



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health  
Freedom of Information Office  
Building 31, Room 5B-35  
31 Center Drive, MSC 2107  
Bethesda, Maryland 20892-2107  
phone: (301) 496-5633  
fax: (301) 402-4541

Via Email: [bmarshall@judicialwatch.org](mailto:bmarshall@judicialwatch.org)

August 1, 2022

William F. Marshall  
Judicial Watch, Inc.  
425 Third Street SW, Suite 800  
Washington, DC 20024

Re: NIH FOIA Case No.: 56471; Judicial Watch v. HHS, Case No. 21-cv-02302

Dear Mr. Marshall:

This is a partial response to the Freedom of Information Act (FOIA) request that is the subject of the complaint filed in *Judicial Watch v. HHS*, 21-cv-02302, now pending in the U.S. District Court for the District of Columbia. Your FOIA request, dated June 8, 2021, was received by the National Institutes of Health (NIH) on the same day.

You requested all emails sent to and from Director Francis Collins related to “gain of function”, “hydroxychloroquine”, “HCQ”, and/or “Wuhan Institute of Virology” for the date range of October 1, 2019 to June 8, 2021.

In accordance with the Court’s order dated August 31, 2021, NIH has processed 300 pages responsive to your request. NIH has determined that 46 pages from this production are non-responsive. Attached to this letter are 254 pages from the current production.

I have determined to withhold portions of the enclosed pages under FOIA exemptions (b)(4), (b)(5) and (b)(6). The information being withheld is protected from release pursuant to Exemptions 4, 5, and 6 of the FOIA, 5 U.S.C. § 552 (b)(4), (b)(5) and (b)(6); and sections 5.31(d), (e) and (f) of the HHS FOIA Regulations, 45 CFR Part 5. Exemption 4 protects from disclosure trade secrets and commercial or financial information that is privileged and confidential. Exemption 5 permits the withholding of internal government records which are predecisional and contain staff advice, opinion, and recommendations. This exemption is intended to preserve free and candid internal dialogue leading to decision-making. Exemption 6 exempts from disclosure records the release of which would cause a clearly unwarranted invasion of personal privacy.

Please direct any questions regarding this response to Joseph Carilli of the Department of Justice, who can be reached at [Joseph.Carilli@usdoj.gov](mailto:Joseph.Carilli@usdoj.gov).

Sincerely,

*for* Gorka Garcia-Malene  
Freedom of Information Act Officer, NIH

**From:** [Collins, Francis \(NIH/OD\) \[E\]](#)  
**To:** [Lauer, Michael \(NIH/OD\) \[E\]](#)  
**Cc:** [Culp, Michelle \(NIH/OD\) \[E\]](#)  
**Subject:** RE: PCORI Board Meeting  
**Date:** Wednesday, January 13, 2021 9:00:00 AM

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(b) (5)

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**From:** Lauer, Michael (NIH/OD) [E] (b) (6)  
**Sent:** Wednesday, January 13, 2021 6:19 AM  
**To:** Collins, Francis (NIH/OD) [E] (b) (6)  
**Cc:** Lauer, Michael (NIH/OD) [E] (b) (6); Culp, Michelle (NIH/OD) [E]  
(b) (6)  
**Subject:** FW: PCORI Board Meeting

Hi Francis

(b) (5) (b) (6), but Bob Zwolak did a solid job presenting the recommendations of the PCORnet group. Christine Goertz held the meeting well.

(b) (4)

Thanks, Mike

**From:** [Wholley, David \(FNIH\) \[T\]](#)  
**To:** [Collins, Francis \(NIH/OD\) \[E\]](#); [Adam, Stacey \(FNIH\) \[T\]](#)  
**Cc:** [Freire, Maria \(FNIH\) \[T\]](#)  
**Subject:** RE: do you think PCORNET would be willing/able to mount a pragmatic outpatient trial of re-purposed agents? jw  
**Date:** Monday, January 18, 2021 9:38:51 AM

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I may be out of email contact until evening, fyi. If anything truly urgent please call cell (b) (6)  
Thanks

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**From:** Collins, Francis (NIH/OD) [E] (b) (6)  
**Sent:** Monday, January 18, 2021 7:23 AM  
**To:** Wholley, David (FNIH) [T] <[dwholley@fnih.org](mailto:dwholley@fnih.org)>; Adam, Stacey (FNIH) [T] <[sadam@fnih.org](mailto:sadam@fnih.org)>  
**Cc:** Freire, Maria (FNIH) [T] <[mfreire@fnih.org](mailto:mfreire@fnih.org)>  
**Subject:** RE: do you think PCORNET would be willing/able to mount a pragmatic outpatient trial of re-purposed agents? jw  
Thanks for this background. We'll definitely need to keep our eyes open.  
FC

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**From:** Wholley, David (FNIH) [T] <[dwholley@fnih.org](mailto:dwholley@fnih.org)>  
**Sent:** Sunday, January 17, 2021 9:21 PM  
**To:** Collins, Francis (NIH/OD) [E] (b) (6); Adam, Stacey (FNIH) [T] <[sadam@fnih.org](mailto:sadam@fnih.org)>  
**Cc:** Freire, Maria (FNIH) [T] <[mfreire@fnih.org](mailto:mfreire@fnih.org)>  
**Subject:** RE: do you think PCORNET would be willing/able to mount a pragmatic outpatient trial of re-purposed agents? jw

Francis,

Stacey is not near her computer just now but texted me. FYI Stacey had already reached out to Adrian Hernandez at Janet's request—Janet just did not include that in her email to Josie. Also, (b) (5)

(b) (5)

(b) (5) David

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**From:** Collins, Francis (NIH/OD) [E] (b) (6)  
**Sent:** Sunday, January 17, 2021 7:14 PM  
**To:** Adam, Stacey (FNIH) [T] <[sadam@fnih.org](mailto:sadam@fnih.org)>; Wholley, David (FNIH) [T] <[dwholley@fnih.org](mailto:dwholley@fnih.org)>  
**Subject:** FW: do you think PCORNET would be willing/able to mount a pragmatic outpatient trial of re-purposed agents? jw

(b) (5)

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**From:** Woodcock, Janet <[Janet.Woodcock@fda.hhs.gov](mailto:Janet.Woodcock@fda.hhs.gov)>

**Sent:** Sunday, January 17, 2021 5:42 PM

**To:** Collins, Francis (NIH/OD) [E] (b) (6)

**Subject:** RE: do you think PCORNET would be willing/able to mount a pragmatic outpatient trial of re-purposed agents? jw

(b) (5)

Jw

**From:** Collins, Francis (NIH/OD) [E] (b) (6)

**Date:** January 17, 2021 at 4:26:55 PM EST

**To:** Woodcock, Janet <[Janet.Woodcock@fda.hhs.gov](mailto:Janet.Woodcock@fda.hhs.gov)>

**Subject:** RE: do you think PCORNET would be willing/able to mount a pragmatic outpatient trial of re-purposed agents? jw

Hi Janet,

I just spoke with Josie Briggs about PCORnet possibly taking this on. (b) (5)

(b) (5) she can see the potential here, and will discuss it with Nakela. (b) (5)

Francis

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**From:** Woodcock, Janet <[Janet.Woodcock@fda.hhs.gov](mailto:Janet.Woodcock@fda.hhs.gov)>

**Sent:** Sunday, January 17, 2021 11:35 AM

**To:** Collins, Francis (NIH/OD) [E] (b) (6)

**Subject:** FW: do you think PCORNET would be willing/able to mount a pragmatic outpatient trial of re-purposed agents? jw

PCORNET would be the best bet I think. I may have trouble working on this starting WED, but is important to get done. Just don't know the vehicle, would need some sort of contract. But I think they would be the fastest. jw

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**From:** Adrian Hernandez, M.D. <[adrian.hernandez@duke.edu](mailto:adrian.hernandez@duke.edu)>

**Sent:** Sunday, January 17, 2021 10:53 AM

**To:** Woodcock, Janet <[Janet.Woodcock@fda.hhs.gov](mailto:Janet.Woodcock@fda.hhs.gov)>

**Subject:** Re: do you think PCORNET would be willing/able to mount a pragmatic outpatient trial of re-purposed agents? jw

Janet

(b) (5)

Let me know how best to learn more. Mobile is below if helpful.

Adrian

(b) (6)

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**From:** Janet Woodcock <[Janet.Woodcock@fda.hhs.gov](mailto:Janet.Woodcock@fda.hhs.gov)>

**Date:** Sunday, January 17, 2021 at 9:51 AM

**To:** "Adrian Hernandez, M.D." <[adrian.hernandez@duke.edu](mailto:adrian.hernandez@duke.edu)>

**Subject:** RE: do you think PCORNET would be willing/able to mount a pragmatic outpatient trial of re-purposed agents? jw

I wanted to know if PCORNET could potentially take on a large, pragmatic, potentially government-funded trial of relatively safe repurposed agents in outpatients with COVID-19. jw

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**From:** Adrian Hernandez, M.D. <[adrian.hernandez@duke.edu](mailto:adrian.hernandez@duke.edu)>

**Sent:** Saturday, January 16, 2021 5:16 PM

**To:** [robertcaliff@verily.com](mailto:robertcaliff@verily.com)

**Cc:** Woodcock, Janet <[Janet.Woodcock@fda.hhs.gov](mailto:Janet.Woodcock@fda.hhs.gov)>

**Subject:** Re: do you think PCORNET would be willing/able to mount a pragmatic outpatient trial of re-purposed agents? jw

Hi

Just let me know what's needed

Adrian

(b) (6)

On Jan 16, 2021, at 5:06 PM, Robert Califf <[robertcaliff@verily.com](mailto:robertcaliff@verily.com)> wrote:

his email address is in the header--he'll respond.

(b) (6)

rmc

On Sat, Jan 16, 2021 at 2:03 PM Woodcock, Janet <[Janet.Woodcock@fda.hhs.gov](mailto:Janet.Woodcock@fda.hhs.gov)> wrote:

Contact info? Tx jw

**From:** Robert Califf <[robertcaliff@verily.com](mailto:robertcaliff@verily.com)>

**Sent:** Saturday, January 16, 2021 4:57 PM

**To:** Woodcock, Janet <[Janet.Woodcock@fda.hhs.gov](mailto:Janet.Woodcock@fda.hhs.gov)>; Adrian Hernandez, M.D. <[adrian.hernandez@duke.edu](mailto:adrian.hernandez@duke.edu)>

**Subject:** Re: do you think PCORNET would be willing/able to mount a pragmatic outpatient trial of re-purposed agents? jw

Adrian Hernandez is PI--

rmc

On Sat, Jan 16, 2021 at 1:55 PM Woodcock, Janet <[Janet.Woodcock@fda.hhs.gov](mailto:Janet.Woodcock@fda.hhs.gov)> wrote:

(b) (5)

Need contact point for PCORNET not PCORI> jw

**From:** Robert Califf <[robertcaliff@verily.com](mailto:robertcaliff@verily.com)>

**Sent:** Saturday, January 16, 2021 12:12 PM

**To:** Woodcock, Janet <[Janet.Woodcock@fda.hhs.gov](mailto:Janet.Woodcock@fda.hhs.gov)>

**Subject:** Re: do you think PCORNET would be willing/able to mount a pragmatic outpatient trial of re-purposed agents? jw

yes; i think it would help it if you put public pressure on the org to deliver will send more info

(b) (5)

rmc

On Sat, Jan 16, 2021 at 8:48 AM Woodcock, Janet <[Janet.Woodcock@fda.hhs.gov](mailto:Janet.Woodcock@fda.hhs.gov)> wrote:

**From:** [Freire, Maria \(FNIH\) \[T\]](#)  
**To:** [Collins, Francis \(NIH/OD\) \[E\]](#)  
**Cc:** [Wholley, David \(FNIH\) \[T\]](#); [Lane, Cliff \(NIH/NIAID\) \[E\]](#)  
**Subject:** ACTIV/DNDi Master Protocol Information  
**Date:** Wednesday, January 27, 2021 8:37:05 AM  
**Attachments:** [Protocol ANTICOV\\_01\\_COV\\_Final\\_V7.0\\_16\\_November\\_2020\\_Clean.pdf](#)

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Francis, below are Stacey's notes on the call with DNDi yesterday.

(b) (5)

(b) (5)

CONFIDENTIAL

Best, M.

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**From:** Adam, Stacey (FNIH) [T] <sadam@fnih.org>  
**Sent:** Tuesday, January 26, 2021 7:37 PM  
**To:** Freire, Maria (FNIH) [T] <mfreire@fnih.org>  
**Cc:** Menetski, Joseph (FNIH) [T] <jmenetski@fnih.org>; Wholley, David (FNIH) [T] <dwholley@fnih.org>  
**Subject:** FW: FW: Cloud Recording - ACTIV/DNDi Master Protocol Information Sharing is now available

Hi Maria,

I just wanted to follow up to you let you know that the first meeting with the DNDi ANTICOV team

(b) (4), (b) (5)

(b) (4), (b) (5) please see below for the summary.

Joe,

(b) (4), (b) (5)

Thanks,  
Stacey

(b) (4), (b) (5)

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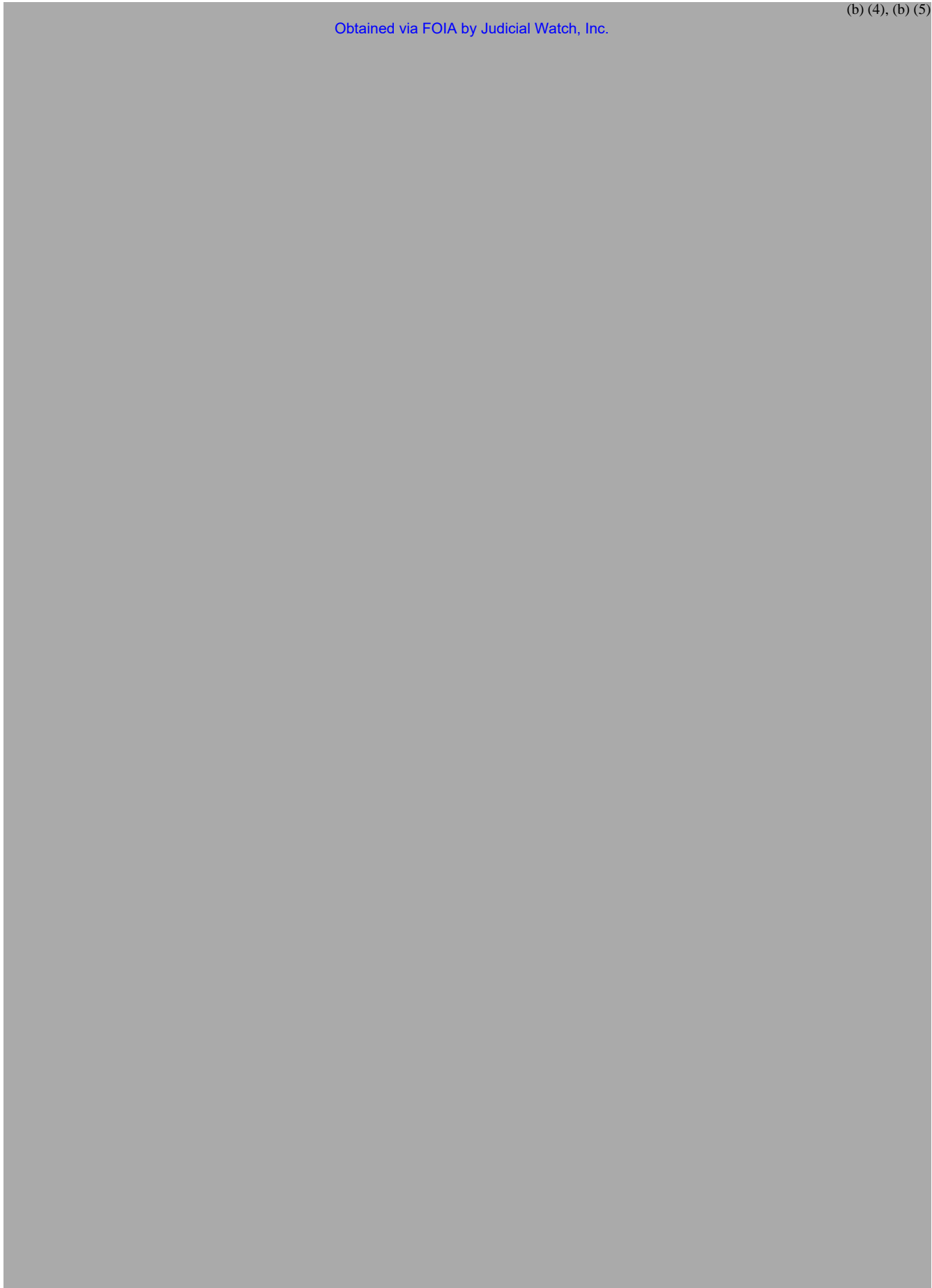
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Obtained via FOIA by Judicial Watch, Inc.







Obtained via FOIA by Judicial Watch, Inc.





