



U.S. Department of Health & Human Services

Food and Drug Administration

SAVE REQUEST

USER: (kml)
FOLDER: K002996 - 231 pages
COMPANY: SMITH & NEPHEW, INC. (SMITNEPH)
PRODUCT: PROSTHESIS, HIP, SEMI-CONSTRAINED, UNCEMENTED, METAL/POLYMER, NON-POROUS, CALICUM-PHOSPHATE (MEH)
SUMMARY: Product: SYNERGY HA COATED POROUS FEMORAL STEMS

DATE REQUESTED: Jan 4, 2016

DATE PRINTED: Jan 4, 2016

Note: Printed



DEC 11 2000

K002996

510(k) Summary
Synergy HA Coated Porous Femoral Stems

Submitter's name: Smith & Nephew, Inc.
Submitter's address: 1450 Brooks Road, Memphis, TN 38116
Submitter's telephone number: 901-399-6487
Contact person: David Henley
Date summary prepared: September 22, 2000
Trade or proprietary device name: Synergy HA Coated Porous Femoral Stems
Common or usual name: Prosthetic Hip Joint – HA Coated Porous Femoral Stem

Classification name: 21 CFR 888.3358 hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis-Class II 87LPH

**Substantially Equivalent
Legally Marketed Devices**

- Global Taper Tapered (Synergy) HA Hip Stem - Smith & Nephew
- Secur-Fit® HA Hip Stem – Osteonics® Corp.
- Omnifit® HA Hip Stem – Osteonics® Corp.
- Meridian® ST/PA Femoral Stem – Howmedica Corp.
- APR Porous HA Hip System – Sulzer Orthopedics, Inc.

Device Description

Synergy HA Coated Porous Femoral Stems are manufactured from titanium material (Ti-6Al-4V, ASTM F1472) and are porous coated with bead material manufactured from titanium material (Ti-6Al-4V, ASTM F67, Grade 2, with a mesh size of -45/+60. These stems are designed for use with existing Smith & Nephew cobalt chrome or ceramic modular femoral heads with a 12/14 taper.

Device Intended Use

Total hip components are indicated uncemented use only in individuals undergoing primary and revision surgery where other treatments or devices have failed in rehabilitating hips damaged as a result of trauma, inflammatory joint disease such as rheumatoid arthritis, or non-inflammatory degenerative joint disease (NIDJD) or any of its composite diagnoses such as osteoarthritis; avascular necrosis; traumatic arthritis; slipped capital epiphysis; fused hip; fracture of the pelvis; diastrophic variant; old, remote osteomyelitis with an extended drainage-free period; nonunion, femoral neck fracture and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques; femoral osteotomy, or Girdlestone resection; fracture dislocation of the hip; and correction of deformity.

The *Synergy HA Coated Porous Femoral Stem* is designed uncemented use only and for single use only.

Technological characteristics:

Synergy HA Coated Porous Femoral Stems are similar to the legally marketed devices listed above. All of these devices are indicated for total hip replacement, are similar in design to *Synergy HA Coated Porous Femoral Stems*, and have the same technological characteristics.

Performance characteristics:

Data indicate that *Synergy HA Coated Porous Femoral Stems* are substantially equivalent to identified legally marketed devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 11 2000

Mr. David Henley
Clinical/regulatory Affairs Specialist
Smith & Nephew, Inc.
1450 Brooks Road
Memphis, Tennessee 38116

Re: K002996
Trade Name: Synergy HA Coated Porous Femoral Stems
Regulatory Class: II
Product Code: MEH
Dated: September 22, 2000
Received: September 25, 2000

Dear Mr. Henley:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

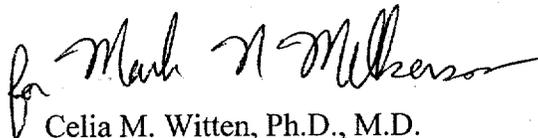
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

Page 2 - Mr. David Henley

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink, appearing to read "for Mark A. Millerson". The signature is written in a cursive style and is positioned above the typed name of the signatory.

Celia M. Witten, Ph.D., M.D.

Director

Division of General, Restorative and

Neurological Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

K002996

Indications Statement
Synergy HA Coated Porous Femoral Stems

Total hip components are indicated for uncemented use only in individuals undergoing primary and revision surgery where other treatments or devices have failed in rehabilitating hips damaged as a result of trauma, inflammatory joint disease such as rheumatoid arthritis, or non-inflammatory degenerative joint disease (NIDJD) or any of its composite diagnoses such as osteoarthritis; avascular necrosis; traumatic arthritis; slipped capital epiphysis; fused hip; fracture of the pelvis; diastrophic variant; old, remote osteomyelitis with an extended drainage-free period; nonunion, femoral neck fracture and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques; femoral osteotomy, or Girdlestone resection; fracture dislocation of the hip; and correction of deformity.

for Mark A. Mulhern

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number _____ *K002996*



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 11 2000

Mr. David Henley
Clinical/regulatory Affairs Specialist
Smith & Nephew, Inc.
1450 Brooks Road
Memphis, Tennessee 38116

Re: K002996
Trade Name: Synergy HA Coated Porous Femoral Stems
Regulatory Class: II
Product Code: MEH
Dated: September 22, 2000
Received: September 25, 2000

Dear Mr. Henley:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

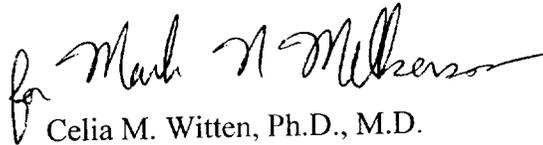
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

Page 2 - Mr. David Henley

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink, appearing to read "for Mark N. Millerson". The signature is written in a cursive style.

Celia M. Witten, Ph.D., M.D.

Director

Division of General, Restorative and

Neurological Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

K002996

Indications Statement
Synergy HA Coated Porous Femoral Stems

Total hip components are indicated for uncemented use only in individuals undergoing primary and revision surgery where other treatments or devices have failed in rehabilitating hips damaged as a result of trauma, inflammatory joint disease such as rheumatoid arthritis, or non-inflammatory degenerative joint disease (NIDJD) or any of its composite diagnoses such as osteoarthritis; avascular necrosis; traumatic arthritis; slipped capital epiphysis; fused hip; fracture of the pelvis; diastrophic variant; old, remote osteomyelitis with an extended drainage-free period; nonunion, femoral neck fracture and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques; femoral osteotomy, or Girdlestone resection; fracture dislocation of the hip; and correction of deformity.

for Mark A. Melkers

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number _____ *K002996*

Memorandum

From: Reviewer(s) - Name(s) Pz Suny

Subject: 510(k) Number K002994

To: The Record - It is my recommendation that the subject 510(k) Notification:

- Refused to accept.
- Requires additional information (other than refuse to accept).
- Is substantially equivalent to marketed devices.
- NOT substantially equivalent to marketed devices.

De Novo Classification Candidate? YES NO

- Other (e.g., exempt by regulation, not a device, duplicate, etc.)
- Is this device subject to Postmarket Surveillance? YES NO
- Is this device subject to the Tracking Regulation? YES NO
- Was clinical data necessary to support the review of this 510(k)? YES NO
- Is this a prescription device? YES NO
- Was this 510(k) reviewed by a Third Party? YES NO
- Special 510(k)? YES NO
- Abbreviated 510(k)? Please fill out form on H Drive 510k/boilers YES NO

This 510(k) contains:

- Truthful and Accurate Statement Requested Enclosed
(required for originals received 3-14-95 and after)
- A 510(k) summary OR A 510(k) statement
- The required certification and summary for class III devices
- The indication for use form (required for originals received 1-1-96 and after)
- Material of Biological Origin YES NO

The submitter requests under 21 CFR 807.95 (doesn't apply for SEs):

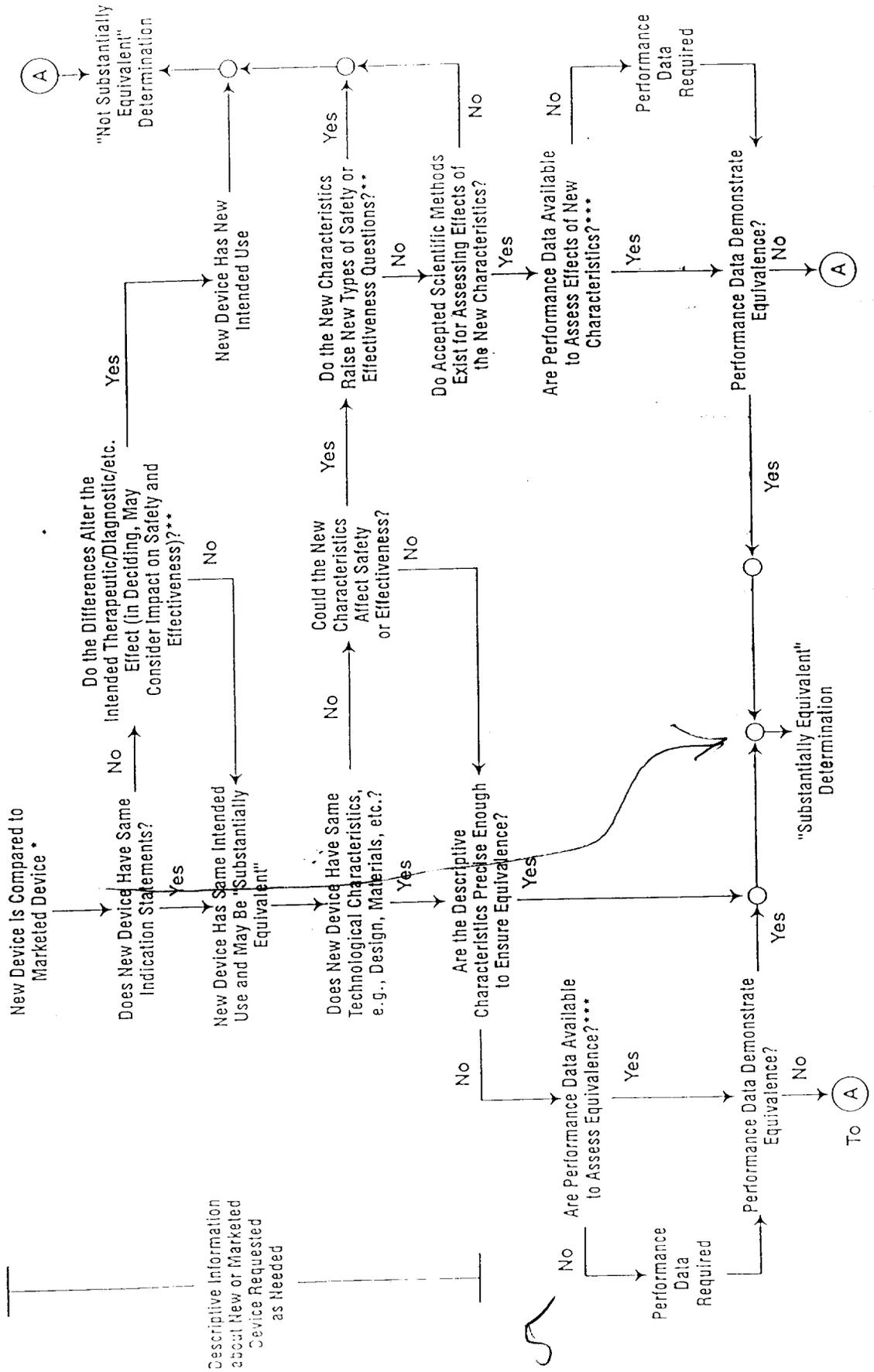
- No Confidentiality
- Confidentiality for 90 days
- Continued Confidentiality exceeding 90 days

Predicate Product Code with class: _____ Additional Product Code(s) with panel (optional): _____

Review: MEH/II _____
 (Branch Chief) (Branch Code) (Date) 12/8/2000

Final Review: Mark A. Melnik _____
 (Division Director) (Date) 12/8/00

510(k) "Substantial Equivalence" Decision-Making Process (Detailed)



* 510(k) Submissions Compare New Devices to Marketed Devices. FDA Requests Additional Information if the Relationship Between Marketed and "Predicate" (pre-Amend.) or Reclassified Post-Amendments) Devices is Unclear.

** This Definition is Normally Based on Descriptive Information Alone, But Limiting Information is Sometimes Required.

*** Data May Be in the 510(k), Other 510(k)s, The Center's Classification Files, or the Literature.

Document: K002996

Device Name: Synergy HA Coated Porous Femoral Stems

Classification: II, 87/MEH

Submitted by: Smith and Nephews

Date Decision Due: 12/24/00

Reviewed by: Pei Sung, Ph.D. *Rev 12/4/00*

Date: 12/5/00

Recommendation:

This subject 510(k) notification:

- is substantially equivalent to the marketed devices.
- requires more data.
- requires premarket approval.

Type letter and wording suggested:

- "SE" Letter Attached
- "SN" Letter Attached
- "AI" Letter Attached
- "AI" via Telephone and/or FAX

Summary:

This Abbreviated 510(k) Includes:

1. Coversheet identifying the application as "Abbreviated 510(k): Special Controls/Conformance to Recognized Standards";
2. Declaration of conformity with standards or guidance documents; and
3. Basic information required for all 510(k) submissions.

The sponsor has provided the necessary to fulfill the requirements for an Abbreviated 510(k). As part of an Abbreviated 510(k), the sponsor is not required to provide much of the information described in the standards or in the guidance documents. Therefore, the "SE" decision is partially/fully based on an administrative review of the conformity with consensus standards and/or guidance documents, as the new FDA regulation was intended.

Indications for Use:

Total hip components are indicated for use in individuals undergoing primary and revision surgery where other treatments or devices have failed in rehabilitating hips damaged as a result of trauma, inflammatory joint disease such as rheumatoid arthritis, or non-inflammatory degenerative joint disease (NIDID) or any of its composite diagnoses such as osteoarthritis; avascular necrosis; traumatic arthritis; slipped capital epiphysis; fused hip; fracture of the pelvis and diastrophic variant; old, remote osteomyelitis with an extended drainage-free period; non-union; femoral neck fracture and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques; femoral osteotomy, or Girdlestone resection; fracture dislocation of the hip; and correction of deformity.

Synergy HA Coated Porous Femoral Stems are not indicated for bony ingrowth (see attached FAX dated 12/5/00). It is for uncemented use and for single use only. These stems can be used with cobalt chrome or ceramic, modular femoral heads with a 12/14 taper.

Description of the Subject Device(s):

Synergy Porous Femoral Stems were previously cleared via K963509 and K991485. The only difference between this subject and the cleared predicates is the addition of an HA coating to the porous coated area on the proximal body of the Synergy porous hip stem, thus creating Synergy HA Coated Porous Femoral Stems. The proprietary HA coating utilized on Synergy HA Coated Porous Femoral Stems is identical to the HA coating used on Smith & Nephew's Hydroxyl apatite Reflection® Acetabular Shells cleared for market under K990666. The design and the manufacturing processes used for the Synergy porous coated femoral stems K963509 and K991485 has not been changed.

Materials:

HA: Biocoat, Inc. MAF-339
Porous Bead: Pure titanium, ASTM F-67
Stem: Ti6Al4V alloy, ASTM F-1472

Device dimension and geometry:

All design characteristics, including sizes, and surface finishes are identical to those predicates cleared via K963509 and K991485.

Device Testing and Results:

The HA coating is identical to the HA coating used on S&N's Hydroxyapatite Reflection® Acetabular Shells cleared via K990666.

Sterilization:

This device is intended to be provided sterile and will be sterilized by a

(b)(5)

No claim of "non-pyrogenic" is made. No pyrogen testing is conducted.

Description of the packaging used to maintain sterility is enclosed. Sterile notation reflects on the sample labeling.

The product is for single use only.

Labeling:

Representative draft samples of the labeling, and package inserts are included in Exhibits 14 and 15.

Contact/Request:

12/5/2k: This reviewer called Mr. David Henly of S&N asking him the indication of this subject device specially whether or not the device is intended to promote bony ingrowth. He stated that this device system is not intended to promote bony ingrowth.

Conclusion:

Additional Information
X This subject device is substantially equivalent to legally marketed device(s), i.e., K963509 and K991485 in terms of the stem design and dimensions. The HA coating is identical to the HA coating used on S&N's Hydroxyapatite Reflection® Acetabular Shells cleared via K990666.

Standards Data Form for Abbreviated 510(k)s

510(k) Number: K003659

Standard Organization No: ASTM
Standard Identification No: 1472, 67
CDRH Internal Reference No: 70, 411

Declaration of Conformity Elements:

Any Adaptations Applied	yes	x	no
Any Requirements Not Applicable	yes	x	no
Any Deviations Applied	yes	x	no
Any Differences in Device Tested and Finished Product	yes	x	no
Is There a Third Party or Test Lab Involved	yes		no x

Comments:

The cited standard does not assure the safety and efficacy of this subject device.



Product to which compared: see review

	YES	NO	
1. Is Product A Device	x		If NO = Stop
2. Is Device Subject To 510(k)?	x		If NO = Stop
3. Same Indication Statement?	x		If YES = Go To 5
4. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?			If YES = Stop NE
5. Same Technological Characteristics?	x		If YES = Go To 7
6. Could The New Characteristics Affect Safety Or Effectiveness?			If YES = Go To 8
7. Descriptive Characteristics Precise Enough?	x		If NO = Go To 10 If YES = Stop SE
8. New Types Of Safety Or Effectiveness Questions?			If YES = Stop NE
9. Accepted Scientific Methods Exist?			If NO = Stop NE
10. Performance Data Available?			If NO = Request Data
11. Data Demonstrate Equivalence?			Final Decision:

Note: "Yes" responses to questions 4,6,8,11, and every "No" response requires an explanation.

1. Explain why not a device:
2. Explain why not subject to 510(k):
3. How does the new indication differ from the predicate device's indication:
4. Explain why there is or is not a new effect or safety or effectiveness issue:
5. Describe the new technological characteristics:
6. Explain how new characteristics could or could not affect safety or effectiveness:
7. Explain how descriptive characteristics are not precise enough:
8. Explain new types of safety or effectiveness questions raised or why the questions are not new:
9. Explain why existing scientific methods can not be used:
10. Explain what performances data are needed:
11. Explain how the performance data demonstrate that the device is or is not substantially equivalent:

Internal Administrative Form

	YES	NO
1. Did the firm request expedited review?		x
2. Did we grant expedited review?		x
3. Have you verified that the Document is labeled Class III for GMP purposes?	x	
4. If, not, has POS been notified?	x	
5. Is the product a device?		x
6. Is the device exempt from 510(k) by regulation or policy?	x	
7. Is the device subject to review by CDRH?		x
8. Are you aware that this device has been the subject of a previous NSE decision?		x
9. If yes, does this new 510(k) address the NSE issue(s), (e.g., performance data)?		
10. Are you aware of the submitter being the subject of an integrity investigation?		x
11. If, yes, consult the ODE Integrity Officer.		
12. Has the ODE Integrity Officer given permission to proceed with the review? (Blue Book Memo #I91-2 and Federal Register 90N0332, September 10, 1991.		

Screening Checklist

2. GENERAL INFORMATION: REQUIRED IN ALL 510(K) SUBMISSIONS							
	NA		YES		NO		
Financial Certification or Disclosure Statement for 510(k)s with a Clinical Study 807.87(i)			SPECIALS		ABBREVIATED		TRADITIONAL
	YES	NO	YES	NO	YES	NO	MISSING
a) trade name, classification name, establishment registration number, device class			x				
b) OR a statement that the device is not yet classified	FDA-may be a classification request; see coordinator						
c) identification of legally marketed equivalent device		NA	x				
d) compliance with Section 514 - performance standards		NA	x				
e) address of manufacturer			x				
f) Truthful and Accurate Statement			x				
g) Indications for Use enclosure			x				
h) SMDA Summary or Statement (FOR ALL DEVICE CLASSES)			x				
i) Class III Certification & Summary (FOR ALL CLASS III DEVICES)							
j) Description of device (or modification) including diagrams, engineering drawings, photographs, service manuals			x				
k) Proposed Labeling:			x				
l) Comparison Information (similarities and differences) to named legally marketed equivalent device			x				
m) If kit, kit certification							
4. ABBREVIATED 510(K):							
a) For a submission, which relies on a guidance document and/or special control(s), a summary report that describes how the guidance and/or special control(s) was used to address the risks associated with the particular device type							
b) If a manufacturer elects to use an alternate approach to address a particular risk, sufficient detail should be provided to justify that approach.							
c) For a submission, which relies on a recognized standard, a declaration of conformity to the standard. Should be included							
d) Data/information to address issues not covered by guidance documents, special controls, and/or recognized standards							
5. Additional Considerations: (may be covered by Design Controls)							
a) Biocompatibility data for all patient-contacting materials, OR certification of identical material/formulation:			x				
b) Sterilization and expiration dating information:			x				
c) Software validation & verification:							

Passed Screening: Yes Reviewed by: Pei Sung Concurred by: _____

Orthopaedic Division

Smith & Nephew, Inc.
1450 Brooks Rd., Memphis, TN 38116 U.S.A.
901-396-2121, For information: 1-800-821-5700
For orders and order inquiries: 1-800-238-7538

Smith+Nephew

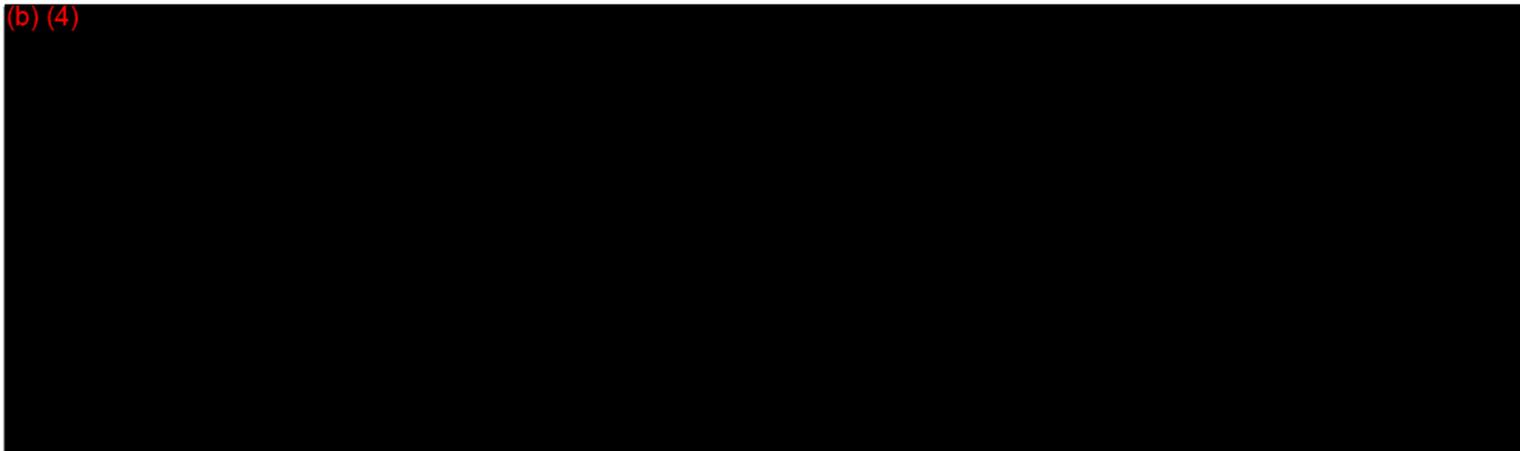
December 5, 2000

Dr. Pei Sung, Reviewer
Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, MD 20850

Re: **K002996**, Abbreviated 510(k) for Synergy HA Coated Porous Femoral Stems

Dear Dr. Sung,

(b) (4)



Sincerely,

SMITH & NEPHEW, INC.

David Henley
Clinical/Regulatory Affairs Specialist

//

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

September 26, 2000

SMITH & NEPHEW, INC.
ORTHOPAEDIC DIVISION
1450 E. BROOKS ROAD
MEMPHIS, TN 38116
ATTN: DAVID HENLEY

510(k) Number: K002996
Received: 25-SEP-2000
Product: SYNERGY HA COATED
POROUS FEMORAL
STEMS

The Center for Devices and Radiological Health (CDRH), Office of Device Evaluation (ODE), has received the Premarket Notification you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act (Act) for the above referenced product. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in any future correspondence that relates to this submission. We will notify you when the processing of your premarket notification has been completed or if any additional information is required. YOU MAY NOT PLACE THIS DEVICE INTO COMMERCIAL DISTRIBUTION UNTIL YOU RECEIVE A LETTER FROM FDA ALLOWING YOU TO DO SO.

On January 1, 1996, FDA began requiring that all 510(k) submitters provide on a separate page and clearly marked "Indication For Use" the indication for use of their device. If you have not included this information on a separate page in your submission, please complete the attached and amend your 510(k) as soon as possible. Also if you have not included your 510(k) Summary or 510(k) Statement, or your Truthful and Accurate Statement, please do so as soon as possible. There may be other regulations or requirements affecting your device such as Postmarket Surveillance (Section 522(a)(1) of the Act) and the Device Tracking regulation (21 CFR Part 821). Please contact the Division of Small Manufacturers Assistance (DSMA) at the telephone or web site below for more information.

Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the Document Mail Center will not be considered as part of your official premarket notification submission. Because of equipment and personnel limitations, we cannot accept telefaxed material as part of your official premarket notification submission, unless specifically requested of you by an FDA official. Any telefaxed material must be followed by a hard copy to the Document Mail Center (HFZ-401).

You should be familiar with the manual entitled, "Premarket Notification 510(k) Regulatory Requirements for Medical Devices" available from DSMA. If you have other procedural or policy questions, or want information on how to check on the status of your submission (after 90 days from the receipt date), please contact DSMA at (301) 443-6597 or its toll-free number (800) 638-2041, or at their Internet address <http://www.fda.gov/cdrh/dsmamain.html> or me at (301) 594-1190.

Sincerely yours,

Marjorie Shulman
Consumer Safety Officer
Premarket Notification Staff
Office of Device Evaluation

12

2602996

Orthopaedic Division

Smith & Nephew, Inc.
1450 Brooks Rd., Memphis, TN 38116 U.S.A.
901-396-2121, For information: 1-800-821-5700
For orders and order inquiries: 1-800-238-7538

Smith+Nephew

September 22, 2000

Office of Device Evaluation
Document Mail Center (HFZ-401)
Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Blvd.
Rockville, MD 20850

RE: Abbreviated 510(k) for Synergy HA (Hydroxylapatite) Coated Porous Femoral Stems

Dear Sir or Madam:

The purpose of this letter is to notify FDA of our intent to market the Synergy HA Coated Porous Femoral Stems that are modifications of Smith & Nephew's Global Taper "Tapered" (Synergy) Porous Hip Stems cleared for market under 510(k)'s K963509 and K991485. Smith & Nephew is submitting an Abbreviated 510(k) in accordance with requirements set forth in *The New 510(k) Paradigm: Alternative Approaches to Demonstrating Substantial Equivalence in Premarket Notifications*, dated March 20, 1998.

Synergy HA Coated Porous Femoral Stems conform to the following guidance documents: *Draft Guidance Document for Femoral Stem Prostheses*, dated August 01, 1995; *Guidance Document for Testing Orthopedic Implants With Modified Metallic Surfaces Apposing Bone or Bone Cement*, dated April 28, 1994; and *Calicum Phosphate (Ca-P) Coating Draft Guidance for Preparation of FDA Submissions for Orthopedic and Dental Endosseous Implants*, dated November 11, 1992 (reformatted 02/21/97). Ceramic heads designed for use with Synergy HA Coated Porous Femoral Stems conform to the *Guidance Document for the Preparation of Premarket Notifications for Ceramic Ball Hip Systems*, dated January 10, 1995. Additionally, this 510(k) follows the content requirements of the *Draft Guidance Document for the Preparation of Premarket Notification [510(k)] Application for Orthopedic Devices*, dated July 16, 1997 and is organized in outline format for ease of locating specific content. A separate **Table of Contents** and **List of Exhibits** are provided with this submission.

We consider our intent to market these devices to be confidential commercial information, and therefore, exempt from public disclosure. To the best of my knowledge, neither I nor anyone else has disclosed through advertising or any other manner our intent to market these devices, except to employees of, or paid consultants to, our company or individuals in an advertising or law firm pursuant to commercial arrangements with appropriate safeguards for secrecy.

We believe this information fulfills the requirements for the present abbreviated 510(k) submission. Please contact us as soon as possible if clarification or additional information is required.

Sincerely
SMITH & NEPHEW, INC.

David Henley
Clinical/Regulatory Affairs Specialist

OR
II

13

SK 26

ABBREVIATED PREMARKET NOTIFICATION
Synergy HA Coated Porous Femoral Stems

I. ADMINISTRATIVE INFORMATION

- A.** The **TRUTHFUL AND ACCURATE STATEMENT** is provided as **Exhibit 1**.
- B.** The **510(k) SUMMARY** and **INDICATIONS STATEMENT** are provided as **Exhibit 2**.

C. MANUFACTURER IDENTIFICATION

Manufacture's Name:	Smith & Nephew, Inc. Orthopaedic Division 1450 Brooks Road Memphis, TN 38116
Establishment Registration Number:	1020279
Primary Contact:	David Henley Clinical/Regulatory Affairs Specialist Ph: 901-399-6487; FAX 901-398-5146
Secondary Contact:	Neal Defibaugh Manager, Clinical/Regulatory Affairs Ph: 901-399-5363; FAX 901-398-5146

D. DEVICE IDENTIFICATION

Proprietary Name
Synergy HA Coated Porous Femoral Stems

Common Name
Prosthetic Hip Joint – HA Coated Porous Femoral Stem

Classification Name and Reference
21 CFR 888.3358 – hip joint metal/polymer/metal semi-constrained porous coated uncemented prosthesis - Class II

Device Classification for the predicate device(s)
21 CFR 888.3358 – hip joint metal/polymer/metal semi-constrained porous coated uncemented prosthesis - Class II

Device Product Code and Panel Code
MEH / 87 (Orthopedics)

II. DEVICE INFORMATION

A. INTENDED USE

Total hip components are indicated for use in individuals undergoing primary and revision surgery where other treatments or devices have failed in rehabilitating hips damaged as a result of trauma, inflammatory joint disease such as rheumatoid arthritis, or non-inflammatory degenerative joint disease (NIDJD) or any of its composite diagnoses such as osteoarthritis; avascular necrosis; traumatic arthritis; slipped capital epiphysis; fused hip; fracture of the pelvis and diastrophic variant; old, remote osteomyelitis with an extended drainage-free period; non-union; femoral neck fracture and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques; femoral osteotomy, or Girdlestone resection; fracture dislocation of the hip; and correction of deformity. *Synergy HA Coated Porous Femoral Stems* are indicated for uncemented use only *and* for single use only. These stems can be used with cobalt chrome or ceramic, modular femoral heads with a 12/14 taper that were cleared for market through the submissions listed in the table below.

Description	Submission Number	Clearance Date
Cobalt Chrome Femoral Heads with 12/14 Taper	K963486	11-27-96
Zirconia Femoral Heads (Desmarquest) with 12/14 Taper	K971414	07-16-97
BioloX Alumina Ceramic Femoral Heads with 12/14 Taper	K981847	07-17-98
BioloX Alumina Ceramic Femoral Head, 28 mm Long with 12/14 Taper	K991162	01-28-00

B. DEVICE DESCRIPTION

Components from the Global Taper Tapered Hip System (currently known as the Synergy Hip System) were cleared for market under 510(k)'s identified in the following table.

Description	Submission Number	Clearance Date
Global Taper Tapered (Synergy) HA Hip Stems	K970337 ✓	02/28/97
Global Taper Tapered (Synergy) Hip System (including porous coated hip stems)	K963509 ✓	02/10/97
Synergy Porous Size 8 Hip Stem	K991485	07/12/99
Synergy Cemented Hip Stems	K990369	03/12/99

Components cleared under 510(k)'s K963509 and K991485 included femoral hip stems with a "rough coat" porous coating on the proximal body. **The purpose of this premarket notification submission is to add *Synergy HA Coated Porous Femoral Stems* to the Synergy Hip System.** A description of *Synergy HA Coated Porous Femoral Stems* is provided in the following sections. Representative drawings are provided as **Exhibit 3**. Summary Reports outlining Smith & Nephew's conformance to the following guidance documents are provided in **Exhibit 4**.

- *Guidance Document for Femoral Stem Prostheses*, dated August 01, 1995.
- *Guidance Document for Testing Orthopedic Implants With Modified Metallic Surfaces Apposing Bone or Bone Cement*, dated April 28, 1994.

- *Calcium Phosphate (Ca-P) Coating Draft Guidance for Preparation of FDA Submissions for Orthopedic and Dental Endosseous Implants*, dated November 11, 1992 (reformatted on 02-21-97).
- *Guidance Document for Preparation of Premarket Notifications for Ceramic Ball Hip Systems*, dated January 05, 1995.

***Synergy HA Coated Porous Femoral Stems*, that are the subject of this submission, utilize previously approved porous coated femoral stems from the Synergy Hip System cleared for market under K963509 and K991485. The only difference is the addition of a proprietary HA coating to the porous coated area on the proximal body of the Synergy porous hip stem, thus creating *Synergy HA Coated Porous Femoral Stems*. The proprietary HA coating utilized on Synergy HA Coated Porous Femoral Stems is identical to the HA coating used on Smith & Nephew's Hydroxylapatite Reflection® Acetabular Shells cleared for market 05-05-99 under K990666. The design of *and the manufacturing processes used for the Synergy porous coated femoral stems (K963509 and K991485)* will not be changed.**

Synergy HA Coated Porous Femoral Stems are straight, tapered, collarless components that utilizes identical design characteristics and geometries found in porous coated femoral stem components currently included in the Synergy Hip System (K963509). The upper, proximal body of *Synergy HA Coated Porous Femoral Stems* will have a "rough coat" porous coated area utilizing a -45/+60 mesh size, CP (commercially pure) titanium, vacuum sintered bead *identical* to that on the currently approved porous coated femoral hip stem components in the Synergy Hip System (K963509 and K991485). *Synergy HA Coated Porous Femoral Stems* will utilize the 12/14 "global taper" for modular femoral head attachment. The taper has the same design as used on components cleared under K963509 and K991485. A proprietary hydroxylapatite (HA) coating will be applied to the porous coated area on the *Synergy HA Coated Porous Femoral Stems* [REDACTED] b(4)Tra [REDACTED] de [REDACTED]. All other design characteristics and surface finishes are *identical* to those utilized on previously cleared Synergy porous coated femoral stems (K963509 and K991485).

Synergy HA Coated Porous Femoral Stem will be made available in sizes 9 through 20 in both standard and high offset versions. Except for sizes 19 and 20, this is the same size range that is presently available with Synergy Porous Femoral Stems (i.e. size 8 cleared under K991485 and sizes 9 through 18 cleared under K963509). As previously mentioned, the size 8 *Synergy HA Coated Porous Femoral Stem* will be available in a *standard offset version only*.

Fatigue Strength Analysis & Static Shear Strength of the Surface/Substrate Interface

For the purposes of this submission, references are made to fatigue strength analyses performed on the worst case stem sizes and an analysis of the static shear strength of the surface/substrate interface as presented in Synergy Hip System 510(k) submissions K963509 and K991485. Several Smith & Nephew Orthopaedic Test Reports, a Technical Memo, and hand calculations reporting these analyses from K963509 and K991485 are summarized below and copies are provided in **Exhibits 5 and 6**.

OR-96-84 - *Fatigue Strength Prediction of a New Tapered Hip Stem*, August 1996 - Originally provided as a part of Exhibit 15 in K963509, this test report evaluated the worst

case, size 9 high offset, Tapered (Synergy) Hip Stem using finite element analysis (FEA) and found it exhibited a fatigue strength (b) (4). This strength was found greater than that for the clinically proven size 10.5 DePuy AML® hip stem (see Exhibit 5).

OR-95-144 - (b) (4)
[Redacted]
(See Exhibit 5)

TM116901/1 - (b) (4)
[Redacted]
(see Exhibit 6).

Hand Calculations - Originally provided as Exhibit 5 in K991485, hand calculation results (b) (4)
[Redacted]
Exhibit 6).

HA Coating Design Validation

As previously mentioned, the proprietary HA coating that will be utilized on *Synergy HA Coated Porous Femoral Stems* is identical to the HA coating used on Smith & Nephew's Hydroxylapatite Reflection® Acetabular Shells cleared for market 05-05-99 under K990666. In addition to previously submitted test reports concerning fatigue strength determinations for the Synergy Porous Hip Stems included in K963509 and K991485, (b) (4)
[Redacted]

These tests were conducted in accordance with the following FDA guidance documents: *Calcium Phosphate (Ca-P) Coating Draft Guidance for Preparation of FDA Submissions for Orthopedic and Dental Endosseous Implants*, dated November 11, 1992 (reformatted effective 02-21-97) and *Guidance Document for Testing Orthopedic Implants with Modified Metallic Surfaces Apposing Bone or Bone Cement*, dated April 28, 1996. Summary reports citing Smith & Nephew's efforts to conform to the requirements of these guidance documents are provided in Exhibit 4.

Stem Use with Ceramic Femoral Heads

Synergy HA Coated Porous Femoral Stems are designed for use with Smith & Nephew cobalt chrome, Biolox Alumina Ceramic, and Zirconia Ceramic femoral heads that utilize the 12/14 global taper (see table of premarket submissions provided under section A, Intended Use, on page 2 of this document). Summary reports of testing for the Biolox Alumina Ceramic Femoral Heads and the Zirconia Femoral Heads are provided as a part of **Exhibit 4**.

Information on the femoral heads contained in **Exhibit 4** is the same as that submitted in Exhibit 12 of K983834, Echelon Hip Stems and Exhibit 9 of K990369, Synergy Cemented Hip Stems. Additional information, such as 510(k) clearance letters and (b) (4) is provided as Exhibits 7 and 8, respectively. A (b) (4) (b) (4) (b) (4), is provided as Exhibit 9. (b) (4) is provided as Exhibit 10. The technical memo provided as Exhibit 10 was previously submitted in support of K991162 (b) (4)

C. MATERIAL INFORMATION

Synergy HA Coated Porous Femoral Stems are manufactured from Ti-6Al-4V, titanium alloy material conforming to the requirements of ASTM F1472-93. This is the same material used in the manufacture of Synergy HA stems (K970337) and Porous hip stems (K963509 and K991485). The requirements for the porous coating are the same as that cleared for Synergy Porous hip stems (K963509 and K991485). (b) (4)

Porous coated stems conform to the *Guidance Document for Testing Orthopedic Implants With Modified Metallic Surfaces Apposing Bone or Bone Cement*, dated April 28, 1994 (see summary report provided as a part of **Exhibit 4**). *Synergy HA Coated Porous Hip Stems* are subsequently coated with a proprietary HA coating applied by a plasma spray technique. The HA coating will be applied by (b) (4) (vendor) to Smith & Nephew, Inc. Additional information relevant to the HA coating can be found in (b) (4) (b) (4) Trade Secret in Exhibit 4. A (b) (4) Trade Secret (b) (4) is provided as Exhibit 16. P T ti

The Biolox Alumina Ceramic Femoral Head is manufactured from (b) (4) Trade Secret (ASTM F603 and ISO 6474). Additional information about this material is available in the masterfile for our supplier, (b) (4) (b) (4) is provided as **Exhibit 11**.

The Zirconia Ceramic Femoral Head is manufactured [REDACTED] (b) (4)
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED] is provided as **Exhibit 12**.

D. STERILIZATION INFORMATION

Synergy HA Coated Porous Femoral Stems will be sterilized by [REDACTED] (b) (4)
[REDACTED]. Sterilization information is provided as **Exhibit 13**. If HA porous coated femoral stems are inadvertently contaminated, users are advised to return the unsoiled prosthesis to Smith & Nephew, Inc. for resterilization. **Porous coated implants are not to be resterilized.** They require specialized cleaning procedures.

E. LABELING

Important medical information contained in a package insert is provided as **Exhibit 14**. A sample of the general package labeling is provided as **Exhibit 15**. All carton labels have the same general design and follow the same format. Unfortunately, advertising literature is not available at this time.

F. SUBSTANTIAL EQUIVALENCE INFORMATION

Synergy HA Coated Porous Femoral Stems are very similar to HA Global Taper Tapered (Synergy) Hip Stems. They are also similar to the competitive devices listed below and in **Table 1** provided as **Exhibit 17**. While *Synergy HA Coated Porous Femoral Stems* are not identical to all of the predicates, any differences that may exist do not significantly affect device safety and effectiveness. Therefore, it is concluded that *Synergy HA Coated Porous Femoral Stems* are substantially equivalent to the devices listed below. See **Exhibit 19** for marketing brochures and 510(k)-clearance information on substantially equivalent devices.

- Global Taper Tapered (Synergy) HA Hip Stems (K970337) – Smith & Nephew, Inc.
- Secur-Fit™ HA Hip System (K990203) – Osteonics® Corp.
- Omnifit® HA Hip Stem (K982032) – Osteonics® Corp.
- Meridian® ST/PA Femoral Stem (K971206) – Howmedica
- APR Porous HA Hip Stem (K973124) – Sulzer Orthopedics, Inc.

Synergy HA Coated Porous Femoral Stems are very similar to the Global Taper Tapered (Synergy) HA Hip Stems cleared for market under K970337. Components from the previously approved Synergy HA hip stems have similar physical geometries. Both Synergy stem varieties are made from identical titanium material, offer uncemented fixation, and have the same indications for use. The only difference between the two stem varieties is that *Synergy HA Coated Porous Femoral Stems* have a proprietary HA coating (b) (4)
[REDACTED]

applicability, are provided to fully describe the variance and its impact on the device and to justify said variance.

David Henley
David Henley
Clinical/Regulatory Affairs Specialist

September 22, 2000
Date

Table of Contents
Synergy HA Coated Porous Femoral Stems

SECTION	PAGE #
I. ADMINISTRATIVE INFORMATION	
A. TRUTHFUL and ACCURATE STATEMENT	Exhibit 1
B. 510(K) SUMMARY & INDICATIONS STATEMENT	Exhibit 2
C. MANUFACTURER IDENTIFICATION	1
Manufacturer's Name	
Establishment Registration Number	
Primary and Secondary Contact	
D. DEVICE IDENTIFICATION	1
Proprietary Name	
Common Name	
Classification Name and Reference	
Device Classification for the Predicate Device	
Device Product Code and Panel Code	
II. DEVICE INFORMATION	
A. INTENDED USE	1 – 2
B. DEVICE DESCRIPTION	2 – 5
C. MATERIAL INFORMATION	5
D. STERILIZATION INFORMATION	6
E. LABELING	6
F. SUBSTANTIAL EQUIVALENCE INFORMATION	6
G. DECLARATION of CONFORMITY with CONSENSUS STANDARDS	7

List of Exhibits
Synergy HA Coated Porous Femoral Stems

- Exhibit 1** Truthful and Accurate Statement
- Exhibit 2** 510(k) Summary and Indications Statement
- Exhibit 3** Drawings
- Exhibit 4** Summary Reports:
1) *Guidance Document for Femoral Stem Prostheses*, August 01, 1995.
2) *Guidance Document for Testing Orthopaedic Implants with Modified Metallic Surfaces Apposing Bone or Bone Cement*, April 28, 1994.
3) *Calicum Phosphate (Ca-P) Coating Draft Guidance for Preparation of FDA Submissions for Orthopaedic and Dental Endosseous Implants*, November 11, 1992 (reformatted 02/21/97).
4) *Guidance Document for Preparation of Premarket Notifications for Ceramic Ball Hip Systems*, January 5, 1995.
- Exhibit 5** 1) *Technical Report: OR-96-84, Fatigue Strength Prediction of a New Tapered Hip Stem*, August 1996.
2) *Technical Report: OR-95-144, Static Lap Shear Testing of Ti-6Al-4V with -45/+60 CP Titanium Bead Coating*, December 1995.
- Exhibit 6** 1) *Technical Memo: TM116901/1, Finite Element Analysis of Porous Coated Synergy Size 8 Hip Stem With +4 and -3 Head Offset*, April 26, 1999.
2) Hand Calculation Spreadsheets – Synergy Porous Size 8 Hip Stem
3) *Technical Report: OR-96-89, Analytical Comparison of Size 10, 11, and 12 Porous-Coated Revision Hip Stems and the Size 10.5 DePuy AML MMA Hip Stem*, August 1996.
4) *Technical Report: OR-96-75, Determination of the Maximum Fatigue Load for the Size 1 High Offset Spectron Stem*, August 1996.
- Exhibit 7** Femoral Head 510(k) Clearance Letters for (b) (4) and Zirconia Ceramic 12/14 Global Taper (GT) Femoral Heads
- Exhibit 8** Engineering Drawings for (b) (4) and Zirconia Ceramic Femoral Heads
- Exhibit 9** *Technical Memo: TM181801, Finite Element Analysis of 28mm Medium Offset vs. 32mm Long Offset (b) (4) -H96CCAC*, July 1, 1998.
- Exhibit 10** *Technical Memo: TM306902, Axial Compression Crush Test of 28mm 12/14 Long Taper (b) (4) Heads*, November 3, 1999.

- Exhibit 11** Letter of Access for (b) (4) Masterfile
- Exhibit 12** Letter of Access for (b) (4) Masterfile
- Exhibit 13** Sterilization Information
- Exhibit 14** Sample Package Insert
- Exhibit 15** Sample Package Label
- Exhibit 16** Letter of Access for (b) (4) Masterfile
- Exhibit 17** Table 1 – Substantial Equivalence Information
- Exhibit 18** Synergy HA Coated Porous Femoral Stem
Calcium Phosphate Coating Characterization Form
- Exhibit 19** Marketing and 510(k) Clearance Information on Substantially Equivalent
Devices

Premarket Notification

Truthful and Accurate Statement

I certify that, in my capacity as a Clinical and Regulatory Affairs Specialist for the Orthopaedic Division of Smith & Nephew, Inc., I believe to the best of my knowledge, that all data and information submitted in this 510(k) premarket notification are truthful and accurate and that no material fact has been omitted.

Signature

David Henley

David Henley
Clinical and Regulatory Affairs Specialist

September 22, 2000

Date

510(k) Summary
Synergy HA Coated Porous Femoral Stems

Submitter's name: Smith & Nephew, Inc.
Submitter's address: 1450 Brooks Road, Memphis, TN 38116
Submitter's telephone number: 901-399-6487
Contact person: David Henley
Date summary prepared: September 22, 2000
Trade or proprietary device name: Synergy HA Coated Porous Femoral Stems
Common or usual name: Prosthetic Hip Joint – HA Coated Porous Femoral Stem

Classification name: 21 CFR 888.3358 hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis-Class II 87LPH

**Substantially Equivalent
Legally Marketed Devices**

- Global Taper Tapered (Synergy) HA Hip Stem - Smith & Nephew
- Secur-Fit® HA Hip Stem – Osteonics® Corp.
- Omnifit® HA Hip Stem – Osteonics® Corp.
- Meridian® ST/PA Femoral Stem – Howmedica Corp.
- APR Porous HA Hip System – Sulzer Orthopedics, Inc.

Device Description

Synergy HA Coated Porous Femoral Stems are manufactured from titanium material (Ti-6Al-4V, ASTM F1472) and are porous coated with bead material manufactured from titanium material (Ti-6Al-4V, ASTM F67, Grade 2, with a mesh size of -45/+60. These stems are designed for use with existing Smith & Nephew cobalt chrome or ceramic modular femoral heads with a 12/14 taper.

Device Intended Use

Total hip components are indicated uncemented use only in individuals undergoing primary and revision surgery where other treatments or devices have failed in rehabilitating hips damaged as a result of trauma, inflammatory joint disease such as rheumatoid arthritis, or non-inflammatory degenerative joint disease (NIDJD) or any of its composite diagnoses such as osteoarthritis; avascular necrosis; traumatic arthritis; slipped capital epiphysis; fused hip; fracture of the pelvis; diastrophic variant; old, remote osteomyelitis with an extended drainage-free period; nonunion, femoral neck fracture and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques; femoral osteotomy, or Girdlestone resection; fracture dislocation of the hip; and correction of deformity.

The *Synergy HA Coated Porous Femoral Stem* is designed uncemented use only and for single use only.

Technological characteristics:

Synergy HA Coated Porous Femoral Stems are similar to the legally marketed devices listed above. All of these devices are indicated for total hip replacement, are similar in design to *Synergy HA Coated Porous Femoral Stems*, and have the same technological characteristics.

Performance characteristics:

Data indicate that *Synergy HA Coated Porous Femoral Stems* are substantially equivalent to identified legally marketed devices.

Indications Statement
Synergy HA Coated Porous Femoral Stems

Total hip components are indicated for uncemented use only in individuals undergoing primary and revision surgery where other treatments or devices have failed in rehabilitating hips damaged as a result of trauma, inflammatory joint disease such as rheumatoid arthritis, or non-inflammatory degenerative joint disease (NIDJD) or any of its composite diagnoses such as osteoarthritis; avascular necrosis; traumatic arthritis; slipped capital epiphysis; fused hip; fracture of the pelvis; diastrophic variant; old, remote osteomyelitis with an extended drainage-free period; nonunion, femoral neck fracture and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques; femoral osteotomy, or Girdlestone resection; fracture dislocation of the hip; and correction of deformity.

SUMMARY REPORT

Guidance Document for Femoral Stem Prostheses

The following information is prepared per requirements set forth in the *Guidance Document for Femoral Stem Prostheses*, dated August 1, 1995. Sections provided below are dedicated to the *Synergy HA Coated Porous Femoral Stem*.

Synergy HA Coated Porous Femoral Stem

Material and Design Description

Synergy HA Coated Porous Femoral Stems are line additions to the Global Taper Tapered (Synergy) Hip System cleared for market under 510(k)'s K963509, K970337, and K991485. Features of the *Synergy HA Coated Porous Femoral Stem* design are described in section II, B, *Device Description* as contained in the Abbreviated Premarket Notification. The *Synergy HA Coated Porous Femoral Stem* is designed to accept a variety of femoral heads as stated in section II, A, *Intended Use*. The subject stems are made from titanium (Ti-6Al-4V) material (ASTM F1472) as stated in section II, C, *Material Information*. Drawings of the femoral component are provided in **Exhibit 3**.

Evaluation of Surface Treatments

(b) (4) [REDACTED] proximal body area that has a proprietary coating of [REDACTED] the surface of the central stem body [REDACTED] information describing stem surface treatments is provided in section II, B, *Device Description* as contained in the Abbreviated Premarket Notification and summary reports provided in **Exhibit 4**.

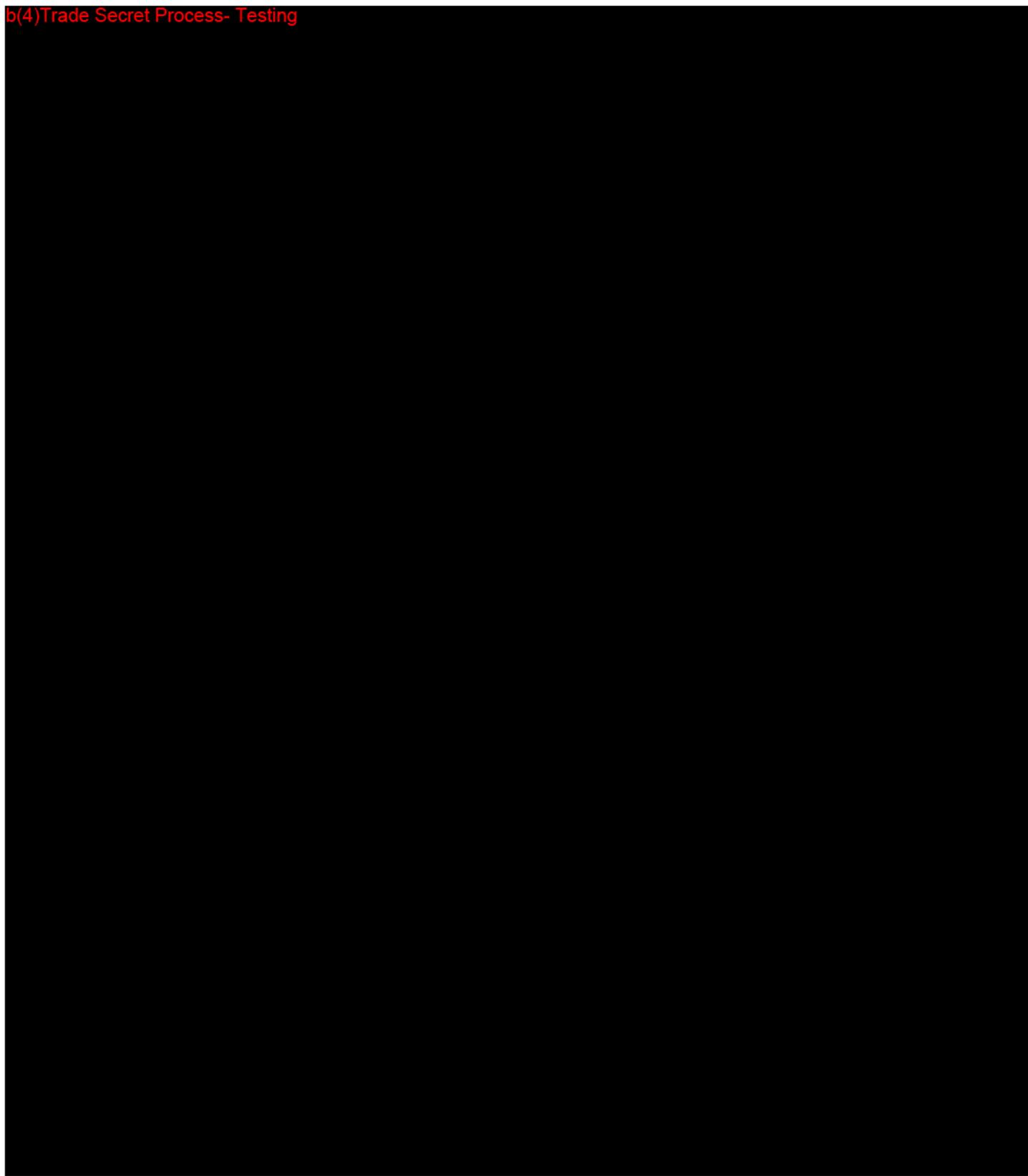
Evaluation of Ceramic Ball Hip Systems

Information describing the evaluation of the *Synergy HA Coated Porous Femoral Stem* per the requirements outlined in the *Guidance Document for Preparation of Premarket Notifications for Ceramic Ball Hip Systems*, dated January 05, 1995, is provided as a part of **Exhibit 4**.

Fatigue Analysis Using FEA and Hand Calculations

(b) (4) [REDACTED] is demonstrated by the [REDACTED]

b(4)Trade Secret Process- Testing



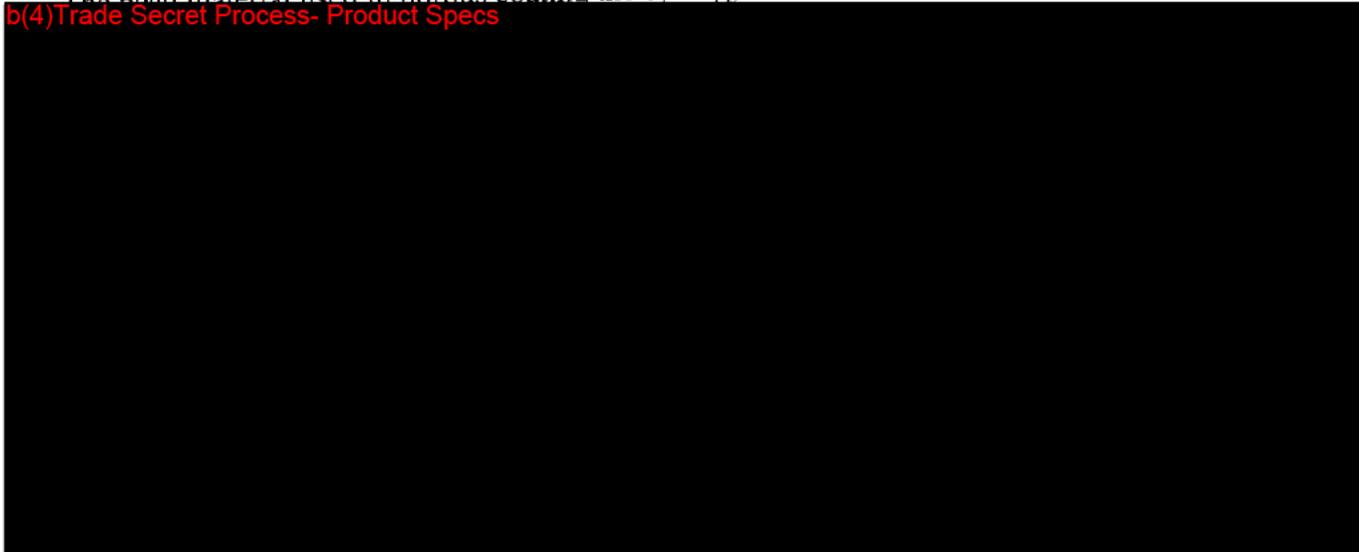
SUMMARY REPORT

Guidance Document for Testing Orthopedic Implants With Modified Metallic Surfaces Apposing Bone or Bone Cement

The following information is prepared per requirements set forth in the *Guidance Document for Testing Orthopedic Implants With Modified Metallic Surfaces Apposing Bone or Bone Cement*, dated April 28, 1994. As this document relates to the Global Taper Tapered (Synergy) Hip System (Synergy Porous Hip Stems) and, more specifically, *Synergy HA Coated Porous Femoral Stems*, engineering drawings for both stem types have identical specifications for porous coating requirements. Thus, the specifications provided below describe conformance to the guidance document request for limited information for *beaded, sintered titanium coatings on a titanium substrate*.

