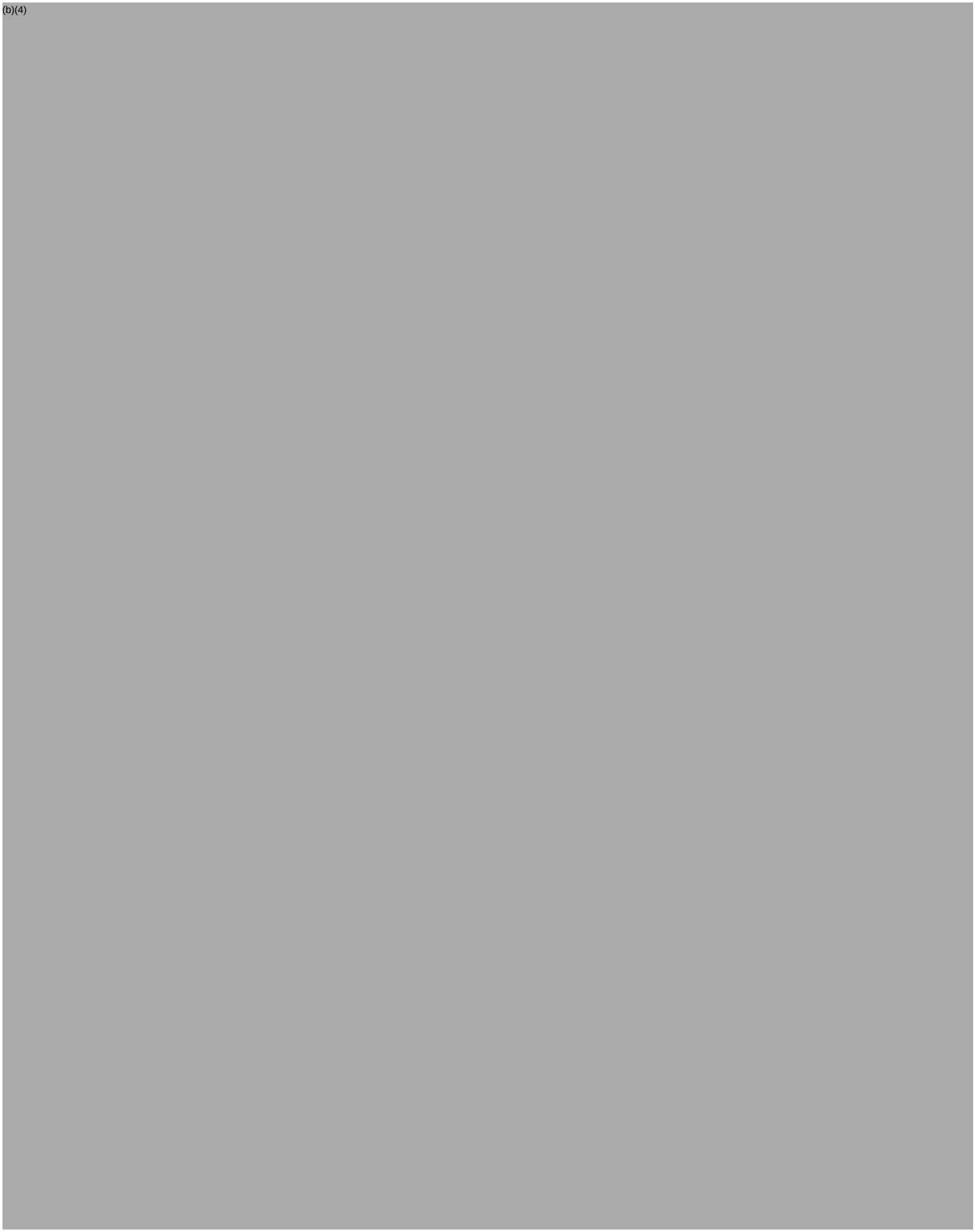

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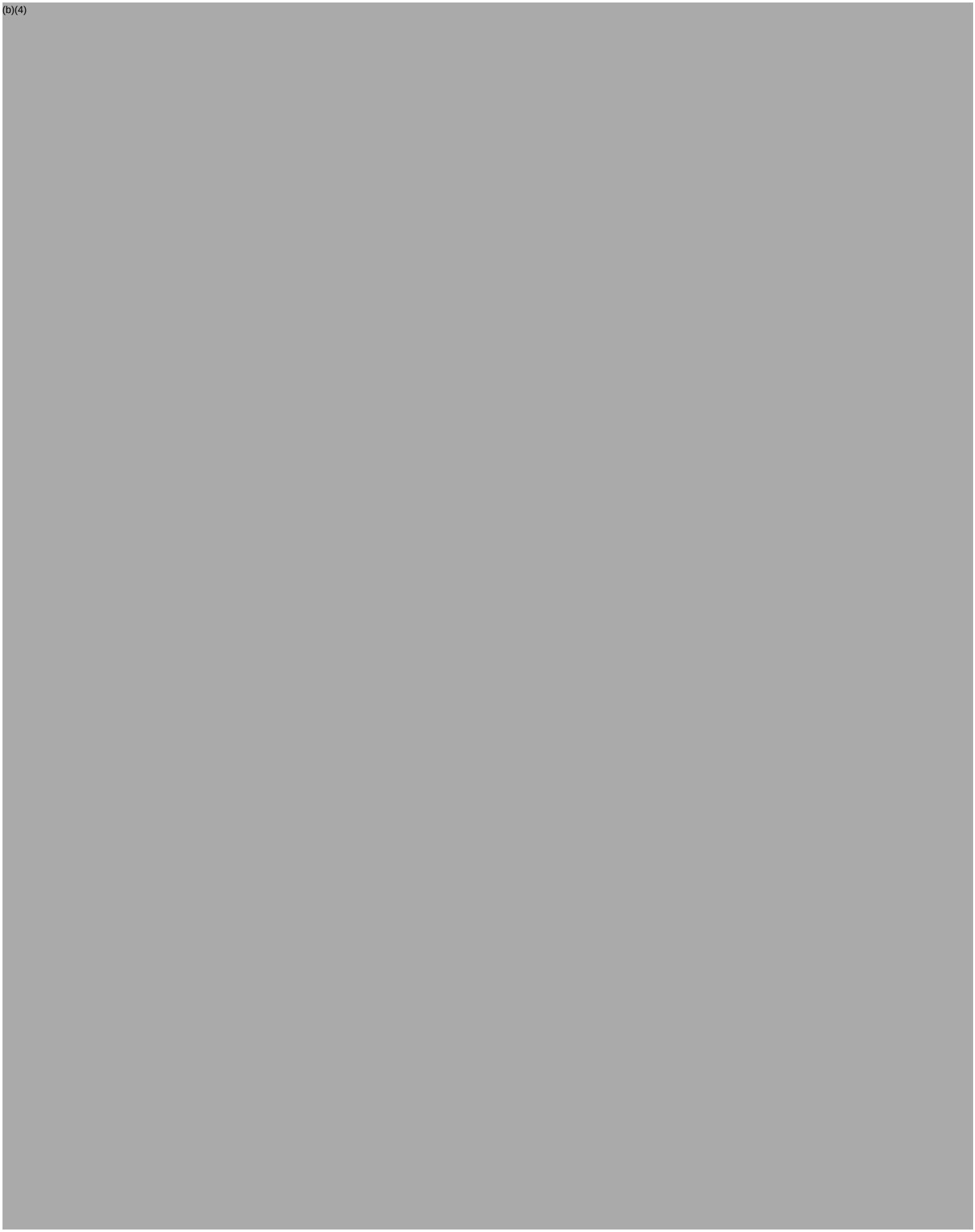

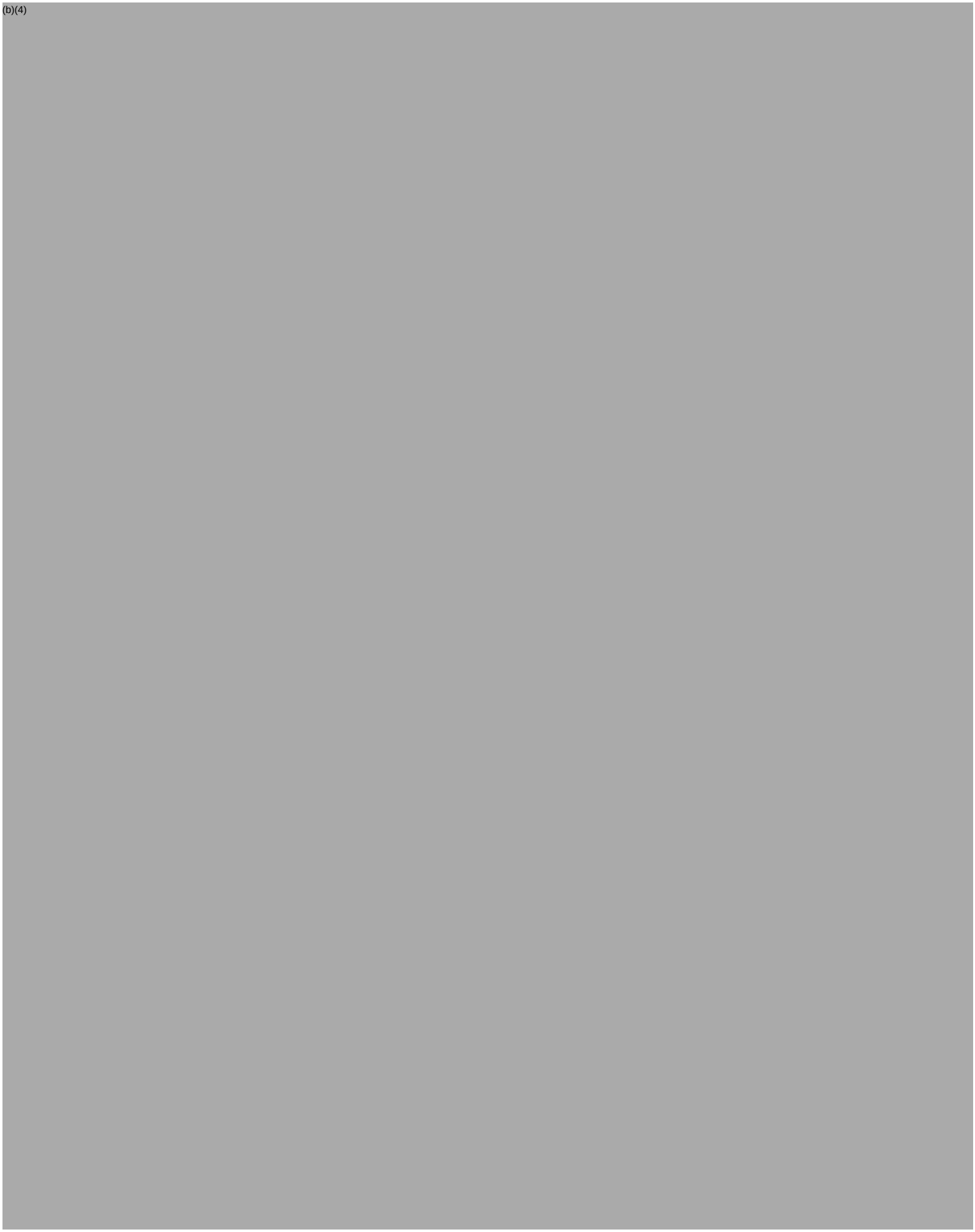
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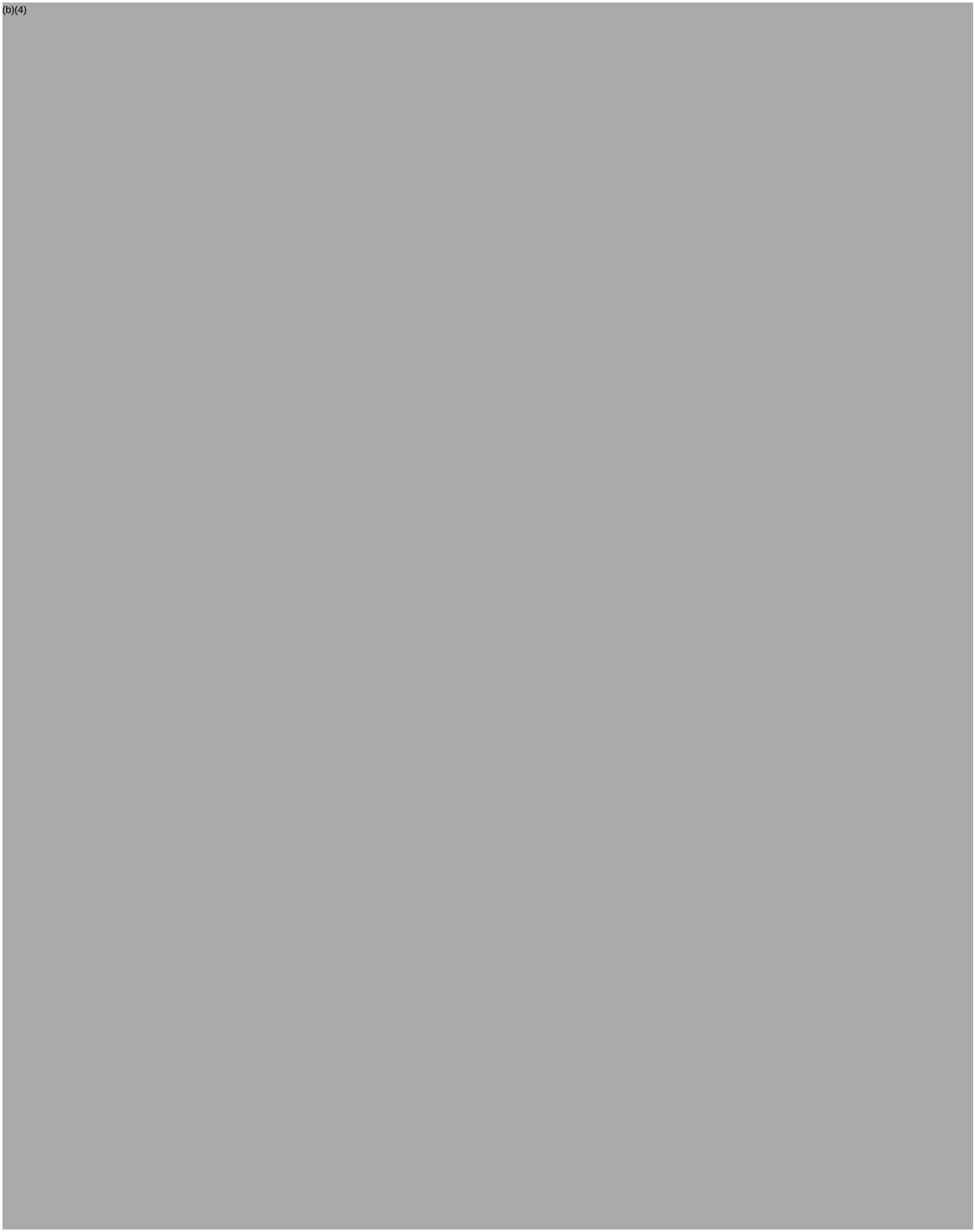
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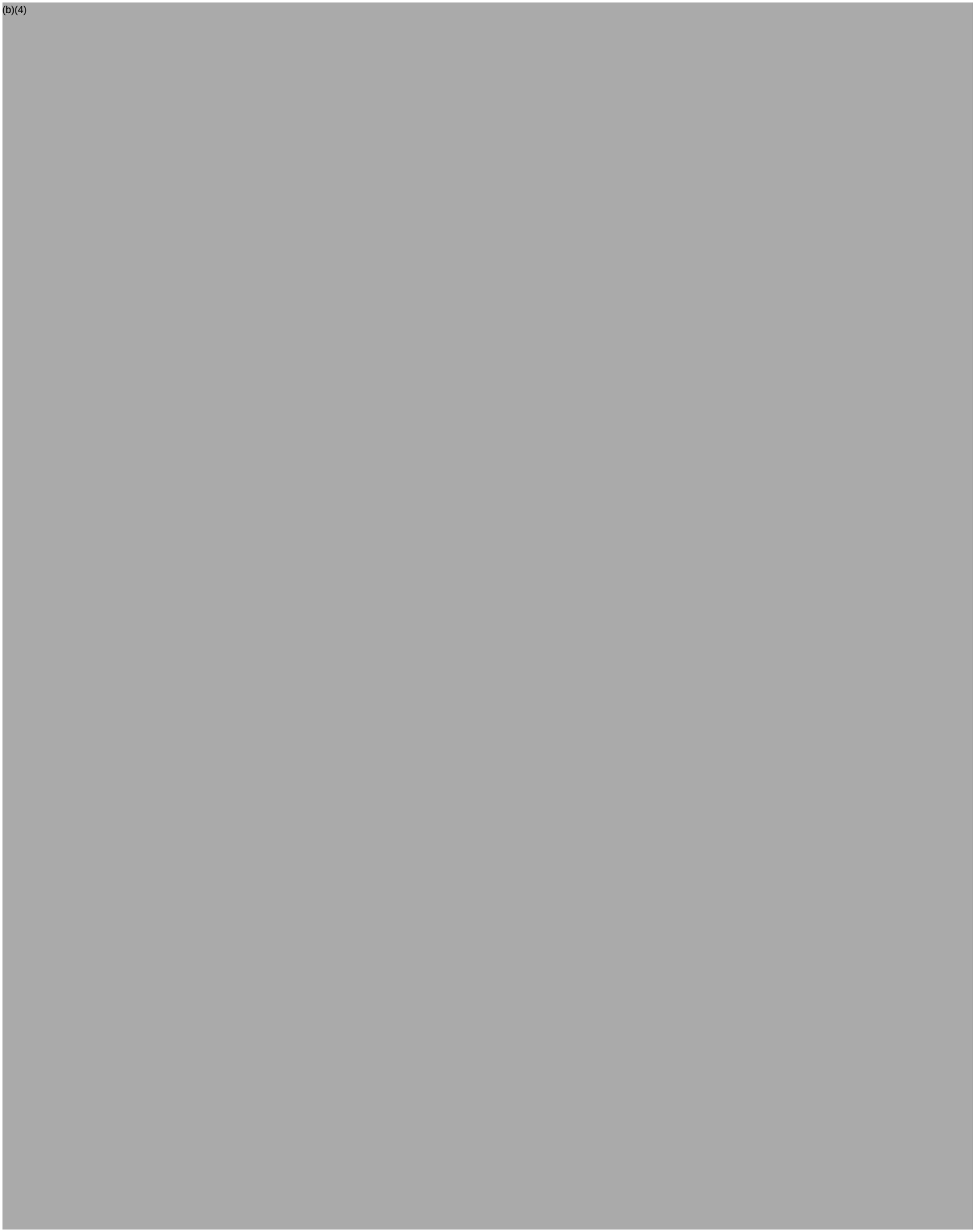
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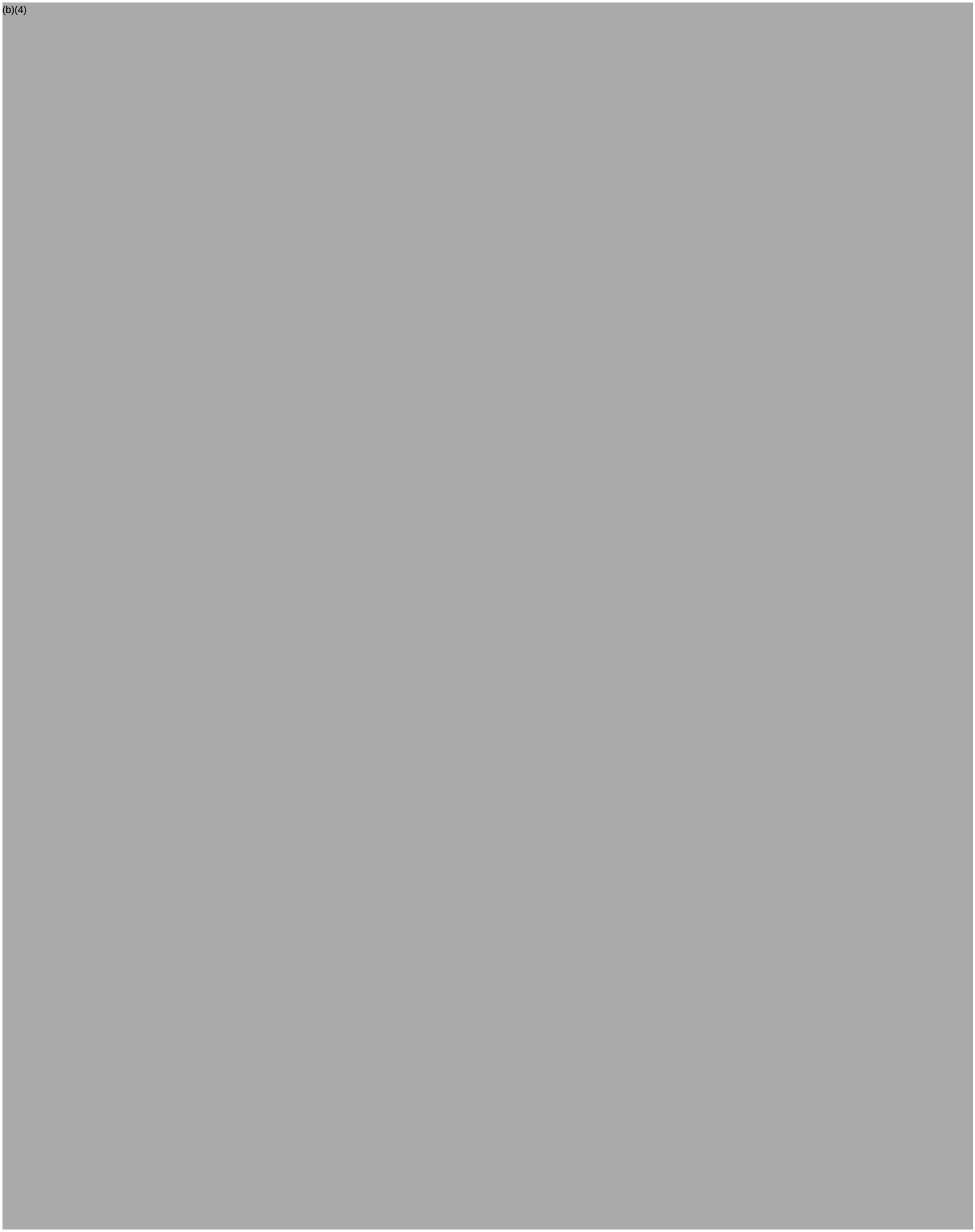

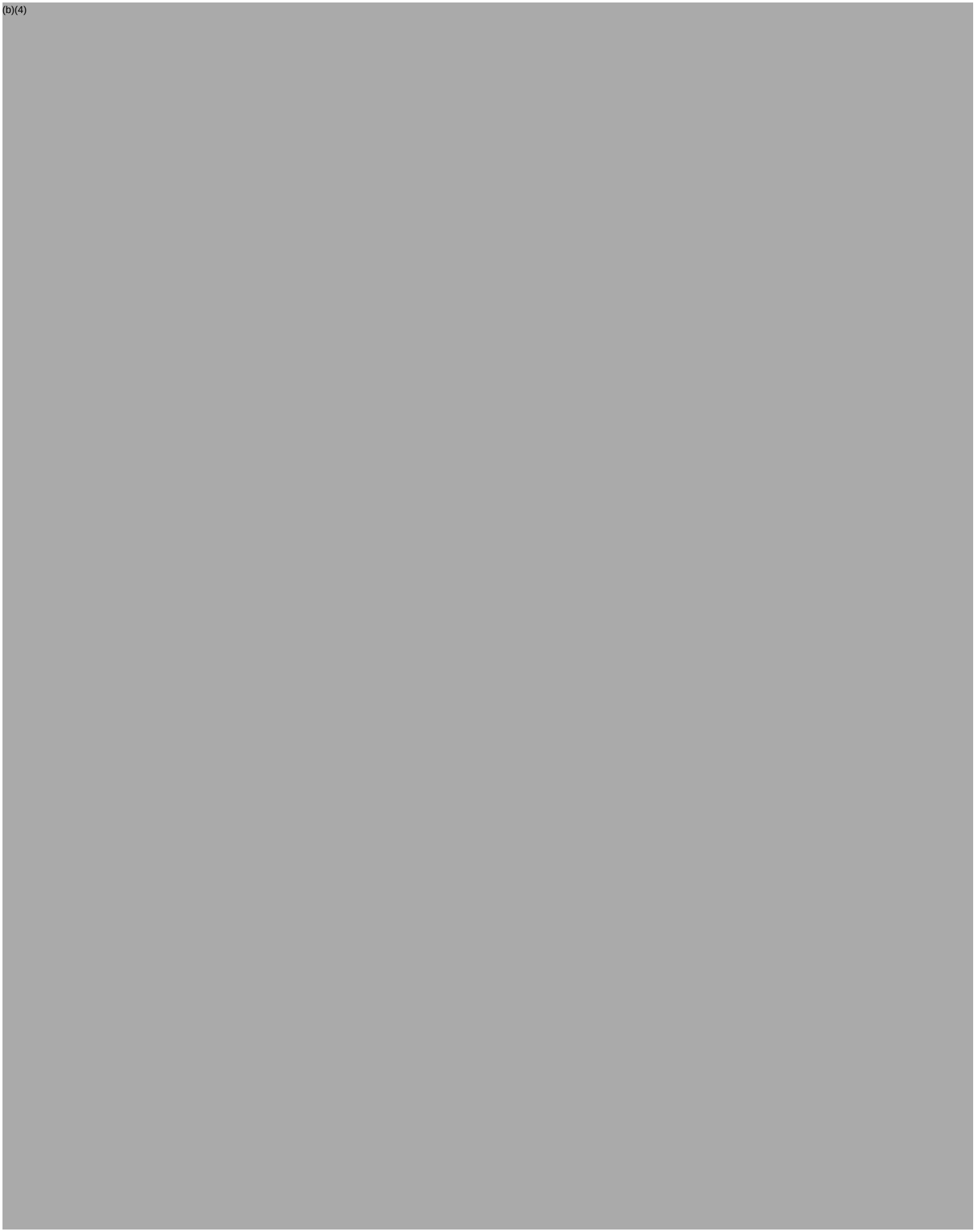
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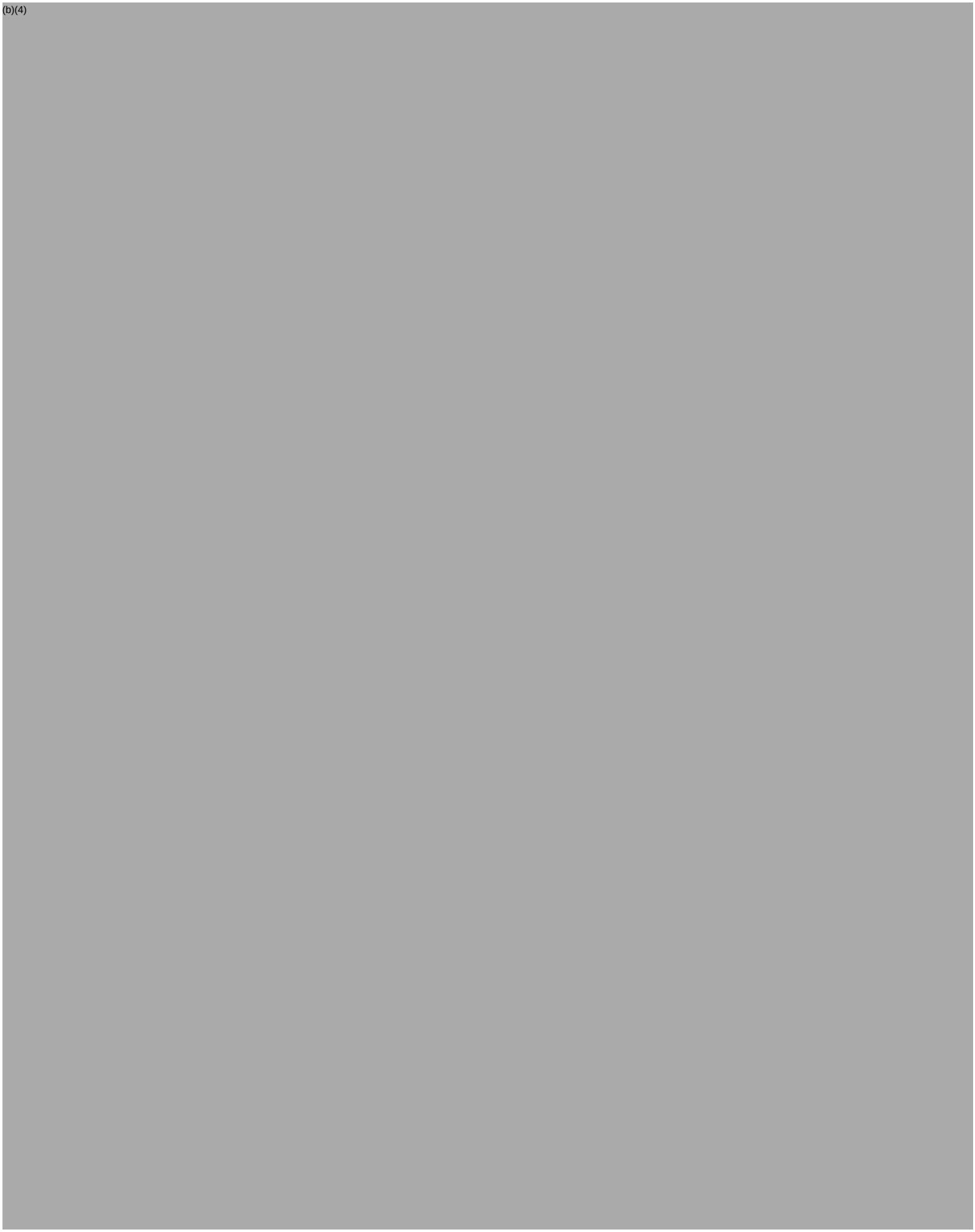
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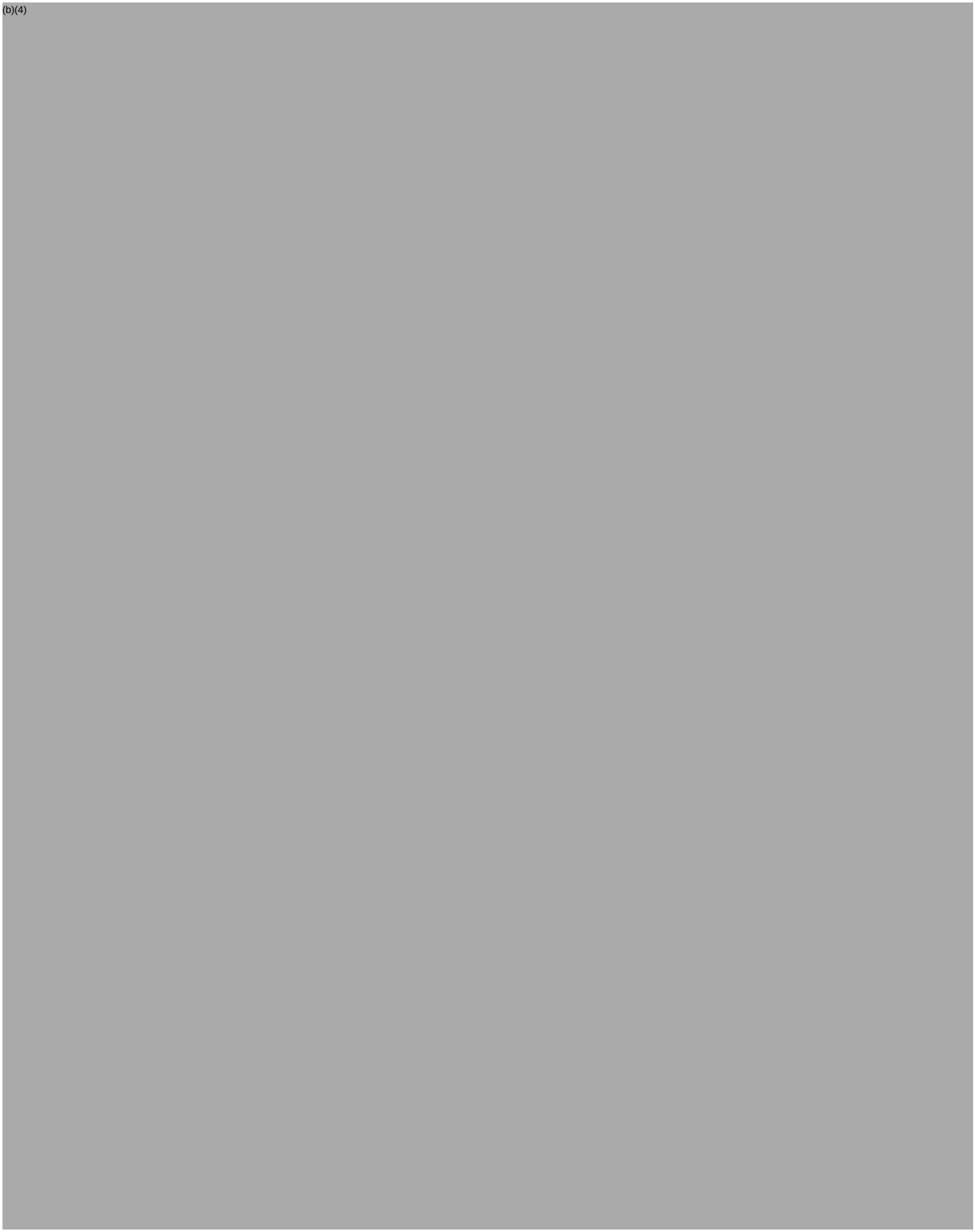
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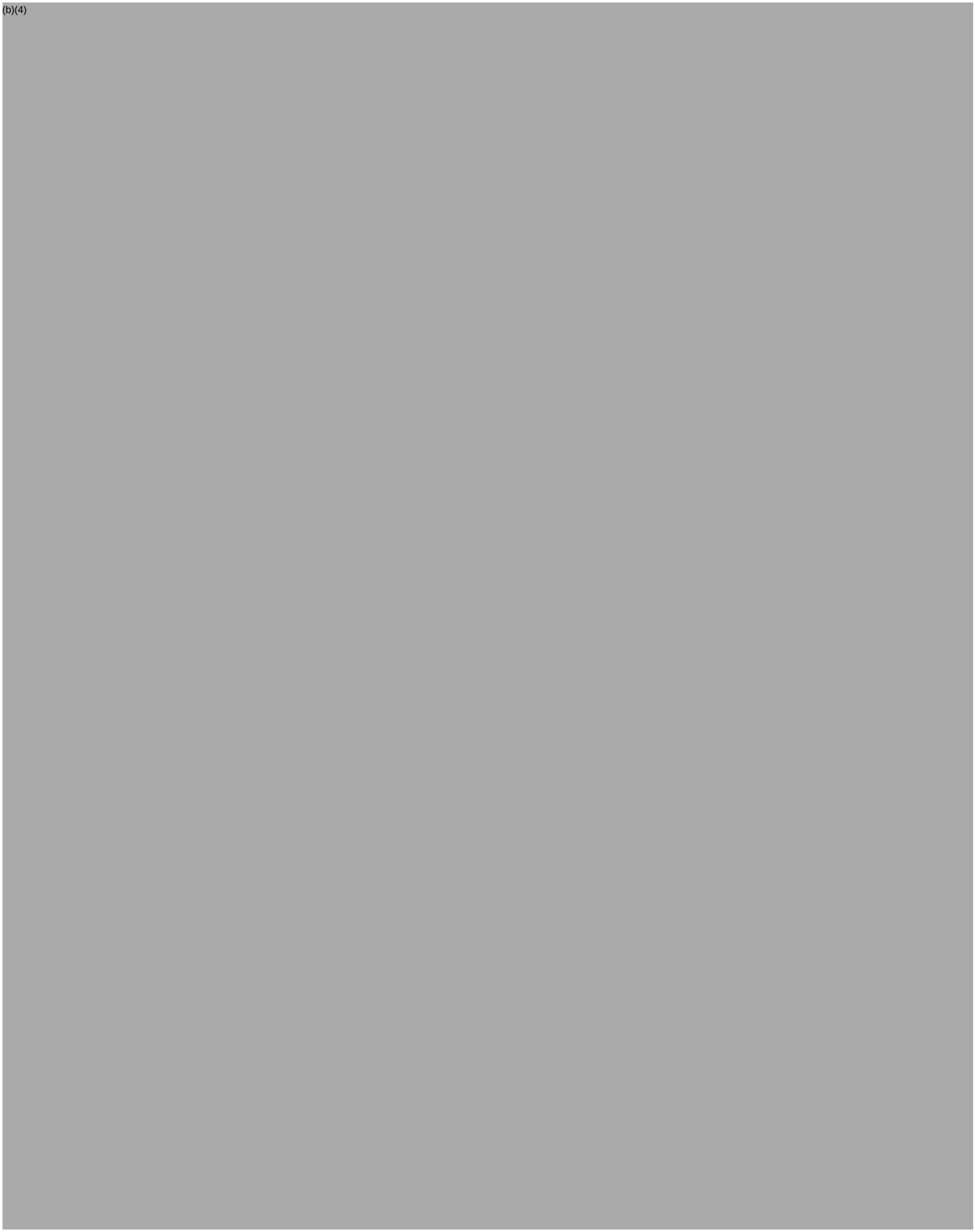