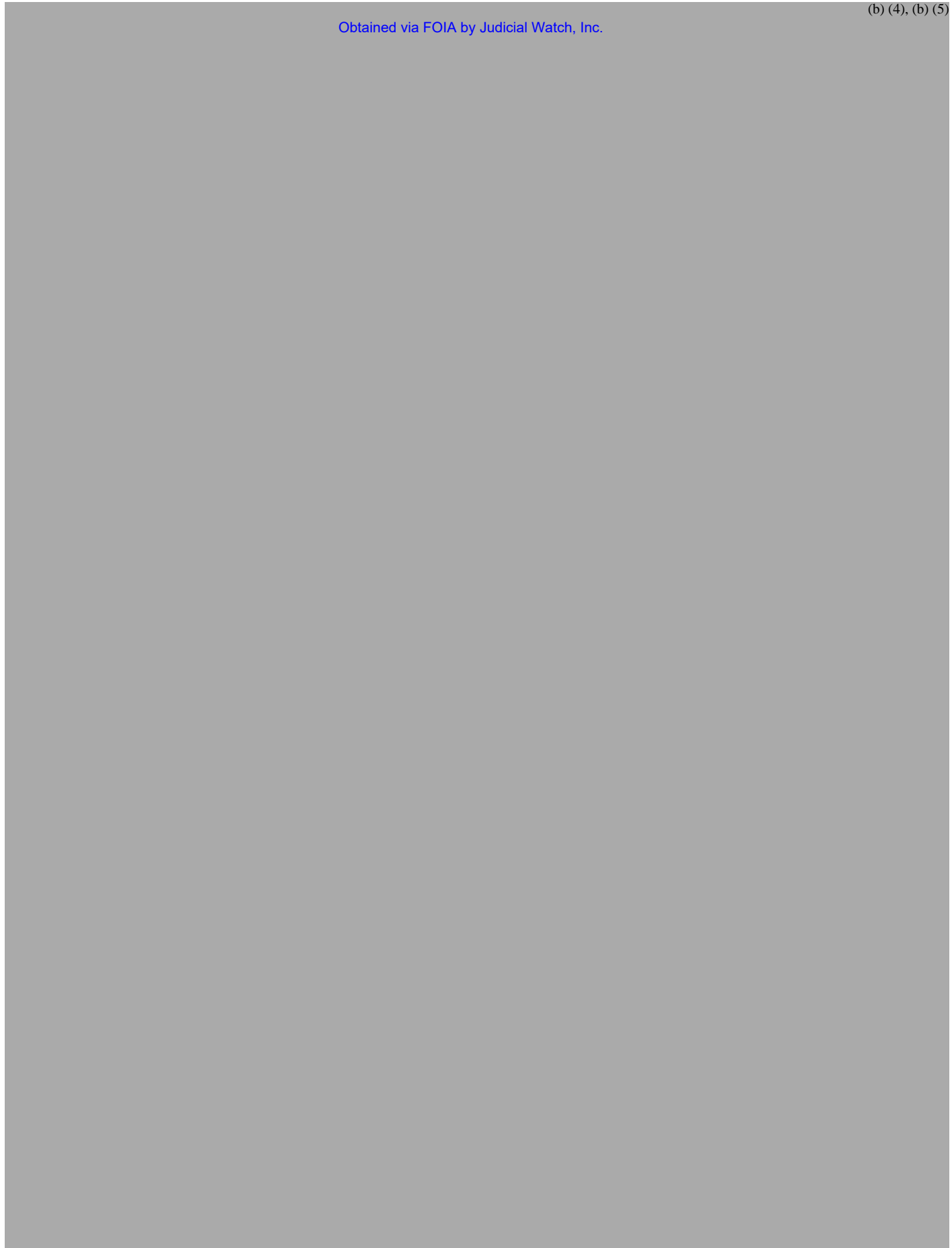
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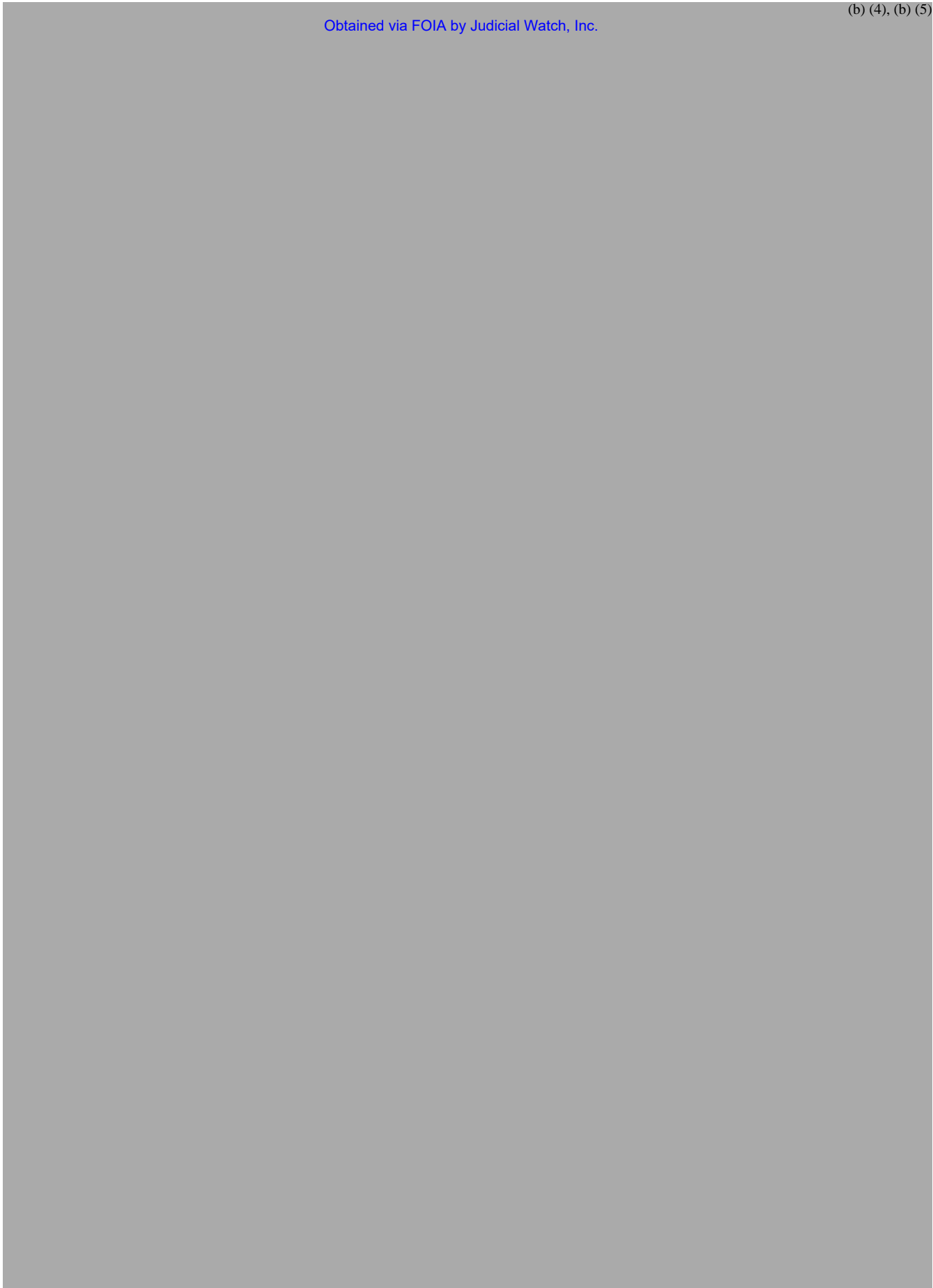
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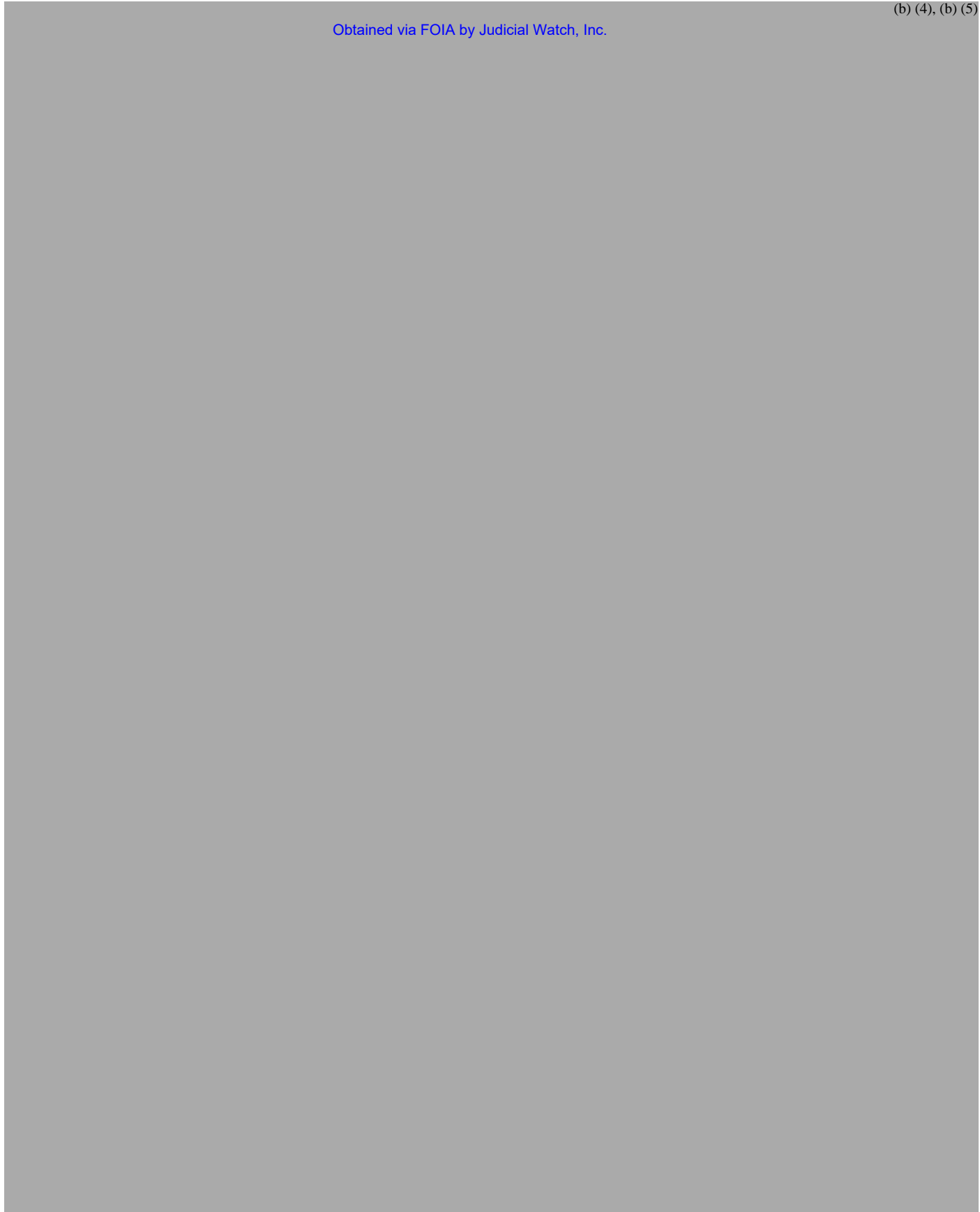






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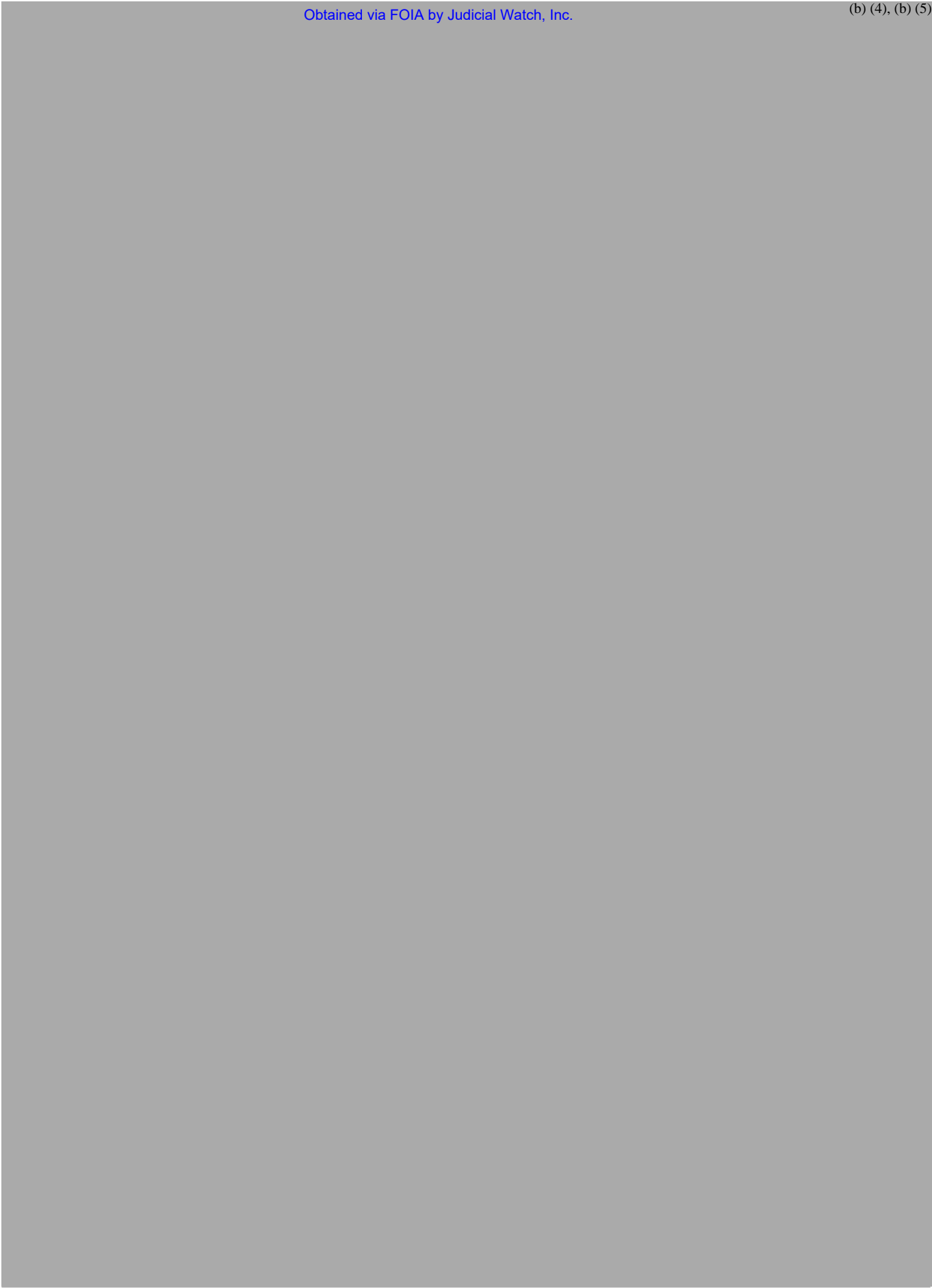


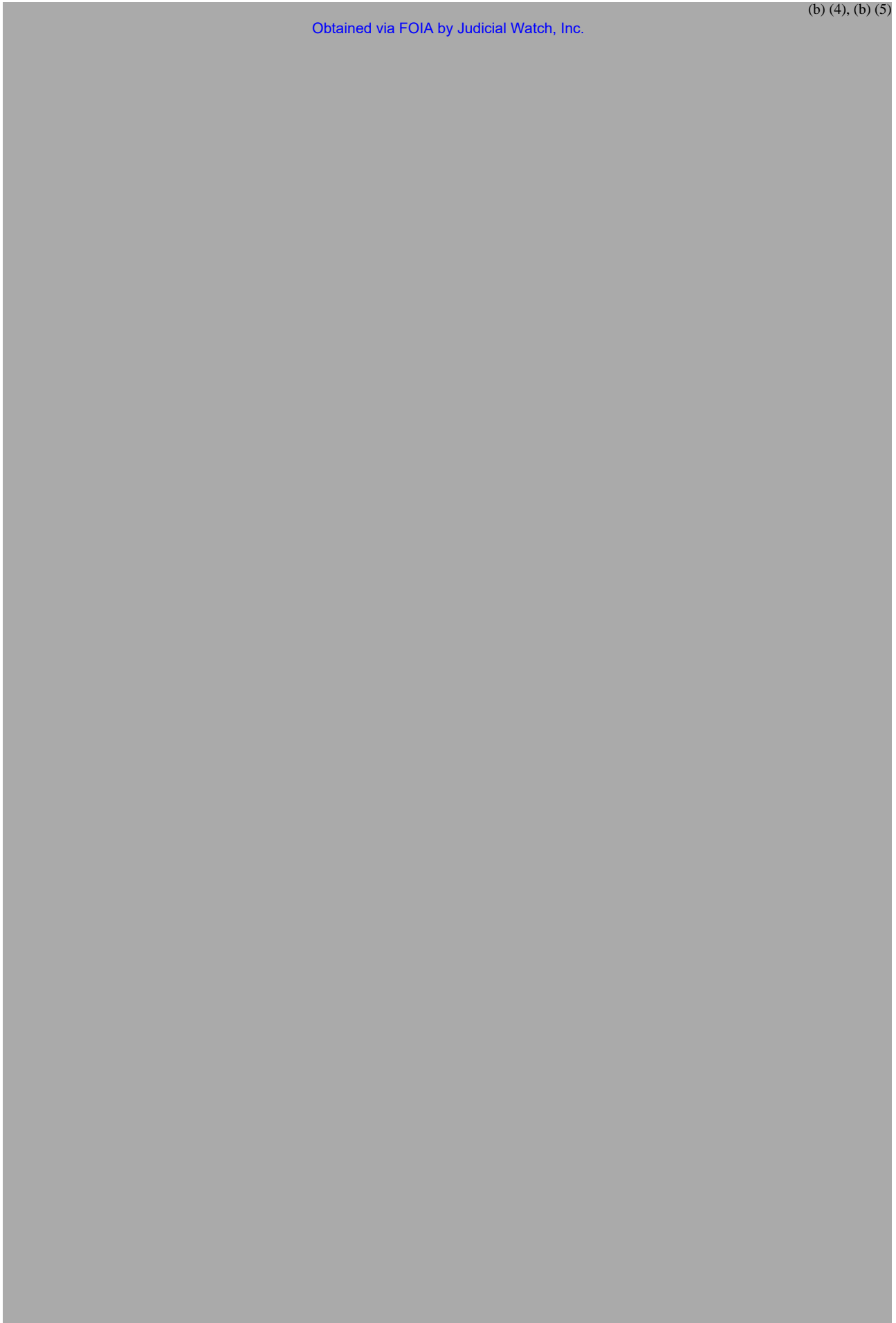
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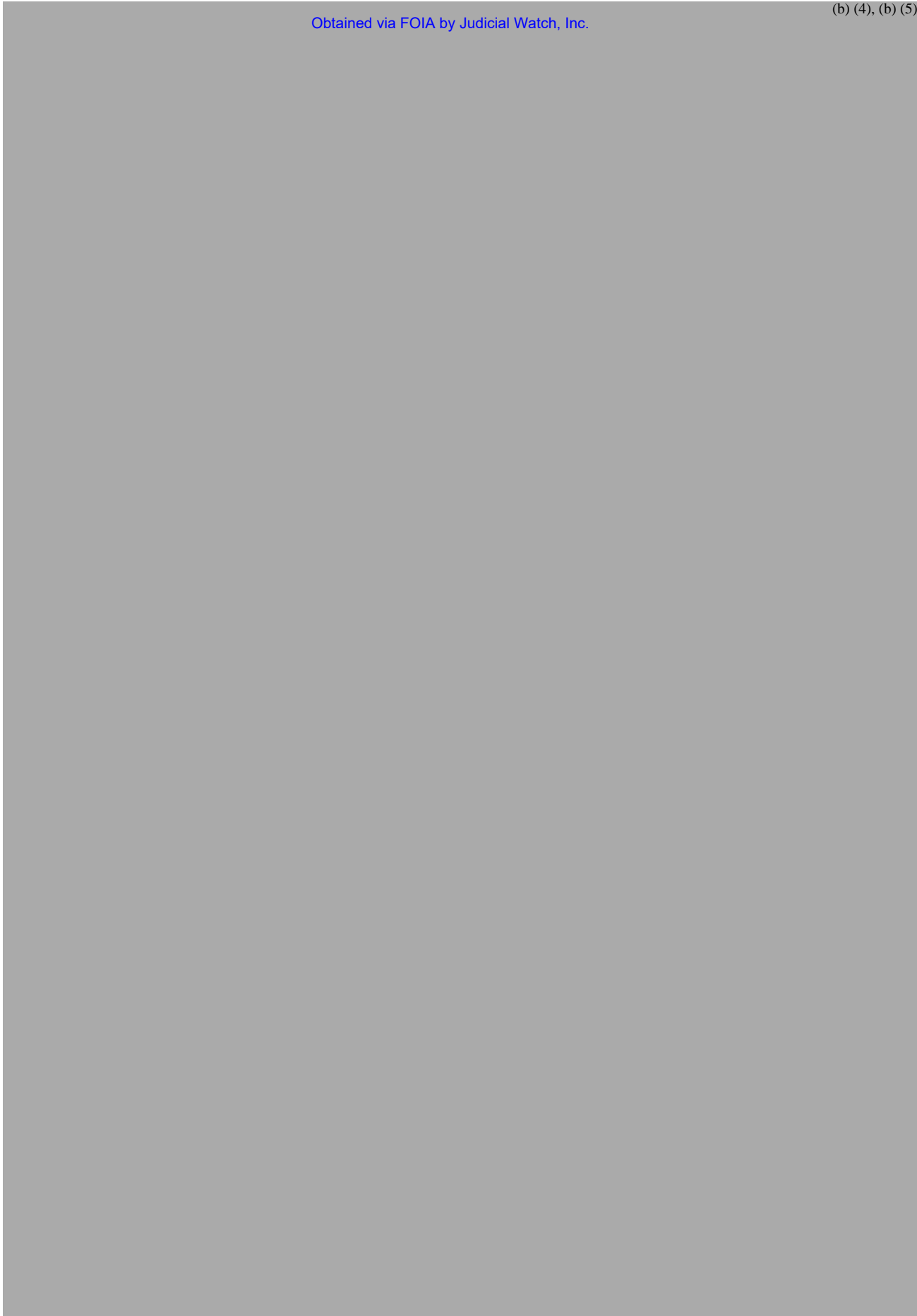