Synergy HA Coated Porous Femoral Stem

The bond material used in porous coating the *Synergy HA Coated Porous Femoral Stem* conforms
b(4)Trade Secret Process- Product Specs



The porous coating information cited above is also contained in Smith & Nephew Orthopaedics test report OR-95-144 and was originally provided in Exhibit 15 of 510(k) K963509 and is included in this submission as a part of **Exhibit 5**.

SUMMARY REPORT

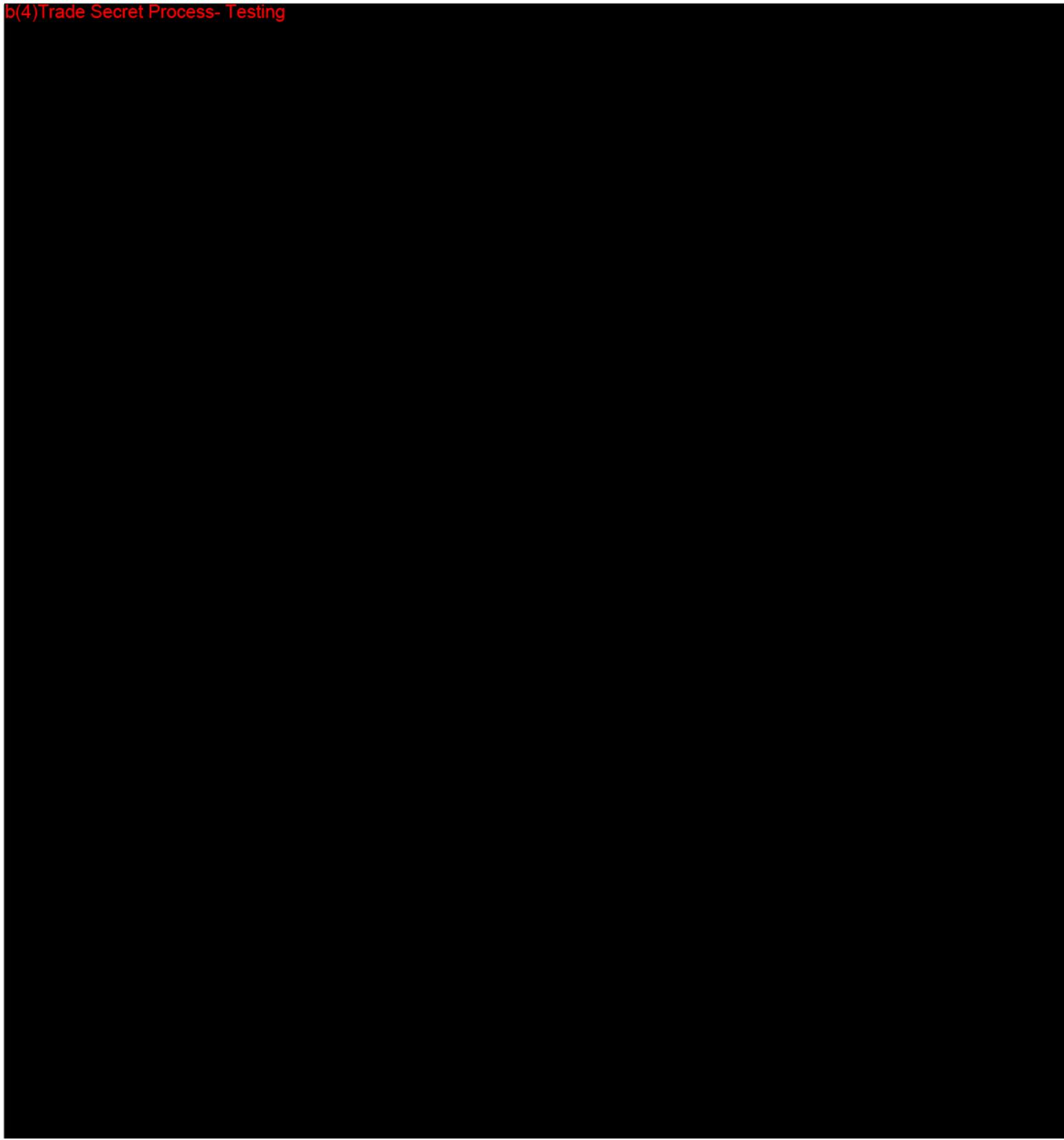
Calcium Phosphate (Ca-P) Coating Draft Guidance for Preparation of FDA Submissions for Orthopedic and Dental Endosseous Implants

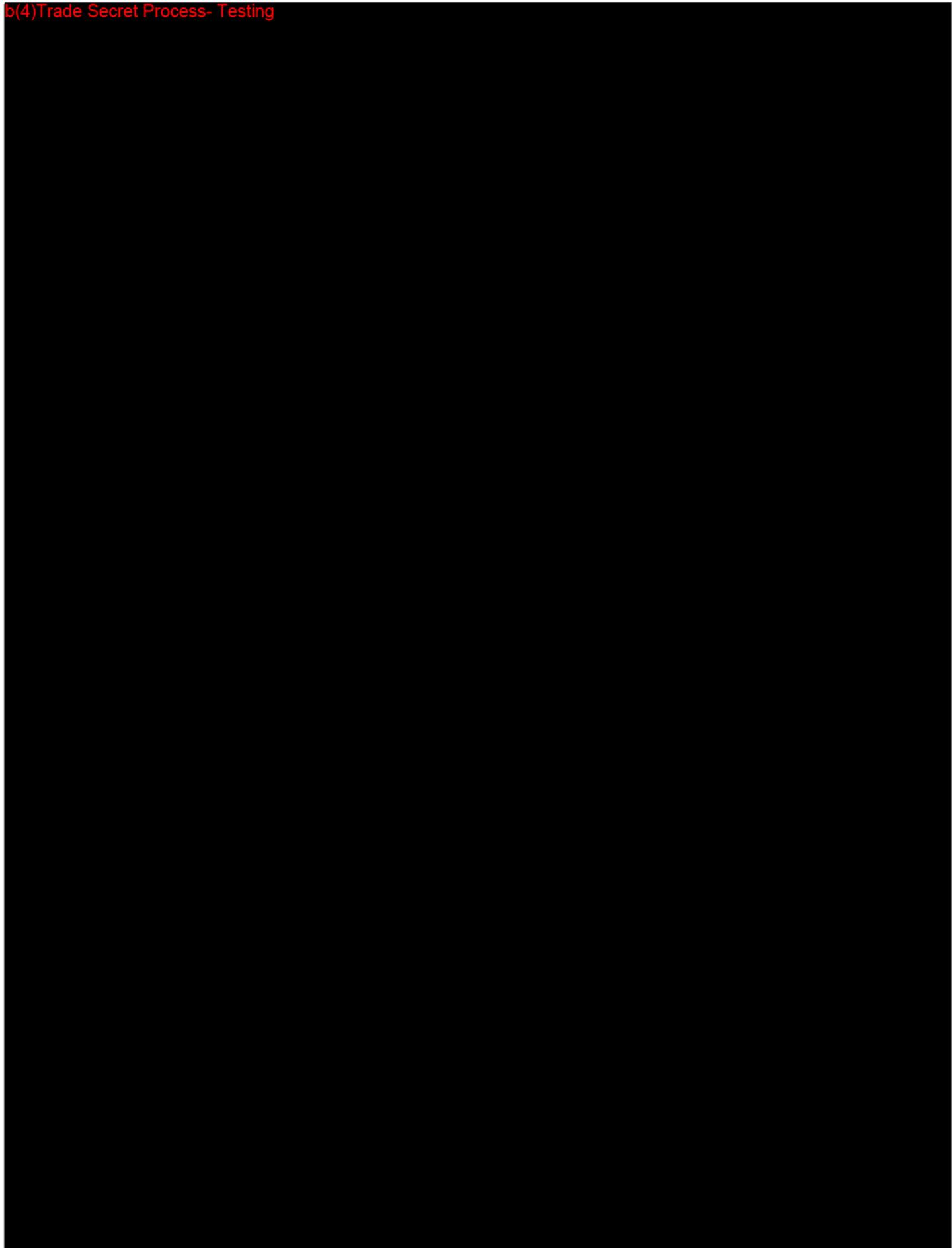
The following information is prepared per requirements set forth in FDA guidance *Calcium Phosphate (Ca-P) Coating Draft Guidance for Preparation of FDA Submissions for Orthopedic and Dental Endosseous Implants*, dated November 11, 1992 (reformatted 2/21/97).

Information on Coating Application and Characterization, as described in sections III and IV of the subject FDA guidance document, is provided in detail in (b) (4) Device Master File, MAF-339. A letter authorizing FDA access to (b) (4) Device Master File in support of regulatory submissions by Smith & Nephew, Inc. is provided as **Exhibit 16**. This information is also provided in summary form as outlined in section VI of the subject FDA guidance document. A summary document entitled Calcium Phosphate Coating Characterization Form, formatted as required by section VI of the guidance document, is provided in this submission as **Exhibit 18**.

SUMMARY OF TESTING

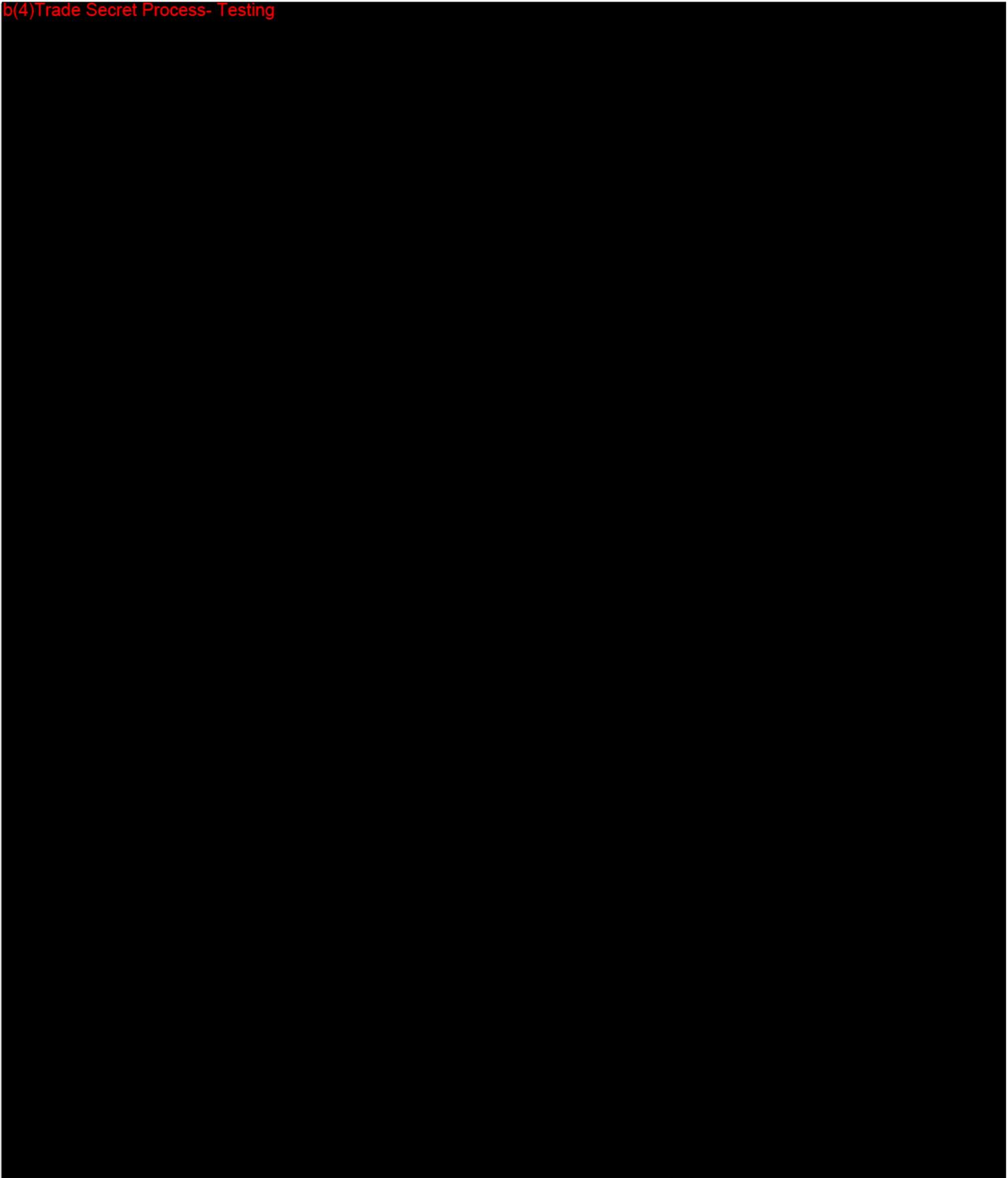
b(4)Trade Secret Process- Testing

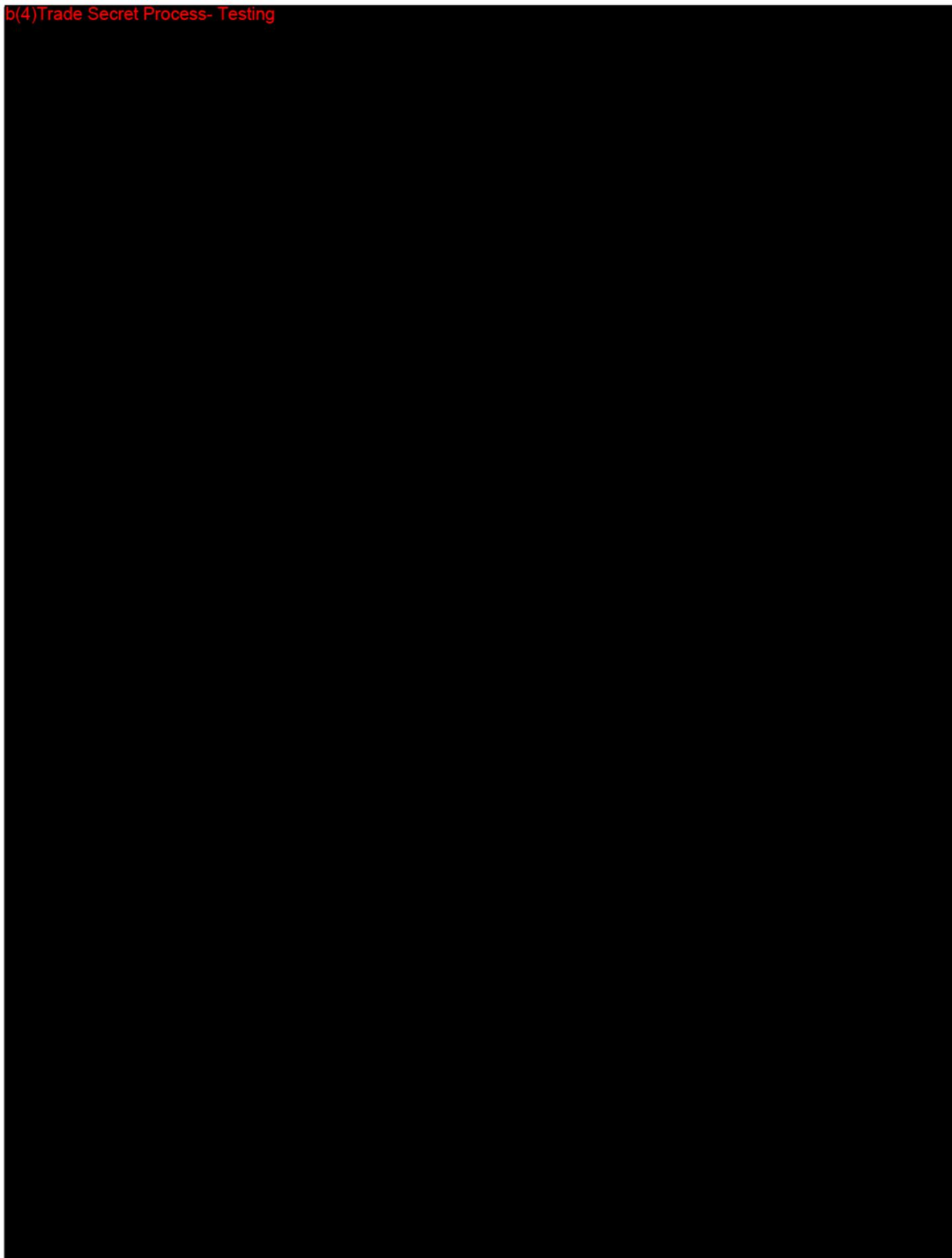




SUMMARY OF TESTING

b(4)Trade Secret Process- Testing





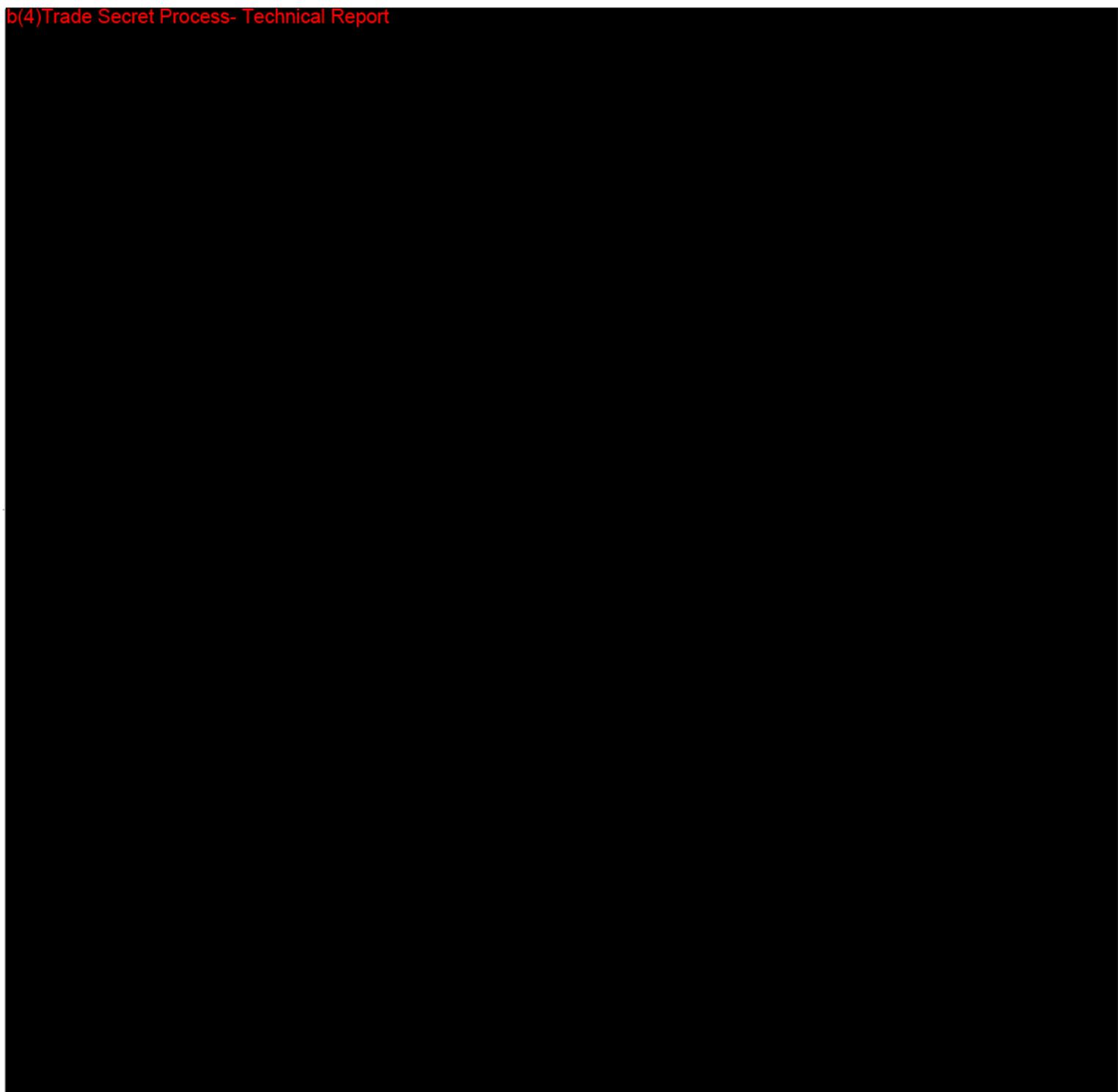
SMITH & NEPHEW ORTHOPAEDICS

Smith & Nephew Richards Inc.
Orthopaedic Research Department
1450 Brooks Road
Memphis, TN 38116

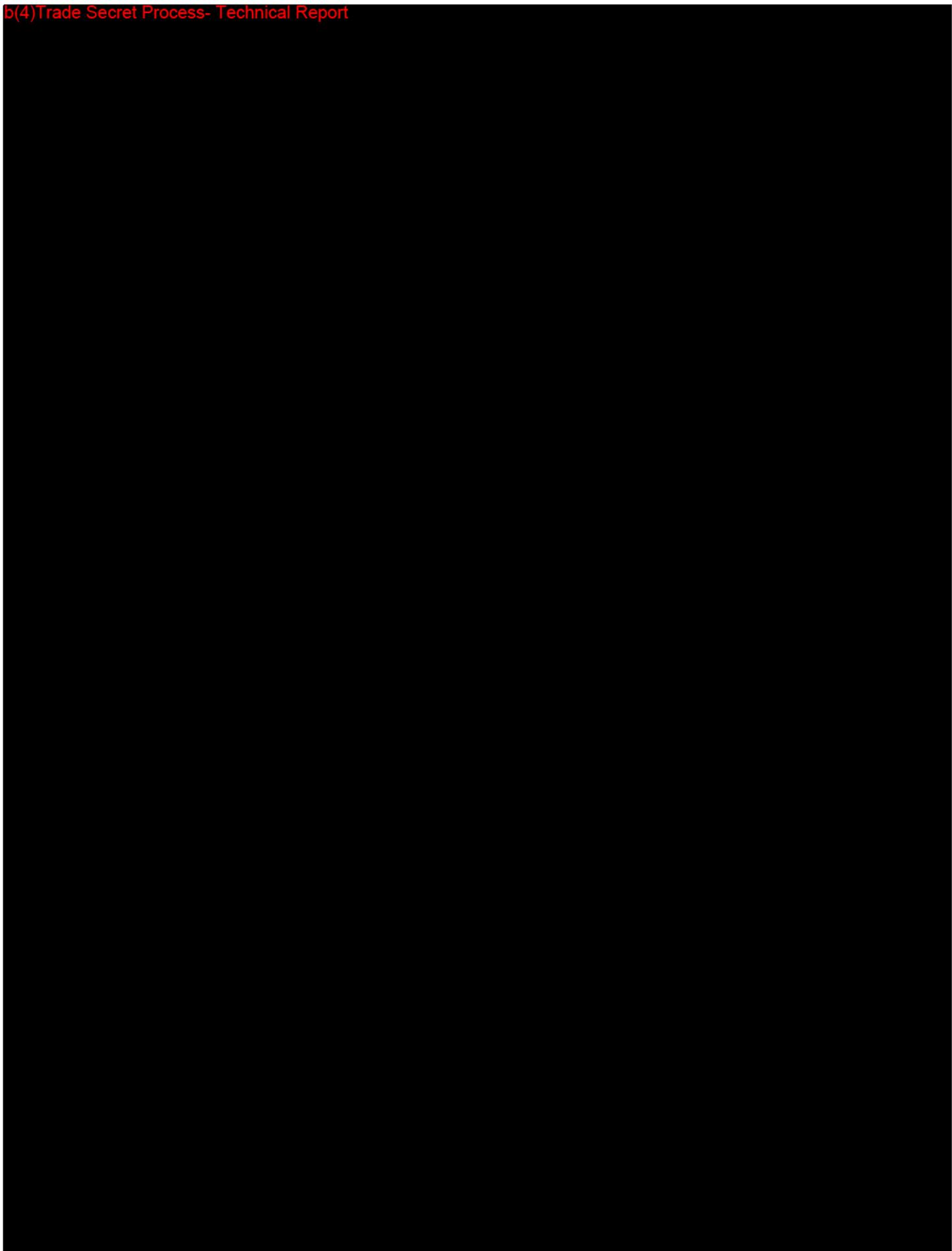
RED IS
CONTROLLED
COPY
COPY _____

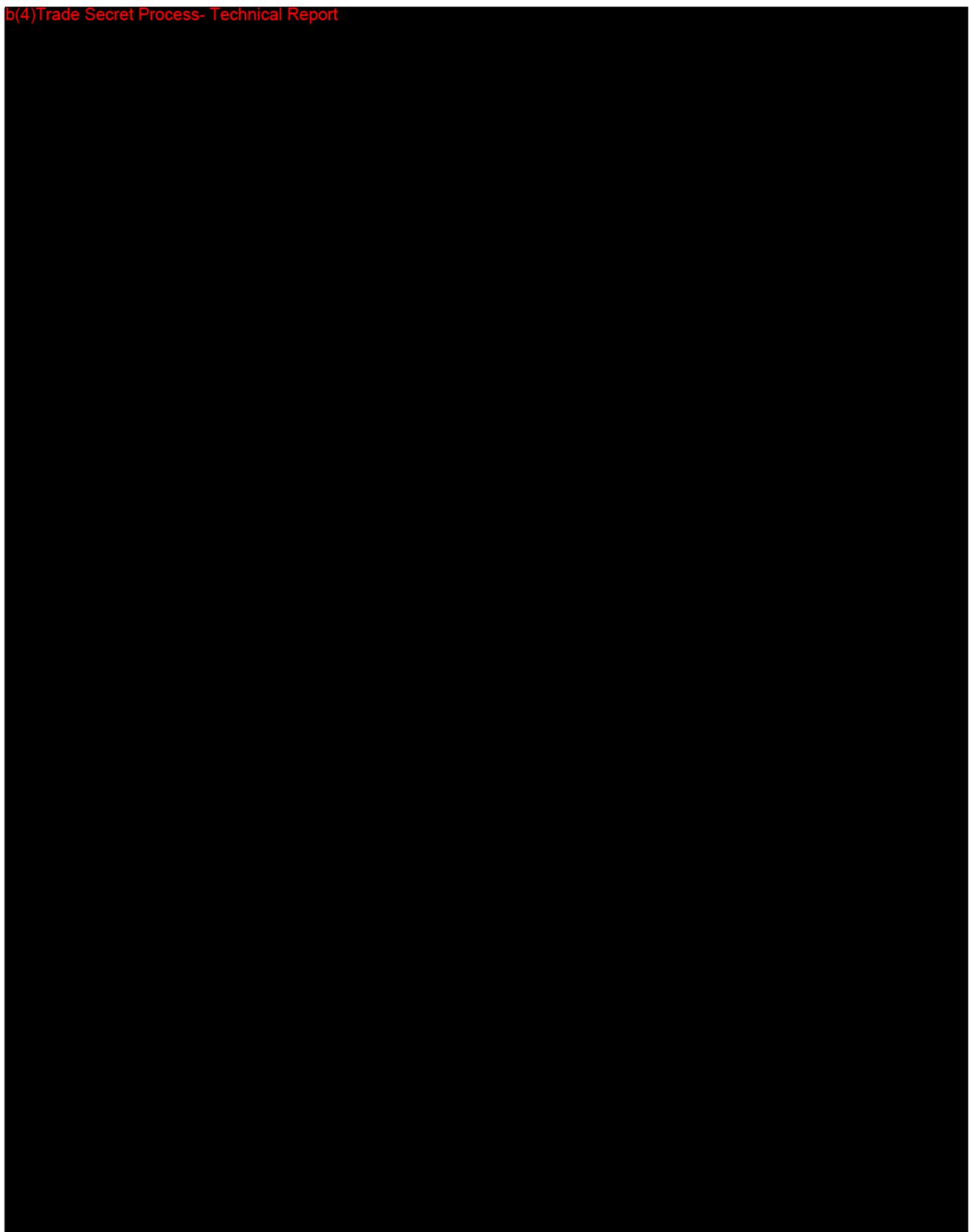
TECHNICAL REPORT

b(4)Trade Secret Process- Technical Report

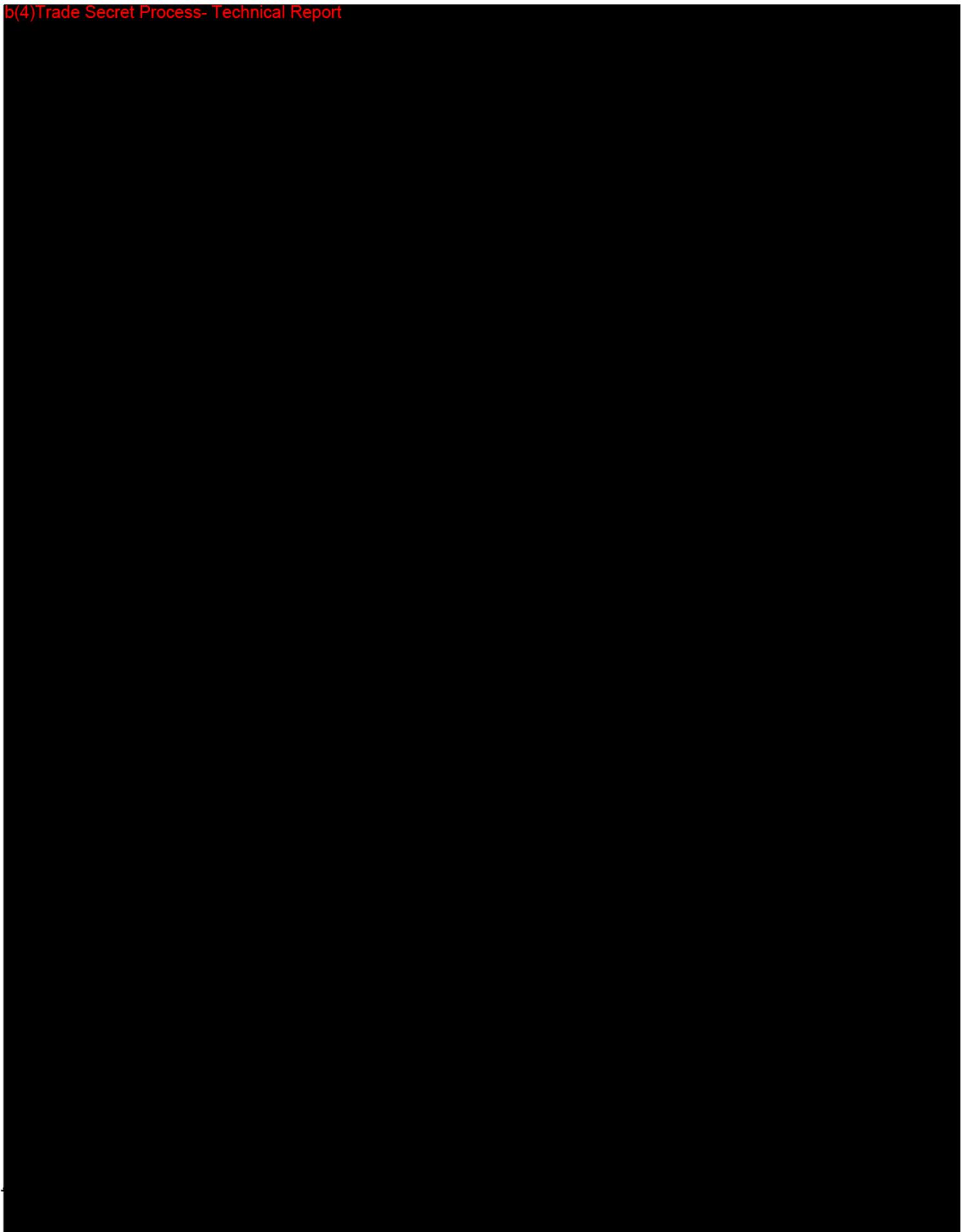


b(4)Trade Secret Process- Technical Report

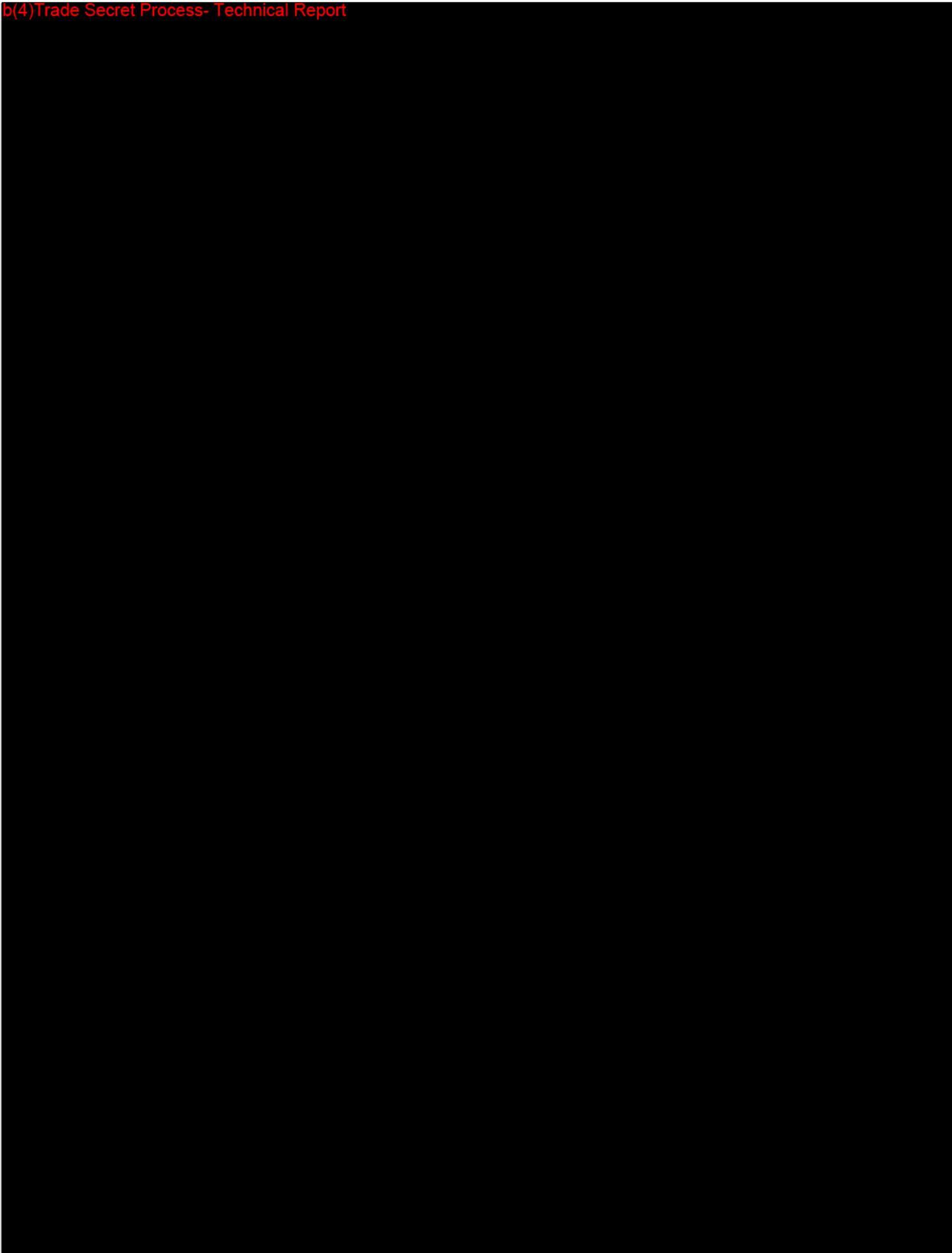


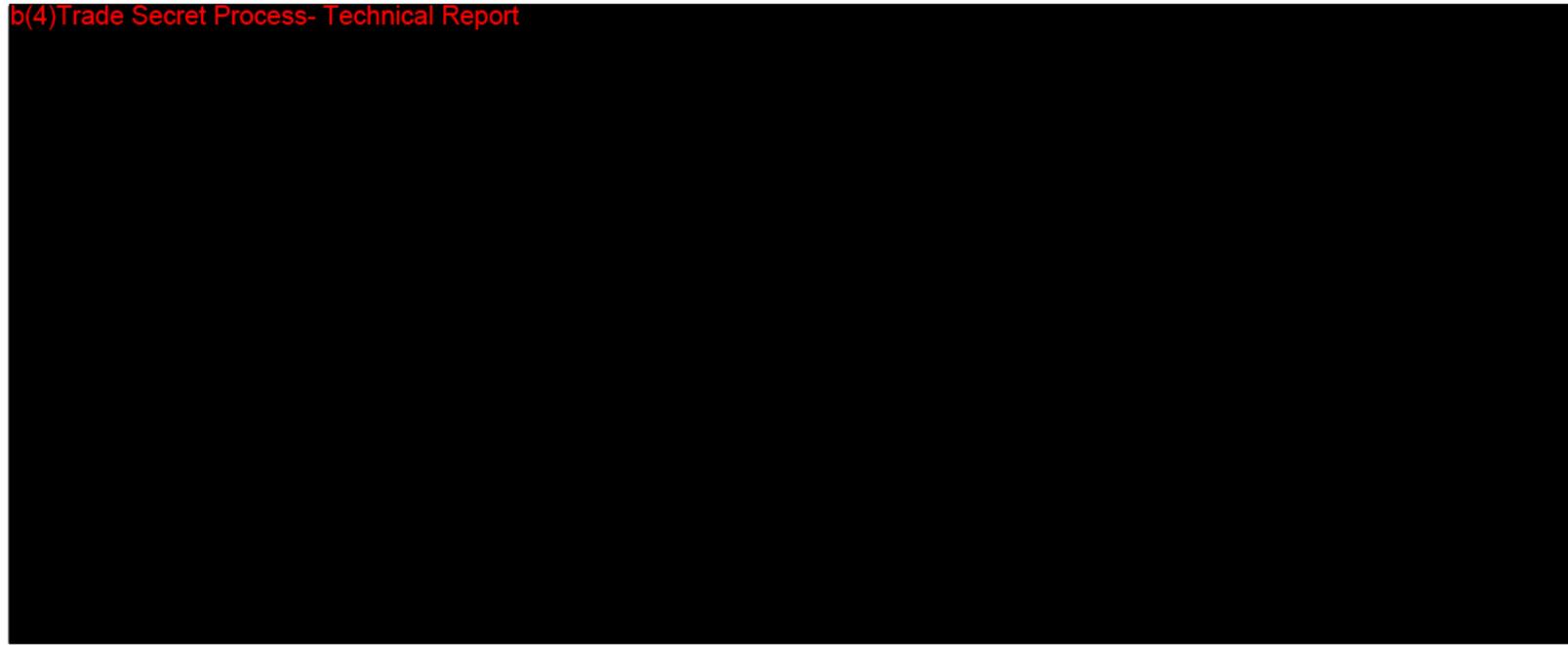


b(4)Trade Secret Process- Technical Report



b(4) Trade Secret Process- Technical Report





b(4)Trade Secret Process- Technical Report

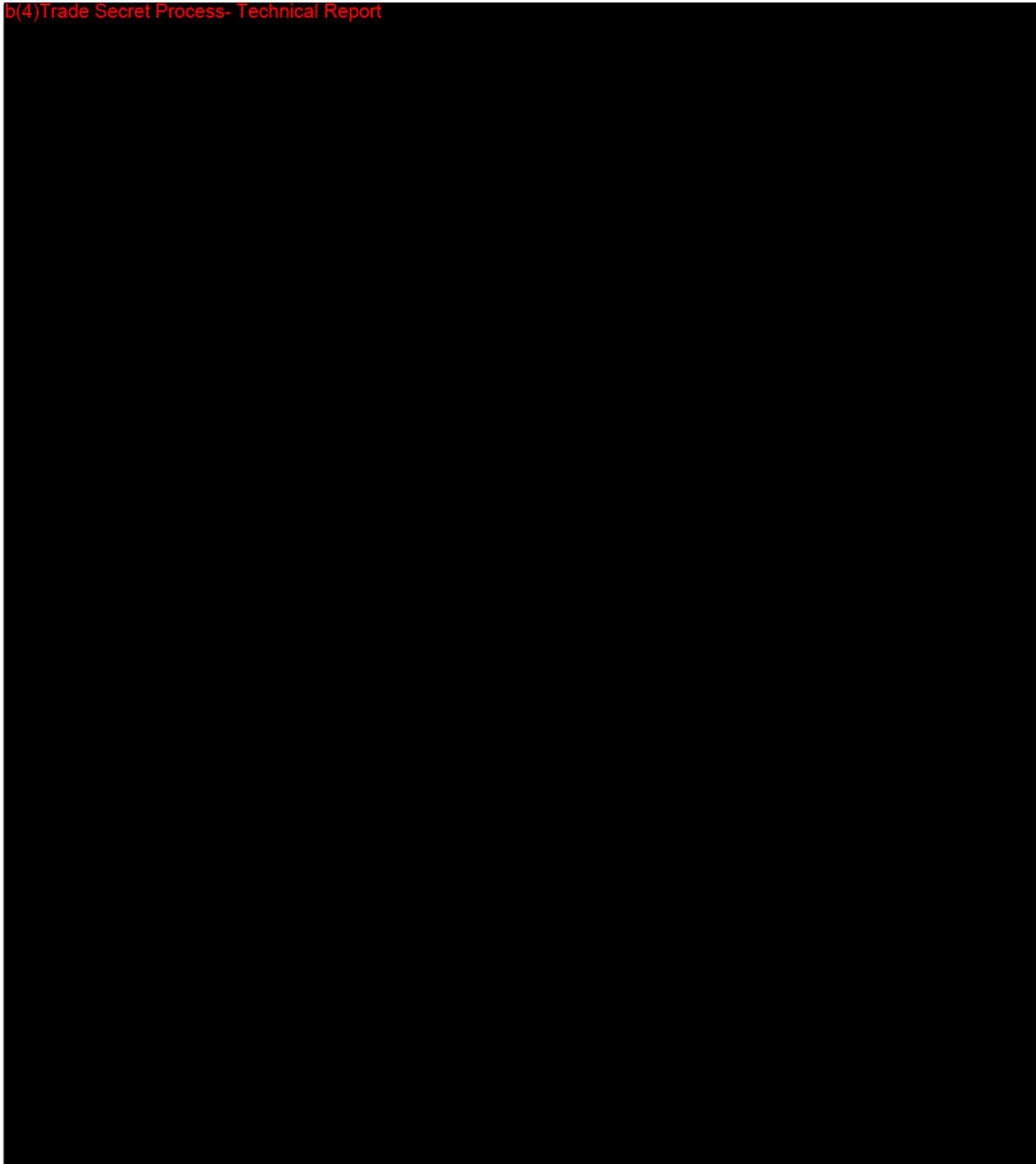


OR-96-84

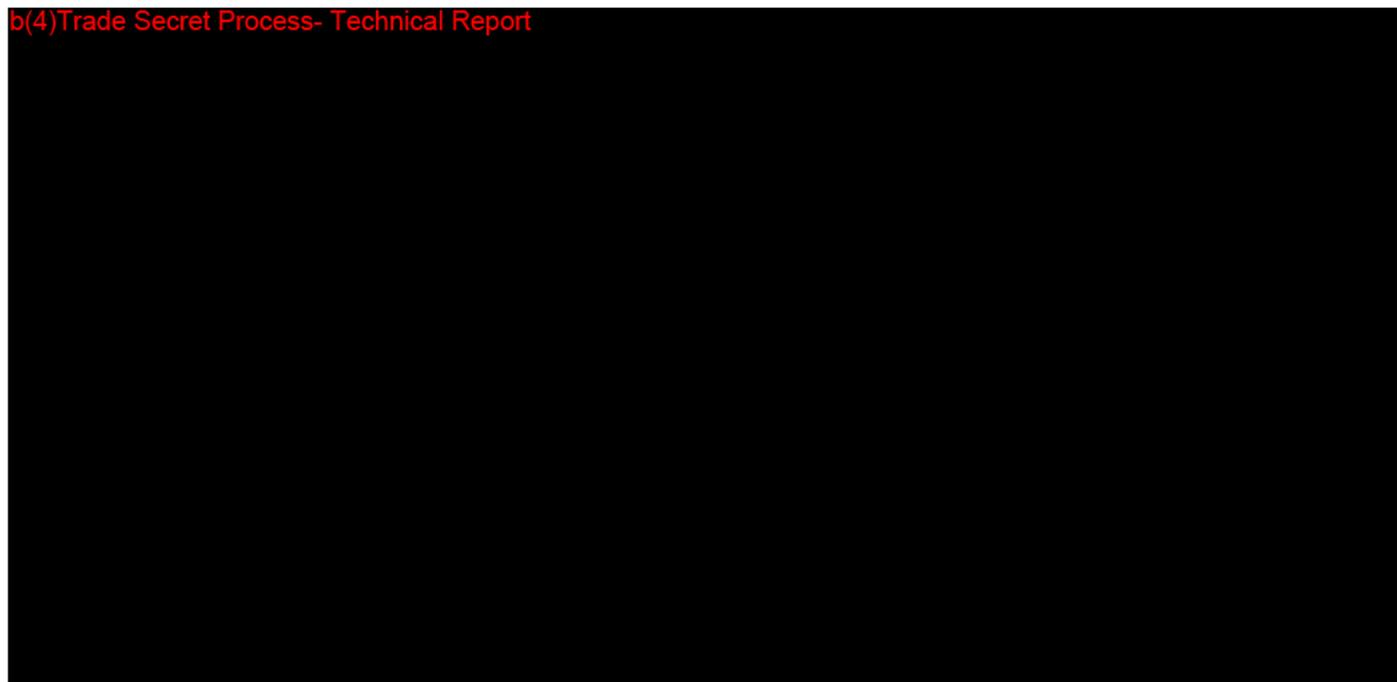
CONFIDENTIAL
SMITH & NEPHEW LIMITED

45

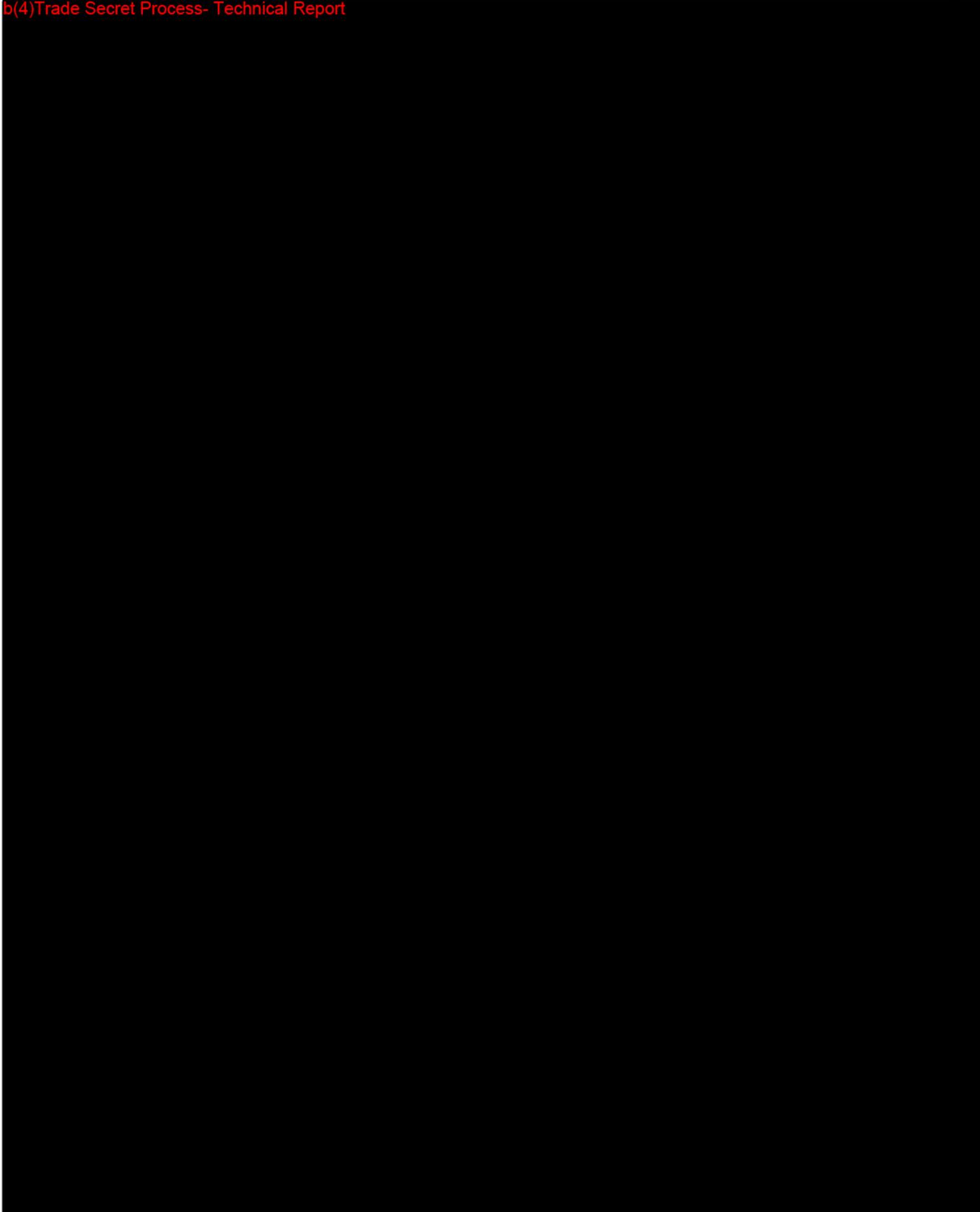
b(4)Trade Secret Process- Technical Report

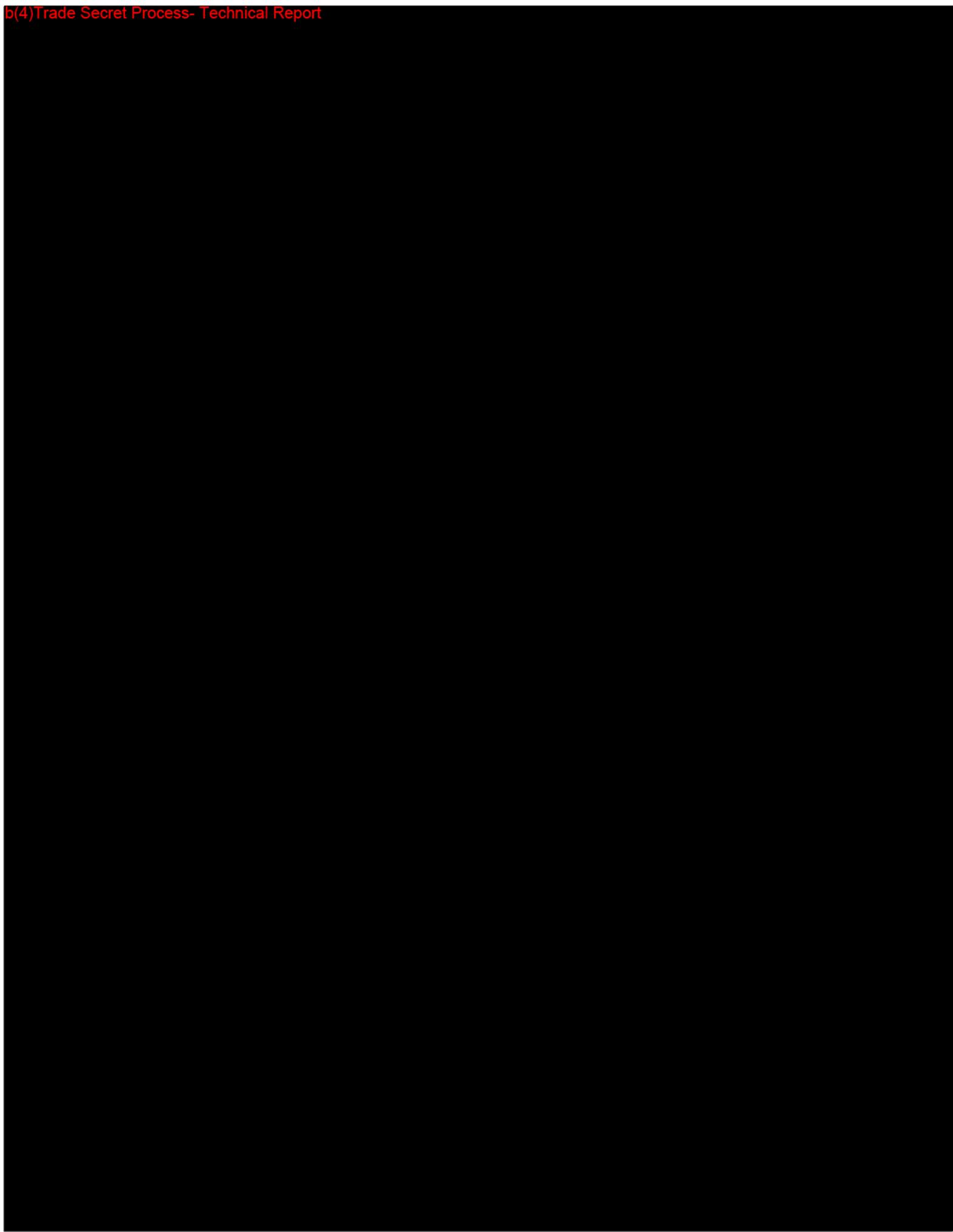


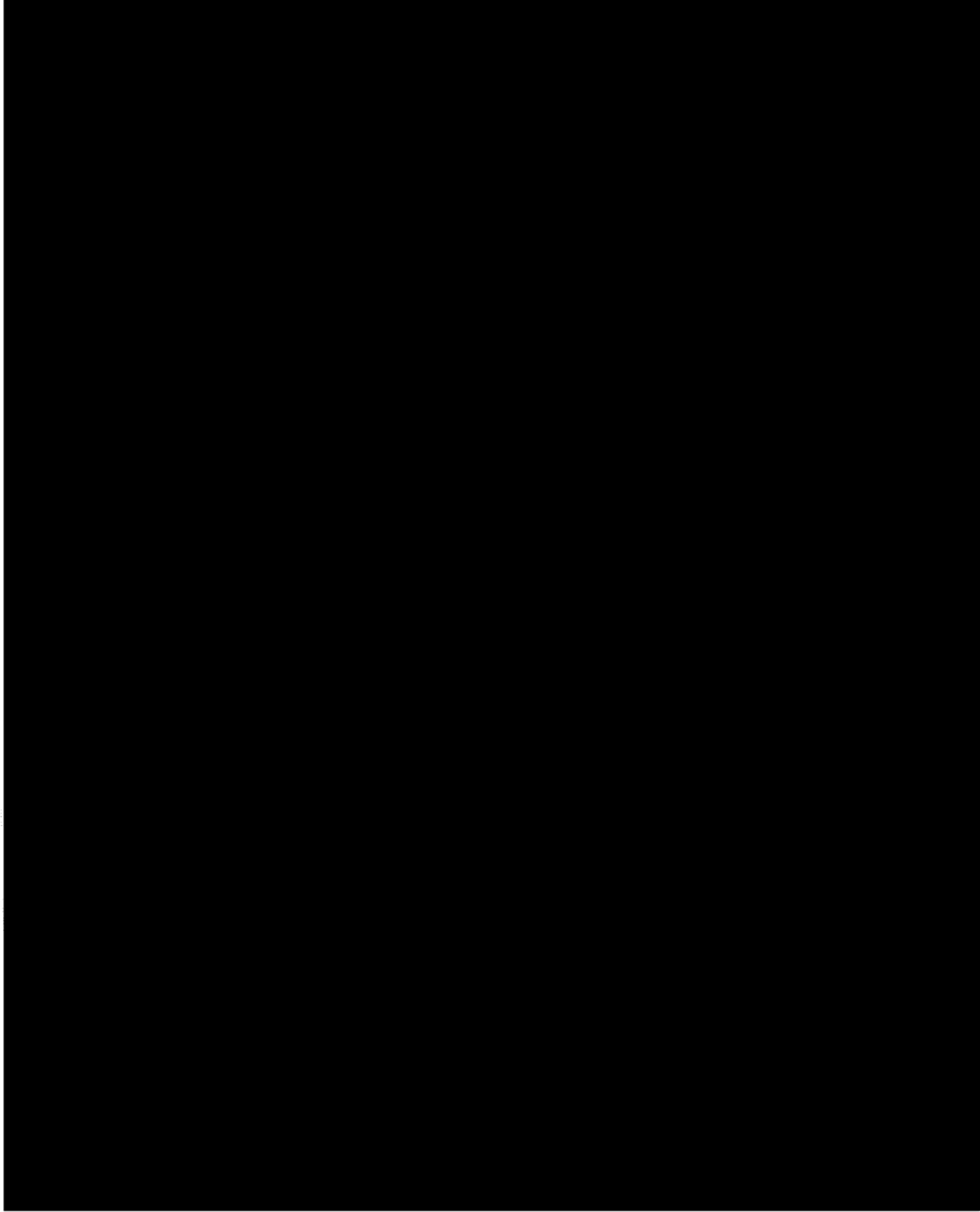
b(4)Trade Secret Process- Technical Report