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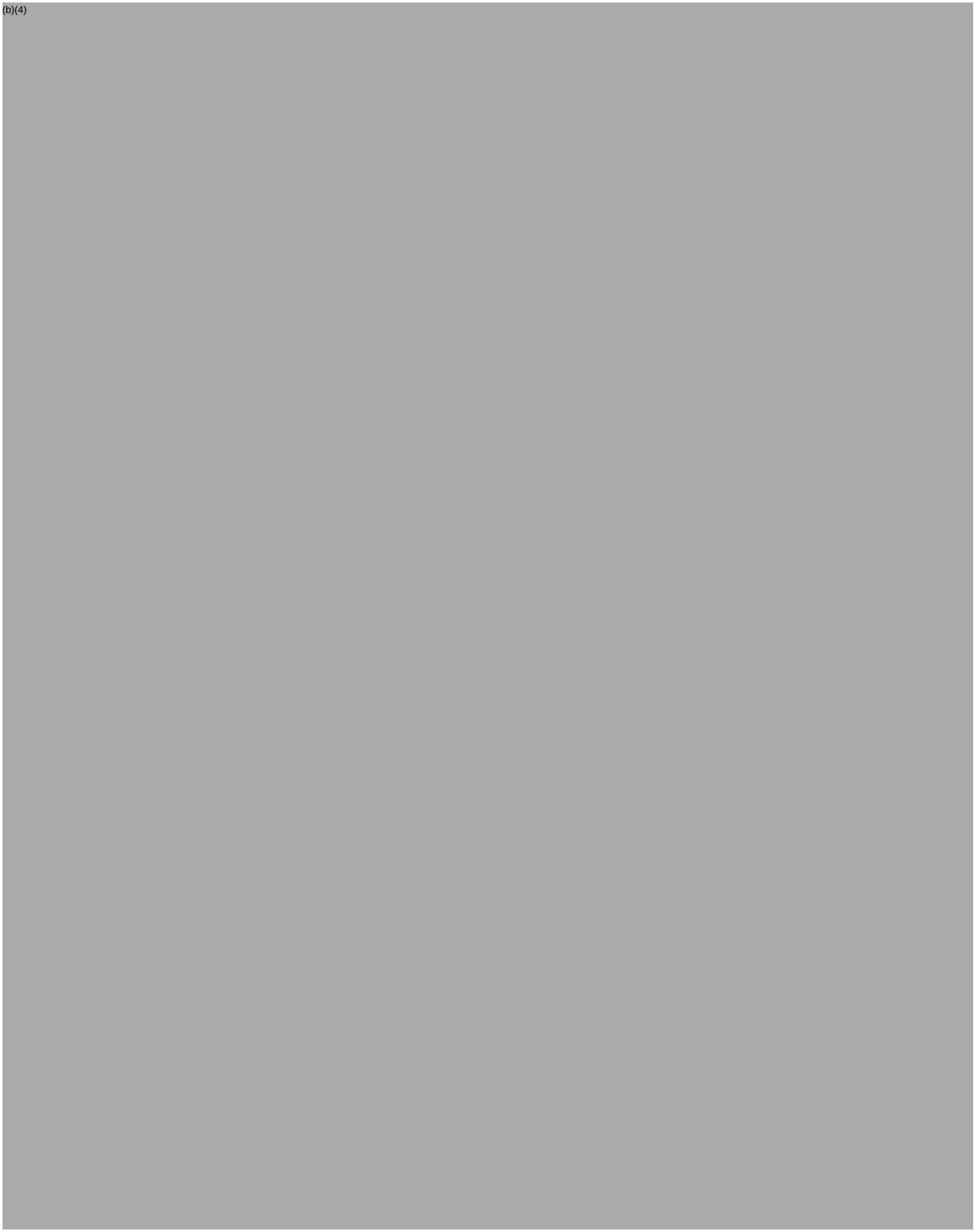

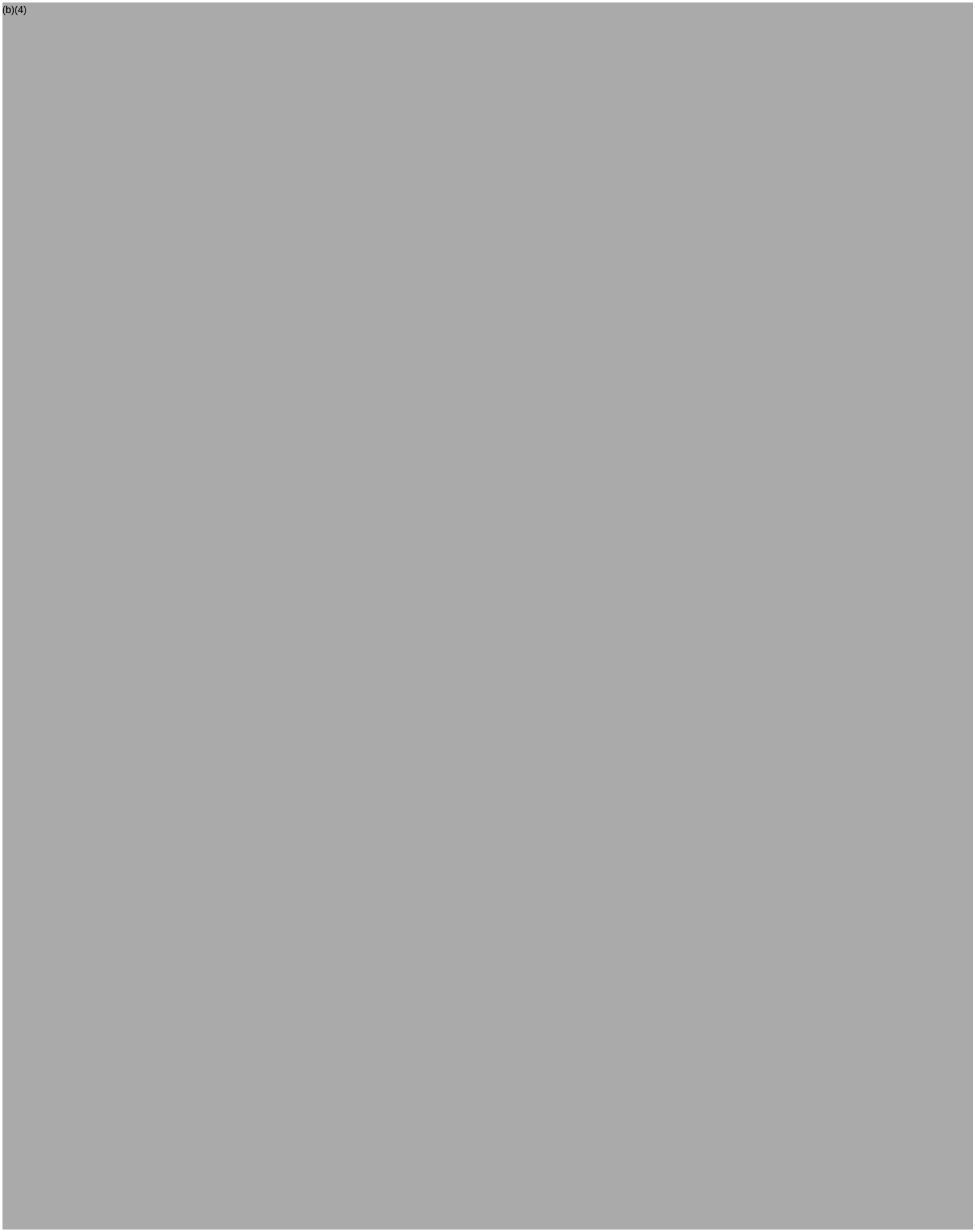
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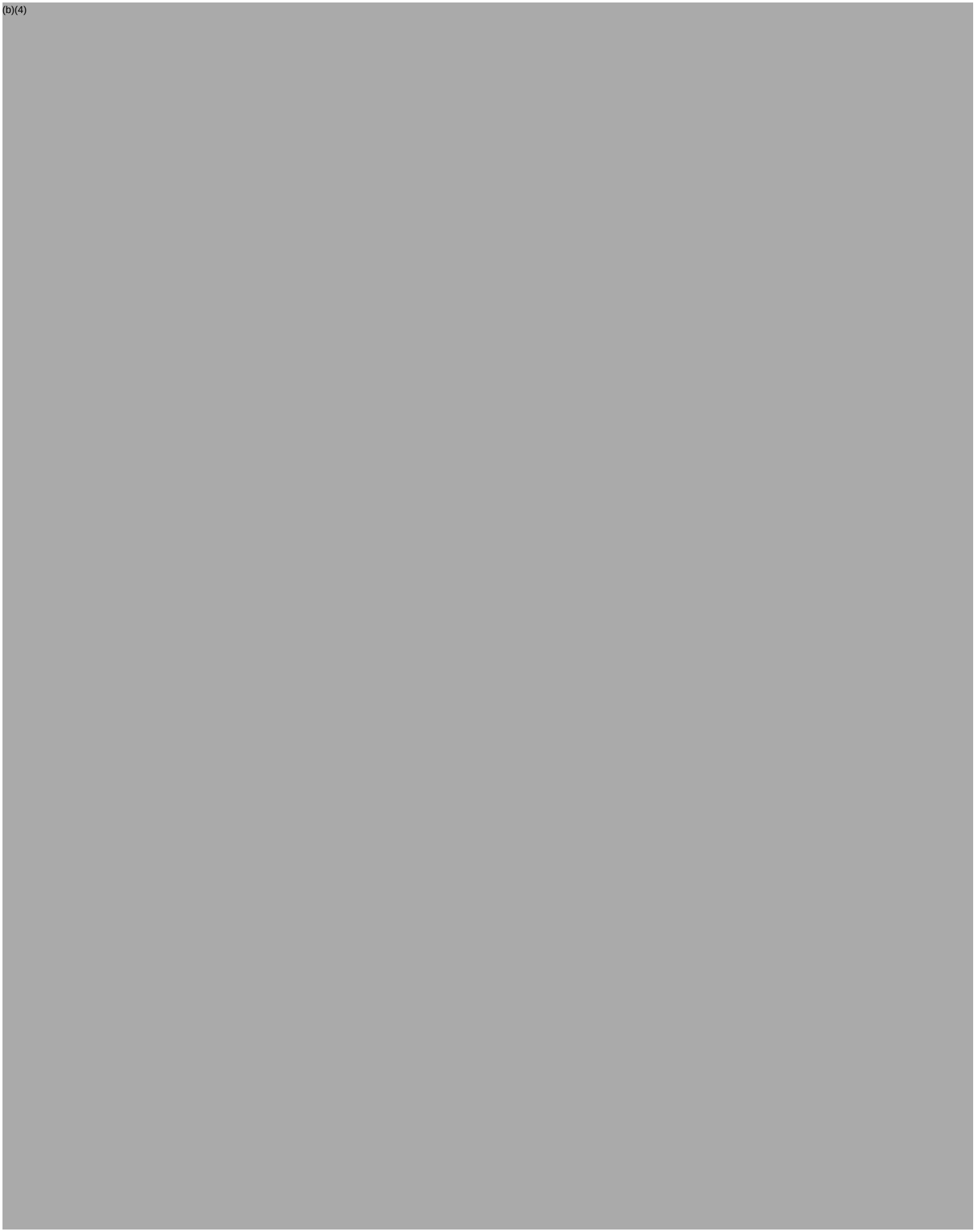
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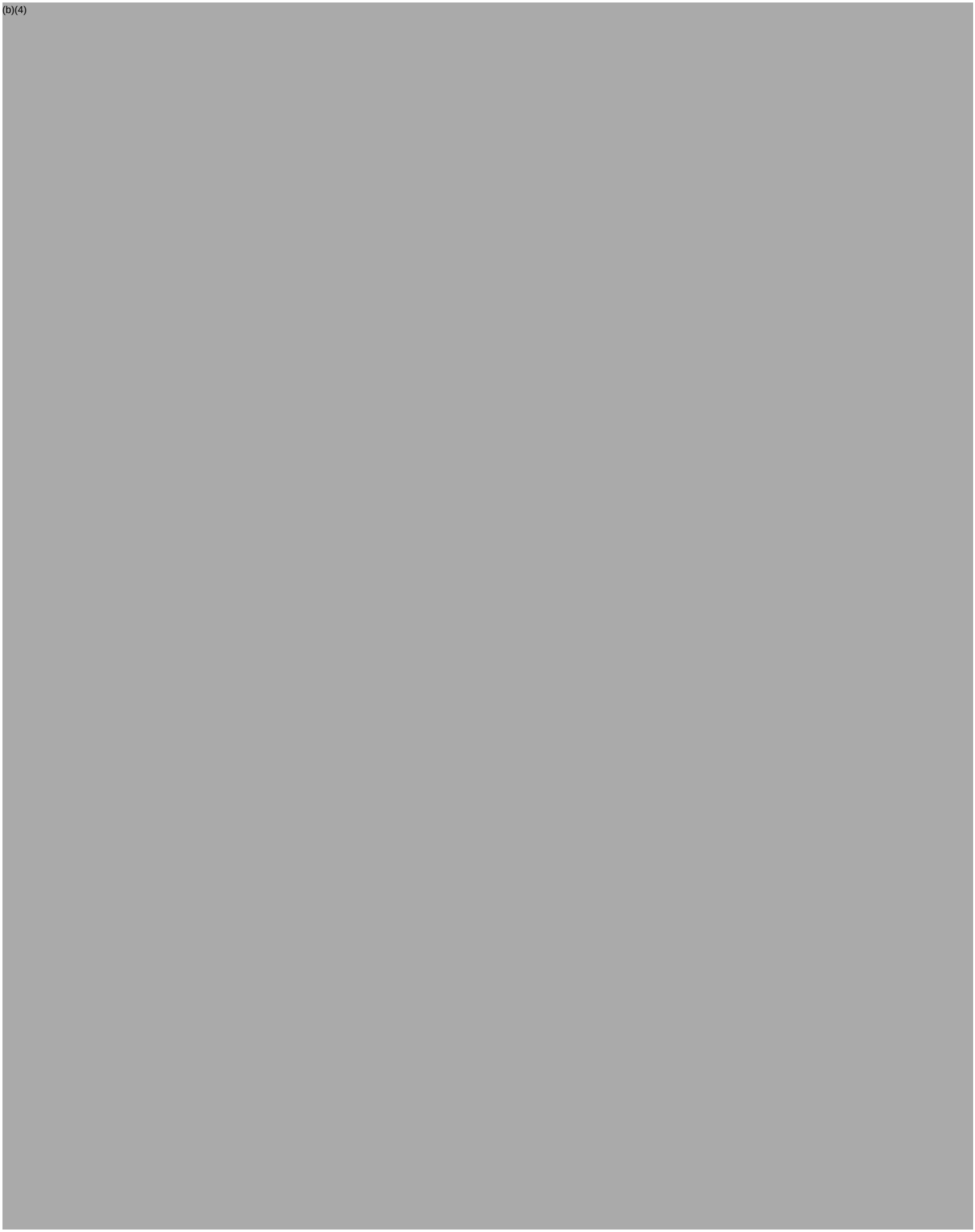

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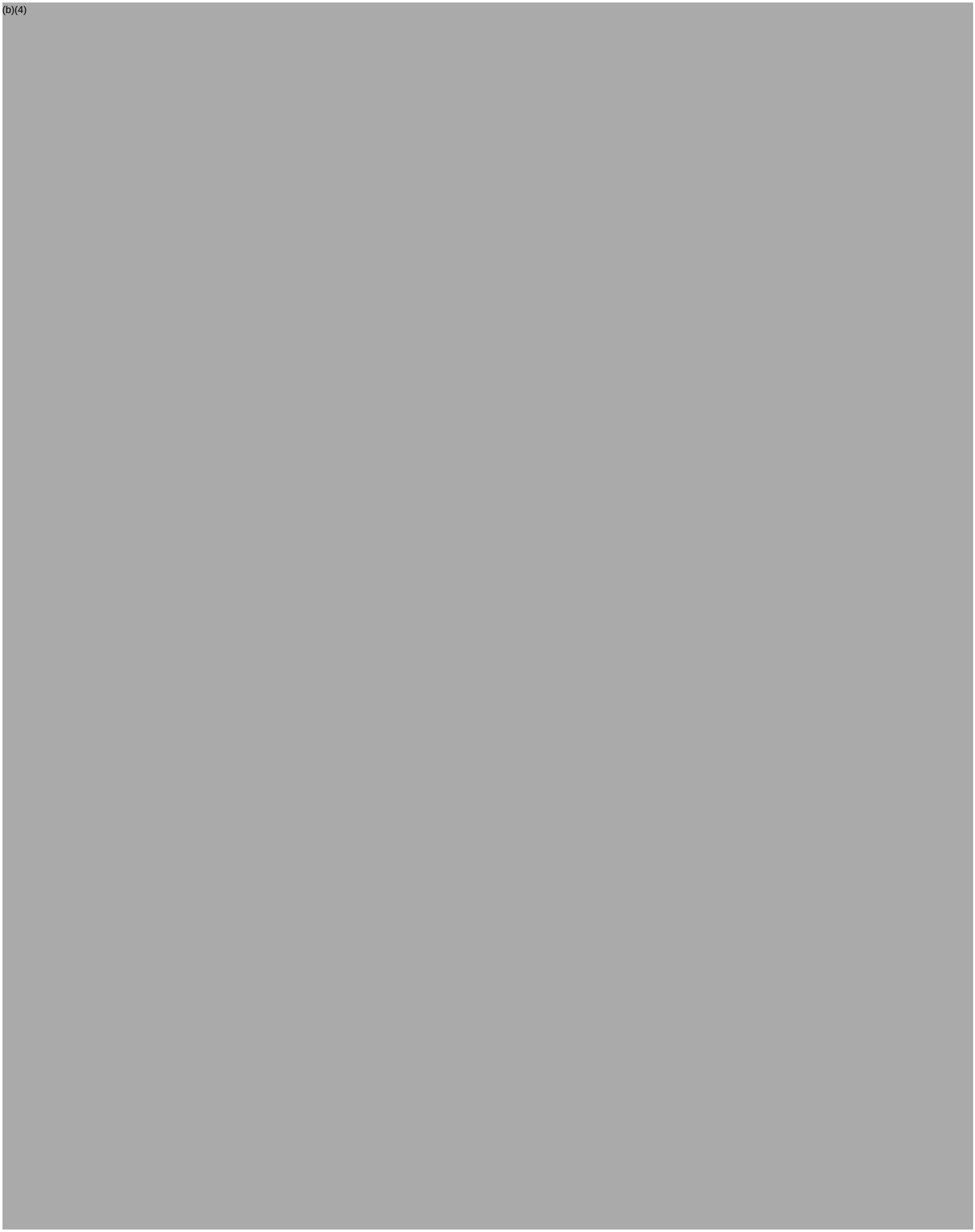

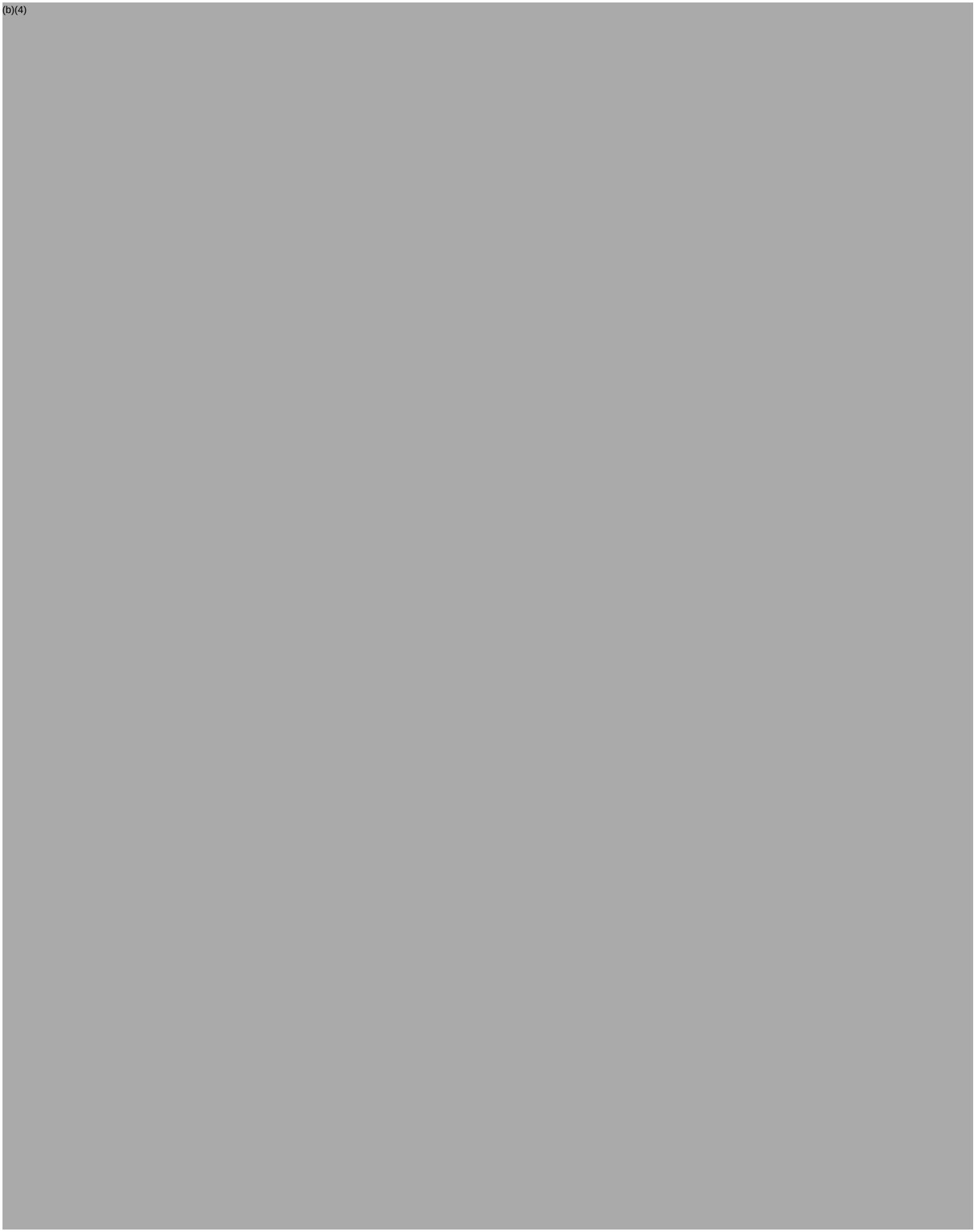
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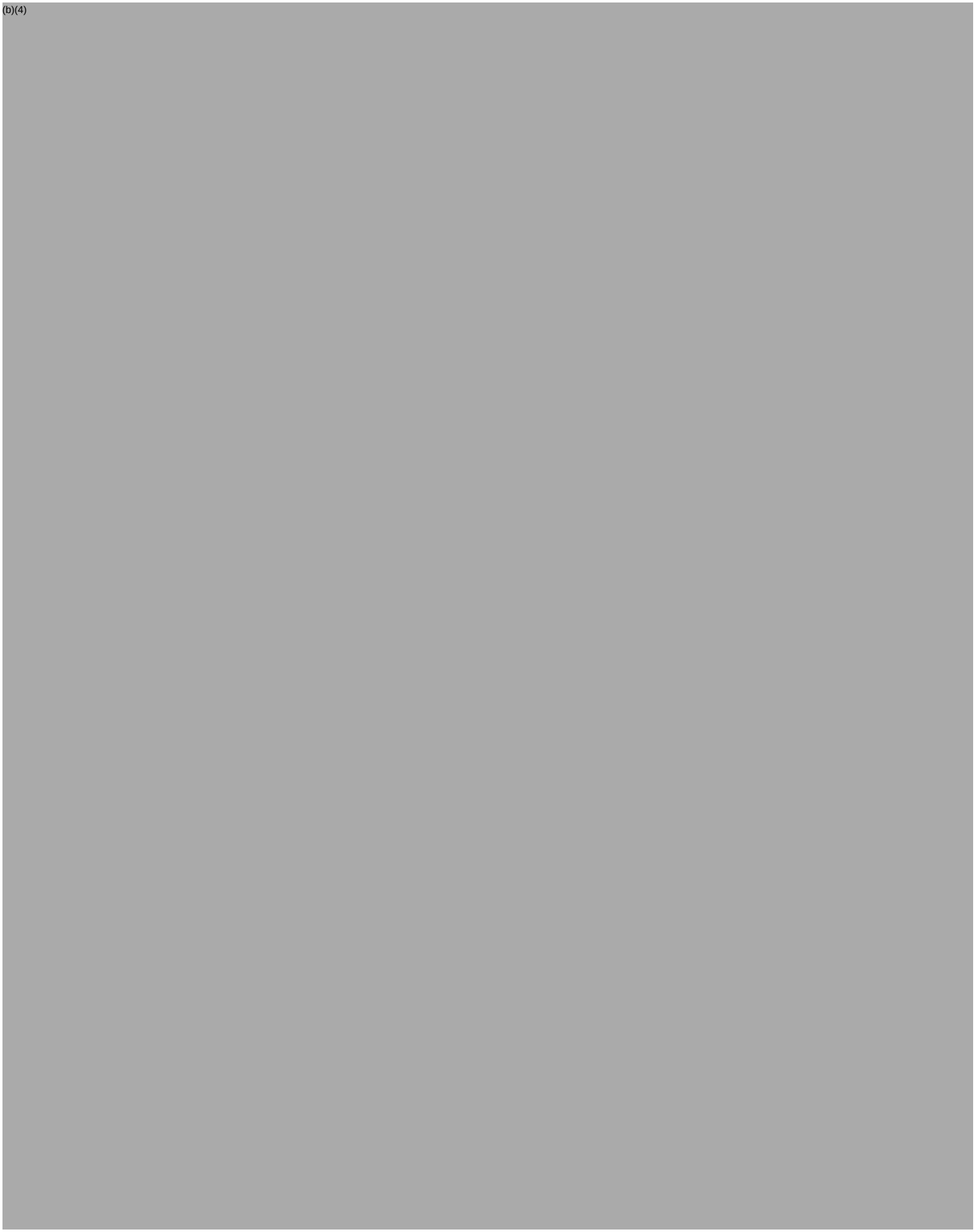

