***The information provided herein is considered JRD, LLC trade secrets, commercial or financial information that JRD, LLC customarily holds close and treats as confidential. The information is being provided under the assurance that the U.S. Department of Health and Human Services and all of its agencies, including the Assistant Secretary for Preparedness and Response, Biomedical Advanced Research and Development Authority, will maintain the confidentiality of the information under the Trade Secrets Act, Procurement Integrity Act, other applicable statutes, regulations, rules, case law contractual provisions, protective orders or otherwise and as such, the information provided herein is exempt from disclosure under Exemption 4 of the Freedom of Information Act ("FOIA").***

**AMENDMENT OF OTHER TRANSACTION AGREEMENT (OTA)**

OTHER TRANSACTION FOR ADVANCED RESEARCH (OTAR)

BETWEEN

**Other Transaction Agreement**

**Agreement Number HHSO100201700018C**
Effective Date of Agreement: August 15, 2017

BETWEEN

**JANSSEN RESEARCH & DEVELOPMENT LLC**
920 ROUTE 202
RARITAN, NJ 08869, USA

AND

**THE UNITED STATES OF AMERICA**
**DEPARTMENT OF HEALTH AND HUMAN SERVICES**
**BIOMEDICAL ADVANCED RESEARCH AND DEVELOPMENT AUTHORITY**
O'NEILL HOUSE OFFICE BUILDING
WASHINGTON, DC 20515

CONCERNING

**INFLUENZA PORTFOLIO AND OTHER EMERGING PATHOGENS DEVELOPMENT CANDIDATES**

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Amendment No. 0007

Effective Date of Modification: Upon Last Signature in Section III

Total Amount of the Agreement is increased by (b)(4) from (b)(4) to (b)(4) Includes Recipient and Government Funding).

Government Share of Total Amount of the Agreement is increased by (b)(4) from (b)(4) to (b)(4)

Recipient Share of Total Amount of the Agreement is increased by (b)(4) from (b)(4) to (b)(4)

Current Government commitment: with the addition and authorization of WPs 7.1 – 7.4.3, 7.5.1 and 7.6.1, the total Funds Obligated is increased by (b)(4) from (b)(4) to (b)(4)

Current Recipient commitment: with the addition and authorization of WPs 7.1 – 7.4.3, 7.5.1 and 7.6.1, the total Recipient Funds Obligated is increased by (b)(4) from (b)(4) to (b)(4)

Period of Performance:

- The Period of Performance of this agreement is extended to from April 30, 2023 to December 31, 2024.

Authority: Section 319L(C)(5) of the Public Health Service Act, 42 USC 247d-7e(C)(5).

Line of Accounting and Appropriation:

| Work Packages | Title | Requisition (OS) | CAN | Obj.Class | Amt. (Govt Share) | Changed |
|---|---|---|---|---|---|---|
| Base Period | Base/Initial – Initial Award (August 15, 2017 – December 31, 2018) | (b)(4) | | | | |
| Option Period Number 1 | Option Period Number 1, January 1, 2019 – December 31, 2019 | | | | | |
| WP 6.1 – 6.7 | COVID-19 - Vaccines discovery thru Phase 1 Trial. | | | | (b)(4) (b)(4) | Redistributed via modification |

| | | | | | | |
|---|---|---|---|---|---|---|
| WP 7.1 – 7.4.3, 7.5.1 and 7.6.1 | COVID-19 TX Antiviral Discovery and Clinical Development (through Phase 2b Trials) | OS256087 | 199COV2 | 25103 | (b)(4) | Added via this modification |
| **Total** | | | | | | (b)(4) |

I. AMENDMENT PURPOSE

During the March 10, 2020 JOC the JOC made decisions regarding both the COVID-19 vaccine work as amended to the Influenza and Emerging Pathogens OTA, OTA number HHSO100201700018C ("Flu" OTA), by Amendment 0006 and work to be added to the Flu OTA involving COVID-19 Antiviral work. In order to ensure clarity, this Amendment 0007 only discusses items related to the JOC's March 10, 2020 decision and recommendation involving the COVID-19 Antiviral work.