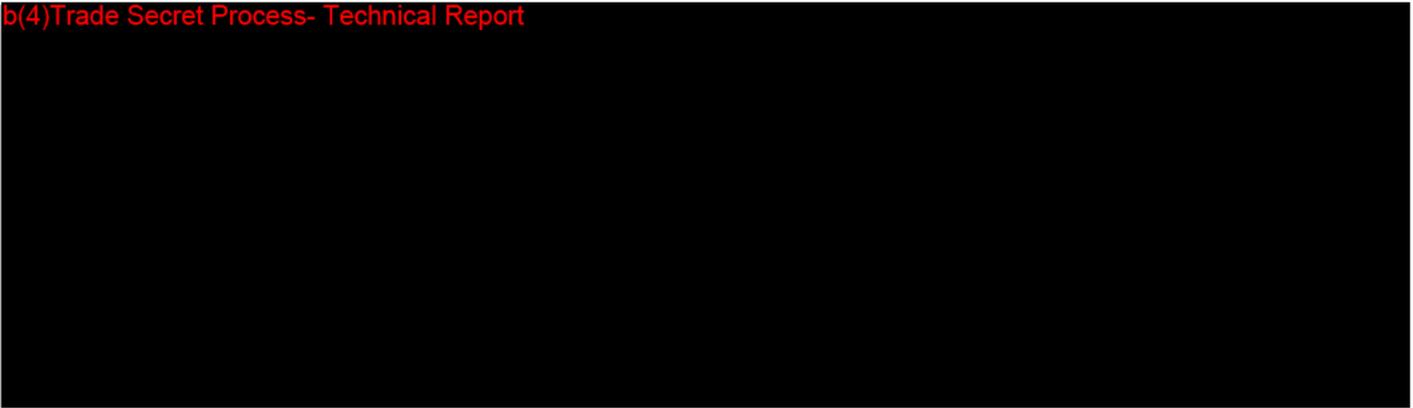
b(4)Trade Secret Process- Technical Report



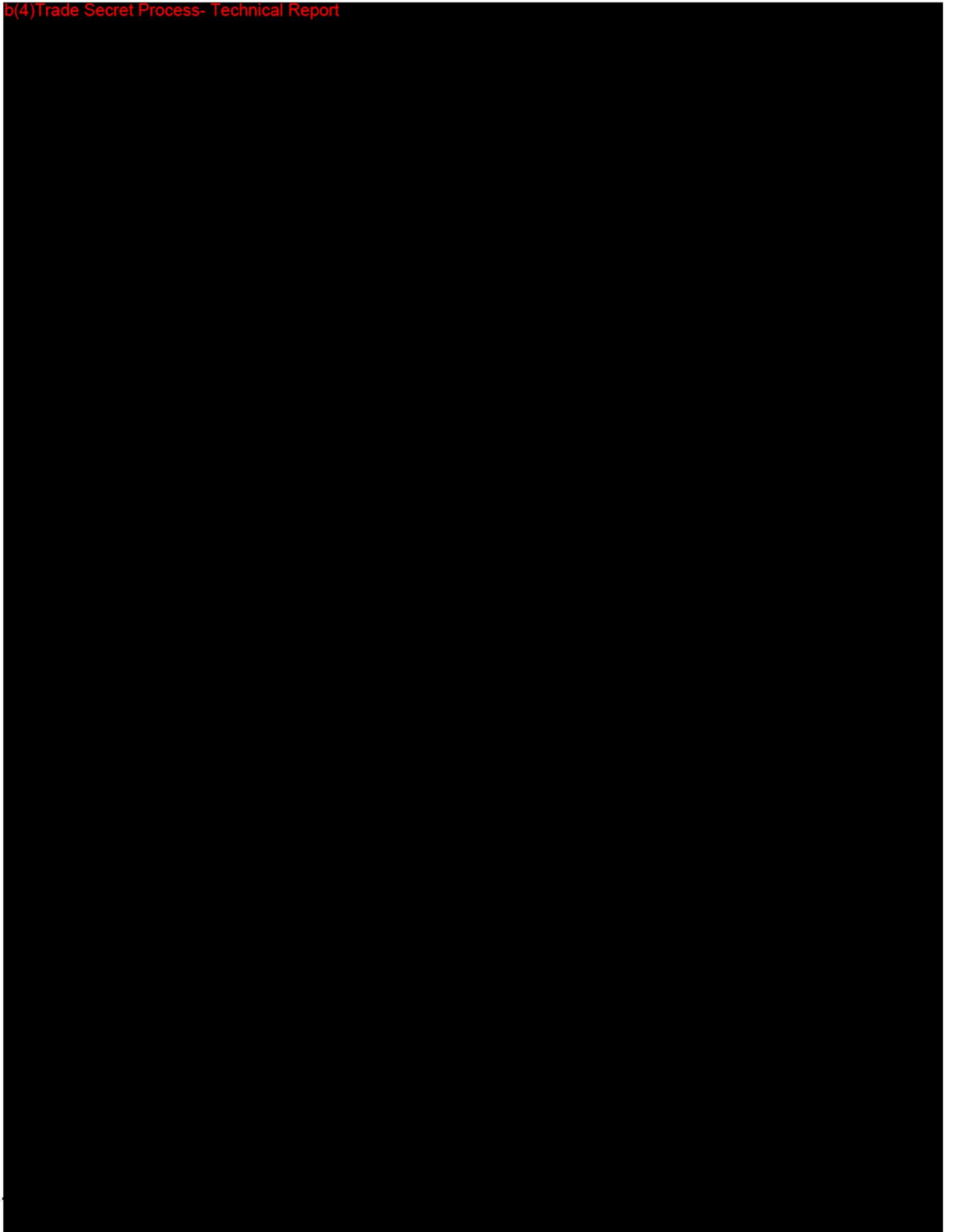




b(4)Trade Secret Process- Technical Report



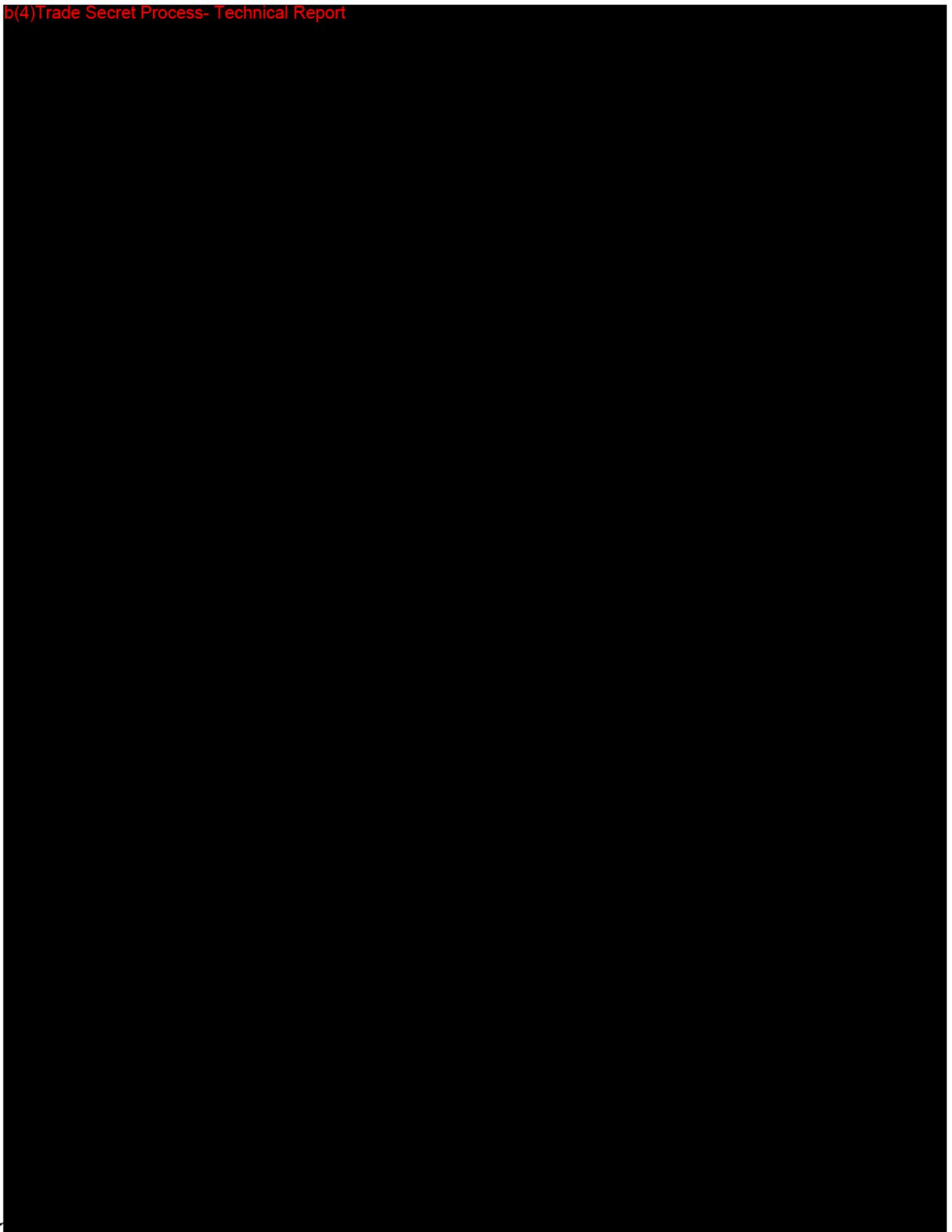
53

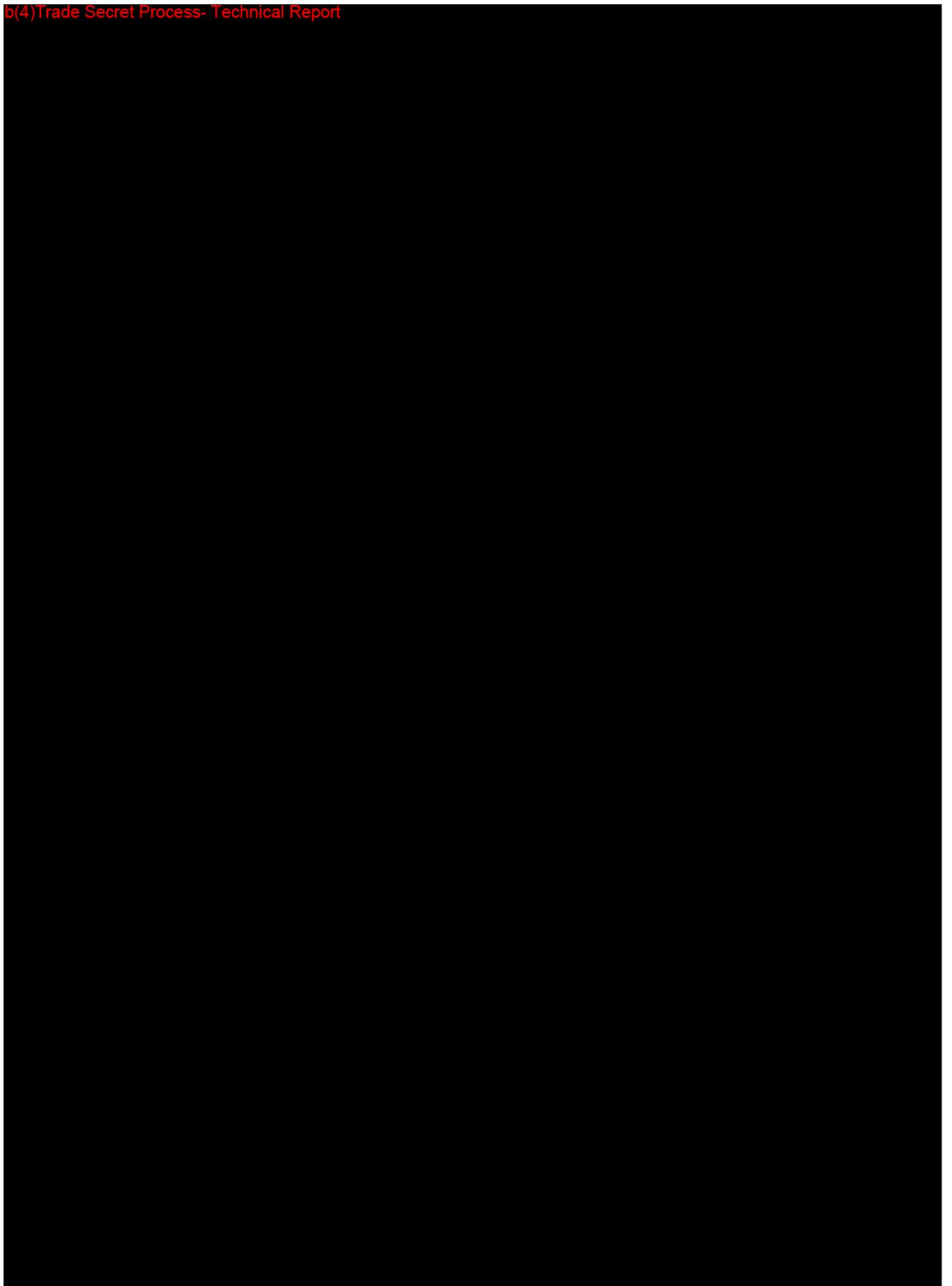


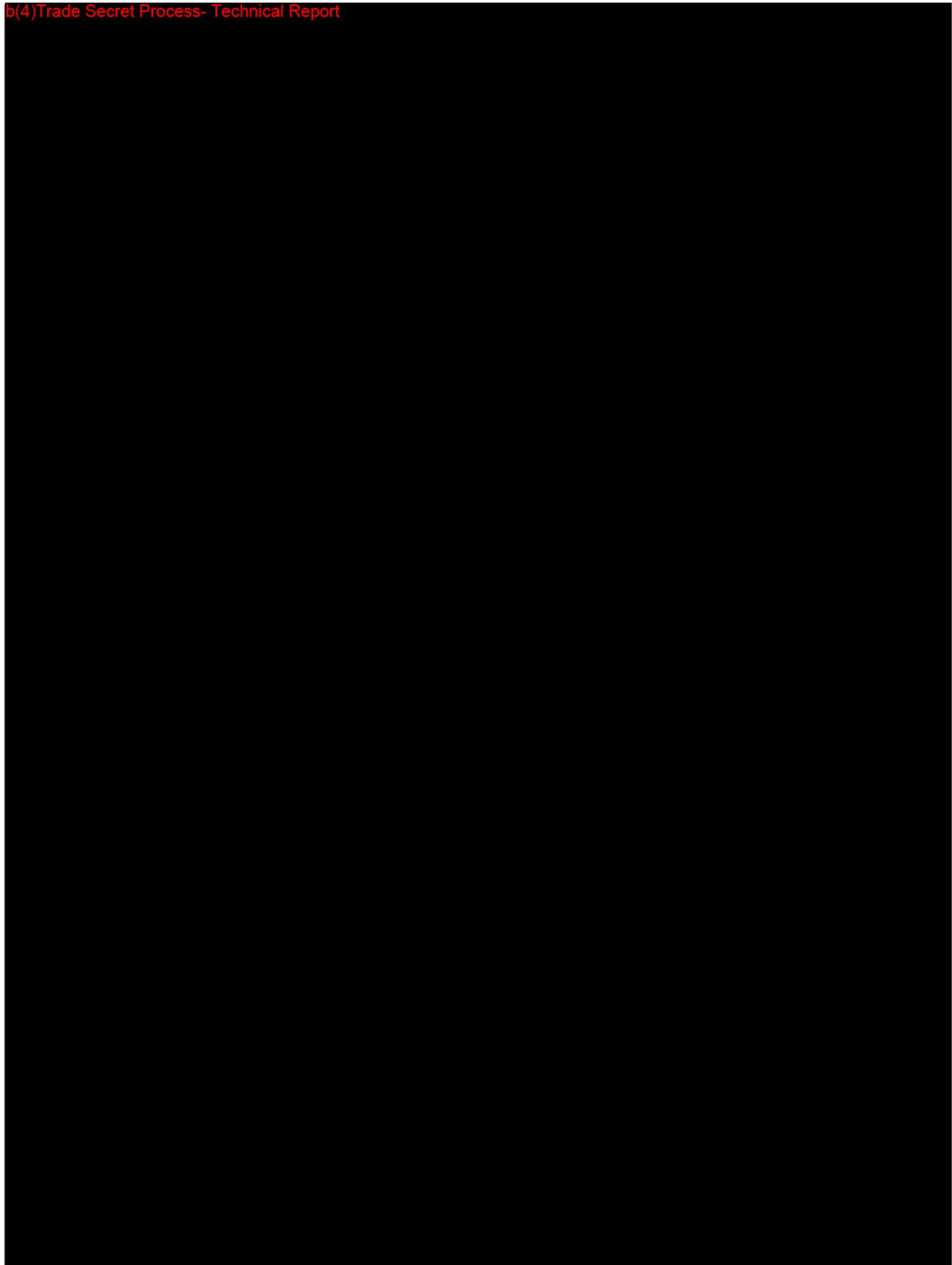


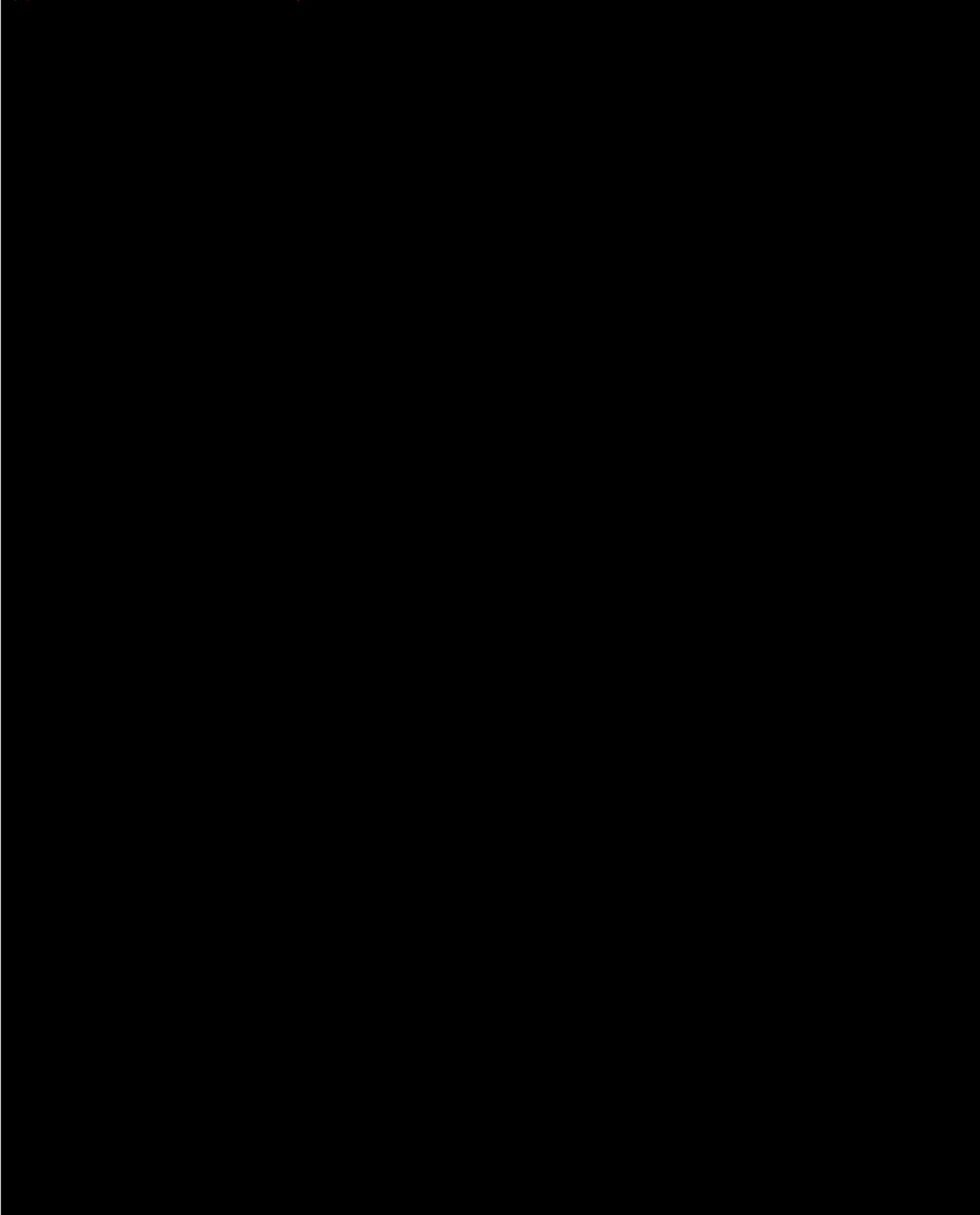
SS

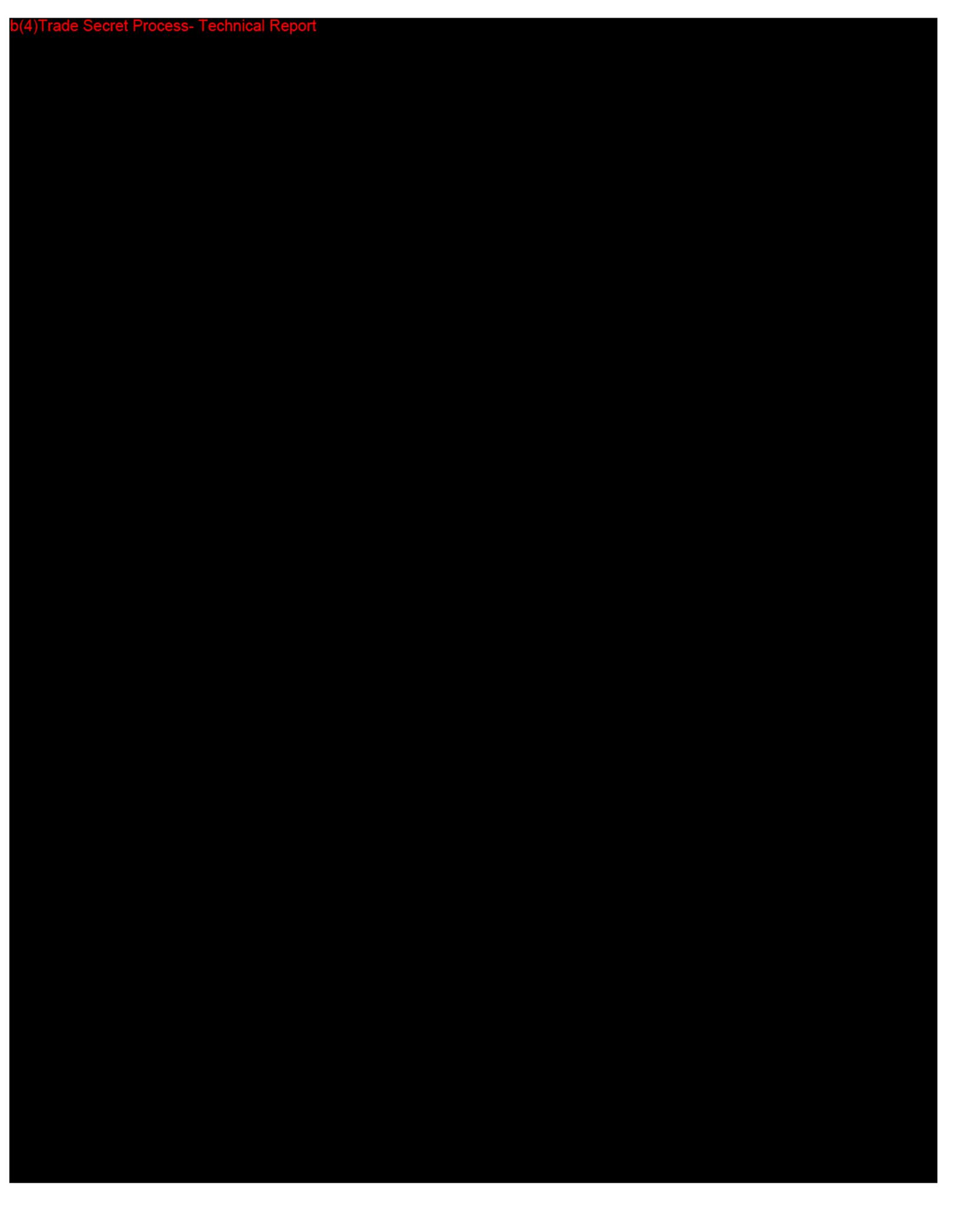
b(4)Trade Secret Process- Technical Report

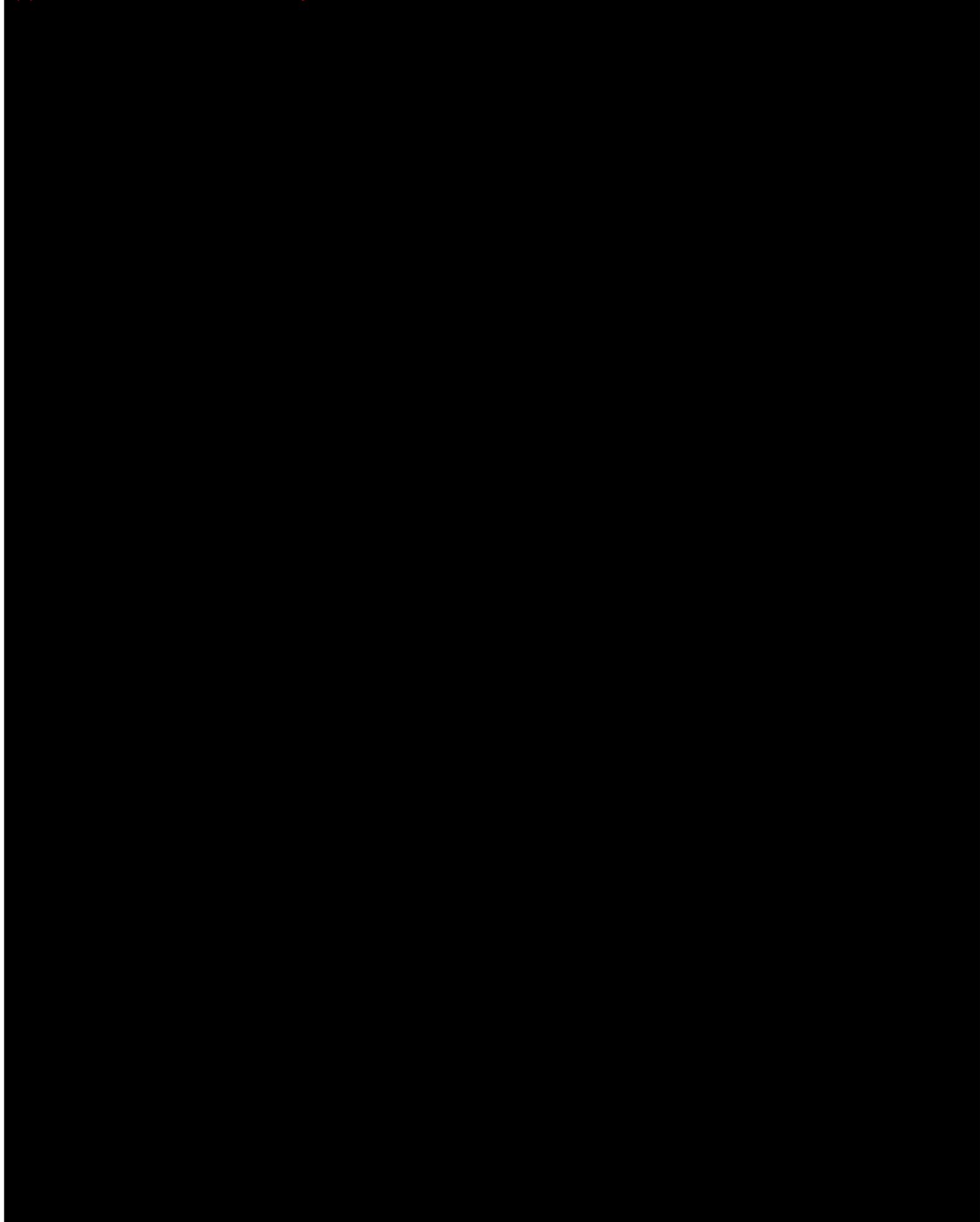


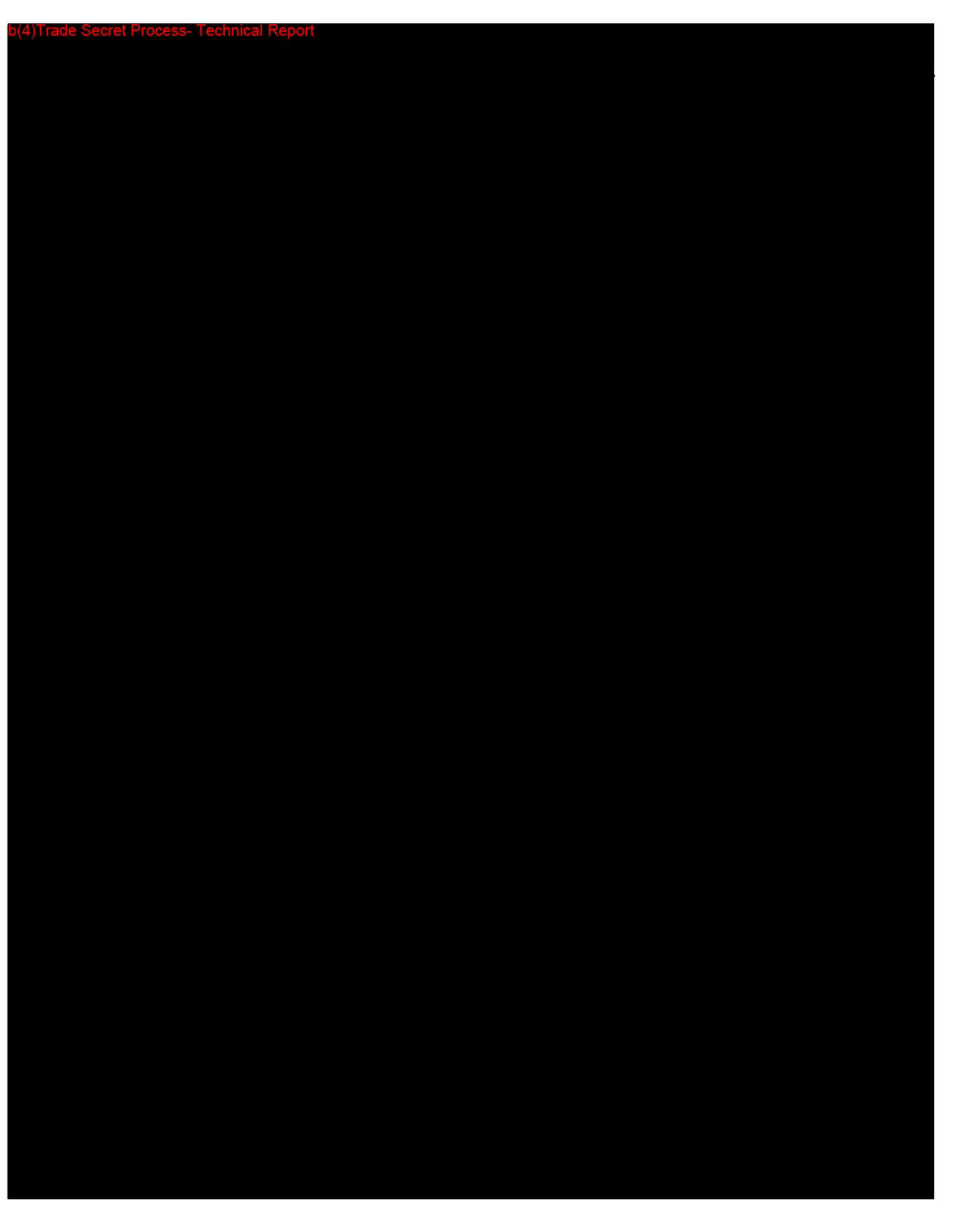


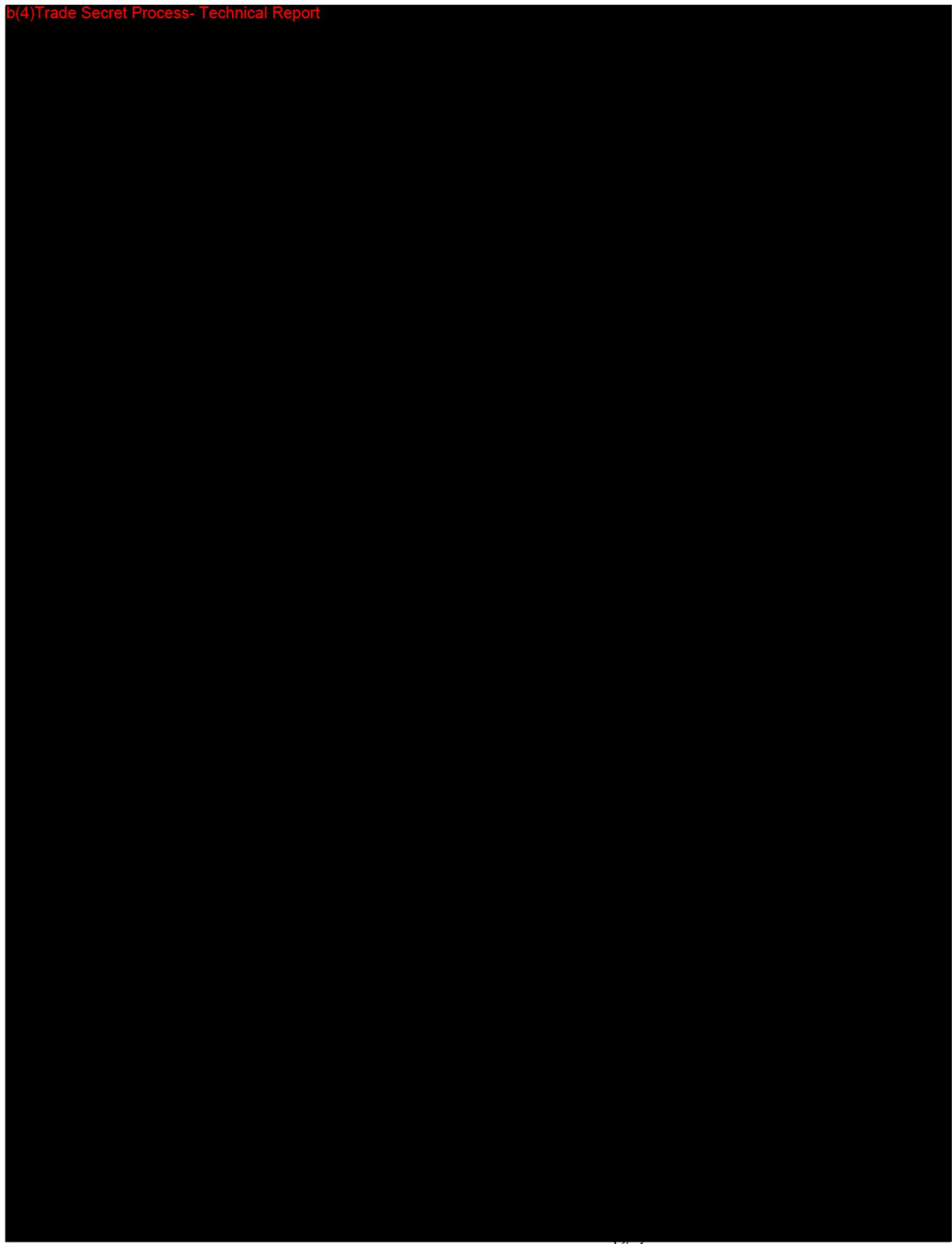










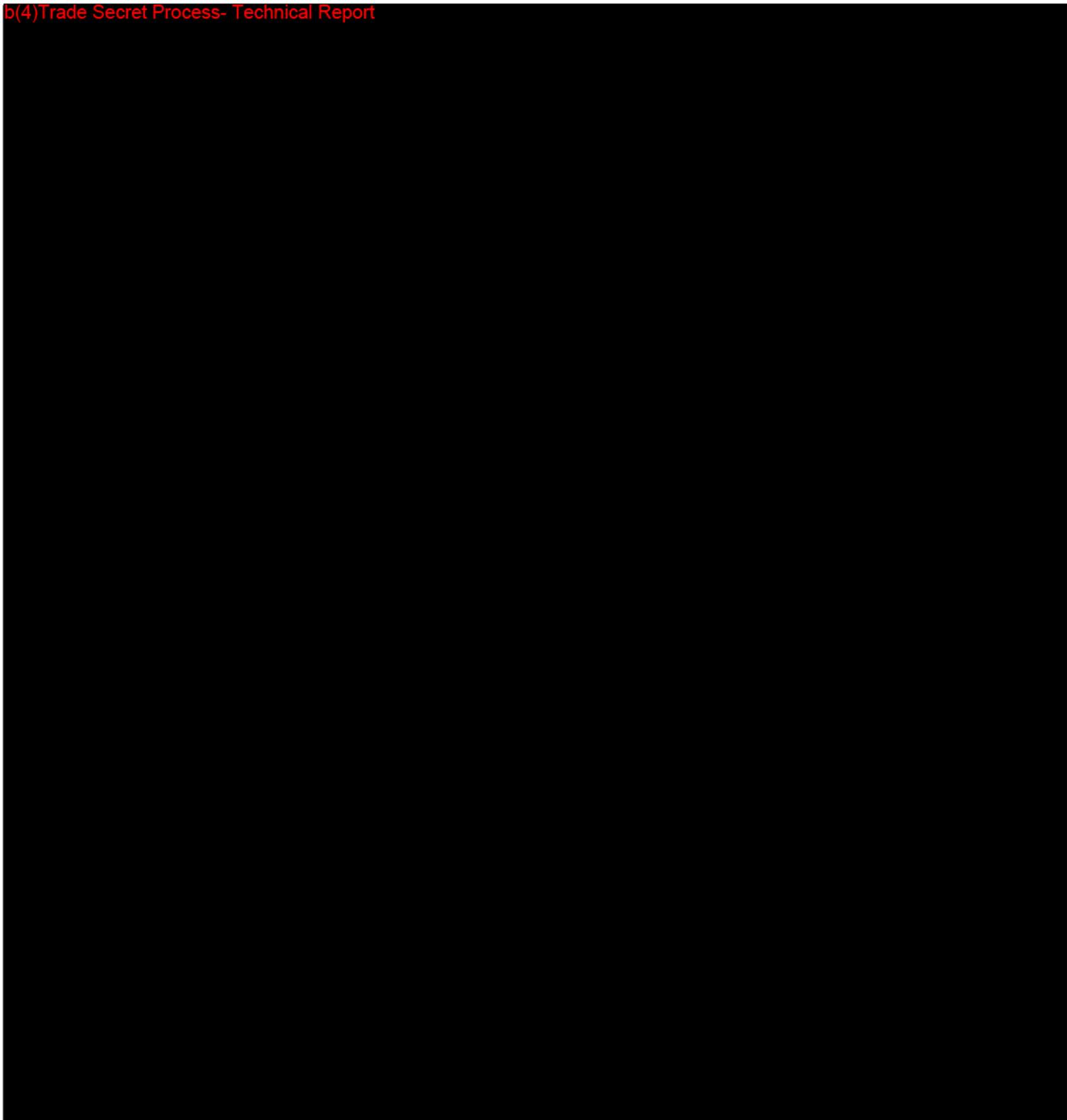


SMITH & NEPHEW RICHARDS INC.
Orthopaedic Research Department
1450 Brooks Road
Memphis, TN 38116

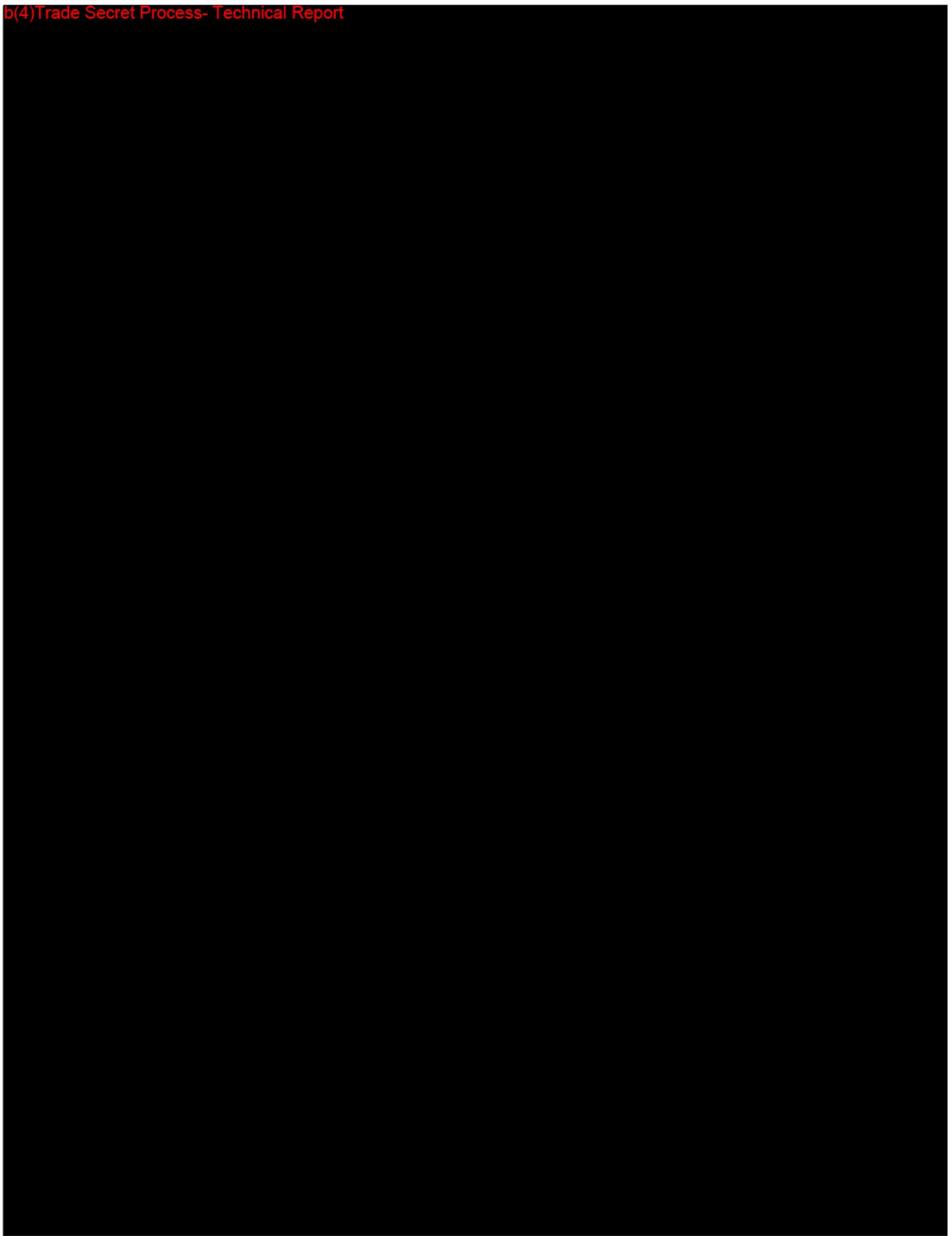
RED IS
CONTROLLED
COPY
COPY _____

Technical Report

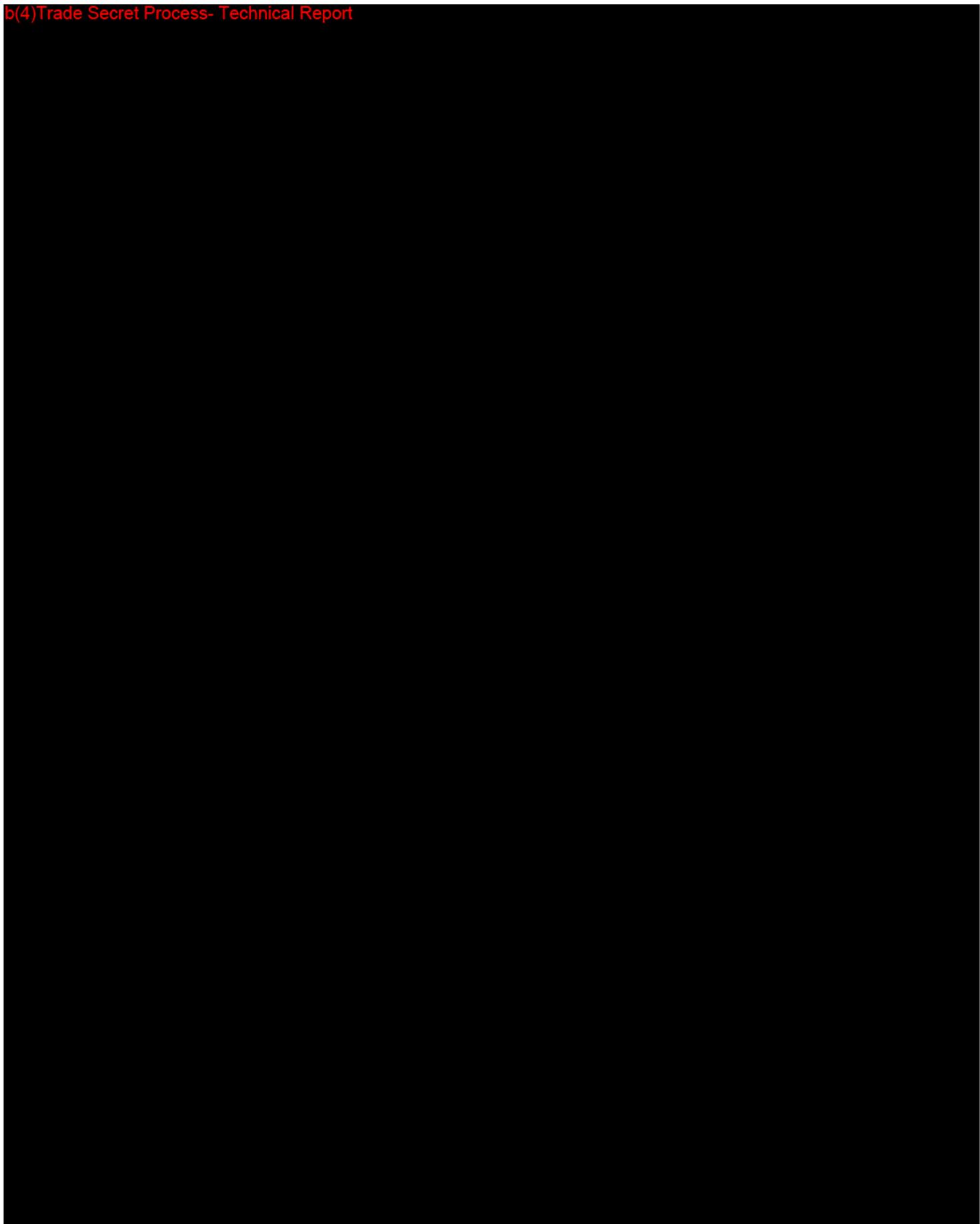
b(4)Trade Secret Process- Technical Report

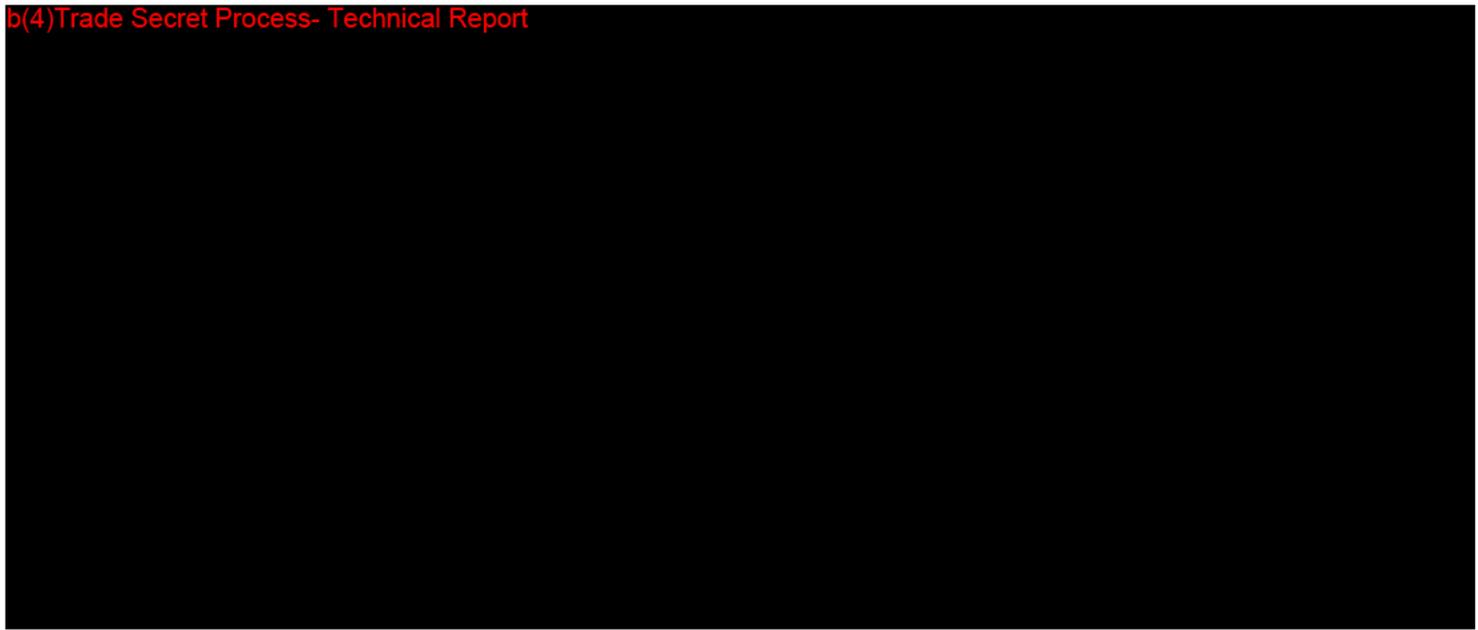


b(4)Trade Secret Process- Technical Report

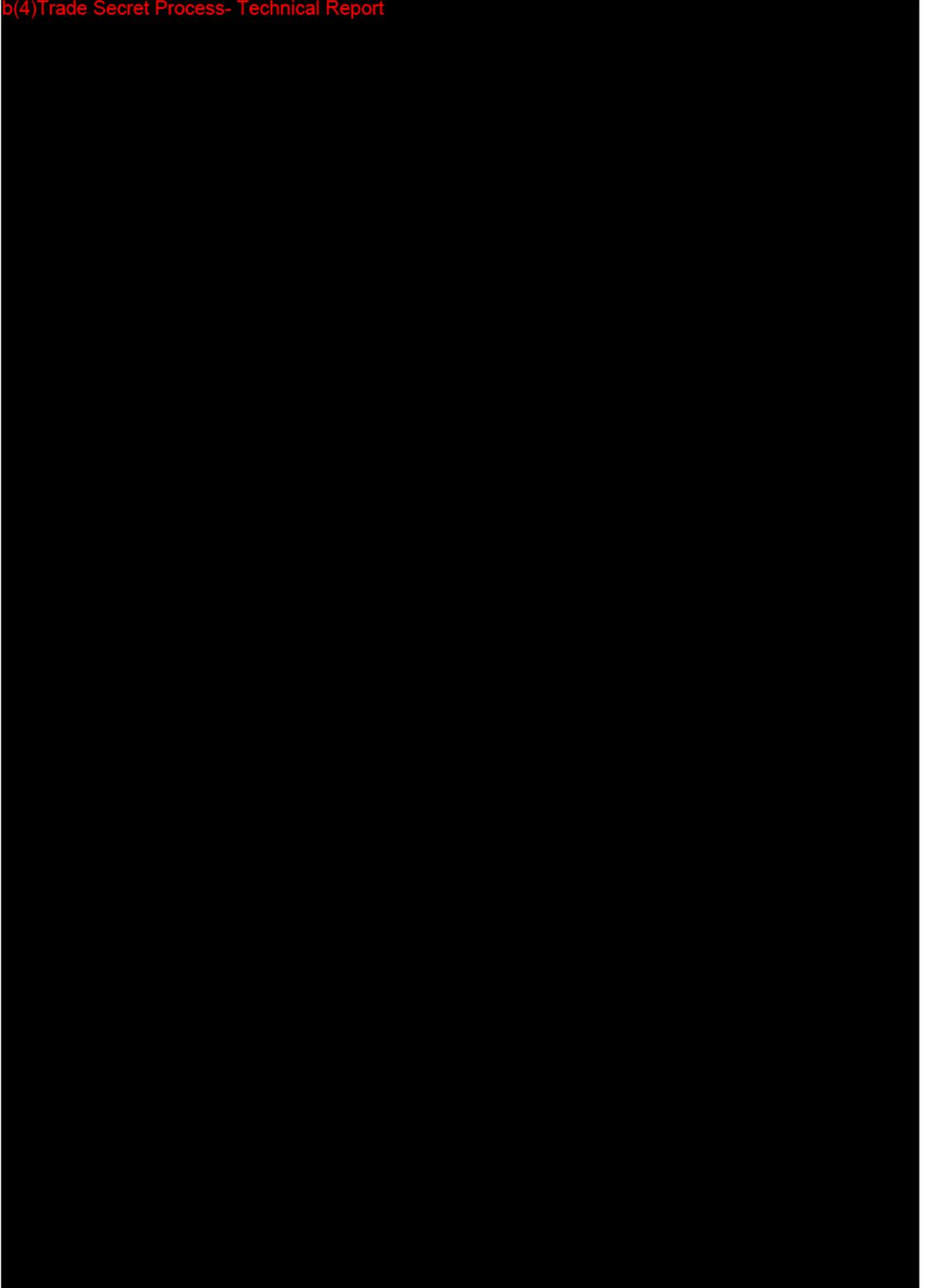


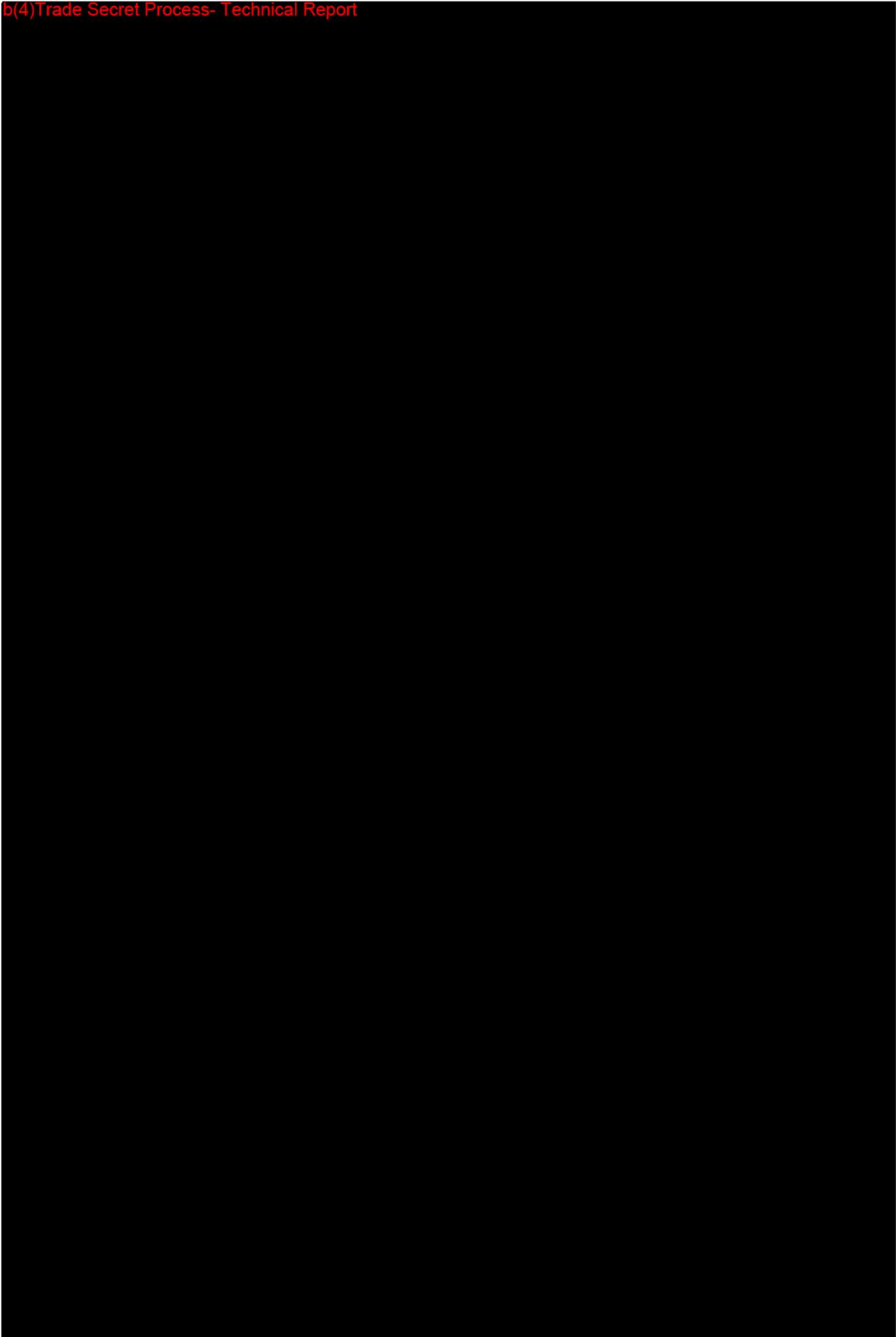
b(4)Trade Secret Process- Technical Report