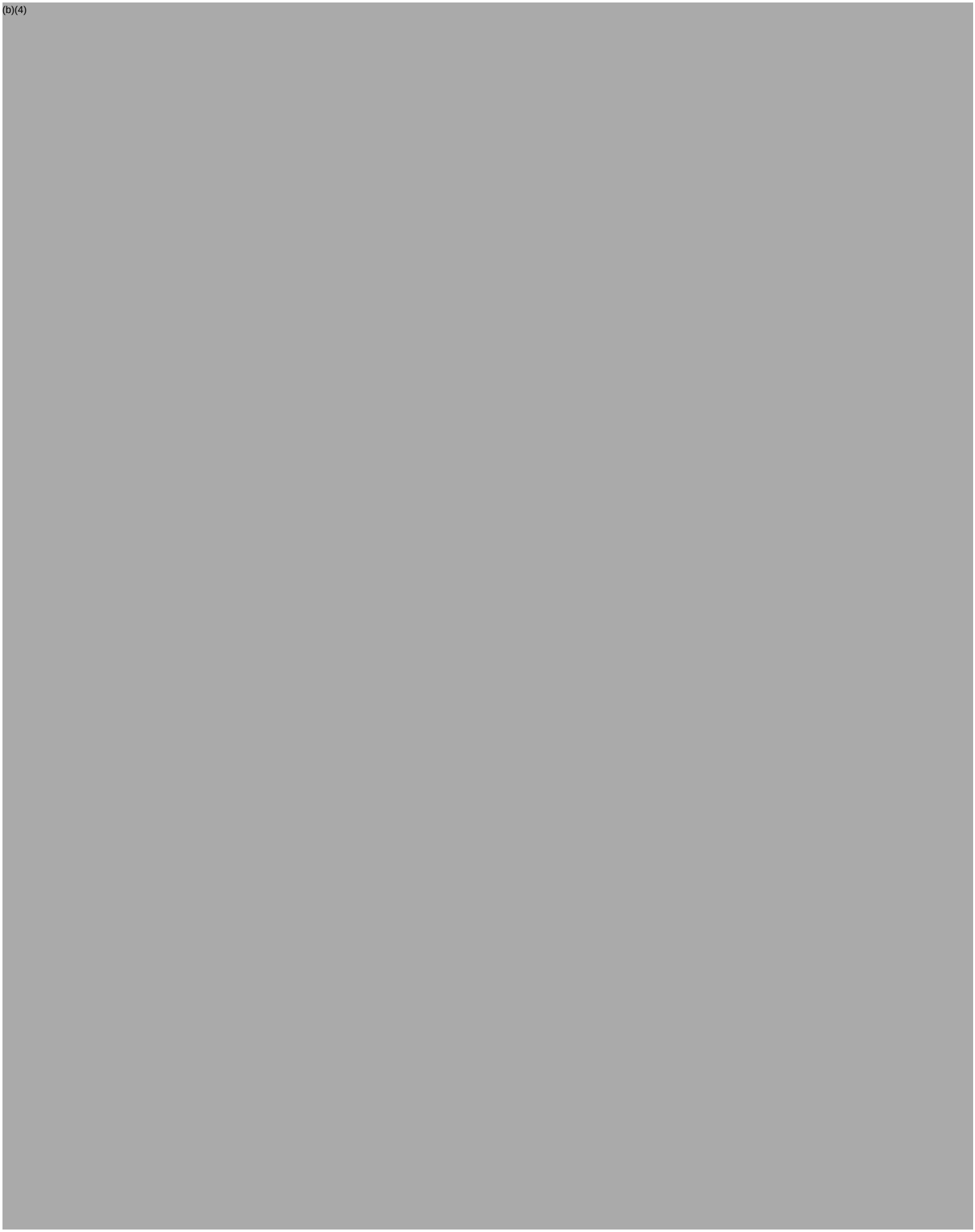
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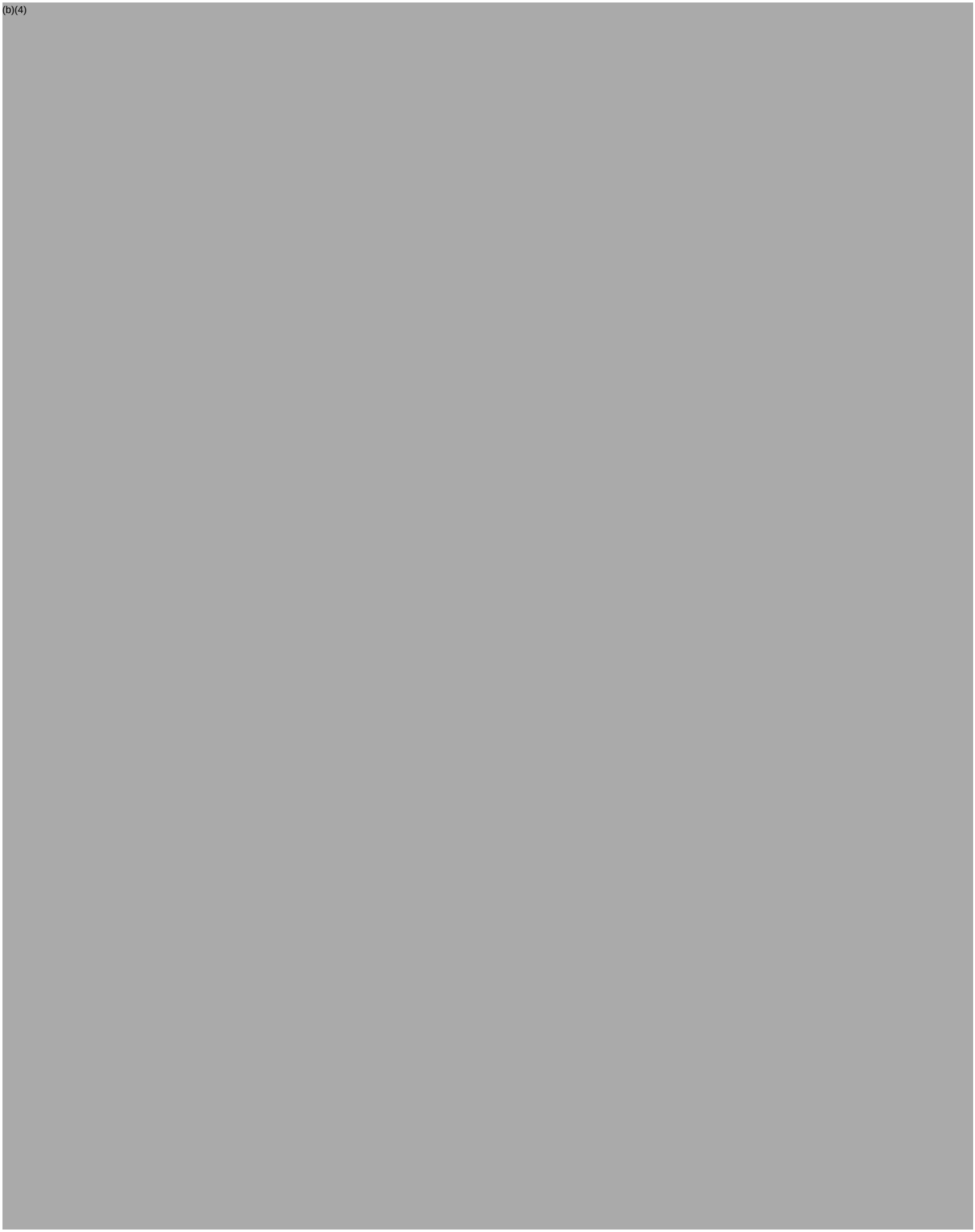
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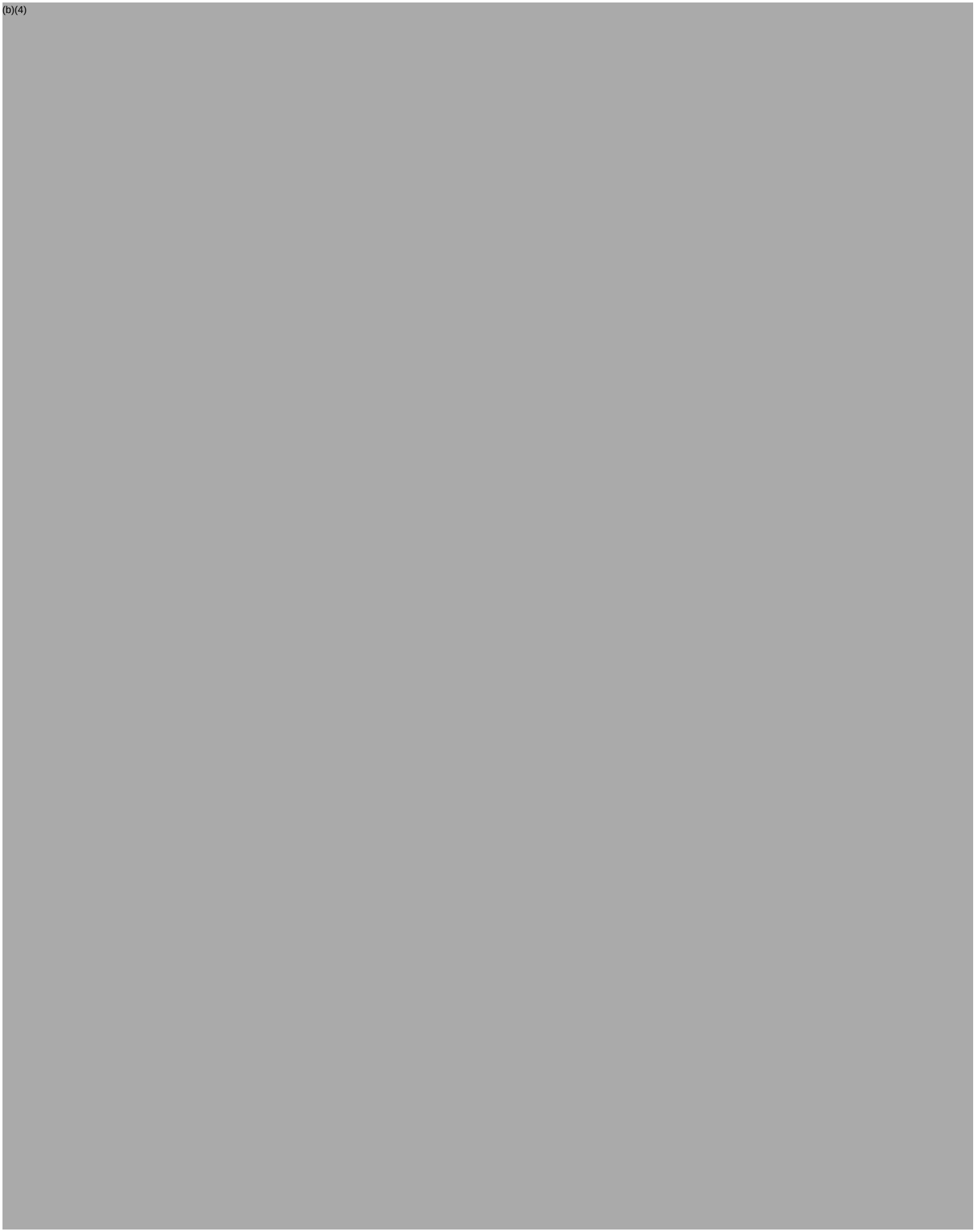
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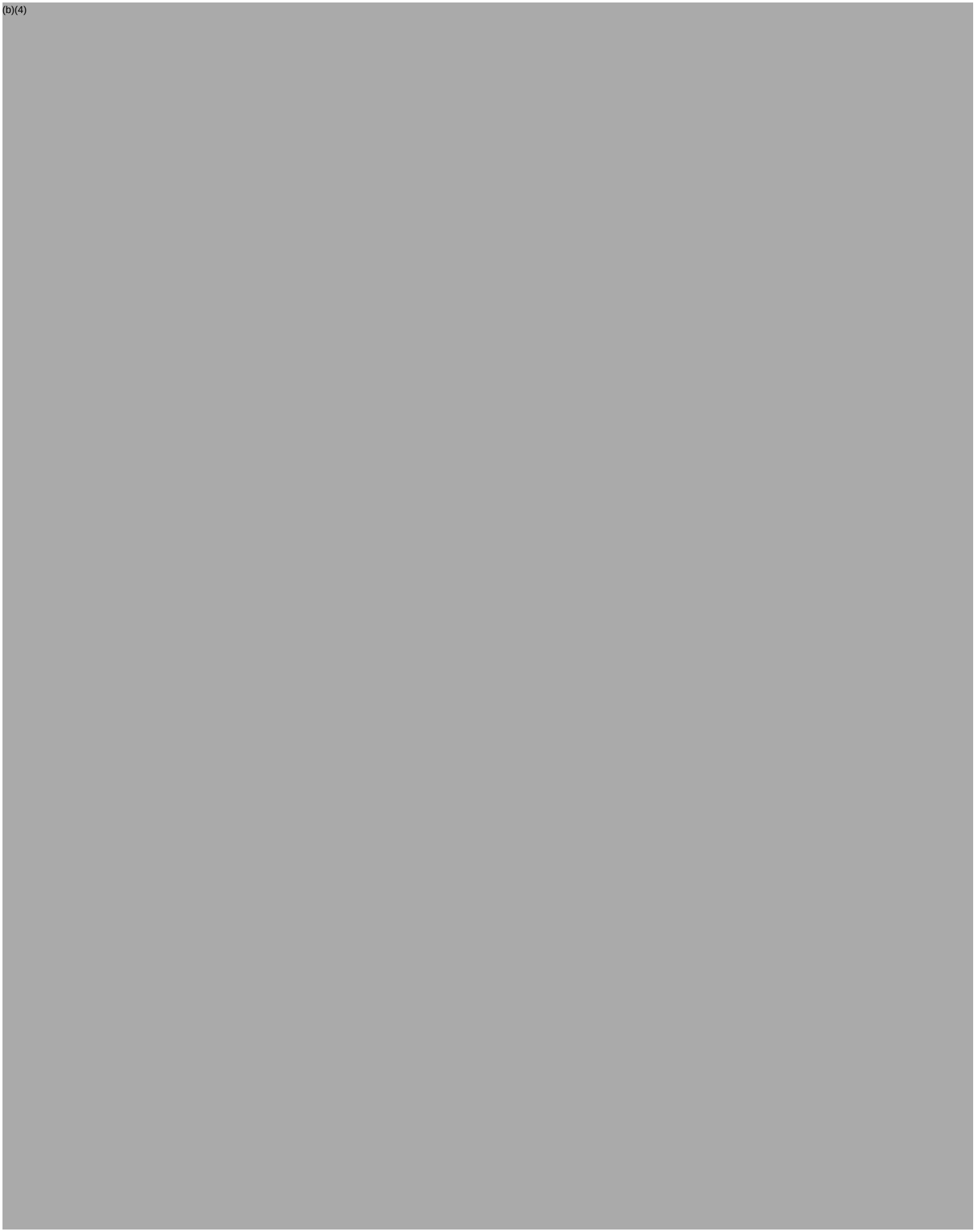
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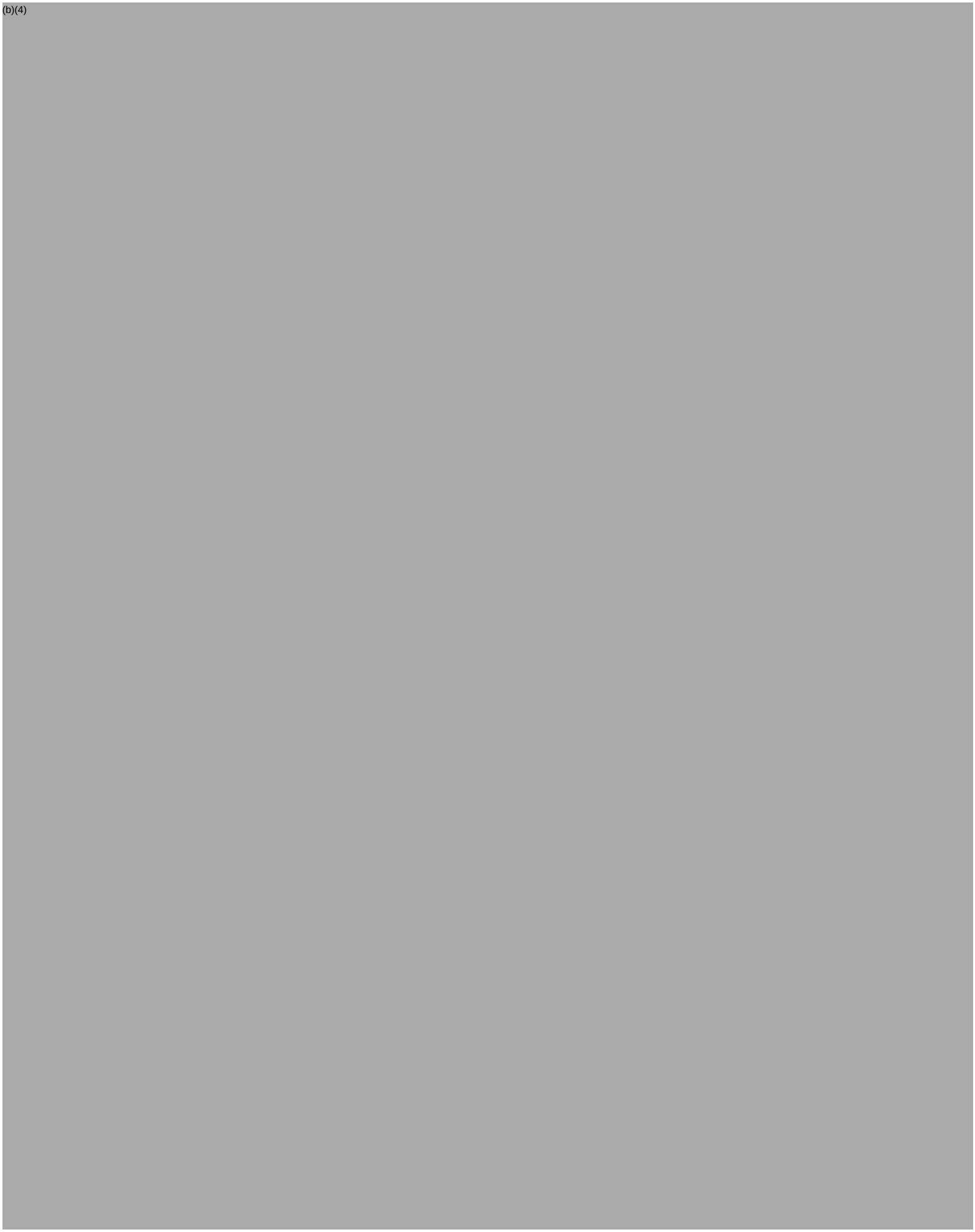

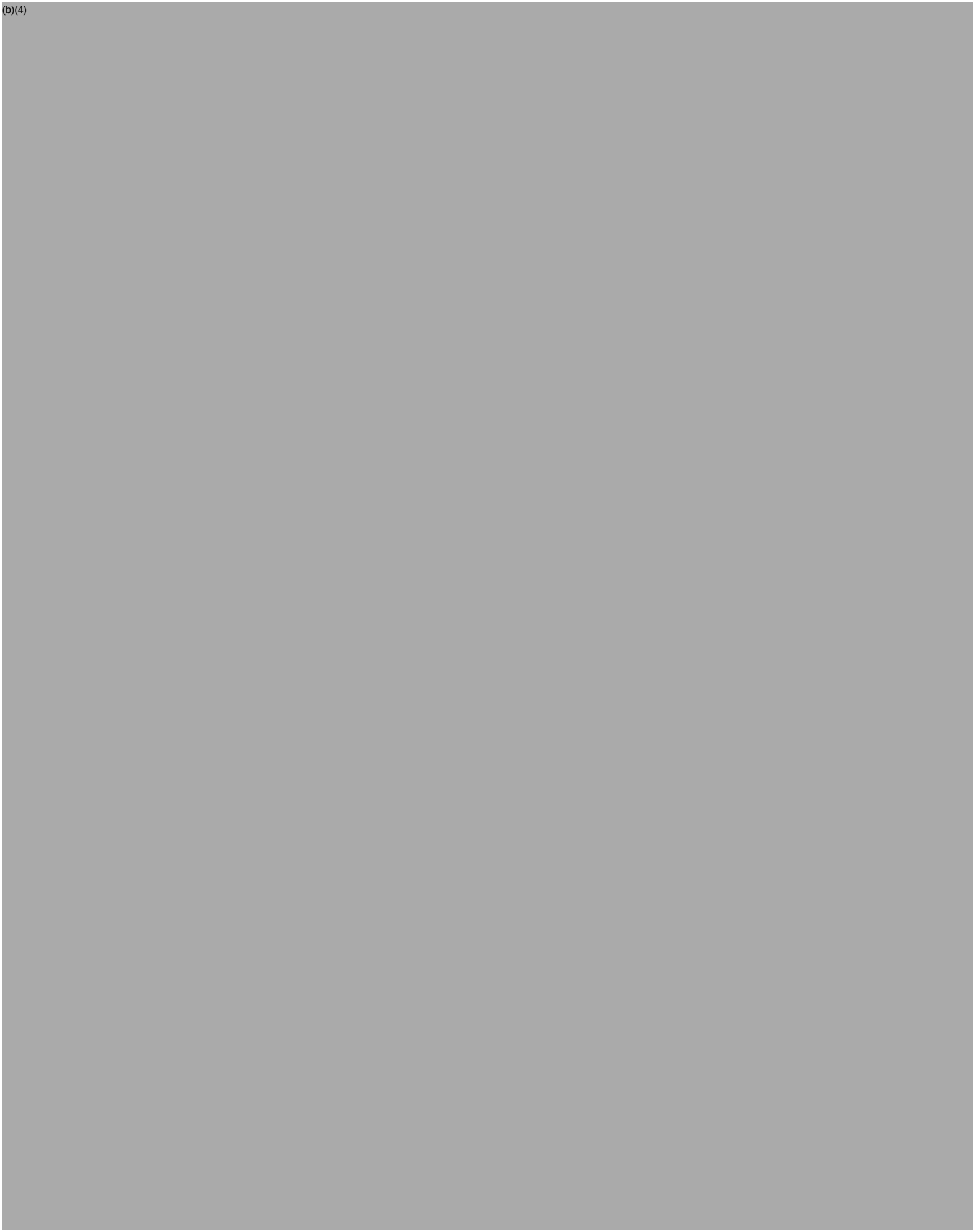
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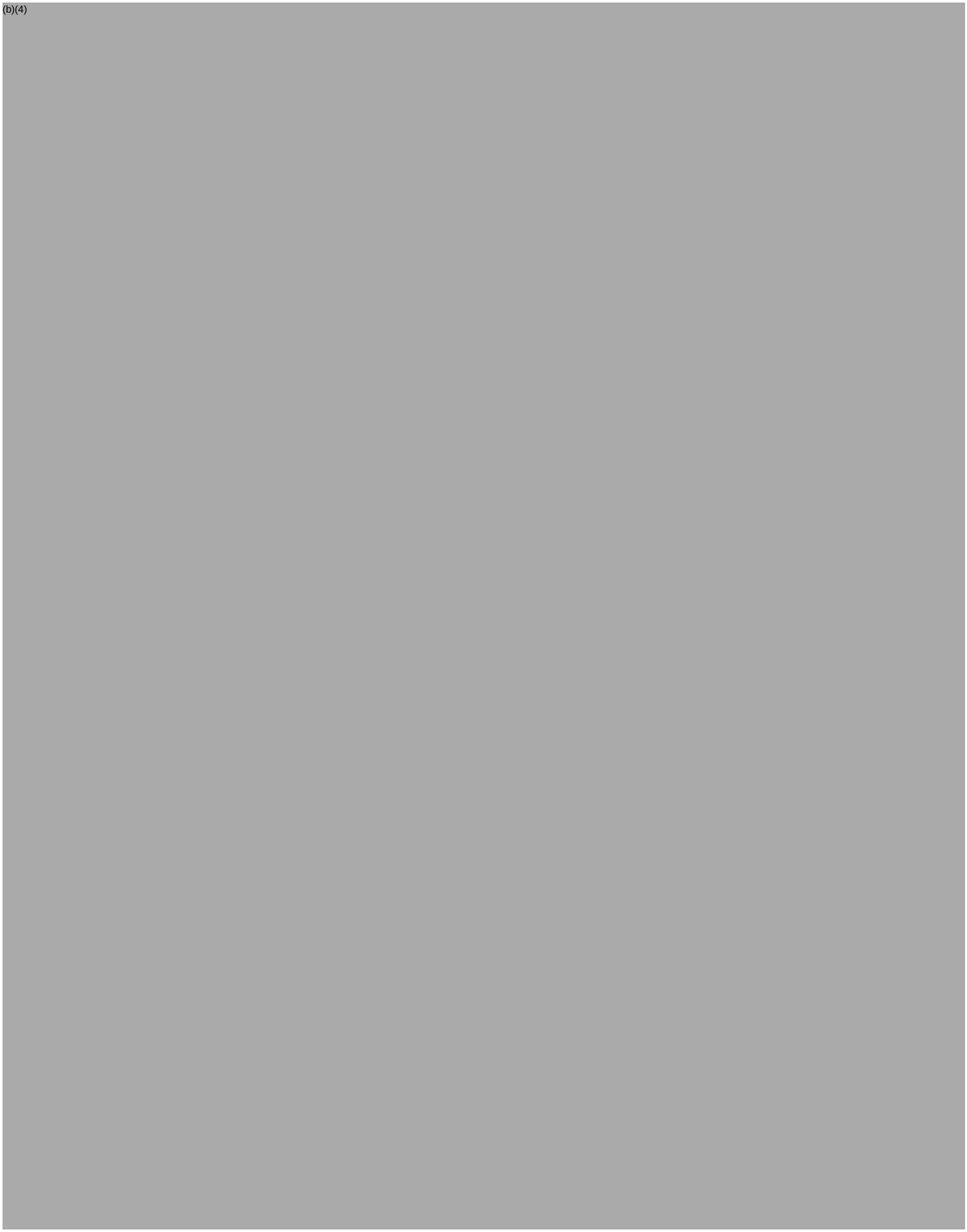

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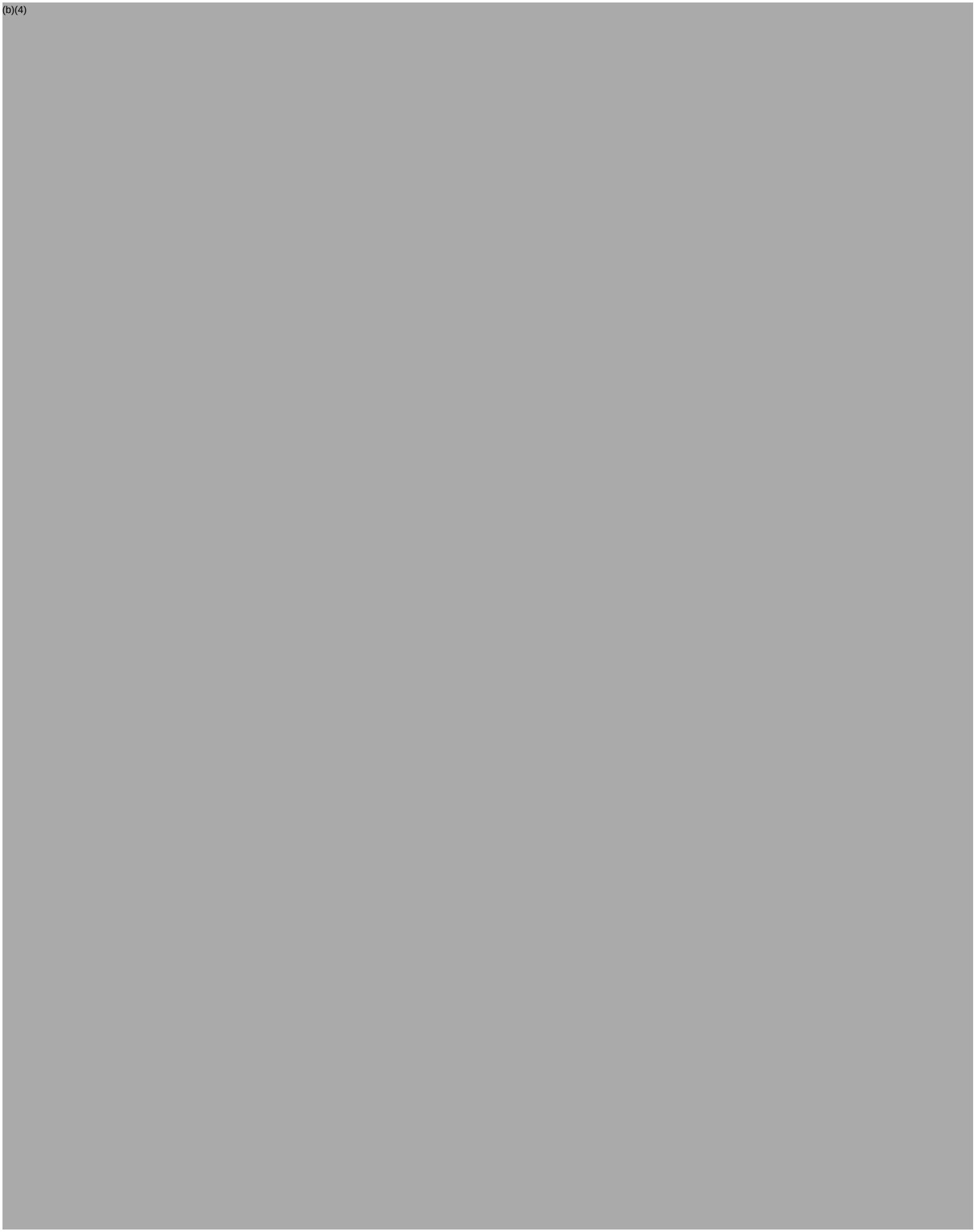