By the Parties' mutual agreement and within the existing Agreement's general scope, this Amendment No. 0007 bilaterally:

i. implements the JOC decision and recommendation of March 10, 2020 to place the next phases of the COVID-19 Antiviral program under this Flu OTA. As such, based on the JOC decision and recommendation, this Amendment 0007 to the Flu OTA, hereby adds Work Packages (WP) 7.1 – 7.6.2, COVID-19 TX Antiviral Discovery and Clinical Development to this OTA.

ii. incorporates an updated (b)(4) to (i) add COVID-19 TX Antiviral Discovery and Clinical Development (WPs 7.1 – 7.6.2), and (ii) (b)(4) t (b)(4) the 2019-nCoV Vaccines (WPs 6.1 – 6.7 activities). Exhibit B Budget Allocations is provided and includes additional information.

iii. updates the Statement of Work (Exhibit-A) to reflect COVID-19 TX Antiviral Discovery and Clinical Development, Work Packages (WP) 7.1 – 7.6.2. The COVID-19 Antiviral Discovery and Clinical Development, Work Packages (WP) 7.1 – 7.4.3 (Clinical Phase 2b Study), 7.5.1 (Regulatory though Phase 2b clinical study) and 7.6.1 (Project Management through to Phase 2b clinical study) as described on the Exhibit-A, Statement of Work are considered added and funded non-severable independent work packages as of the date of this amendment. Work Packages 7.4.4 (Clinical Phase 3 Study), WP 7.5.2 (Regulatory for Phase 3 and registration) and WP 7.6.2 (Project Management for Phase 3 and registration) are identified as Options to be exercised at a future date based on (i) JOC recommendation, (ii) availability of funding and (iii) a signed amendment between the Parties.

iv. Within Agreement Number HHSO100201700018C, Article IV Management of the Project the following updates are made:

a. Section A (3) Organizational Chart, is updated to include the respective Technical Leads for the COVID-19 program

b. Within Section B, Project Committees and Meetings, paragraph 5. "Cost Share Determination (CSD) Meeting" is added.

II. AMENDMENTS TO AGREEMENT

A. Incorporate new Cost Share Estimates/Budget Summary and Budget Allocation/Workplan Structure to reflect the new COVID-19 TX Antiviral Discovery and Clinical Development estimated costs and cost shares.

1) Pursuant to Agreement Article VI(C), the budget allocation summary of assets is hereby replaced to incorporate the following.

(b)(4)

2) Budget Allocation/Workplan Structure (also included as Exhibit B) reflects the budget allocation summary and provides details for the budget incorporated in this Amendment 0007. Please note that work packages (b)(4) (b)(4) (b)(4) to the 2019-nCoV activities (b)(4)

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(b)(4)

B. Updated the Statement of Work

1) The Statement of Work shall be replaced to reflect the new COVID-19 TX Antiviral Discovery and Clinical Development, Work Packages (WP) 7.1 – 7.6.2. The updated SOW for incorporation in the OTA is included in Exhibit A.

C. Article IV Management of the Project, the following updates are made:

1) Article IV *Management of the Project* Section A (3) *Organizational Chart* is deleted and replaced with the following:

(b)(4)

2) Article IV Management of the Project, Section B, Project Committees and Meetings, paragraph 5. "Cost Share Determination (CSD) Meeting" is added:

**5. Cost Share Determination (CSD) Meeting:** Either by conference call or in person, the OTAO, and/or the OTAS, OTTR and the PI/PML/Business Interface will discuss and review cost share contributions of the Agreement. During this meeting, the PI/PML/Business Interface will discuss assets progression to date and provide an update on the commercial viability of portfolio assets. These meetings will be held on annual basis and may be scheduled on an ad-hoc basis after the receipt of study data, FDA feedback and/or future public health scenarios that will guide in the activation of future elements of the Agreement. The recipient will submit to the Government meeting minutes and a revised budget (if applicable) as result of discussions.

Except as provided in this Amendment, all terms and conditions of the Agreement, as heretofore changed, remain unchanged and in full force and effect.