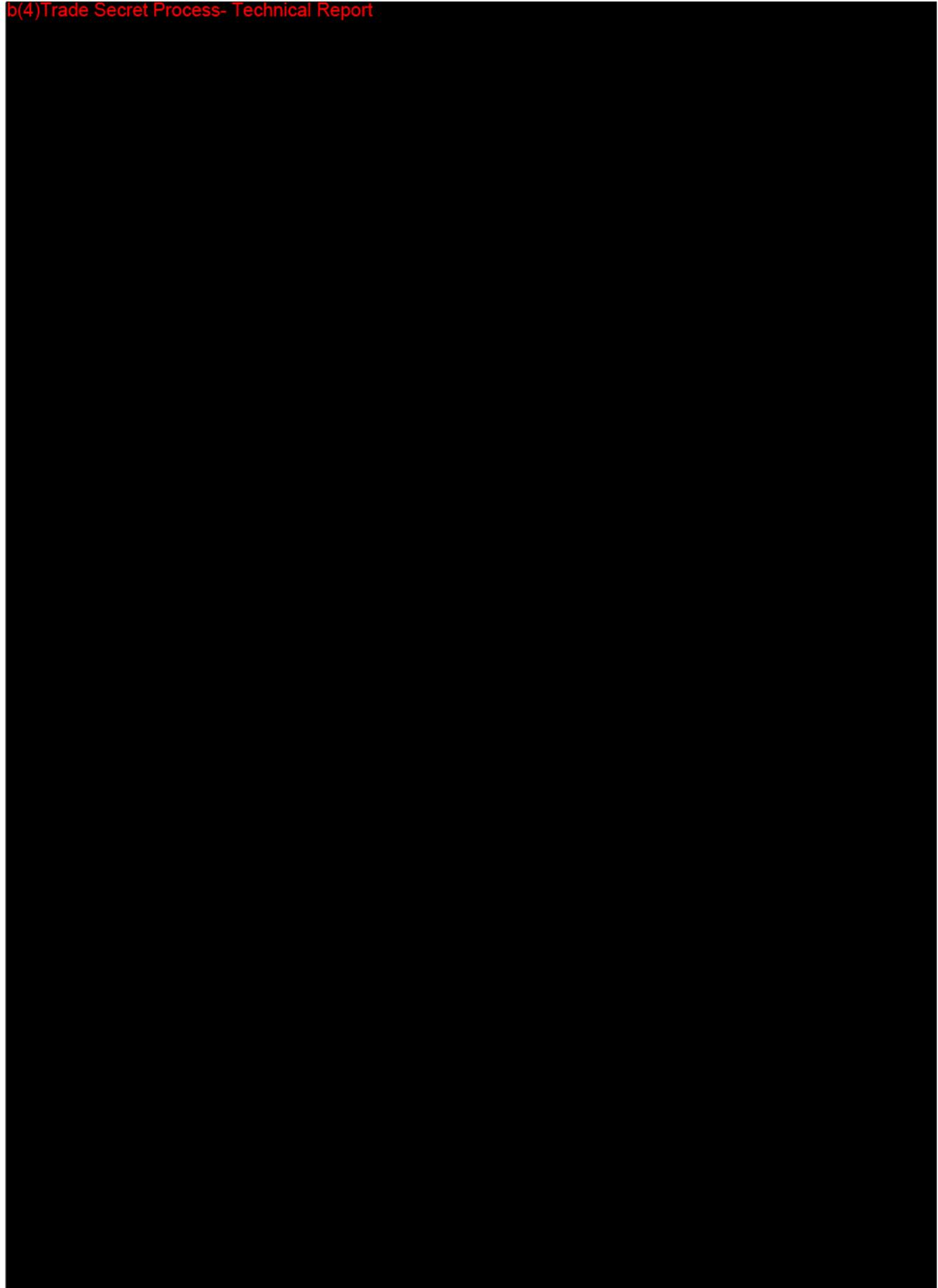


b(4)Trade Secret Process- Technical Report

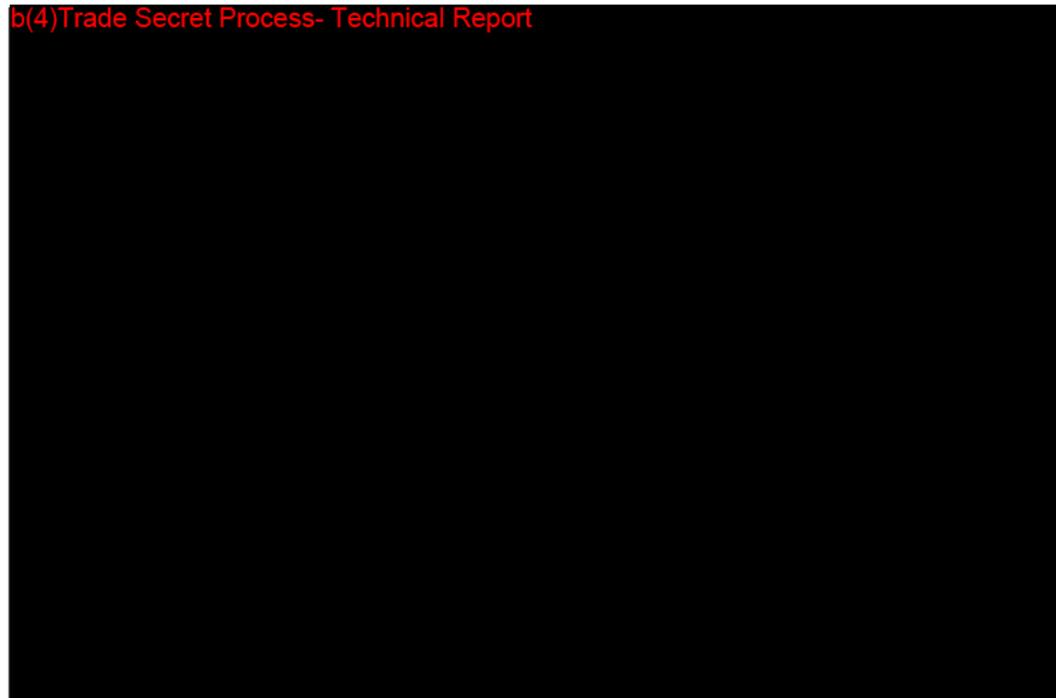




b(4)Trade Secret Process- Technical Report



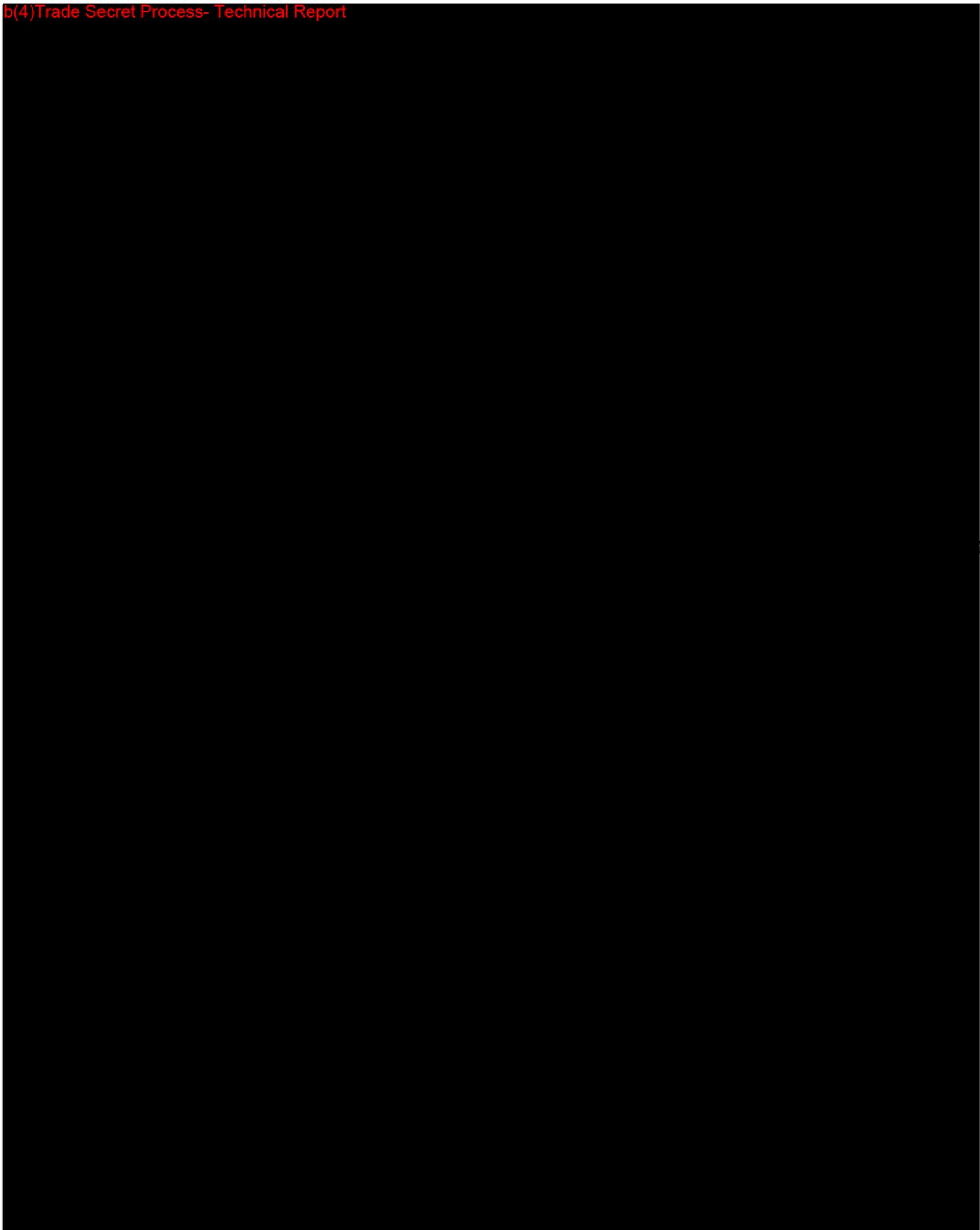
b(4)Trade Secret Process- Technical Report



CONFIDENTIAL

75

b(4)Trade Secret Process- Technical Report



Orthopaedic Division

Smith & Nephew, Inc.
1450 Brooks Rd., Memphis, TN 38116 U.S.A.
901-396-2121, For information: 1-800-821-5700
For orders and order inquiries: 1-800-238-7538

Smith+Nephew

Memorandum

To: David Henley
From: ^{SS} Jeff Sprague

Date: April 26, 1999

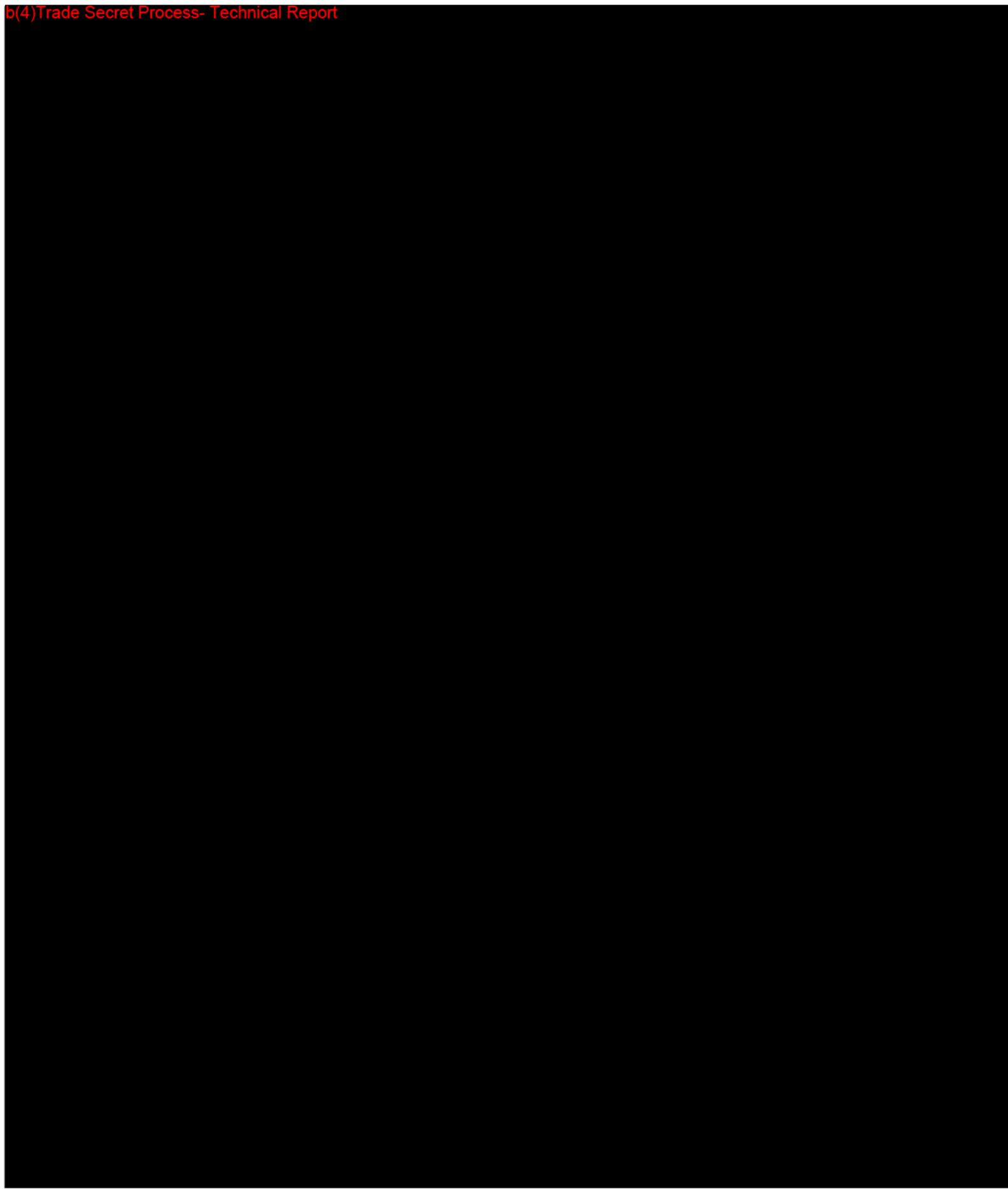
Subject: *Technical Memo* - [REDACTED] Hip Stem [REDACTED]

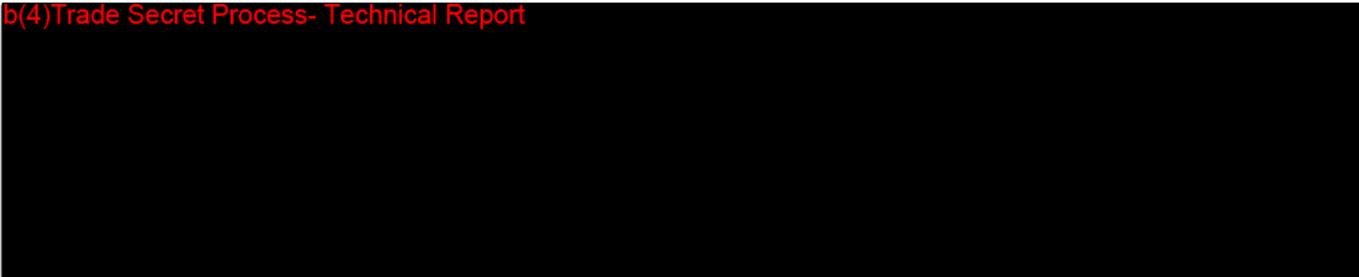
cc: P. Frederick, M. Harbaugh, A. Salehi, D. Ryan

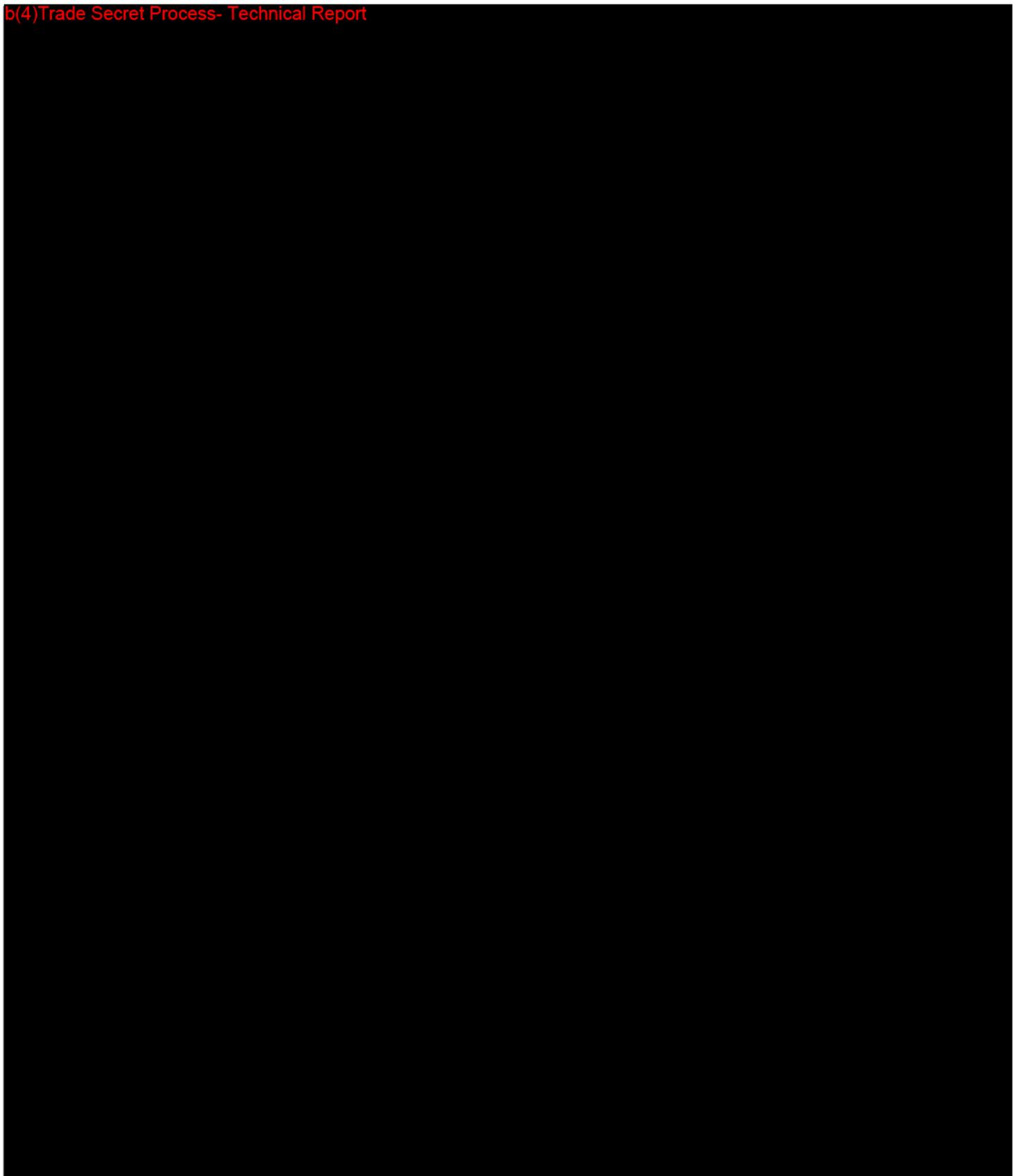
b(4)Trade Secret Process- Technical Report

[REDACTED]

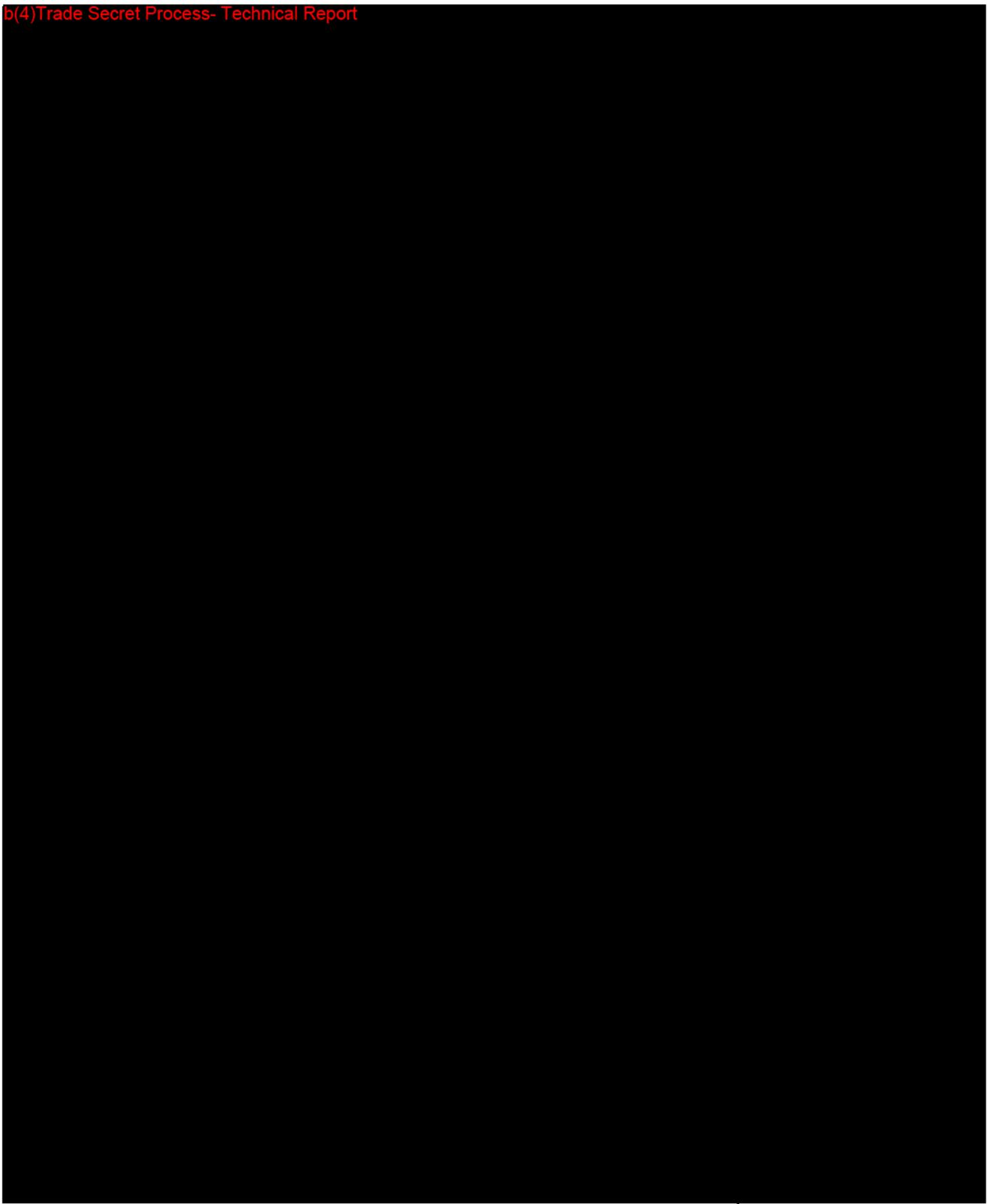
b(4)Trade Secret Process- Technical Report

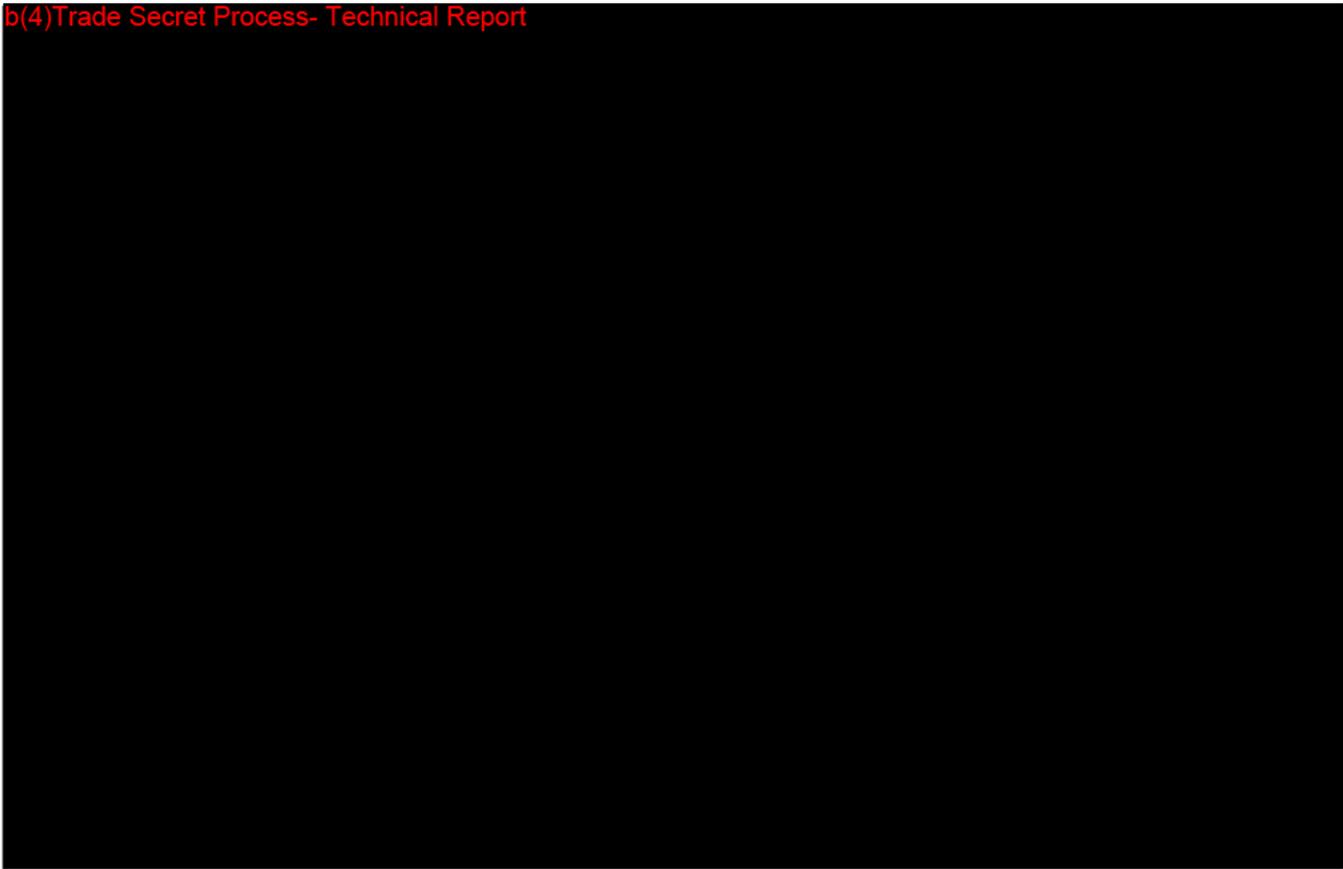


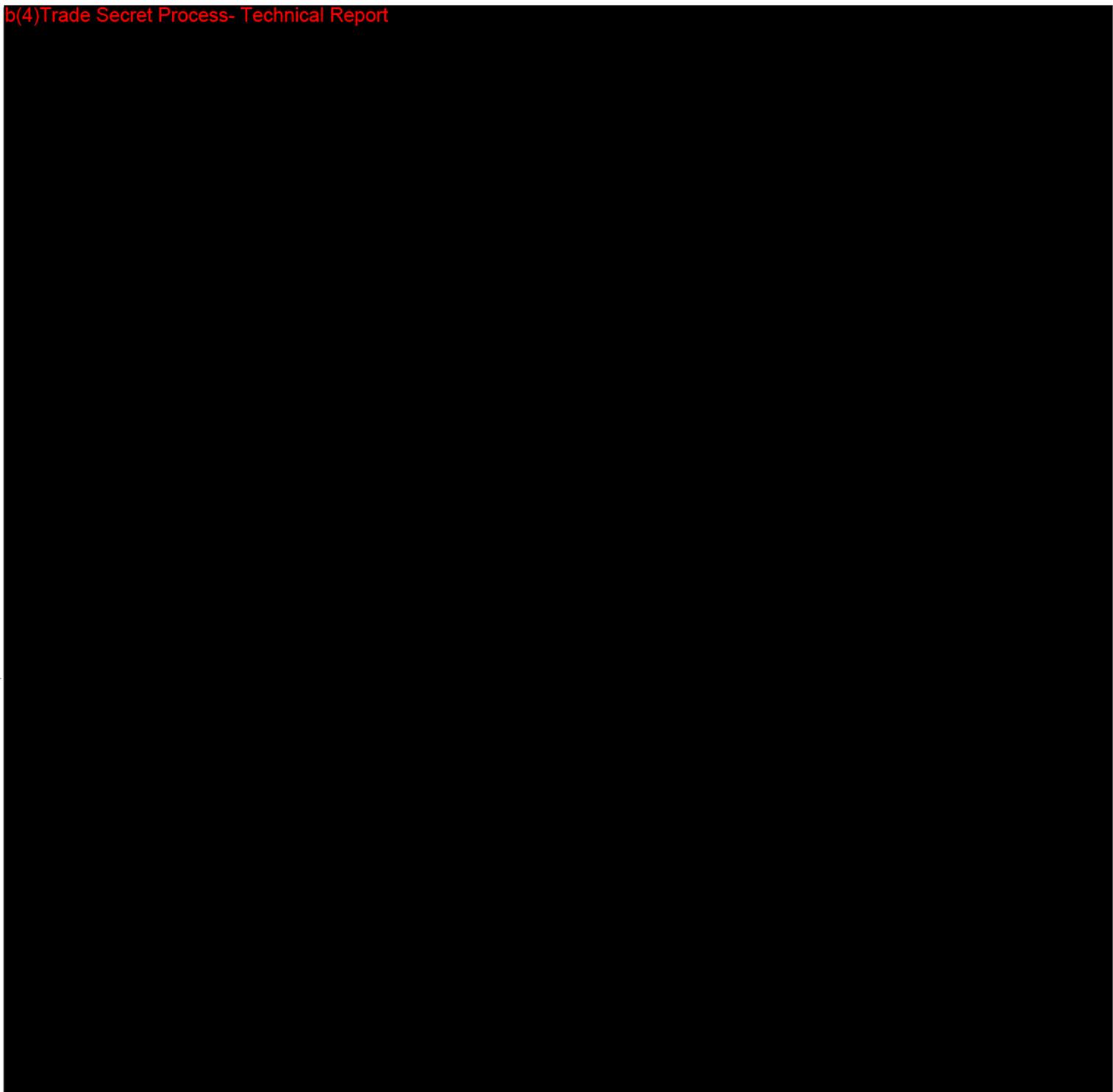


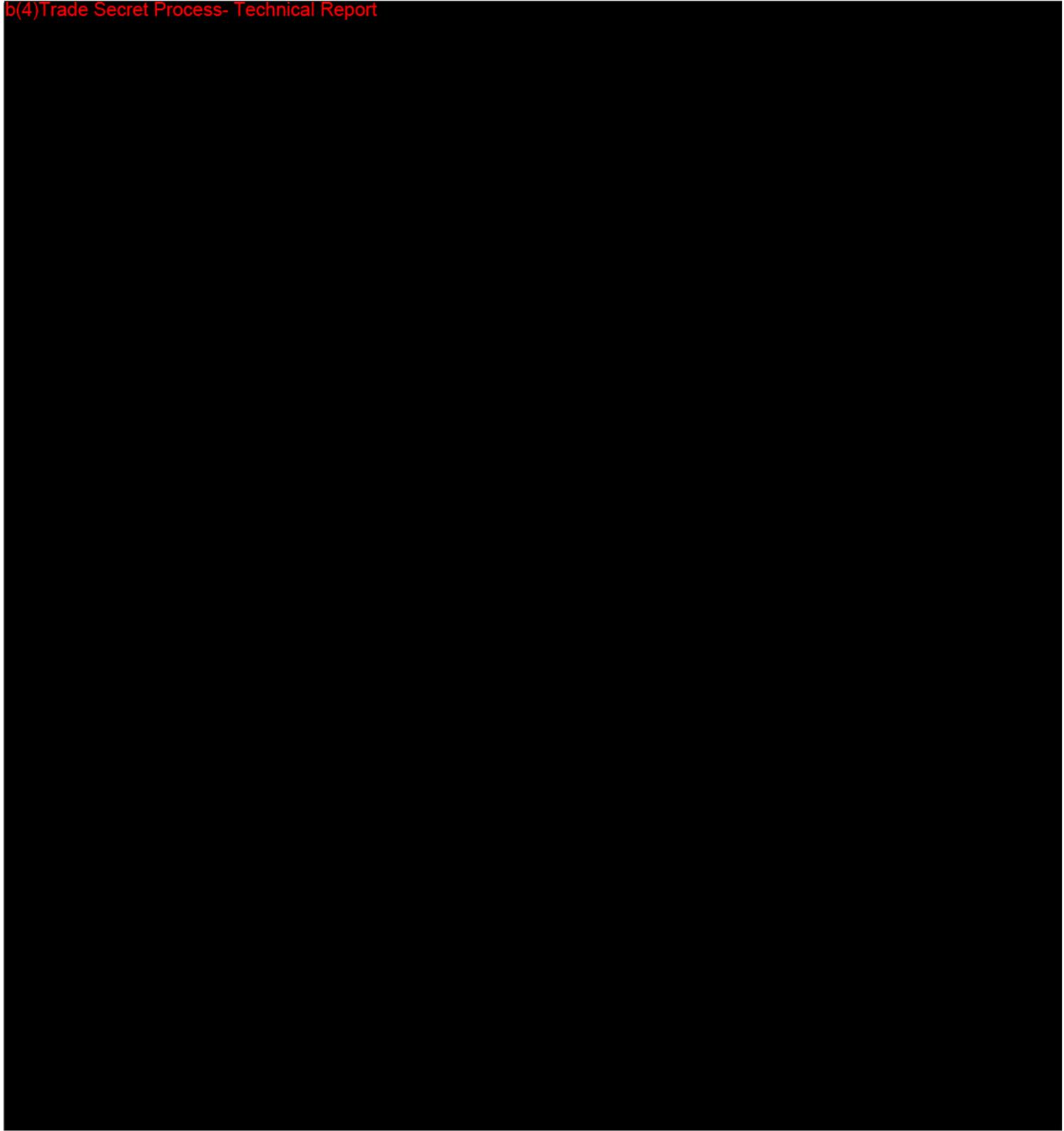


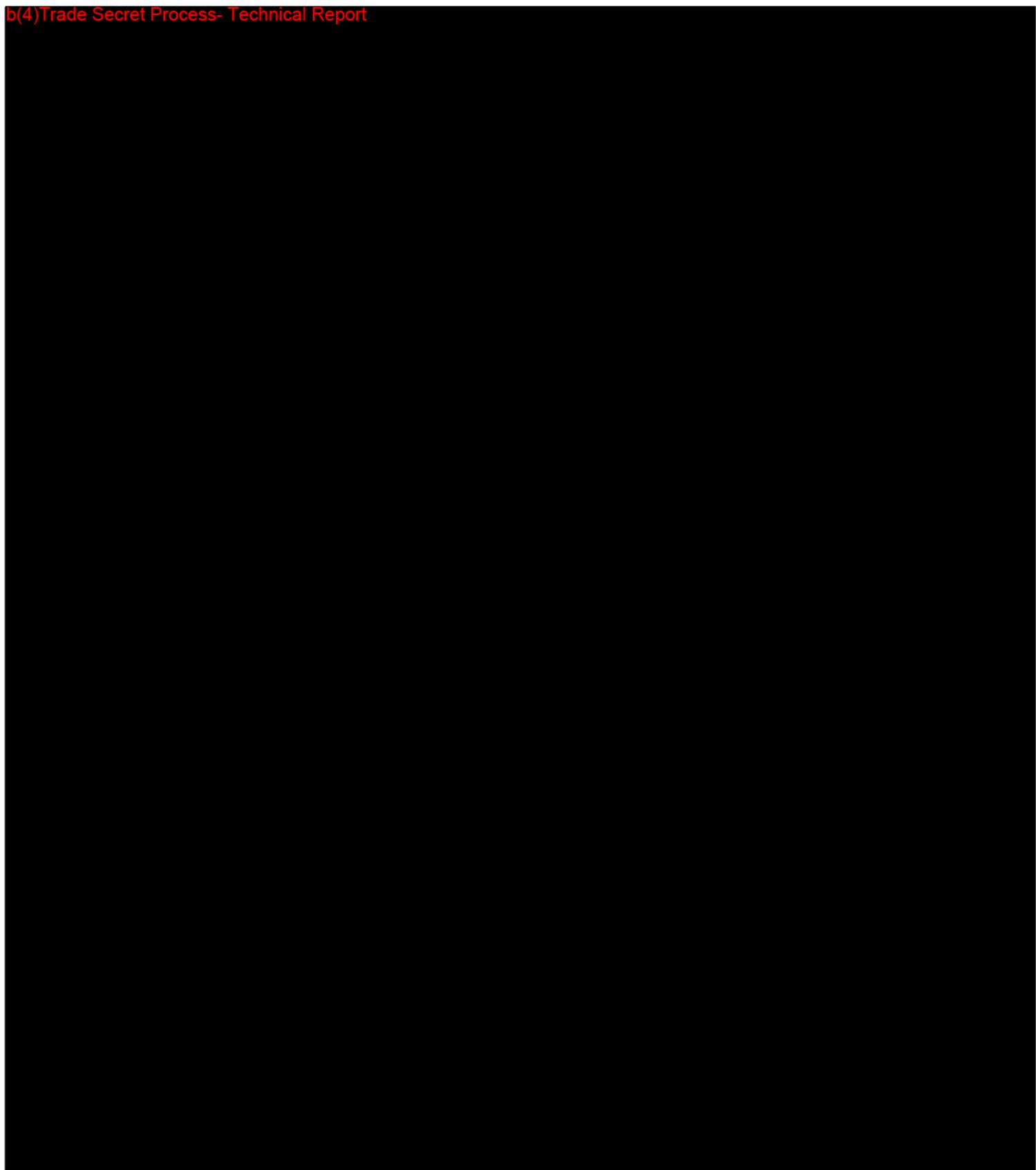




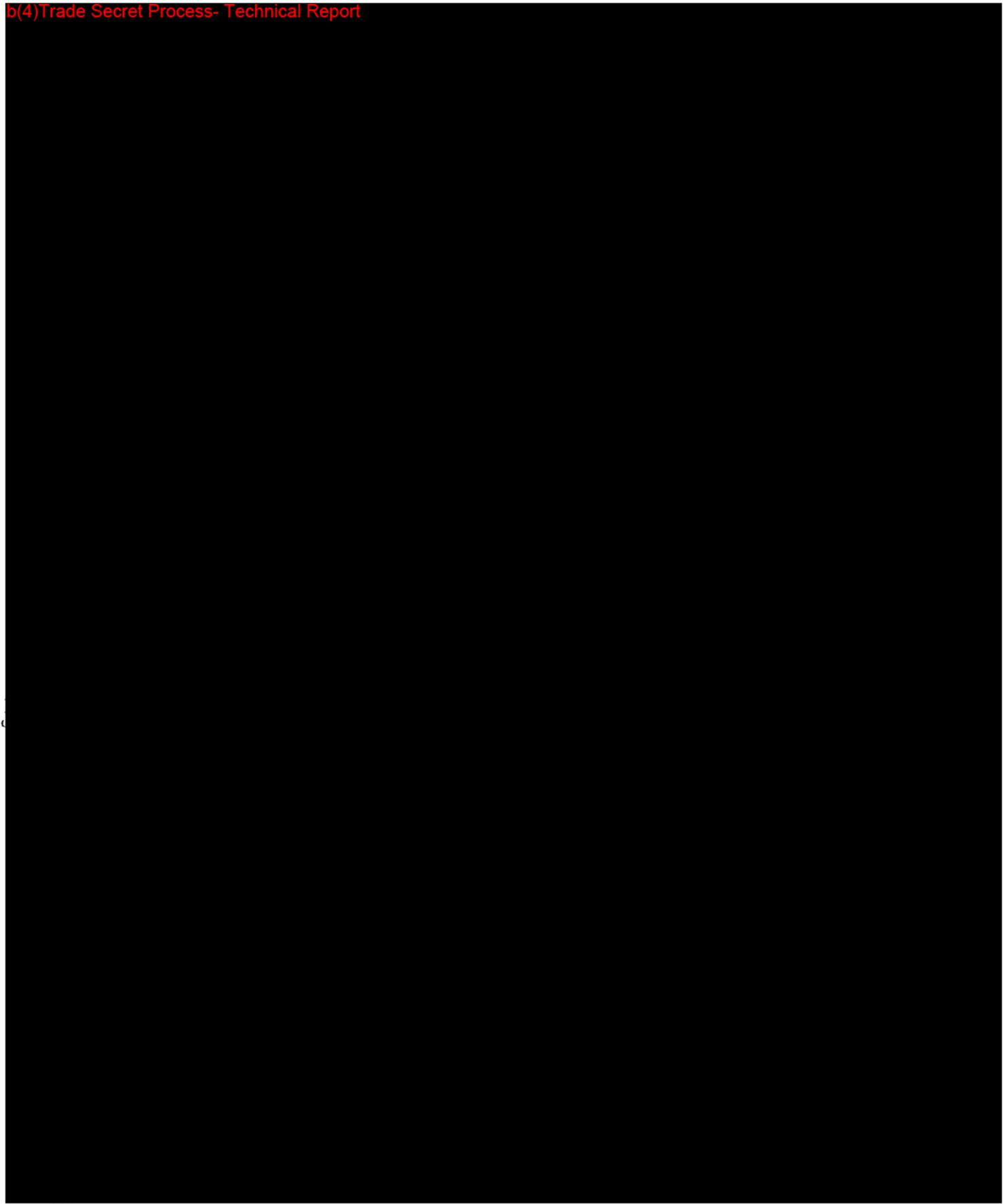


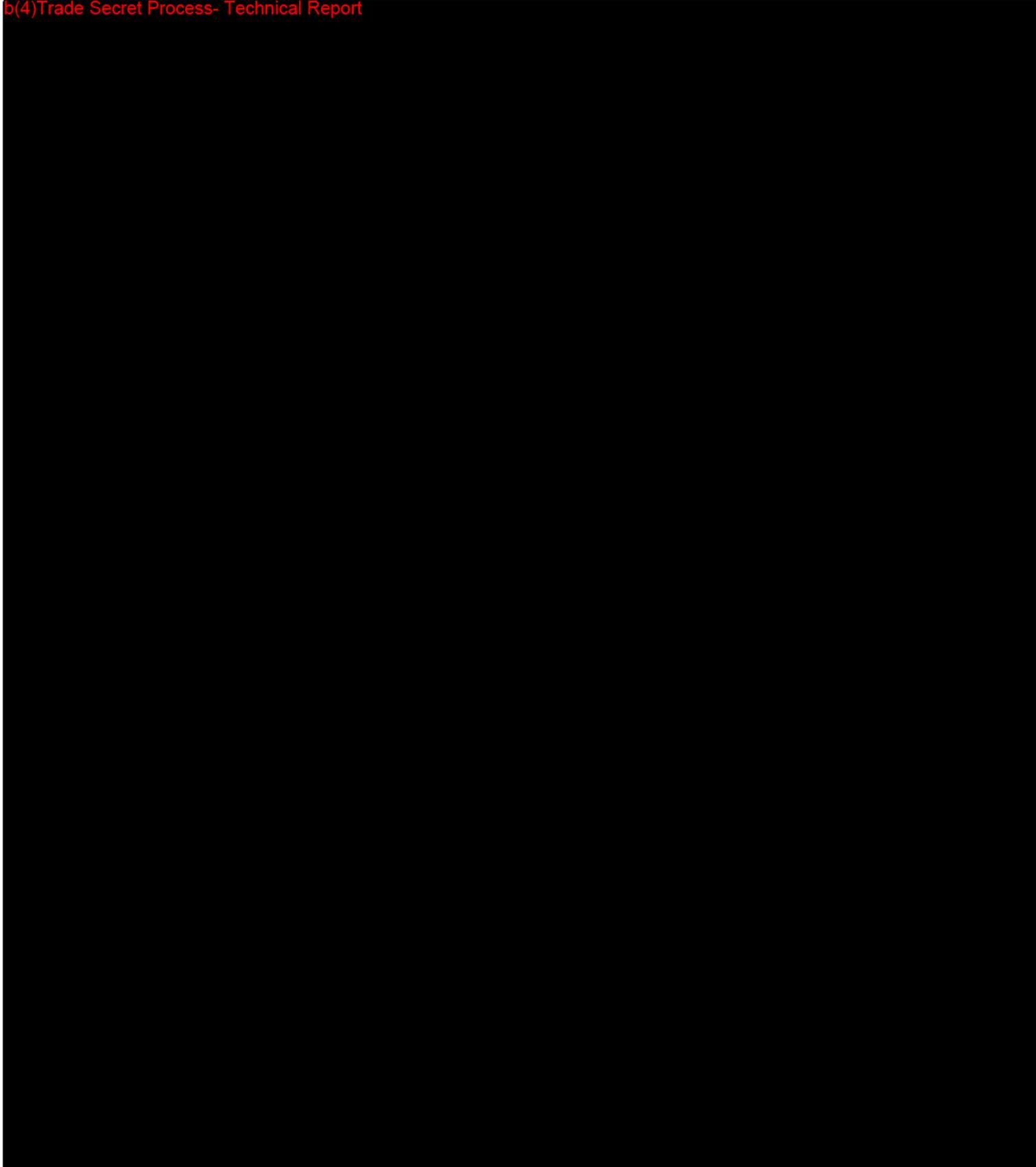


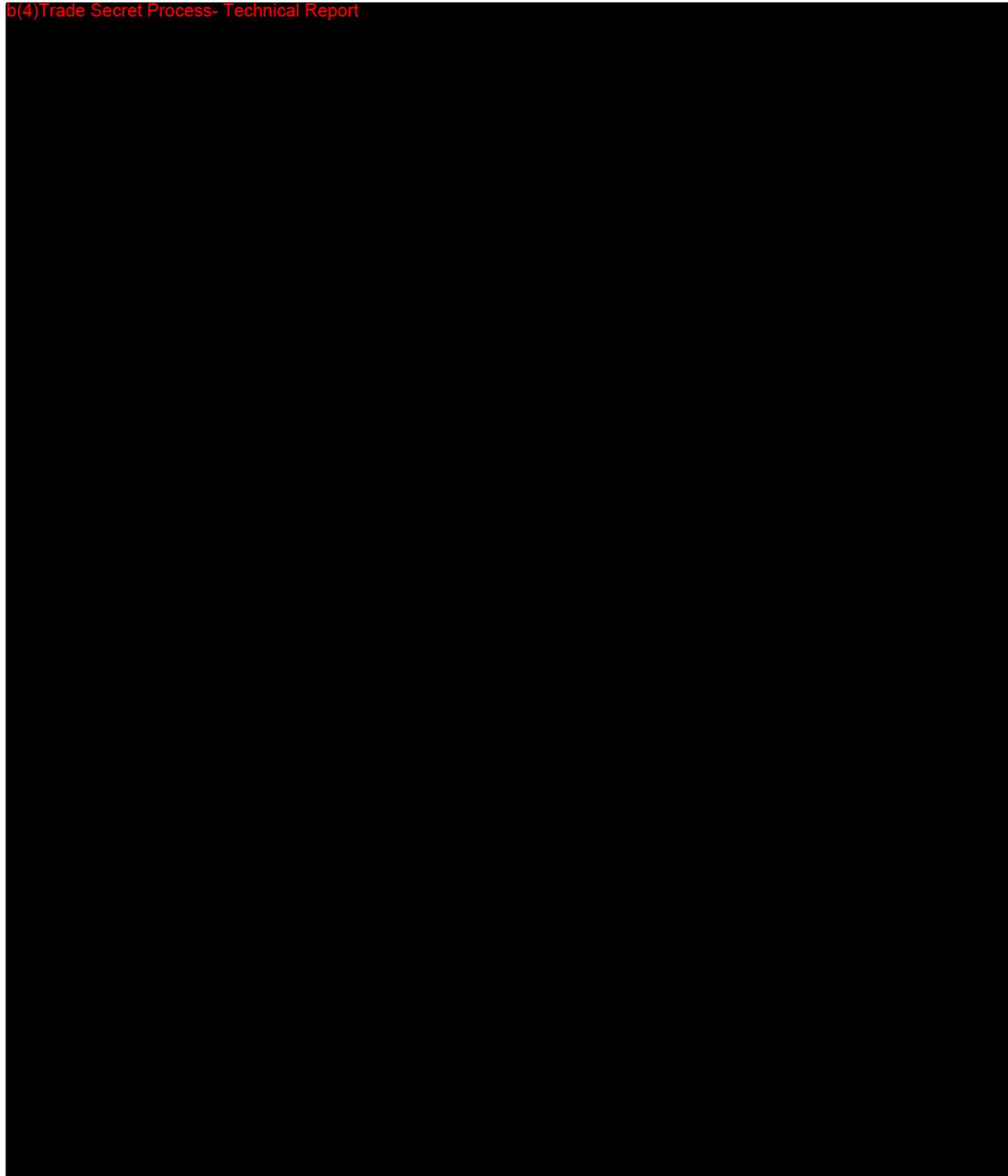


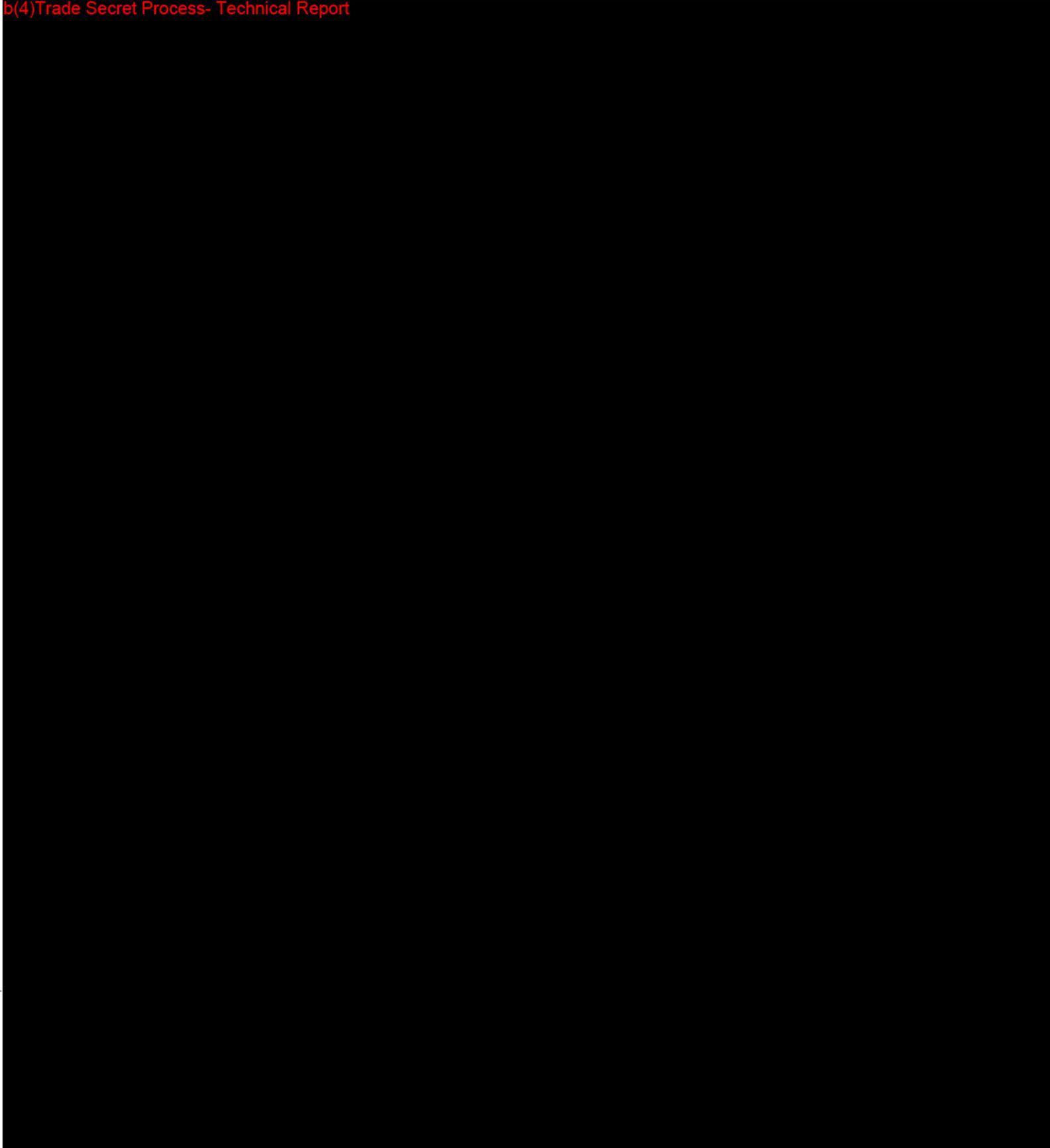


JS









SMITH & NEPHEW ORTHOPAEDICS

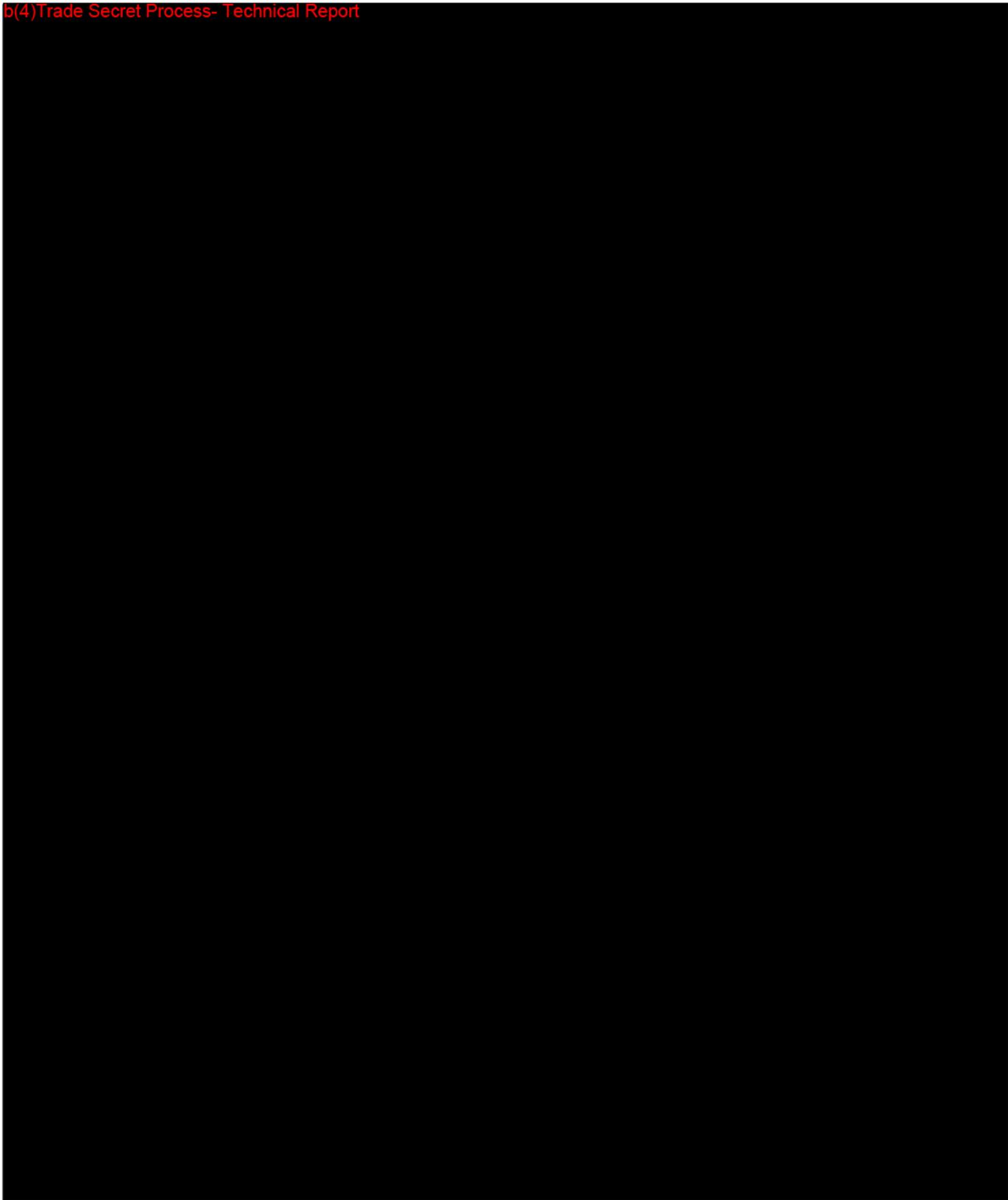
Smith & Nephew Richards Inc.
Orthopaedic Research Department
1450 Brooks Road
Memphis, TN 38116