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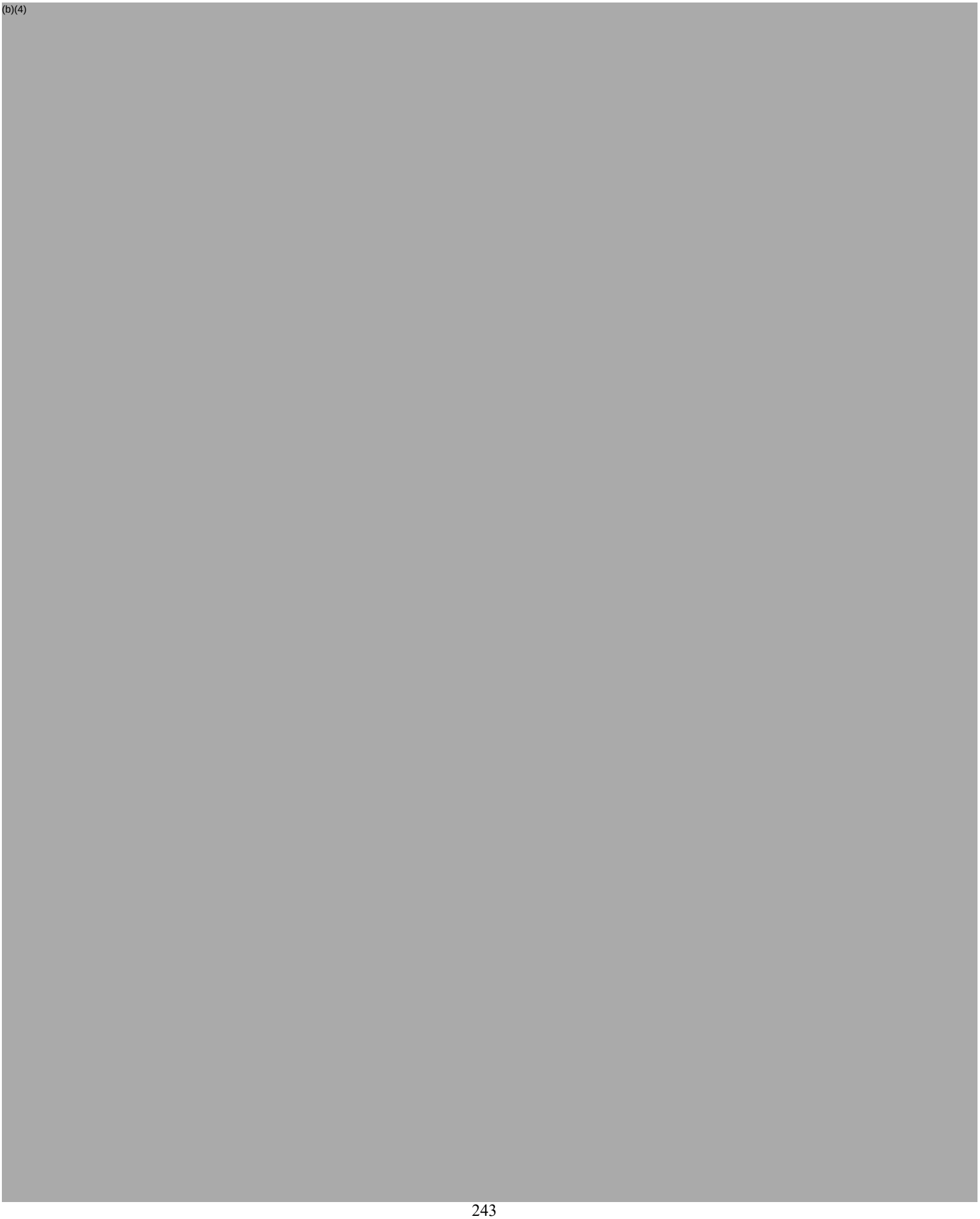

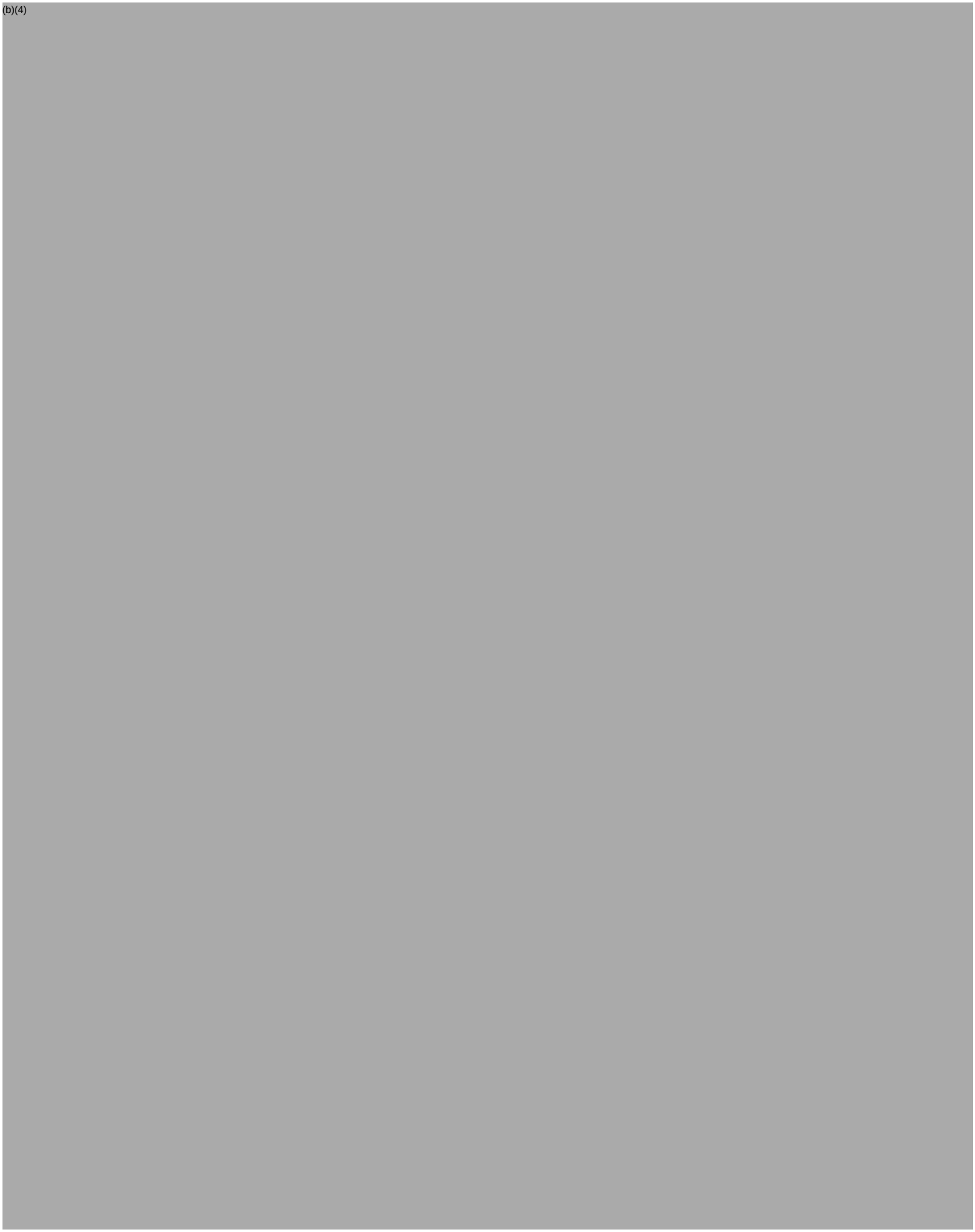
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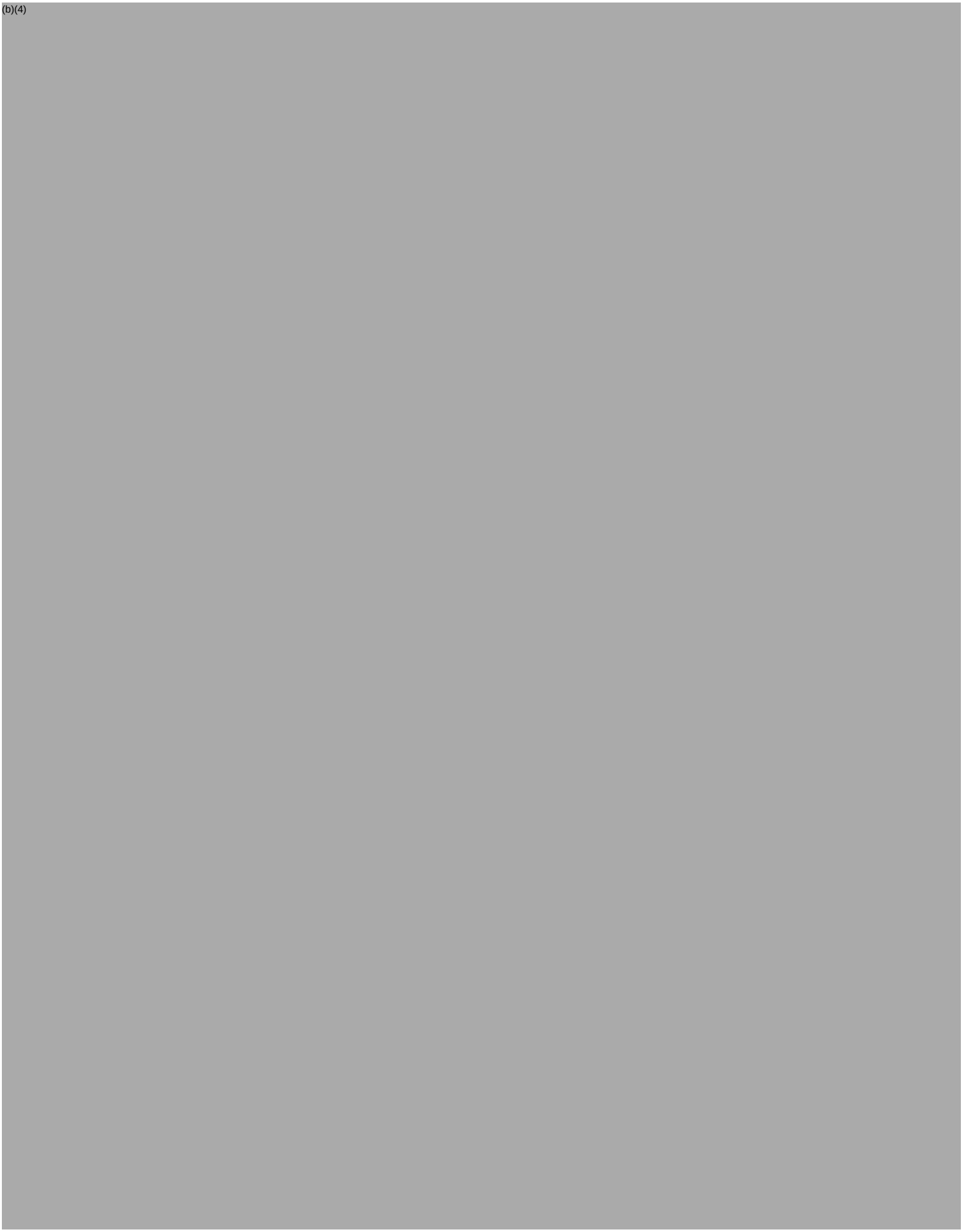

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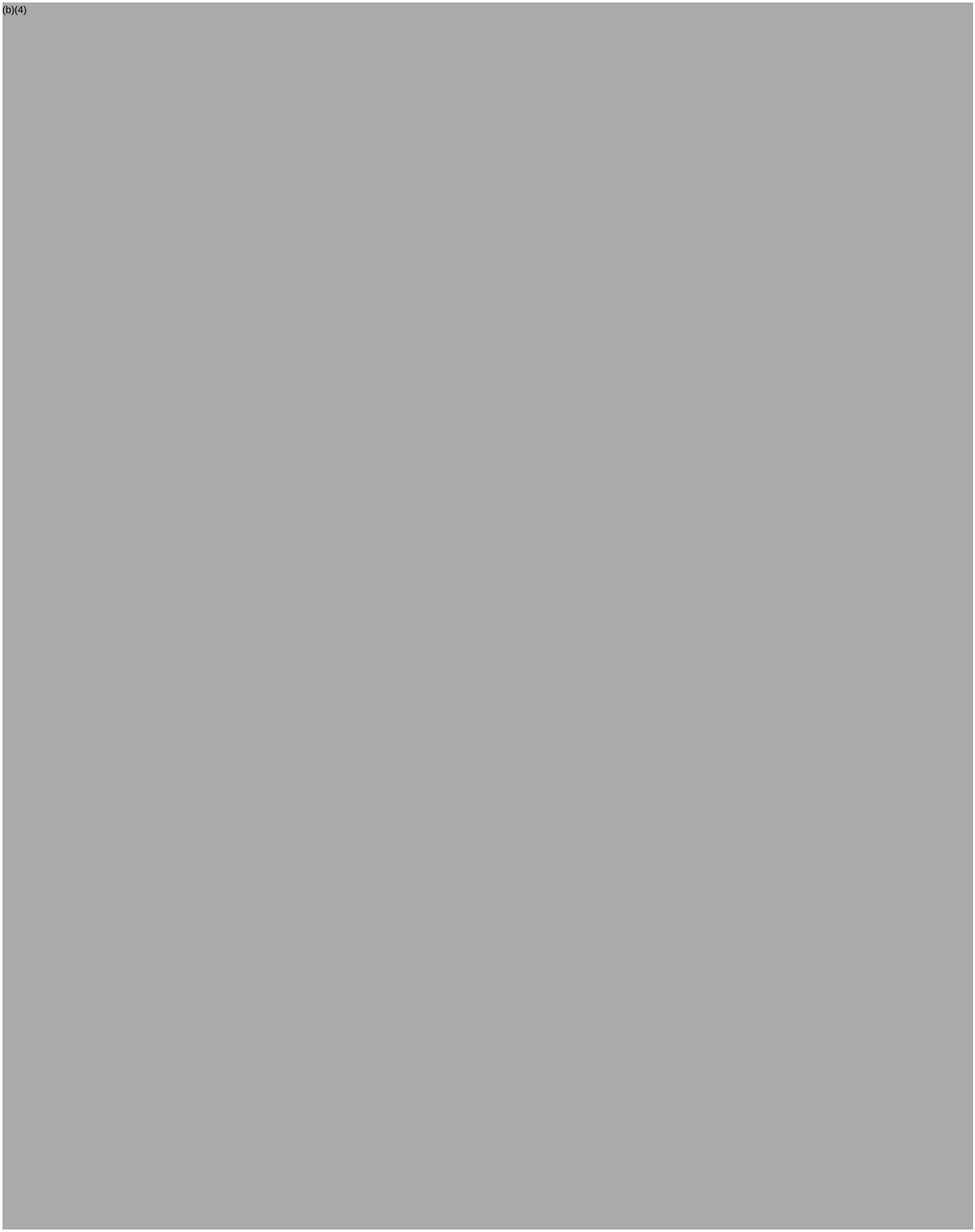