III. SIGNATURES

Acknowledged, accepted, and agreed for

JANSSEN RESEARCH & DEVELOPMENT, LLC

(b)(6)

U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES
OFFICE OF THE ASSISTANT SECRETARY FOR PREPAREDNESS & RESPONSE
BIOMEDICAL ADVANCED RESEARCH & DEVELOPMENT AUTHORITY

BY: Wendell Conyers -S Digitally signed by Wendell Conyers -S Date: 2020.03.20 17:53:40 -04'00'

NAME: WENDELL CONYERS
ITS: OTHER TRANSACTION AGREEMENT OFFICER
DATE:

## ATTACHMENT 1: TASK DESCRIPTION DOCUMENT (SOW)

Overall Objectives and Scope

Seasonal and pandemic influenza remains one of the most important public health threats despite current vaccine and therapeutic options. The Consortium is developing a broad portfolio of innovative and novel countermeasures against influenza and other emerging infectious diseases comprising small molecules, biologics and vaccines. The portfolio employs (b)(4) modes of action complementary to current Standard of Care treatments to develop single or combination therapies that have the potential to increase therapeutic benefit and preclude the rapid emergence of drug resistance. The (b)(4) aims to (b)(4) the influenza vaccine field by providing broad protection for both seasonal and pandemic influenza.

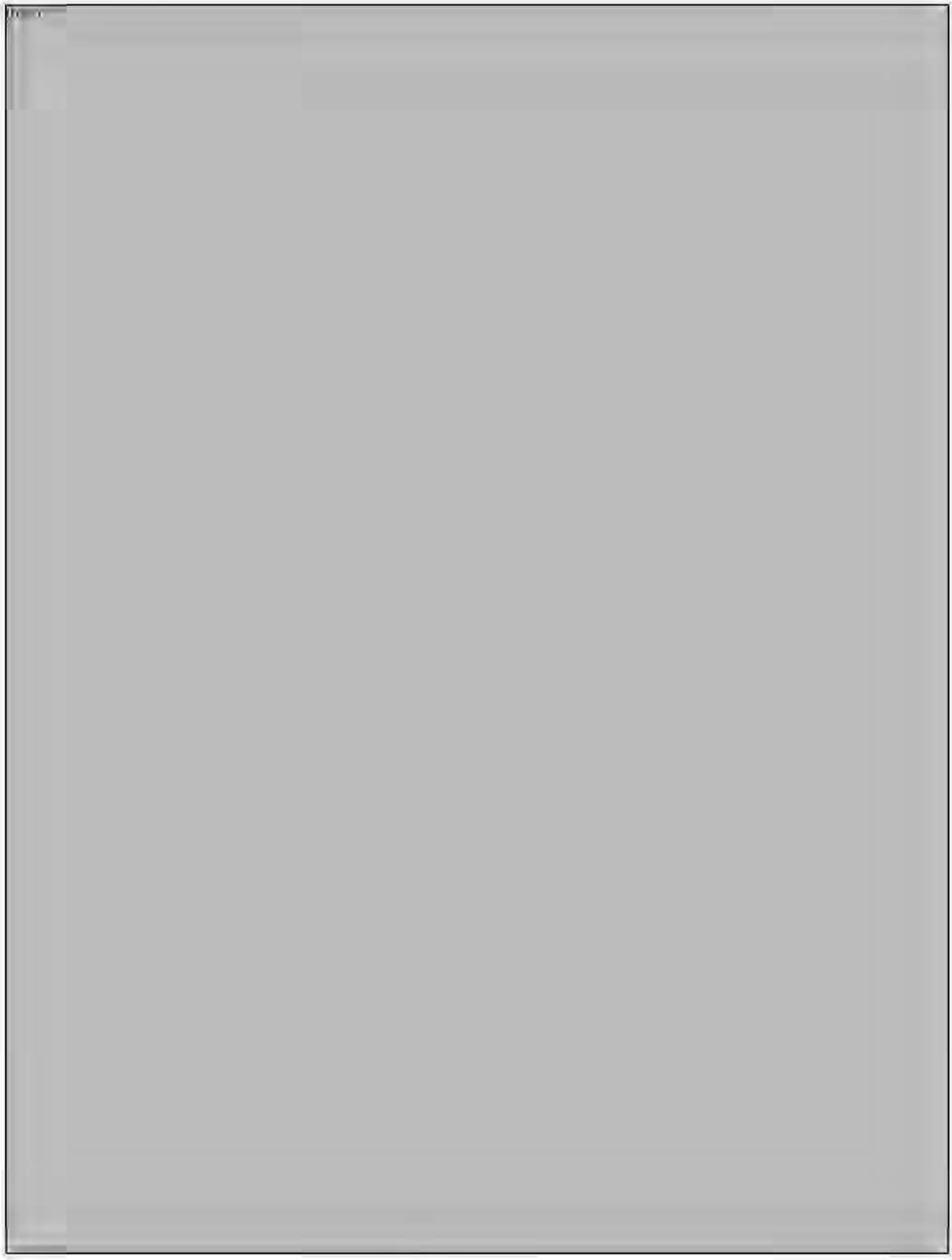
Specifically, this Agreement includes: an influenza (b)(4) that is now ready for (b)(4)