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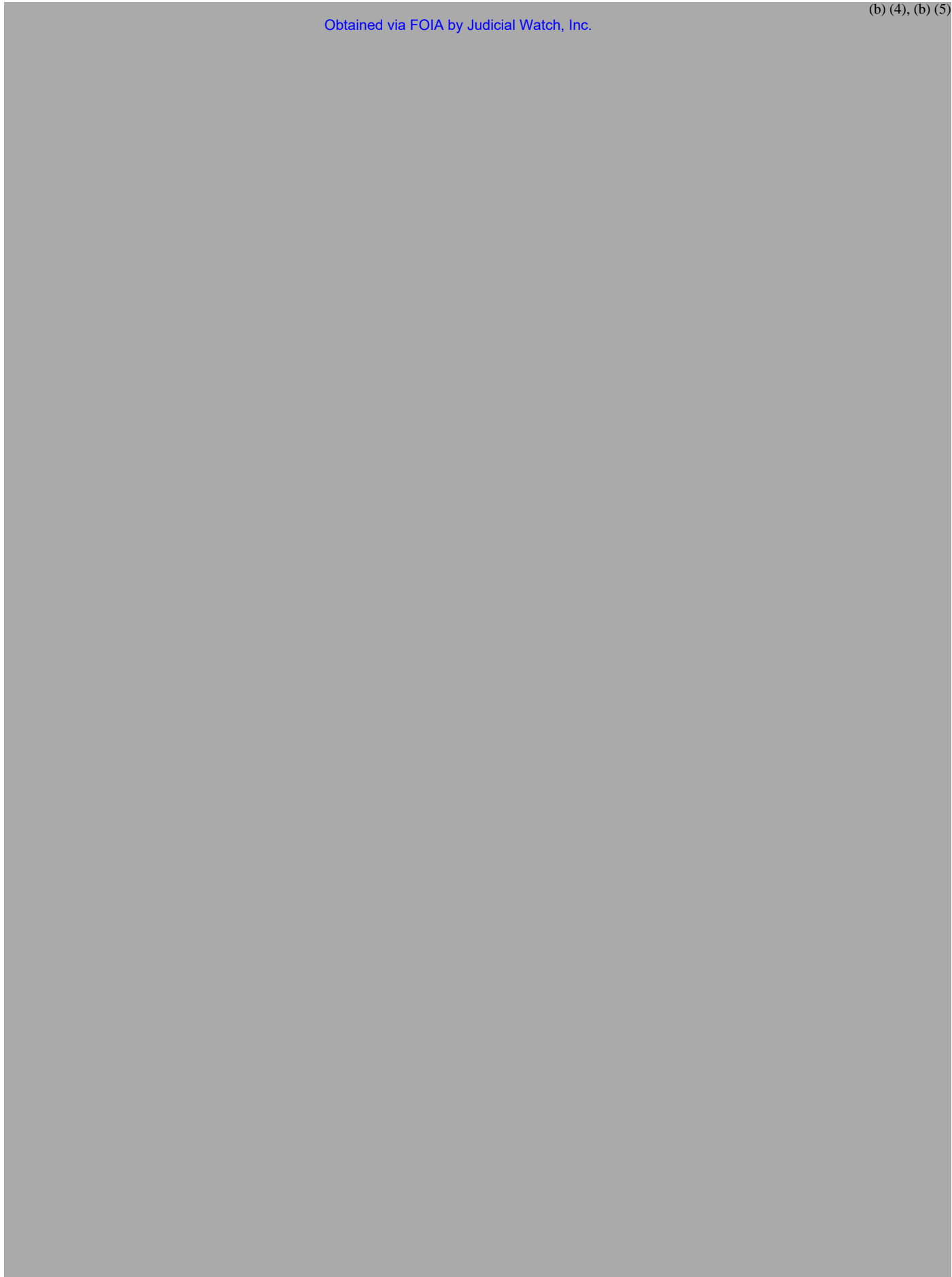




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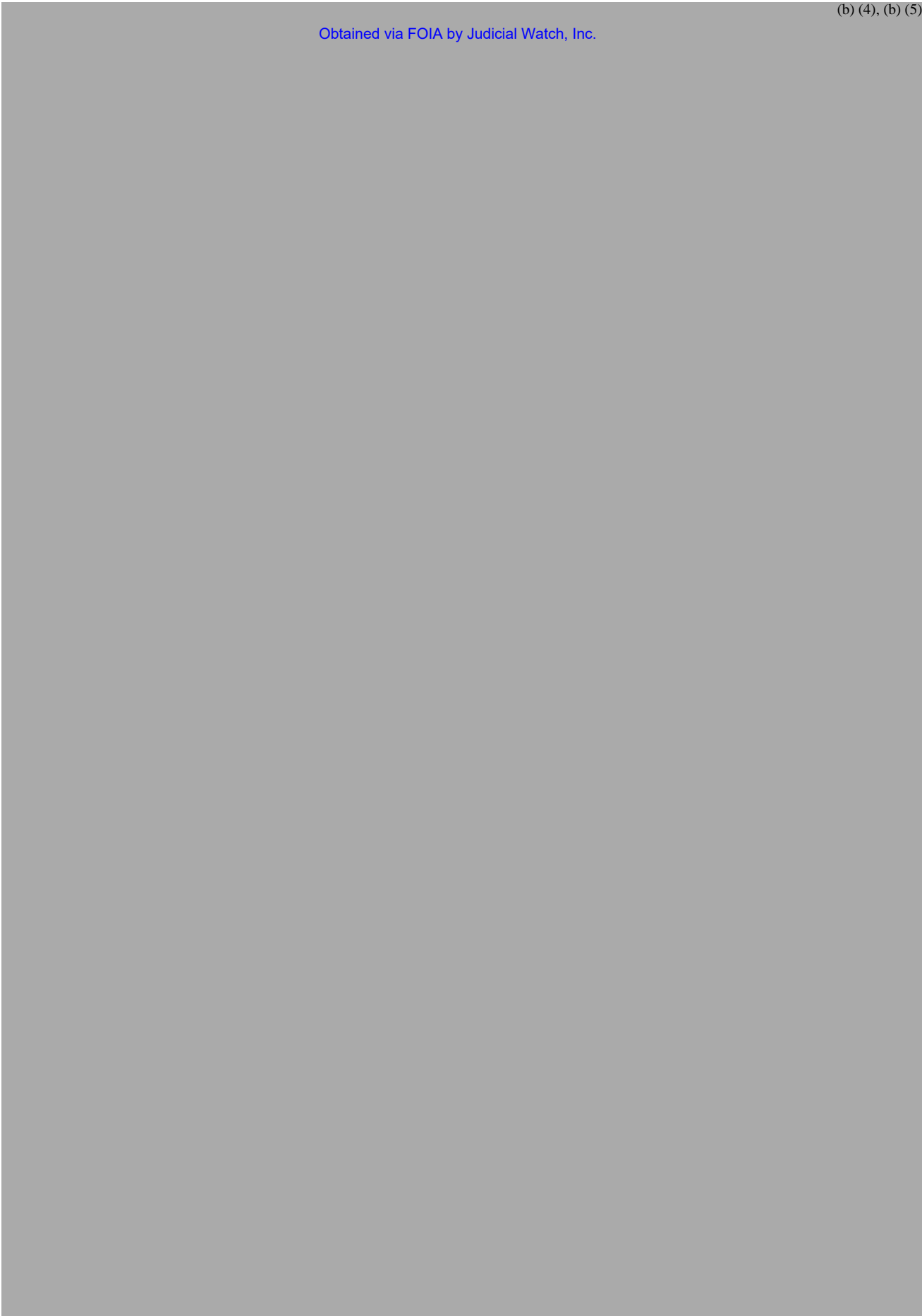


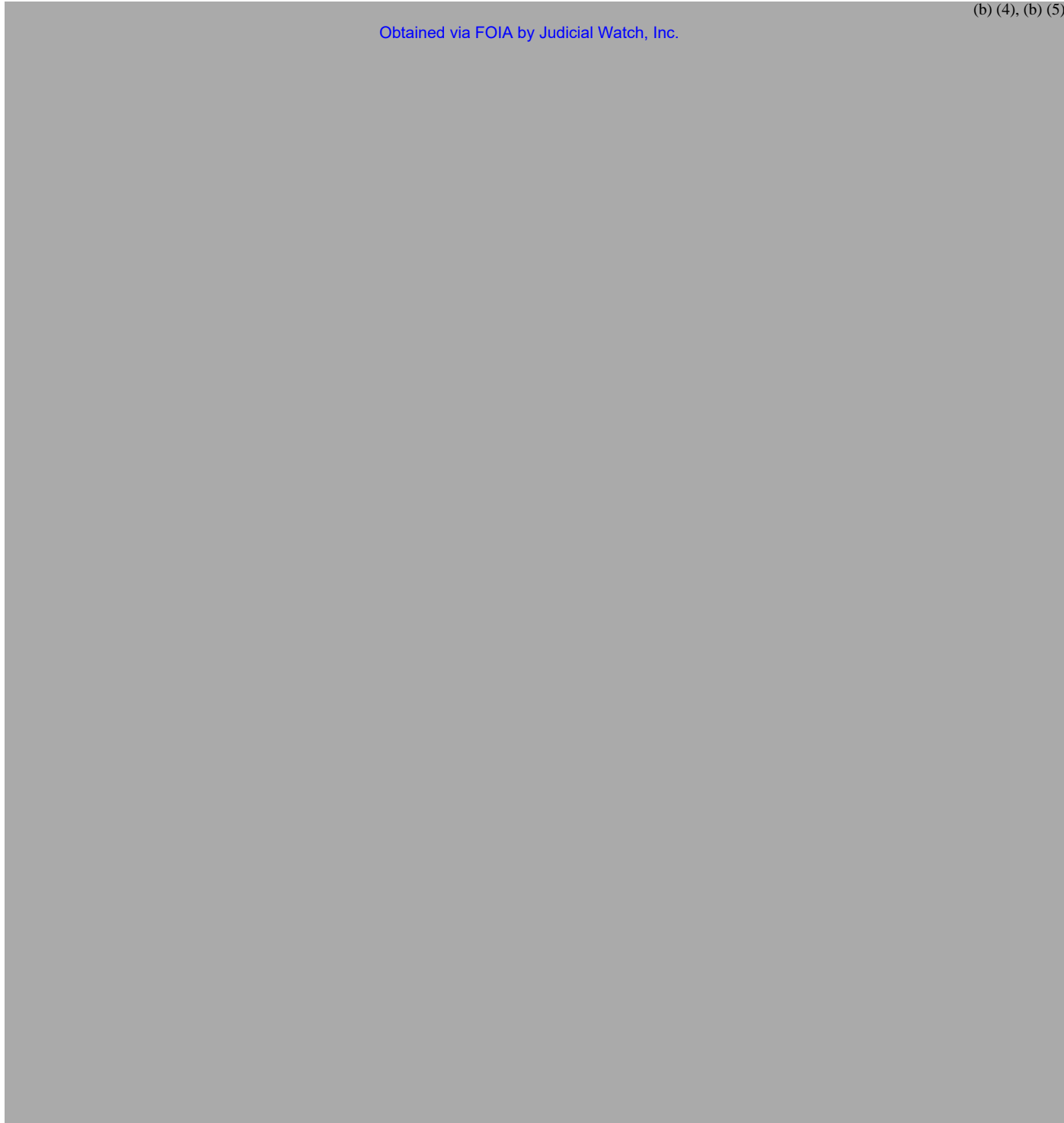






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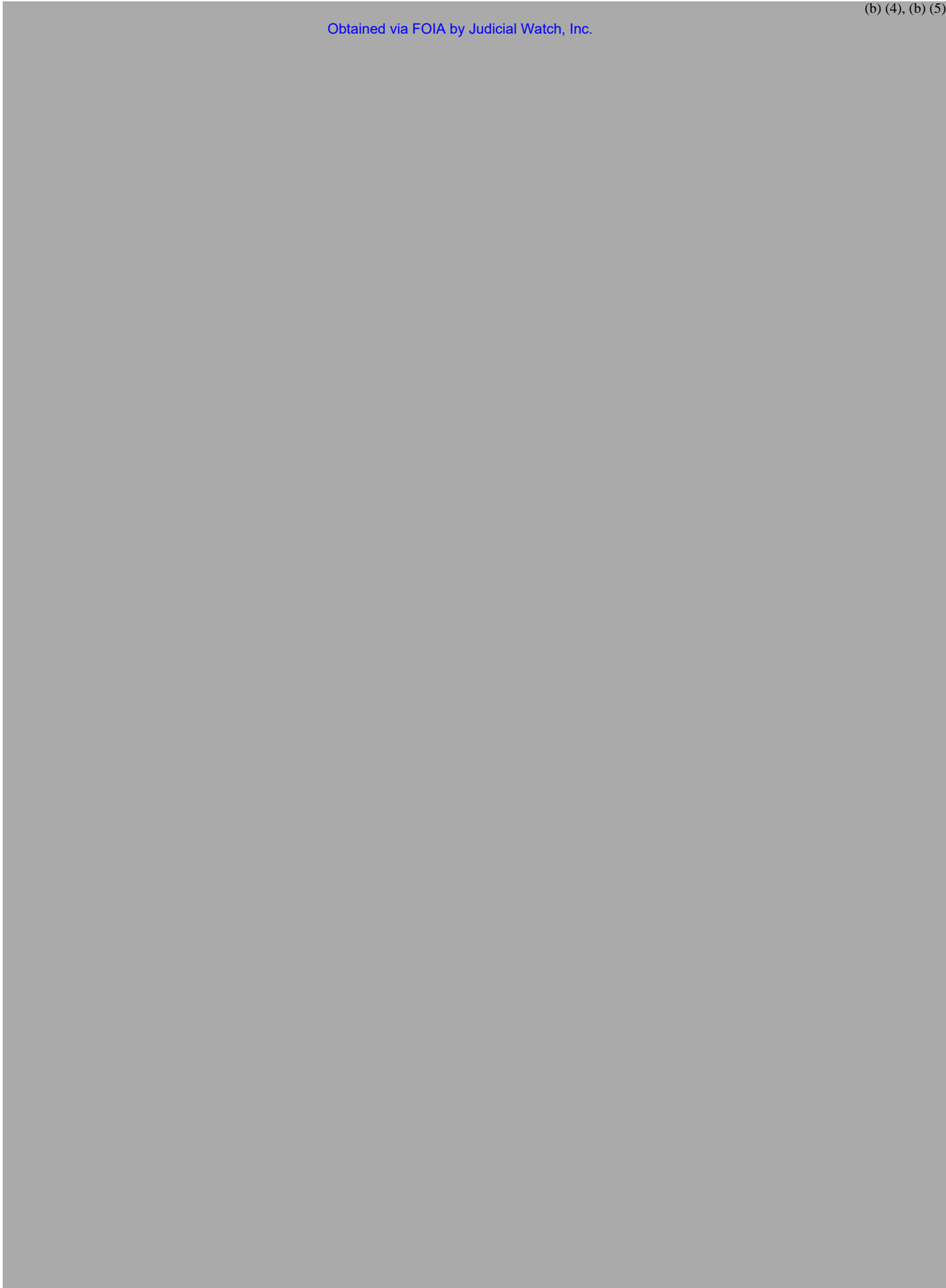