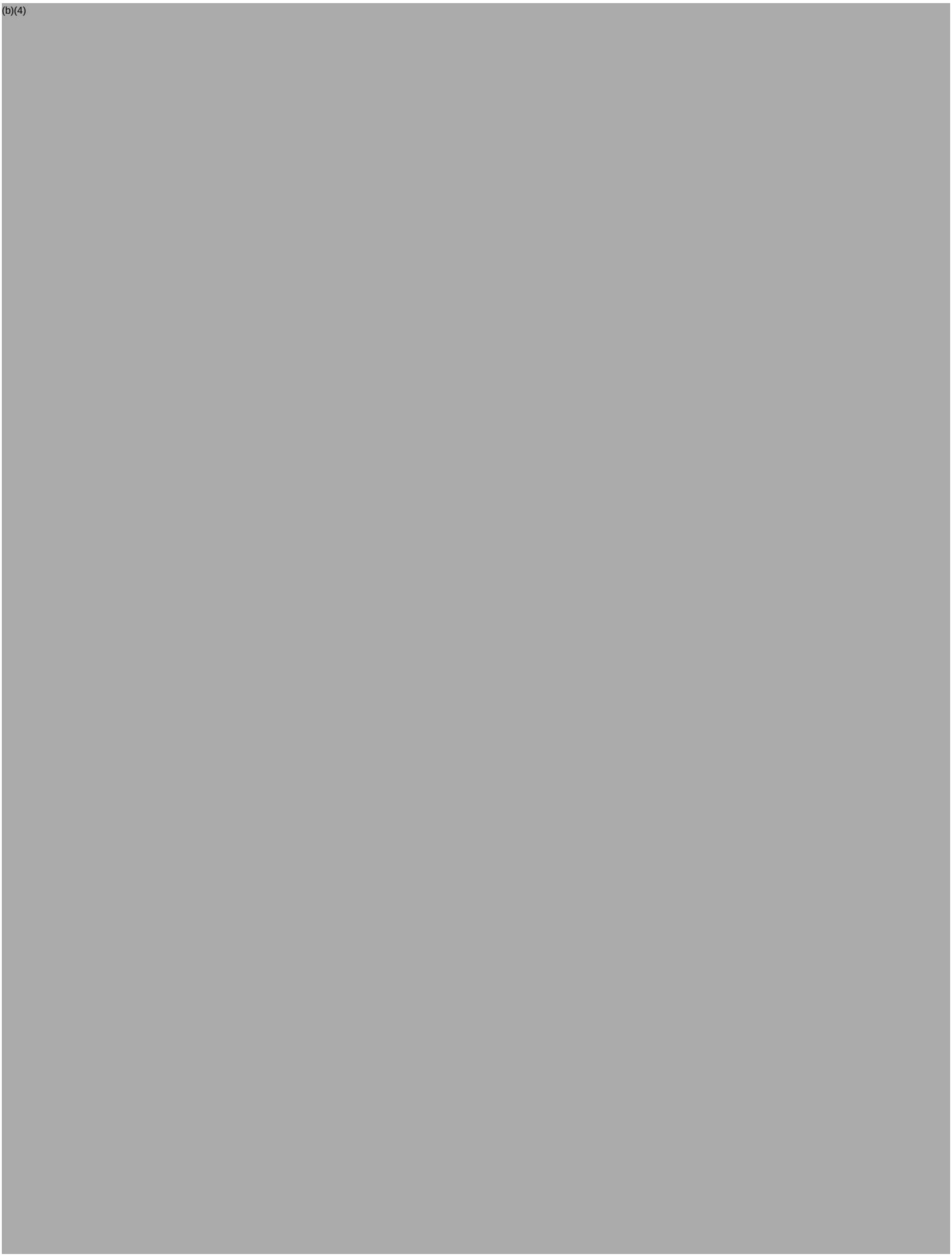
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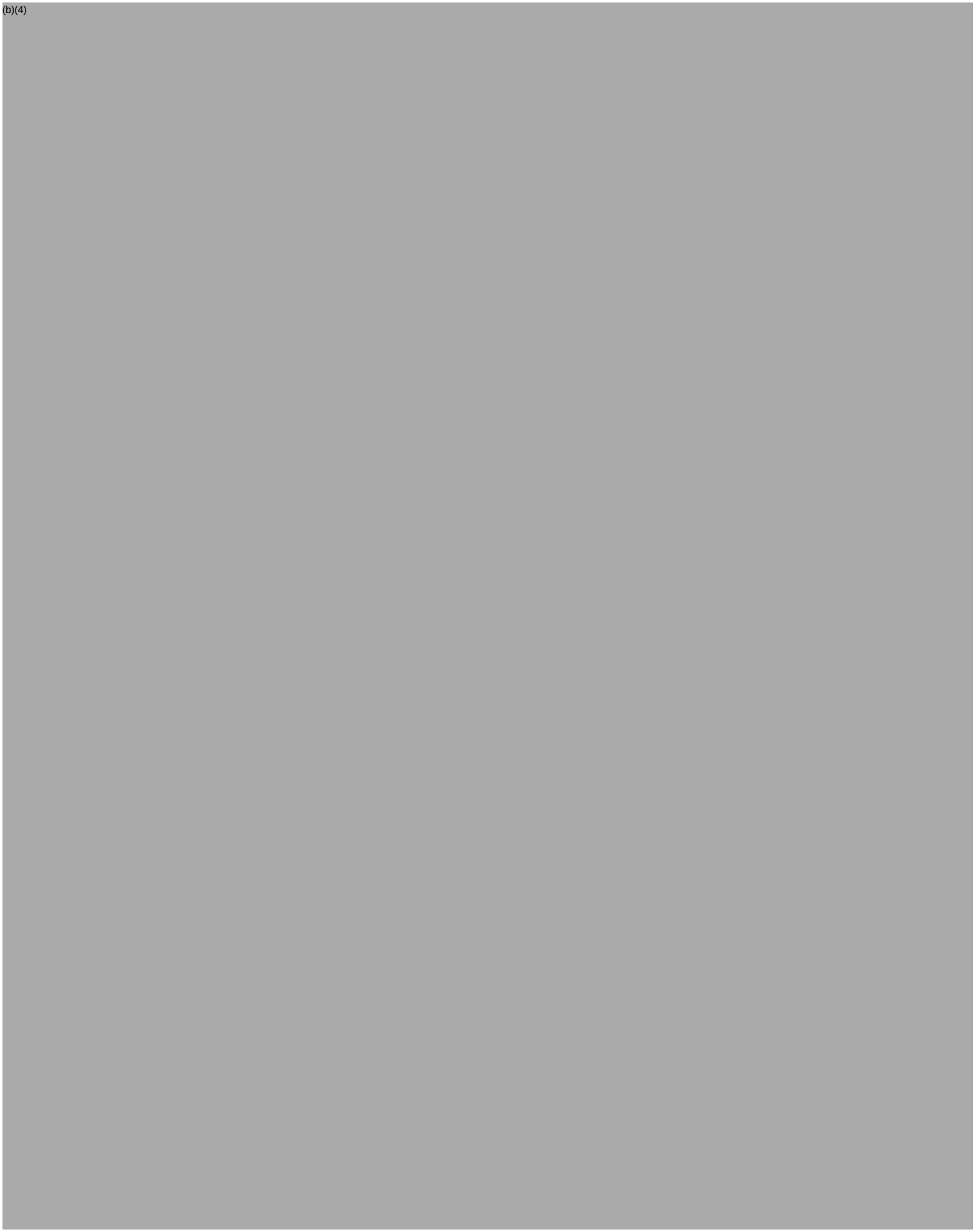
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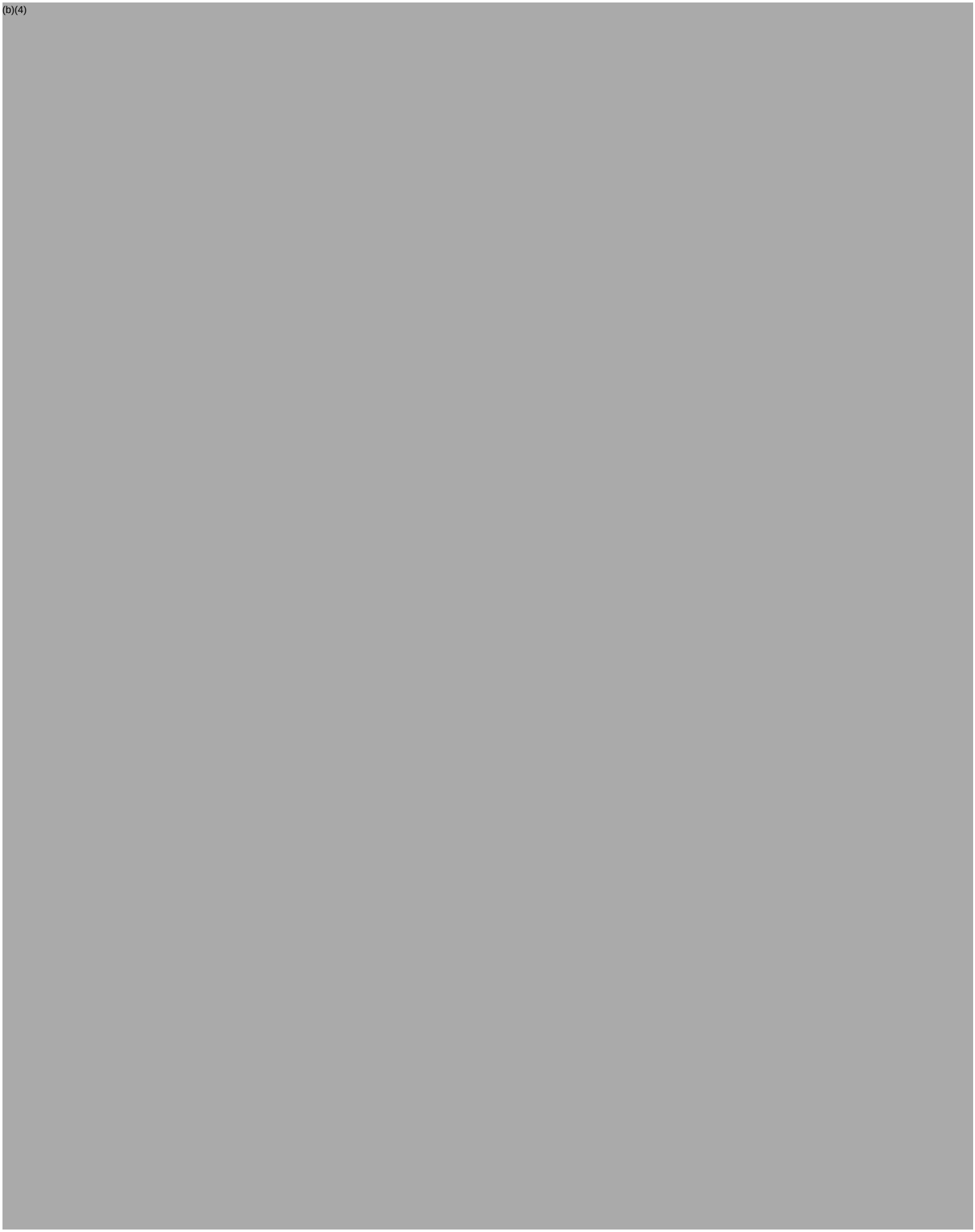
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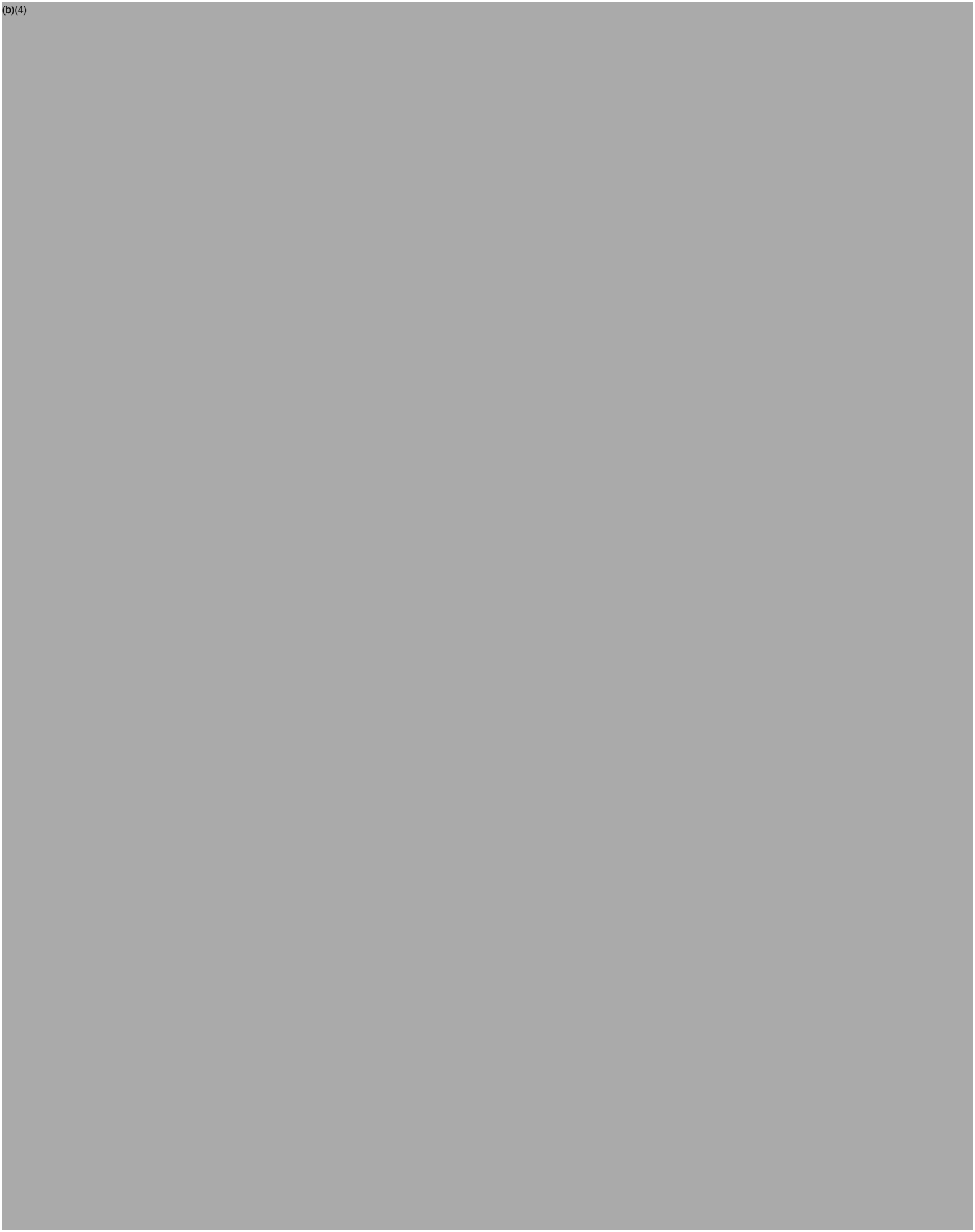
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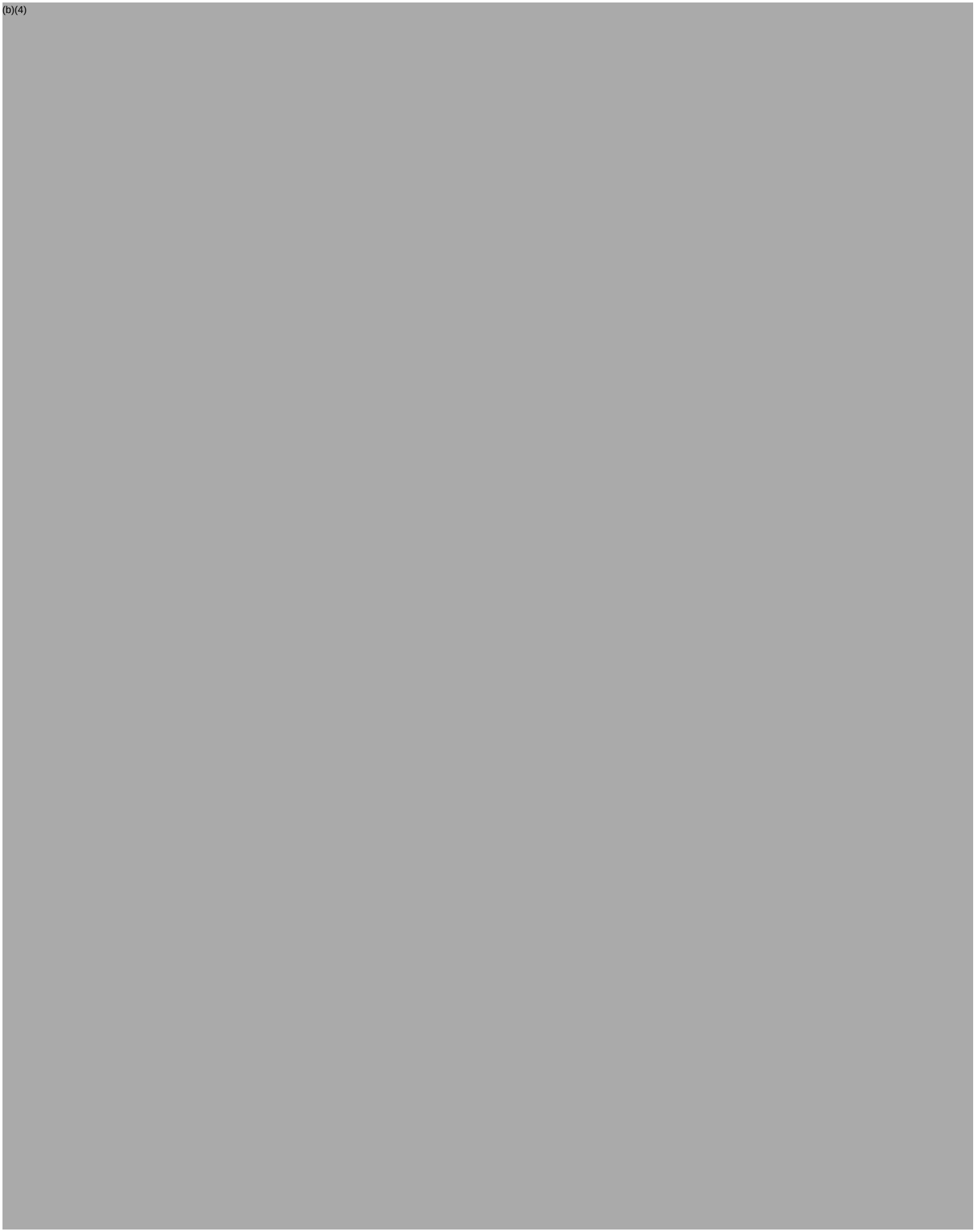
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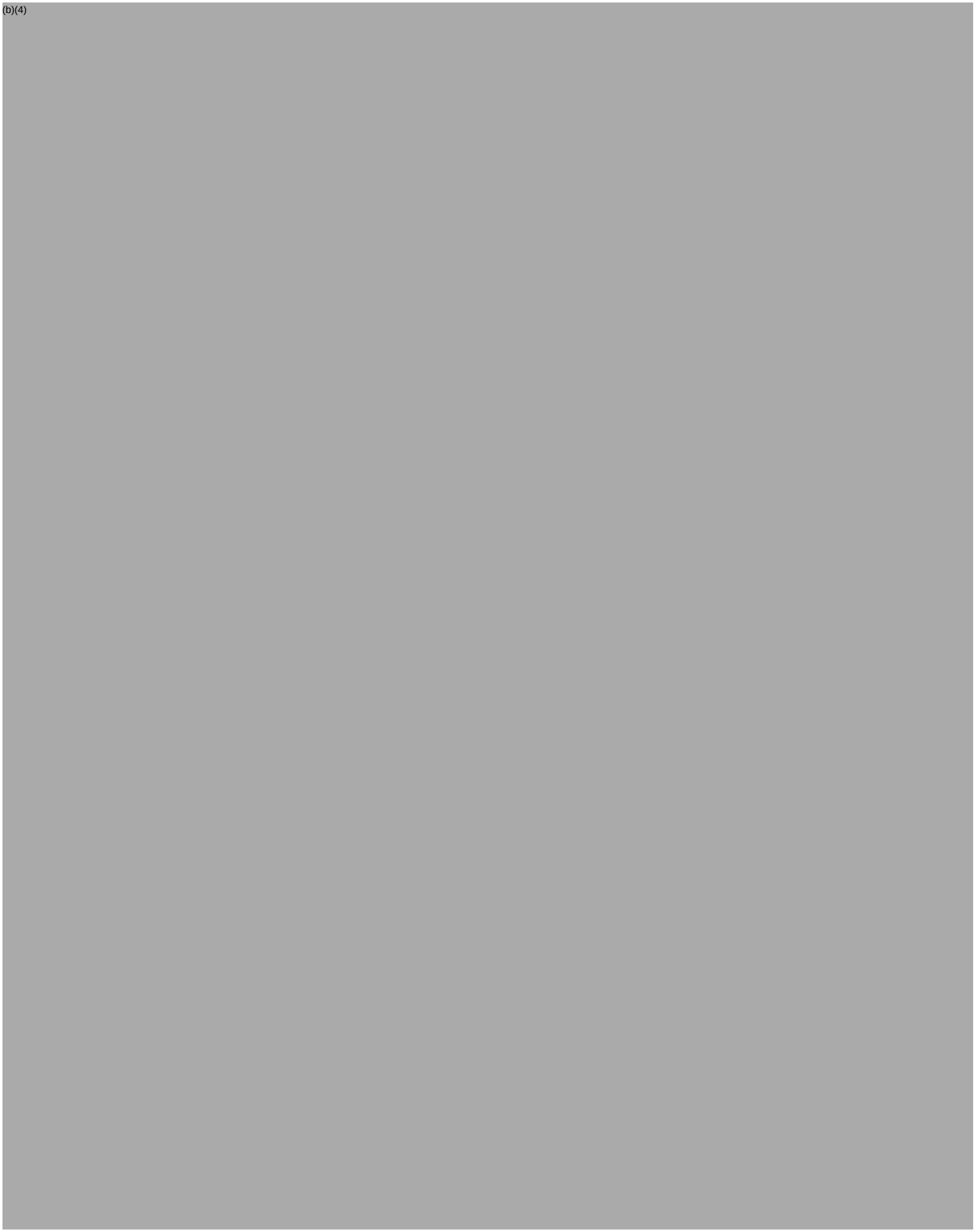
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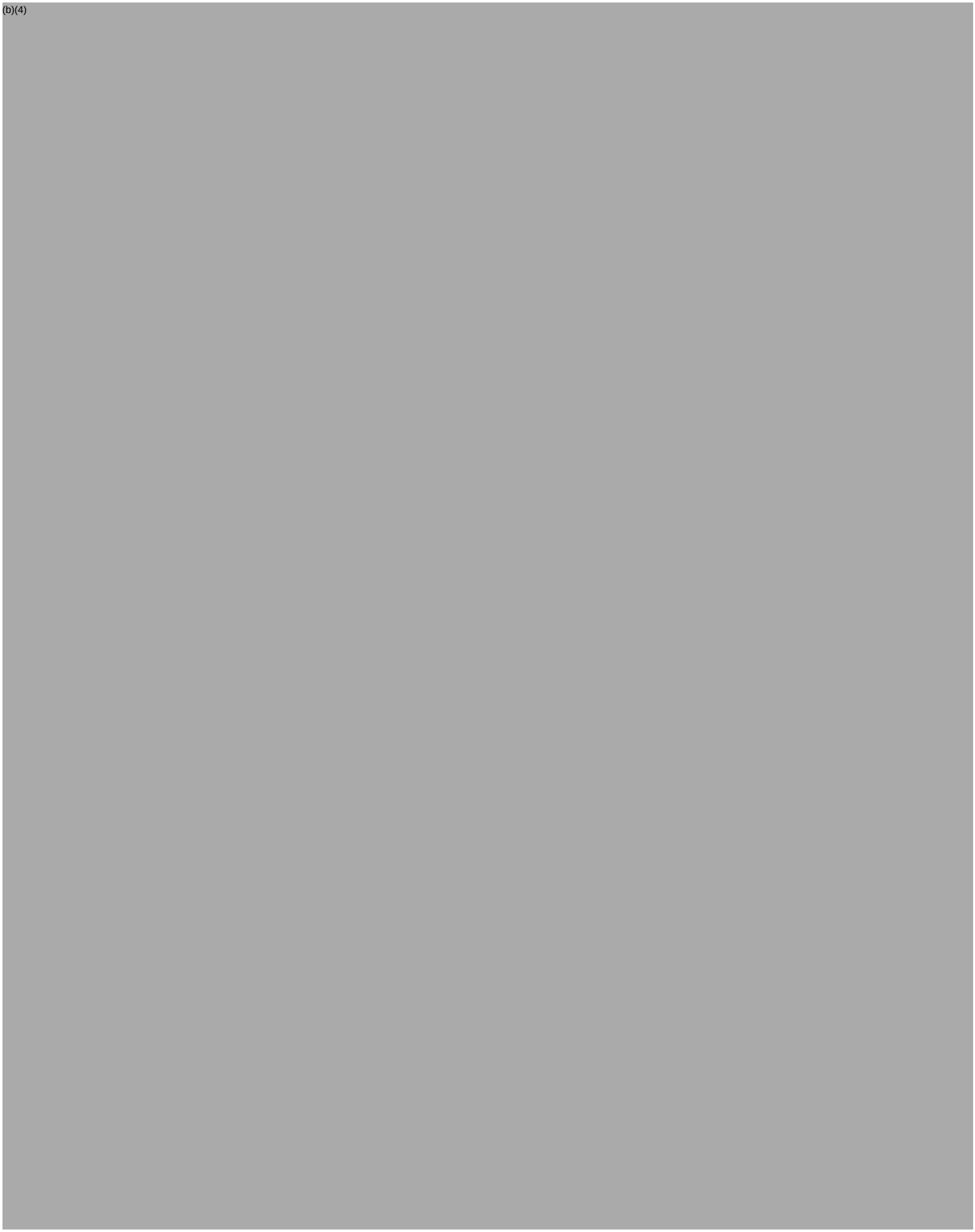
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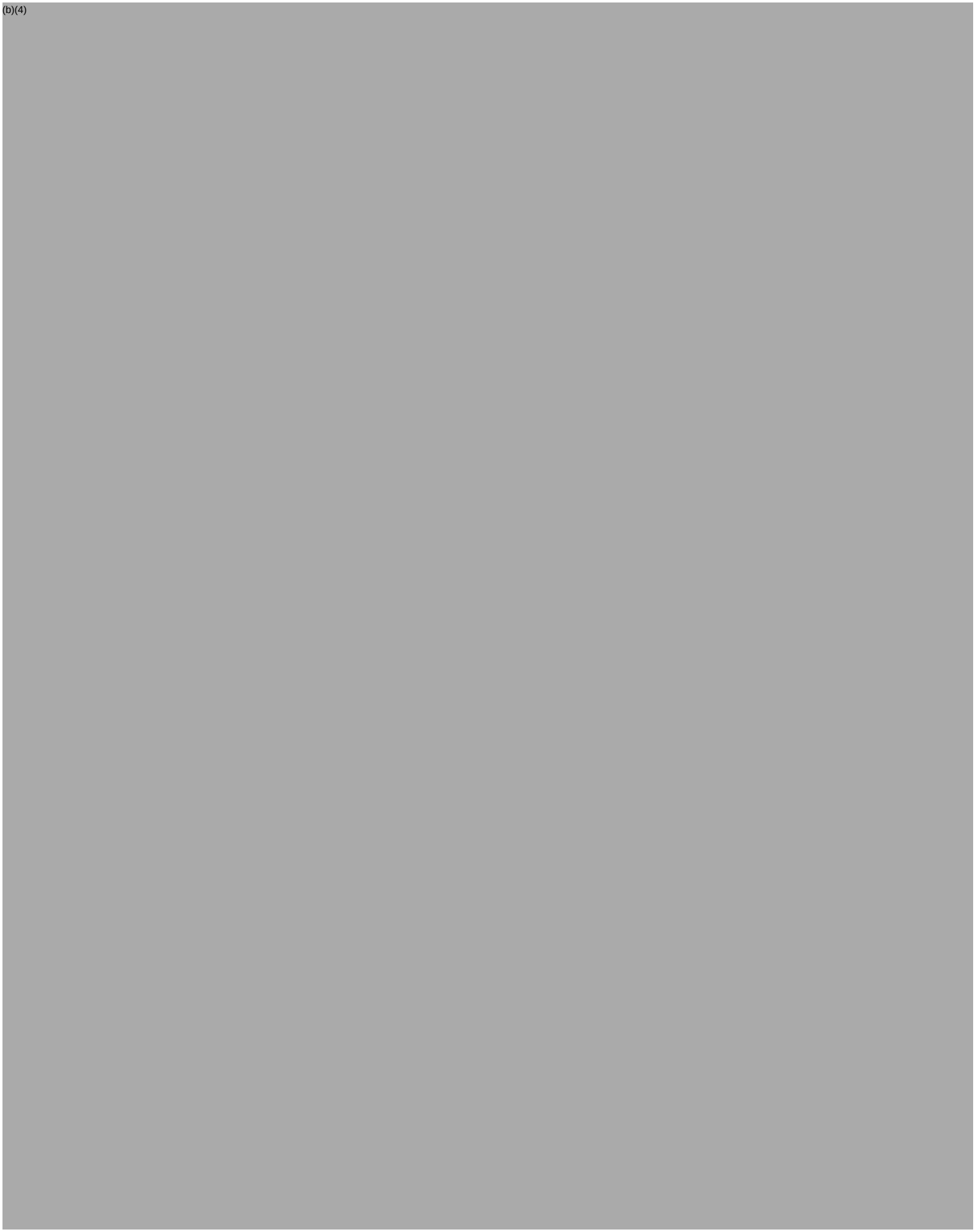
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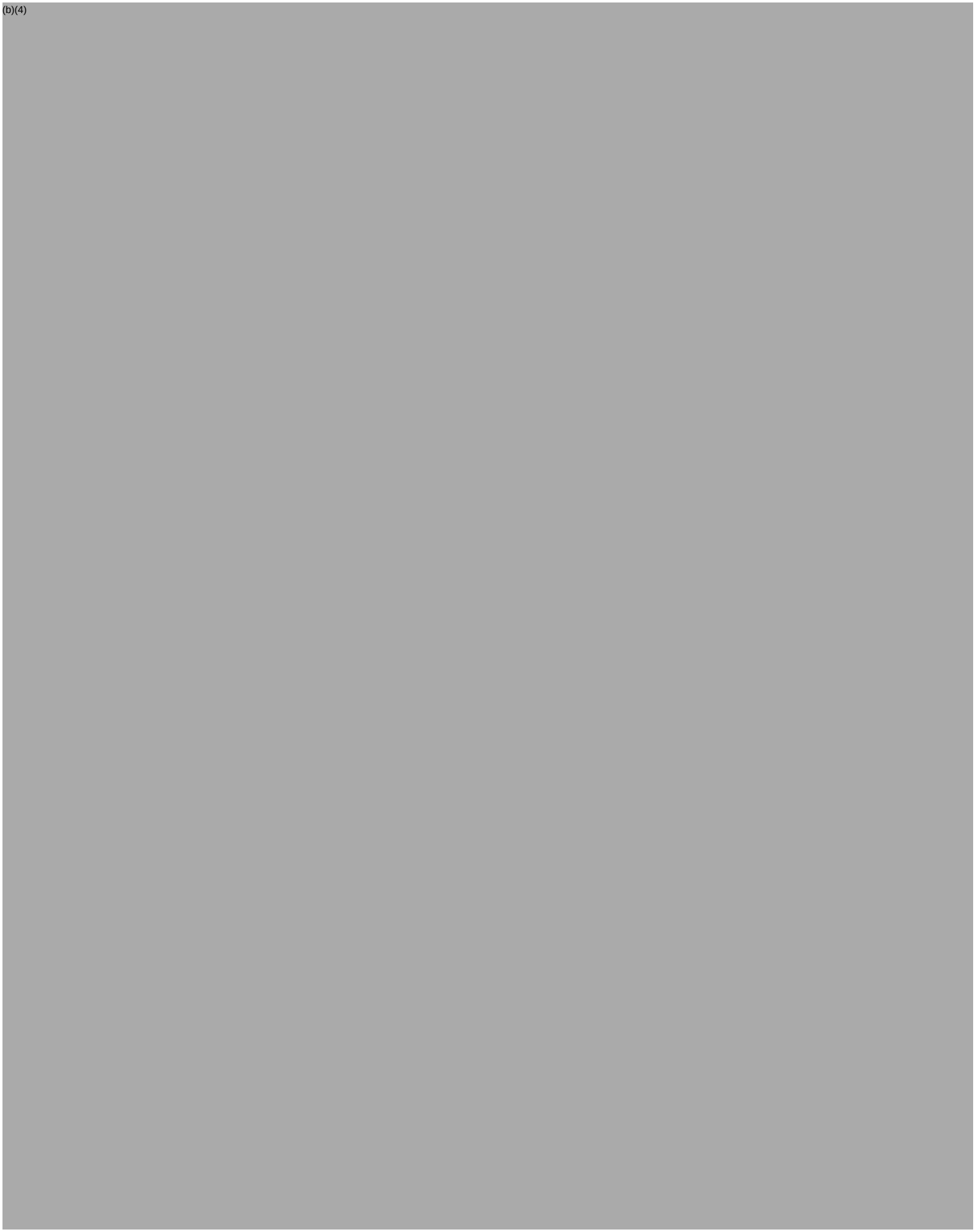
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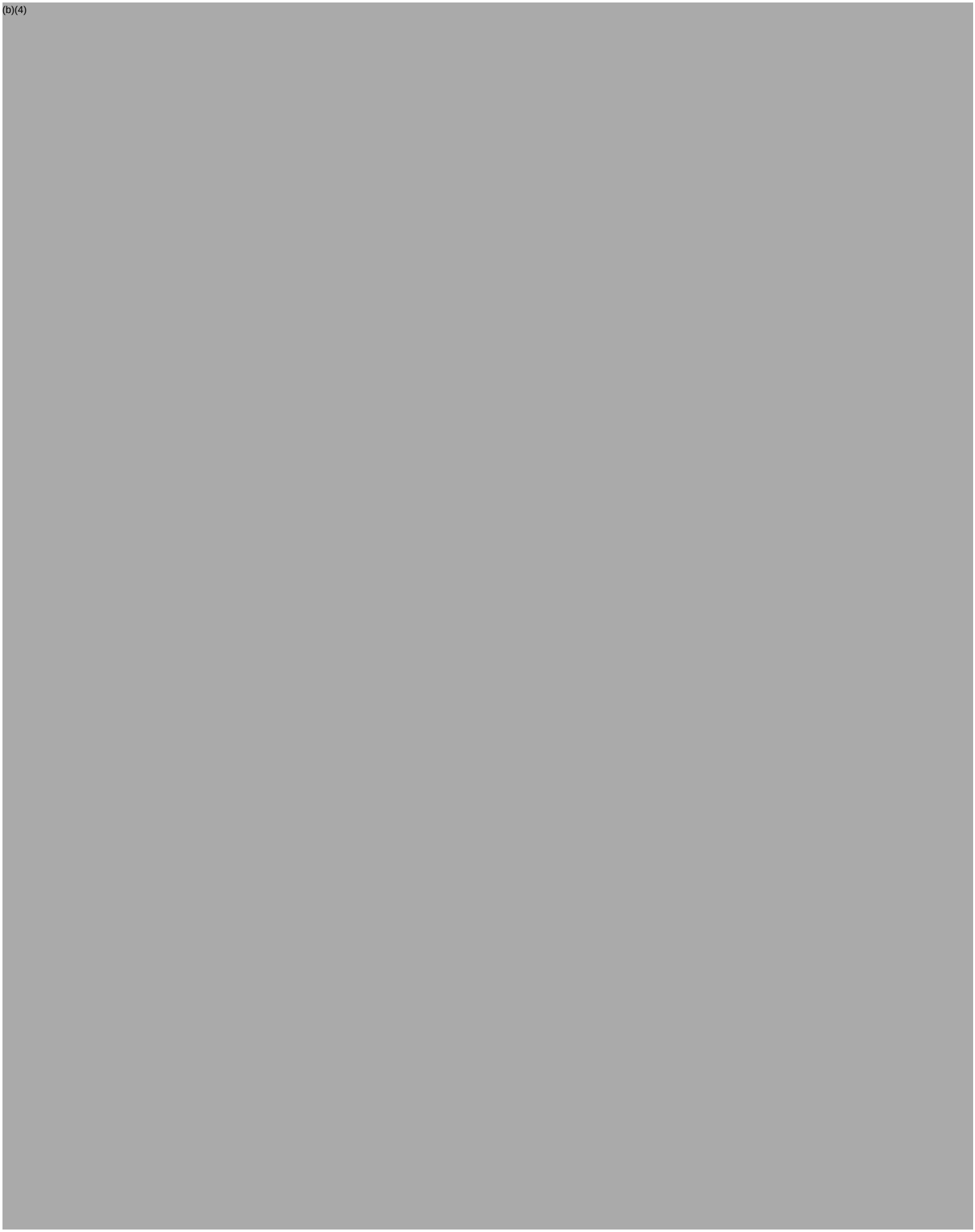
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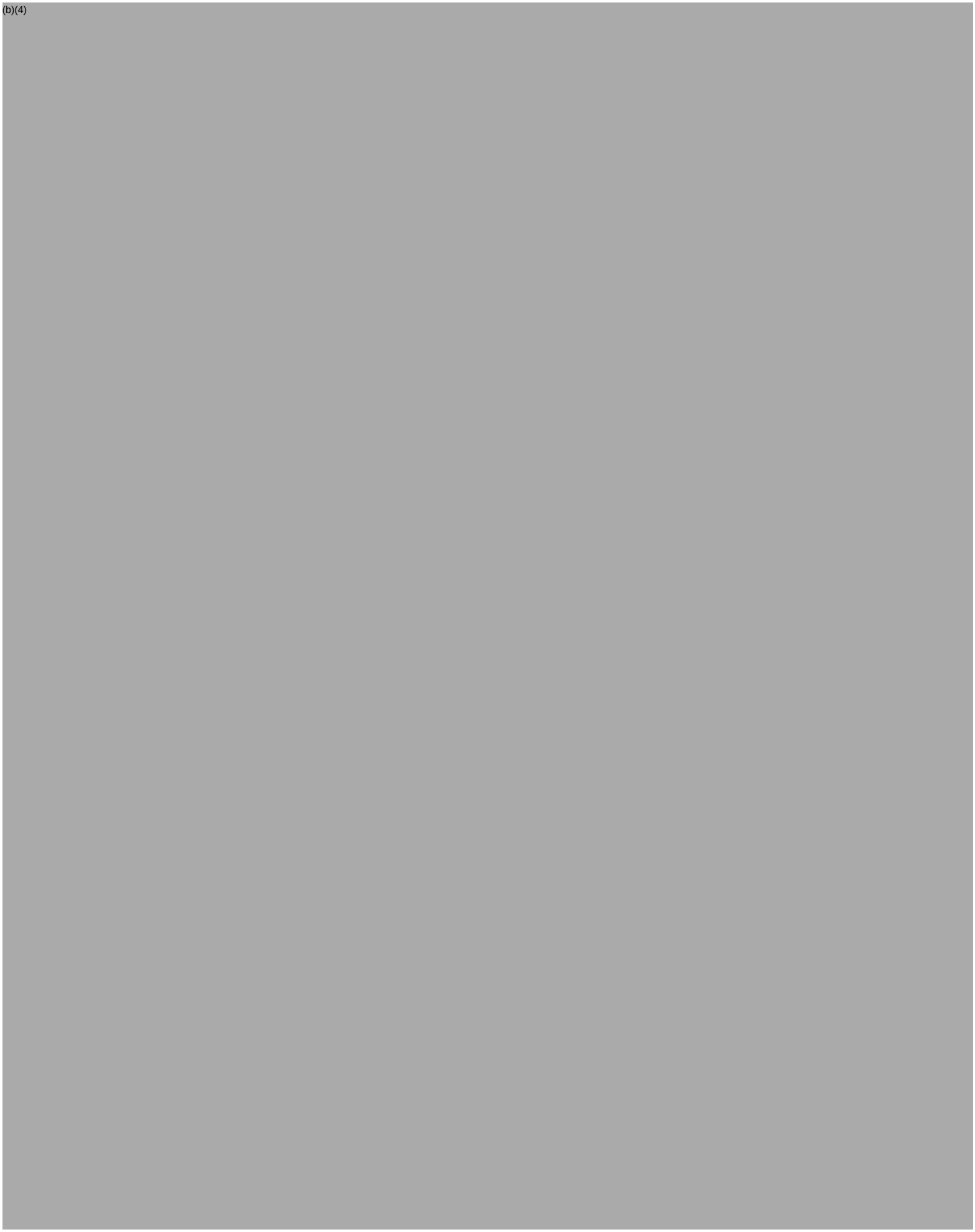
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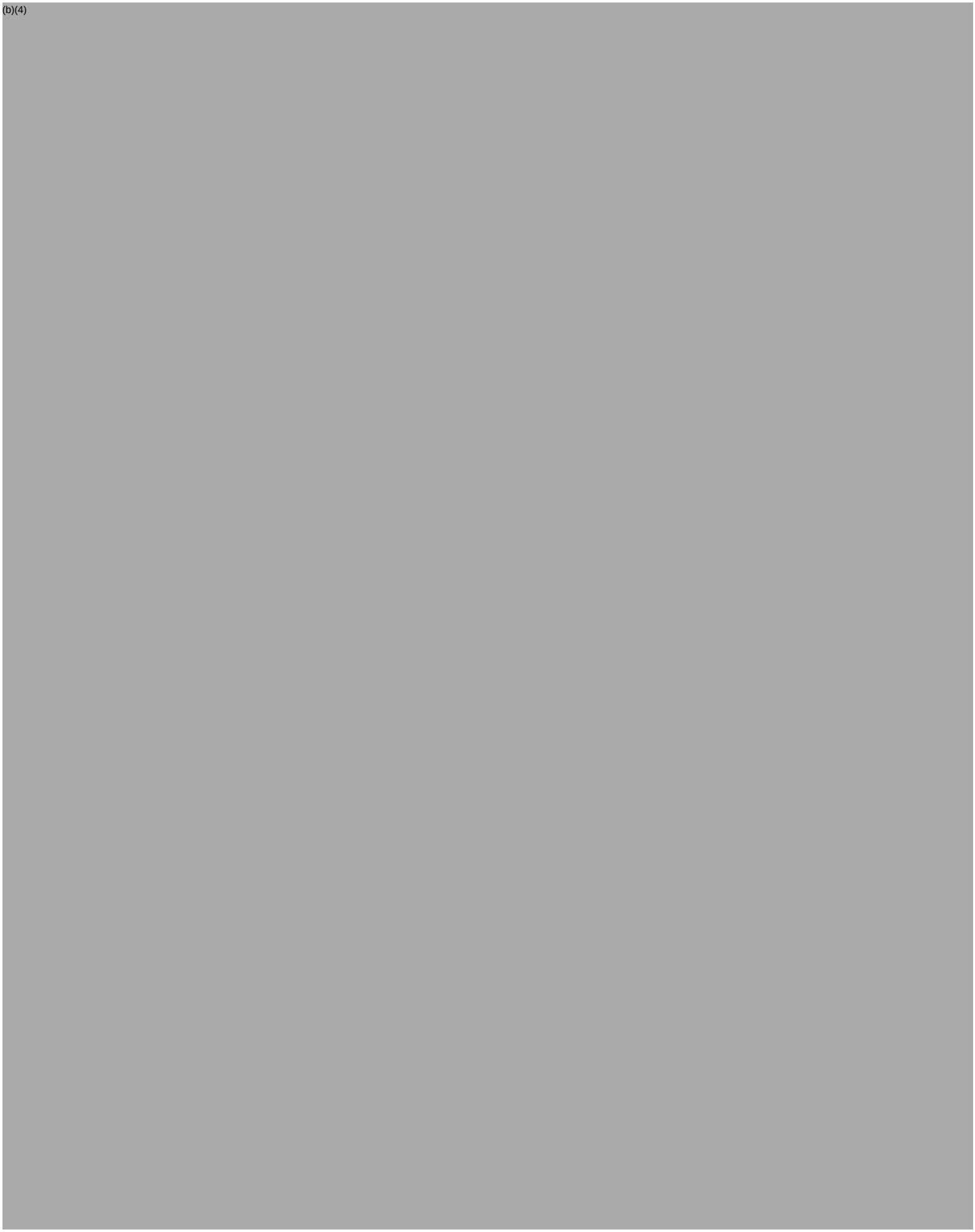