(b)(4)

In addition, Recipient may propose to augment the portfolio by replacing molecules listed in this SOW with backup molecules from their ongoing research programs. With support from the JOC, the Consortium may also consider in-licensing drug or vaccine candidates to supplement the Program's portfolio of emerging infectious disease medical countermeasures in the Field. Recipient may also add Consortium Members as may be appropriate or complimentary to the performance and goals of this Agreement.

(b)(4)

M0007 Exhibit A



(b)(4)

## 6 Novel Coronavirus ("2019-nCoV") Vaccine

### 6.1 Antigen design, manufacturability testing and preMVS manufacturing

*Activities*

- Several designs based on the 2019-nCoV spike sequence will be made and (b)(4)
  (b)(4)
- Ad26 research batches encoding the different spike (b)(4)

(b)(4)

(b)(4)

(b)(4)

- Several critical reagents such as expression plasmids, soluble proteins, peptide pools and detection antibodies will be generated or ordered

(b)(4)

[redacted]

### 6.2 pre-clinical immunology and protective efficacy

*Activities*

(b)(4)

[redacted]

### 6.3 CMC development

*Activities*

(b)(4)

- Minimal method development will occur to make insert specific assays fit for purpose.

(b)(4)

### 6.4 Clinical development

*Activities*

- Setup of immunological assays
  - (b)(4)
- Writing of protocol elements document (PED)
- Protocol writing
- Writing and submission of preIND document
- Writing and submission of IND documents
- Contracting with CRO clinical site

(b)(4)

(b)(4)

## 6.5 GLP Toxicology

*Activities*

- A GLP Toxicity study will be performed (b)(4)
- (b)(4)
- (b)(4)

(b)(4)

### 6.6 GMP manufacturing

*Activities*

- Master Virus Seed manufacturing and release
- Drug substance manufacturing at appropriate scale i (b)(4) (b)(4)
- Drug product manufacturing (b)(4) (b)(4)
- DS and DP stability analysis

(b)(4)

(b)(4)

**6.7 Ph1 clinical trial**

*Activities*

- Randomized, placebo-controlled, double blind study in healthy adult volunteers
- Primary objective will be assessment of safety and reactogenicity. Secondary and exploratory endpoints will evaluate vaccine-induced immunogenicity.

(b)(4)

(b)(4) 20+5 subjects (b)(4) 125 subjects (b)(4)

25 of these subjects (b)(4)

(b)(4)

(b)(4)

(b)(4)

## 7 COVID-19 Antiviral Discovery and Clinical Development

Outlined below is the full development program for a typical hit from screening a library of compounds that have not been clinically tested in humans for any uses. Steps described below cover (b)(4) (b)(4) (b)(4) (b)(4) Described activities are therefore subject to change upon data-driven decision.

In case (b)(4) (b)(4) , the development program could be significantly accelerated. Depending on the availability of e.g. (b)(4) (b)(4) upon joint decision.

(b)(4)

Depending on the nature of the identified (b)(4) additional efforts may need to be undertaken to (b)(4) (b)(4)

### WP 7.2 Lead and Late Lead Optimization

(b)(4) (b)(4) . (b)(4) and a go-no go decision will be taken whether or not to move to pre-clinical development.

### WP 7.3 Pre-Clinical development

This phase includes studies in s (b)(4) (b)(4) . This may include, but not be limited to (b)(4) (b)(4)

This phase will also include (b)(4) and Phase 1 clinical trials, including stability studies. It may also include pre-formulation for Phase 1 clinical trials.