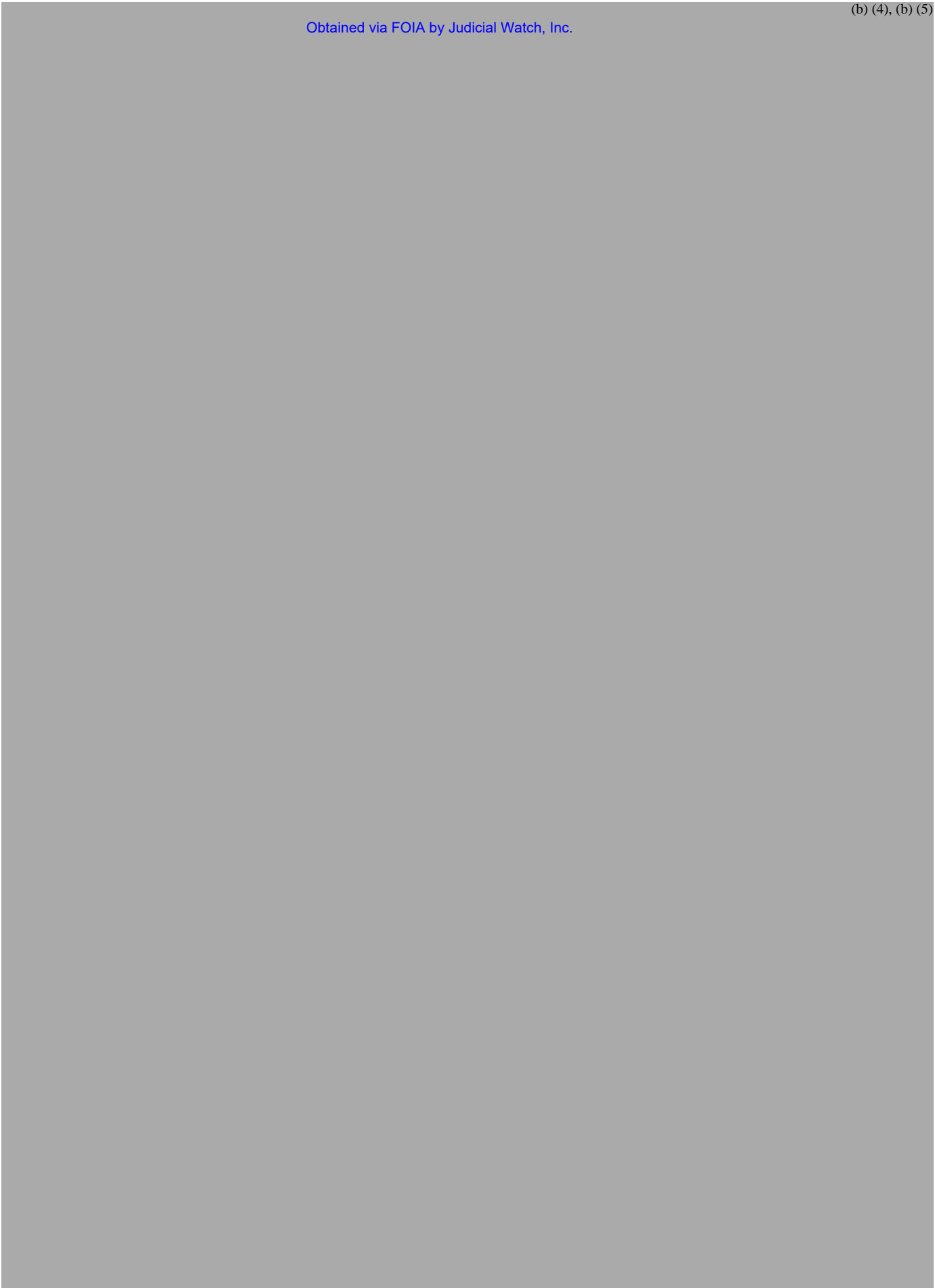
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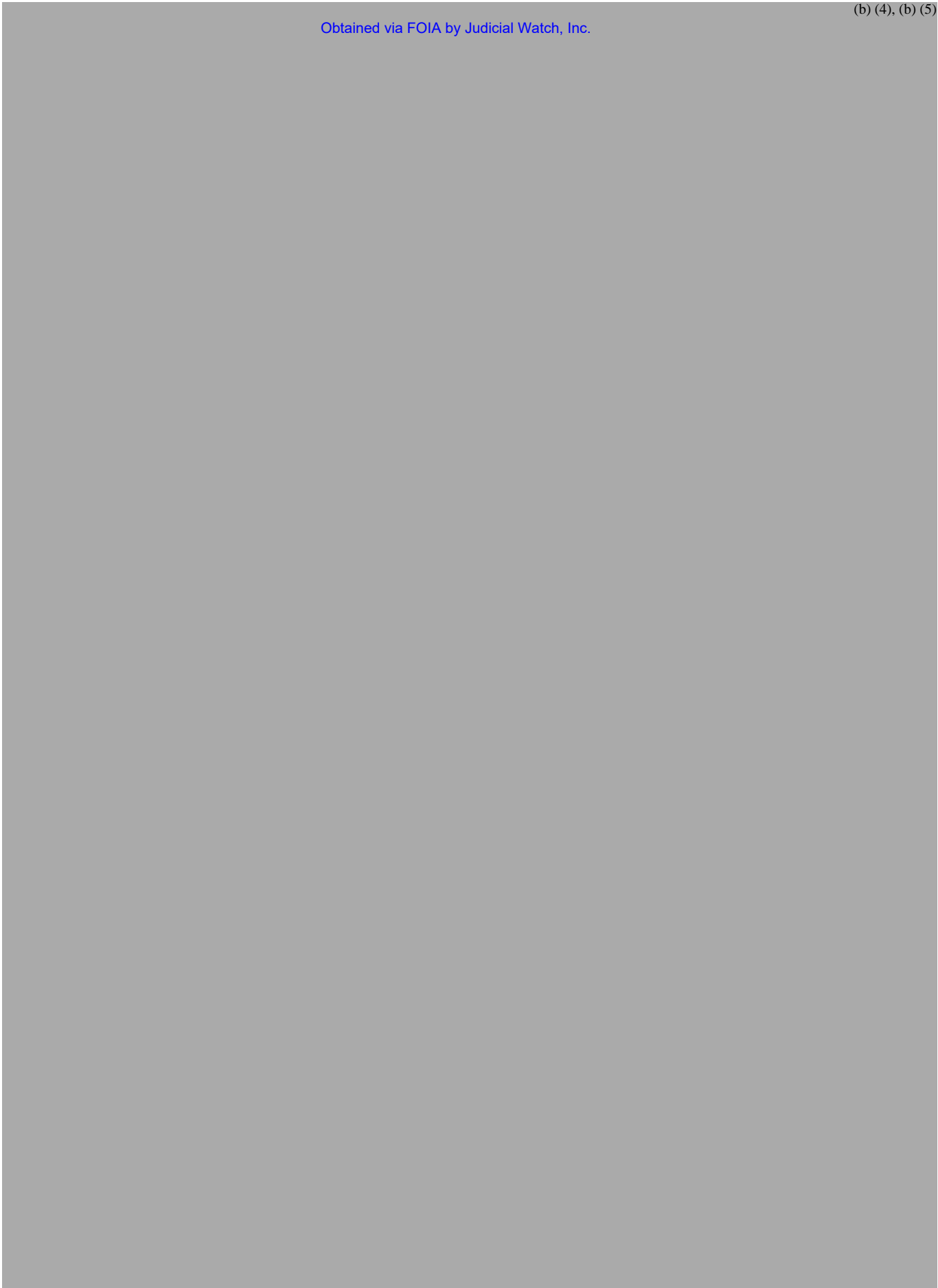


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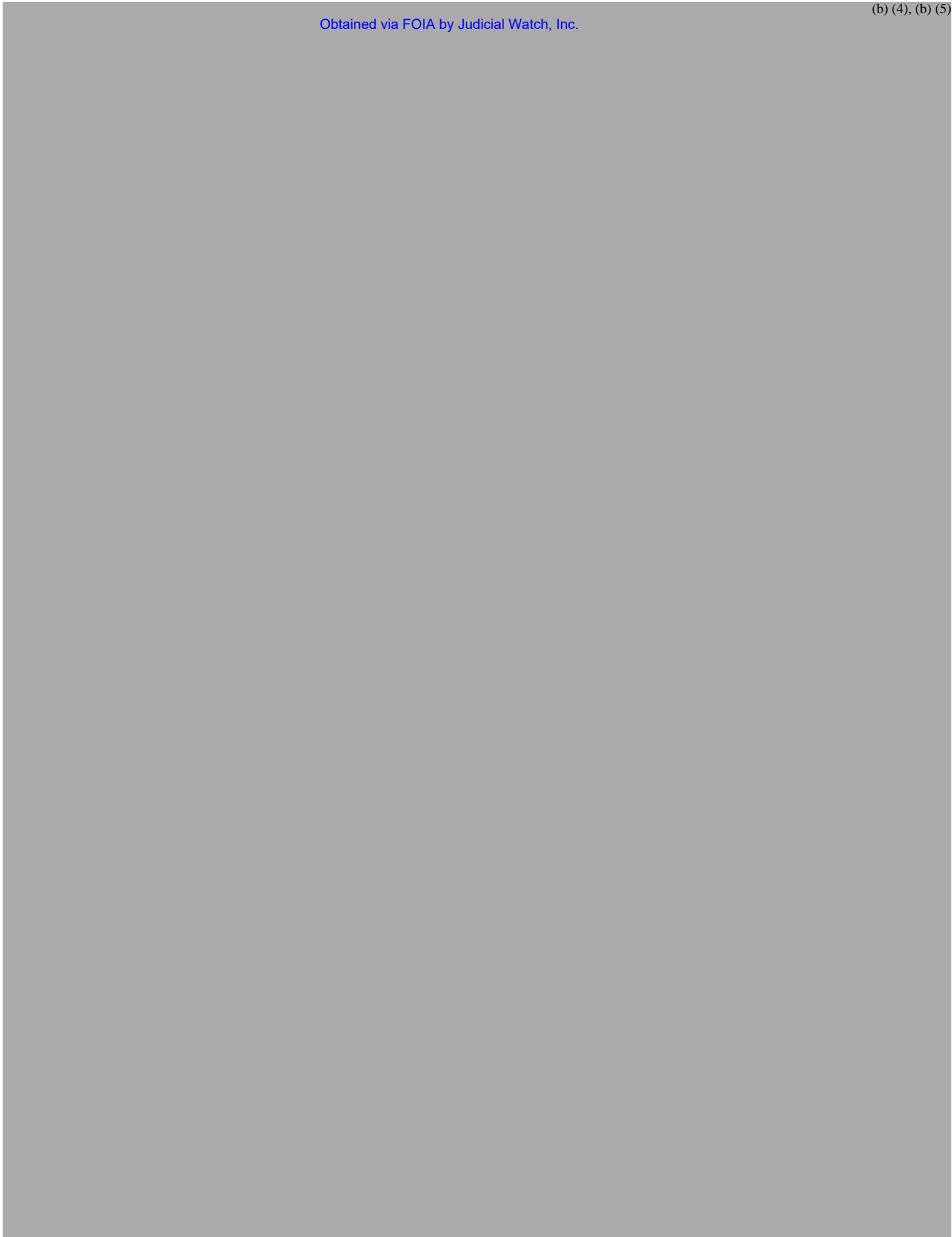
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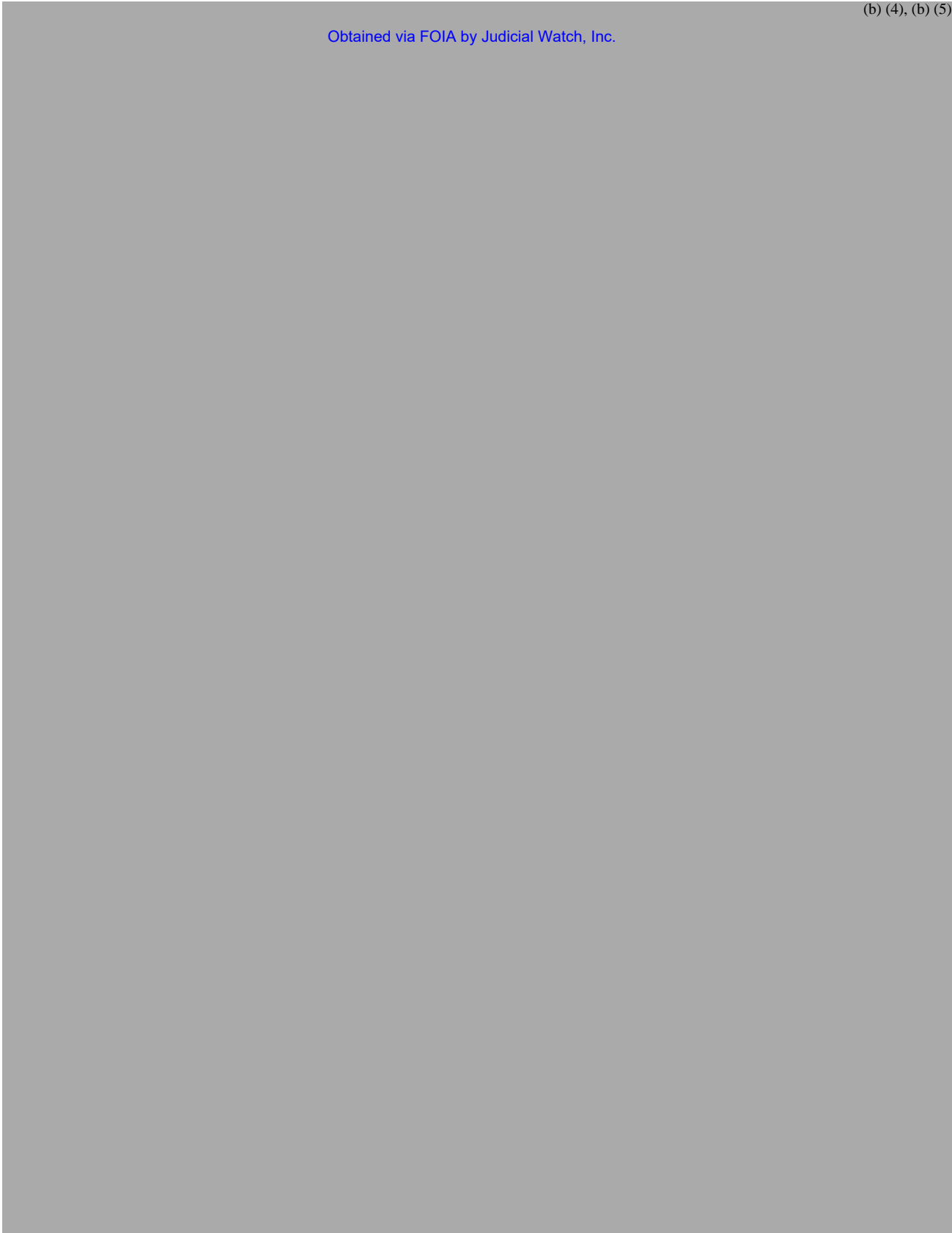