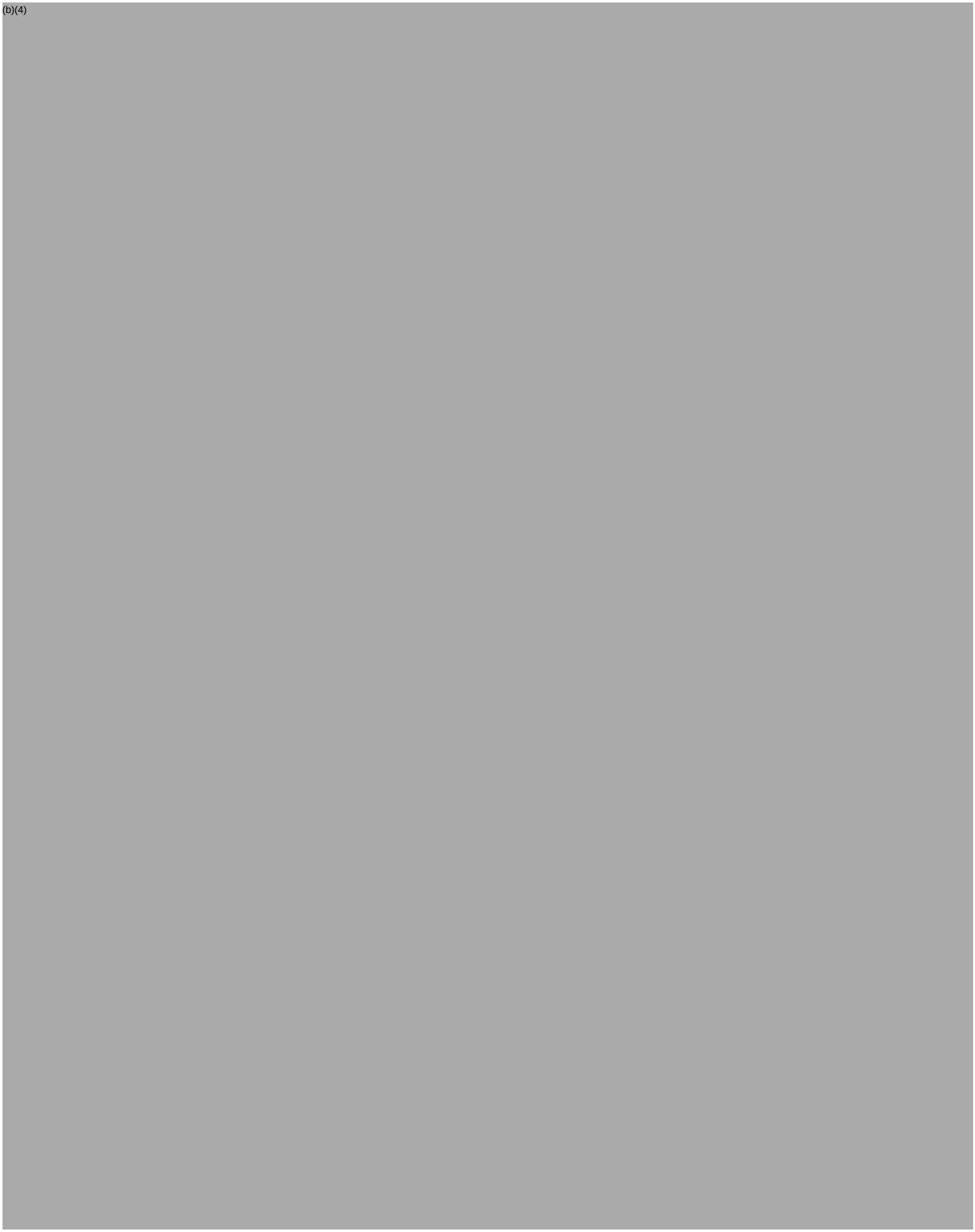
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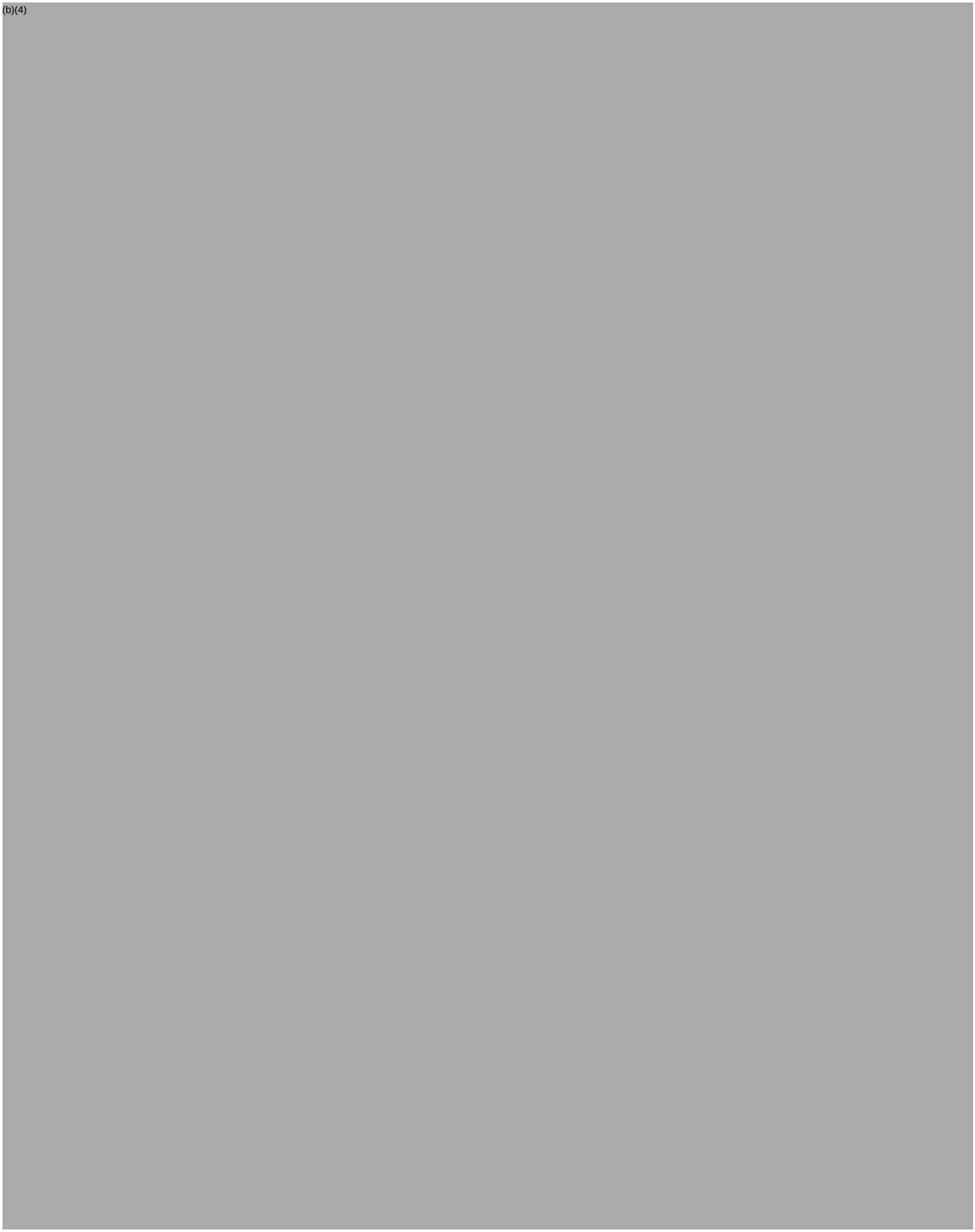
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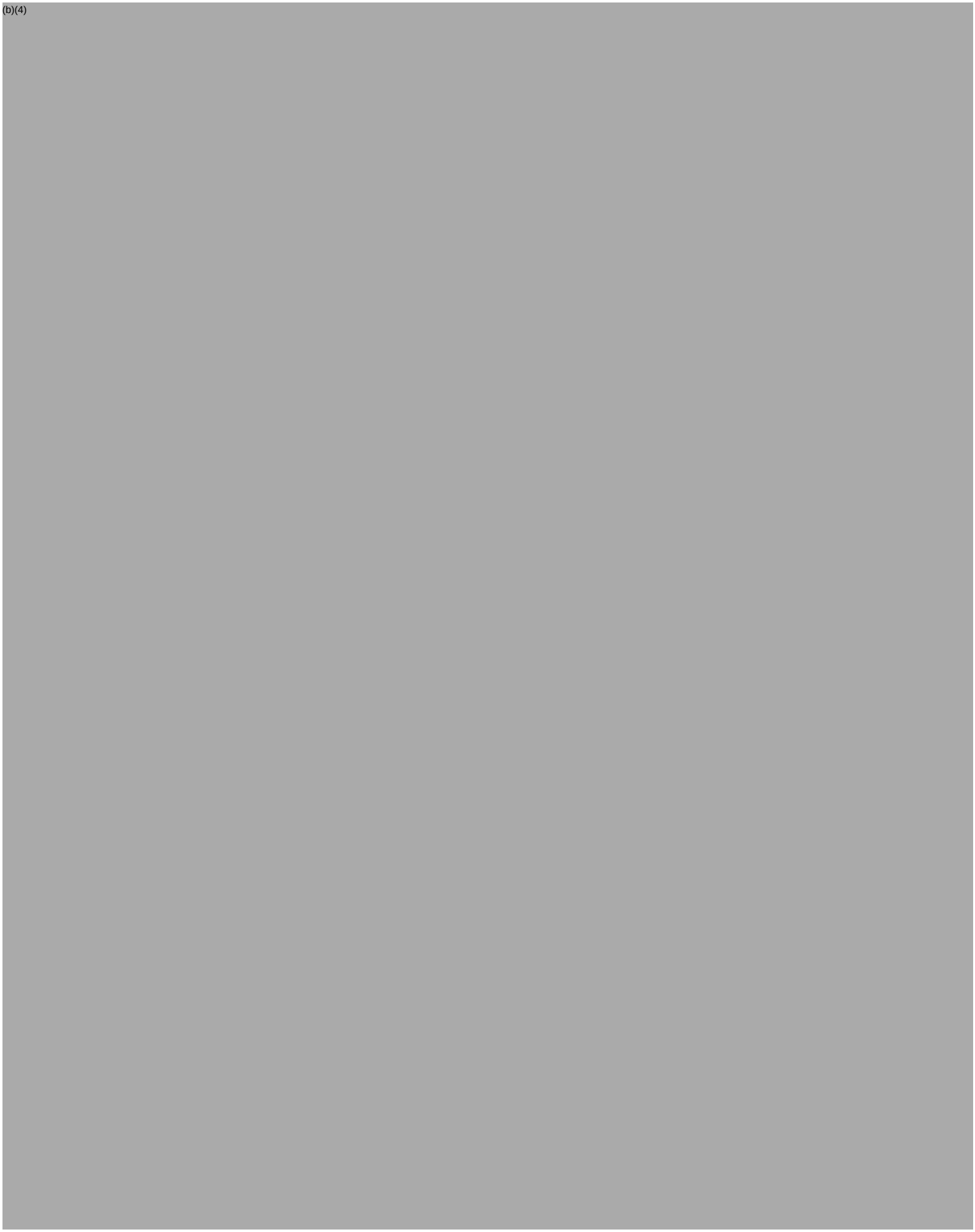
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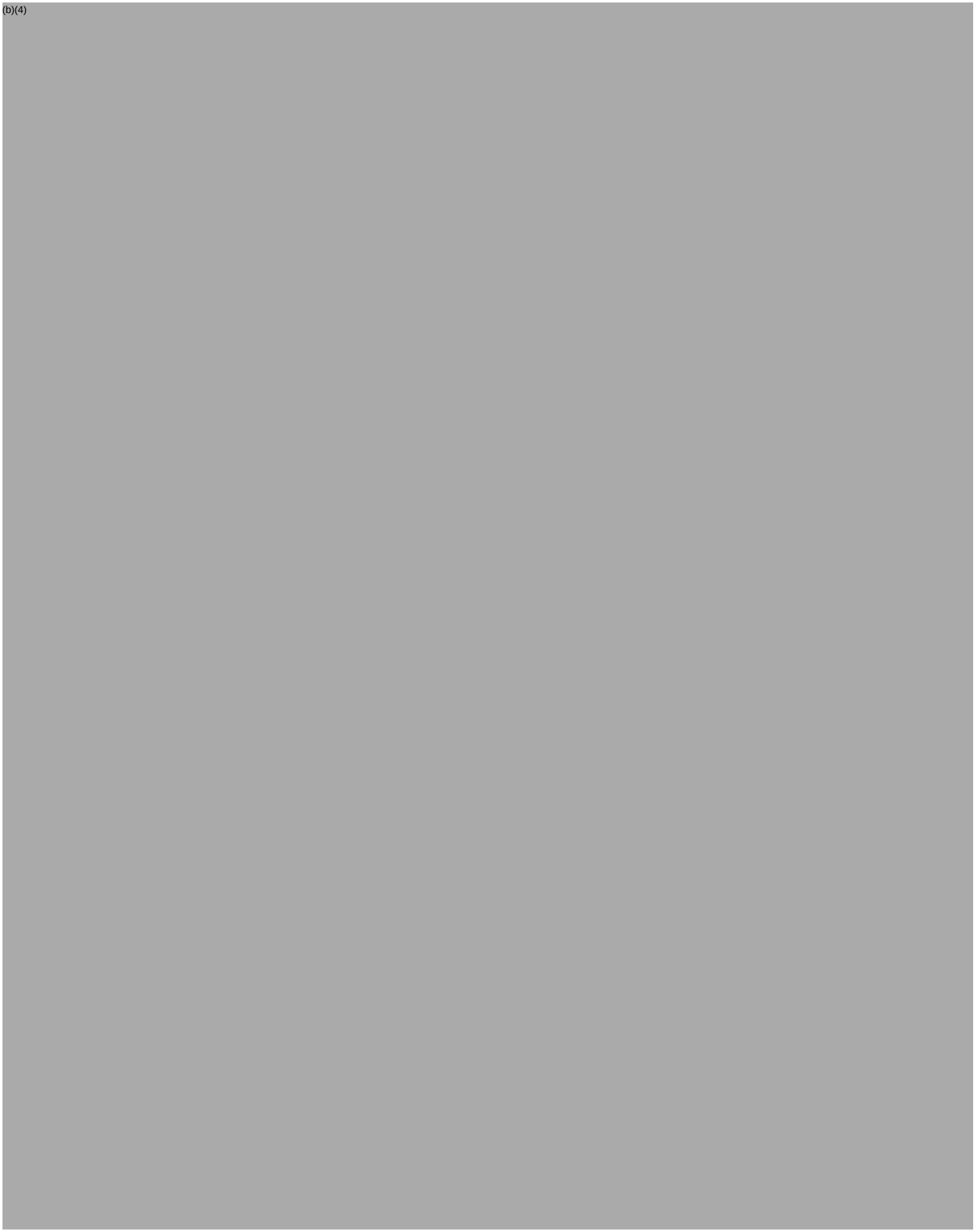
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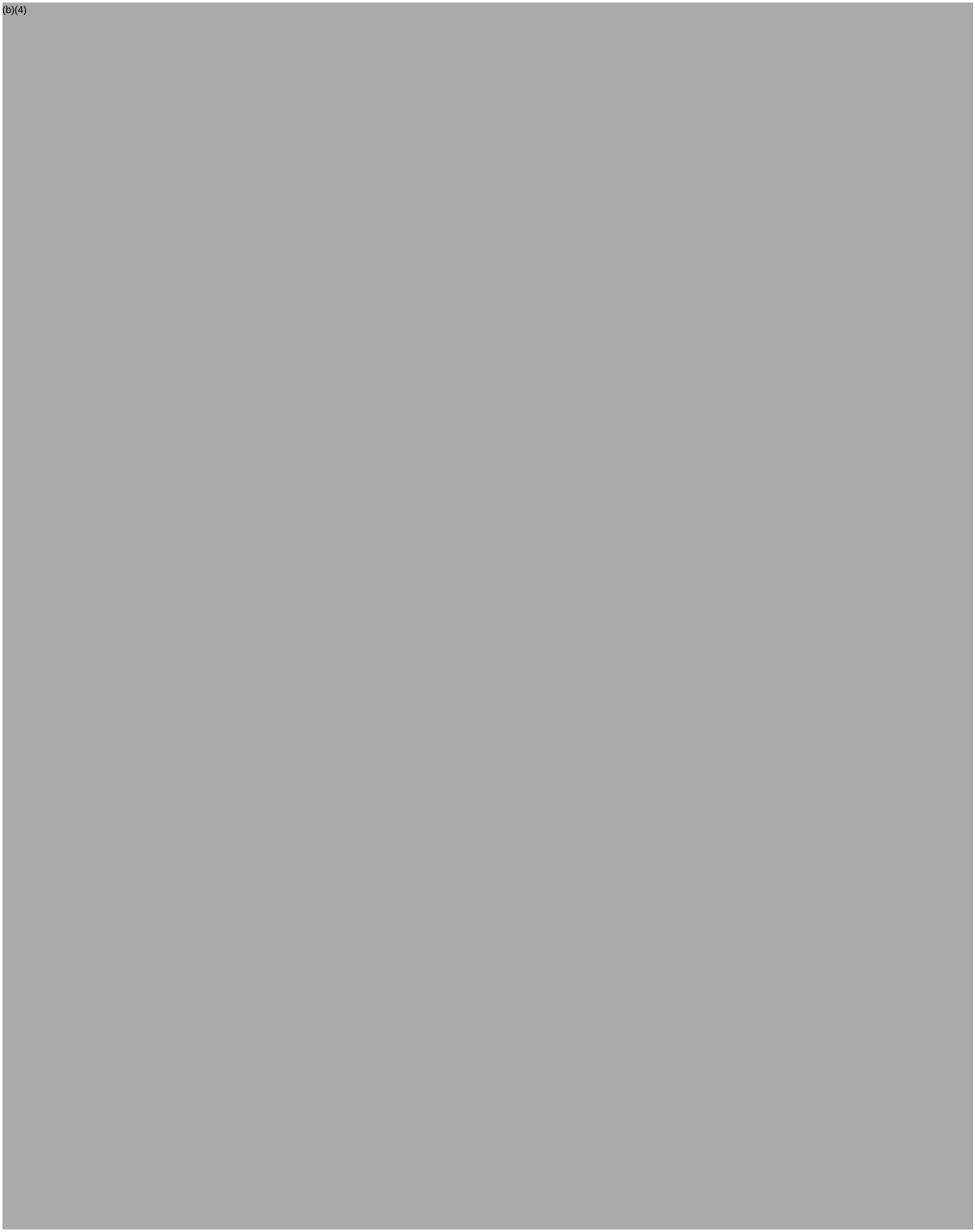

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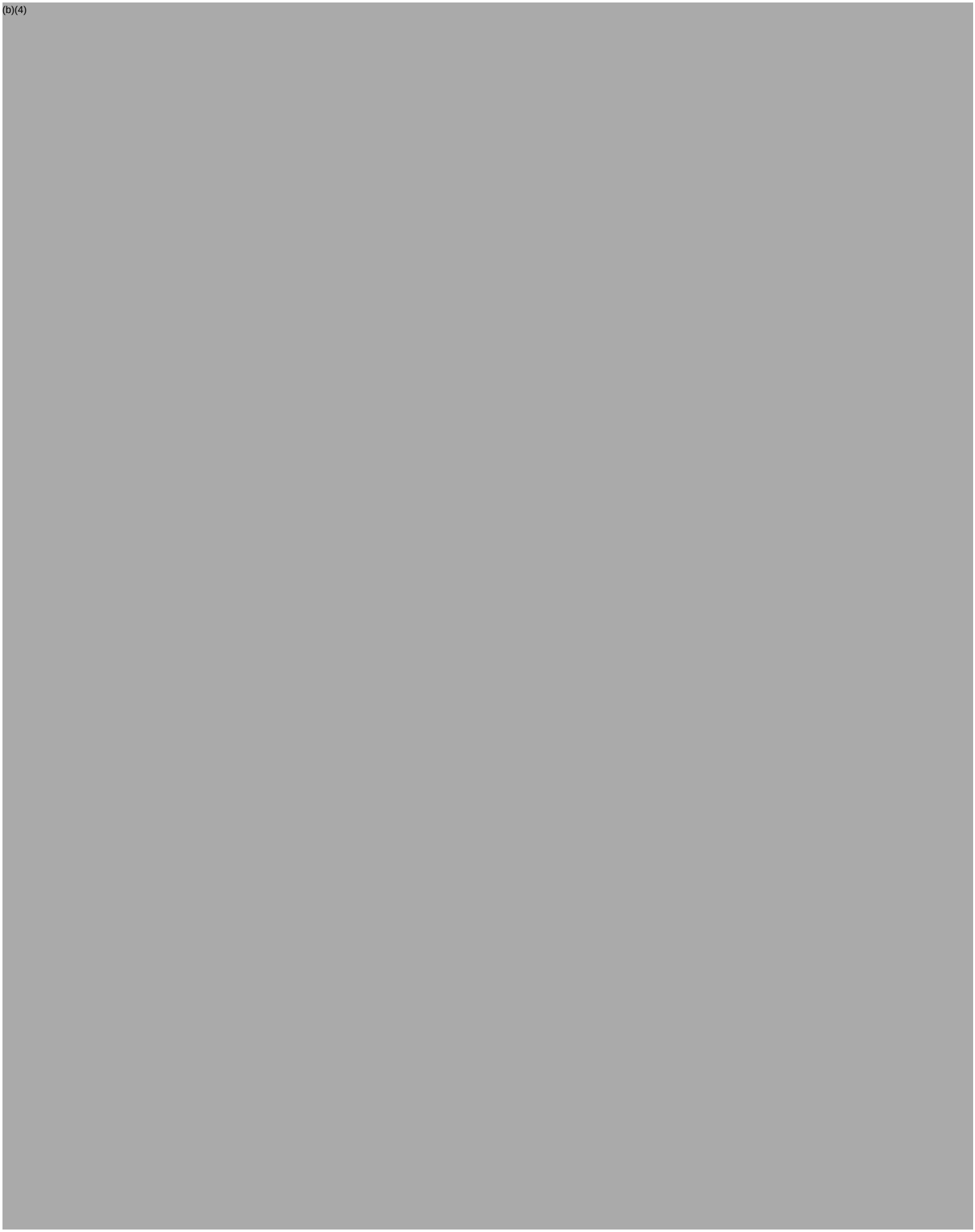

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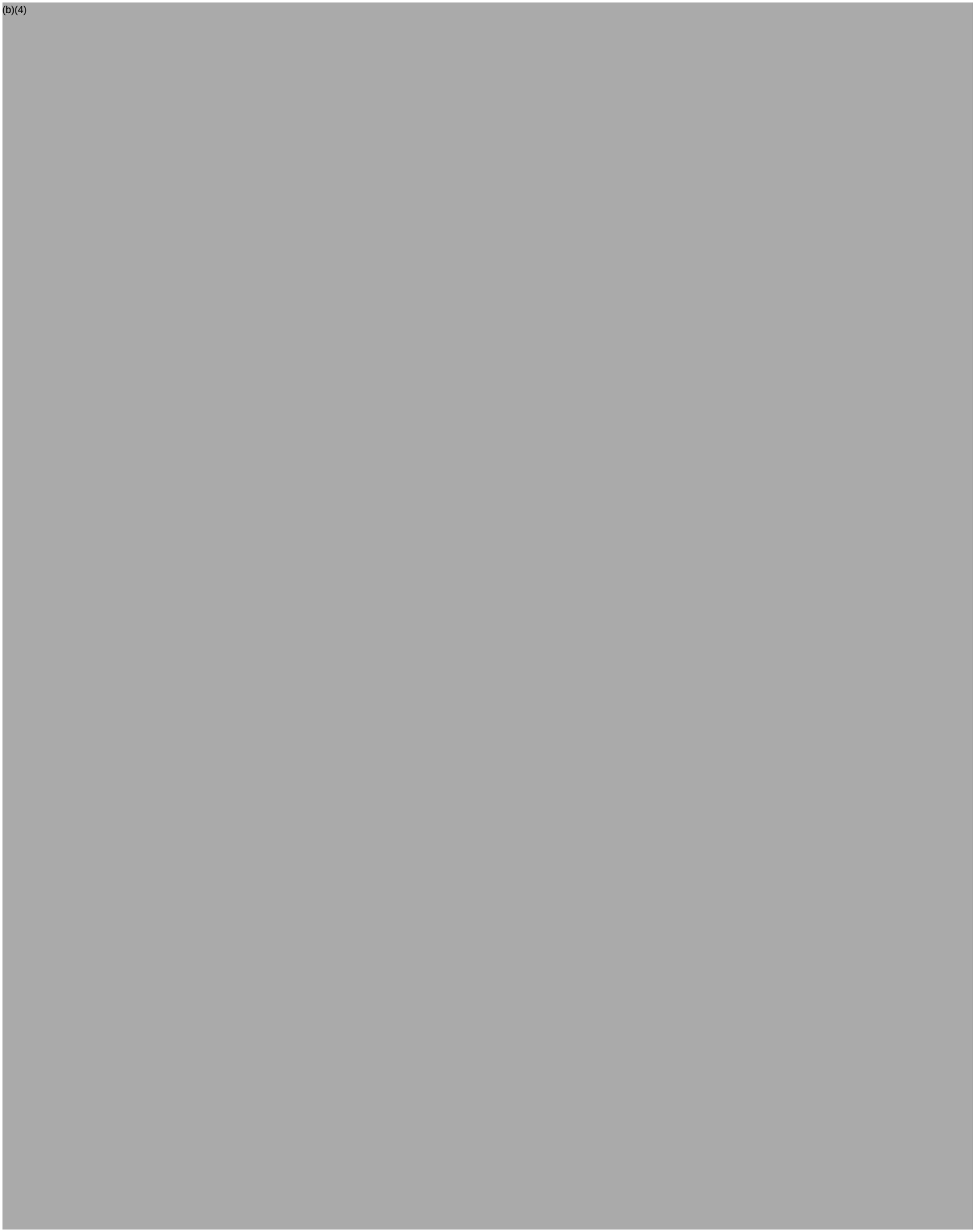

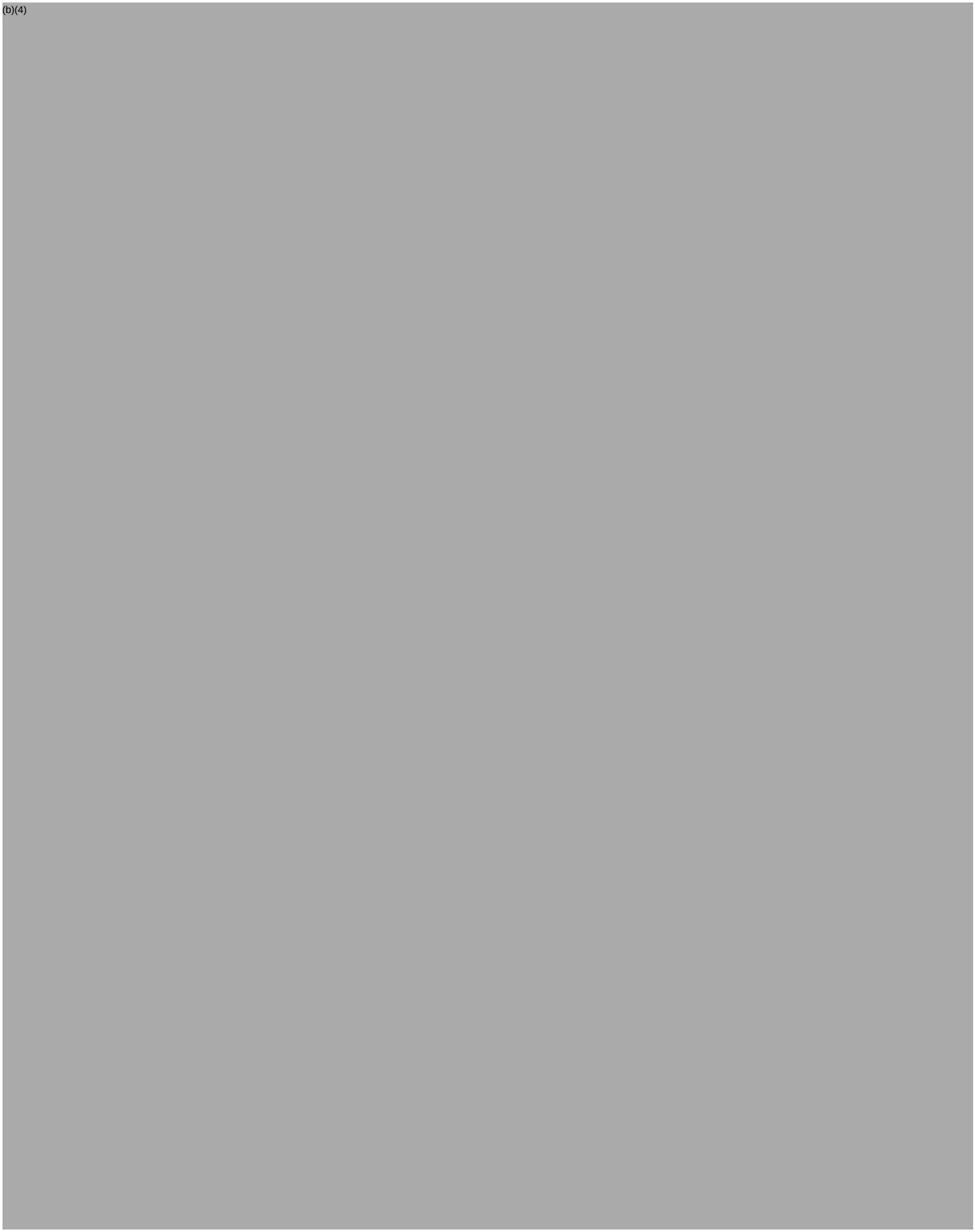
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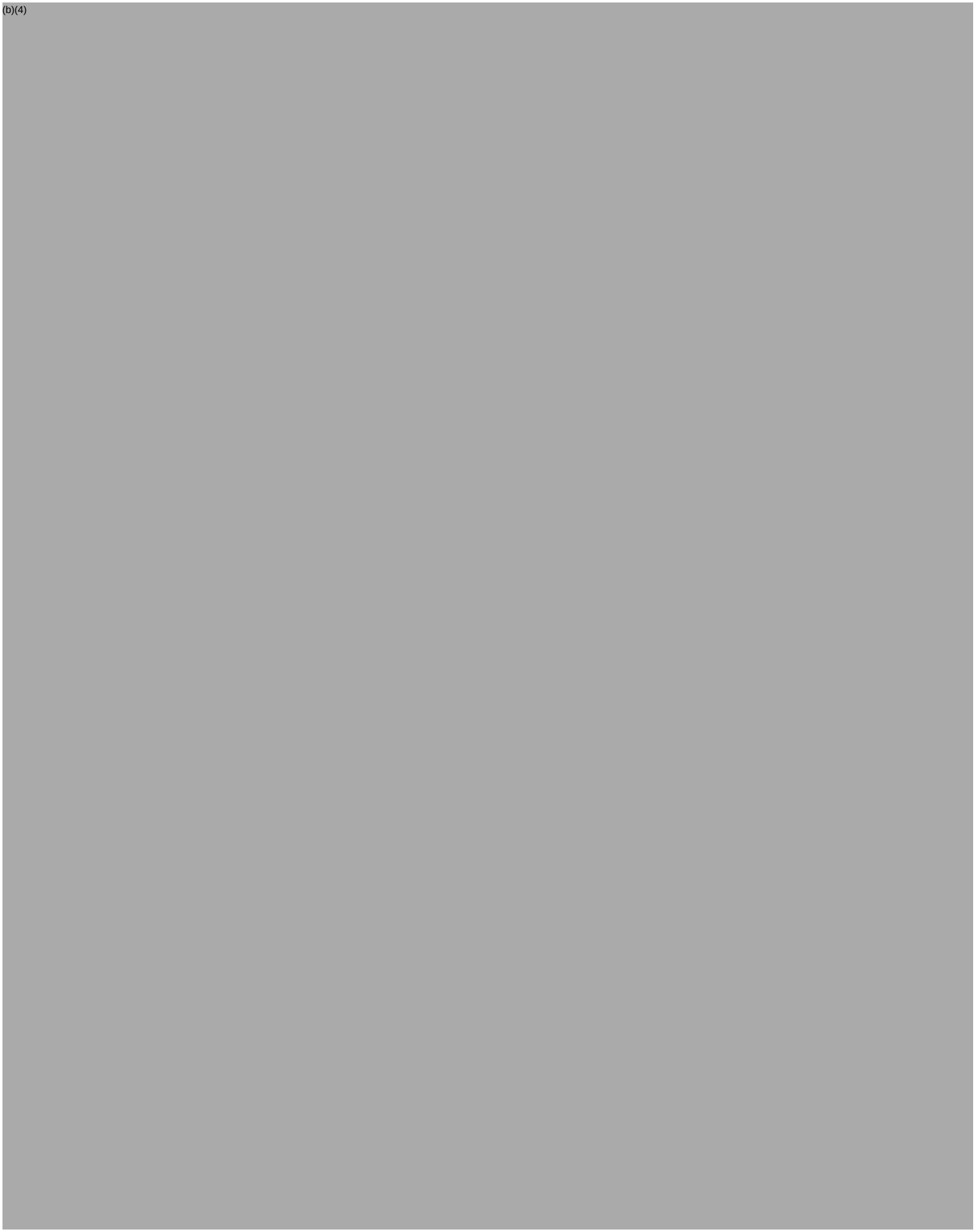
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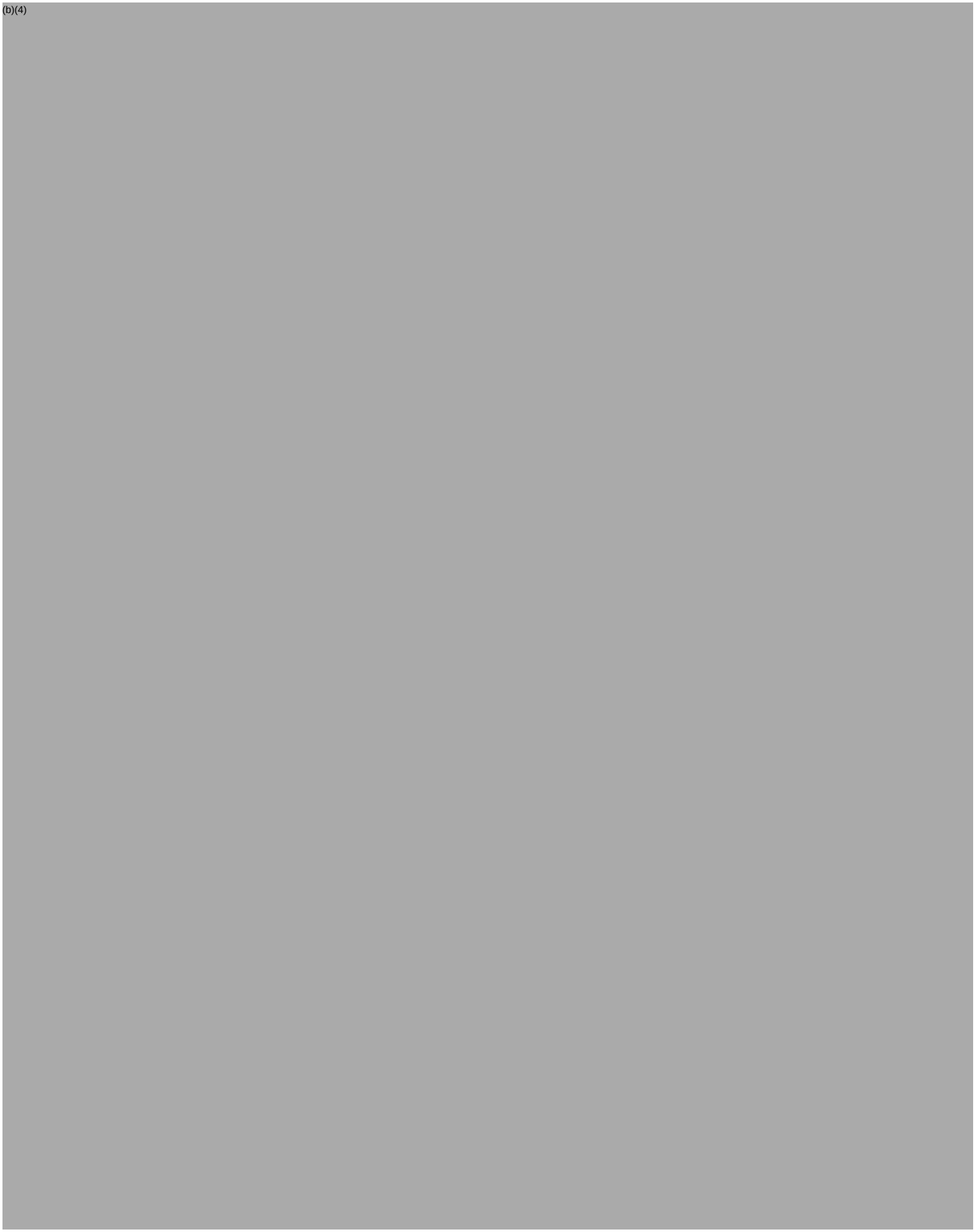
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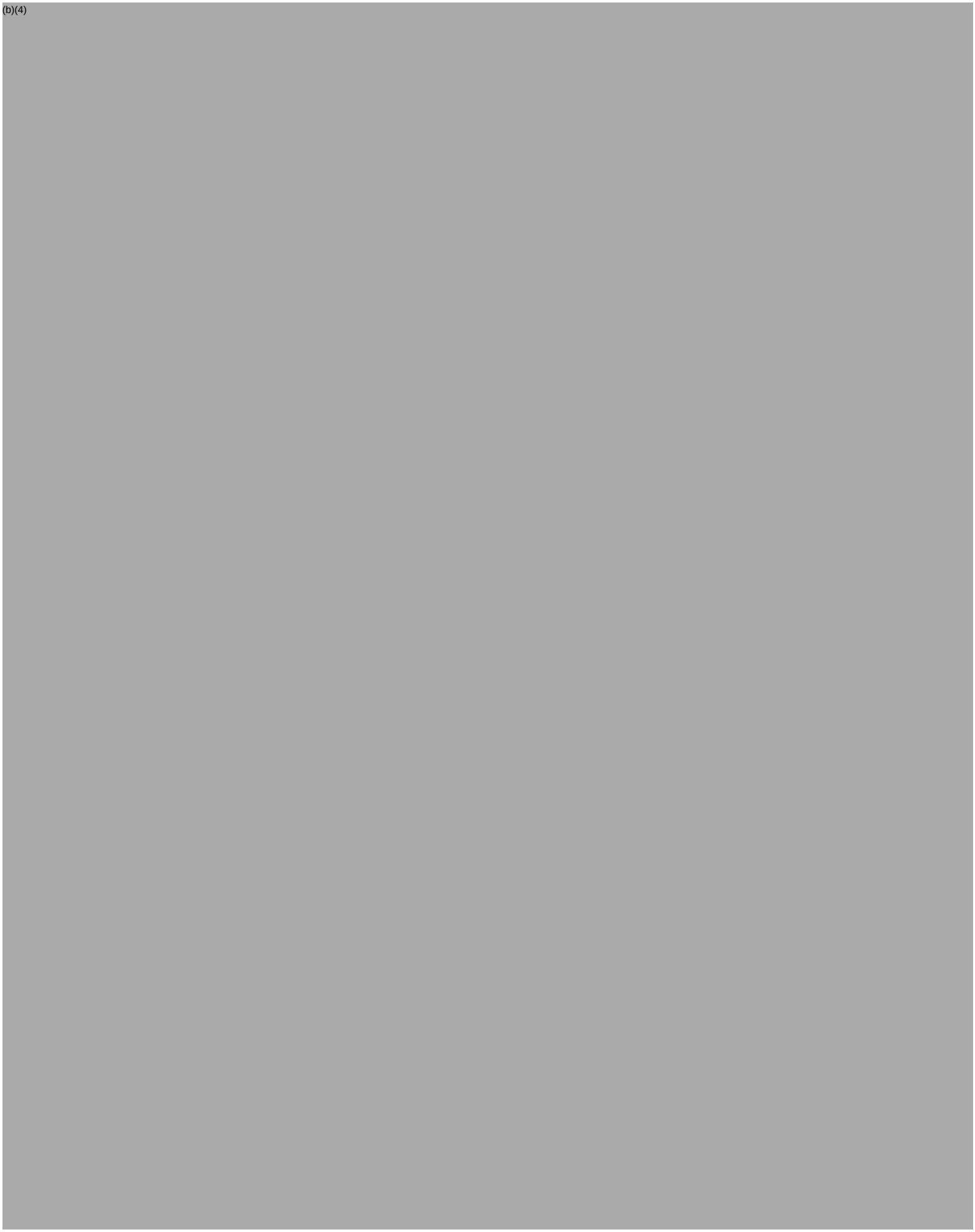