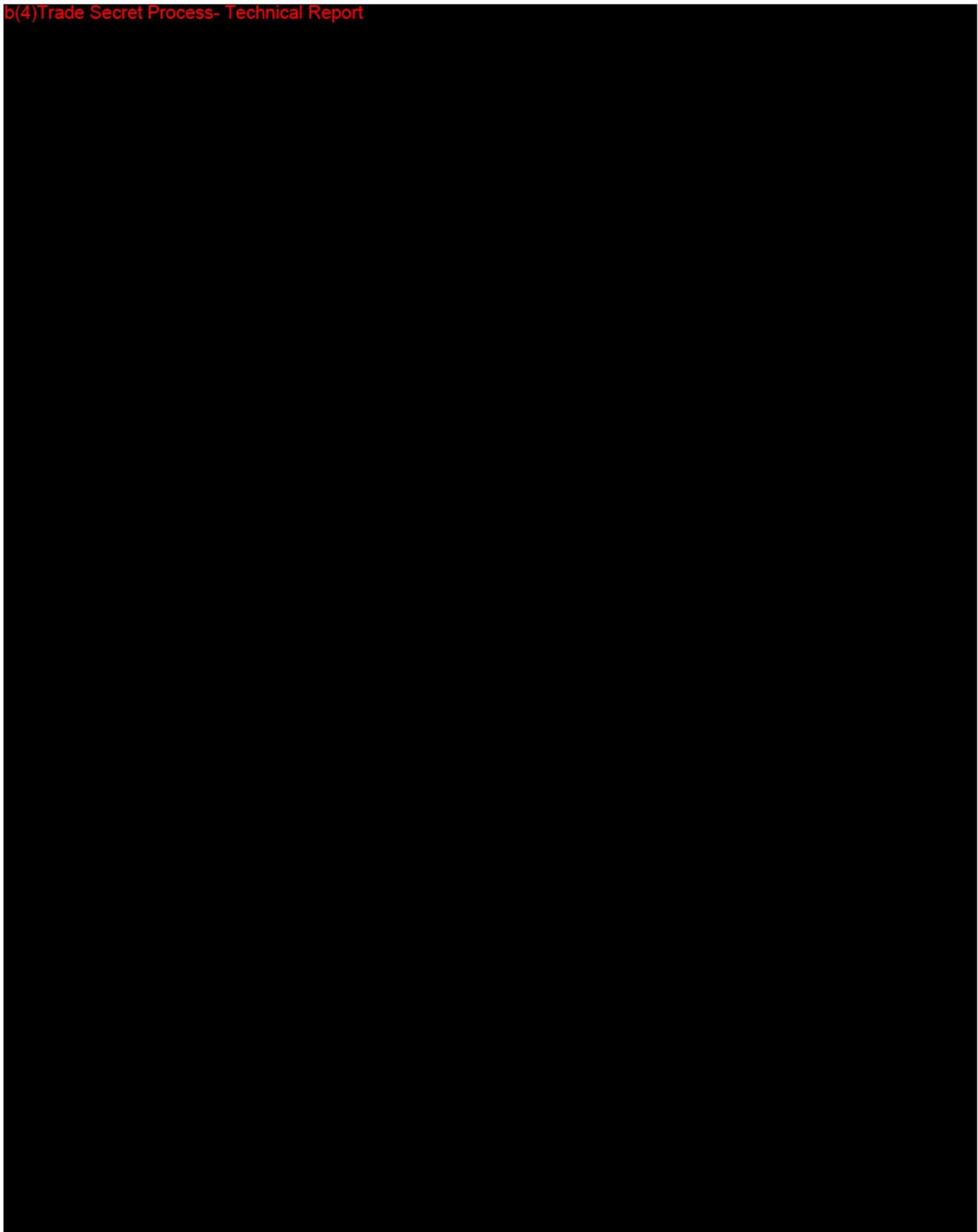
RED IS
CONTROLLED
COPY _____

TECHNICAL REPORT

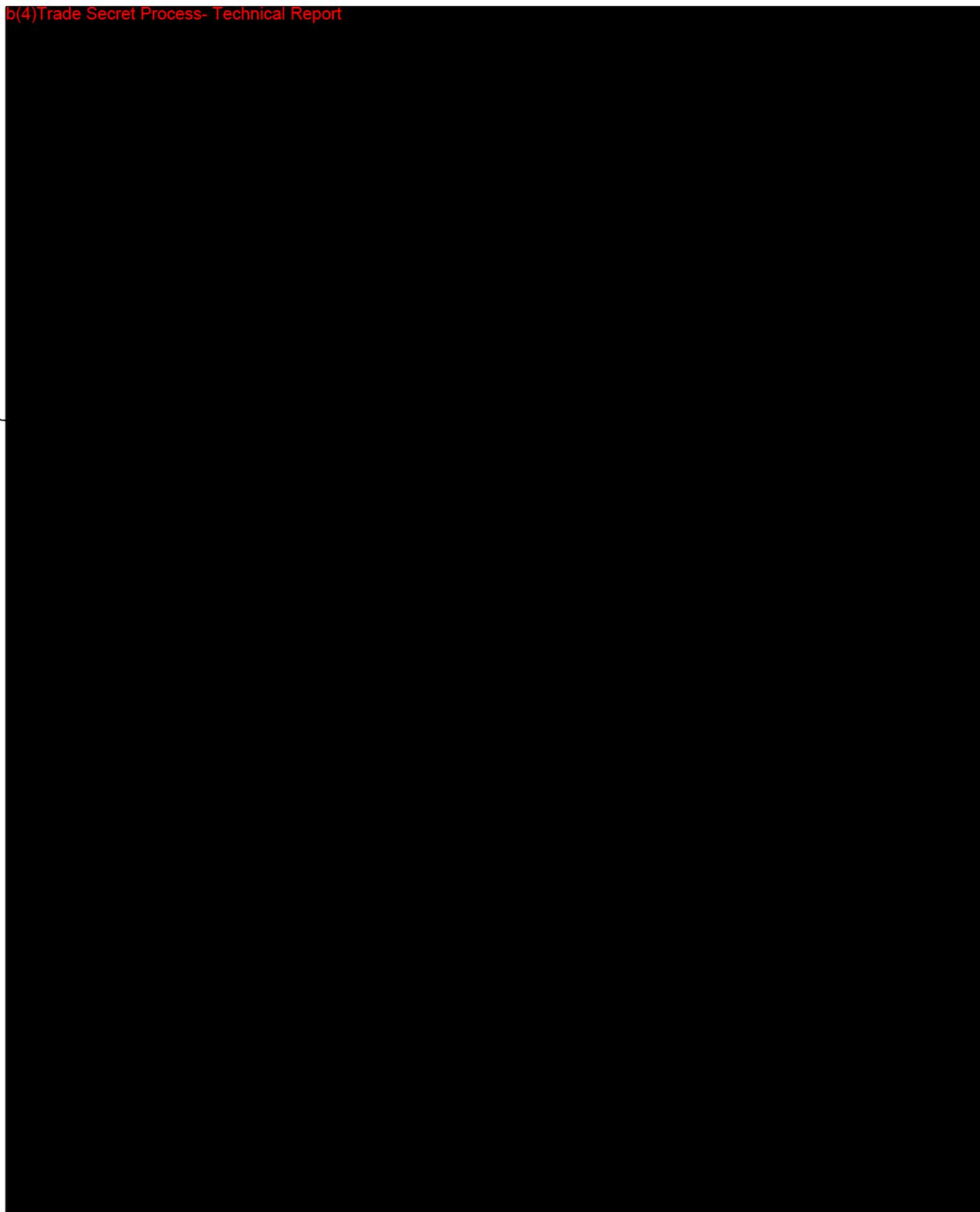
b(4)Trade Secret Process- Technical Report

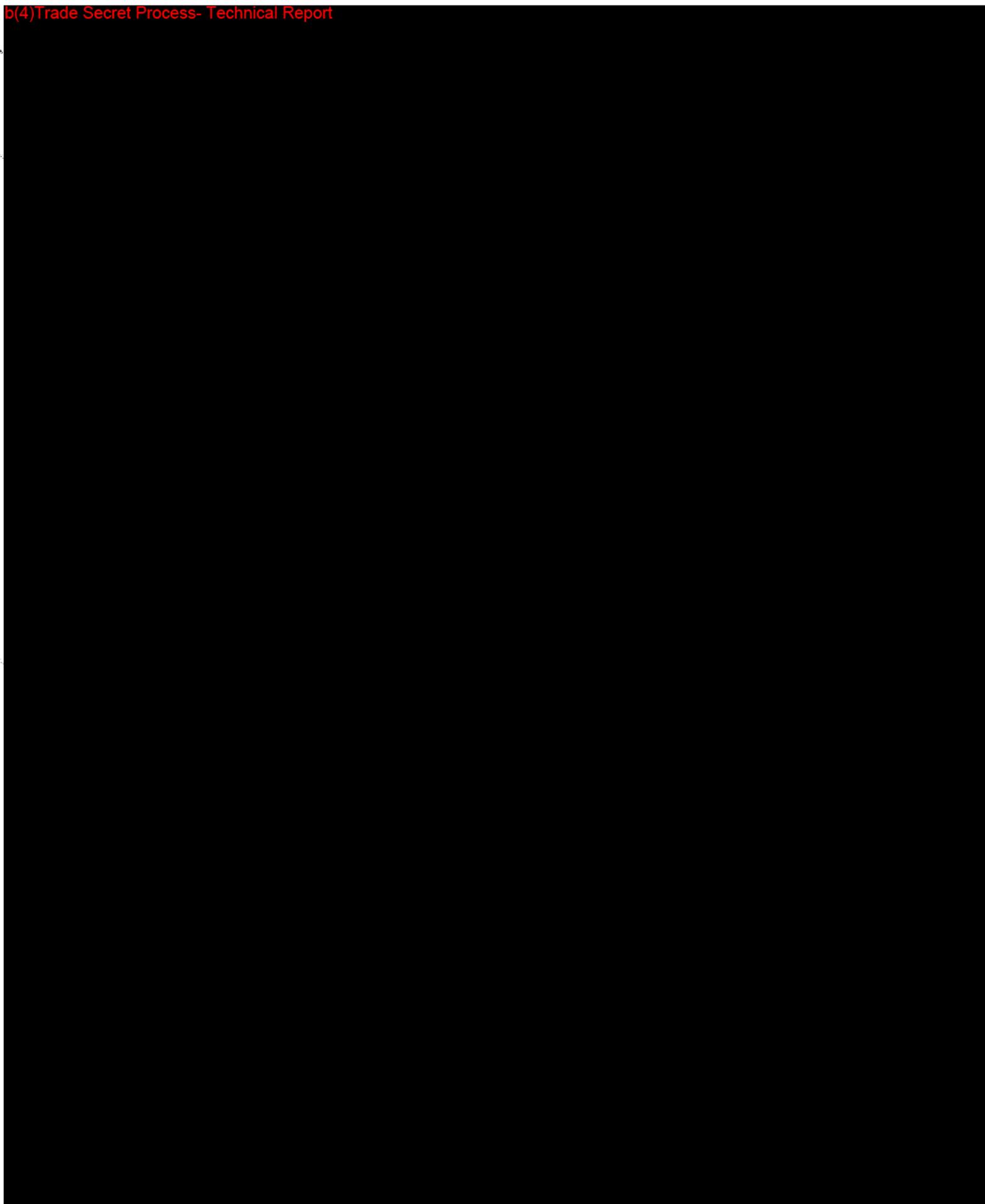


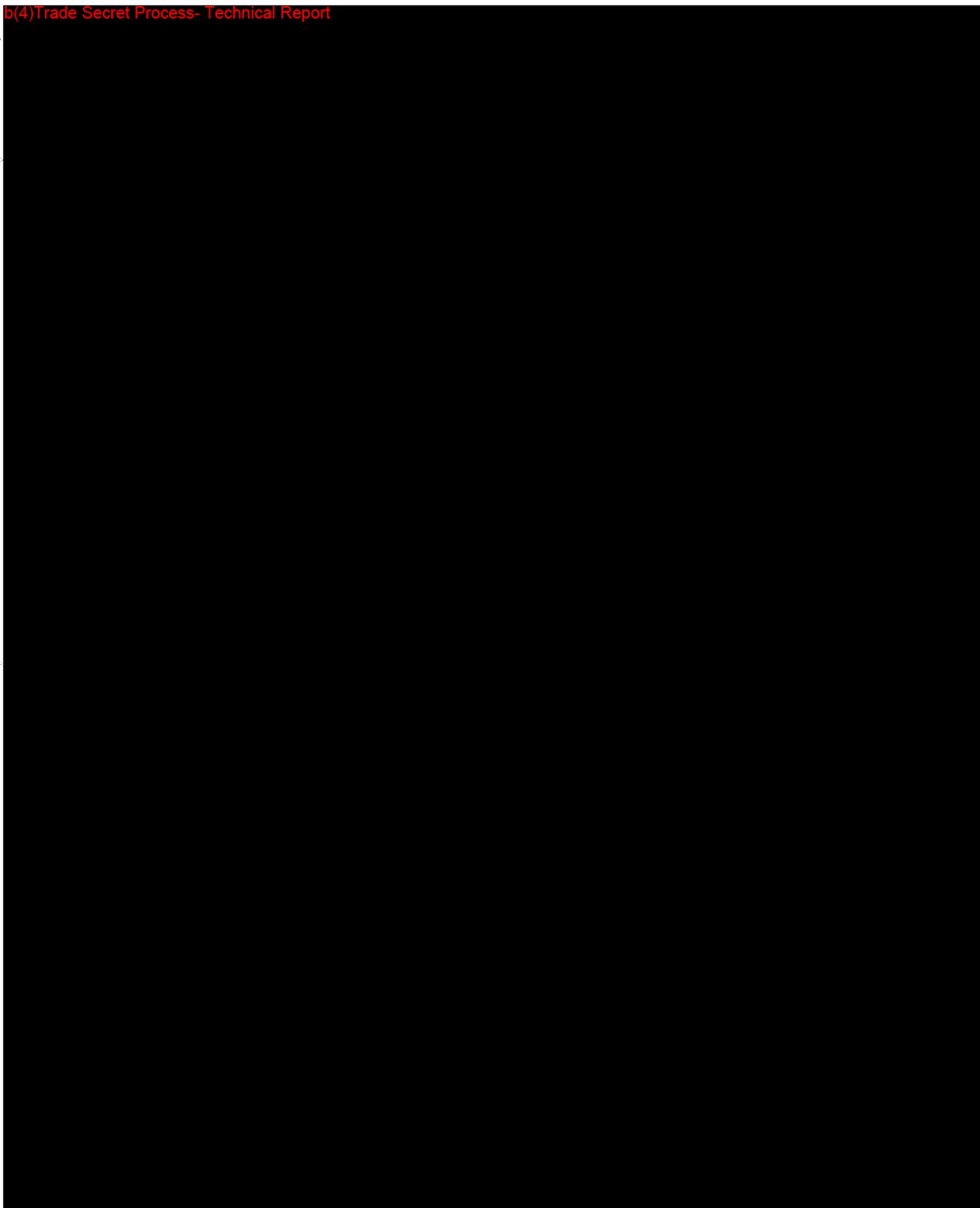


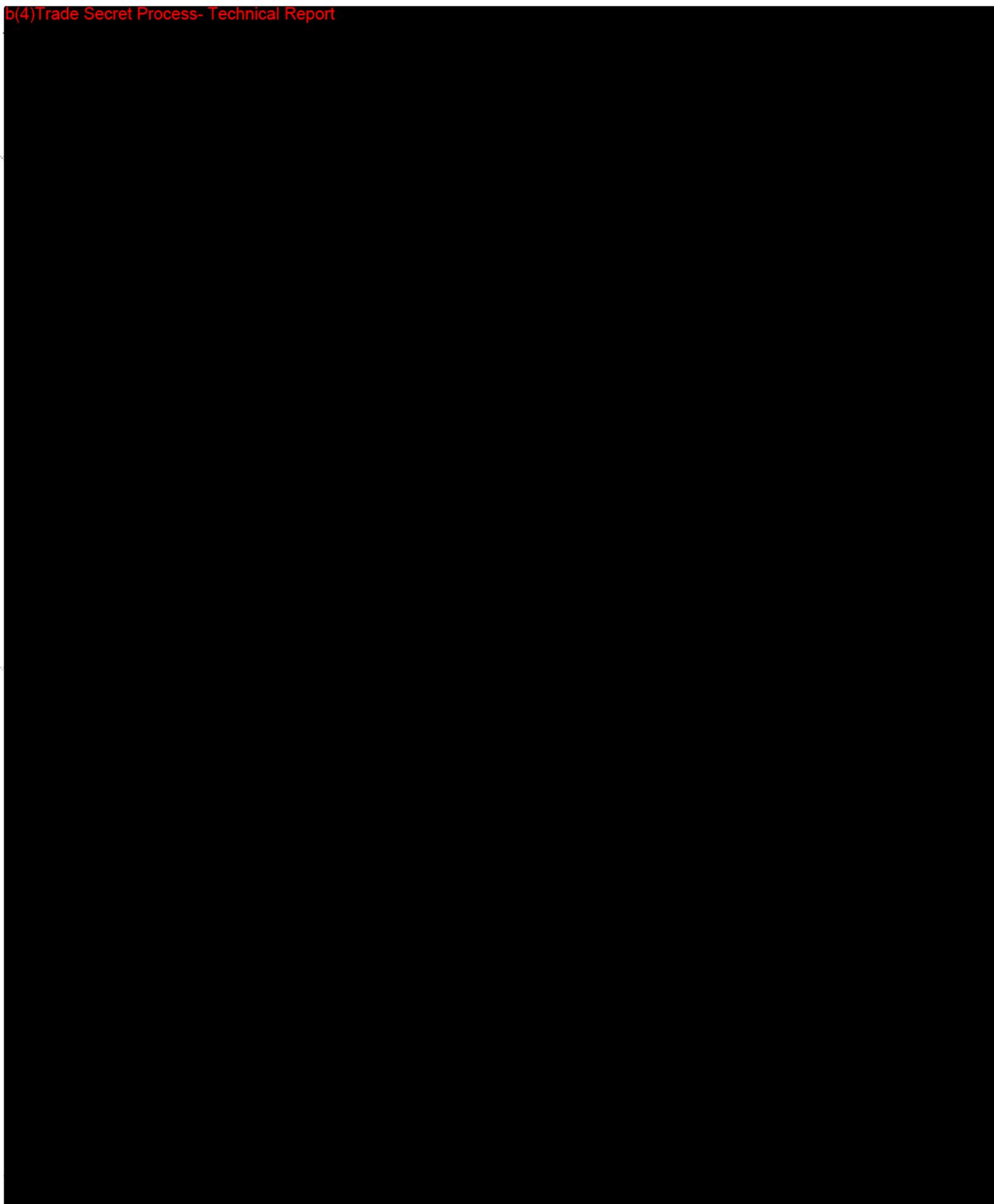








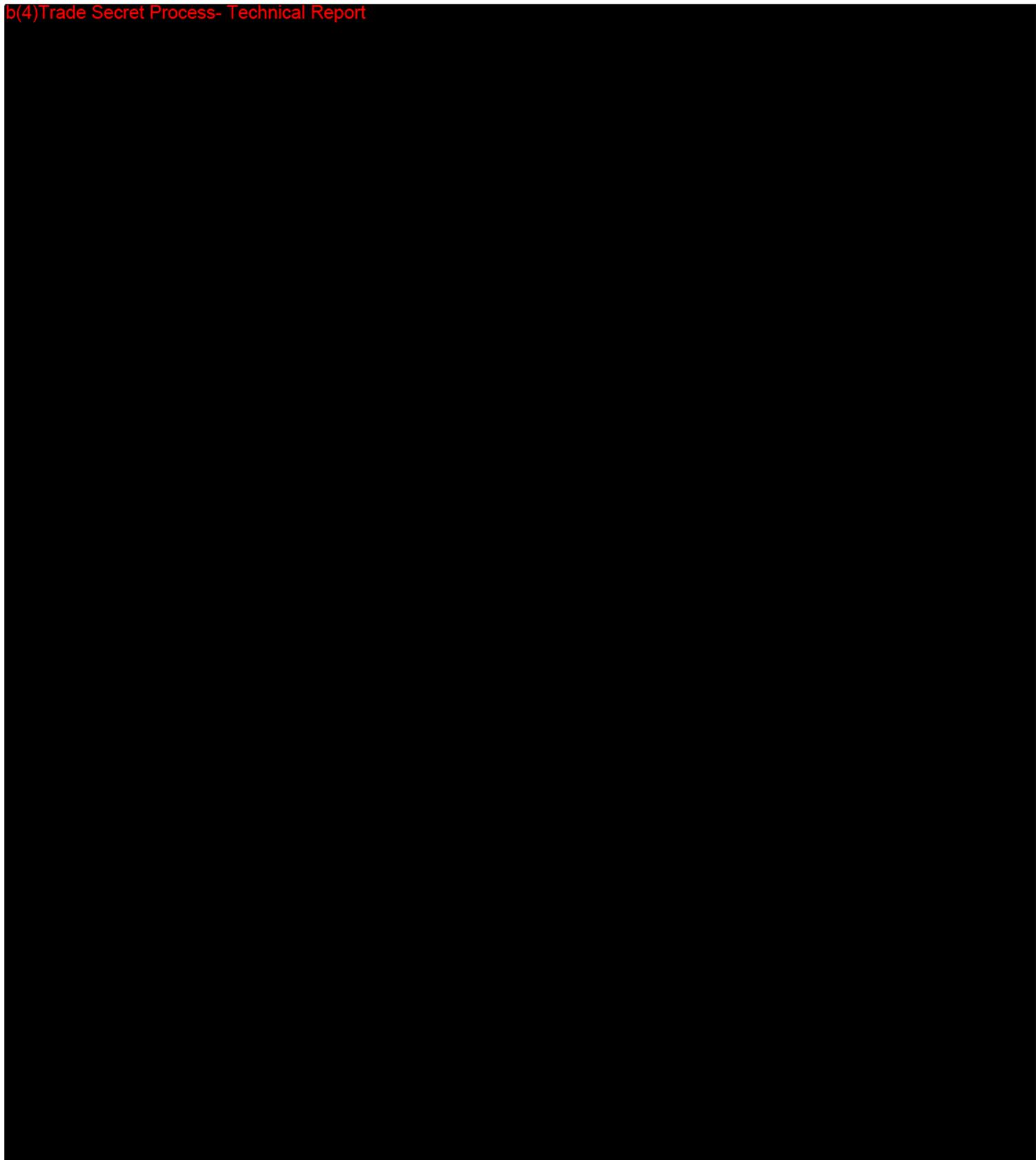


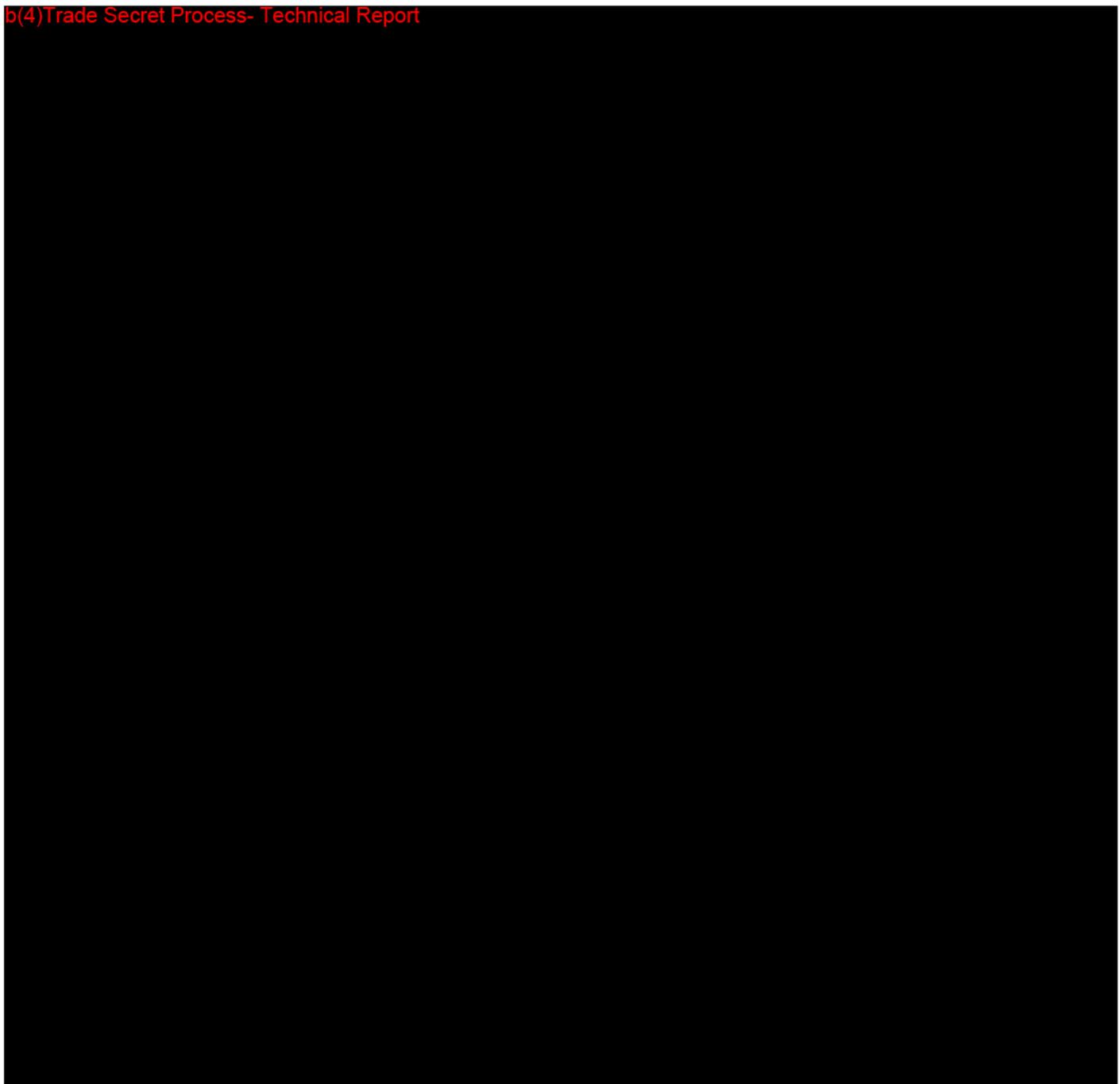


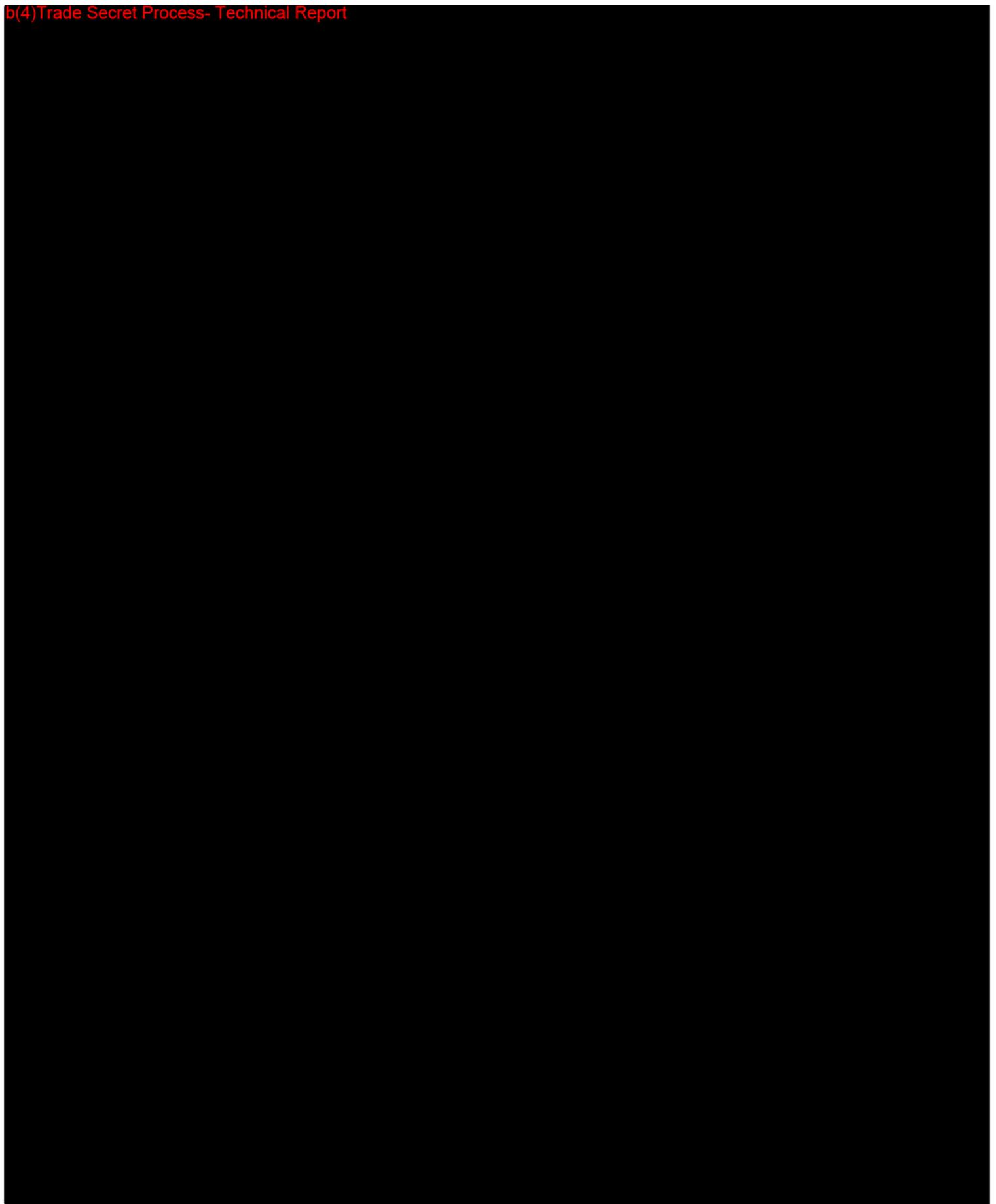
104

b(4)Trade Secret Process- Technical Report



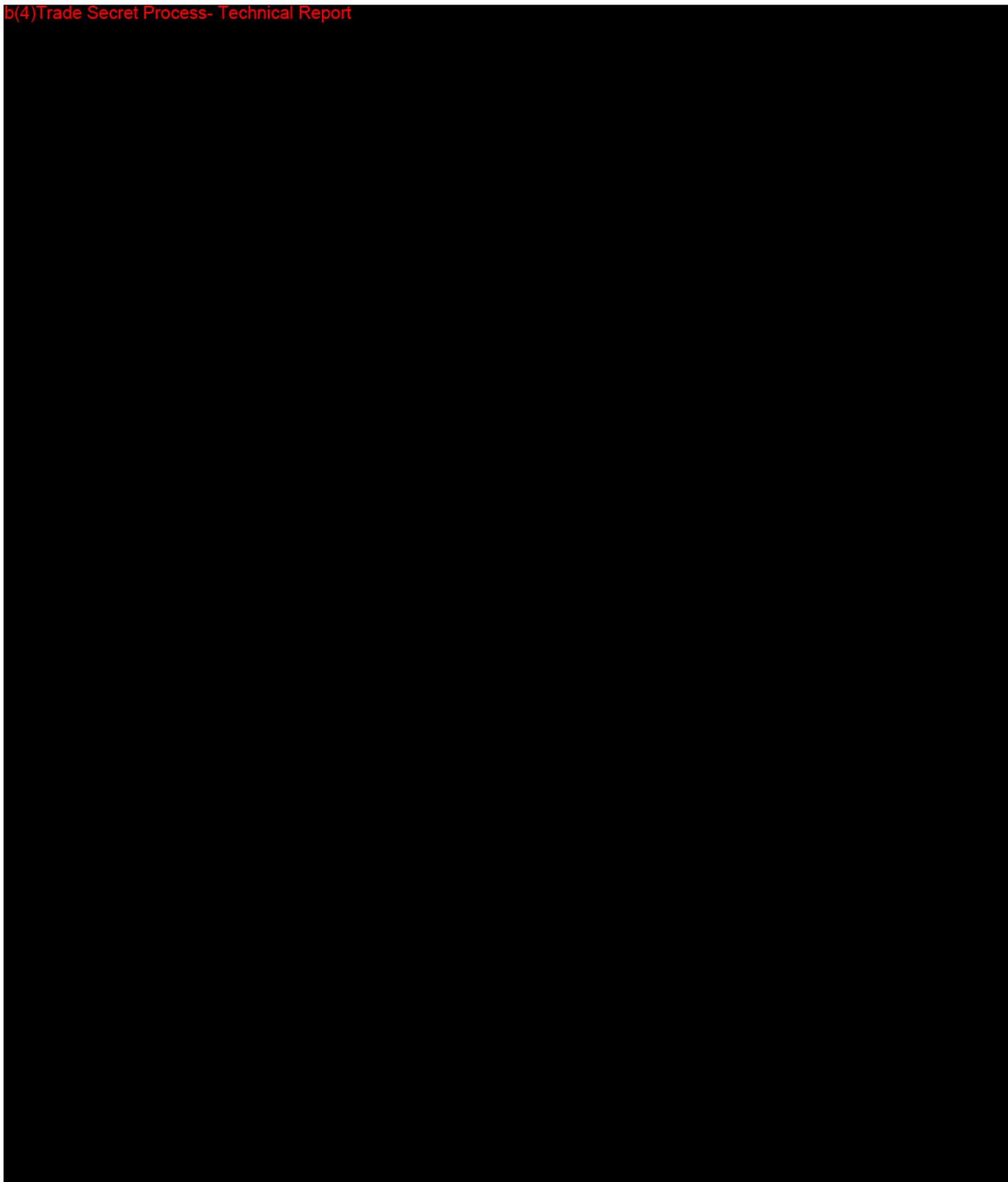


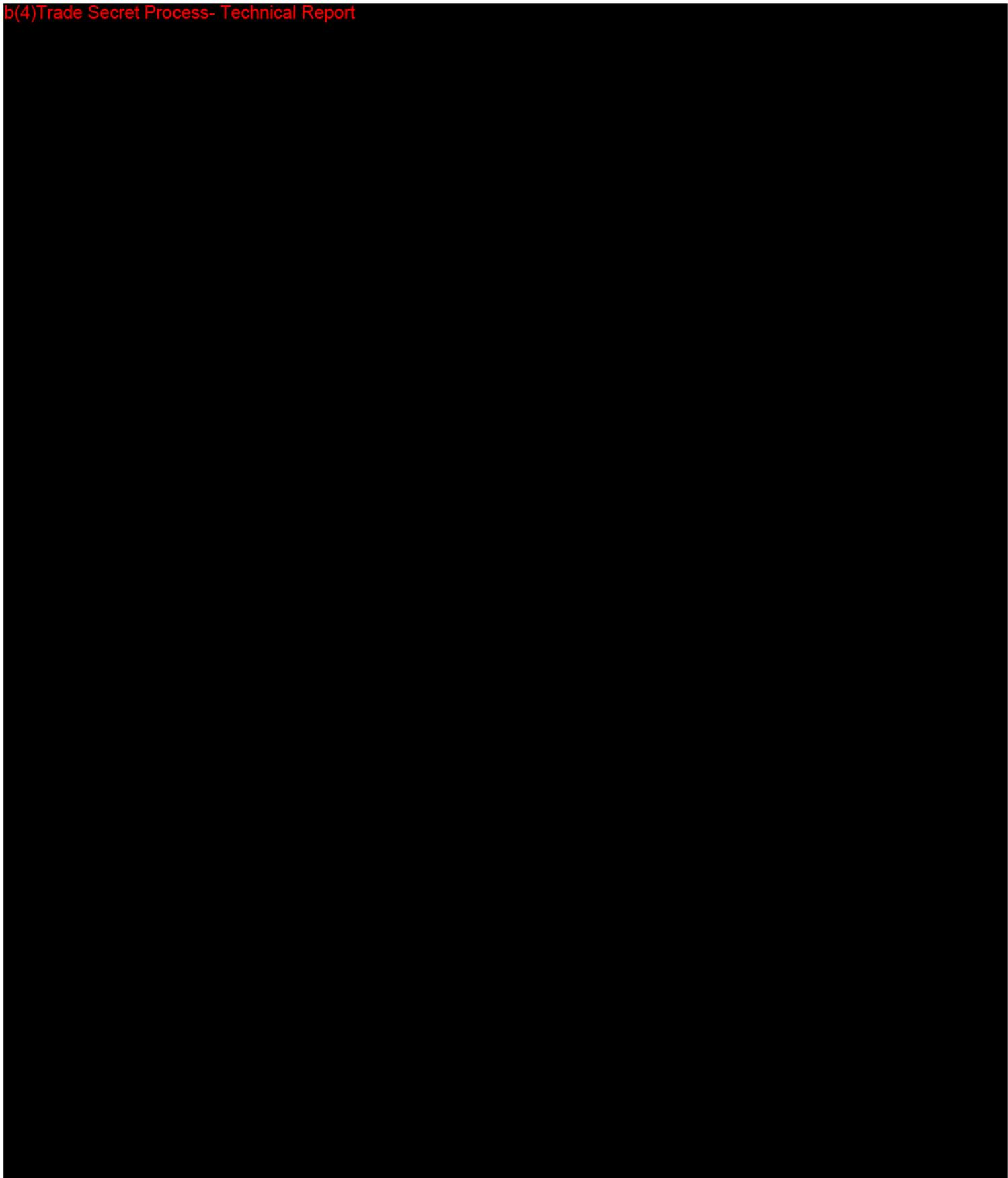


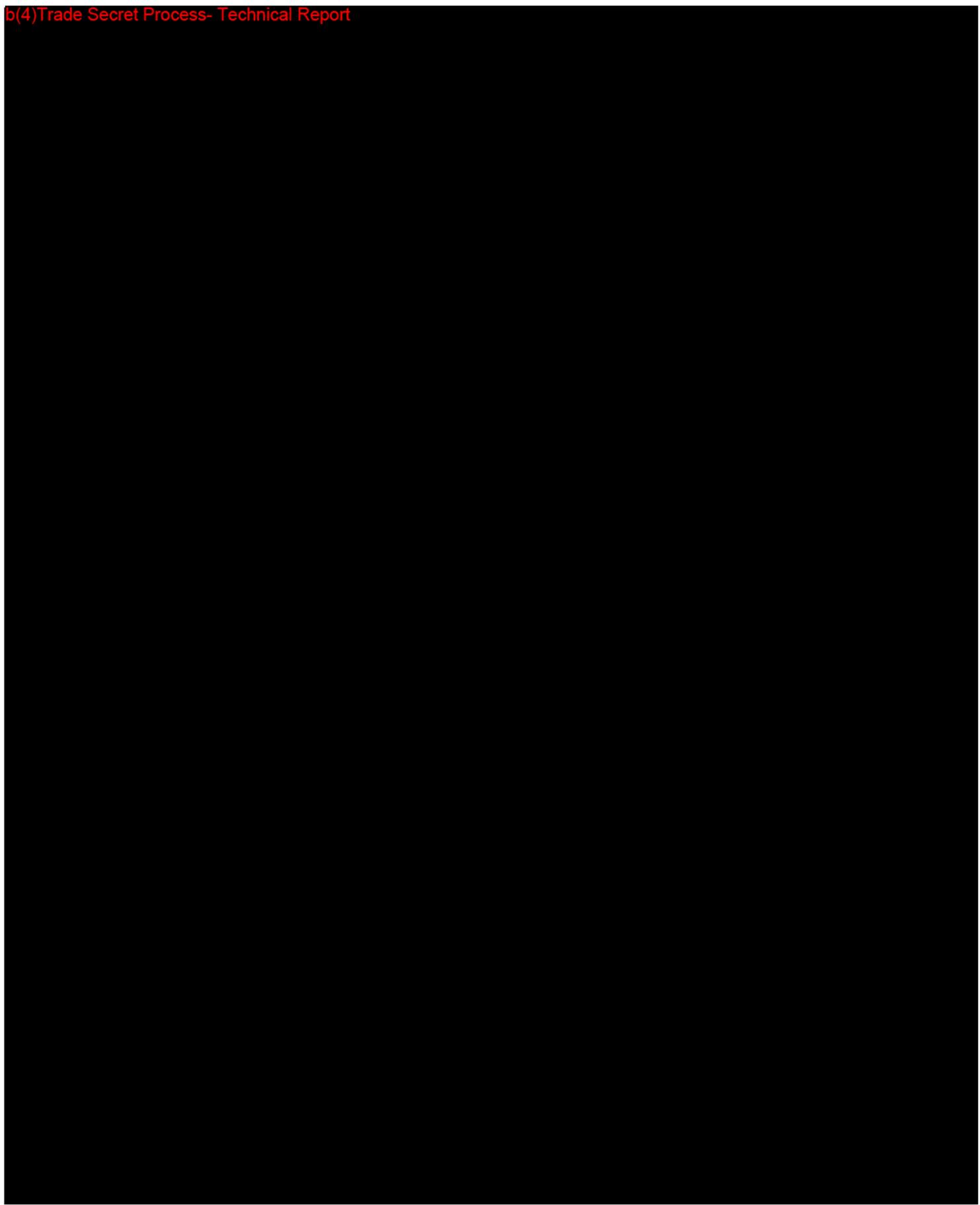


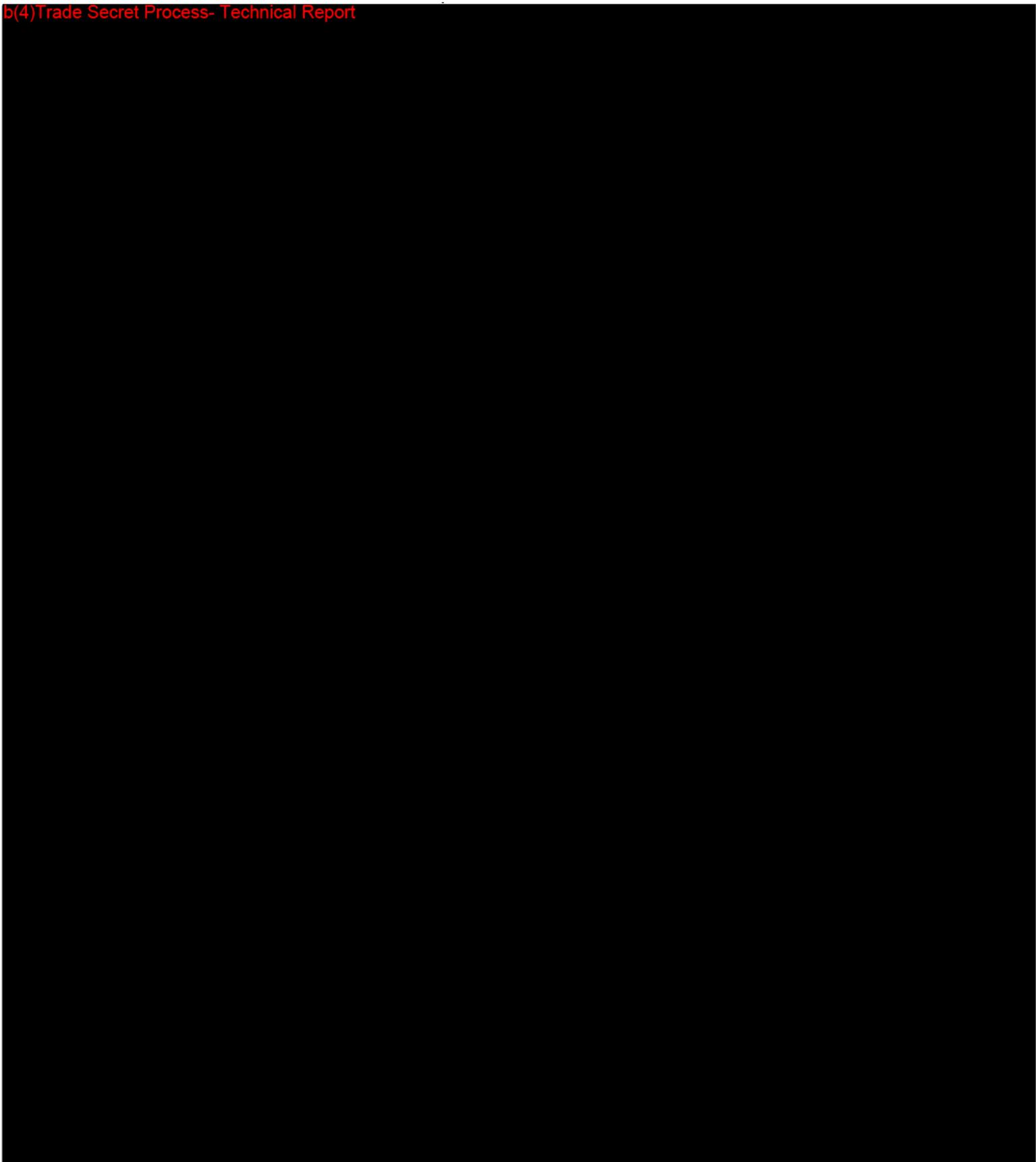
b(4)Trade Secret Process- Technical Report