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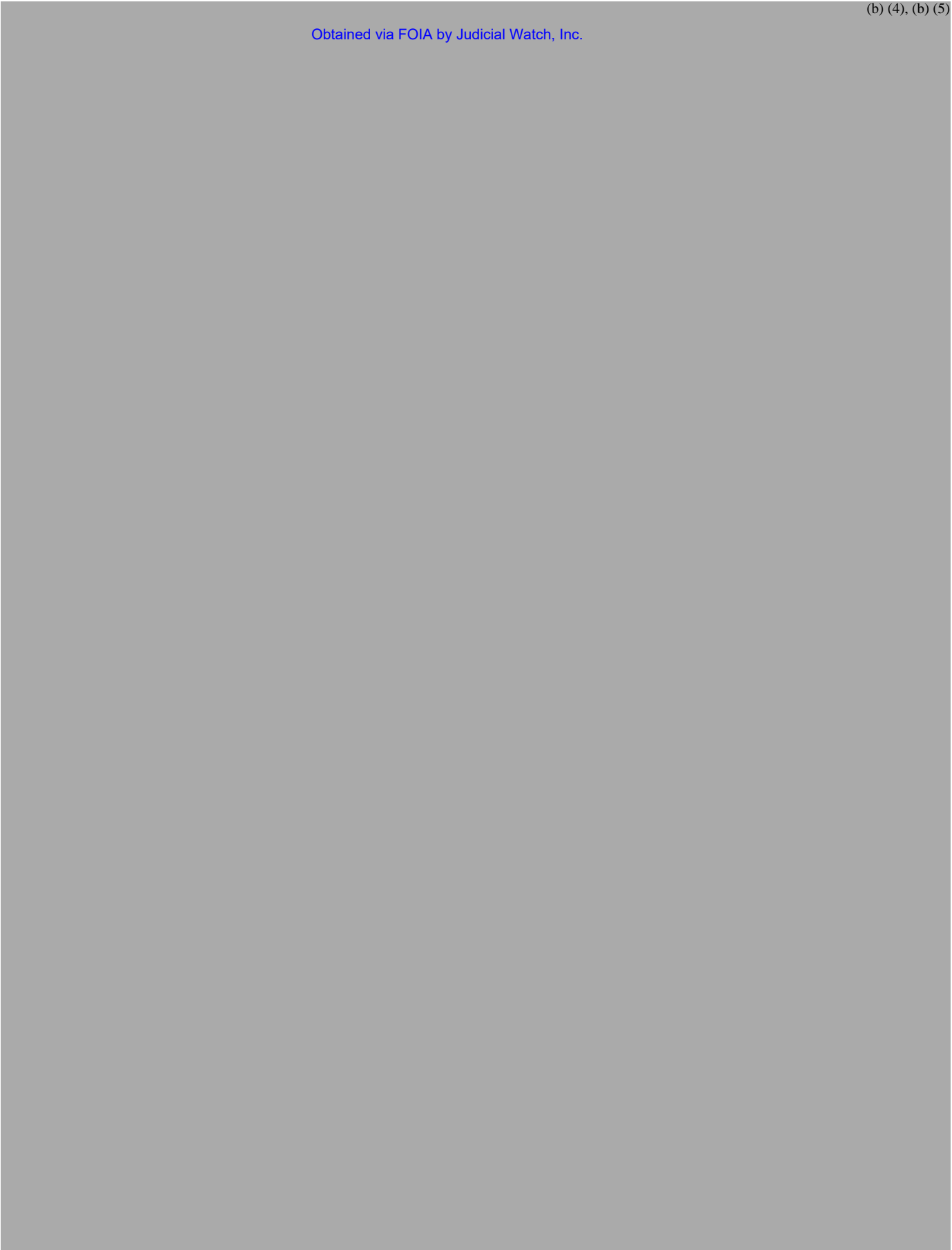
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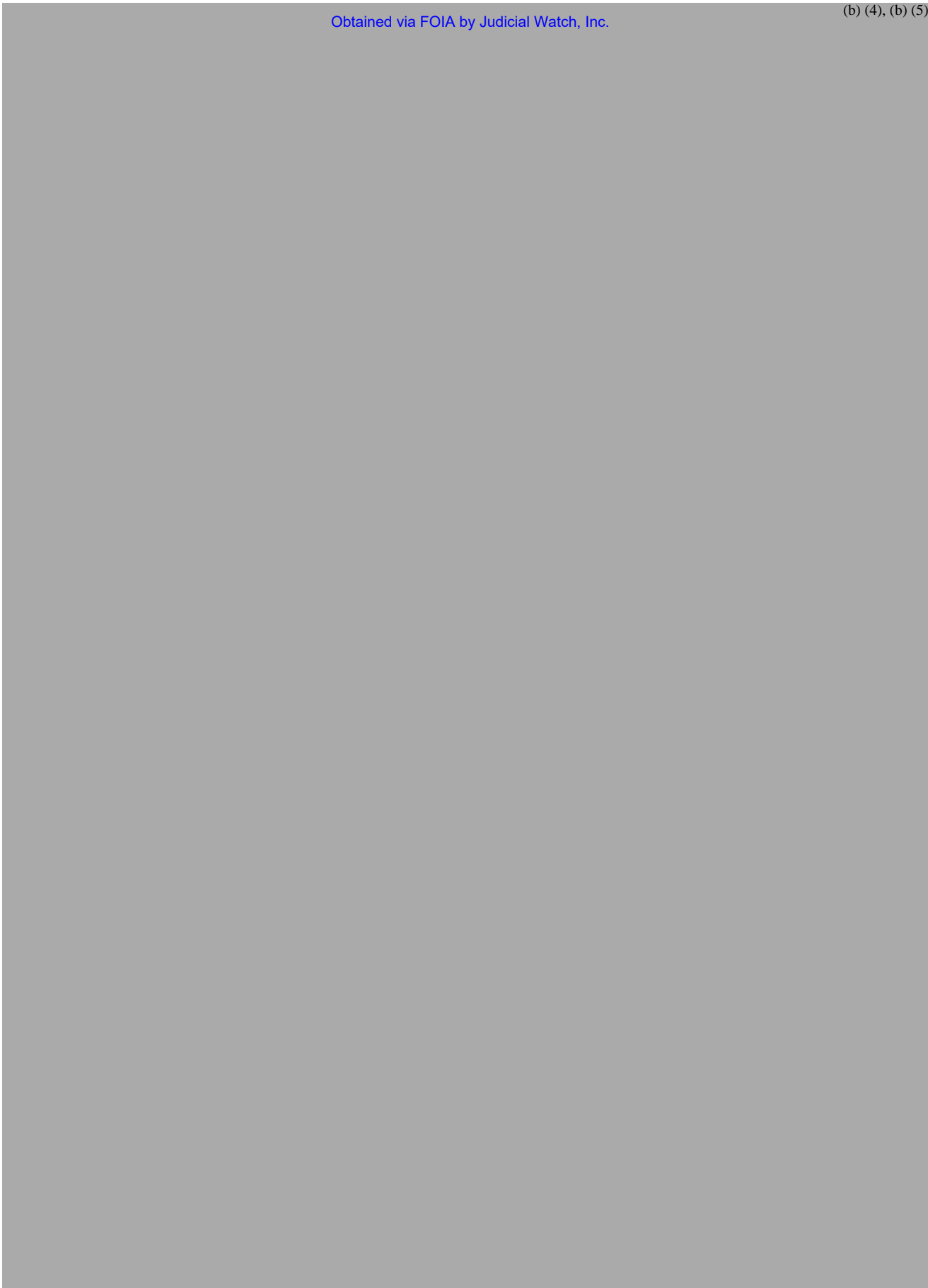


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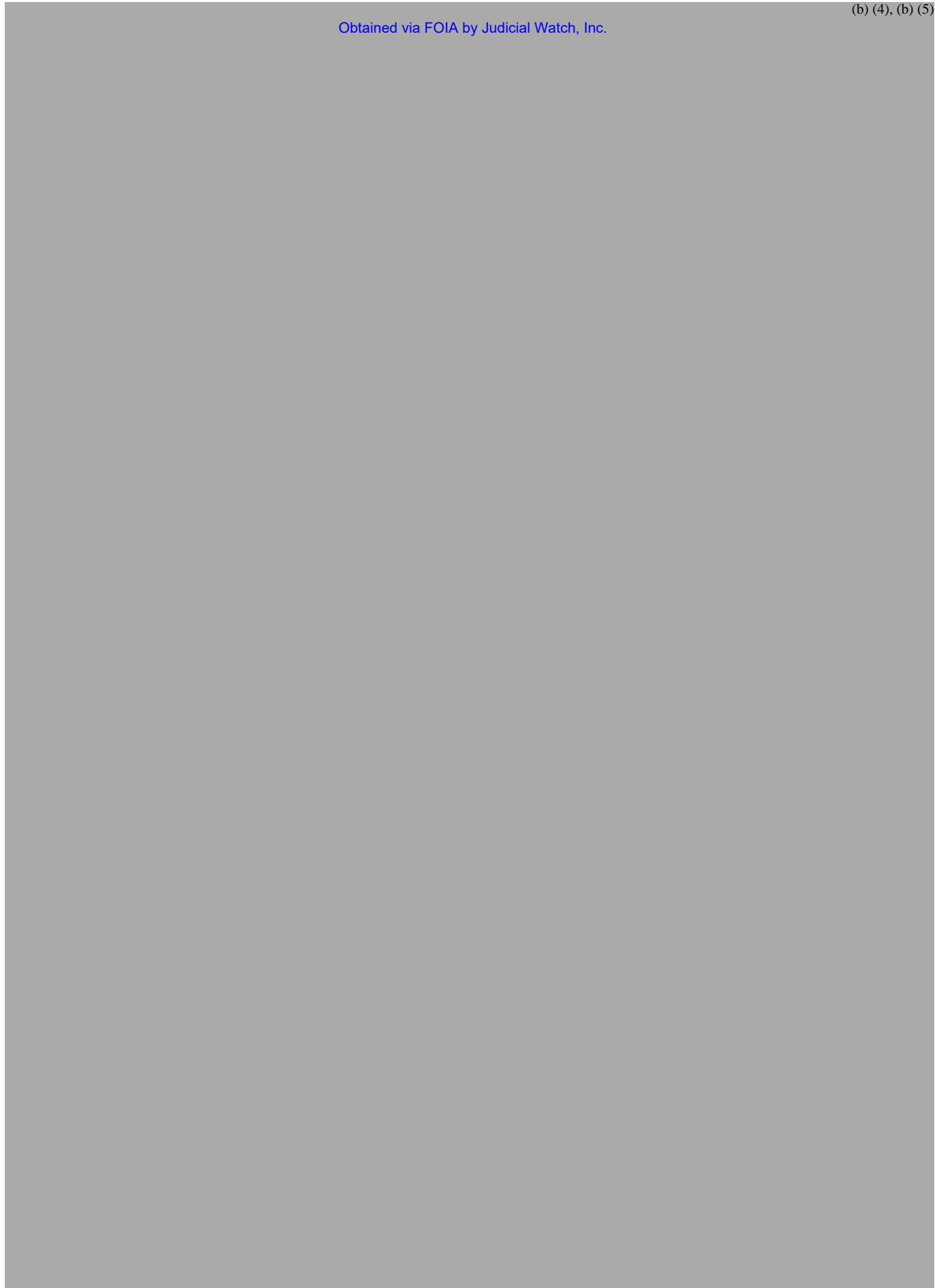


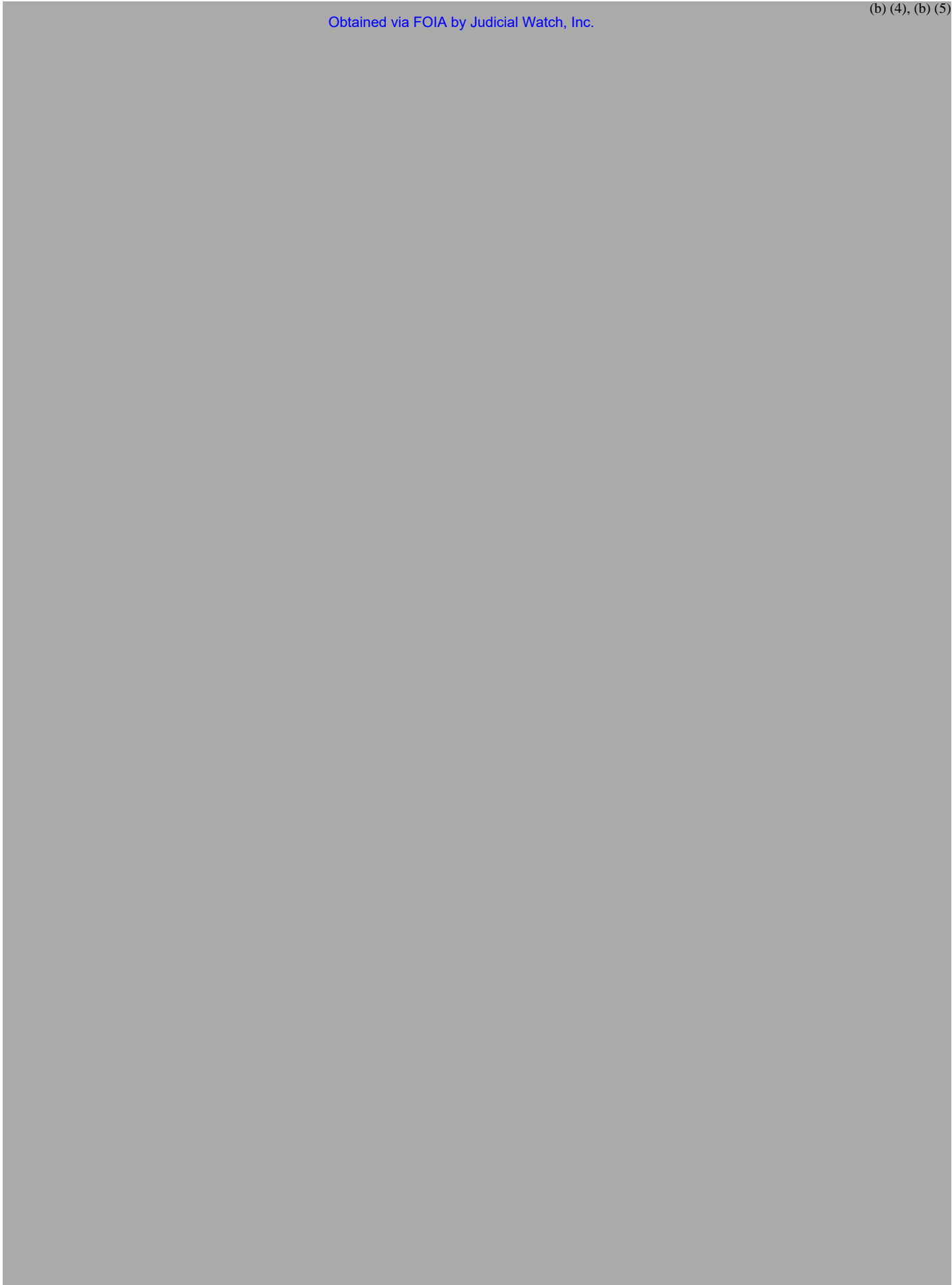
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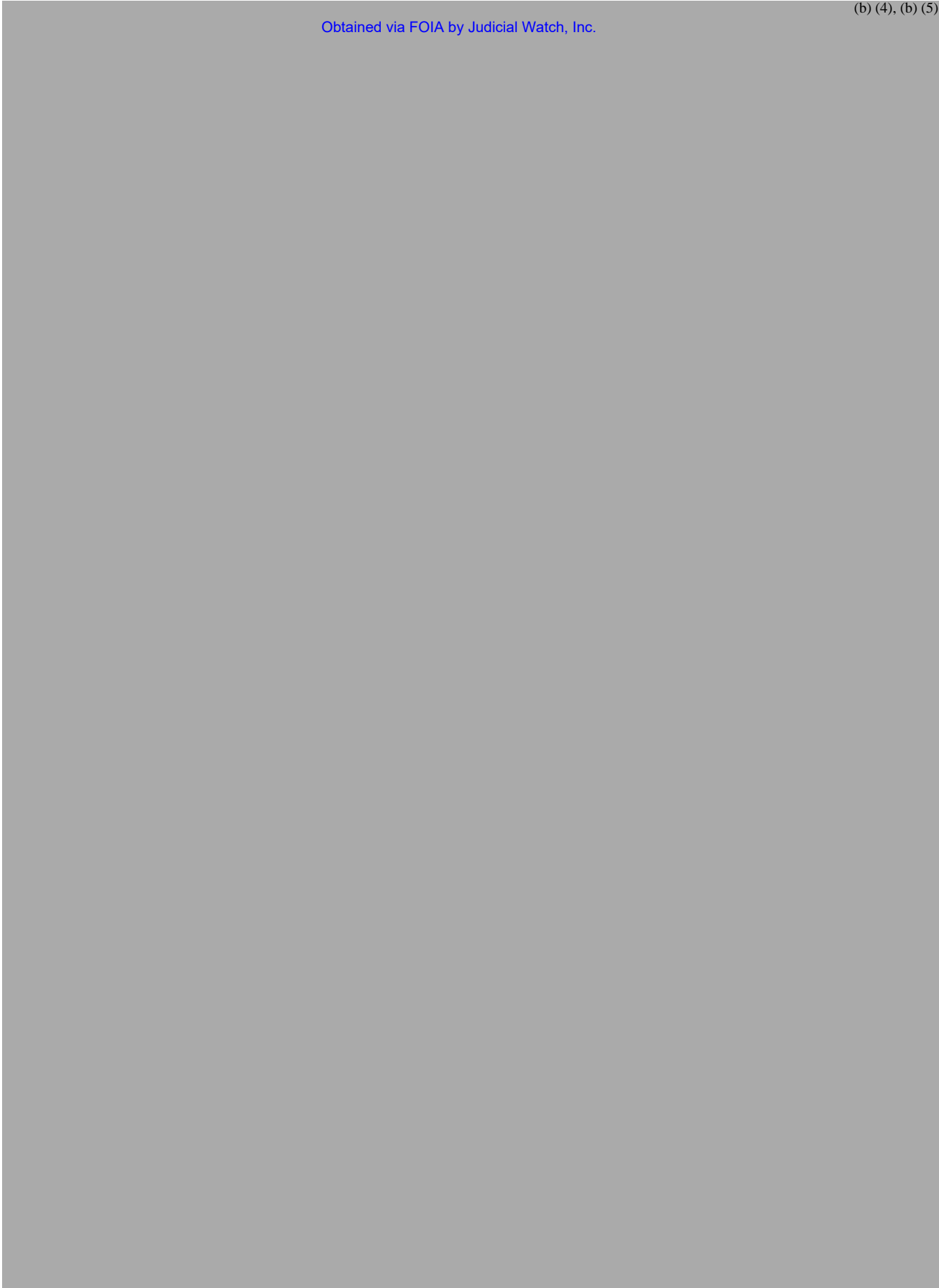