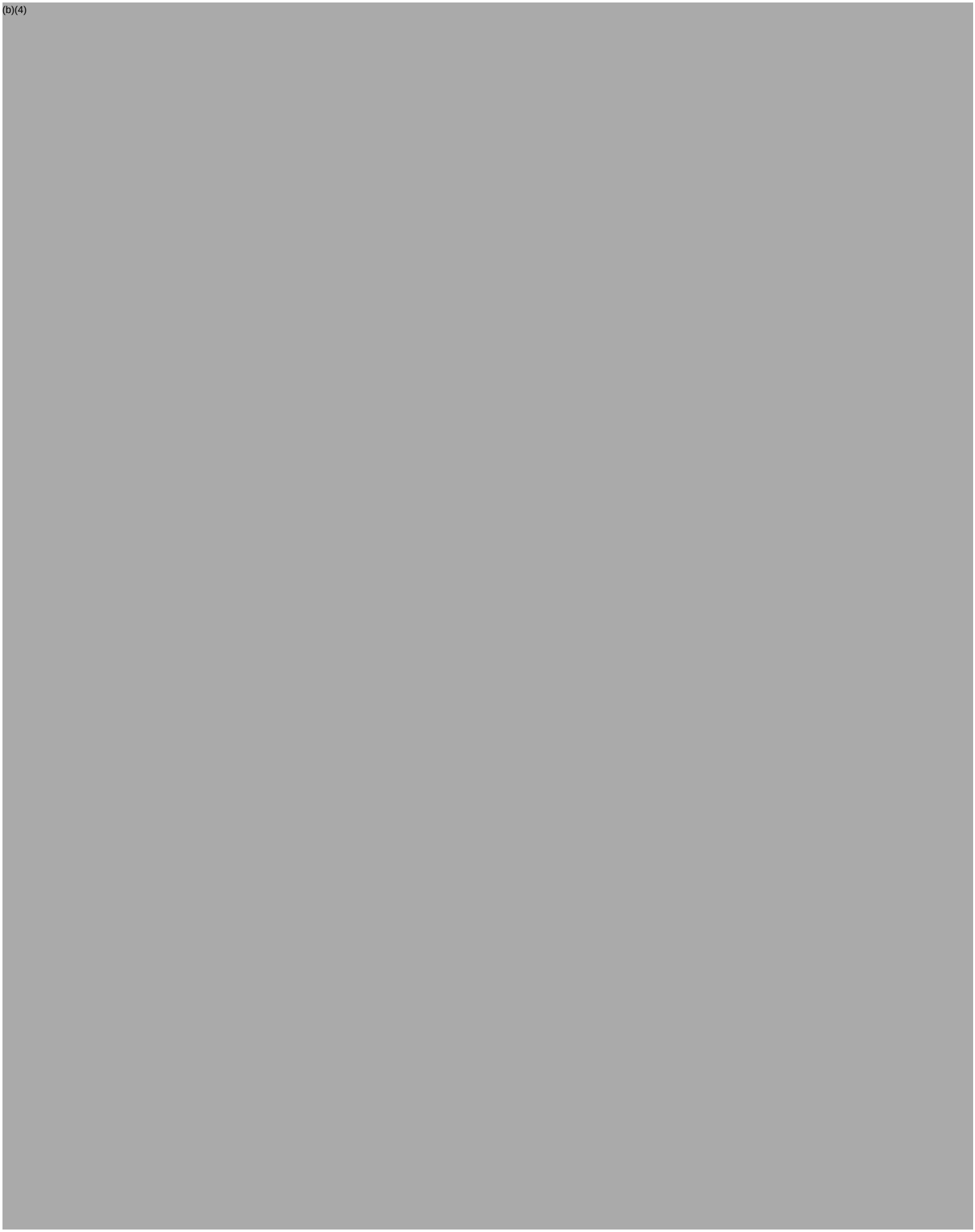
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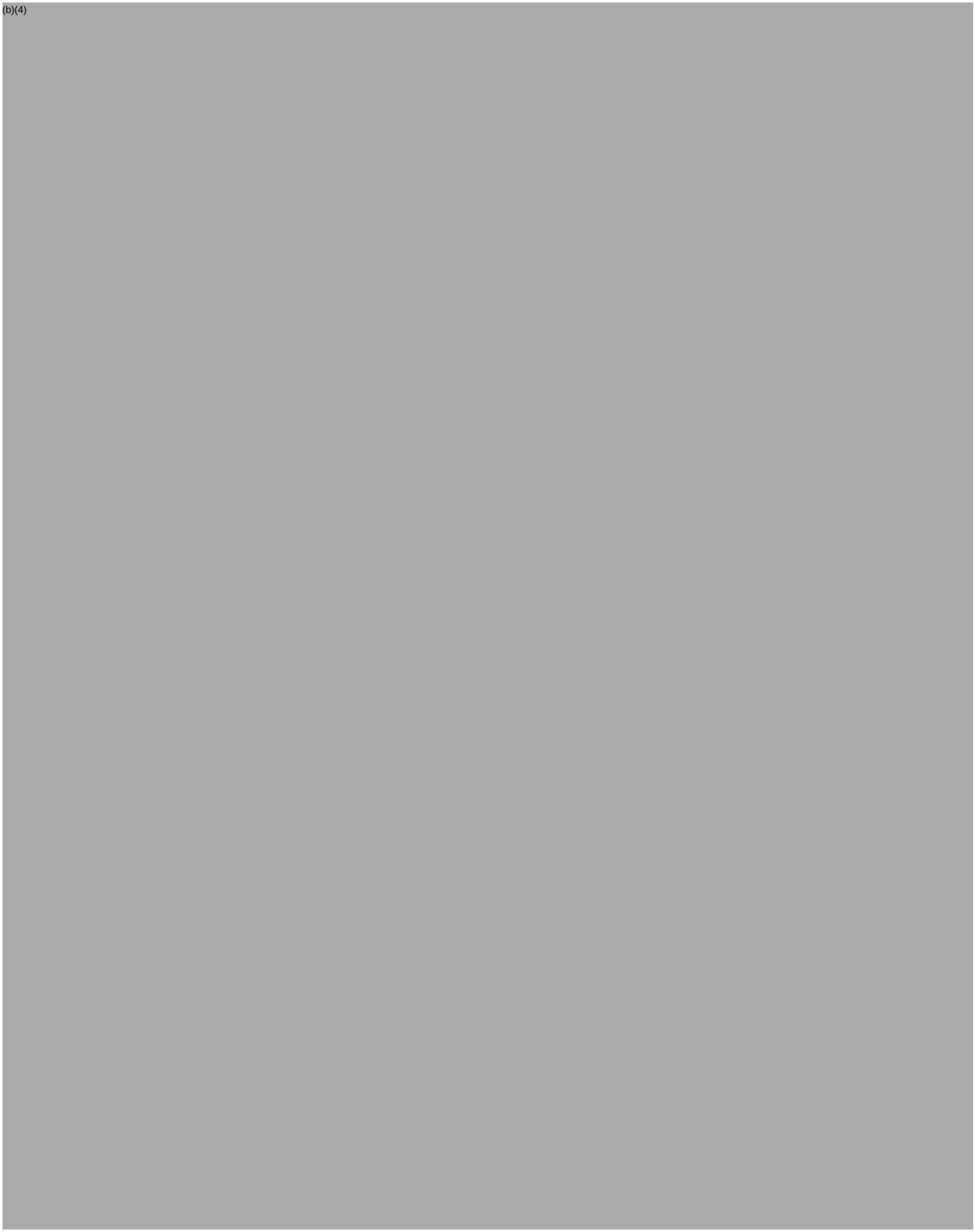
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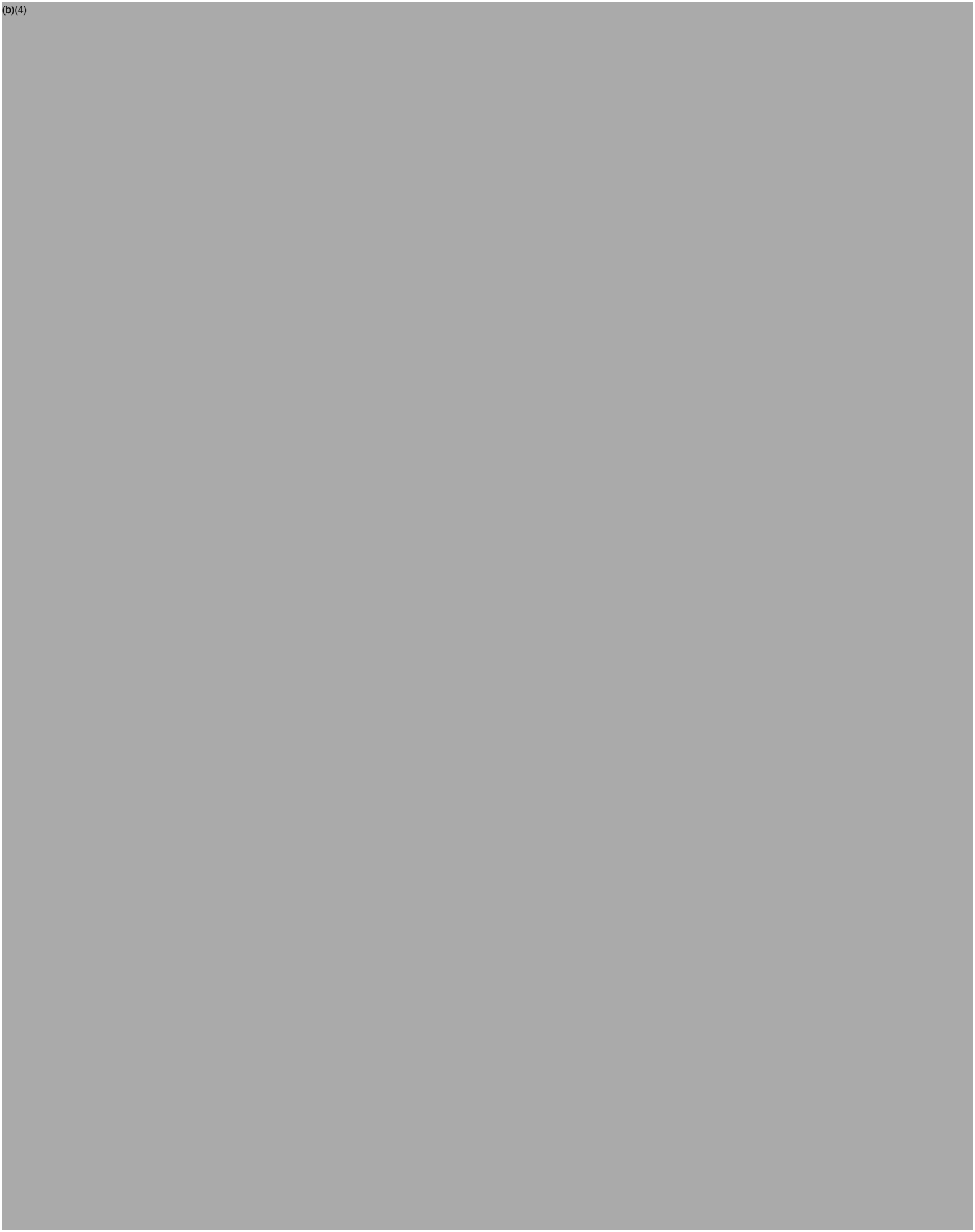
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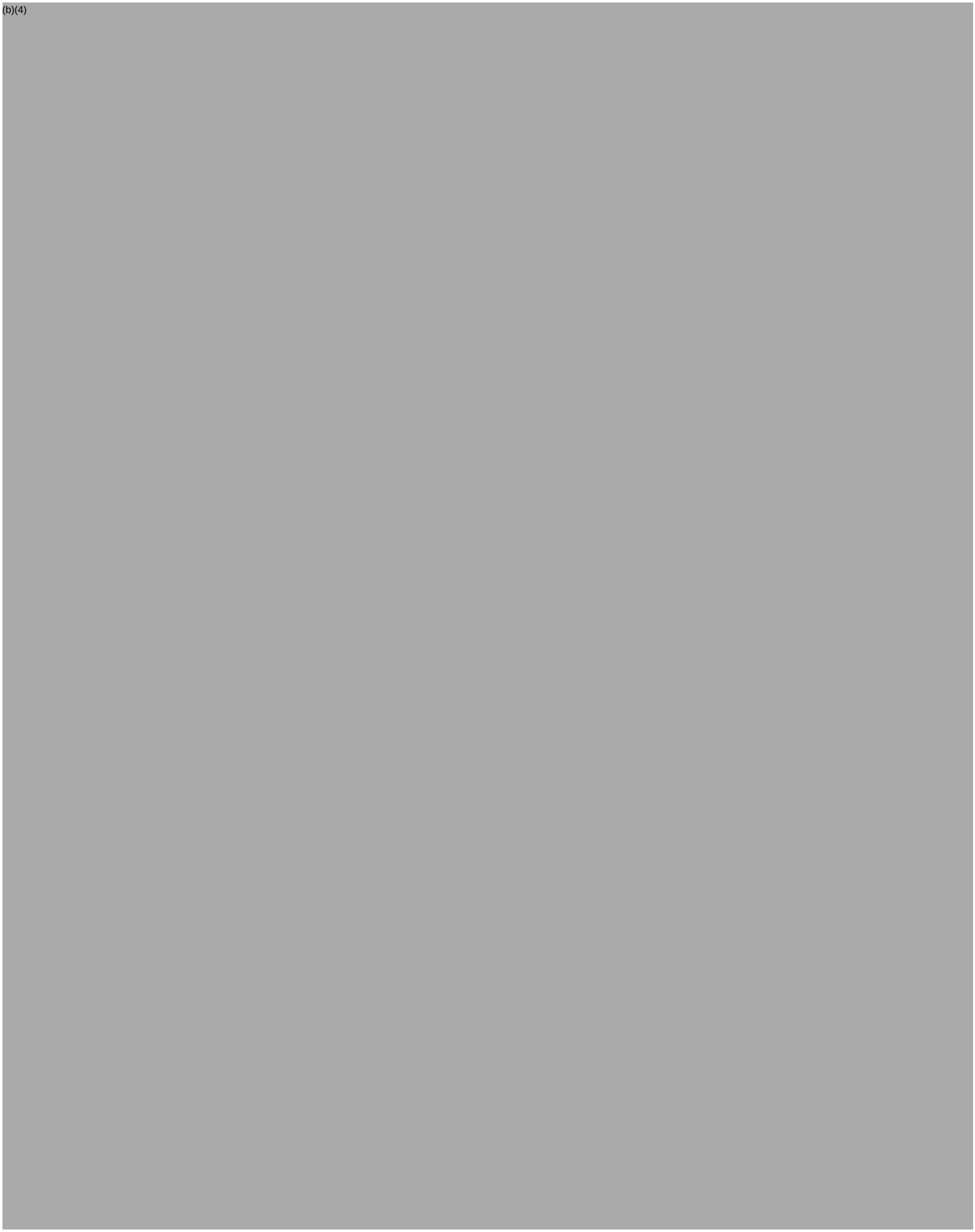
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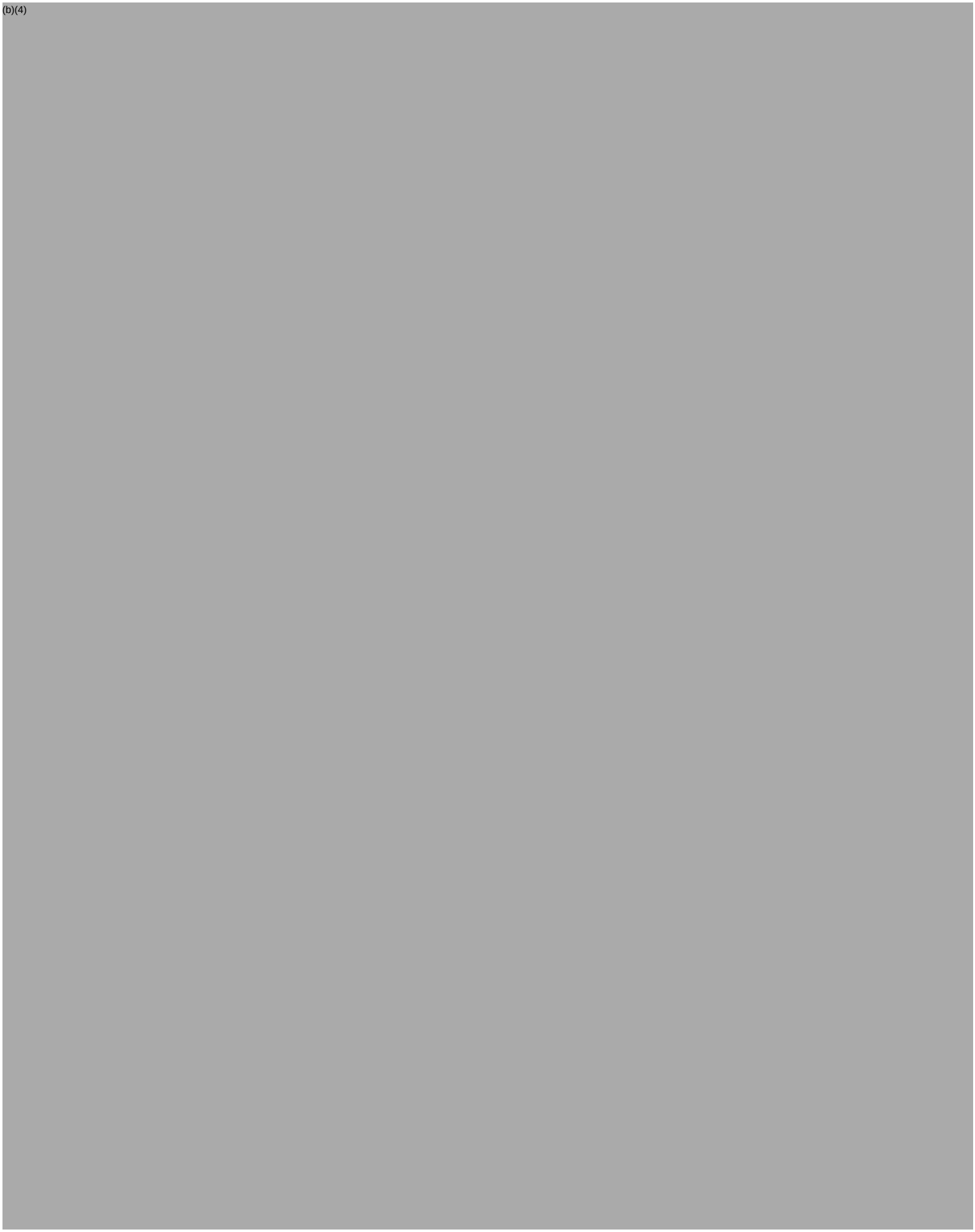
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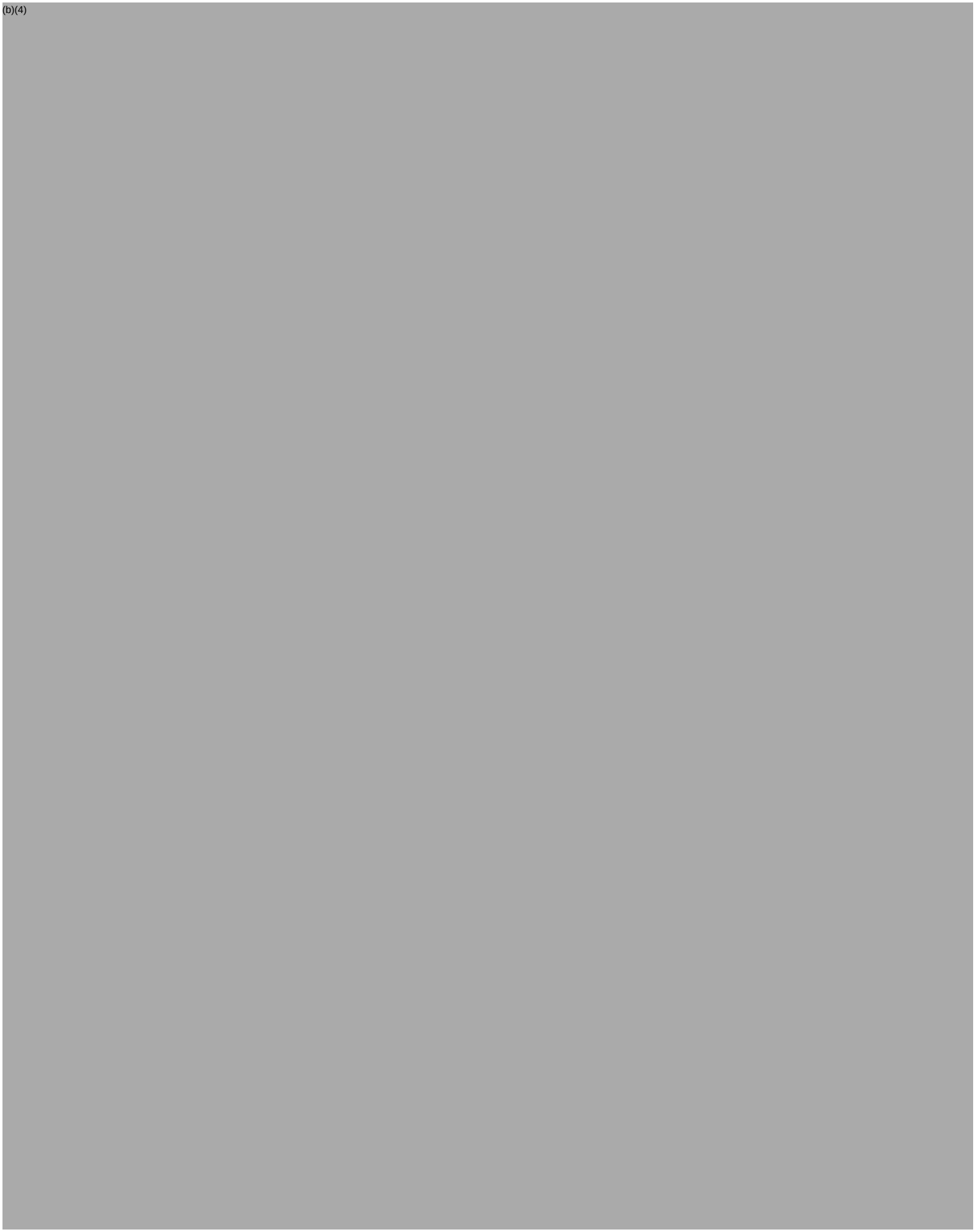