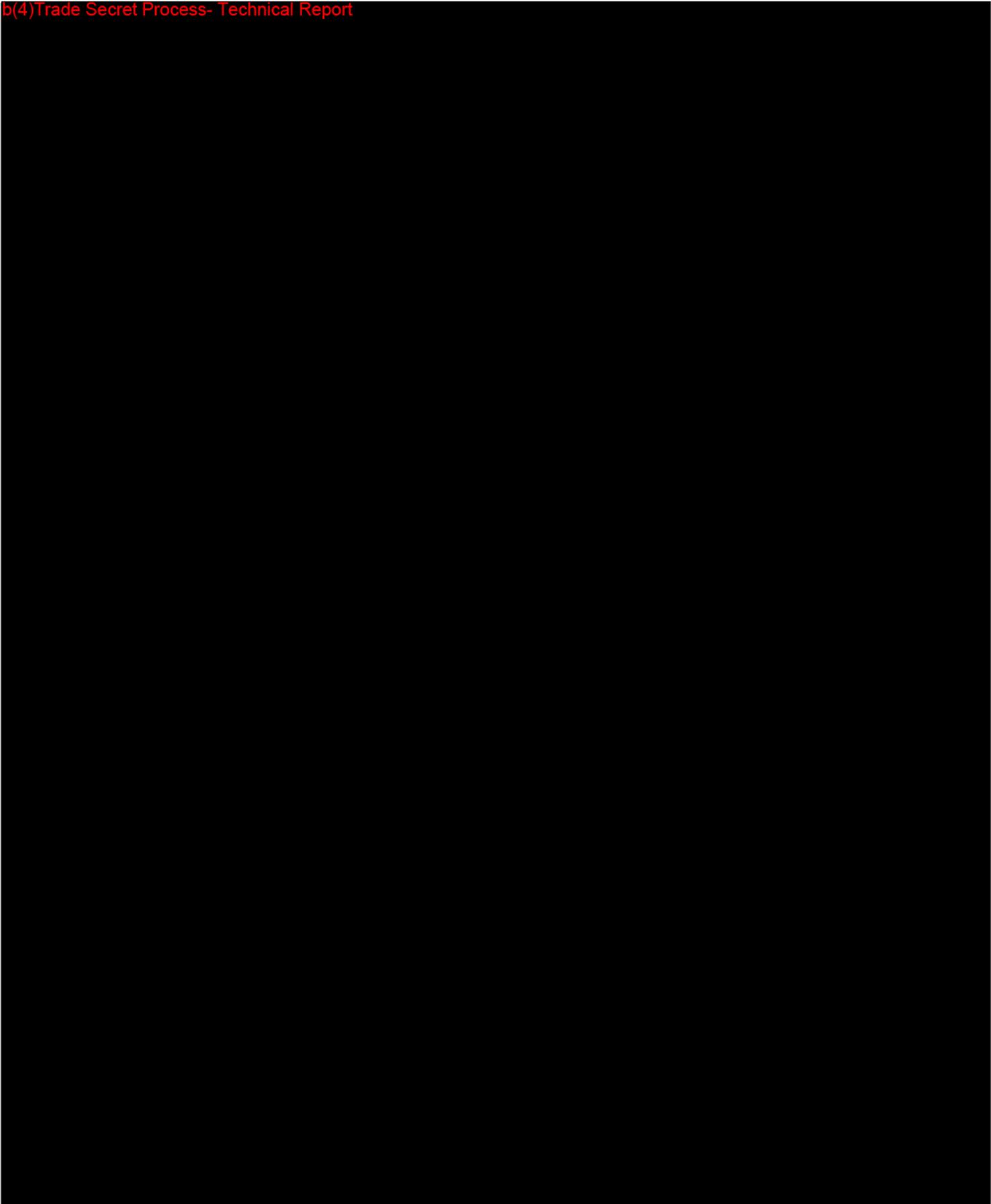


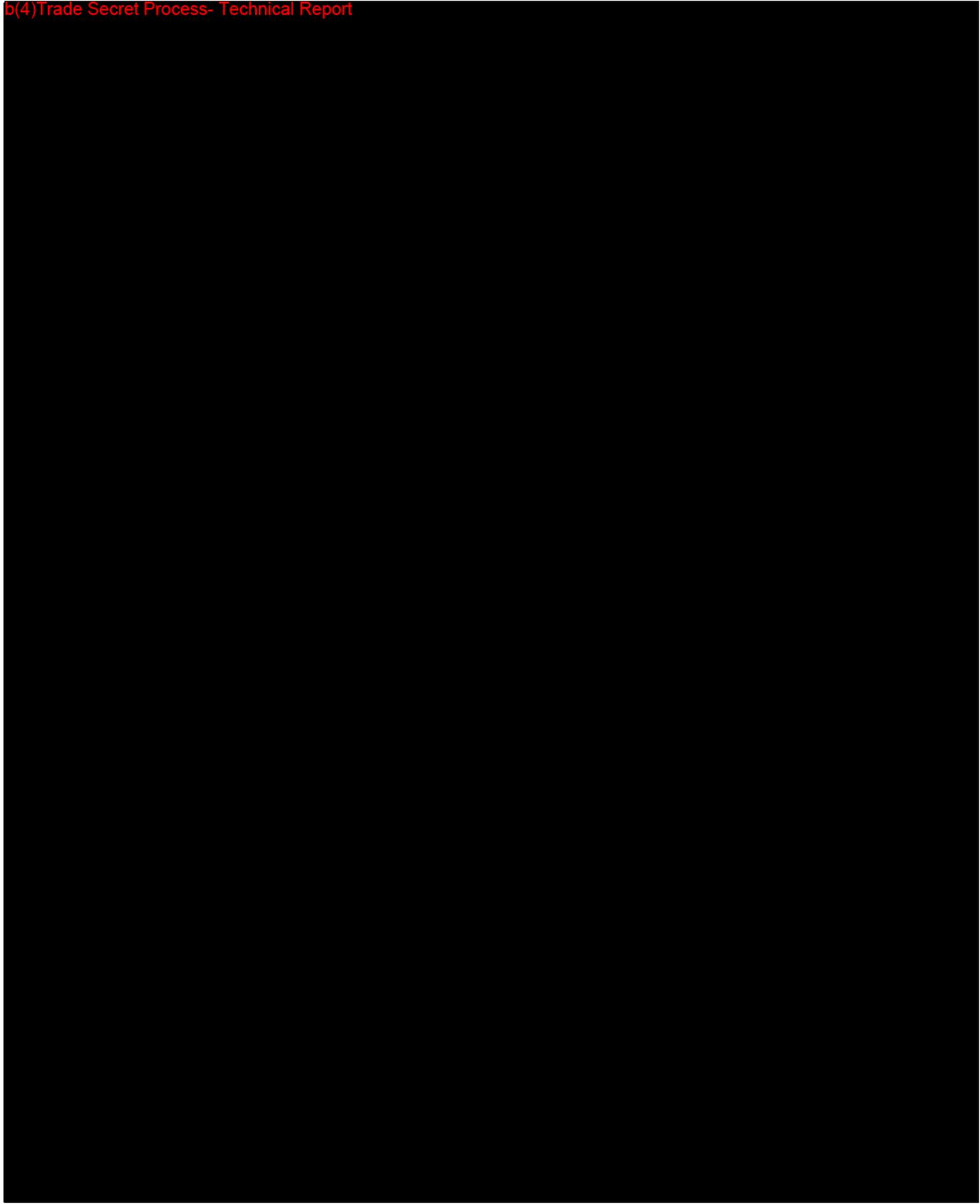


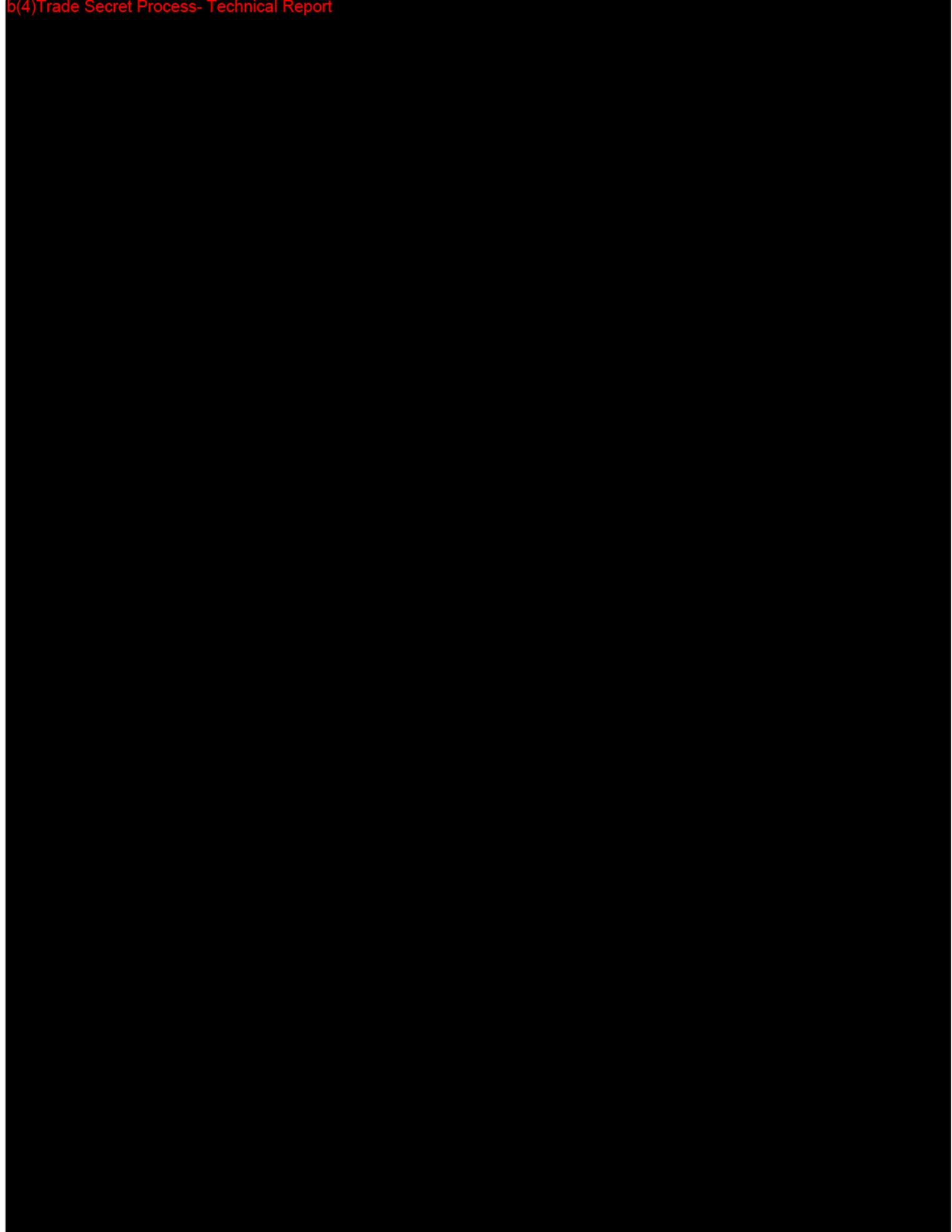


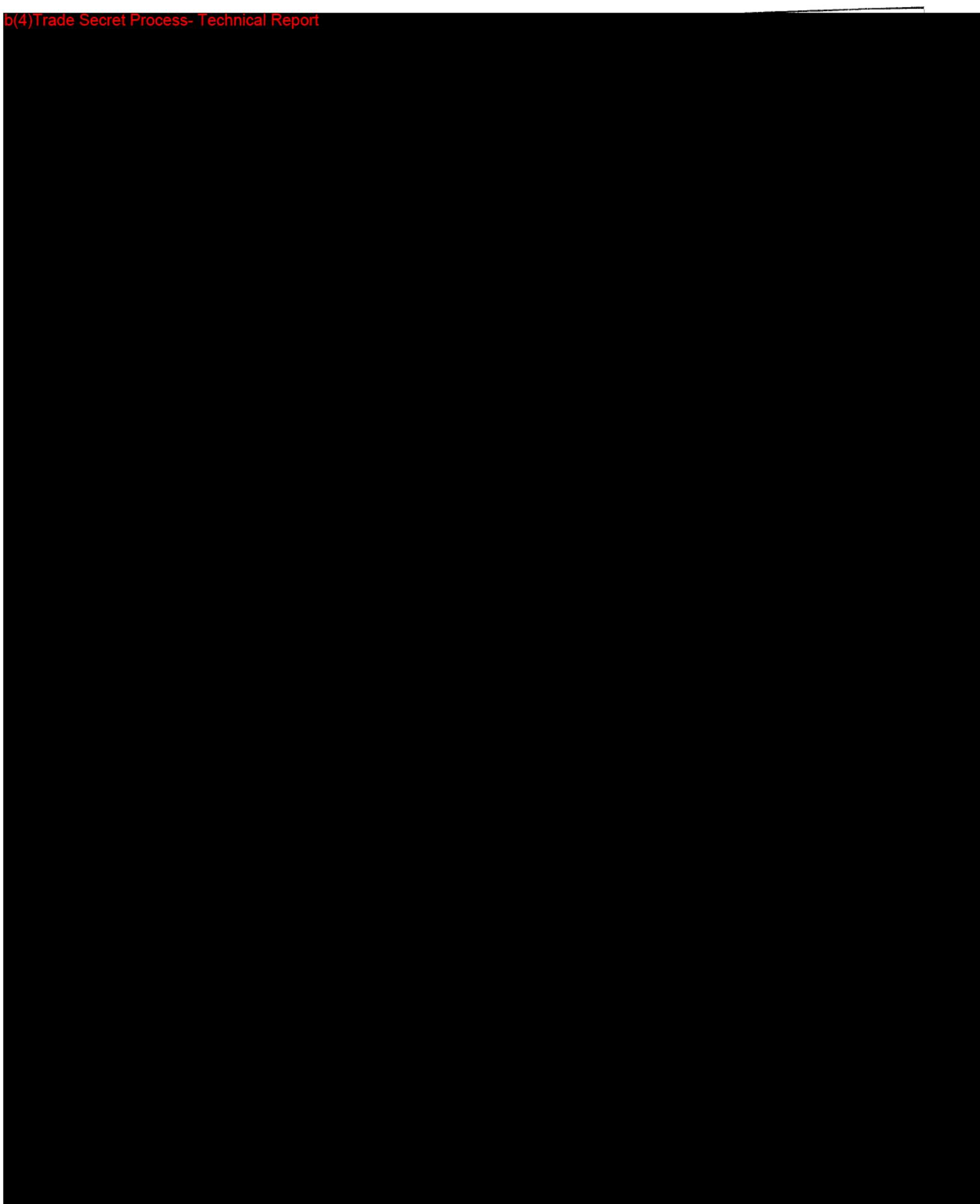


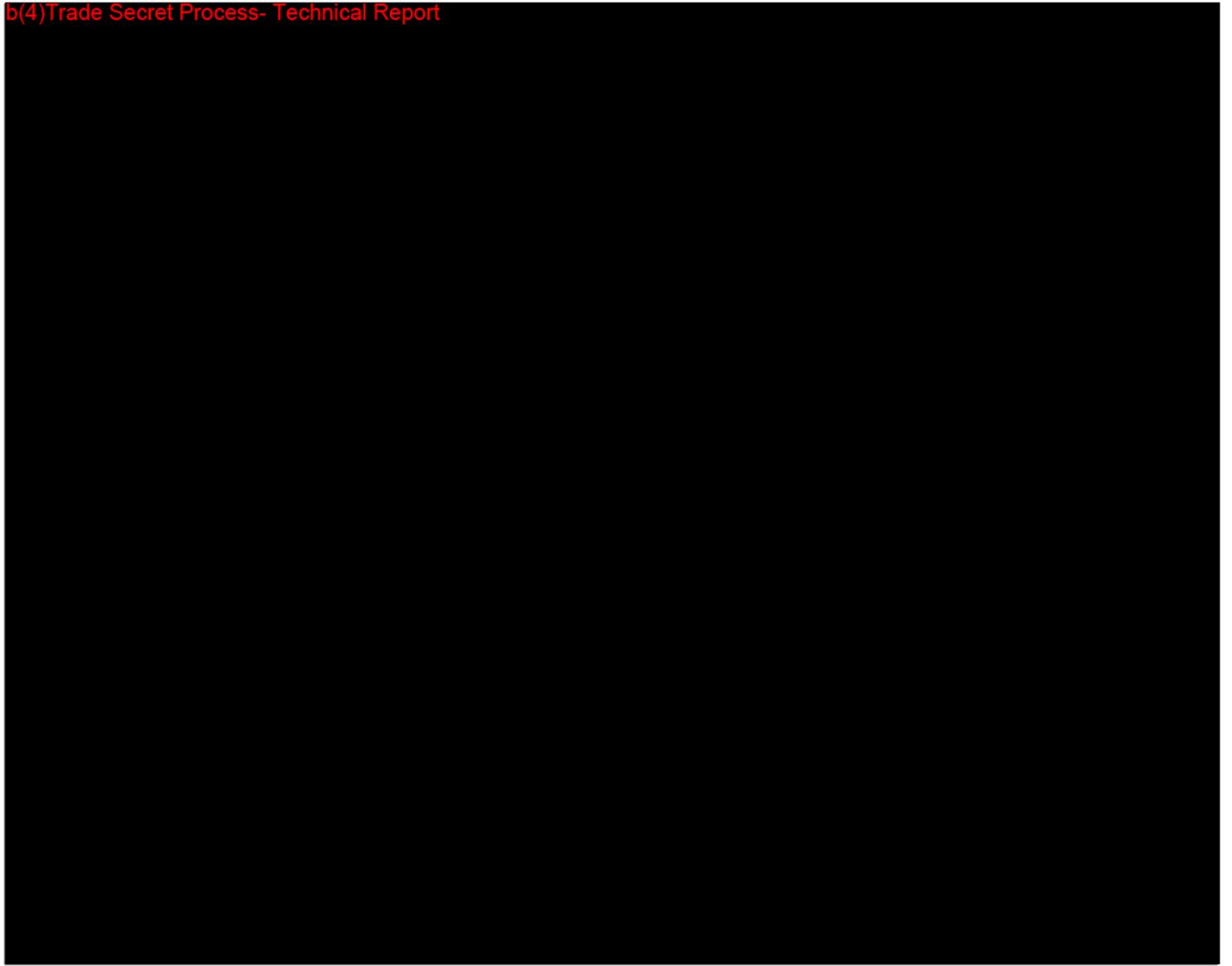










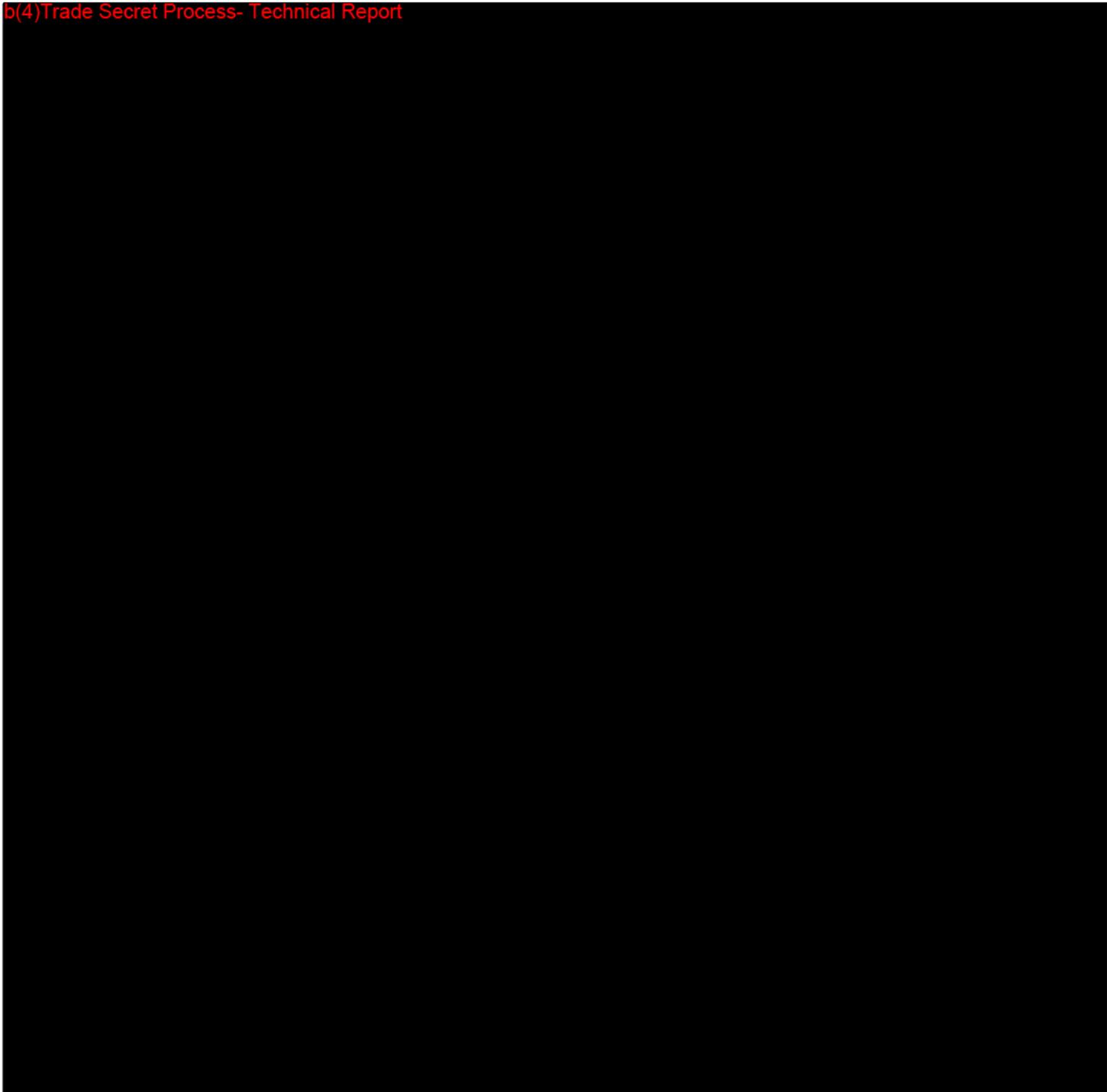


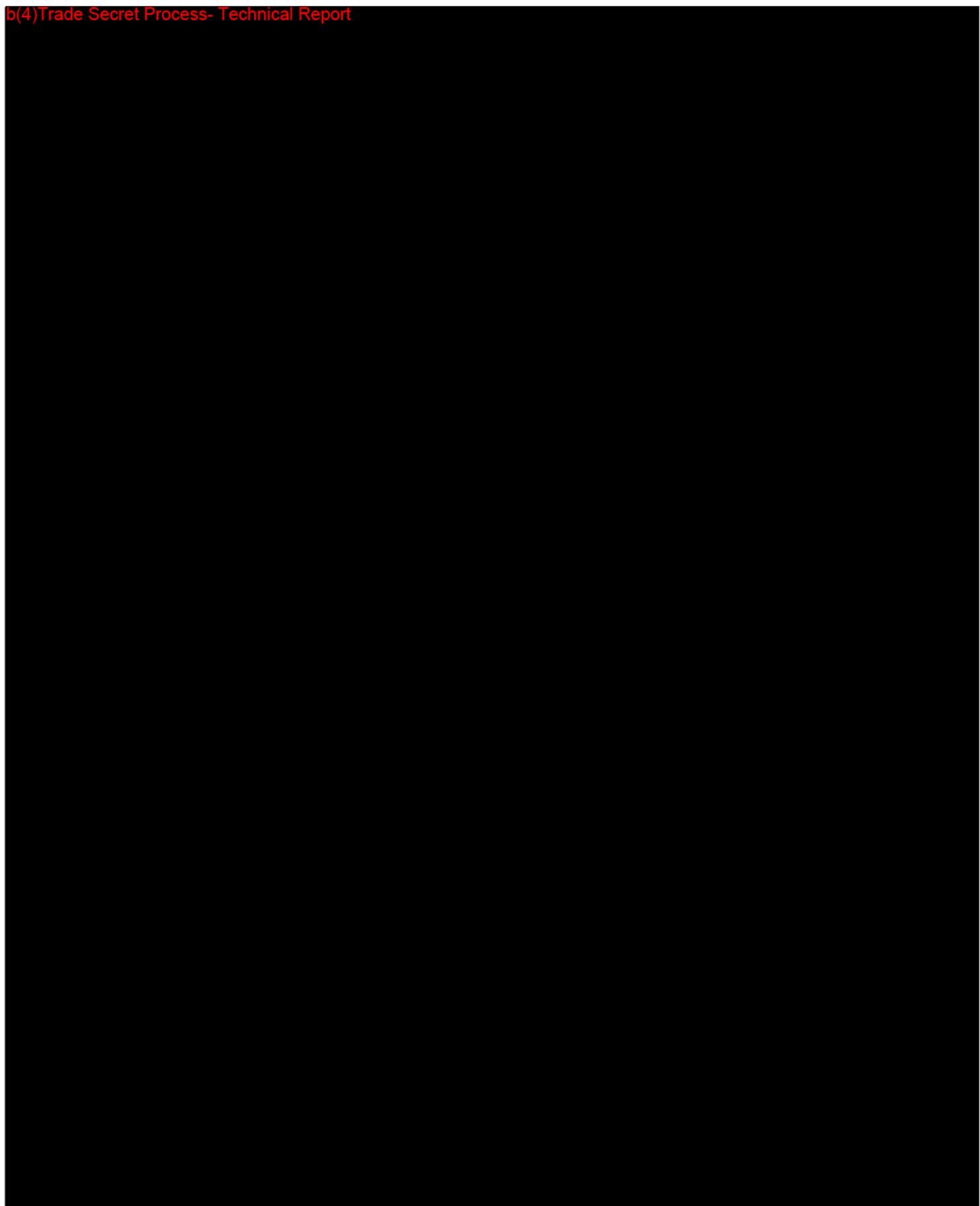
SMITH & NEPHEW ORTHOPAEDICS
Smith & Nephew Richards Inc.
Orthopaedic Research Department
1450 E. Brooks Road
Memphis, TN 38116

RED IS
CONTROLLED
COPY _____
COPY _____

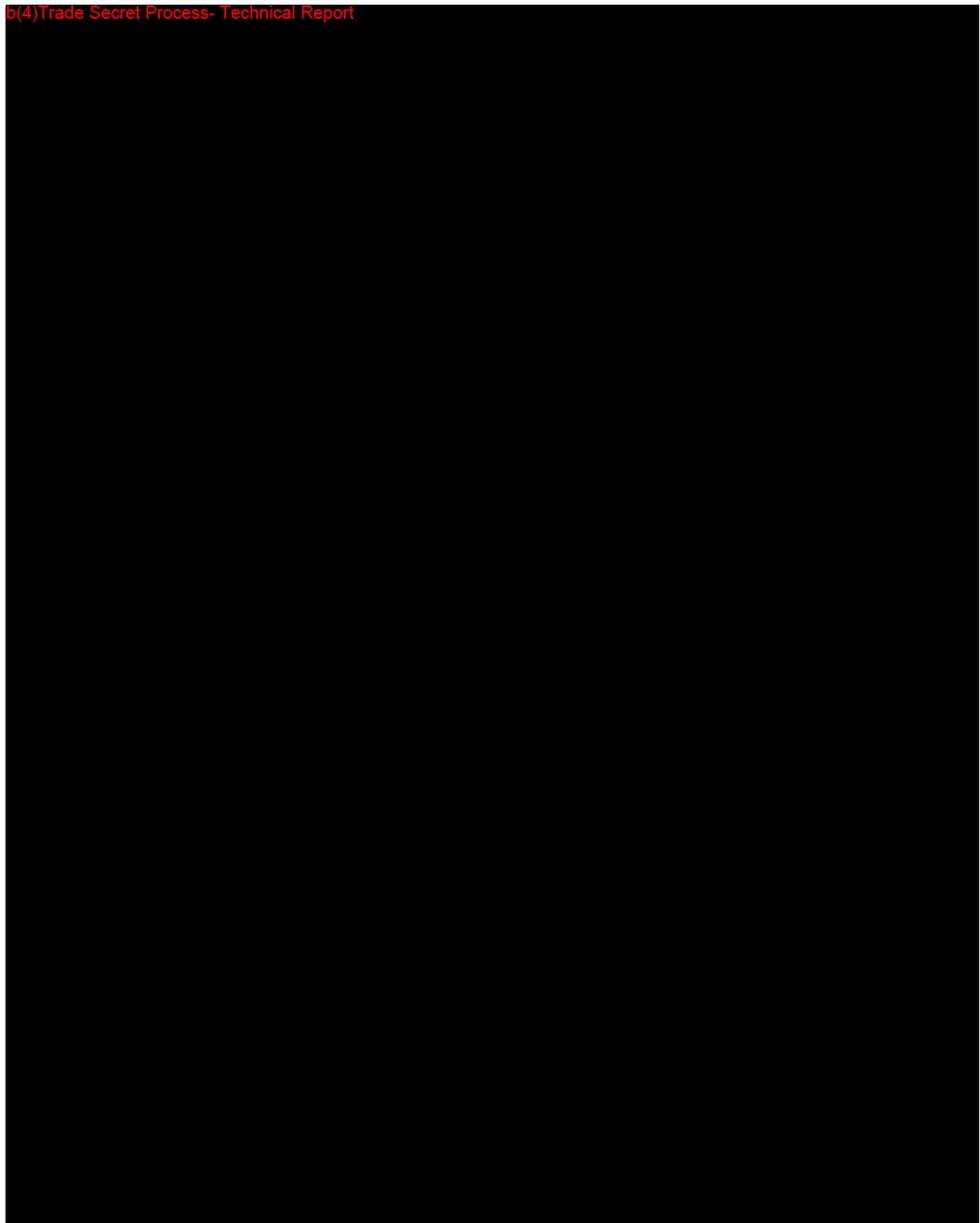
TECHNICAL REPORT

b(4) Trade Secret Process- Technical Report

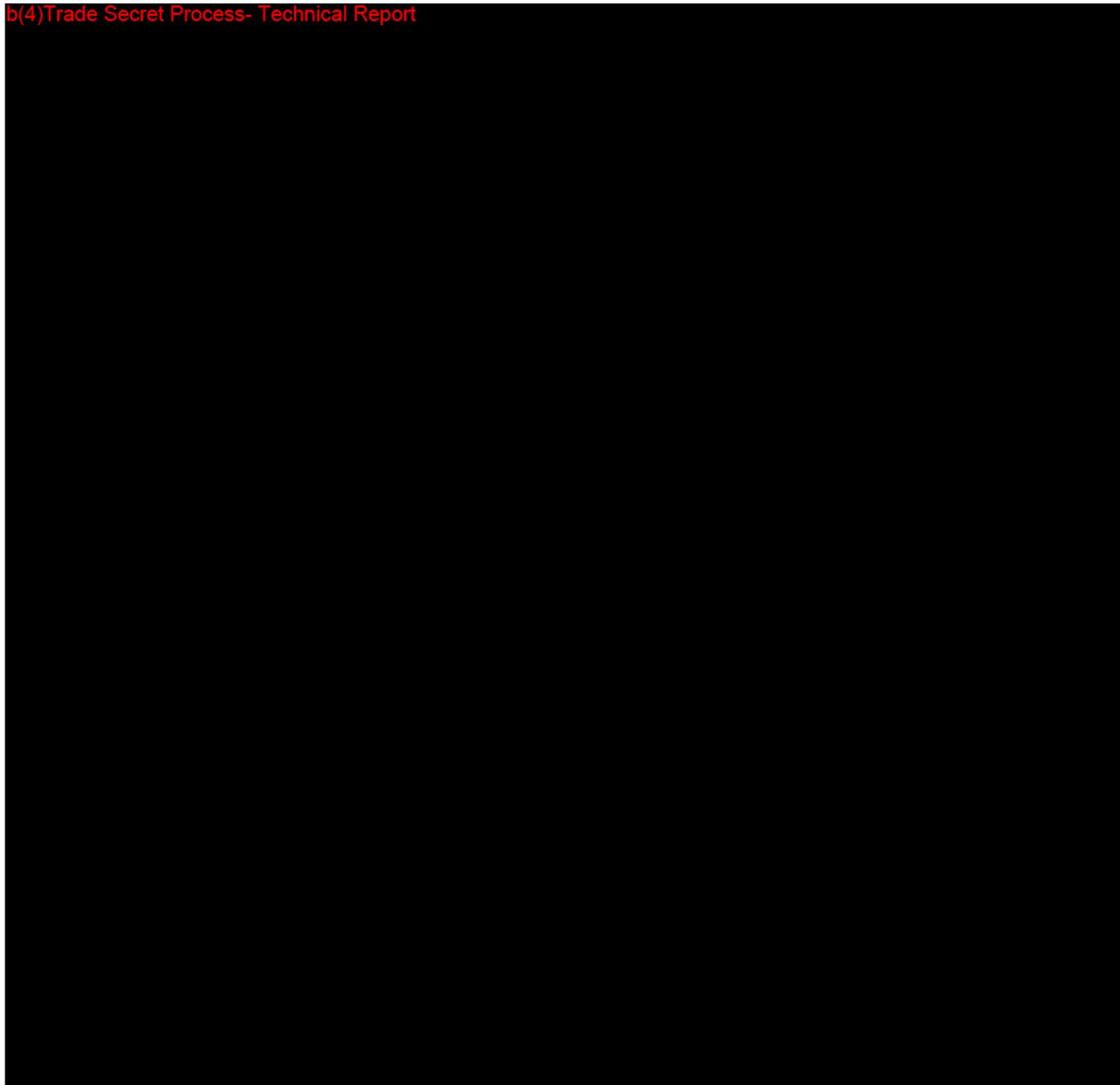




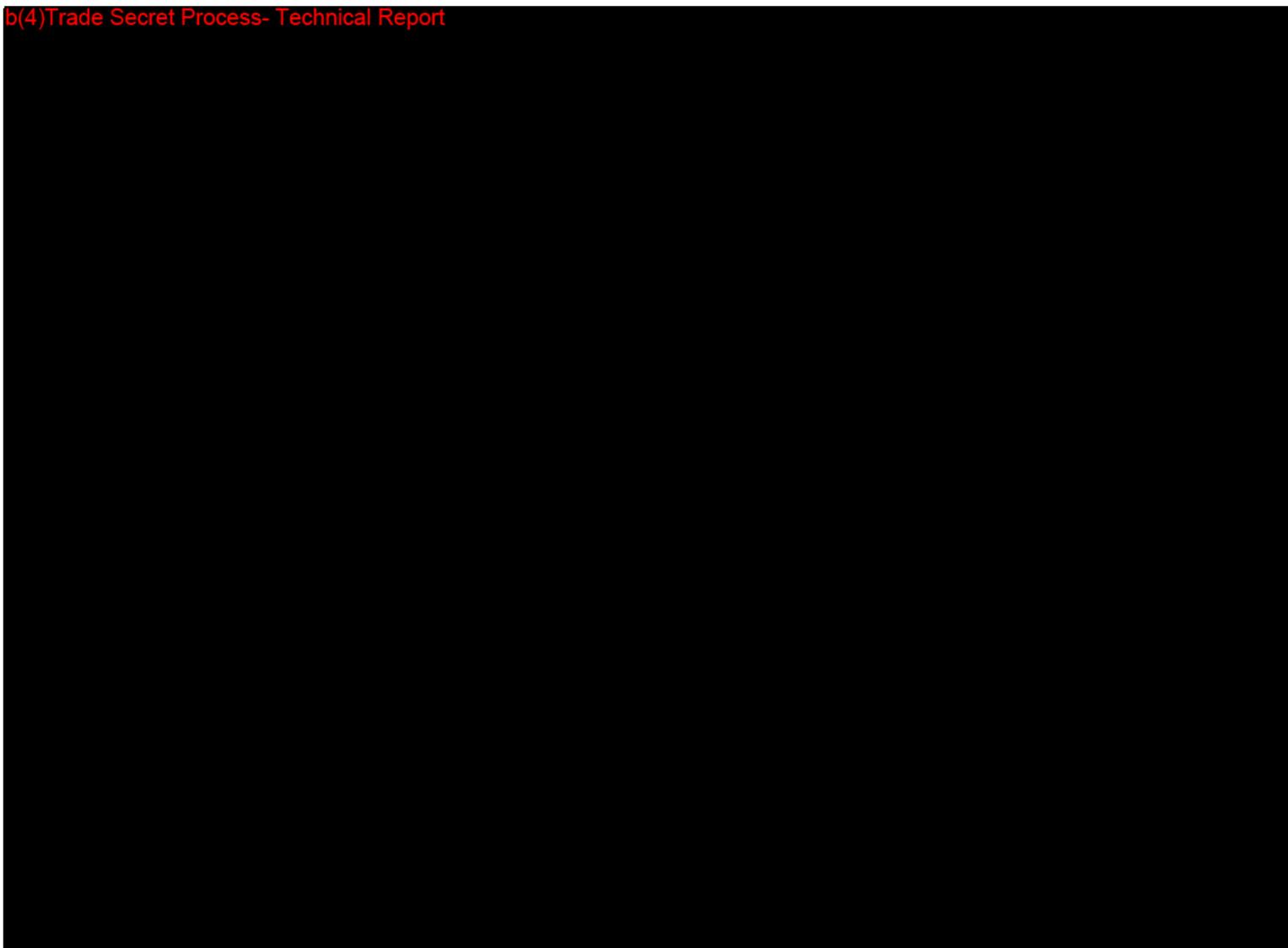
lit

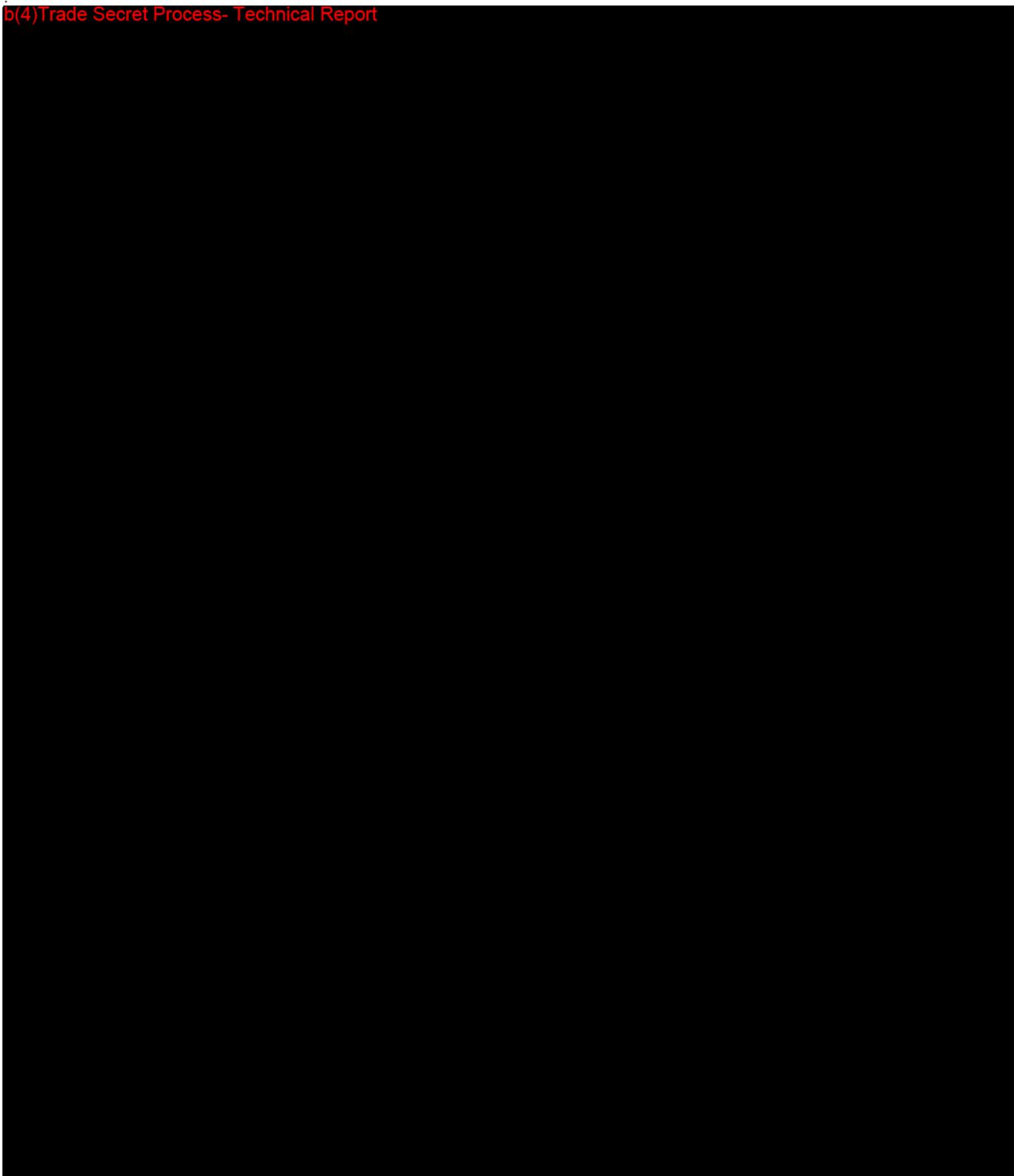


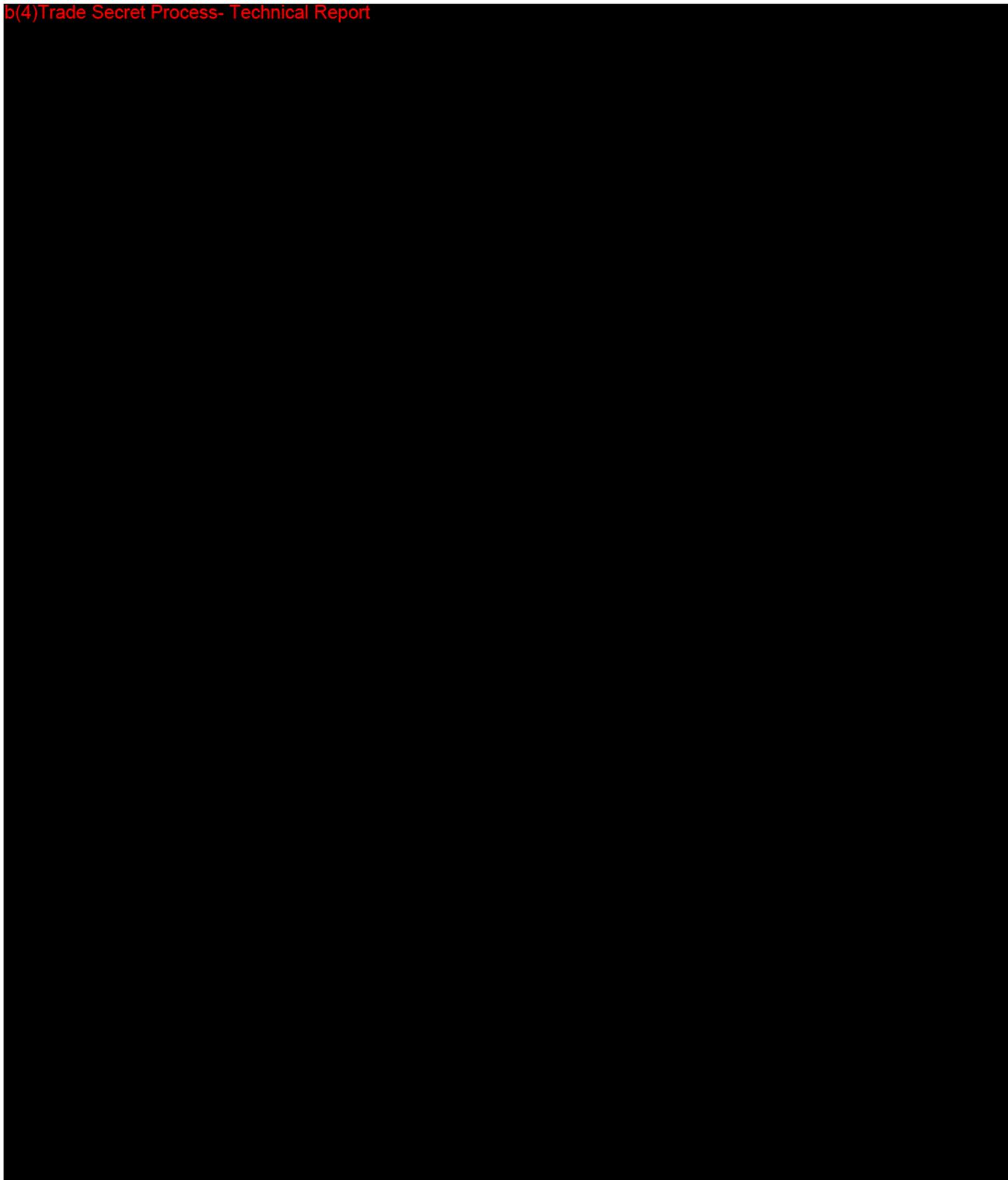
b(4)Trade Secret Process- Technical Report



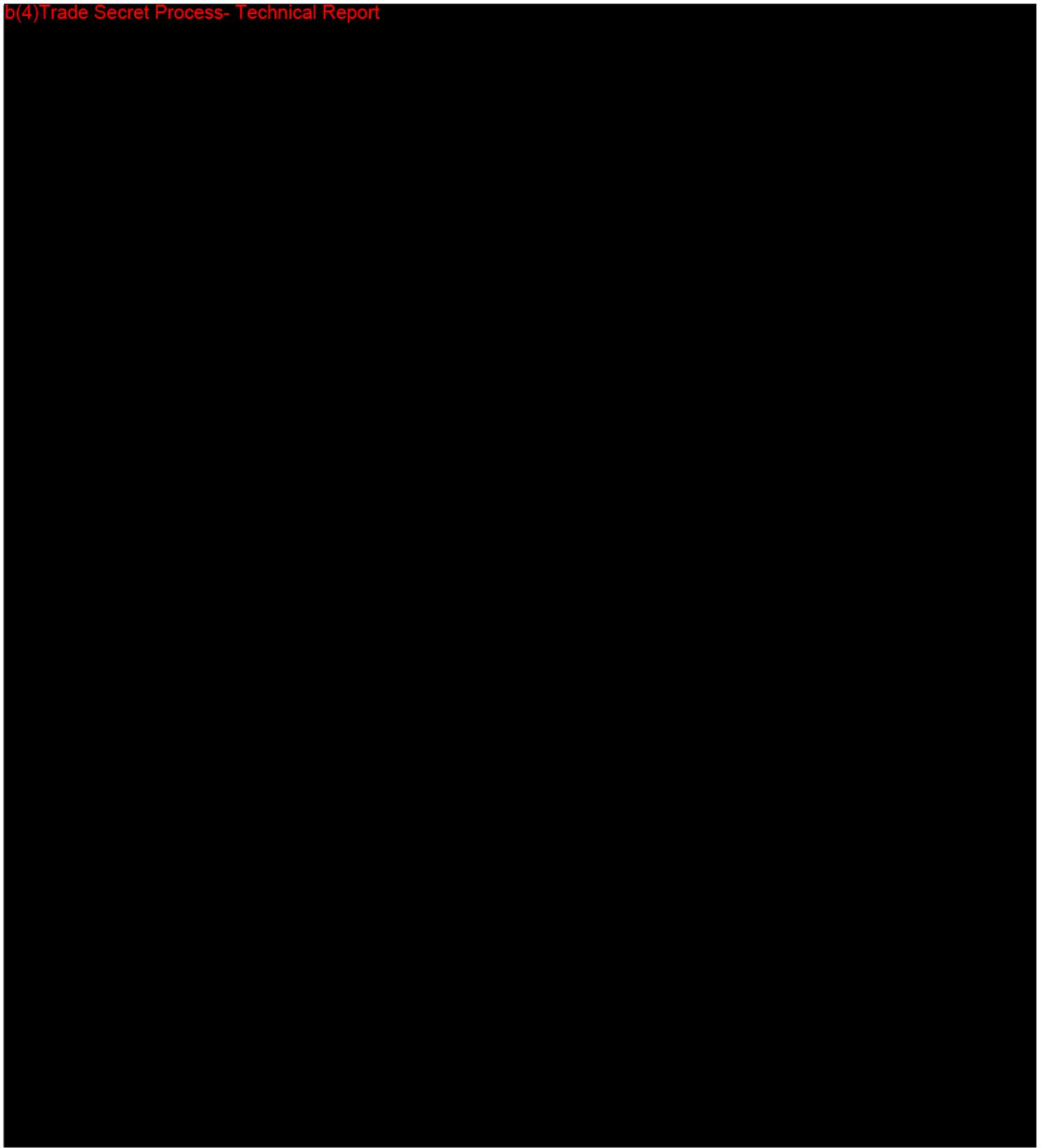
124





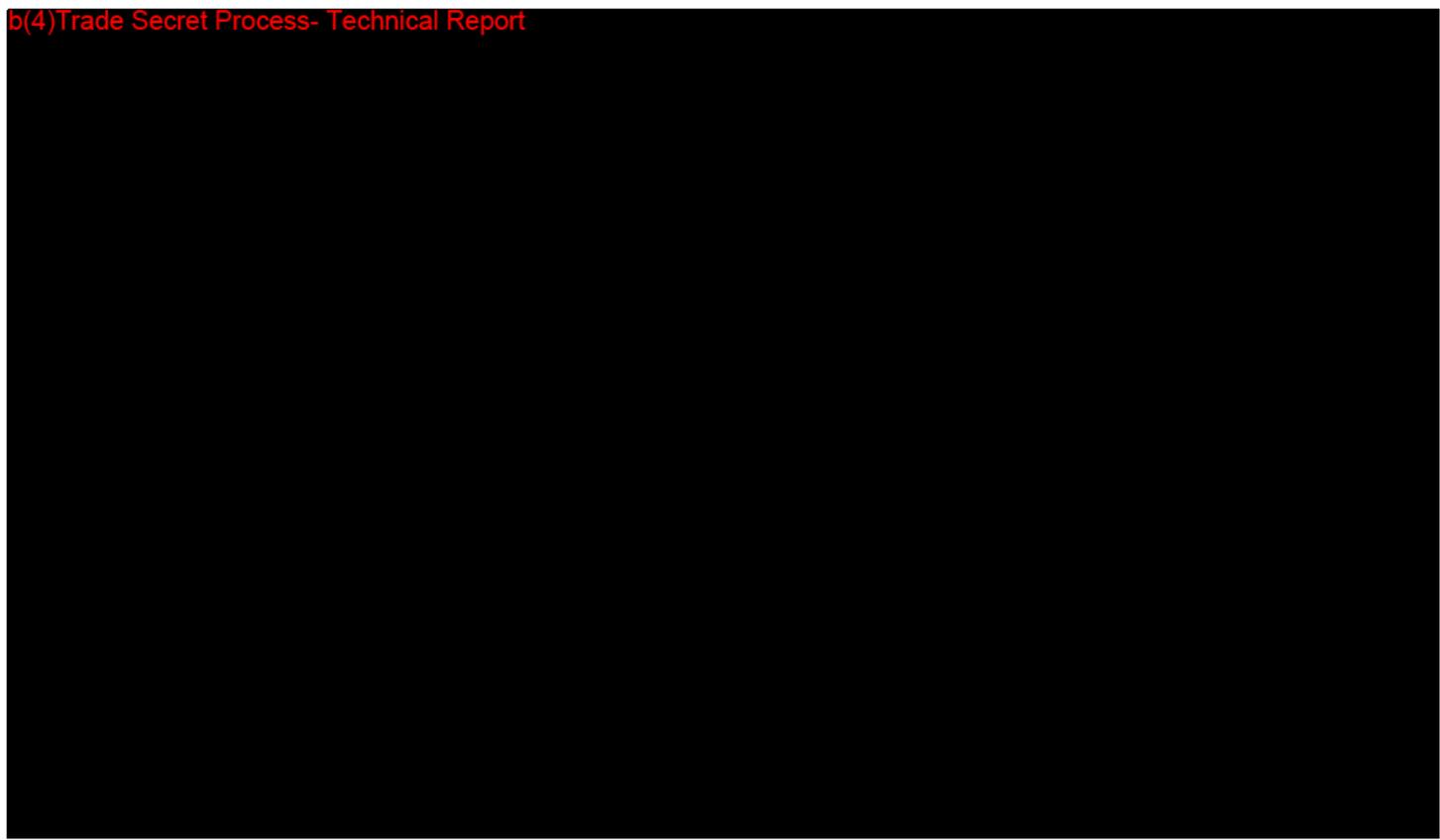


b(4)Trade Secret Process- Technical Report



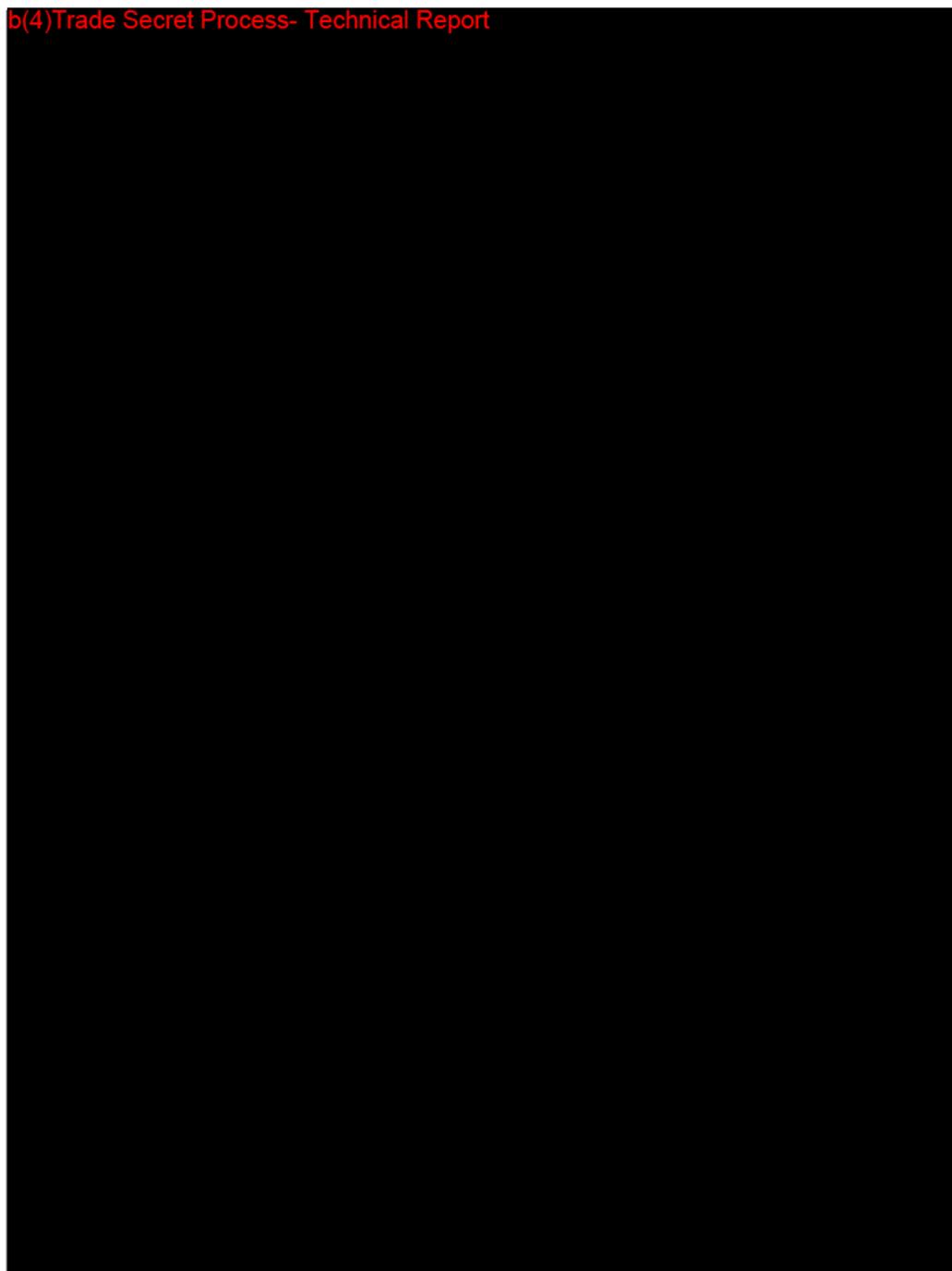
128

b(4)Trade Secret Process- Technical Report



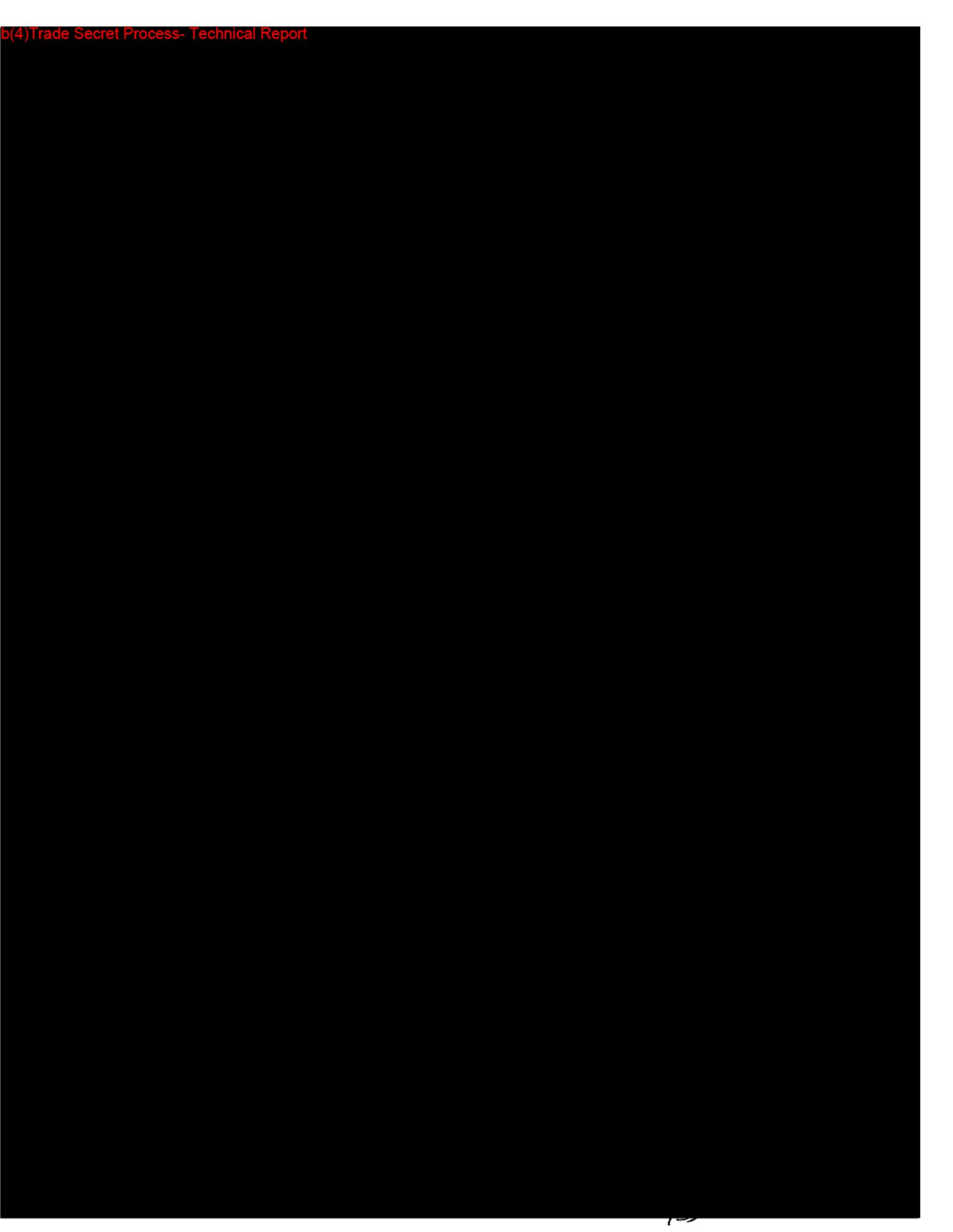
Appendix B: Calculations

b(4)Trade Secret Process- Technical Report



Appendix C: Print

132





JUL 17 1998

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. JoAnn M. Kuhne
Manager, Regulatory Affairs
Smith & Nephew, Inc.
Orthopaedic Division
1450 East Brooks Road
Memphis, Tennessee 38116

Re: K981847
Biolox Alumina Ceramic Femoral Heads
Regulatory Class: II
Product Code: LZO
Dated: May 22, 1998
Received: May 26, 1998

Dear Ms. Kuhne:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act and the following limitation that the package insert must reflect that the Biolox Alumina Ceramic Femoral Heads are to be used only with cobalt-chrome and Ti6Al4V alloy Smith & Nephew hip stems with the 12/14 taper trunnions, and that the 28 mm long sized femoral head is not for use with cobalt-chrome tapers.

The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that,

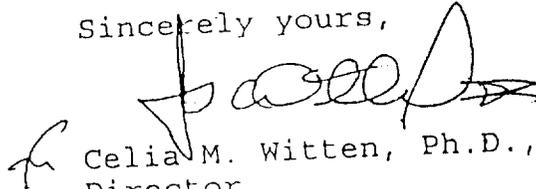
134

through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal Laws or Regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification immediately. An FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,

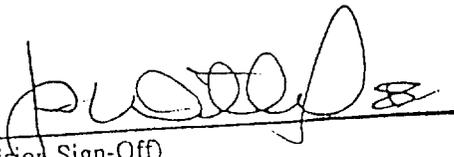

Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications Statement
Biolox Alumina Ceramic Femoral Head

Total hip components are indicated for individuals undergoing primary and revision surgery where other treatments or devices have failed in rehabilitating hips damaged as a result of trauma; inflammatory joint disease such as rheumatoid arthritis, or noninflammatory degenerative joint disease (NIDJD) or any of its composite diagnoses such as osteoarthritis; avascular necrosis; traumatic arthritis; slipped capital epiphysis; fused hip; fracture of the pelvis; diastrophic variant; old, remote osteomyelitis with an extended drainage-free period; nonunion; femoral neck fracture and trochanteric fractures of the proximal femur with heads involvement that are unmanageable using other techniques; femoral osteotomy, or Girdlestone resection; fracture dislocation of the hip; and correction of deformity.

Prescription Use X
(Per 21 CFR 801.109)



(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K981847



JAN 28 2000

Food and Drug Administration
9200 Corporate Boulevard
Rockville, MD 20850



Mr. David Henley
Clinical/Regulatory Affairs Specialist
Smith & Nephew, Inc.
1450 Brooks Road
Memphis, Tennessee 38116

Re: K991162
Trade Name: Biolox Alumina Ceramic Femoral Head, 28 mm Long, 12/14 Taper
Regulatory Class: II
Product Code: LZO
Dated: November 3, 1999
Received: November 4, 1999

Dear Mr. Henley:

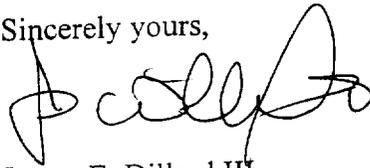
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general control provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,



James E. Dillard III
Acting Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

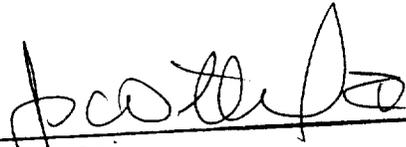
138

K991162

Indications Statement

28 mm. Long Biolox Alumina Ceramic Femoral Head

Total hip components are indicated for individuals undergoing primary and revision surgery where other treatments or devices have failed in rehabilitating hips damaged as a result of trauma, inflammatory joint disease such as rheumatoid arthritis, or noninflammatory degenerative joint disease (NIDJD) or any of its composite diagnoses such as osteoarthritis; avascular necrosis; traumatic arthritis; slipped capital epiphysis; fused hip; fracture of the pelvis; diastrophic variant; old, remote osteomyelitis with an extended drainage free period; nonunion; femoral neck fracture and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques; femoral osteotomy, or Girdlestone resection; fracture dislocation of the hip; and correction of deformity.



(Division Sign-Off)
Division of General Restorative Devices K99 1162
510(k) Number _____

Prescription Use X
(Per 21 CFR 801.109)

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850



Ms. JoAnn Kuhne
Manager, Regulatory and Clinical Affairs
Smith and Nephew, Inc.
1450 Brooks Road
Memphis, Tennessee 38116

JUL 16 1997

Re: K971414
Zirconia Ceramic 12/14 Global
Taper (GT) Femoral Heads
Regulatory Class: II
Product Code: LZ0
Dated: April 15, 1997
Received: April 16, 1997

Dear Ms. Kuhne:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act and the following limitation that the package insert must reflect that the Zirconia Ceramic 12/14 Global Taper (GT) Femoral Heads are to be used only with cobalt-chrome and Ti6Al4V alloy hip stems with the 5°43' Morse taper trunnions.

The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal Laws or Regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification immediately. An FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market.

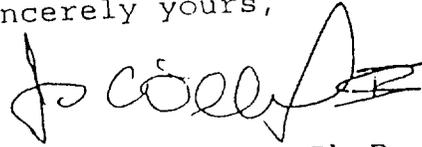
If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be

141

Page 3 - Ms. JoAnn Kuhne

obtained from the Division of Small Manufacturers Assistance
at its toll-free number (800) 638-2041 or (301) 443-6597 or at
its Internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,



fr

Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Exhibit 2

Indications for Use:

INTENDED USE:

The Zirconia femoral head components are to be used with other total hip components as part of a total hip arthroplasty. The components are indicated for cemented and uncemented use for individuals undergoing primary and revision surgery where other treatments or devices have failed for rehabilitating hips damaged as a result of trauma, or non-inflammatory degenerative joint disease (NIDJD) or any of its composite diagnoses of osteoarthritis, avascular necrosis, traumatic arthritis, slipped capital epiphysis, fused hip, fracture of the pelvis, and diastrophic variant.

Indications also include inflammatory degenerative joint disease including rheumatoid arthritis, arthritis secondary to a variety of diseases and anomalies, and congenital dysplasia; old, remote osteomyelitis with an extended drainage-free period, in which case, the patient should be warned of an above normal danger of infection postoperatively; treatments of nonunion, femoral neck fracture and trochanteric fractures of the proximal femur with heads involvement that are unmanageable using other techniques; endoprosthesis, femoral osteotomy, or Girdlestone resection; fracture-dislocation of the hip; and correction of deformity.

The devices are for single use. These head devices may be used with stems that are available with cementless or cement fixation. These heads have not been submitted to the FDA for identical or different intended uses.