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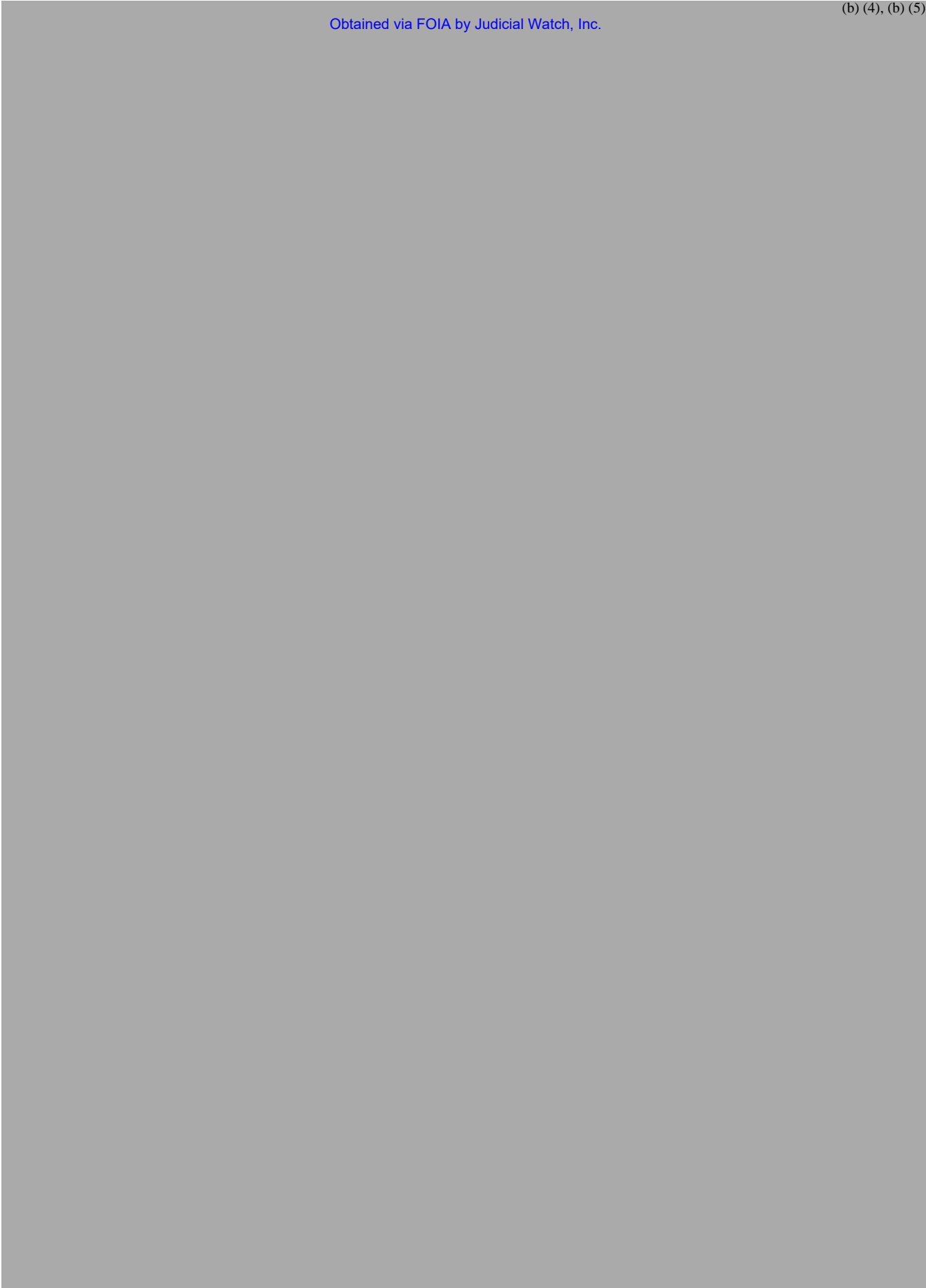
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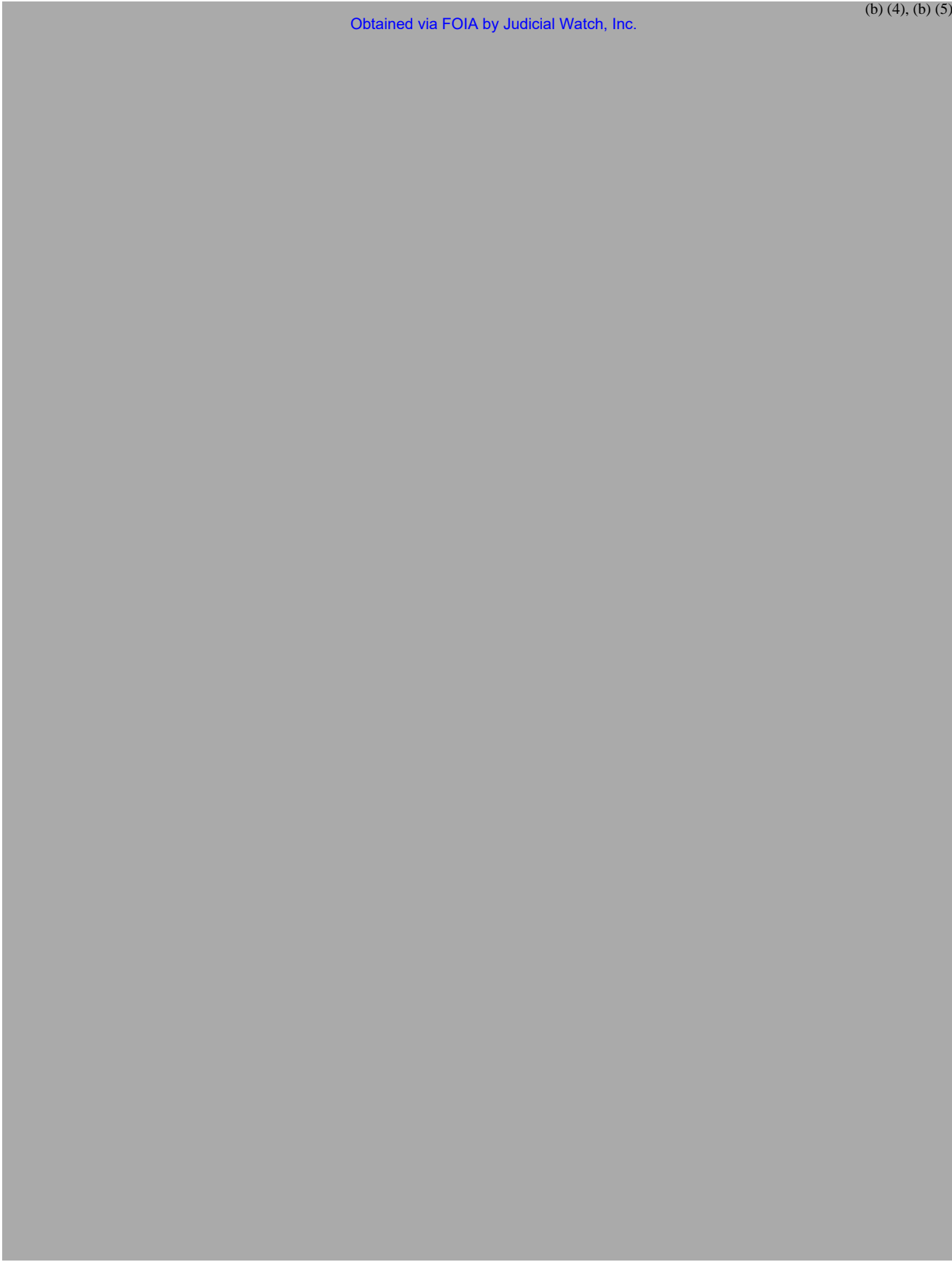


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**From:** Hallett, Adrienne (NIH/OD) [E]  
**Sent:** Wed, 19 May 2021 06:44:59 -0500  
**To:** Collins, Francis (NIH/OD) [E]  
**Cc:** Tabak, Lawrence (NIH/OD) [E]; Jorgenson, Lyric (NIH/OD) [E]; Lauer, Michael (NIH/OD) [E]; Gottesman, Michael (NIH/OD) [E]; Burklow, John (NIH/OD) [E]  
**Subject:** Re: Endless Frontiers Act Substitute - NIH related provisions

(b) (5)

On May 19, 2021, at 7:39 AM, Collins, Francis (NIH/OD) [E]

(b) (6) wrote:

Thanks. (b) (5) If not, can you forward your note to Carrie?

FC

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**From:** Hallett, Adrienne (NIH/OD) [E] (b) (6)  
**Sent:** Tuesday, May 18, 2021 9:34 PM  
**To:** Tabak, Lawrence (NIH/OD) [E] (b) (6); Collins, Francis (NIH/OD) [E] (b) (6); Jorgenson, Lyric (NIH/OD) [E] (b) (6); Lauer, Michael (NIH/OD) [E] (b) (6); Gottesman, Michael (NIH/OD) [E] (b) (6); Burklow, John (NIH/OD) [E] (b) (6)  
**Subject:** Endless Frontiers Act Substitute - NIH related provisions

Hi all,

We got a draft of the substitute amendment for the Endless Frontiers Act this morning. That means, this will be the base text that will be brought up in the Senate later this week.

(b) (5)

(b) (5)

(b) (5)





**From:** [Melencio, Cheryl \(FNIH\) \[T\]](#) on behalf of [Wholley, David \(FNIH\) \[T\]](#)  
**To:** [Austin, Christopher \(NIH/NCATS\) \[E\]](#); [Bancel, Stephane](#); [Carter, Kara](#); [Cavaleri, Marco](#); [Cihlar, Tomas](#); [Collins, Francis \(NIH/OD\) \[E\]](#); [Corey, Larry](#); [Culp, Michelle \(NIH/OD\) \[E\]](#); [Victoria Davey](#); [Disbrow, Gary \(OS/ASPR/BARDA\)](#); [Dolsten, Mikael](#); [Embry, Alan \(NIH/NIAID\) \[E\]](#); [Erbelding, Emily \(NIH/NIAID\) \[E\]](#); [Erck, Stan](#); [Fauci, Anthony \(NIH/NIAID\) \[E\]](#); [Freire, Maria \(FNIH\) \[T\]](#); [Gadbois, Ellen \(NIH/OD\) \[E\]](#); [Gibbons, Gary \(NIH/NHLBI\) \[E\]](#); [Hudson, Thomas](#); [James, Stephanie \(FNIH\) \[T\]](#); [Johnson, Robert \(OS/ASPR/BARDA\)](#); [Kramer, Lynn](#); [Lane, Cliff \(NIH/NIAID\) \[E\]](#); [Lepore, John](#); [Marks, Peter \(FDA/CBER\)](#); [Mascola, John \(NIH/VRC\) \[E\]](#); [Meeker, David](#); [Menetski, Joseph \(FNIH\) \[T\]](#); [Messonnier, Nancy \(CDC/DDID/NCIRD/OD\)](#); [Pandya, Hitesh](#); [Pangalos, Mene](#); [Pao, William](#); [Parker, Ashley \(NIH/OD\) \[E\]](#); [Paul, Steve](#); [Perlmutter, Roger](#); [Plenge, Robert](#); [Plump, Andy](#); [Rachel Ramoni](#); [Reed, John](#); [Reese, David](#); [Rouse, Doris](#); [Santos, Michael \(FNIH\) \[T\]](#); [Skovronsky, Daniel](#); [Stein, Peter \(FDA/CDER\)](#); [Stoffels, Paul](#); [Tabak, Lawrence \(NIH/OD\) \[E\]](#); [Talley, Michael](#); [Tsai, John](#); [Vessey, Rupert](#); [Virgin, Skip](#); [Wholley, David \(FNIH\) \[T\]](#); [Woodcock, Janet \(FDA/OC\)](#); [Young, John](#); [Colvis, Christine \(NIH/NCATS\) \[E\]](#); [Desrosiers, Betsy](#); [Eric Hughes](#); [Jansen, Kathrin](#); [Kurilla, Michael \(NIH/NCATS\) \[E\]](#); [Lowy, Douglas \(NCI\)](#); [Read, Sarah \(NIH/NIAID\) \[E\]](#); [Young, John](#)  
**Cc:** [Anderson, James \(NIH/OD\) \[E\]](#); [Burklow, John \(NIH/OD\) \[E\]](#); [Carluccio, Dana](#); [Castillejos, Carlos](#); [Culp, Michelle \(NIH/OD\) \[E\]](#); [FNIH Central Account](#); [Gadbois, Ellen \(NIH/OD\) \[E\]](#); [Hallett, Adrienne \(NIH/OD\) \[E\]](#); [Lumsden, Joanne \(NIH/NCATS\) \[C\]](#); [Myles, Renate \(NIH/OD\) \[E\]](#); [Wolinetz, Carrie \(NIH/OD\) \[E\]](#); [Adam, Stacey \(FNIH\) \[T\]](#); [Margaret Anderson](#); [Appell, Evan](#); [Chen, Helen](#); [Connelly, Sarah](#); [Dally, Nicole](#); [Gonzalez, Nina](#); [Hawk, Harrison](#); [Mendelson, Jesse](#); [Menetski, Joseph \(FNIH\) \[T\]](#); [Nasr, Hana](#); [Santos, Michael \(FNIH\) \[T\]](#); [Sorosa, Alex](#); [Stratton, Benjamin](#); [Tolman, Brett](#); [Wachtel, Jonathan](#); [Wholley, David \(FNIH\) \[T\]](#); [Burklow, John \(NIH/OD\) \[E\]](#); [Hallett, Adrienne \(NIH/OD\) \[E\]](#); [Meltzer, Abbey \(FNIH\) \[T\]](#); [Myles, Renate \(NIH/OD\) \[E\]](#); [Wolinetz, Carrie \(NIH/OD\) \[E\]](#)  
**Subject:** ACTIV Joint Executive Committee & Leadership Team Meeting: tomorrow, February 17, 2021  
**Date:** Tuesday, February 16, 2021 7:03:40 PM  
**Attachments:** [02.17.21 ACTIV EC and Leadership Team Meeting 20210216\\_vF.pdf](#)  
[02.17.21 ACTIV EC and Leadership Team Meeting APPENDIX 20210216\\_vF.pdf](#)  
[2021-01-14 ACTIV Leadership Team and Executive Committee Meeting Summary\\_vF.pdf](#)

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Dear ACTIV Leadership Team and meeting attendees:

Attached please find the slides for our meeting **tomorrow, Wednesday, February 17, from 11:30 a.m. to 1:00 p.m. Eastern U.S. Time.** The minutes from the January 14 Executive Committee/Leadership Team call are also attached to this note.

The logistics for the Zoom call, which were previously sent to you in the Outlook calendar invitation, are as follows:

Join Zoom Meeting

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Meeting ID: [REDACTED] (b) (6)

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One tap mobile

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+81 3 4578 1488 Japan  
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+81 524 564 439 Japan  
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+41 31 528 09 88 Switzerland  
+41 43 210 70 42 Switzerland  
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Please let Joe Menetski or Cheryl Melencio here at FNIH (copied) know if you are having any problems connecting. I look forward to a productive meeting.


Regards,

David

**David Wholley**  
**Senior Vice-President, Research Partnerships**  
**Foundation for the National Institutes of Health**  
(301) 594-6343  
[fnih.org](http://fnih.org)  
11400 Rockville Pike Suite 600 North Bethesda, MD 20852

*In 2019, the FNIH earned the highest rating from Charity Navigator for the fifth consecutive year and was recognized as an organization that exceeds industry standards.*

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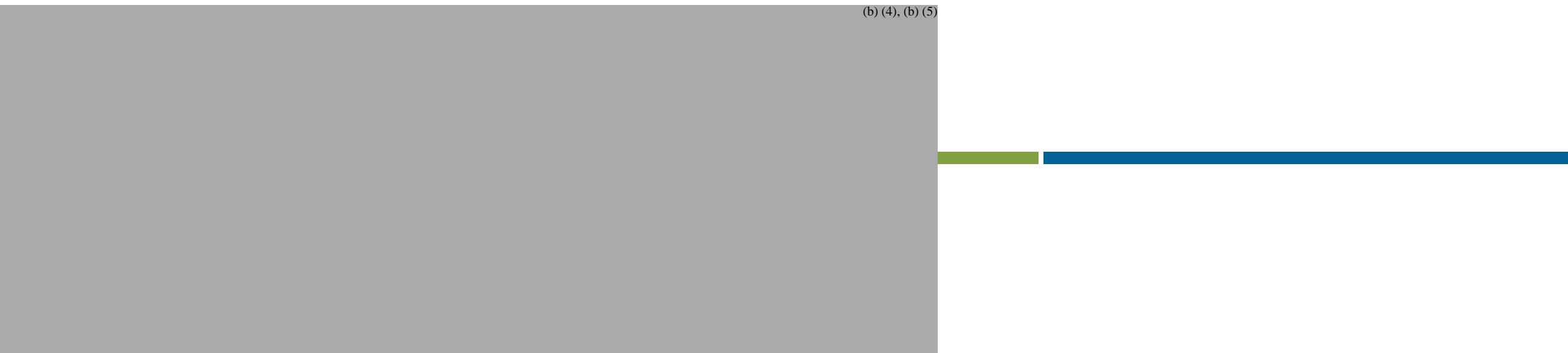
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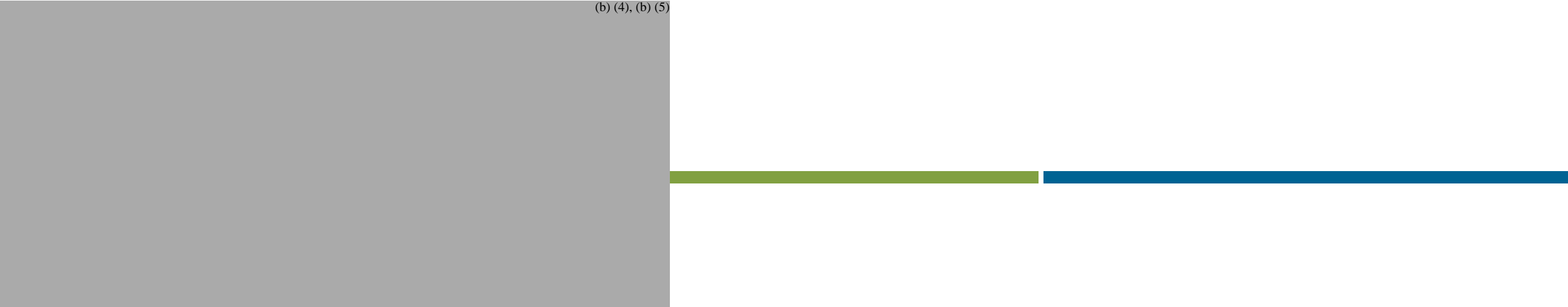
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**From:** [Woodcock, Janet](#)  
**To:** [Kessler, David \(HHS/IOS\)](#); [Collins, Francis \(NIH/OD\) \[E\]](#); [Fauci, Anthony \(NIH/NIAID\) \[E\]](#); [Bugin, Kevin \(FDA/CDER\)](#); [Teyhen, Deydre \(HHS/IOS\)](#); [Adam, Stacey \(FNIH\) \[T\]](#)  
**Subject:** FW: [EXTERNAL] URGENT: The BIRD meeting proceedings and recommendation on covid-19 prevention and treatment  
**Date:** Friday, February 26, 2021 1:20:25 PM  
**Attachments:** [Draft BIRD Proceedings 25-02-2021 v 1.4.pdf](#)

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(b) (5). jw

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**From:** Tess Lawrie <tess@e-bmc.co.uk>  
**Sent:** Friday, February 26, 2021 10:59 AM  
**To:** Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Yiannas, Frank <Frank.Yiannas@fda.hhs.gov>; james.sigg@fda.hhs.gov; Tyler, James <James.Tyler@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>; Abdoo, Mark <Mark.Abdoo@fda.hhs.gov>; Araojo, Richardae <Richardae.Araojo@fda.hhs.gov>; McMeekin, Judith <Judith.McMeekin@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Roth, Lauren <Lauren.Roth@fda.hhs.gov>; Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>; Vasisht, Kaveeta <Kaveeta.Vasisht@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Mettler, Erik <Erik.Mettler@fda.hhs.gov>; Miller, Elizabeth <Elizabeth.Miller@fda.hhs.gov>; Rogers, Michael <Michael.Rogers@fda.hhs.gov>; Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>; Mayne, Susan <Susan.Mayne@fda.hhs.gov>; Pazdur, Richard <Richard.Pazdur@fda.hhs.gov>; Jeffrey.shuren@fda.hhs.gov; Slikker, William <William.Slikker@fda.hhs.gov>; Solomon, Steven M <Steven.Solomon@fda.hhs.gov>; Mitch.zeller@fda.hhs.gov; Stein, Peter <Peter.Stein@fda.hhs.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Sally.chloe@fda.hhs.gov  
**Cc:** claire Mock-Muñoz de Luna <claire@e-bmc.co.uk>; Ketan Gajjar <ketan.gajjar@nhs.net>; Andy Bryant <andy.bryant@newcastle.ac.uk>; Tony Tham (b) (6); Scott Mitchell <scott.mitchell@gov.gg>; Tina Peers <tina@drtinapeers.com>  
**Subject:** [EXTERNAL] URGENT: The BIRD meeting proceedings and recommendation on covid-19 prevention and treatment

**CAUTION:** This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Dear Dr. Stein and FDA Colleagues,

We are writing to share with you the evidence to decision framework of the British Ivermectin Recommendation Development (BIRD) Meeting that was held on Saturday 20th February 2021 via Zoom from Bath, United Kingdom. The expert panel of health and allied professionals and other stakeholders included representatives from 16 countries, namely Argentina, Australia, Belgium, Botswana, Canada, France, Hungary, India, Ireland, Japan, Peru, Nigeria, South Africa, The Philippines, United States, United Kingdom. The ethos of the BIRD meeting was that of scientific rigour and transparency in the spirit of international collaboration towards a common goal – that of saving lives.