Phase 1 first-in-human formulation development will follow the (b)(4) (b)(4) (conditional to JOC approval). Based on the result of the formulation development work, clinical study materials packaging, labeling and distribution will start and clinical pharmacy manual of Phase 1 trial will be developed.

**WP 7.4 Clinical development**

***WP 7.4.1 Clinical Phase 1***

This stage includes a first-in-human clinical Phase 1 and may include additional supportive clinical Phase 1 studies as well.

**7.4.2 Clinical Phase 2a Study**

(b)(4) this stage may include a clinical Phase 2a study to investigate the therapeutic efficacy and safety of the drug in (b)(4) (b)(4) This Phase 2a study may or may not include (b)(4) depending on available data for the asset selected.

**7.4.3 Clinical Phase 2b Study**

Depending on the available data of the asset and the results of the Ph2a study, a confirmatory Ph2b study can be performed as a separate study, or in (b)(4)

This stage also includes further Drug Substance and Drug Product development for Phase 2 studies.

These (b)(4) will continue in the next phases:

- (b)(4)
- Registration and Validation phase

***Clinical Phase 3 - OPTION***

***7.4.4 Clinical Phase 3 – (Option)***

This stage may include one or more clinical Phase 3 trials in (b)(4) (b)(4)

### WP 7.5 Regulatory

#### WP 7.5.1 Regulatory through to Phase 2b clinical study

Janssen intends to seek regulatory and scientific advice from the regulatory authorities throughout the development of the project, (b)(4)

(b)(4)

#### WP 7.5.2 Regulatory from Phase 3 and registration

Janssen will continue to seek regulatory and scientific advice from the regulatory authorities throughout Phase 3 of the project. (b)(4)

(b)(4)

## 8 Project Management

Coordinating project management has been brought under WP 5.6 as per JOC memo 4 (initially in 1.6) and subsequently adjusted to reflect new Assets.

### 8.1 Joint Oversight Committee

The Joint Oversight Committee (JOC) is the larger decision-making body that provides guidance, direction and control to the projects to ensure execution of the projects according to the SOW. The JOC will discuss and approve any changes to the SOW. To that extent, the JOC will meet at critical decision points in the program, but no less than two times per year, preferably face to face or alternatively by WebEx or telephone conference. Ad hoc meetings will be organized when urgent matters arise. The JOC will consist of voting and non-voting members from BARDA and Janssen. Additional, non-voting members can be assigned or invited on an ad hoc basis. Decisions to reprioritize specific projects and resources as the need arises will be taken by consensus. In case such a decision cannot be reached in the JOC, the decision will be escalated to one BARDA and one Janssen senior management member identified at the start of the project.

### 8.2 PMO Steering Committee

The PMO (Program Management Organization) steering committee has dual responsibilities. One area of responsibility is the communication and coordination with BARDA regarding day to day management and execution of the project e.g. organizing meetings on a regular agreed basis. In addition, the PMO Steering Committee will coordinate all SOW activities and provide the technical and administrative infrastructure to ensure efficient planning, initiation, implementation, direction, management and completion of all tasks. This will be coordinated by the Project Manager Leader (PML). The

Steering Committee will assess progress and where needed will work out strategic changes to be decided upon by the JOC. The Steering Committee consists of a group of dedicated and specialized Project Management experts, key personnel and additional specific expertise for the functions that are required for executing the specific work scope for each proposed asset area.

8.3 Asset Project Management (WP 2.5, WP 5.5, WP 7.6.1 and 7.6.2)

These WPs include the Program Management activities associated with each of the assets. Each asset will have an (b)(4) L) who will oversee their specific (b)(4) requirements. This includes conducting frequent and regular (b)(4) meetings to ensure the accurate developing and tracking of the budget, timeline and resource plan. The (b)(4) (b)(4) team of each asset will also include relevant functional (b)(4) and a (b)(4) Each asset will also have an (b)(4) who will oversee their specific Technical requirements. This includes conducting frequent and regular (b)(4) meetings to define the overall development strategy. The (b)(4) of each asset will include Technical Lead, Preclinical Leader, Clinical Leader, the CMC Leader and, the Regulatory Leader. Additional expertise required for executing asset-specific work possibly including subcontractors may be added as part of (b)(4) and (b)(4)