Prescription Use _____
(Per 21 CFR 801.109)

[Handwritten signature]

[Handwritten signature]

(Division Sign-Off)
Division of General Restorative Devices

510(k) Number K971414

BioloX Alumina Ceramic
Femoral Heads

Engineering Drawings

Orthopaedic Division

Smith & Nephew, Inc.
1450 Brooks Rd., Memphis, TN 38116 U.S.A.
901-396-2121, For information: 1-800-821-5700
For orders and order inquiries: 1-800-238-7538

Smith+Nephew

Memorandum

To: Janet Green

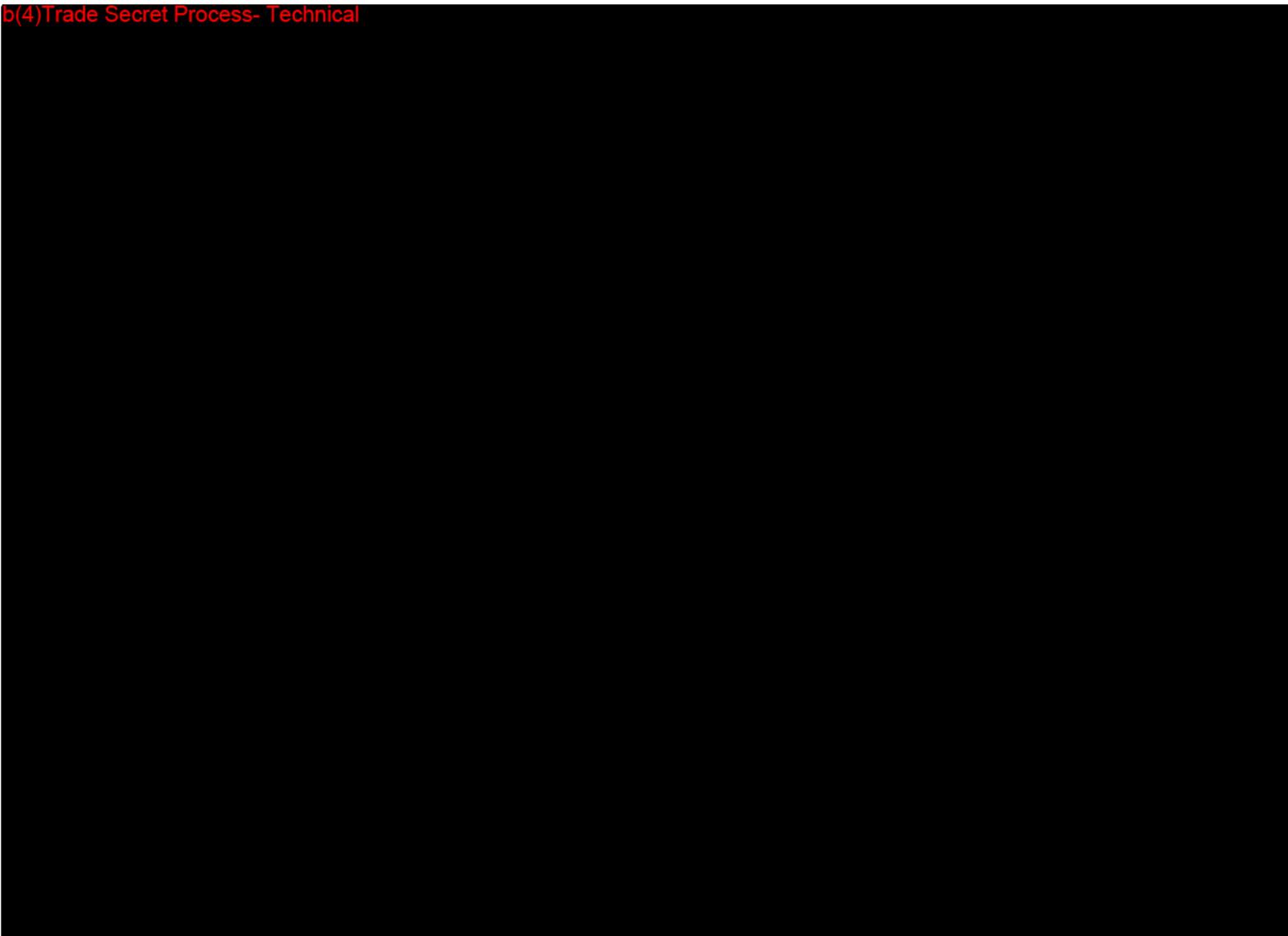
Date: July 6, 1998

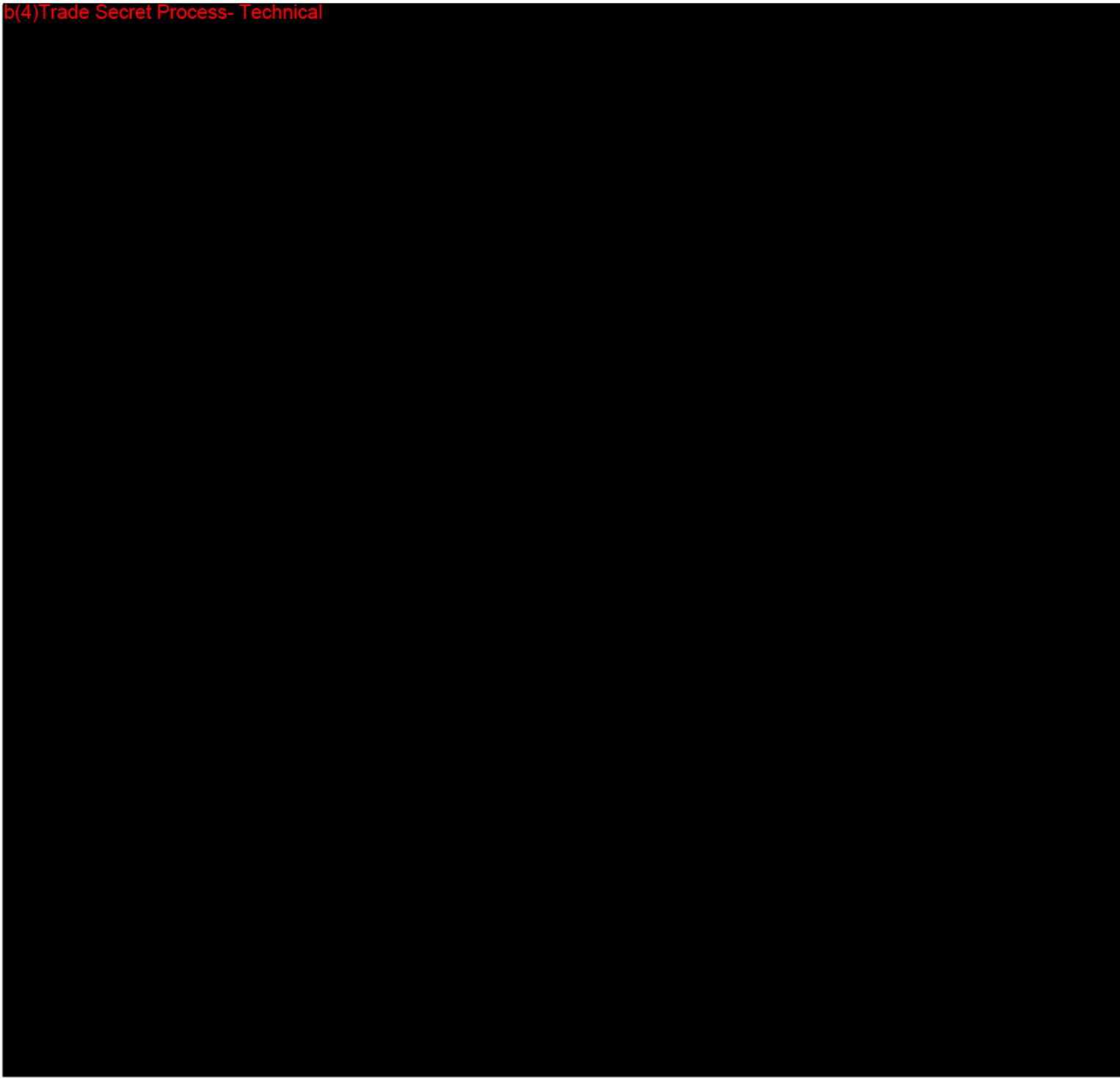
From: Mary Anthony *Mary*

cc: J. Shea, M. Harbaugh,
A. Salehi, D. Todd, File

Subject: Technical Memo- **b(4)Trade Secret** [redacted] Long Offset Biolog
Process- Technical [redacted]
[redacted]

b(4)Trade Secret Process- Technical





APPENDIX A

28 M and 32 L Alumina BioloX Head Prints

Orthopaedic Division

Smith & Nephew, Inc.
1450 Brooks Rd., Memphis, TN 38116 U.S.A.
901-396-2121, For information: 1-800-821-5700
For orders and order inquiries: 1-800-238-7538

Smith+Nephew

Memorandum

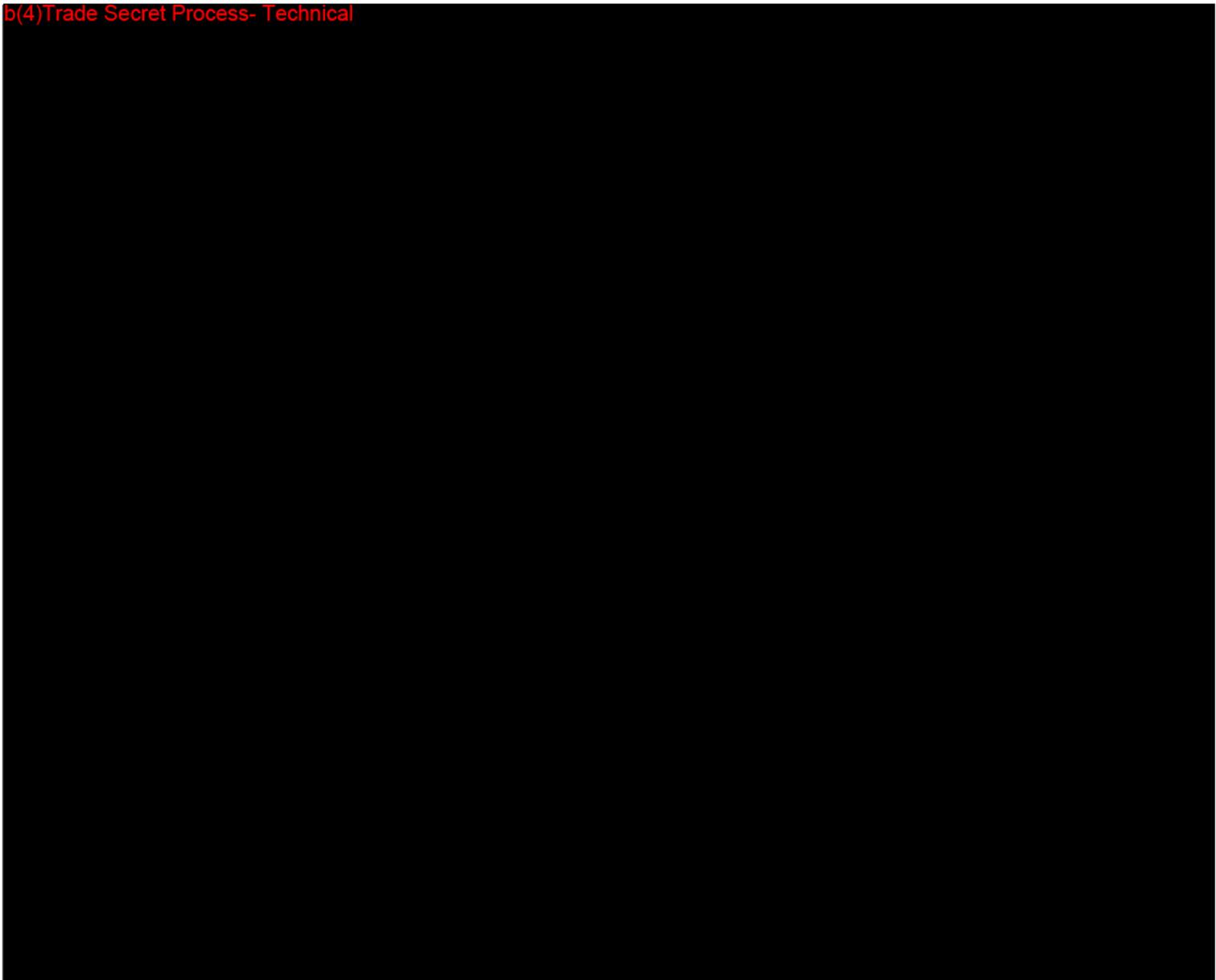
To: Jeff Shea

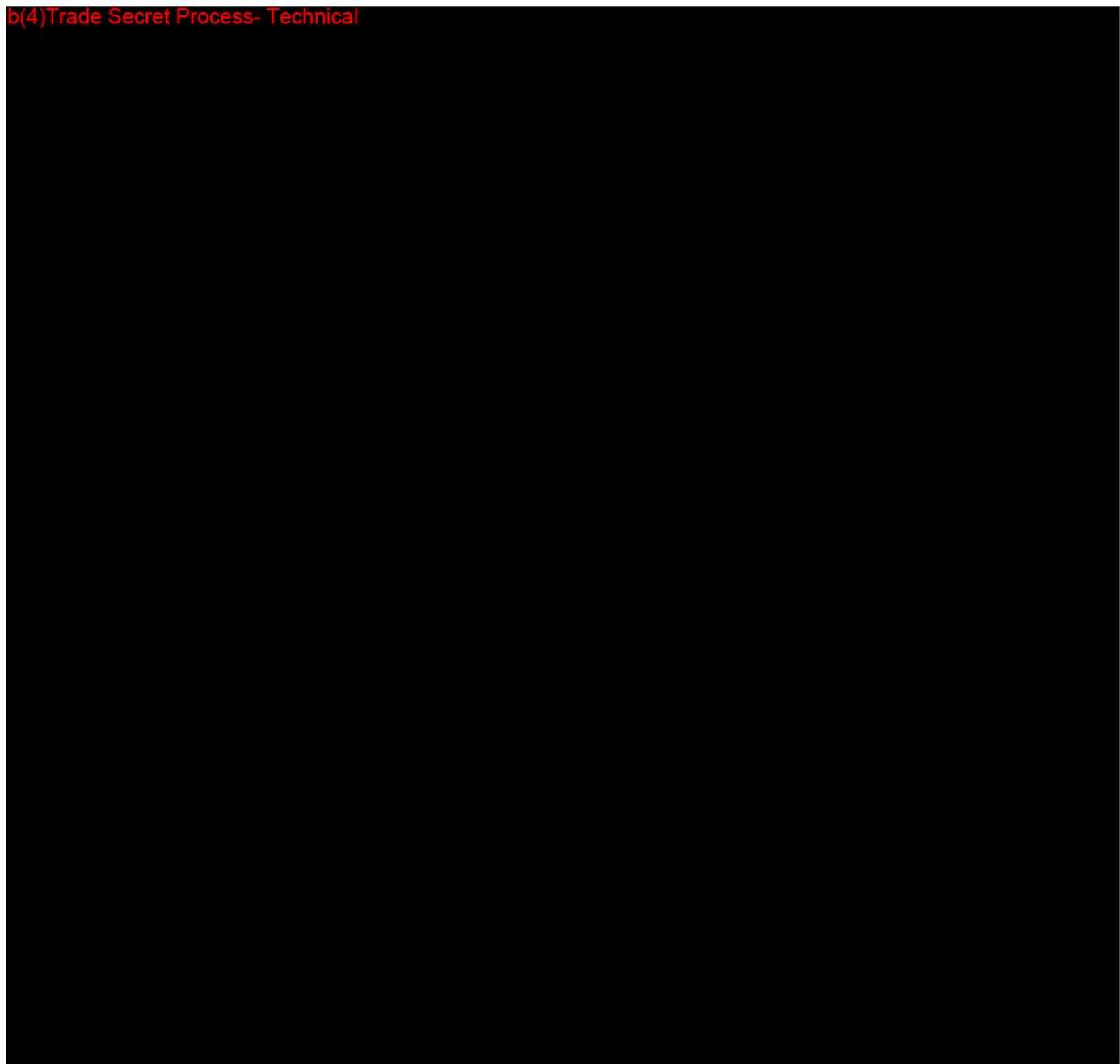
Date: November 3, 1999

From: Abraham Salehi and Reginald Thomas

Subject: *Technical Memo* - b(4)Trade Secret Process- Technical

b(4)Trade Secret Process- Technical





STERILITY INFORMATION

Gamma Irradiation

Source / Type of Sterilization:	Cobalt 60 / Gamma irradiation
Sterility Assurance Level:	10^{-6}
Type of Cycle:	Overkill
Dosage:	25 Kilo grays minimum
Validation:	Validation is accomplished by following the procedures set forth by the Association for the Advancement of Medical Instrumentation (AAMI) Guideline for Gamma Radiation Sterilization, ANSI / AAMI ST32-1991.
Description of Packaging:	The packaging is PETG thermoformed tray with Tyvek lid heat sealed to the tray and placed inside a second PETG tray with Tyvek lid. The trays are inserted into a paper board carton that is shrink wrapped.
Pyrogen Statement:	These products are not labeled as "non-pyrogenic". Applications of orthopedic implants are such that routine pyrogen testing is not required.
Primary Contract Sterilizer:	SteriGenics International 1700 North Airport Road West Memphis, AR 72301 SteriGenics International 3001 Wichita Court Fort Worth, TX 76140

IMPORTANT MEDICAL INFORMATION
Warnings and Precautions
Total Hip System

IMPORTANT NOTE

Total hip replacement arthroplasty has become a successful procedure for relieving pain and restoring motion in patients who are disabled from hip arthropathy. The goals of total hip replacement are to decrease pain, increase function, and increase mobility.

MATERIALS

Femoral components are cobalt chromium alloy, titanium 6Al-4V alloy or stainless steel. Femoral heads are cobalt chromium alloy, zirconia ceramic, alumina ceramic or stainless steel. Acetabular liners are ultra-high molecular weight polyethylene or alumina ceramic. Acetabular components are ultra-high molecular weight polyethylene. Acetabular shells are titanium 6Al-4V alloy. The component material is provided on the outside carton label.

NOTE: Ceramic/ceramic implants are not available in the USA.

Some of the alloys needed to produce orthopedic implants contain some metallic components that may be carcinogenic in tissue cultures or intact organism under very unique circumstances. Questions have been raised in the scientific literature as to whether or not these alloys may be carcinogenic in implant recipients. Studies conducted to evaluate this issue have not identified conclusive evidence of such phenomenon, in spite of the millions of implants in use.

DESCRIPTION OF SYSTEM

The Total Hip System consists of femoral components, proximal pads, taper sleeves, distal sleeves, acetabular components, fixation screws and pegs, hole covers, centralizers, and femoral heads. Components may be grit blasted, porous coated, hydroxylapatite (HA) coated, or HA porous coated. All implantable devices are designed for single use only.

Femoral Components

Femoral components are available in a variety of sizes. Porous coated components are coated for biological ingrowth. Proximally and distally modular femoral components accept proximal pads and distal sleeves, respectively. Non-porous femoral components can feature PMMA centralizers that help produce a uniform thickness of cement.

Femoral components are available with a Small, Large (14/16), or 12/14 global taper.

Small taper femoral components mate and lock directly with a 22 mm metal or ceramic head. The Small taper also mates with a taper sleeve which, in turn, mates with either metal or ceramic heads (26, 28, or 32 mm), bipolar or unipolar components.

Large taper femoral components mate and lock with either metal heads (26, 28, or 32 mm), ceramic heads (28 or 32 mm), bipolars or unipolar components.

Femoral components with a 12/14 taper mate and lock with either metal heads (22, 26, 28, or 32 mm), ceramic heads (22, 26, 28, or 32 mm), bipolar or unipolar components.

Small, Large, and 12/14 taper femoral component tapers are machined to mate and lock with ceramic heads, thus preventing rotation of the ceramic head on the stem, which would cause wear of the stem taper.

Taper Sleeves

A taper sleeve is required to be impacted on the Small taper femoral component prior to impacting a femoral head size 26, 28, or 32 mm. A taper sleeve is required to attach a unipolar head. Unipolar taper sleeves are available in Small, Large, and 12/14 tapers. Never place more than one taper sleeve on a femoral component.

Femoral Heads

Cobalt chromium (22, 26, 28, and 32 mm) and ceramic (22, 26, 28, and 32 mm) heads are available in multiple neck lengths for proper anatomic and musculature fit. Heads are highly polished for reduced friction and wear. The following zirconia ceramic heads are available for use only with Small and Large taper femoral components:

Zirconia Ceramic	Head Diameter	Neck Length	
42-7815	32 mm	Standard	0 mm
42-7816	32 mm	Long	+ 4 mm
42-7817	32 mm	X-Long	+ 8 mm
42-7818	28 mm	Standard	0 mm
42-7819	28 mm	Long	+ 4 mm
42-7820	28 mm	X-Long	+ 8 mm

Note: 32 mm heads with a -3 mm neck length are not available for use with the Small taper stems.

In addition to the components listed above, the following components are available for use only with Small taper femoral components:

Zirconia Ceramic	Head Diameter	Neck Length	
7132-0002	22 mm	Long	+ 4 mm
7132-0006	22 mm	X-Long	+ 8 mm

Note: 22 mm Zirconia Ceramic Heads used with Small taper femoral components are not available in the U.S.A.

The following zirconia ceramic heads are available for use only with 12/14 taper femoral components:

Zirconia Ceramic	Head Diameter	Neck Length
7132-0028	28 mm	0 mm
7132-0428	28 mm	+ 4 mm
7132-0828	28 mm	+ 8 mm
7132-0026	26 mm	0 mm
7132-0426	26 mm	+ 4 mm
7132-0826	26 mm	+ 8 mm
7132-0422	22 mm	+ 4 mm
7132-0822	22 mm	+ 8 mm

The following alumina ceramic heads are available for use only with 12/14 taper femoral components:

Alumina Ceramic	Head Diameter	Neck Length
7133-2800	28 mm	0 mm
7133-2804	28 mm	+ 4 mm
7133-2808	28 mm	+ 8 mm
7133-3200	32 mm	0 mm
7133-3204	32 mm	+ 4 mm
7133-3208	32 mm	+ 8 mm

Acetabular Components

Acetabular components can be one piece all polyethylene, two-piece component consisting of a titanium shell and a polyethylene liner or a titanium shell and an alumina ceramic liner. Please see Warnings and Precautions for specific information on screws, pegs and hole covers use. Acetabular reinforcement and reconstruction rings are used with an all polyethylene acetabular component. Note: The metal shell and ceramic liner in the Ceramic/Ceramic Acetabular System are not available in the U.S.A.

Femoral components and femoral heads are designed for use with any Smith & Nephew polyethylene acetabular component or polyethylene-lined, metal-backed acetabular component having an appropriately-sized inside diameter.

INDICATIONS, CONTRAINDICATIONS, AND ADVERSE EFFECTS

Hip components are indicated for individuals undergoing primary and revision surgery where other treatments or devices have failed in rehabilitating hips damaged as a result of trauma or noninflammatory degenerative joint disease (NIDJD) or any of its composite diagnoses of osteoarthritis, avascular necrosis, traumatic arthritis, slipped capital epiphysis, fused hip, fracture of the pelvis, and diastrophic variant.

Hip components are also indicated for inflammatory degenerative joint disease including rheumatoid arthritis, arthritis secondary to a variety of diseases and anomalies, and congenital dysplasia; old, remote osteomyelitis with an extended drainage-free period, in which case, the

patient should be warned of an above normal danger of infection postoperatively; treatments of nonunion, femoral neck fracture and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques; endoprosthesis, femoral osteotomy, or Girdlestone resection; fracture-dislocation of the hip; and correction of deformity.

Acetabular reinforcement and reconstruction rings are intended to be used in primary and revision surgeries where the acetabulum has the deficiencies of the acetabular roof, anterior or posterior pillar, medial wall deficiency, and / or protrusion as a result of the indications listed previously.

Some of the diagnoses listed above and below may also increase the chance of complications and reduce the chance of a satisfactory result.

Contraindications

1. Conditions that would eliminate or tend to eliminate adequate implant support or prevent the use of an appropriately- sized implant, e.g.:
 - a. blood supply limitations;
 - b. insufficient quantity or quality of bone support, e.g., osteoporosis, or metabolic disorders which may impair bone formation, and osteomalacia; and
 - c. infections or other conditions which lead to increased bone resorption.
2. Mental or neurological conditions which tend to impair the patient's ability or willingness to restrict activities.
3. Physical conditions or activities which tend to place extreme loads on implants, e.g., Charcot joints, muscle deficiencies, multiple joint disabilities, etc.
4. Skeletal immaturity.
5. The zirconia ceramic head is contraindicated for use with any other product than an UHMW polyethylene cup or a metal backed UHMW polyethylene cup.
6. The alumina ceramic liner is contraindicated for use with any product other than the metal shell with the correlating inner taper geometry and the appropriate sized alumina ceramic head. The alumina ceramic liner should only be used with the alumina ceramic head.

Contraindications may be relative or absolute and must be carefully weighted against the patient's entire evaluation and the prognosis for possible alternative procedures such as non-operative treatment, arthrodesis, femoral osteotomy, pelvic osteotomy, resection arthroplasty, hemiarthroplasty and others.

Conditions presenting increased risk of failure include: osteoporosis, metabolic disorders which may impair bone formation, and osteomalacia.

Possible Adverse Effects

1. Wear of the polyethylene and ceramic articulating surfaces of acetabular components may occur. Higher rates of wear may be initiated by the presence of particles of cement, metal, or other debris which can develop during or as a result of the surgical procedure and cause abrasion of the articulating surfaces. Higher rates of wear may shorten the useful life of the prosthesis, and lead to early revision surgery to replace the worn prosthetic components.
2. With all joint replacements, asymptomatic, localized, progressive bone resorption (osteolysis) may occur around the prosthetic components as a consequence of foreign-body reaction to

- particulate wear debris. Particles are generated by interaction between components, as well as between the components and bone, primarily through wear mechanisms of adhesion, abrasion, and fatigue. Secondly, particles may also be generated by third-body particles lodged in the polyethylene or ceramic articular surfaces. Osteolysis can lead to future complications necessitating the removal or replacement of prosthetic components.
3. Loosening, bending, cracking, or fracture of implant components may result from failure to observe the Warnings and Precautions below. Fracture of the implant can occur as a result of trauma, strenuous activity, improper alignment, or duration of service.
 4. Dislocations, subluxation, decreased range of motion, or lengthening or shortening of the femur caused by improper neck selection, positioning, looseness of acetabular or femoral components, extraneous bone, penetration of the femoral prosthesis through the shaft of the femur, fracture of the acetabulum, intrapelvic protrusion of acetabular component, femoral impingement, periarticular calcification, and/or excessive reaming.
 5. Fracture of the pelvis or femur: post-operative pelvic fractures are usually stress fractures. Femoral fractures are often caused by defects in the femoral cortex due to misdirected reaming, etc. Intraoperative fractures are usually associated with old congenital deformity, improper stem selection, improper broaching, and/or severe osteoporosis.
 6. Infection, both acute post-operative wound infection and late deep wound sepsis.
 7. Neuropathies; femoral, sciatic, peroneal nerve, and lateral femoral cutaneous neuropathies have been reported. Temporary or permanent nerve damage resulting in pain or numbness of the affected limb.
 8. Wound hematoma, thromboembolic disease including venous thrombosis, pulmonary embolus, or myocardial infarction.
 9. Myositis ossificans, especially in males with hypertrophic arthritis, limited pre-operative range of motion and/or previous myositis. Also, periarticular calcification with or without impediment to joint mobility can cause decreased range of motion.
 10. Trochanteric nonunion usually associated with early weight bearing and/or improper fixation of the trochanter, when a transtrochanteric surgical approach is used.
 11. Although rare, metal sensitivity reactions and/or allergic reactions to foreign materials have been reported in patients following joint replacement.
 12. Damage to blood vessels.
 13. Traumatic arthrosis of the knee from intraoperative positioning of the extremity.
 14. Delayed wound healing.
 15. Aggravated problems of the affected limb or contralateral extremity caused by leg length discrepancy, excess femoral medialization, or muscle deficiency.
 16. Failure of the porous coating/ substrate interface or hydroxylapatite coating/ porous coating bonding may result in bead separation delamination.
 17. Stem migration or subsidence has occurred in conjunction with compaction grafting procedures usually resulting from insufficient graft material or improper cement techniques. Varus stem alignment may also be responsible.

WARNINGS AND PRECAUTIONS

The patient should be warned of surgical risks, and made aware of possible adverse effects. The patient should be warned that the device does not replace normal healthy bone, that the implant can break or become damaged as a result of strenuous activity or trauma, and that it has a finite expected service life and may need to be replaced in the future. Do not mix components from

different manufacturers. Additional Warnings and Precautions may be included in component literature.

Preoperative

1. Use extreme care in handling and storage of implant components. Cutting, bending, or scratching the surface of components can significantly reduce the strength, fatigue resistance, and/or wear characteristics of the implant system. These, in turn, may induce internal stresses that are not obvious to the eye and may lead to fracture of the component. Implants and instruments should be protected from corrosive environments such as salt air during storage. Do not allow the porous surfaces to come in contact with cloth or other fiber-releasing materials.
2. Allergies and other reactions to device materials, although infrequent, should be considered, tested for (if appropriate), and ruled out preoperatively.
3. Fixation and expected longevity of components expected to be left in place at revision surgery should be thoroughly assessed.
4. Surgical technique information is available upon request. The surgeon should be familiar with the technique. Refer to medical or manufacturer literature for specific product information.
5. Intraoperative fracture or breaking of instruments can occur. Instruments which have experienced extensive use or excessive force are susceptible to fracture. Instruments should be examined for wear, or damage, prior to surgery.
6. Do not cold water quench ceramic components and never sterilize ceramic heads while fixed on the stem taper. (See sterilization section, below.)
7. Select components such that the Zirconia ceramic head always articulates with a UHMW polyethylene cup or a metal backed UHMW polyethylene cup. Zirconia ceramic should never articulate against metal because severe wear of the metal will occur.
8. Select only Smith & Nephew femoral components that indicate their use with ceramic heads. This is important because the taper on the stem is machined to tightly mate and lock with the ceramic head thus preventing rotation of the ceramic head on the stem. Also, an improperly dimensioned taper could result in fracture of the ceramic head.
9. The zirconia ceramic head is composed of a new ceramic material with limited clinical history. Although mechanical testing demonstrates that when used with a polyethylene acetabular component, the yttria stabilized zirconia ball produces a relatively low amount of particulates, the total amount of particulate remains undetermined. Because of the limited clinical and preclinical experience, the biological effect of these particulates can not be predicted.
10. Alumina ceramic should never articulate against metal because severe wear could occur.

Intraoperative

1. The general principles of patient selection and sound surgical judgment apply. The correct selection of the implant is extremely important. The appropriate type and size should be selected for patients with consideration of anatomical and biomechanical factors such as patient age and activity levels, weight, bone and muscle conditions, any prior surgery and anticipated future surgeries, etc. Generally, the largest cross-section component which will allow adequate bone support to be maintained is preferred. Failure to use the optimum-sized

- component may result in loosening, bending, cracking, or fracture of the component and/or bone.
2. Correct selection of the neck length and cup, and stem positioning, are important. Muscle looseness and/or malpositioning of components may result in loosening, subluxation, dislocation, and/or fracture of components. Increased neck length and varus positioning will increase stresses which must be borne by the stem. The component should be firmly seated with the component insertion instruments.
 3. Care should be taken not to scratch, bend (with the exception of the Reconstruction Rings) or cut implant components during surgery for the reasons stated in Number One of the "Pre-Operative" section of "Warnings and Precautions."
 4. **A +12 mm or +16 mm femoral head should not be used with any Small taper stems.**
 5. **Distal sleeves should not be used to bridge cortical defects that lie within 25 mm of the tip of the base stem.**
 6. Matrix Small taper stem sizes 8S - 10L must have a minimum neck length of +8 mm when used with a bipolar component; and Small taper stem sizes 12S - 16L must have a minimum neck length of +4 mm when used with a bipolar component.
 7. Modular heads and femoral components should be from the same manufacturer to prevent mismatch of tapers.
 8. Clean and dry stem taper prior to impacting the femoral head or taper sleeve. The modular femoral head component must be firmly seated on the femoral component to prevent disassociation.
 9. Take care, when positioning and drilling screw and peg holes, to avoid penetration of the inner cortex of the pelvis, penetration of the sciatic notch, or damage to vital neurovascular structures. Perforation of the pelvis with screws that are too long can rupture blood vessels causing the patient to hemorrhage. Do not place a screw in the center hole of the acetabular prosthesis. Placement of drills and screws in the anterior or medial portions of the prosthesis is associated with a high risk of potentially fatal vascular injury. Bone screws must be completely seated in the holes of the shell to allow proper locking for the acetabular component liner. If the tapered pegs need to be removed from the shell after impaction of the pegs, do not reuse the pegs or the peg shell holes. Use new pegs and different shell holes, or a new shell if necessary.
 10. **USE ONLY REFLECTION[®] TITANIUM BONE SCREWS, UNIVERSAL CANCELLOUS BONE SCREWS, TAPERED PEGS, AND HOLE COVERS** with the Reflection Acetabular Component and **USE ONLY OPTI-FIX[®] TITANIUM BONE SCREWS AND UNIVERSAL CANCELLOUS BONE SCREWS** with the Opti-Fix Acetabular Component. The Reflection InterFit and the Reflection For Screws Only (FSO) shells accept Universal Cancellous, Reflection screws, and tapered screw-hole covers, not pegs. Tapered pegs can only be used with Reflection V Shells. The threaded center hole in Reflection Shells only accepts the threaded hole cover, not screws or pegs. The InterFit threaded hole cover is only for use with Reflection Interfit. The Reflection threaded hole cover can be used with both Reflection and InterFit shells. Refer to product literature for proper adjunctive fixation and hole cover usage.
 11. Prior to seating modular components, surgical debris including tissue must be cleaned from the surfaces. Debris, including bone cement, may inhibit the component locking mechanism. If the shell is to be cemented in place, remove extraneous cement with a plastic sculps tool to ensure proper locking of the liner. During liner insertion, make sure soft tissue does not

interfere with the shell/liner interface. Chilling the liner reduces the impaction force required to seat the liner. Modular components must be assembled securely to prevent disassociation. Debris inhibits the proper fit and locking of modular components which may lead to early failure of the procedure. Failure to properly seat the acetabular liner into the shell can lead to disassociation of the liner from the shell.

12. Avoid repeated assembly and disassembly of the modular components which could compromise the critical locking action of the locking mechanism.
13. Care is to be taken to assure complete support of all parts of the device embedded in bone cement to prevent stress concentration which may lead to failure of the procedure. During curing of the cement, care should be taken to prevent movement of the implant components.
14. If components are to be left in place at revision surgery, they should first be thoroughly checked for signs of looseness, etc. and replaced if necessary. The head/neck component should be changed only when clinically necessary.
15. Once removed from the patient, implants previously implanted should never be reused, since internal stresses which are not visible may lead to early bending or fracture of these components.
16. With the congenitally dislocated hip, special care should be taken to prevent sciatic nerve palsy. Also, note that the femoral canal is often very small and straight and may require an extra-small straight femoral prosthesis; however, a regular-sized prosthesis should be used when possible. Note that the true acetabulum is rudimentary and shallow. A false acetabulum should not ordinarily be utilized as a cup placement site for anatomical and biomechanical reasons.
17. With rheumatoid arthritis, especially for those patients on steroids, bone may be extremely osteoporotic. Care should be taken to prevent excessive penetration of the acetabular floor or fracture of the medial acetabular wall, femur, or greater trochanter.
18. Revision procedures for previous arthroplasty, Girdlestone, etc., are technically demanding and difficult to exercise. Common errors include misplacement of the incision, inadequate exposure or mobilization of the femur, inadequate removal of ectopic bone, or improper positioning of components. Postoperative instability as well as excessive blood loss can result. In summary, increased operative time, blood loss, increased incidence of pulmonary embolus and wound hematoma can be expected with revision procedures.
19. Prior to closure, the surgical site should be thoroughly cleaned of cement, bone chips, ectopic bone, etc. Ectopic bone and/or bone spurs may lead to dislocation or painful or restricted motion. Range of motion should be thoroughly checked for early contact or instability.
20. When using a ceramic liner and metal shell, proper shell and liner alignment and positioning are critical to implant performance. If the ceramic liner and shell are not fully seated or are aligned incorrectly after final impaction, it will be necessary to revise the shell and liner with new components. An improper impaction will damage the shell and liner taper which can increase the chance of subsequent liner fracture or other component failure. Refer to the surgical technique for specific information on shell assembly and the implantation method.
21. Proper positioning of the components is important to minimize impingement which could lead to early failure, premature wear, and/or dislocation.

Postoperative

1. Postoperative directions and warnings to patients by physicians, and patient care, are extremely important. Gradual weight bearing is begun after surgery in ordinary total hip

- arthroplasty. However, with trochanter osteotomy or certain complex cases, weight-bearing status should be individualized with the non or partial weight-bearing period extended.
2. Patients should be warned against unassisted activity, particularly use of toilet facilities and other activities requiring excessive motion of the hip.
 3. Use extreme care in patient handling. Support should be provided to the operative leg when moving the patient. While placing the patient on bedpans, changing dressings, and clothing, and similar activities, precautions should be taken to avoid placing excessive load on the operative part of the body.
 4. Postoperative therapy should be structured to regain muscle strength around the hip and a gradual increase of activities.
 5. Periodic x-rays are recommended for close comparison with immediate postoperative conditions to detect long-term evidence of changes in position, loosening, bending and/or cracking of components or bone loss. With evidence of these conditions, patients should be closely observed, the possibilities of further deterioration evaluated, and the benefits of early revision considered.
 6. Prophylactic antibiotics should be recommended to the patient similar to those suggested by the American Heart Association for conditions or situations that may result in bacteremia.

PACKAGING AND LABELING

Components should only be accepted if received by the hospital or surgeon with the factory packaging and labeling intact.

STERILIZATION/RESTERILIZATION

Most implants are supplied sterile and have been packaged in protective trays. The method of sterilization is noted on the package label. All radiation sterilized components have been exposed to a minimum of 25 kiloGrays of gamma radiation. If not specifically labeled sterile, the implants and instruments are supplied non-sterile and must be sterilized prior to use. Inspect packages for punctures or other damage prior to surgery.

Metal Components

Nonporous or non-HA coated metal components may be initially sterilized or resterilized, if necessary, by steam autoclaving in appropriate protective wrapping, after removal of all original packaging and labeling. Protect the devices, particularly mating surfaces, from contact with metal or other hard objects which could damage the product. The following process parameters are recommended for these devices:

- Prevacuum Cycle: 4 pulses (Maximum = 26.0 psig (2.8 bars) & Minimum = 10.0 inHg (339 millibars)) with a minimum dwell time of 4 minutes at 270°F to 275°F (132°C to 135°C), followed by a 1 minute purge and at least 15 minutes of vacuum drying at 10 inHg (339 millibars) minimum.
- Gravity Cycle: 270°F to 275°F (132°C to 135°C) with a minimum dwell time at temperature of 10 minutes, followed by a 1 minute purge and at least 15 minutes of vacuum drying at 10 inHg (339 millibars) minimum.

Smith & Nephew does not recommend the use of low temperature gravity cycles or flash sterilization on implants.

Do not resterilize femoral prostheses with ceramic heads seated on the stem.

If porous coated or HA coated implants are inadvertently contaminated, return the unsoiled prosthesis to Smith & Nephew for resterilization. **DO NOT RESTERILIZE** porous coated or HA coated implants. The porous coating requires special cleaning procedures.

Plastic Components

Plastic components may be resterilized by ethylene oxide gas. The following parameters are recommended as starting points for cycle validation by the health care facility:

Sterilant	Temp.	Humidity	Maximum Pressure	Concentration	Exposure Time
100% EtO	131°F (55°C)	40-80% (70% Target)	10 PSIA (689 millibars)	725 mg/l	60-180 minutes

Suggested initial starting point for aeration validation is 12 hours at 120°F (49°C) with power aeration. Consult aerator manufacturer for more specific instructions.

Ceramic Components

Do not resterilize ceramic femoral heads or liners.

INFORMATION

For further information, please contact Customer Service at (800) 238-7538 for calls within the continental USA and (901) 396-2121 for all international calls.

Authorized EC Representative: Smith & Nephew Orthopaedics GmbH, Tuttlingen, Germany.

Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician.

Matrix, Opti-Fix and Reflection are trademarks of Smith & Nephew, Inc.

Orthopaedic Division

Smith & Nephew, Inc.
 1450 Brooks Rd., Memphis, TN 38116 U.S.A.
 901-396-2121, For information: 1-800-821-5700
 For orders and order inquiries: 1-800-238-7538





Sample Labels

General Product Carton Label

71309008

**Size 8, Synergy HA Coated
Porous Femoral Component
Standard Offset, 12/14 Taper
Ti-6Al-4V**

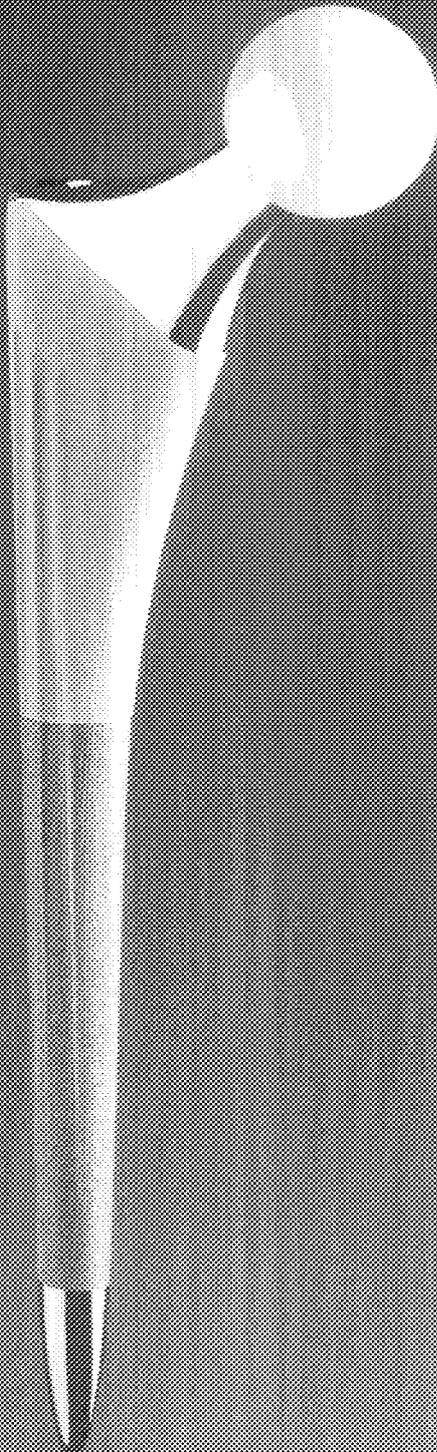
Qty. (1)
STEM
Sterile

For Use With Smith & Nephew
12/14 Femoral Heads Only

Pkg. Date: mm/yy Lot No. XXXXXXXX
Smith & Nephew, Inc., Orthopaedic Division, Memphis, TN USA

**Caution: Federal (USA) law restricts this device to sale by or on
the order of a physician.**

SYNERGY[™]
HA-COATED STEM

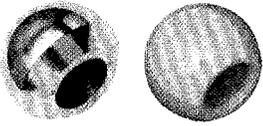


Smith+Nephew
Leadership in Worldwide Orthopaedics

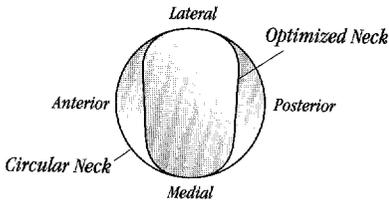
186



H A - C O A T E D S T E M



12/14 taper allows use of 22, 26, 28 and 32 mm metal or ceramic femoral heads. Proven taper design minimizes potential for corrosion and debris generation.



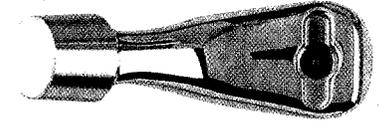
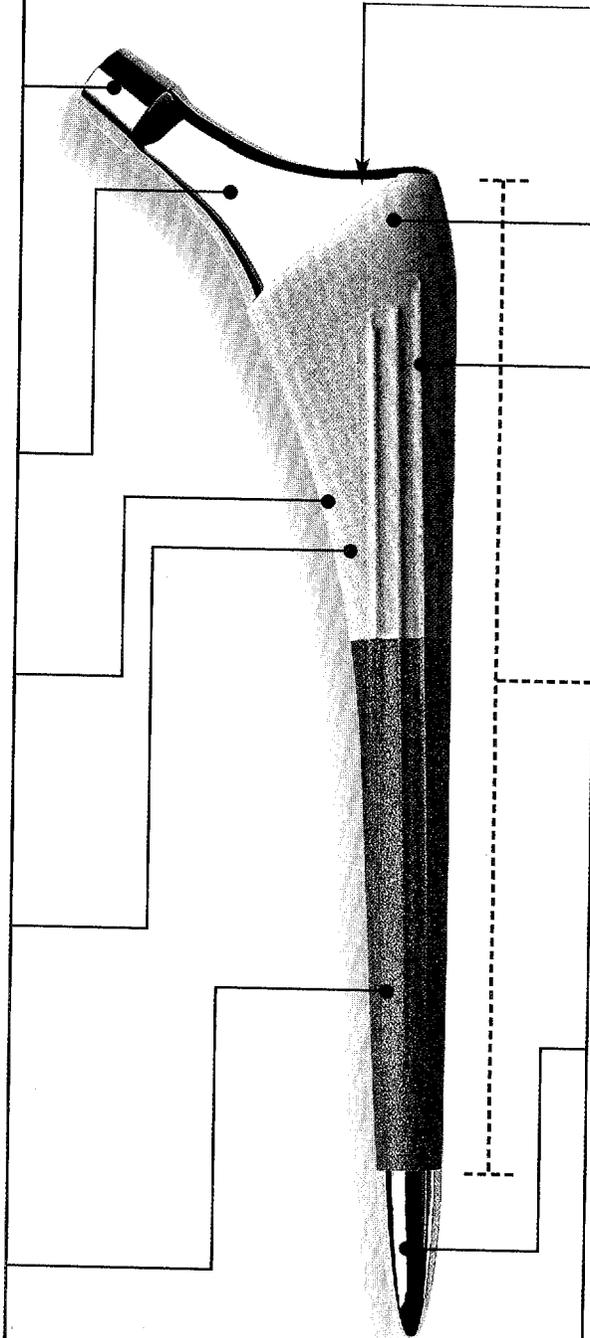
Polished circulo-trapezoidal neck increases range of motion while reducing the risk of dislocation.

10 sizes in 1 mm increments cover a wide range of patient variability. All sizes come in standard and high offset.



Rounded medial curvature matches proximal femoral geometry.

Roughened forged titanium surface allows bone ongrowth and promotes stability.



Threaded in-line driving platform provides version control.

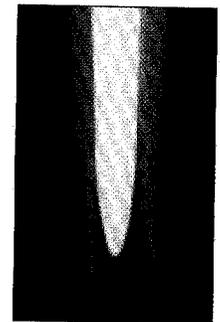
Proximal geometry coated with 50µm high shear strength hydroxylapatite coating.



3/4 mm flutes increase rotational stability.



3° proximal to distal taper increases implant stability. 3 point contact (posterior-anterior-posterior) provides immediate rigid fixation.



Polished distal bullet tip reduces end of stem cortical bone contact.

187

Smith+Nephew

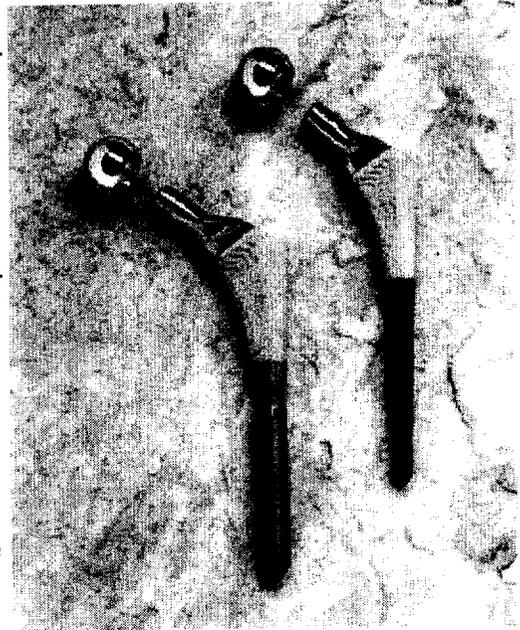
Leadership in Worldwide Healthcare

Smith & Nephew, Inc. • 1450 Brooks Road • Memphis, TN 38116 U.S.A.
(901) 396-2121 • For information: 1-800-821-5700 • For orders and order inquiries: 1-800-238-7538

Secur-Fit™ HA Hip System

The Secur-Fit™ HA Hip System is designed with specific features to achieve immediate, initial and long-term fixation. A normalized implant geometry which enhances implant stability, bone loading, and implant to bone interlock from time of insertion, is plasma sprayed with clinically established hydroxylapatite surface treatment.

- 127° and 132° neck angle options provide proper restoration of joint kinematics and enhance head offset.
- Proximal HA surface treatment over Arc Deposit CP Ti coating.
- Distal tri-slot provides distal implant flexibility.
- Distal flutes increase rotational stability.
- Distal/proximal sizing matrix for each implant offers two distal diameters for each proximal size and two proximal sizes for each distal diameter.



stryker
Howmedica
OSTEONICS

188

Center for Devices and Radiological Health

Releasable 510(k) Search

Device Classification Name	PROSTHESIS, HIP, SEMI-CONSTRAINED, UNCEMENTED, METAL/POLYMER, NON-POROUS, CALICUM-PHOSPHATE
510(k) Number	K990203
Device Name	OSTEONICS PRIMARY SECUR-FIT PLUS HIP STEMS
Applicant	OSTEONICS CORP. 59 ROUTE 17 ALLENDALE, NJ 07401 1677
Contact	KATE SUTTON
Product Code	MEH
Date Received	01/21/1999
Decision Date	02/18/1999
Decision	SUBSTANTIALLY EQUIVALENT
Classification Advisory Committee	Orthopedic
Review Advisory Committee	Orthopedic
Statement/Summary/Purged Status	Summary only
Summary/Approval Letter	<u>SUMMARY</u>
Type	Special

[CDRH Home Page](#)
 [FDA Home Page](#)
 [Comments](#)
 [Return to Search](#)

(Database Updated May 10, 2000)

189

2/18/99

K990203

**Special 510(k) - Device Modification
Summary of Safety and Effectiveness
for the
Osteonics® Primary Secur-Fit™ Plus Hip Stems**

Submission Information

**Name and Address of the Sponsor
of the 510(k) Submission:**

Osteonics Corporation
59 Route 17
Allendale, NJ 07401-1677

Contact Person:

Kate Sutton
Regulatory Affairs Specialist

Date of Summary Preparation:

January 18, 1999

Device Identification

Proprietary Name:

Osteonics® Primary Secur-Fit™™ Plus Hip
Stem Series

Common Name:

Hip Prosthesis

Classification Name and Reference:

Hip Joint, Metal/Ceramic/Polymer, Semi-
Constrained, Cemented or Non-Porous
Uncemented Prosthesis
21 CFR §888.3353

Predicate Device Identification

The modified features of the Osteonics® Primary Secur-Fit™ Plus Hip Stems are substantially equivalent to features of the following Osteonics predicate device, which has been cleared for marketing via the 510(k) process:

- Osteonics® Primary Secur-Fit™™ Plus Hip Stem Series

Device Description

The Osteonics® Primary Secur-Fit™ Plus Hip Stems are currently marketed devices that are being modified. The modification involves the addition of two smaller sizes, 5 and 6, and elimination of

298

the distal tri-slot on stems with a 9mm or 10mm distal diameter. All other aspects of the Osteonics® Primary Secur-Fit™ Plus Hip Stems will remain unchanged.

Intended Use:

The Osteonics® Primary Secur-Fit™ Plus Hip Stems are single use components. They are intended for cementless fixation within the prepared femoral canals of patients requiring hip arthroplasty. The modified and predicate hip stems are intended to be used in conjunction with any commercially available Osteonics C-Taper femoral bearing head. For use as a total hip replacement, the modified and predicate stems may be used in conjunction with any legally marketed Osteonics acetabular component. The Osteonics® Primary Secur-Fit™ Plus Hip Stems are manufactured from titanium alloy (ASTM F-620-96). The indications for the Osteonics® Primary Secur-Fit™ Plus Hip Stems include the following:

For Use as a Bipolar Hip Replacement:

- Femoral head/neck fractures or non-unions.
- Aseptic necrosis of the femoral head.
- Osteo-, rheumatoid, and post-traumatic arthritis of the hip with minimal acetabular involvement or distortion.

Other Considerations:

- Pathological conditions or age considerations which indicate a more conservative acetabular procedure and an avoidance of the use of bone cement in the acetabulum.
- Salvage of failed total hip arthroplasty.

For Use as a Total Hip Replacement:

- Painful, disabling joint disease of the hip resulting from: degenerative arthritis, rheumatoid arthritis, post-traumatic arthritis or late stage avascular necrosis.
- Revision of previous unsuccessful femoral head replacement, cup arthroplasty or other procedure.
- Clinical management problems where arthrodesis or alternative reconstructive techniques are less likely to achieve satisfactory results.

Performance Data:

Mechanical testing has been performed to demonstrate the substantial equivalence of this Osteonics stem design to predicate stem designs in terms of its fatigue strength.

Statement of Technological Comparison:

The modification involves the addition of two smaller sizes, 5 and 6, and elimination of the distal tri-slot on stems with a 9mm or 10mm distal diameter. All other aspects of the Osteonics® Primary Secur-Fit™ Plus Hip Stems will remain unchanged.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 18 1999

Ms. Elizabeth A. Staub
Director, Quality Assurance
and Regulatory Affairs
Osteonics Corporation
59 Route 17
Allendale, New Jersey 07401-1677

Re: K990203
Osteonics® Primary Secur-Fit™ Plus Hip Stem Series
Regulatory Class: II
Product Code: MEH
Dated: January 18, 1999
Received: January 21, 1999

Dear Ms. Staub:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). This decision is based on consideration of the specific design of stem and coating composition detailed in this application. You may, therefore, market the device, subject to the general controls provisions of the Act and the following limitation:

You may not label or in any way promote these devices for "biological attachment, enhanced clinical or radiographic performance, enhanced fixation and/or long-term stable fixation." The data presented support equivalence with no additional claims over a conventional press-fit hip prosthesis (i.e., mechanical interlock, only).

Additional limitations for more specific claims of safety and effectiveness may be forthcoming. Should additional limitations be applied you will be contacted in writing to inform you of the additional labeling limitations.

The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

192

You may market your device under the above limitations as class II devices. These devices would be considered not substantially equivalent to a legally marketed predicate device if labeled with other intended uses and/or claims of safety or effectiveness. Any other intended uses or claims may cause the device to be classified into Class III under Section 513(f) of the Act. Class III devices are required to have an approved premarket approval (PMA) application prior to marketing.

Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal Laws or Regulations.

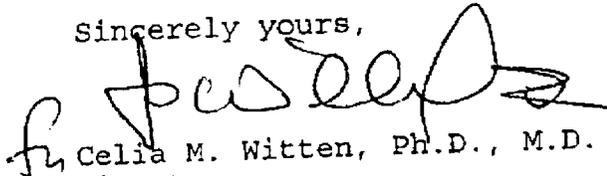
This letter will allow you to begin marketing your device as described in your 510(k) premarket notification immediately. An FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be

Page 3 - Ms. Elizabeth A. Staub

obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K 990203

Device Name: Osteonics® Primary Secur-Fit™ Plus Hip Stems

Indications For Use:

The indications for the use of the Osteonics® Primary Secur-Fit™ Plus Hip Stems, in keeping with those of other legally marketed Osteonics femoral components, are as follows:

For Use as a Bipolar Hip Replacement:

- Femoral head/neck fractures or non-unions.
- Aseptic necrosis of the femoral head.
- Osteo-, rheumatoid, and post-traumatic arthritis of the hip with minimal acetabular involvement or distortion.

Other Considerations:

- Pathological conditions or age considerations which indicate a more conservative acetabular procedure and an avoidance of the use of bone cement in the acetabulum.
- Salvage of failed total hip arthroplasty.

For Use as a Total Hip Replacement:

- Painful, disabling joint disease of the hip resulting from: degenerative arthritis, rheumatoid arthritis, post-traumatic arthritis or late stage avascular necrosis.
- Revision of previous unsuccessful femoral head replacement, cup arthroplasty or other procedure.
- Clinical management problems where arthrodesis or alternative reconstructive techniques are less likely to achieve satisfactory results.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use Yes
(Per 21 CFR 801.109)

OR

Over-The-Counter Use No

(Optional Format 1-2-96)

[Signature]
 (Division Sign-Off)
 Division of General Restorative Devices
 510(k) Number K990203

195

INTRODUCING FROM OSTEONICS



The
OMNIFIT-[®]HA[™]

Surface Treated with Hydroxylapatite

OMNIFIT-HA™

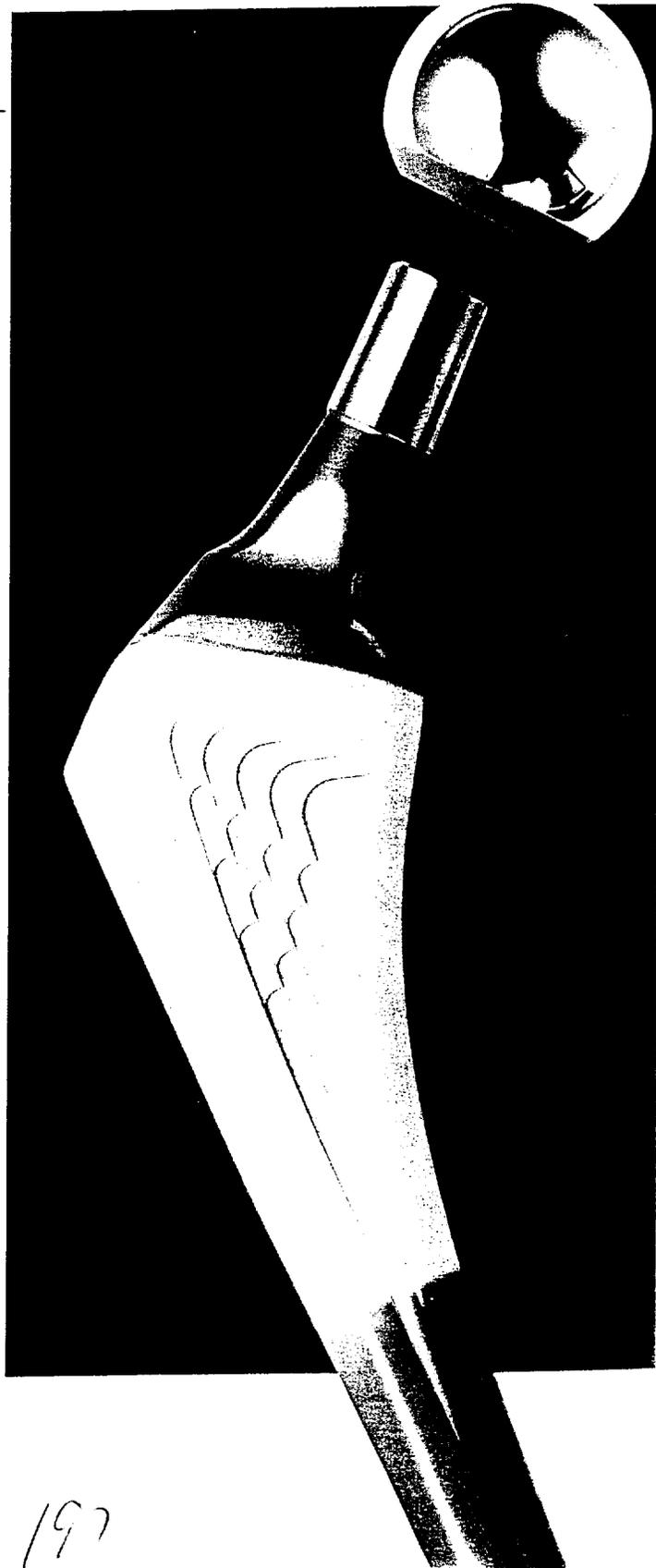
The Right Stem with the Right Surface Treatment

The Omnifit Hip Stem Geometry . . .