The recommendation was developed according *The WHO Handbook of Guideline Development (2014)*. BIRD panel conclusions are that ivermectin should be approved immediately for prevention and treatment of covid-19.

### **The BIRD recommendation on covid-19 prevention and treatment**

*The British Ivermectin Recommendation Development Panel recommends ivermectin for the prevention and treatment of covid-19 to reduce morbidity and mortality associated with covid-19 infection and to prevent covid-19 infection among those at higher risk.*

The BIRD Steering Group has taken heed of the WHO statement on 'Developing global norms for sharing data and results during public health emergencies' that states that 'public disclosure of information of relevance to public health emergencies should not be delayed', and also notes the 'very great risks' that can occur from 'withholding data and results arising from analyses'. We are, therefore, sharing this evidence-to-decision framework within just a few days of the BIRD meeting to avoid delay.

Further, due to the urgency related to the communication and dissemination of this recommendation that is aimed at saving thousands of lives daily, please forgive the limitations of the draft proceedings document attached. Information on the process and methods can be found among the annexes. An Executive Summary is being finalised and will be available on Monday.

We look forward to hearing from you soon and would be happy meet with you via teleconference if you think this will be helpful.

Please do not hesitate to contact us with any questions.

Kind regards,

Dr. Tess Lawrie, on behalf of the BIRD Steering Group and Recommendation Development Panel  
Evidence-based Medicine Consultancy Ltd  
[e-bmc.co.uk](http://e-bmc.co.uk)

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BIRD Working draft version 1.3

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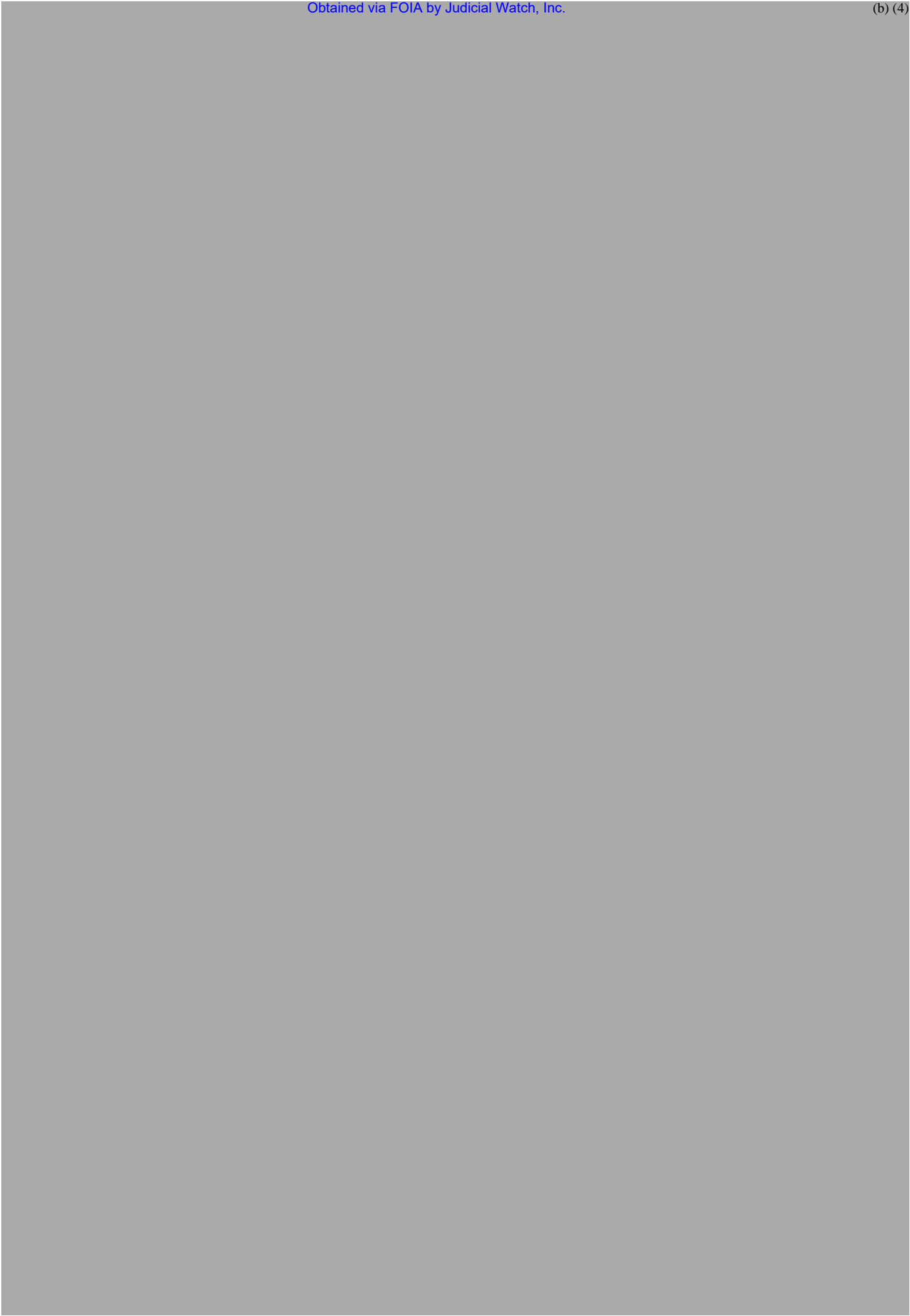