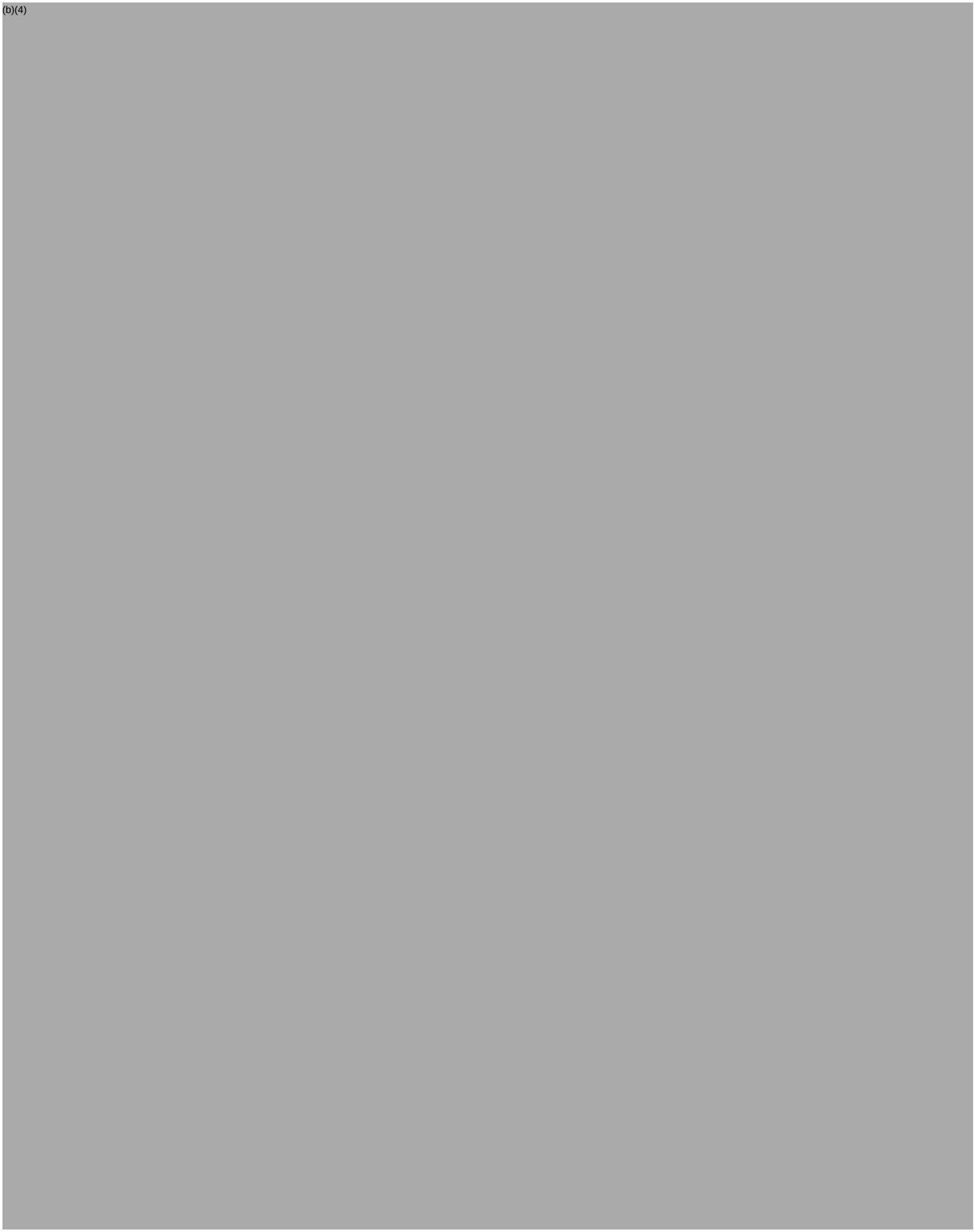
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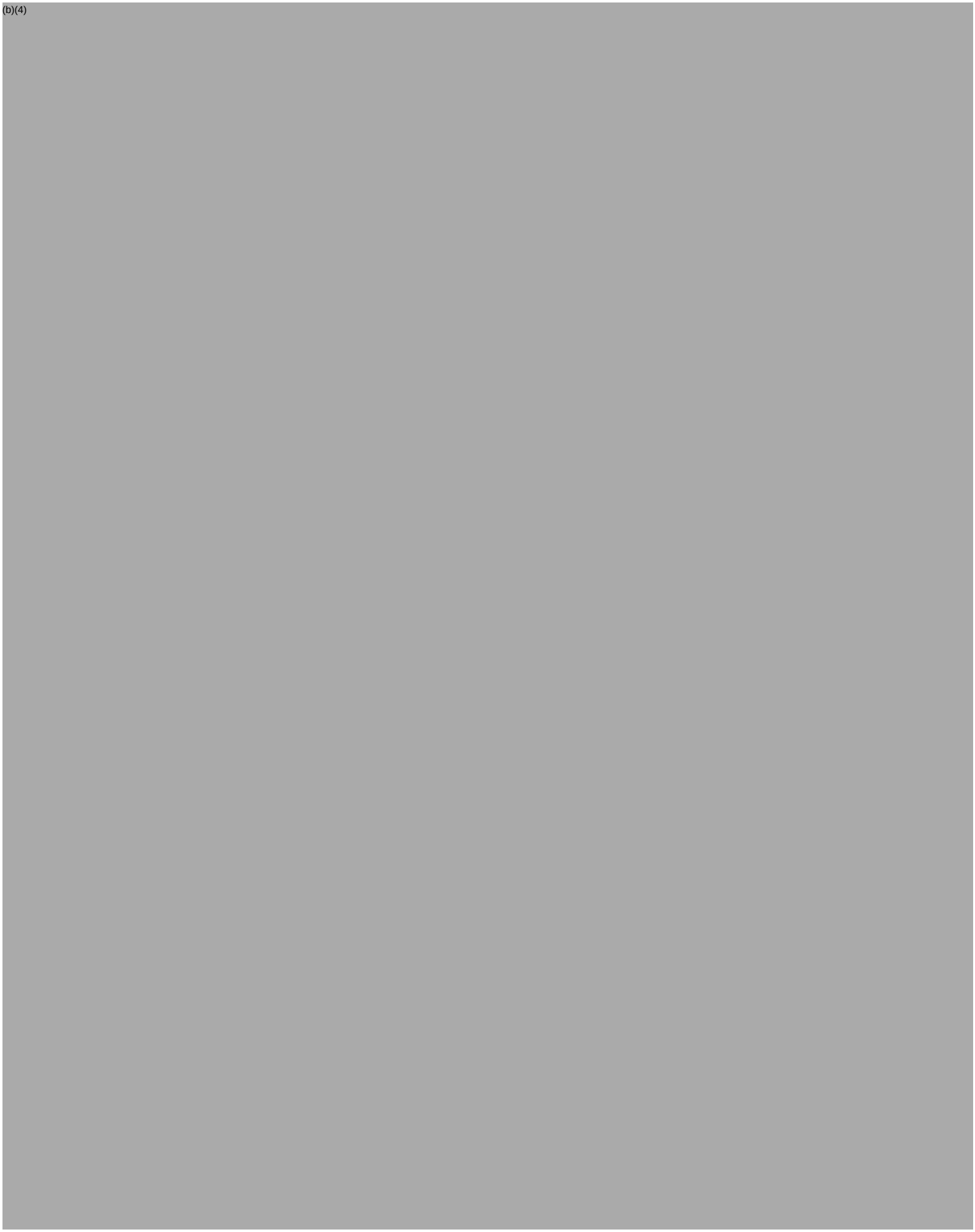
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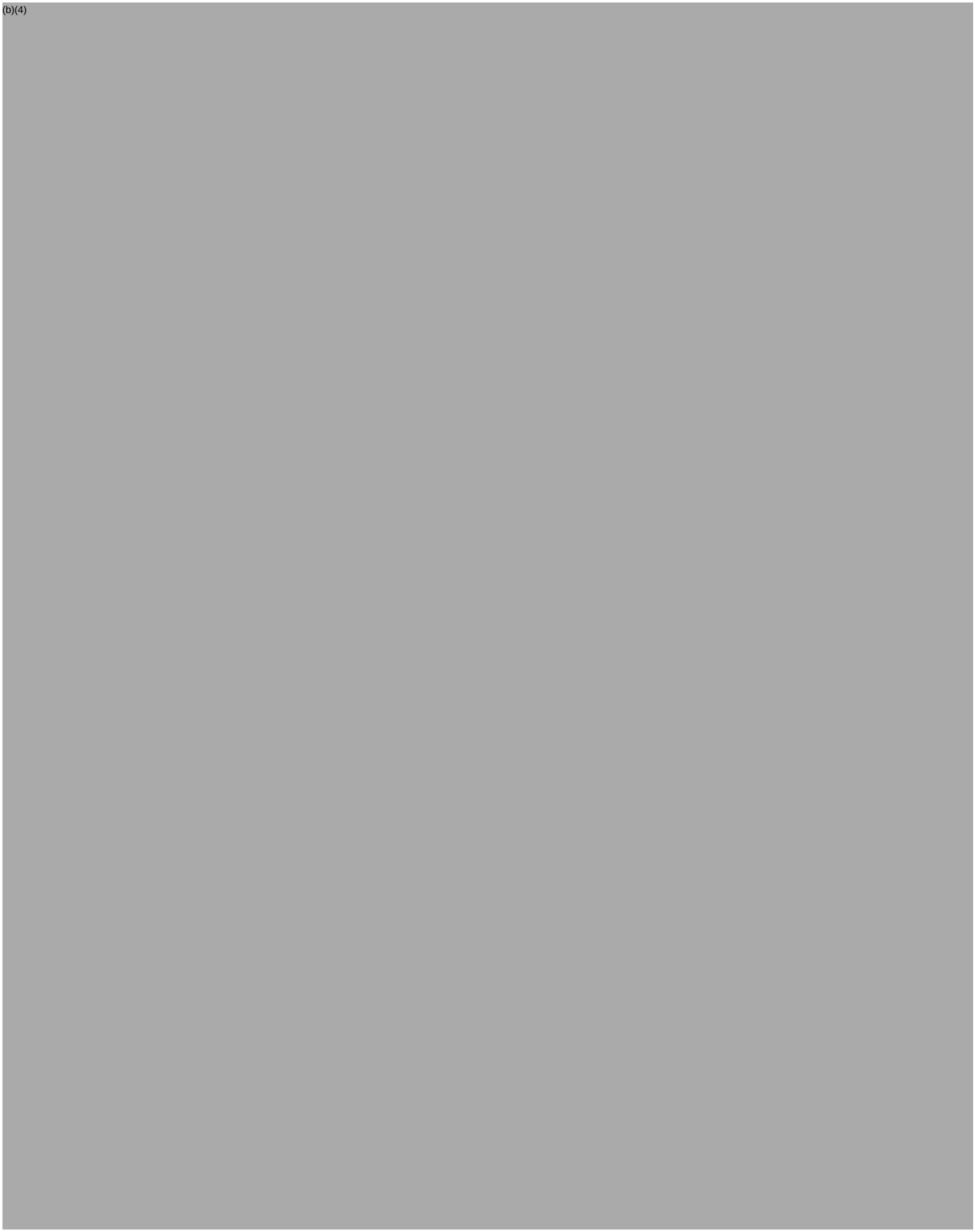
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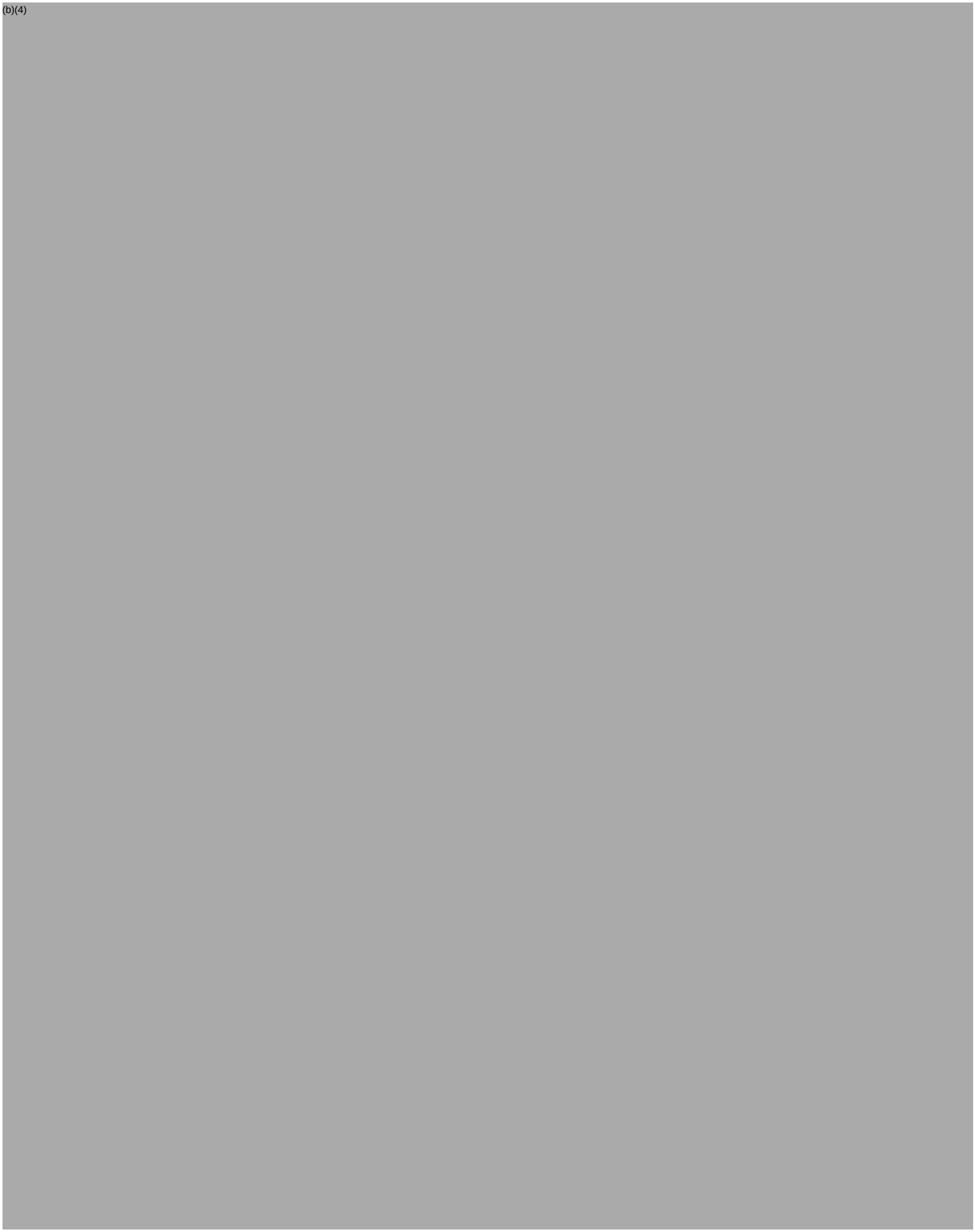
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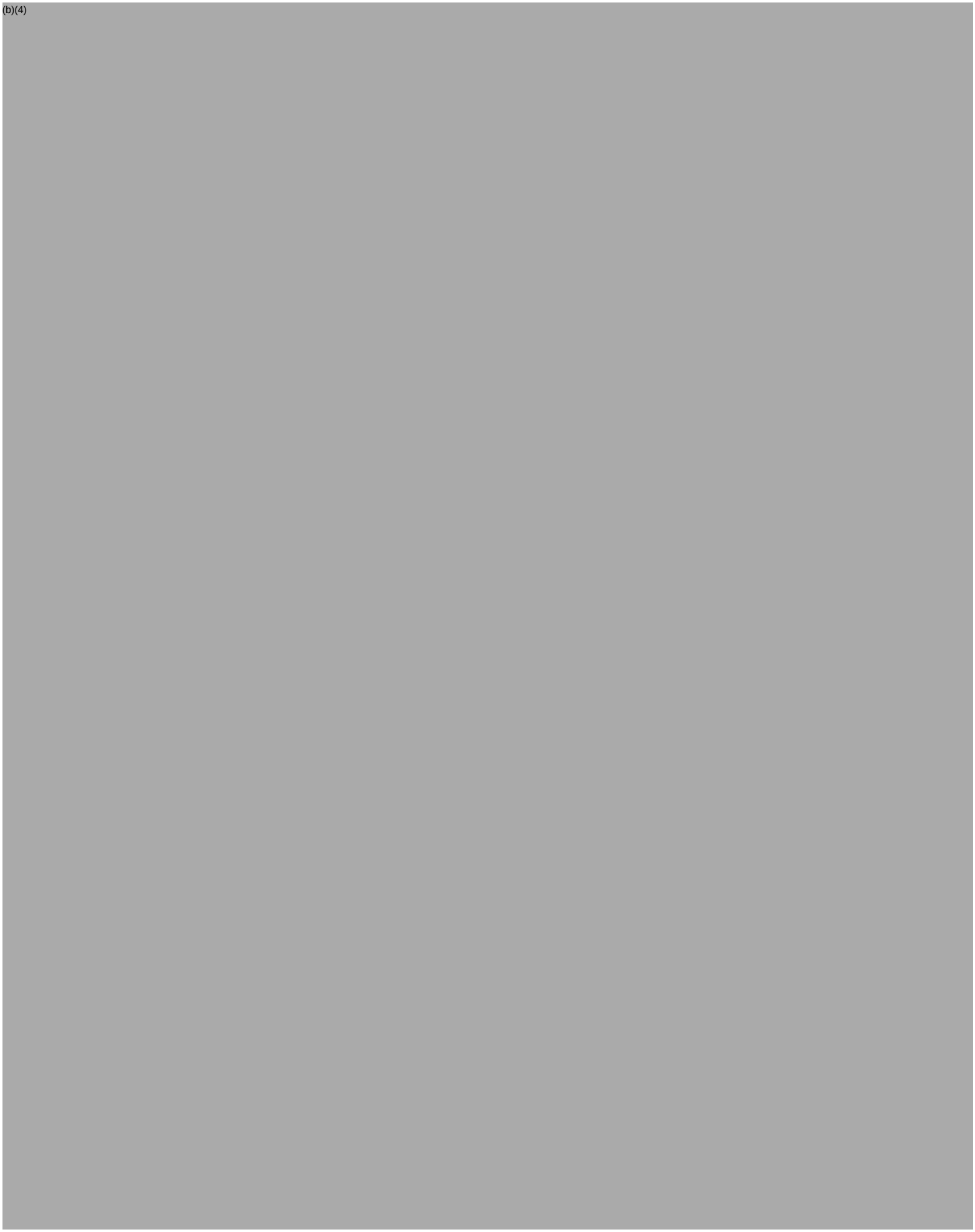
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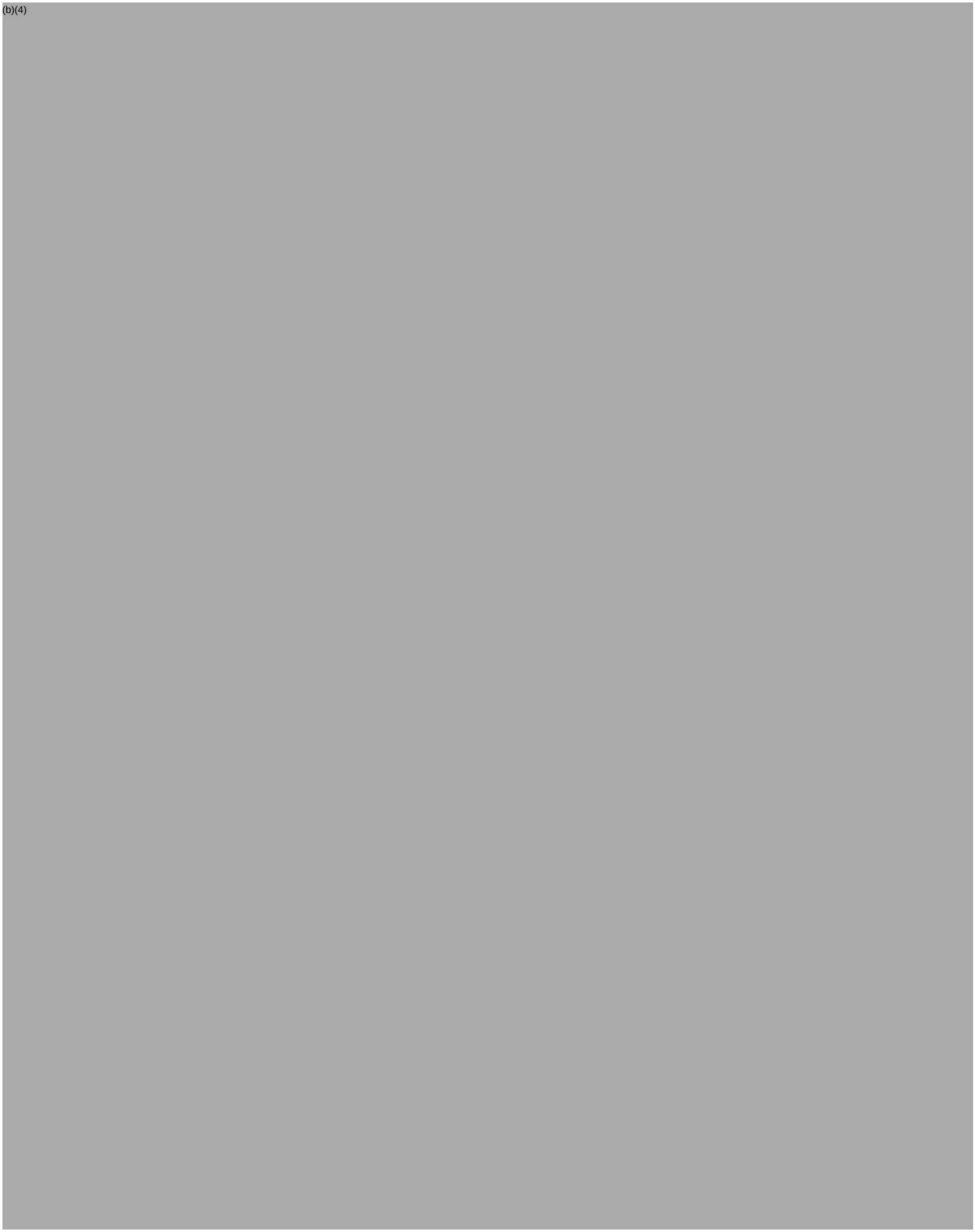
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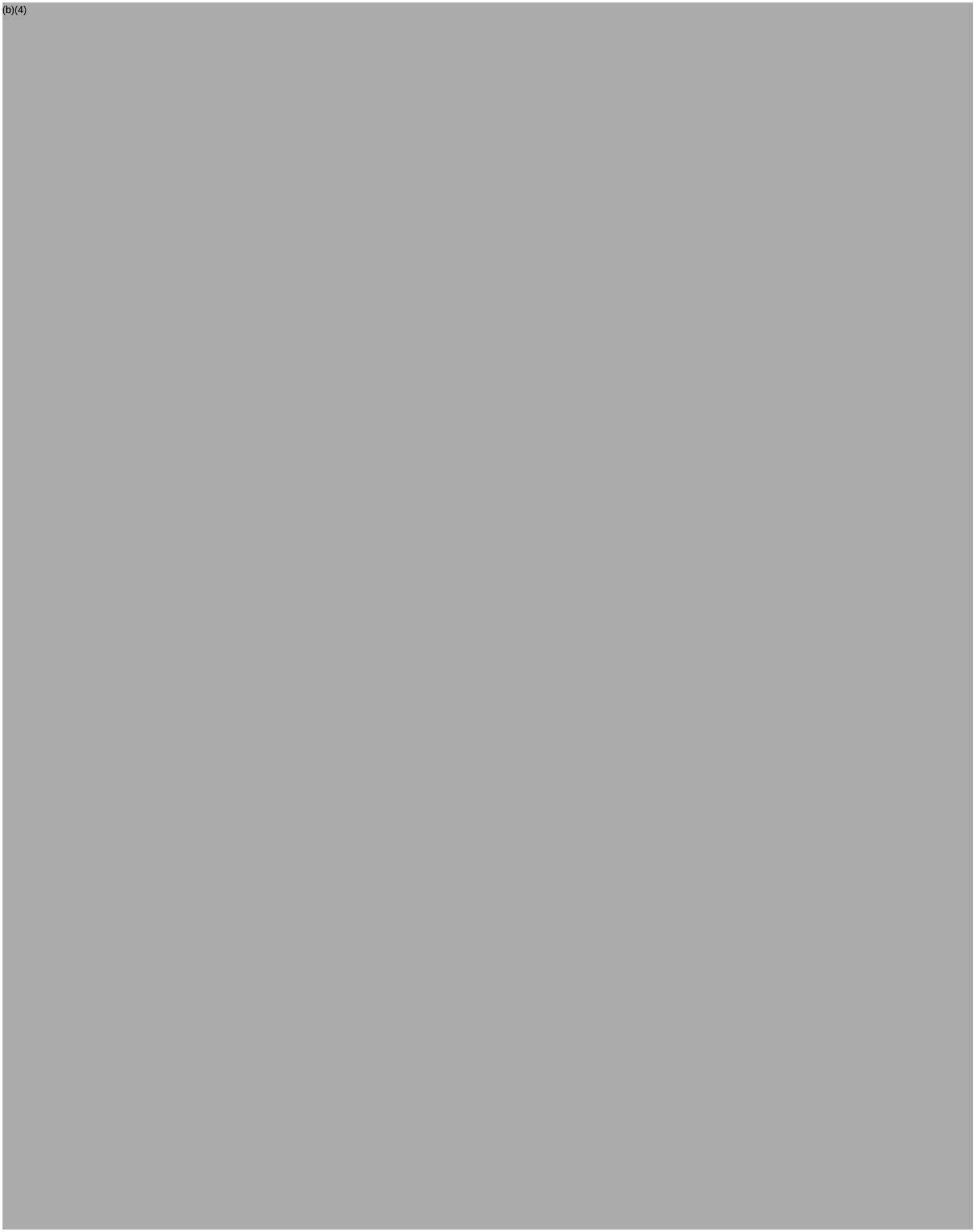
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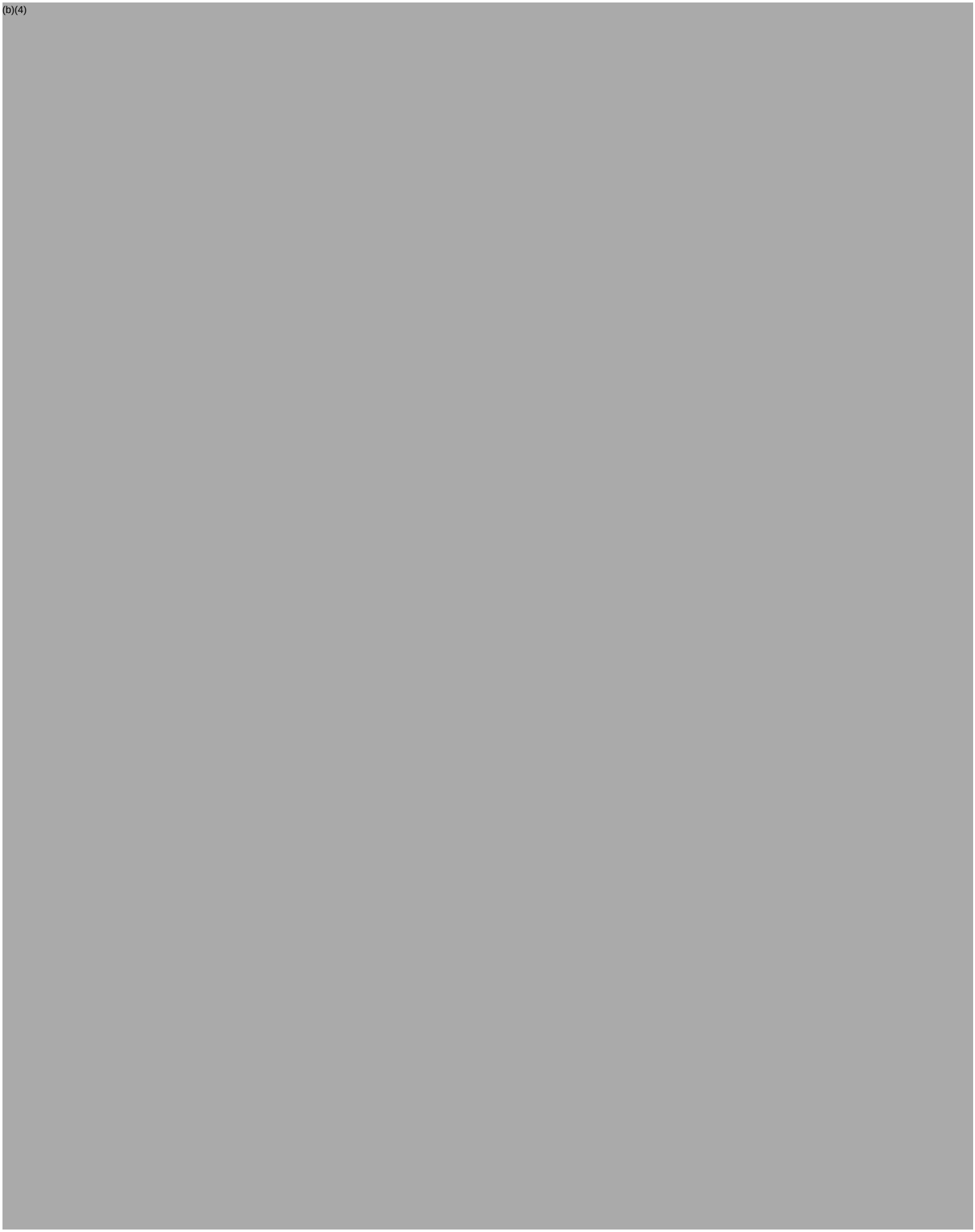
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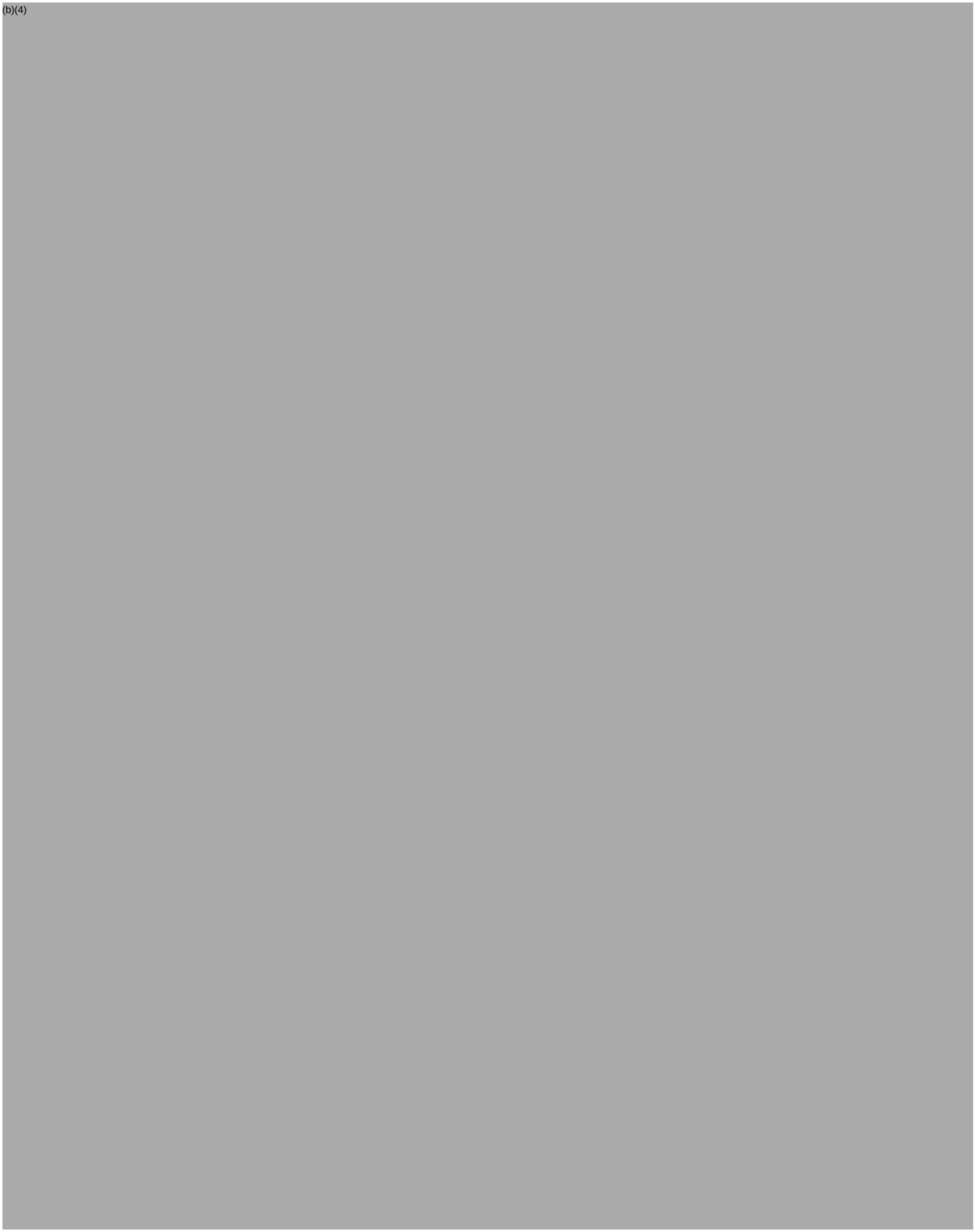
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