(b)(4)

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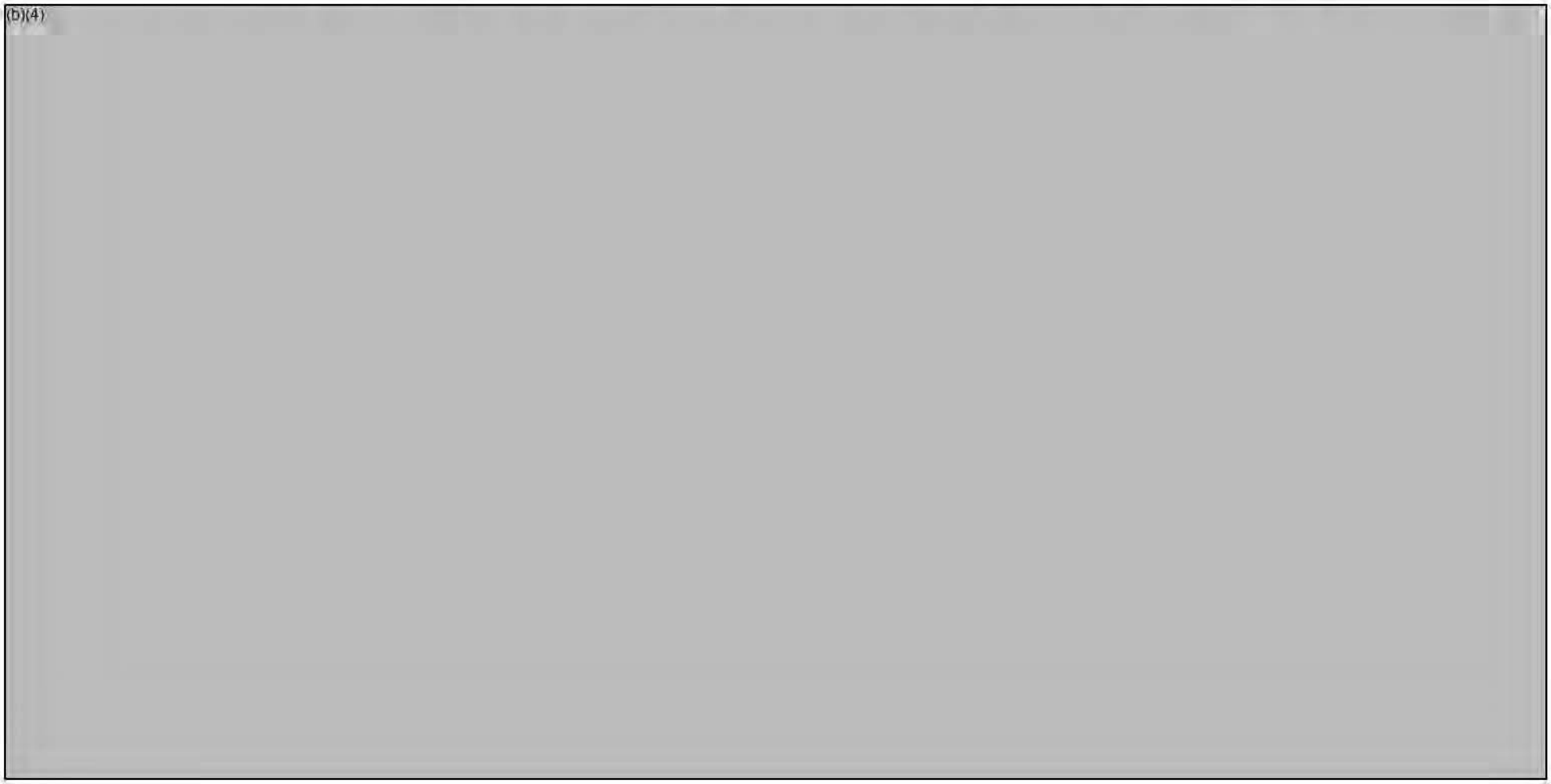
(b)(4)



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(b)(4)