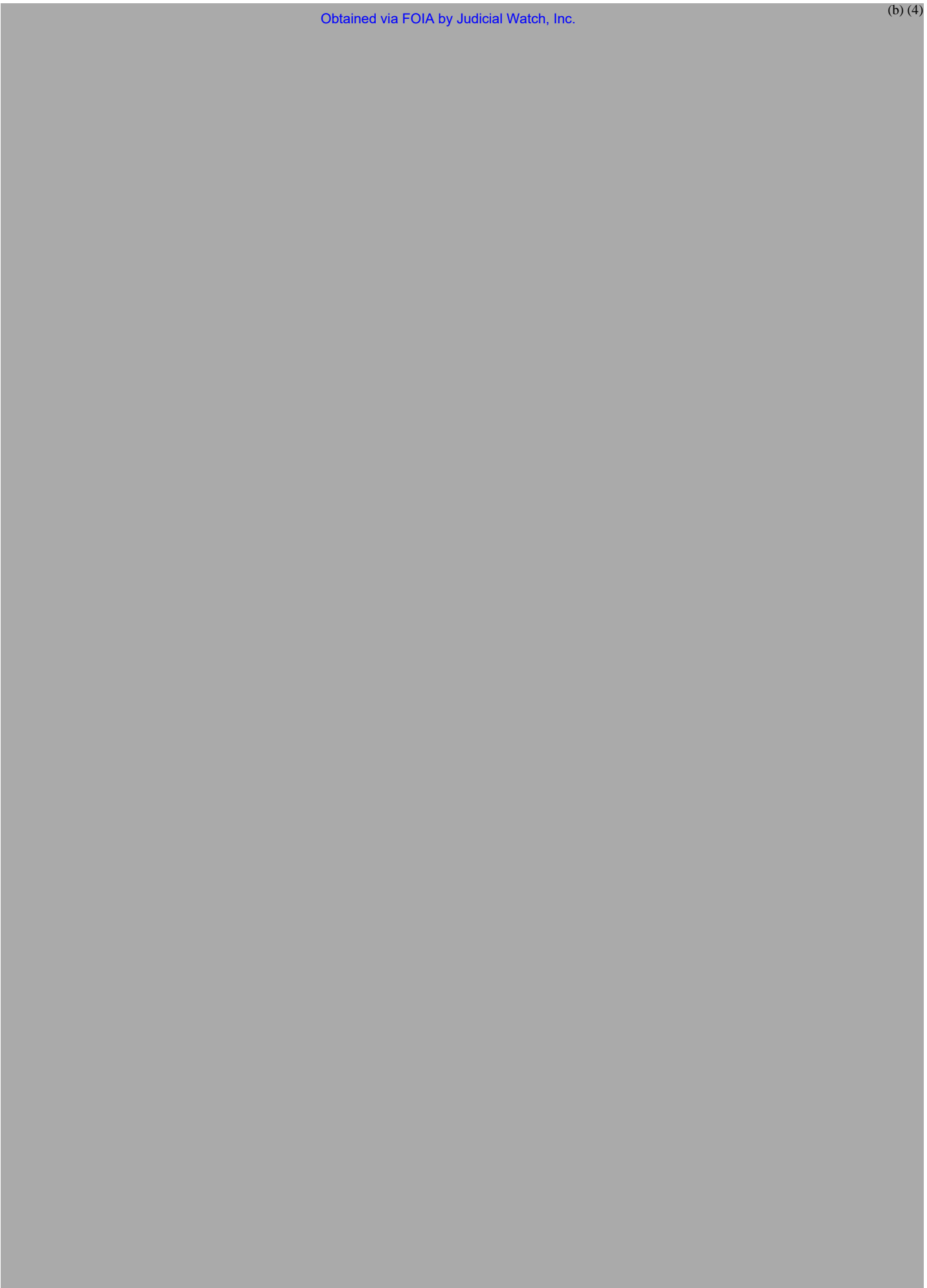


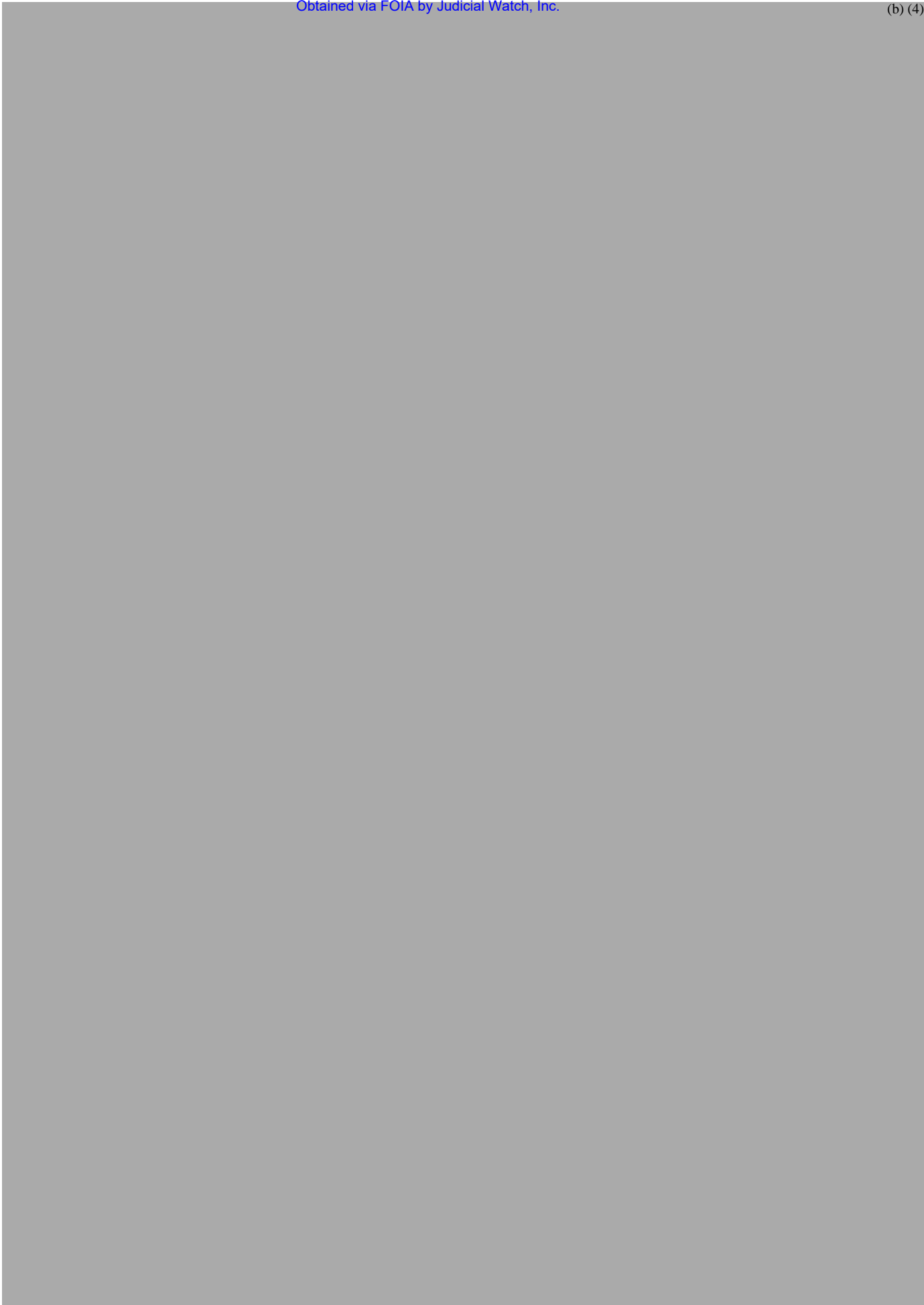


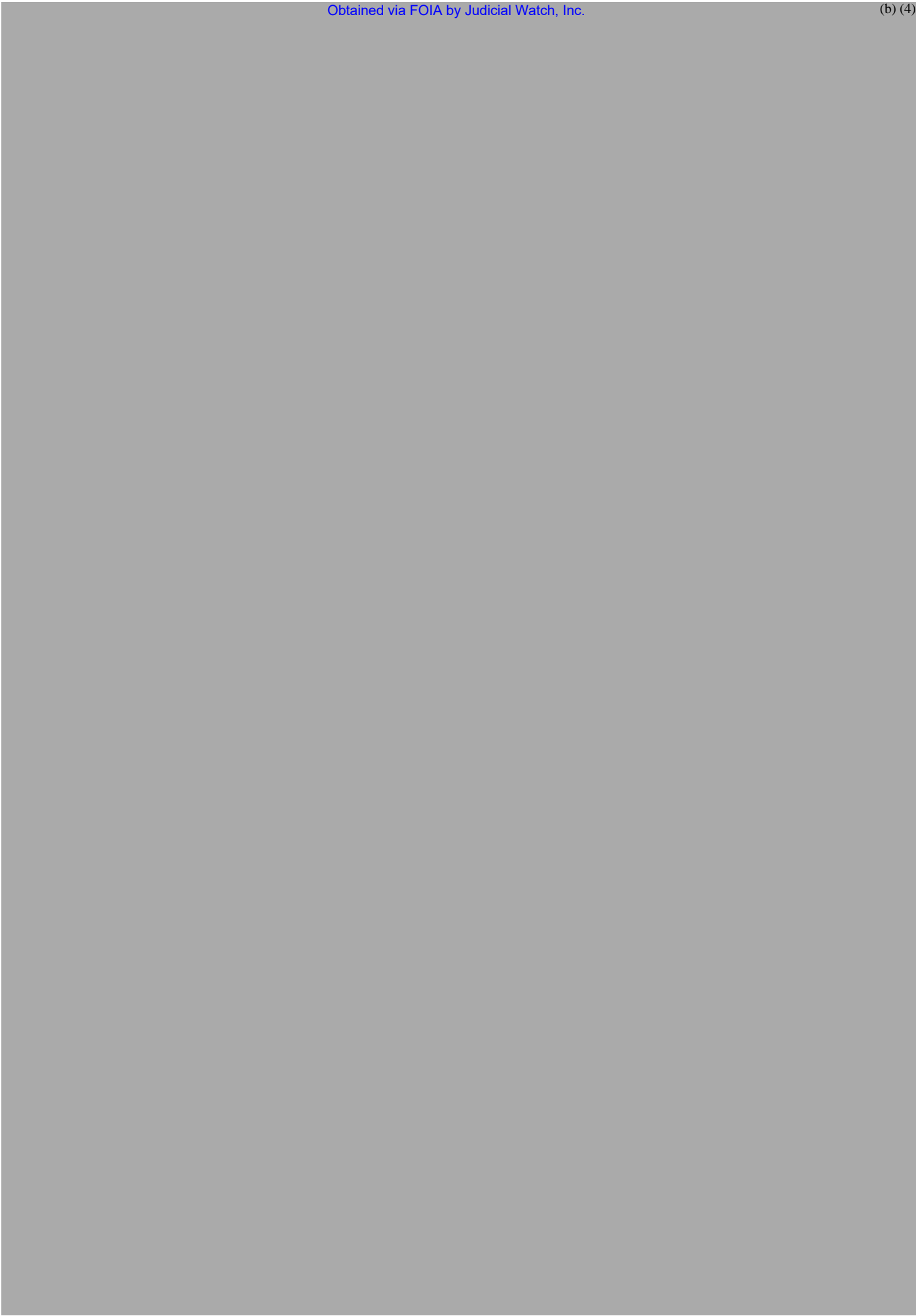
























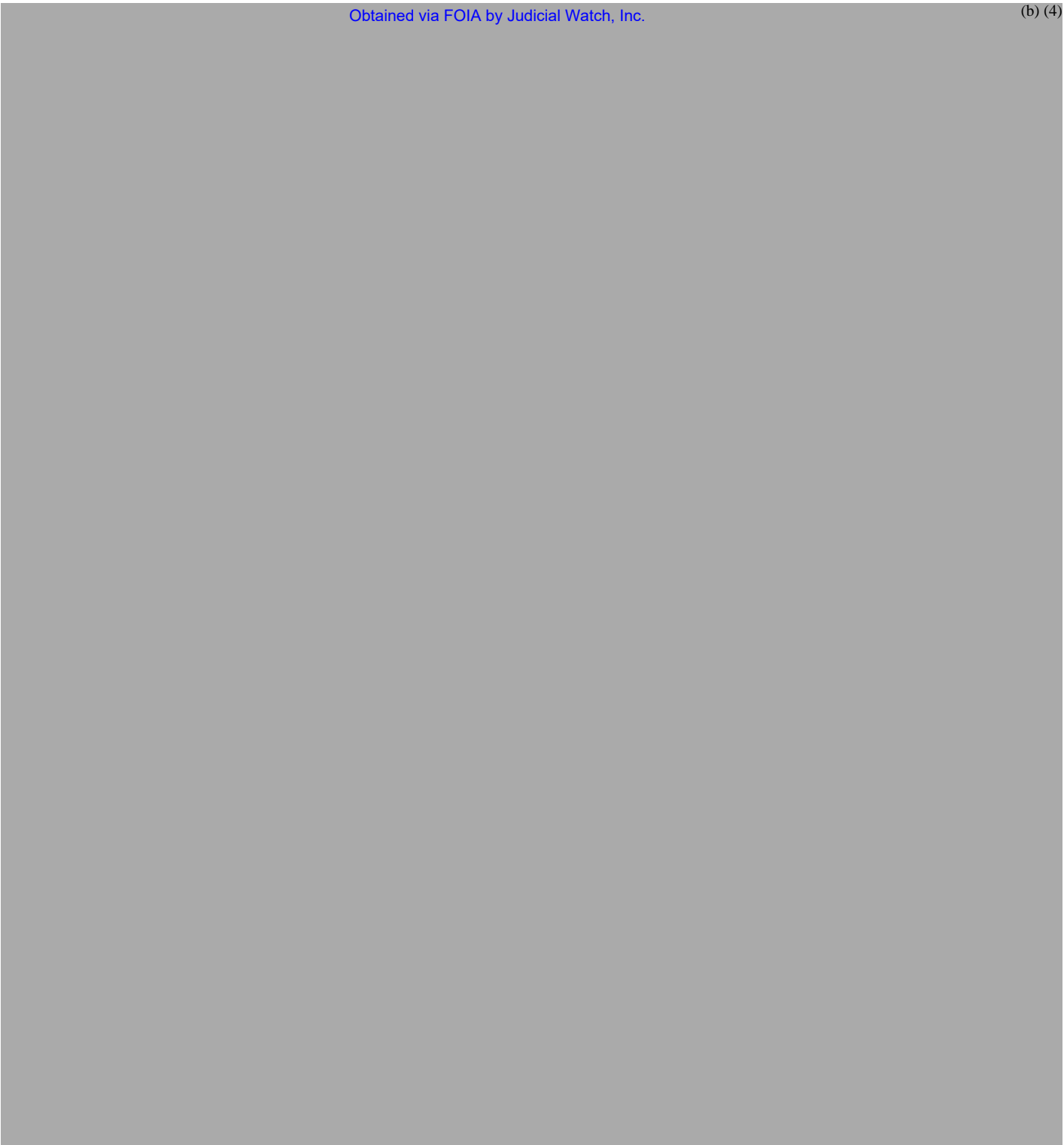






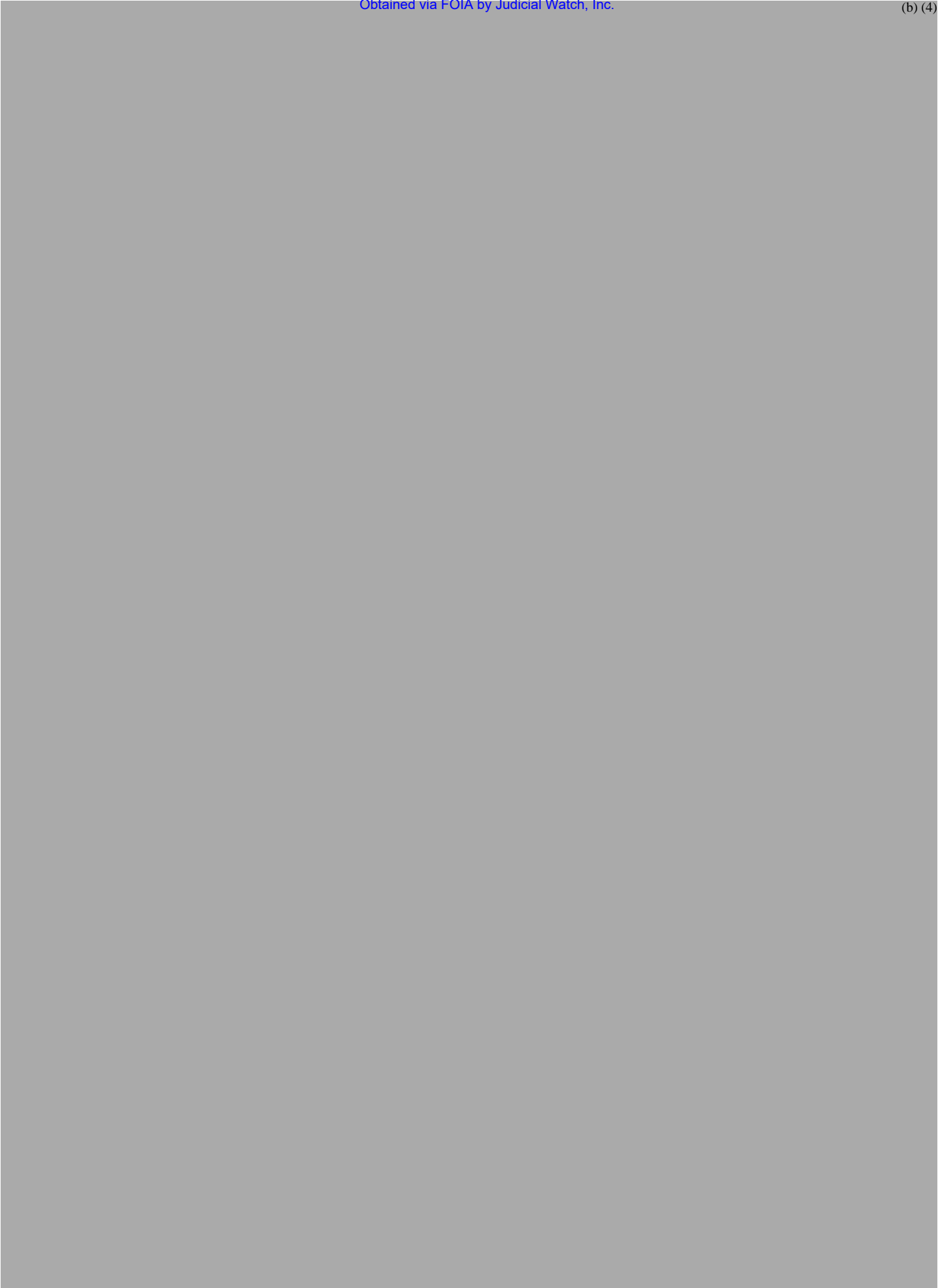




















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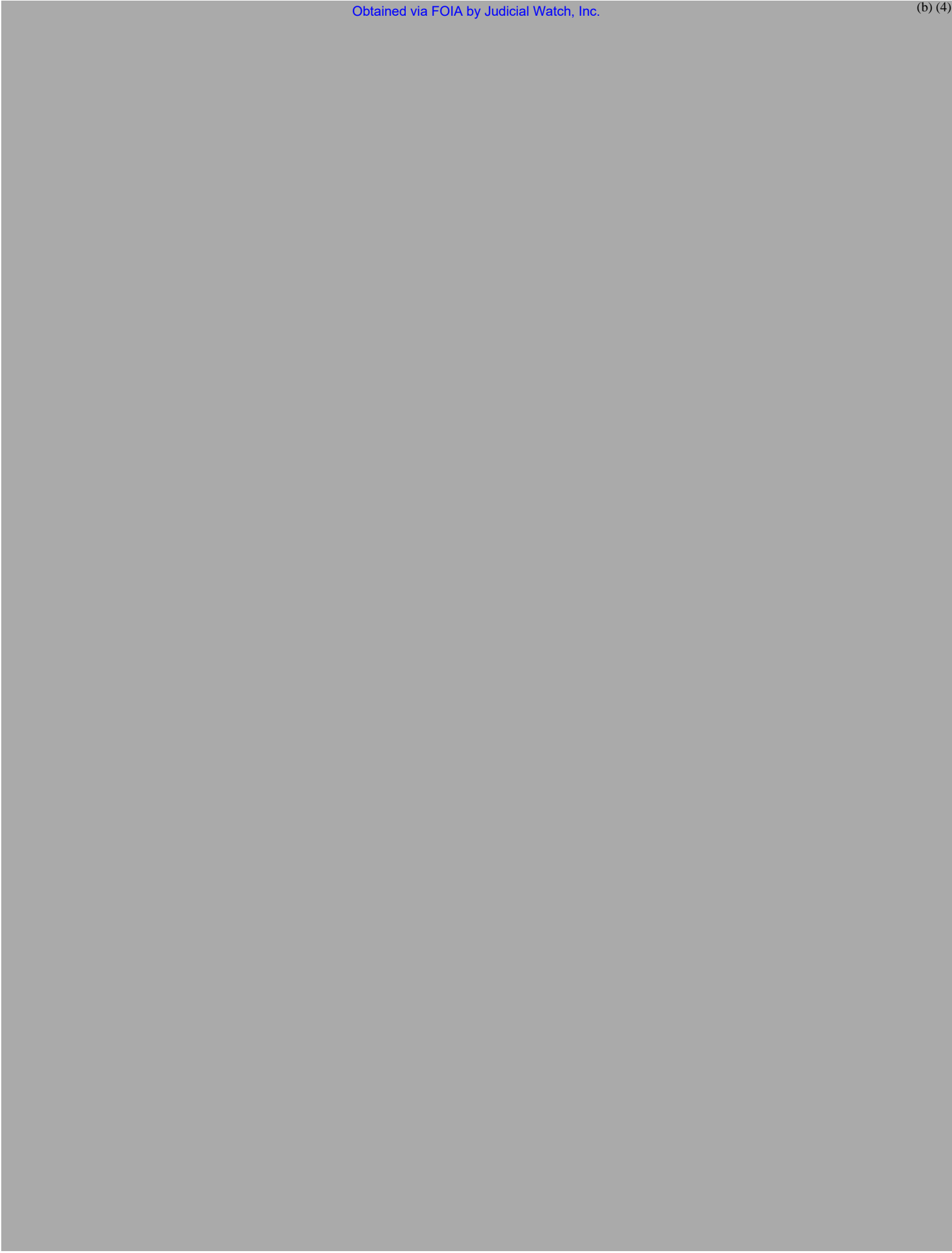










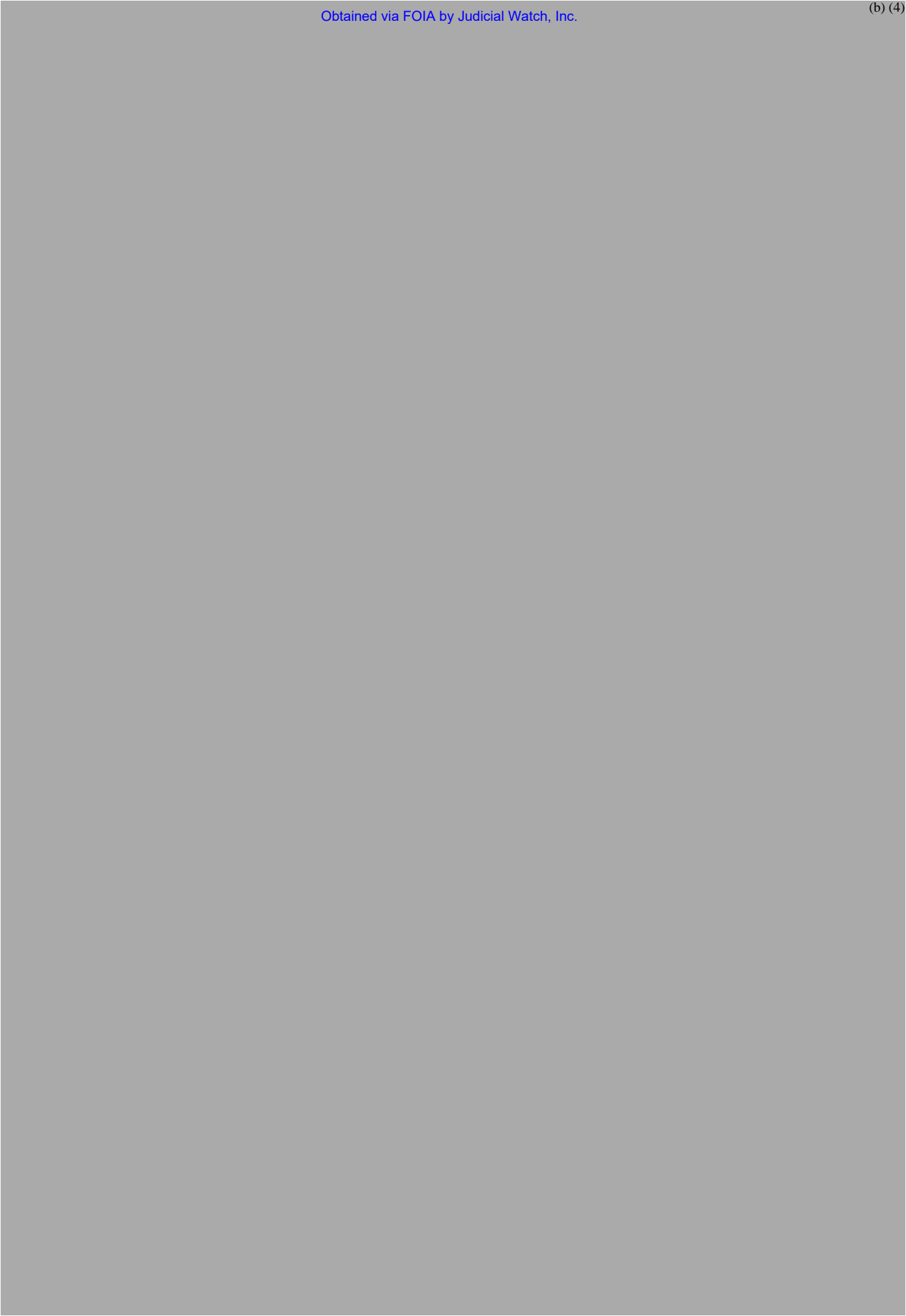


































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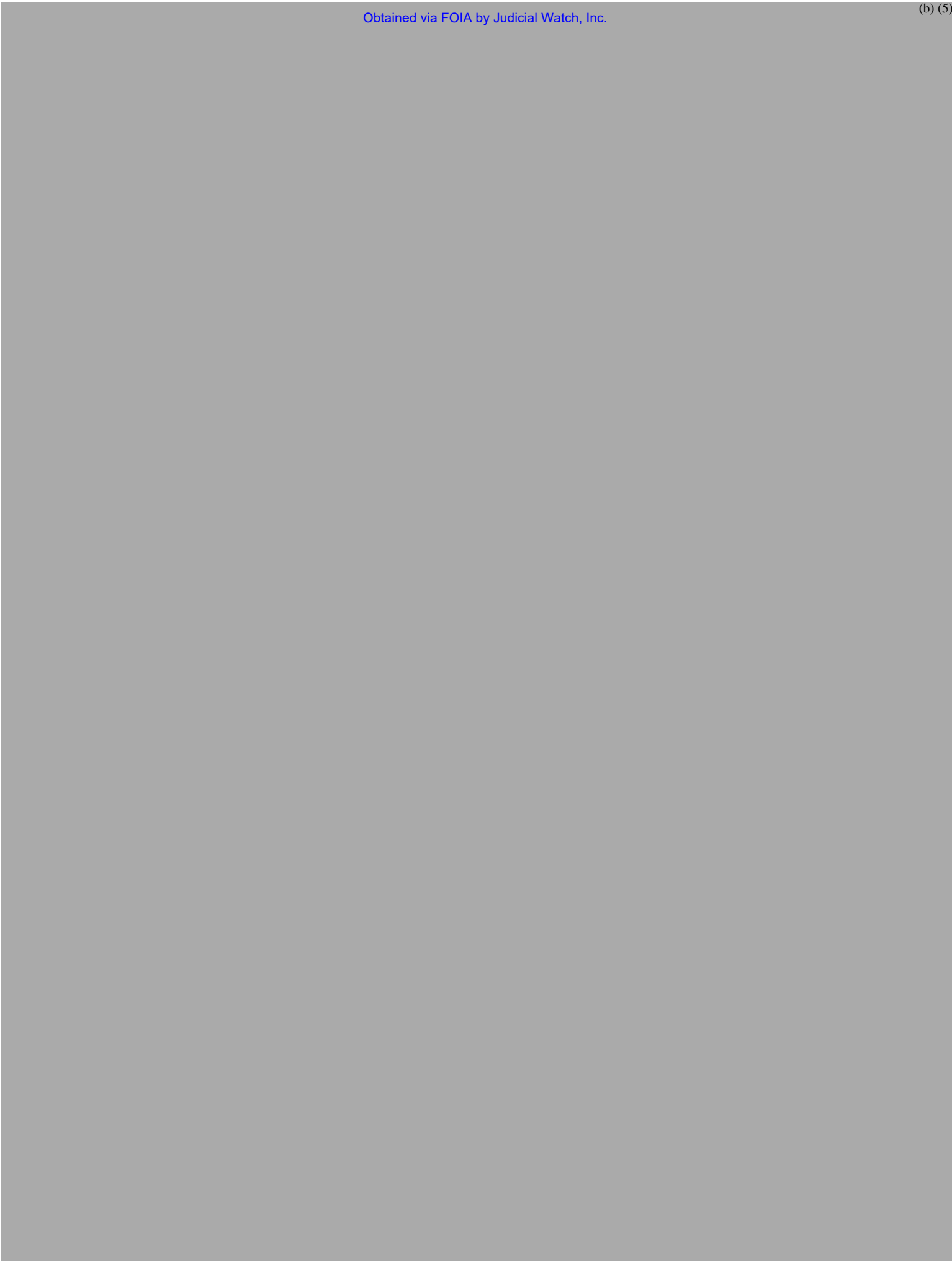






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