- *Proximal Canal Filling Geometry* ^(3,20,21,22,24,26,27)
This canal filling design and associated instrumentation enables exacting canal fit which minimizes stem subsidence, medial migration, and reduces peak stresses proximally.
- *Proportional Stem Design* ^(2, 26)
A proportionally sized implant system provides the surgeon with the ability to fit the prosthesis to the patient and reconstruct the joint more physiologically.
- *Normalizations* ^(3, 12, 23, 26)
Often referred to as intramedullary collars, normalizations are placed at 90° to the applied load. Normalizations act to convert shear to compressive stress at the bone/stem interface and help reduce medial migration and subsidence.
- *Forged Titanium Alloy*
Provides strength and biocompatibility.
- *Ten years of Clinical Experience with this Canal Filling Geometry* ⁽¹²⁾
A proven implant design.

The Hydroxylapatite Surface Treatment

- *Hydroxylapatite of High Density, High Purity* ^(13, 15,16,18, 25)
Provides proven biocompatibility and longevity. ⁽⁶⁾
- *Calcium Phosphate Ratio close to that of bone*
Helps minimize surface treatment resorption.
- *Fifty micron Surface Treatment Thickness* ^(4,6,14)
Provides excellent adhesion and excellent fatigue strength.
- *Strategically Placed* ^(1,8,9)
Located in proximal load transfer zones.
- *Extensively Evaluated* ^(4,5,6,7,8,9,17,18,19,22)
Seven years material development.
Four years clinical experience.



197

Typical Radiographic Findings

Surgeon: *Omar Crothers M.D.*
Maine Medical Center
Portland, ME

Patient: *GW*
 Age: *59*
 Weight: *225 lbs*
 Height: *71 inches*
 Diagnosis: *Osteoarthritis*
 Stem Size: *9*



Preop

Harris Hip Scores

53



6 months

96*

Surgeon: *James D'Antonio M.D.*
Sewickley Valley Hospital
Sewickley, PA

Patient: *LB*
 Age: *60*
 Weight: *148 lbs*
 Height: *70 1/2 inches*
 Diagnosis: *Osteoarthritis*
 Stem Size: *11*



Preop

Harris Hip Scores

59



6 months

100

Surgeon: *William Jaffe M. D.*
Hospital for Joint Diseases
Orthopaedic Institute
New York, NY

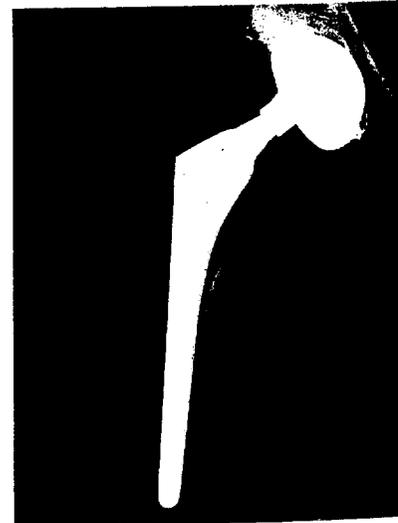
Patient: *RK*
 Age: *30*
 Weight: *230 lbs*
 Height: *78 inches*
 Diagnosis: *Traumatic Arthritis*
 Stem Size: *10*



Preop

Harris Hip Scores

35



6 months

100

* Scores influenced by contralateral hip disease.

Findings with OMNIFIT-HA™

1 year



87°

2 year



97°

1 year



100

2 year



100

1 year



100

2 year

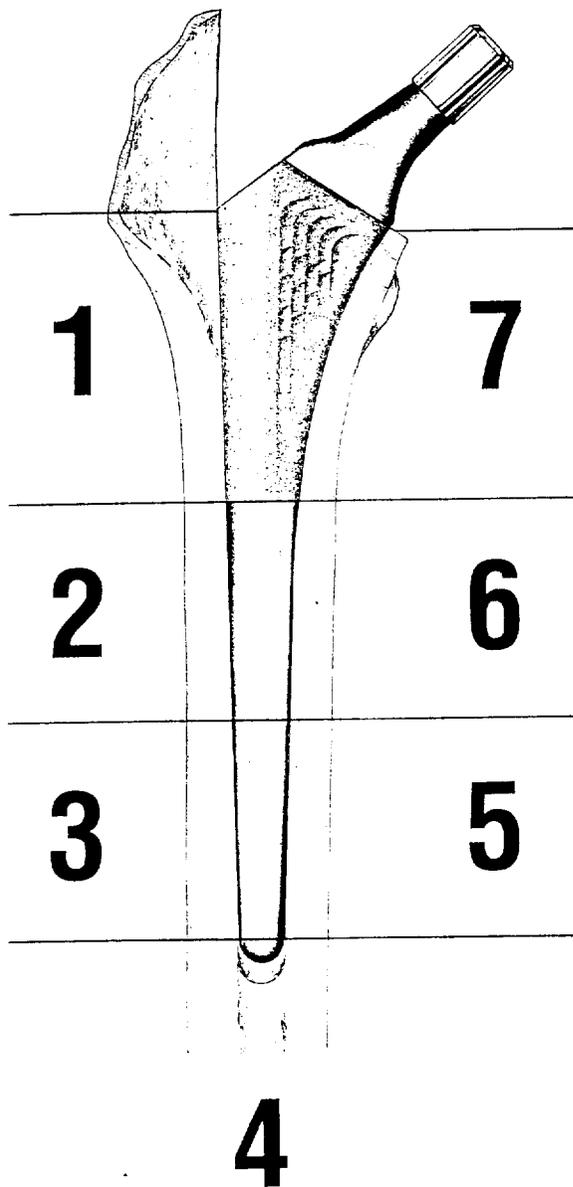


100

199

Two year Radiographic⁽¹⁰⁾ Findings as determined by a single Reviewer

Reactive Lines
0.8% at 2 years



Reactive Lines
0.0% at 2 years

Calcar Atrophy
0.5% at 2 years

Hypertrophy
3.8% at 2 years

Two Year Clinical Results OMNIFIT-HA™ For

Function expressed as a percent of Total Population:

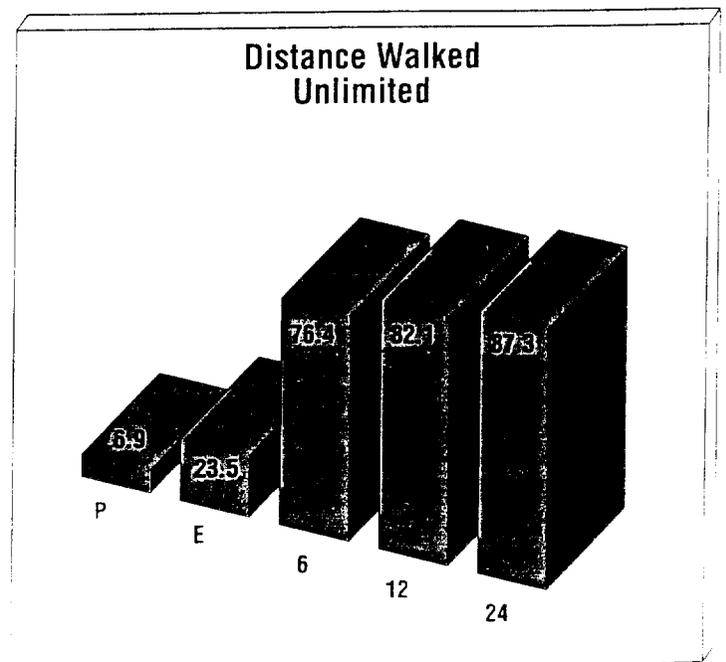
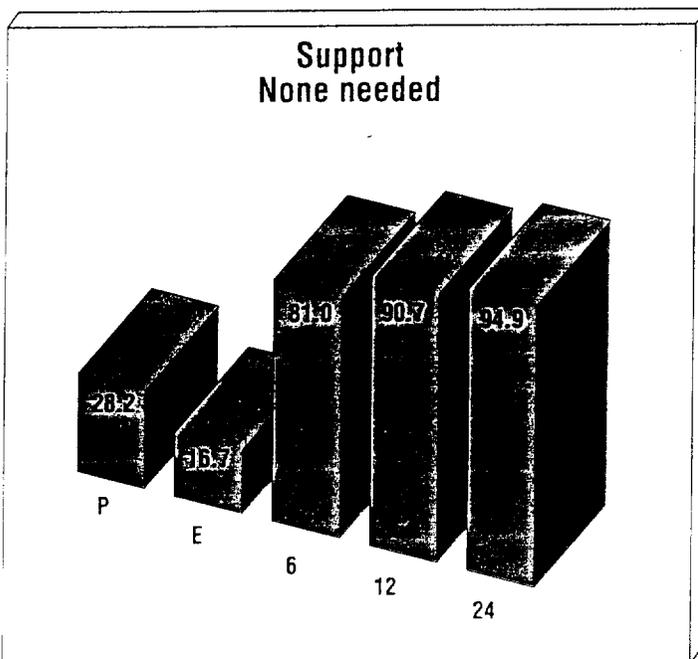
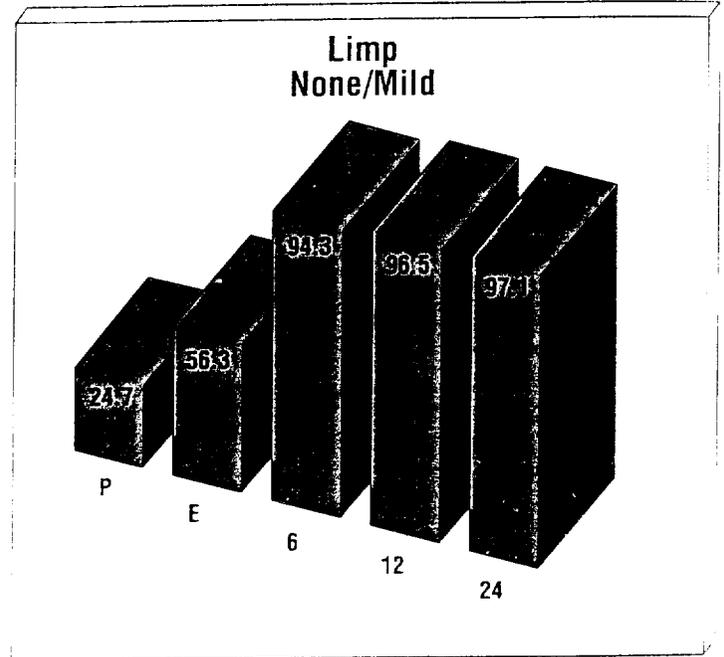
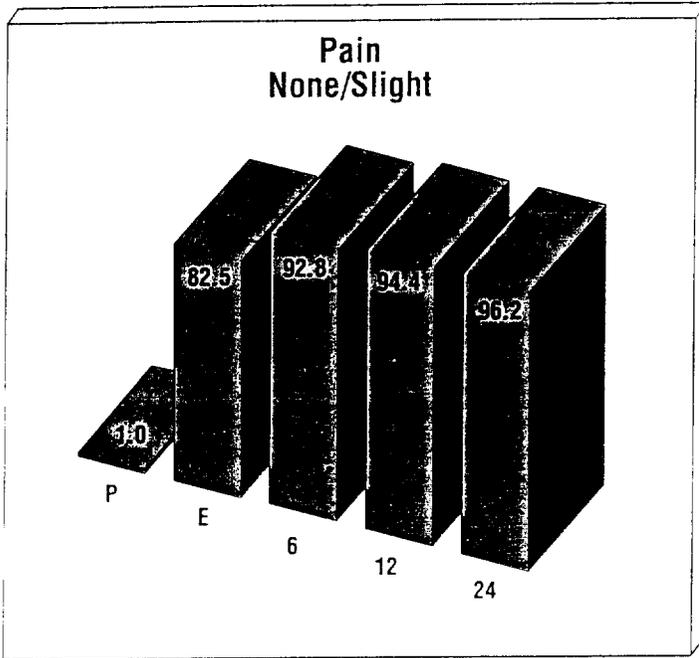
459 - Total No. of patients

523 - Total No. of implants

236 - Total No. of implants @ 2 years

KEY

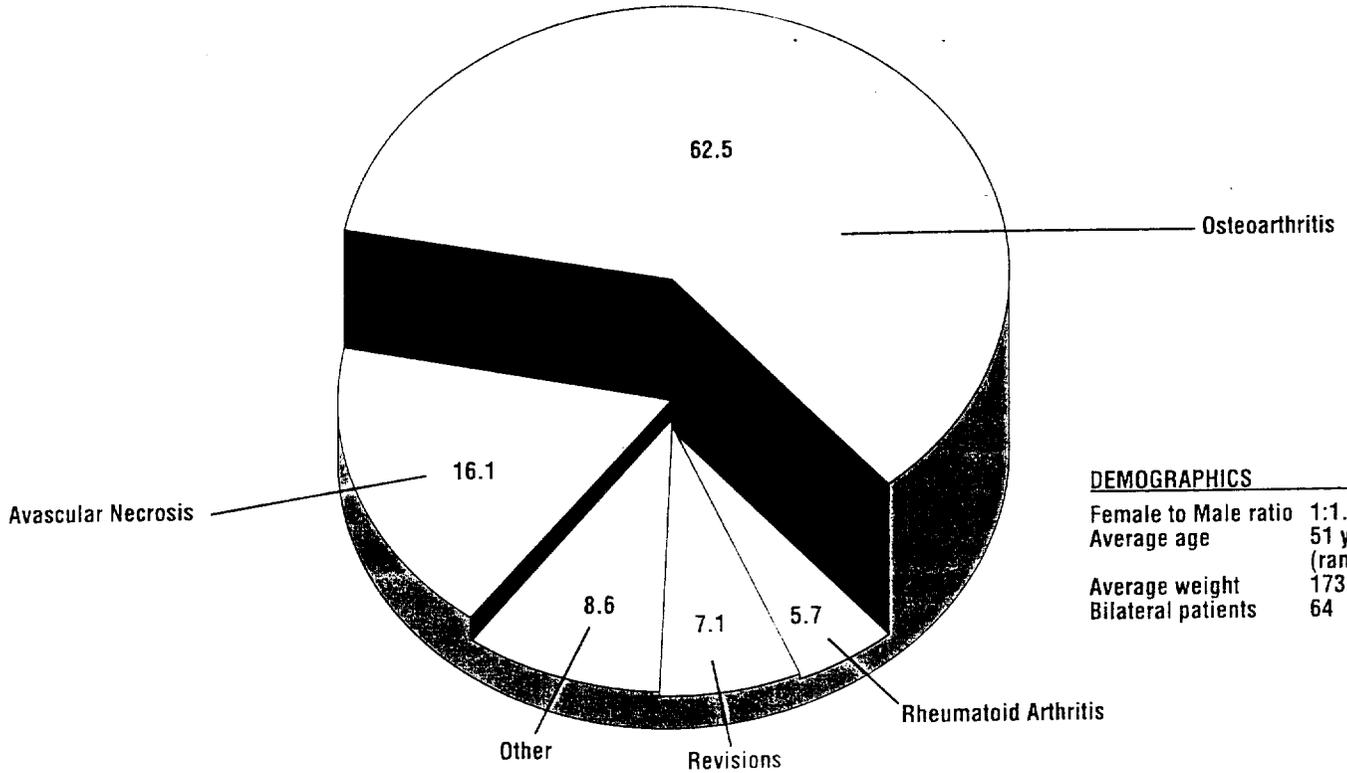
- P - Pre-op
- E - Early
- 6 - 6 months
- 12 - 12 months
- 24 - 24 months



* The values and categories selected are as defined by the Harris Hip rating**
 ** Numbers are rounded to the nearest 0.10

Results with Osteonics Clinical Components

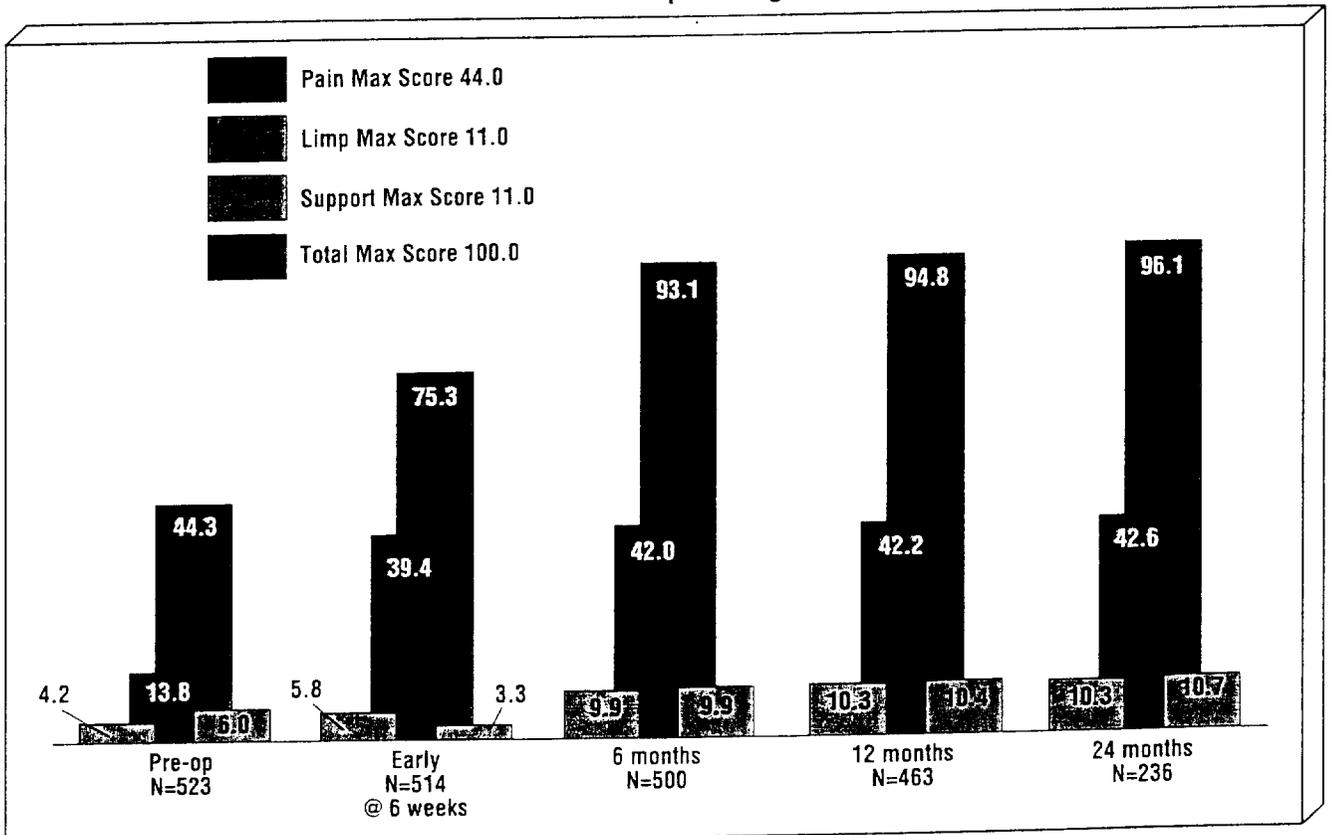
Diagnoses



DEMOGRAPHICS

Female to Male ratio 1:1.18
 Average age 51 years - (range 16-81)
 Average weight 173.2 lbs
 Bilateral patients 64

Harris Hip Ratings



References

1. Abrahams, T.G., Crothers, O.D., Preliminary Radiographic Patterns of an Investigational Hydroxyapatite Total Hip Arthroplasty, presented at the 75th Scientific Assembly of the Radiological Society of North America. Nov. 26-Dec. 1, 1989
2. Averill, R.G., Pachtman, N., Jaffe, W.L., A Basic Dimensional Analysis of the Normal Human Proximal Femora, Proceedings of the Eighth Annual Northeast Bioengineering Conference 1980, Massachusetts Institute of Technology, pp. 352-356.
3. Capello, W.N., The Osteonics Prosthesis, Bristol-Meyer/Zimmer Orthopaedic Symposium (3rd: 1987: Phoenix, Arizona) Non-Cemented Total Hip Arthroplasty, Fitzgerald R. H., editor, Raven Press, 1988, pp. 451-458.
4. de Groot, K., Geesink, R., Klein, C.P.A.T., Serekian, P., Plasma Sprayed Coatings of Hydroxylapatite, Journal of Biomedical Materials Research, No. 21, 1987, pp. 1375-1381.
5. Geesink, R., de Groot, K., Klein, C.P.A.T., Chemical Implant Fixation Using Hydroxyl-Apatite Coatings, Clinical Orthopaedics and Related Research, No. 225, 1987, pp. 147-170.
6. Geesink, R., Hydroxyl-Apatite Coated Hip Implants, Ph.D. Thesis, Rijksuniversiteit Limburg te Maastricht, Maastricht, Netherlands, 1988.
7. Geesink, R., de Groot, K., Klein, C.P.A.T., Bonding of Bone to Apatite-Coated Implants, Journal of Bone and Joint Surgery, Vol. 70-B, 1988, pp. 17-22
8. Geesink, R., Experimental and Clinical Experience with Hydroxyapatite-Coated Hip Implants, Orthopedics, Vol. 12, No. 9, 1989, pp. 1239-1242.
9. Geesink, R., Hydroxyapatite-Coated Total Hip Prostheses: Two-Year Clinical and Roentgenographic Results of 100 Cases, Clinical Orthopaedics and Related Research, No. 261, 1990, pp. 39-58.
10. Gruen, T.A., Mc Niece, G.M., Amstutz, H.C., "Modes of Failure" of Cemented Stem-type Femoral Components, Clinical Orthopaedics and Related Research, No. 141, 1979, pp. 17-27.
11. Harris, W.H., Traumatic Arthritis of the Hip after Dislocation and Acetabular Fractures: Treatment by Mold Arthroplasty, Journal of Bone and Joint Surgery, Volume 51-A, No. 4, 1969, pp. 737-757.
12. Jaffe W.L., Kuflik, P.L., Gold, S.M., Normalized and Proportionalized Femoral Stem Design- A Ten Year Clinical Experience with the Osteonics Stem Geometry, Omnifit-C Brochure, 1990, Osteonics Corporation, Allendale, NJ
13. Jarcho, M., Calcium Phosphate Ceramics as Hard Tissue Prosthetics, Clinical Orthopaedics and Related Research, No. 157, 1981, pp. 259-277.
14. Kester, M.A., Manley, M.T., Taylor, S.K., Cohen, R.C., Influence of Thickness on the Mechanical Properties and Bond Strength of HA Coatings Applied to Orthopaedic Implants, 37th Annual Meeting, ORS, March 4-7, Anaheim CA, 1991.
15. Klein, C.P.A.T., Driessen, A.A., de Groot, K., Relationship between the Degradation Behavior of Calcium Phosphate Ceramics and their Physical-Chemical Characteristics and Ultrastructural Geometry, Biomaterials, No. 5, 1984, pp. 157-160.
16. Koeneman, J., Lemons, J., Ducheyne, P., Laceyfield, W., Magee, F., Calahan, T., Kay, J., Workshop on Characterization of Calcium Phosphate Materials, Journal of Applied Biomaterials, Vol.1, 1990, pp.79-90.
17. Lee, D.R., Lemons, J.E., LeGeros, R.Z., Dissolution Characterization of Commercially Available Hydroxyapatite Particulate, 15th Annual Meeting of the Society for Biomaterials, April 28-May 2, 1989, Lake Buena Vista, FL.
18. Lemons, J.E., Hydroxyapatite Coatings, Clinical Orthopaedics and Related Research, No. 235, 1988, pp. 220-222.
19. Lemons, J.E., Bioceramics: Is there a Difference, Clinical Orthopaedics and Related Research, No. 261, 1990, pp. 153-158.
20. Loudon, J.R., Chamley, J., Subsidence of the Femoral Prosthesis in Total Hip Replacement in Relation to the Design of the Stem, Journal of Bone and Joint Surgery, Vol. 62-B, No. 4, 1980, pp. 450-453.
21. Manley, M.T., Capello, W.N., Averill, R., Cohen, R., Effect of Stem Design Parameters, Stem Fit and Bone Quality on the Torsional Stability of Femoral Stems, Presented in part at the 1990 AAOS, New Orleans, February 1990.
22. Manley, M.T., Kay, J.F., Uratsuji, M., Stern, B.N., Stulberg, B.N., Hydroxyapatite Coatings Applied to Implants Subjected to Functional Loads, 13th Annual Meeting of the Society for Biomaterials, 210, New York, New York, 1987.
23. Pugh, J., Averill, R., Pachtman, N., Bartel, D., Jaffe, W., Prosthesis Surface Design to Resist Loosening: Stress Normalization, 27th Transactions, ORS, p.189, Las Vegas, NV, February 1981.
24. Tarr, R., Clarke, I.C., Gruen, T.A., Sarmiento, A., Espiritu, E., Hull, D.B., Mc Guire, P., Sew Hoy, A.L., Mc Kellop, H.A., Total Hip Femoral Component Design, Orthopaedic Review, Vol. 11, No. 12, 1982, pp. 23-36.
25. Thomas, K.A., Cook, S.D., Haddad, R.J., Kay, J.F., Jarcho, M., Biologic Response to Hydroxylapatite-coated Titanium Hips, Journal of Arthroplasty, Vol. 4, No. 1, 1989, pp. 43-53.
26. "The Science of Better Fit", Osteonics Corporation, Allendale, NJ, 1981.
27. Manley, M.T., Pachtman, N., Stern, L., Strain Levels in the Proximal Femur as a Function of Projected Medial Stem Area, 28th Annual ORS, New Orleans LA, January 19-21, 1982 pg 250

For additional technical information see Osteonics white papers:

**Preclinical Histological Evaluation of Hydroxylapatite Implants*

**Two-Year Clinical Results with Hydroxylapatite Surface Treated Femoral Components*

OSTEONICS® and OMNIFIT® are registered trademarks of Osteonics Corp.

OMNIFIT-HA is a trademark of Osteonics Corp.

© Osteonics Corp. 1991

Lit. No. LHA1

Printed in U.S.A.

OSTEONICS CORP.

The Science of
Better Fit

59 Route 17
Allendale, N.J. 07401
A Subsidiary of **stryker** Corp.

203

Center for Devices and Radiological Health

Releasable 510(k) Search

Device Classification Name	PROSTHESIS, HIP, SEMI-CONSTRAINED, UNCEMENTED, METAL/POLYMER, NON-POROUS, CALICUM-PHOSPHATE
510(k) Number	K982032
Device Name	OSTEONICS OMNIFIT HA HIP STEM SERIES, OSTEONICS S
Applicant	OSTEONICS CORP. 59 ROUTE 17 ALLENDALE, NJ 07401 1677
Contact	KATE SUTTON
Product Code	MEH
Date Received	06/10/1998
Decision Date	07/09/1998
Decision	SUBSTANTIALLY EQUIVALENT
Classification Advisory Committee	Orthopedic
Review Advisory Committee	Orthopedic
Statement/Summary/Purged Status	Summary only
Summary/Approval Letter	<u>SUMMARY</u>
Type	Special

[CDRH Home Page](#)[FDA Home Page](#)[Comments](#)[Return to Search](#)

(Database Updated May 10, 2000)

204

JUL - 9 1998

K982032

**Special 510(k) - Device Modification
Summary of Safety and Effectiveness
for the
Osteonics® C-Tapered Titanium Stems**

Submission Information

**Name and Address of the Sponsor
of the 510(k) Submission:**

Osteonics Corporation
59 Route 17
Allendale, NJ 07401-1677

Contact Person:

Kate Sutton
Regulatory Affairs Specialist

Date of Summary Preparation:

June 9, 1998

Device Identification

Proprietary Name:

Osteonics® Omnifit® HA Hip Stem Series
Osteonics® Secur-Fit™ HA Hip Stem Series
Osteonics® Primary Secur-Fit™ Plus Hip
Stem Series

Common Name:

Hip Prosthesis

Classification Name and Reference:

Hip Joint, Metal/Ceramic/Polymer, Semi-
Constrained, Cemented or Non-Porous
Uncemented Prosthesis
21 CFR §888.3353

Predicate Device Identification

The modified features of the Osteonics® C-Tapered Titanium Stems (Osteonics® Omnifit HA Hip Stem Series, Osteonics® Secur-Fit HA Hip Stem Series, Osteonics® Primary Secur-Fit Plus Hip Stem Series) are substantially equivalent to features of the following Osteonics predicate devices, which has been cleared for marketing via the 510(k) process:

- Osteonics® Omnifit® HA Hip Stem Series
- Osteonics® Secur-Fit™ HA Hip Stem Series
- Osteonics® Primary Secur-Fit™ Plus Hip Stem Series

205

Device Description

The Osteonics® C-Tapered Titanium Stems (Osteonics® Omnifit HA Hip Stem Series, Osteonics® Secur-Fit Hip Stem Series, Osteonics® Primary Secur-Fit Plus HipStem Series) are currently marketed devices that are being modified. The modification involves shortening the trunnion and reducing the diameter of the stem neck. All other aspects of the Osteonics® C-Tapered Titanium Stems will remain unchanged.

Intended Use:

The Osteonics® C-Tapered Titanium Stems are single use components. They are intended for cementless fixation within the prepared femoral canals of patients requiring hip arthroplasty. The modified and predicate hip stems are intended to be used in conjunction with any commercially available Osteonics C-Taper femoral bearing head. For use as a total hip replacement, the modified and predicate stems may be used in conjunction with any legally marketed Osteonics acetabular component. The Osteonics® C-Tapered Titanium Stems are manufactured from titanium alloy (ASTM F-620-96). The indications for the Osteonics® C-Tapered Titanium Stems include the following:

For Use as a Bipolar Hip Replacement:

- Femoral head/neck fractures or non-unions.
- Aseptic necrosis of the femoral head.
- Osteo-, rheumatoid, and post-traumatic arthritis of the hip with minimal acetabular involvement or distortion.

Other Considerations:

- Pathological conditions or age considerations which indicate a more conservative acetabular procedure and an avoidance of the use of bone cement in the acetabulum.
- Salvage of failed total hip arthroplasty.

For Use as a Total Hip Replacement:

- Painful, disabling joint disease of the hip resulting from: degenerative arthritis, rheumatoid arthritis, post-traumatic arthritis or late stage avascular necrosis.
- Revision of previous unsuccessful femoral head replacement, cup arthroplasty or other procedure.
- Clinical management problems where arthrodesis or alternative reconstructive techniques are less likely to achieve satisfactory results.

Performance Data:

Mechanical testing has been performed to demonstrate the substantial equivalence of this Osteonics stem design to predicate stem designs in terms of its fatigue strength.

Statement of Technological Comparison:

All features of the Osteonics® C-Tapered Titanium Stems (Osteonics® Omnifit HA Hip Stem Series, Osteonics® Secur-Fit Hip Stem Series, Osteonics® Primary Secur-Fit Plus HipStem Series) will remain the same with the exception of the trunnion, which will be shortened, and the neck diameter, which will be slightly reduced.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL - 9 1998

Ms. Kate Sutton
Regulatory Affairs Specialist
Osteonics Corporation
59 Route 17
Allendale, New Jersey 07401-1677

Re: K982032
Osteonics® C-Tapered Titanium Stems
Regulatory Class: II
Product Code: MEH
Dated: June 8, 1998
Received: June 10, 1998

Dear Ms. Sutton:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). This decision is based on consideration of the specific design of stem and coating composition detailed in this application. You may, therefore, market the device, subject to the general controls provisions of the Act and the following limitation:

You may not label or in any way promote these devices for "biological attachment, enhanced clinical or radiographic performance, enhanced fixation and/or long-term stable fixation." The data presented support equivalence with no additional claims over a conventional press-fit hip prosthesis (i.e., mechanical interlock, only).

Additional limitations for more specific claims of safety and effectiveness may be forthcoming. Should additional limitations be applied you will be contacted in writing to inform you of the additional labeling limitations.

The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

208

You may market your device under the above limitations as class II devices. These devices would be considered not substantially equivalent to a legally marketed predicate device if labeled with other intended uses and/or claims of safety or effectiveness. Any other intended uses or claims may cause the device to be classified into Class III under Section 513(f) of the Act. Class III devices are required to have an approved premarket approval (PMA) application prior to marketing.

Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal Laws or Regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification immediately. An FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market.

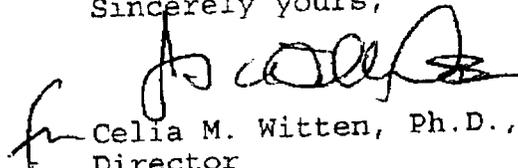
If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be

209

Page 3 - Ms. Kate Sutton

obtained from the Division of Small Manufacturers Assistance
at its toll-free number (800) 638-2041 or (301) 443-6597 or at
its Internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K982032

Device Name: Osteonics® C-Tapered Titanium Stems

Indications For Use:

The indications for the use of the Osteonics® C-Tapered Titanium Stems , in keeping with those of other legally marketed Osteonics femoral components, are as follows:

For Use as a Bipolar Hip Replacement:

- Femoral head/neck fractures or non-unions.
- Aseptic necrosis of the femoral head.
- Osteo-, rheumatoid, and post-traumatic arthritis of the hip with minimal acetabular involvement or distortion.

Other Considerations:

- Pathological conditions or age considerations which indicate a more conservative acetabular procedure and an avoidance of the use of bone cement in the acetabulum.
- Salvage of failed total hip arthroplasty.

For Use as a Total Hip Replacement:

- Painful, disabling joint disease of the hip resulting from: degenerative arthritis, rheumatoid arthritis, post-traumatic arthritis or late stage avascular necrosis.
- Revision of previous unsuccessful femoral head replacement, cup arthroplasty or other procedure.
- Clinical management problems where arthrodesis or alternative reconstructive techniques are less likely to achieve satisfactory results.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General Restorative Devices

510(k) Number K982032 OR Over-The-Counter Use _____

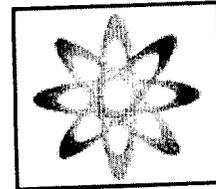
Prescription Use
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

211

▲ PARTNERSHIP™ SYSTEM

Meridian™ PA Femoral Component



- back -

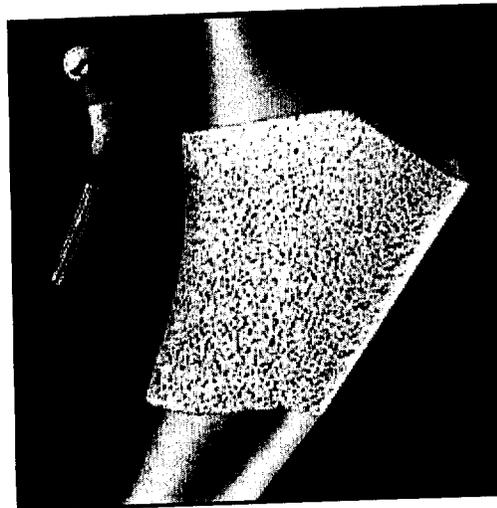
MERIDIAN® PA Femoral Component

The Howmedica Partnership System unites the highest standards of science and technology to achieve a new level of surgical efficiency and clinical performance.

With the Meridian PA Femoral Component, the coating of a hip stem with hydroxyapatite has become a reality for orthopaedic surgeons who want to use a porous coated surface for biological ingrowth. Previously, HA coatings were only available on press-fit prostheses.

Howmedica Osteonics has created a technologically advanced coating that makes it possible to completely coat all areas of a porous ingrowth surface down to the metal substrate surface. The entire proximal circumferential porous surface, including the undersides of both the top and bottom layer of beads, is coated in a uniformly thin layer of precipitated hydroxyapatite, designed to be 20 microns thick so it does not block the pores for biological fixation.

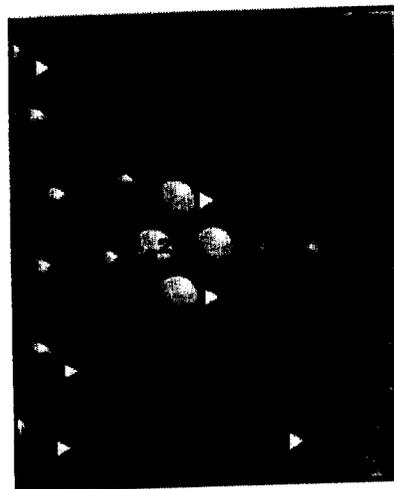
The Meridian PA Femoral Component has been developed to the highest standards of the Partnership System. Now it is ready to meet the highest orthopaedic standards of quality, efficiency, and performance of all ... yours.



MERIDIAN PA:

A Proximal-Canal-Filling Straight Stem with Three-Dimensional Hydroxyapatite Coating Covering the Circumferential Porous Coating

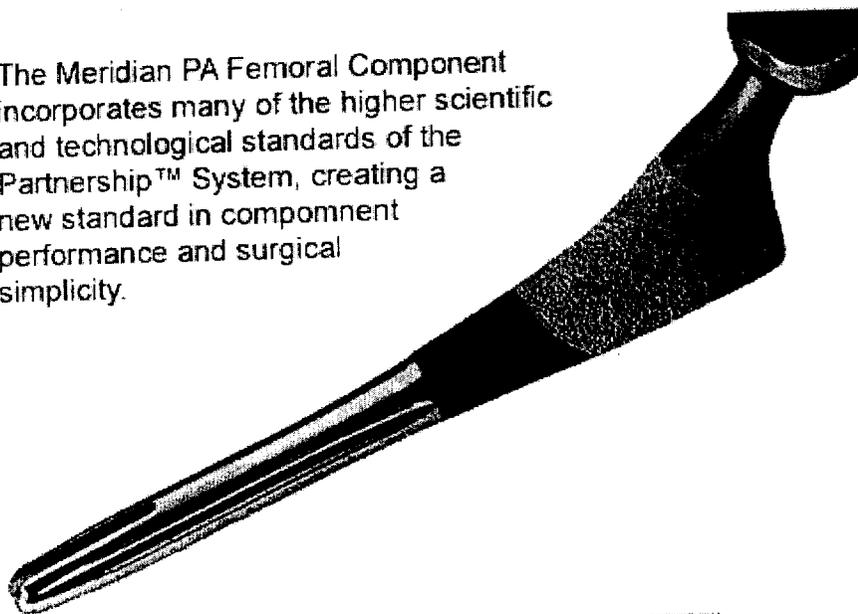
212



Low Temperature Aqueous Crystallization Process which Forms Calcium Hydroxyapatite Directly on the Prosthesis with No Detectable Effect on Substrate

APPLYING HIGHER STANDARDS

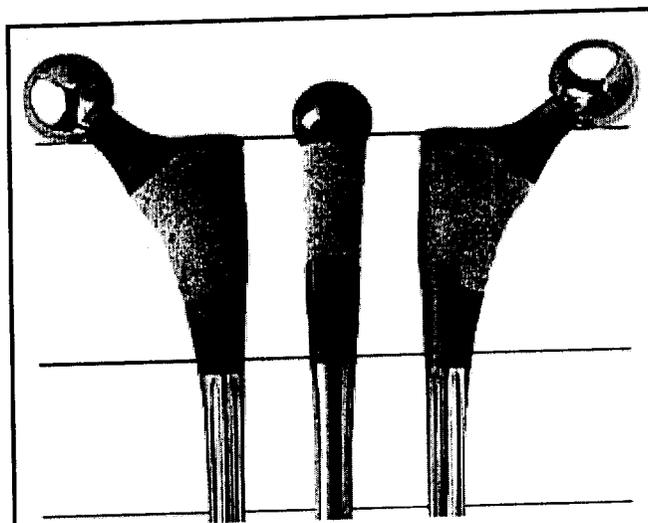
The Meridian PA Femoral Component incorporates many of the higher scientific and technological standards of the Partnership™ System, creating a new standard in component performance and surgical simplicity.



- V40™ Forged Femoral Head
- 3-Dimensional HA Uniform (20 micron) Coverage
- Anatomic Offset
- Circumferential Porous Coating
- GADS Forged Vitallium® Alloy
- Enhanced Canal Fit and Fill
- 18 Stem Sizes
- Polished Distal Stem
- Distal Grooves
- Gradual Taper & Rounded Distal Tip
- Distal Split

2/3

- **Complete three-dimensional coverage with hydroxyapatite** of porous ingrowth area.
- **Thin (20 micron) uniform HA coating** does not block the porosity of the ingrowth area.
- **High surface area HA** due to the solution deposition process.
- **HA never exposed to high temperatures.** Thus, no uncontrolled phase transformations (tri-calcium phosphates/ calcium oxide) or partial melting of the HA and no effect on the substrate material.
- **HA precipitated** in a manner similar to the process of bone mineralization.
- **Physiological pH (7.4)** during HA precipitation.
- **Anatomic offsets** enhance joint stability and help restore hip biomechanics by providing the opportunity to tighten soft tissue without creating leg-length discrepancies.
- **Circumferential porous coating** creates a proximal seal that prevents migration of wear debris and particulate matter.
- **Unique distal split and grooves** are designed to improve patient comfort by reducing distal stiffness without affecting component strength. Distal stem stiffness is cited as a contributing factor in minimizing the incidence of thigh pain. 1
- **Polished distal stem** helps to prevent distal fixation that can interrupt and weaken proximal fixation.
- **Gradual taper and rounded distal tip** maintain a larger, more dispersed contact area between stem and bone than typical, blunt-tipped, rigged stems.
- **Secure engagement/insertion feature** simplifies component implantation.
Connects the stem securely to the Command insertion/alignment instrument.
- **GADS Forged Vitallium ® Alloy** provides the strength that makes the Meridian PA Femoral Component design and broad stem size selection possible.
 - Retains fatigue strength after sintering.
 - Permits extra and extra-extra small porous coated stem sizes.
- **18 Stem Sizes:** 11 Proximal sizes; two distal diameters for sizes #2 through #8 for a better match of Type "A" and Type "B" canals.
- **V40™ Forged Femoral Heads** offer a new taper geometry for a larger range of offsets and neck lengths (-4mm to +16mm).





Circumferential View of HA Coating

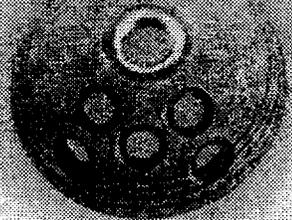
Meridian ST || Meridian PA || Meridan TMZF
Definition || Reliance || Citation || Command

1 Skinner HB, Curlin FJ. Decreased Pain Without Flexural Rigidity of Uncemented Femoral Prostheses. Orthopaedics. Vol 13, No 11, Nov 1990.

Copyright 1997, Howmedica Osteonics Corp.

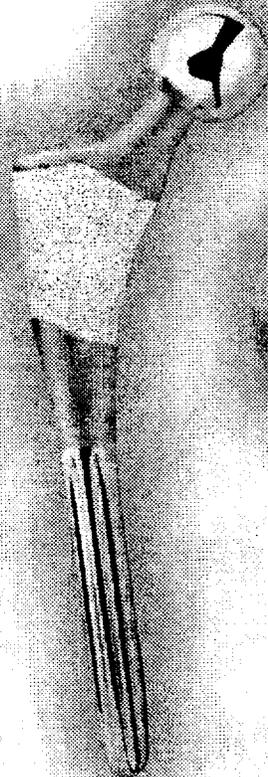
215

Succession



Secur-Fit[®] HA Acetabular Shell
 The combination of an arc deposited CP Titanium coating with a 50-micron thick surface treatment of PureFix[™] HA enhances implant stability and performance.

HA



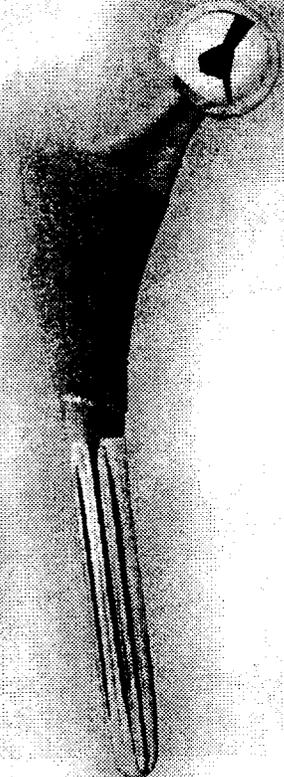
Meridian[®] PA Hip System
 An innovative process produces complete three-dimensional coverage of a porous ingrowth surface with precipitated hydroxyapatite.

PA



Crossfire[™]
 Highly crosslinked polyethylene demonstrates a 90% reduction in polyethylene wear compared to standard polyethylene.

UHMWPE



Meridian[®] TMZF[®] Hip System
 A proprietary beta titanium alloy combines the benefits of a 25% lower modulus with a 20% higher tensile strength than Ti-6Al-4V.

TMZF

LEADING TO SCIENTIFIC SOLUTIONS

1-877-HOWOST 1 www.howost.com/info

stryker[®]
Howmedica
OSTEONICS

Crossfire[™], Duration[™], Eon[™], Exeter[™], PureFix[™], and Secur-Fit[™] are trademarks of Howmedica Osteonics Corp. Meridian[®], Simplex[®] P, and TMZF[®] are registered trademarks of Howmedica Osteonics Corp. Stryker[®] is a registered trademark of Stryker Corporation. *See package insert for full prescribing information.

359 Veterans Boulevard
 Rutherford, NJ 07070
 59 Route 17 South
 Allendale, NJ 07401

216

Center for Devices and Radiological Health

Releasable 510(k) Search

Device Classification Name	PROSTHESIS, HIP, SEMI-CONSTRAINED, METAL/POLYMER, POROUS UNCEMENTED
Regulation Number	888.3358
510(k) Number	K971206
Device Name	MERIDIAN ST FEMORAL STEM AND VITALOCK SOLID BACK
Applicant	HOWMEDICA CORP. 359 VETERANS BOULEVARD RUTHERFORD, NJ 07070
Contact	MARGARET CROWE
Product Code	LPH
Date Received	03/12/1997
Decision Date	02/11/1998
Decision	SUBSTANTIALLY EQUIVALENT FOR SOME INDICATIONS
Classification Advisory Committee	Orthopedic
Review Advisory Committee	Orthopedic
Statement/Summary/Purged Status	Summary/purged 510(k)
Summary/Approval Letter Type	<u>SUMMARY</u> Traditional

[CDRH Home Page](#)
[FDA Home Page](#)
[Comments](#)
[Return to Search](#)

(Database Updated June 5, 2000)

217

K971206

FEB 11 1998

510(k) Summary

Device: Meridian® ST Femoral Stem and Vitalock® Solid Back Shell with Peri-Apatite™ Coating

Classification Name and Reference:

Hip Joint Metal/Polymer/Metal Semi-Constrained Porous Coated Uncemented Prosthesis 21 CFR 888.3358

Proposed Regulatory Class: Class II (reclassified 1-8-93)

For information contact: Margaret F. Crowe
Manager, Regulatory Affairs
Howmedica Inc.
359 Veterans Boulevard
Rutherford, NJ 07070
Telephone: (201) 507-7431
Fax: (201) 507-6870

The Meridian® ST Femoral Stem and Vitalock® Solid Back Shell with Peri-Apatite™ Coating are intended to be used in the primary uncemented reconstruction of the proximal femur and acetabulum damaged as a result of non-inflammatory joint disease, avascular necrosis or trauma. These devices are identical to the Meridian® ST femoral stem and Vitalock® Solid Back shell previously released under K940307, K930223, and K952397 respectively, except for the presence of a thin layer of hydroxyapatite coating applied to the porous coated surface.

The Meridian™ ST Femoral Stem and Vitalock® Solid Backed Acetabular Shell with Peri-Apatite™ Coating are equivalent to other legally marketed devices in commercial distribution. These products are listed below:

1. Meridian™ ST Femoral Stem - Howmedica
2. Vitalock® Solid Backed Acetabular Shell - Howmedica
3. Osteolock™ HA Femoral Stem - Howmedica

This equivalence is based upon similarities in intended use, material, design, and operational principles to the legally marketed devices.

Testing to characterize the Peri-Apatite™ coating was presented, along with the results of an animal study.

2/8

Sulzer Orthopedics**Products****Surgical Support****Services****Education****About Us****Sales Force****Site Map****Search****What's New****Sulzer Orthopedics
Worldwide****The APR[®] Hip System**

For over a decade, the APR Hip System has been successfully addressing issues such as proximal fill and anatomic fit to maximize long-term stability and performance. A full range of options with three proximal body sizes for each distal diameter allow for precise patient anatomy matching.

The APR Hip System offers a complete product line to precisely match patient needs and surgeon preferences...

**Non-porous**

Cobalt Chromium closely matches the stiffness of cement, protecting the mantle from fatigue. The proximal cement channels aid in cement distribution compression and adhesion. Proximal and distal PMMA centralizers assure uniform cement mantle and help ensure correct positioning.

Intended only for use with bone cement.

**Porous Distally Polished**

Cancellous-Structured Titanium (CSTi) mimics human cancellous bone, providing a reinforced flow barrier between the proximal area and the diaphysis, which may prevent osteolytic potential AND provides for biologic fixation.

Available in Standard and Large Bodies

**Porous Distally Textured**

Grit-blasted surface technology provides a stable fixation of the stem.

The collared stem loads the calcar to resist subsidence. The collarless stem suits the needs of surgeons who believe the stem should find its natural place.

Available in Standard, Large and Oversized Bodies

**Porous HA Distally Textured**

Sulzer Orthopedics is the first company to offer Hydroxyapatite (HA) coating over CSTi. HA porous surfaces encourage effective filling of the proximal femur, avoiding further degeneration.

Available in Standard, Large and Oversized Bodies



Intended only for use without bone cement.

Nonporous Fully Textured

With the same geometry as the porous option but without the porous coating, the fully textured stem offers a lower-cost press-fit option to cementing.

Available in Large and Oversized Bodies

Non-porous	Standard Body	Large Body	Oversized
CoCr	Porous Distally Polished	Porous Distally Polished	Porous Distally Textured
	Porous Distally Textured	Porous Distally Textured	
	Porous HA Distally Textured	Porous HA Distally Textured	Porous HA Distally Textured
	Porous Collarless Distally Textured	Porous Collarless Distally Textured	Nonporous Fully Textured
Nonporous Fully Textured			

[APR Hip](#) | [Design Rationale](#) | [X-Ray Templates](#) | [Bibliography](#) |

270

Center for Devices and Radiological Health

Releasable 510(k) Search

Device Classification Name	PROSTHESIS, HIP, SEMI-CONSTRAINED, METAL/POLYMER, POROUS UNCEMENTED
Regulation Number	888.3358
510(k) Number	K973124
Device Name	APR POROUS HA HIP SYSTEM
Applicant	SULZER ORTHOPEDICS, INC. 9900 SPECTRUM DR. AUSTIN, TX 78717
Contact	LORI K HOLDER
Product Code	LPH
Date Received	08/20/1997
Decision Date	11/03/1997
Decision	SUBSTANTIALLY EQUIVALENT FOR SOME INDICATIONS
Classification Advisory Committee	Orthopedic
Review Advisory Committee	Orthopedic
Statement/Summary/Purged Status	Summary only
Summary/Approval Letter Type	<u>SUMMARY</u> Traditional

[CDRH Home Page](#)[FDA Home Page](#)[Comments](#)[Return to Search](#)*(Database Updated May 10, 2000)*

221



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV - 3 1997

Lori Kleinschrodt Holder, RAC
Regulatory Affairs Specialist
Sulzer Orthopedics Inc.
9900 Spectrum Drive
Austin, Texas 78717

Re: K973124
APR Porous HA Hip Stem
Regulatory Class: II
Product Codes: LPH and MEH
Dated: August 19, 1997
Received: August 20, 1997

Dear Ms. Holder:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). This decision is based on consideration of the specific design of stem and coating composition detailed in this application. You may, therefore, market the device, subject to the general controls provisions of the Act and the following limitation:

You may not label or in any way promote these devices for enhanced clinical or radiographic performance, enhanced biological fixation and/or long-term stable fixation. The data presented support equivalence with no additional claims over a conventional porous-coated uncemented hip prosthesis (i.e., biological fixation, only).

Additional limitations for more specific claims of safety and effectiveness may be forthcoming. Should additional limitations be applied you will be contacted in writing to inform you of the additional labeling limitations.

The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

222

You may market your device under the above limitations as class II devices. These devices would be considered not substantially equivalent to a legally marketed predicate device if labeled with other intended uses and/or claims of safety or effectiveness. Any other intended uses or claims may cause the device to be classified into Class III under Section 513(f) of the Act. Class III devices are required to have an approved premarket approval (PMA) application prior to marketing.

Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal Laws or Regulations.

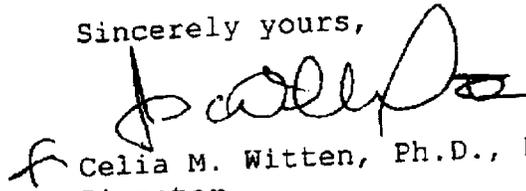
This letter will allow you to begin marketing your device as described in your 510(k) premarket notification immediately. An FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be

Page 3 - Lori Kleinschrodt Holder, RAC

obtained from the Division of Small Manufacturers Assistance
at its toll-free number (800) 638-2041 or (301) 443-6597 or at
its Internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

224

510(k) Number (if known): K973124

Device Name: APR Porous HA System

Indications For Use:

1. Patient conditions of non-inflammatory degenerative joint disease (NIDJD), e.g., avascular necrosis, osteoarthritis and inflammatory joint disease (IJD), e.g., rheumatoid arthritis.
2. Those patients with failed previous surgery where pain, deformity, or dysfunction persists.
3. Revision of previously failed arthroplasty.

The APR Porous HA System is intended only for use without bone cement.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

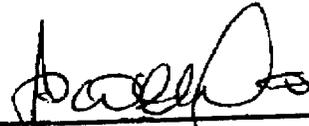
Concurrence of CDREH, Office of Device Evaluation (ODE)

Prescription Use X

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)



(Division Sign-Off)
Division of General Restorative Devices

510(k) Number _____

K973124

225

K973124

510(k) SUMMARY

In accordance with the Food and Drug Administration Rule to implement provisions of the Safe Medical Devices Act of 1990 and in conformance with 21 CFR 807, this is to serve as a 510(k) Summary for the APR Porous HA Hip Stem.

Submitter: Sulzer Orthopedics, Inc.
9900 Spectrum Drive
Austin, Texas 78717
(512) 432-9900

Date: August 19, 1997

Contact Person: Jacquelyn Hughes
Manager, Regulatory Affairs

Classification Name: Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis, 21 CFR 888.3358.

Common/Usual Name: Biologically fixed total hip prosthesis, semi-constrained

Trade/Proprietary Name: APR Porous HA Hip Stem

PRODUCT DESCRIPTION

The APR Porous HA femoral stem is anatomically designed with right and left components. These stems are available in three proximal body styles to optimize fit of the hip stem in the femoral canal: a standard body, a large body in which the proximal anterior dimension has been widened slightly to maximize filling of the proximal femur, and an oversized for the patient exhibiting the endosteal canal shape (sometimes referred to as Type A) in which the diaphysis is disproportionately smaller than the metaphysis. The larger sizes of the stems are stems feature distal hollowing for increased stem flexibility.

The stems are manufactured from wrought Ti-6Al-4V (ASTM F-136). The stems are fabricated with a neck and stem designed to match the natural shape and curve of the femur. Ceramic hydroxylapatite (HA) coated Cancellous-Structured Titanium (CSTi) is located on the inferior side of the collar as well as the proximal femoral body. A Morse-type taper on the proximal aspect of the stem permits attachment of one of a variety of femoral heads.

This device is intended for use with the following previously cleared devices:

- IOI metallic femoral bearing heads
- IOI Biolox Bearing Heads
- Zirconia Bearing Heads
- IOI acetabular components

226

SPECIFIC DIAGNOSTIC INDICATIONS

The APR Porous HA Hip Stem is intended to replace the anatomy of the femur in cases of total hip or hemi-hip replacement. The general indications associated with the use of the APR Porous HA Hip Stem in total hip arthroplasty include:

1. Patient conditions of noninflammatory degenerative joint disease (NIDJD), e.g., avascular necrosis, osteoarthritis, and inflammatory joint disease (IJ), e.g., rheumatoid arthritis.
2. Those patients with failed previous surgery where pain, deformity, or dysfunction persists.
3. Revision of previously failed hip arthroplasty

Total hip replacements may be considered for younger patients if any unequivocal indication outweighs the risks associated with the age of the patient, and modified demands regarding activity and hip joint loading are assured. This includes severely crippled patients with multiple joint involvement, for whom an immediate need of hip mobility leads to an expectation of significant improvement in the quality of their lives.

The APR Porous HA Hip Stem is intended only for use without bone cement in the United States. This device is intended for single use only.

SUBSTANTIAL EQUIVALENCE

The APR Porous HA Hip Stem is substantially equivalent to the Natural-Hip HA Stem (Sulzer Orthopedics Inc.) and the APR Universal Hip Stem with Calcite®-Coated CSTi (Sulzer Orthopedics Inc.).

227