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UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION

COMMISSIONERS: **Edith Ramirez, Chairwoman**
Julie Brill
Maureen K. Ohlhausen
Terrell McSweeny

In the Matter of	)	
PFIZER INC.,	)	
a corporation;	)	
and	)	**Docket C-4537**
HOSPIRA, INC.,	)	
a corporation.	)	

DECISION AND ORDER
[Public Record Version]

The Federal Trade Commission ("Commission"), having initiated an investigation of the proposed acquisition by Respondent Pfizer Inc. ("Pfizer") of the voting securities of Respondent Hospira, Inc. ("Hospira"), collectively "Respondents," and Respondents having been furnished thereafter with a copy of a draft of Complaint that the Bureau of Competition proposed to present to the Commission for its consideration and which, if issued by the Commission, would charge Respondents with violations of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45; and

Respondents, their attorneys, and counsel for the Commission having thereafter executed an Agreement Containing Consent Orders ("Consent Agreement"), containing an admission by Respondents of all the jurisdictional facts set forth in the aforesaid draft of Complaint, a statement that the signing of said Consent Agreement is for settlement purposes only and does not constitute an admission by Respondents that the law has been violated as alleged in such Complaint, or that the facts as alleged in such Complaint, other than jurisdictional facts, are true, and waivers and other provisions as required by the Commission's Rules; and

The Commission having thereafter considered the matter and having determined that it

E. "Acquirer(s)" means the following:

1. a Person specified by name in this Order to acquire particular assets or rights that a Respondent(s) is required to assign, grant, license, divest, transfer, deliver, or otherwise convey pursuant to this Order and that has been approved by the Commission to accomplish the requirements of this Order in connection with the Commission's determination to make this Order final and effective; or

2. a Person approved by the Commission to acquire particular assets or rights that a Respondent(s) is required to assign, grant, license, divest, transfer, deliver, or otherwise convey pursuant to this Order.

F. "Acquisition" means Respondent Pfizer's acquisition of fifty percent (50%) or more of the voting securities of Hospira. Respondents entered an *Agreement and Plan of Merger* on February 5, 2015, to effect the Acquisition, among Pfizer Inc., Perkins Holding Company, and Hospira Inc., that was submitted to the Commission.

G. "Acquisition Date" means the date on which the Acquisition is consummated.

H. "Acetylcysteine Products" means the following: the Products manufactured, marketed, sold, in Development, owned or controlled by Respondent Pfizer pursuant to the following Applications:

1. ANDA Number 203-853;

2. ANDA Number 204-674; and,

3. any supplements, amendments, or revisions to these Applications.

I. "Acetylcysteine Product Divestiture Assets" means the following assngr pursu4(e e(ua)(sn)2(-4(ct)-6( )-9

L. "Agency(ies)" means any government regulatory authority or authorities in the world responsible for granting approval(s), clearance(s), qualification(s), license(s), or permit(s) for any aspect of the research, Development, manufacture, marketing, distribution, or sale of a Product. The term "Agency" includes, without limitation, the United States Food and Drug Administration ("FDA").

M. "Alvogen" means Alvogen Group, Inc., a corporation organized, existing and doing business under and by virtue of the laws of the State of Delaware with its principal executive offices located at 10 Bloomfield Avenue, Building B, Pine Brook, NJ 07058, or any of its wholly-owned subsidiaries.

N. "Application(s)" means all of the following: "New Drug Application" ("NDA"), "Abbreviated New Drug Application" ("ANDA"), "Supplemental New Drug Application" ("SNDA"), or "Marketing Authorization Application" ("MAA"), the applications for a Product filed or to be filed with the FDA pursuant to 21 C.F.R. Part 314 et seq., and all supplements, amendments, and revisions thereto, any preparatory work, registration dossier, drafts and data necessary for the preparation thereof, and all correspondence between a Respondent and the FDA related thereto. The term "Application" also includes an "Investigational New Drug Application" ("IND") filed or to be filed with the FDA pursuant to 21 C.F.R. Part 312, and all supplements, amendments, and revisions thereto, any preparatory work, registration dossier, drafts and data necessary for the preparation thereof, and all correspondence between a Respondent and the FDA related thereto.

O. "Business" means the research, Development, manufacture, commercialization, distribution, marketing, importation, advertisement and sale of a Product.

P. "Categorized Assets" means the following assets and rights of Hospira, as such assets and rights are in existence as of the date Hospira signs the Agreement Containing Consent Orders in this matter and as are maintained by the Respondents in accordance with the Order to Maintain Assets until the Closing Date:

1. all rights to all of the Applications related to the specified Divestiture Product;
2. all Product Intellectual Property related to the specified Divestiture Product that is not Product Licensed Intellectual Property;
3. all Product Approvals related to the specified Divestiture Product;
4. all Product Manufacturing Technology related to the specified Divestiture Product that is not Product Licensed Intellectual Property;
5. all Product Marketing Materials related to the specified Divestiture Product;
6. all Product Scientific and Regulatory Material related to the specified Divestiture Product;
7. all Website(s) related exclusively to the specified Divestiture Product;

8. the content related exclusively to the specified Divestiture Product that is displayed on any Website that is not dedicated exclusively to the specified Divestiture Product;

9. for each specified Divestiture Product that has been marketed or sold by a Respondent prior to the Closing Date, a list of all of the NDC Numbers related to the specified Divestiture Product, and rights, to the extent permitted by Law:

    a. to require Respondents to discontinue the use of those NDC Numbers in the sale or marketing of the specified Divestiture Product *except* for returns, rebates, allowances, and adjustments for such Product sold prior to the Closing Date and *except* as may be required by applicable Law and *except* as is necessary to give effect to the transactions contemplated under any applicable Remedial Agreement;

    b. to prohibit Respondents from seeking from any customer any type of cross-referencing of those NDC Numbers with any Retained Product(s) *except* for returns, rebates, allowances, and adjustments for such Product sold prior to the Closing Date and *except* as may be required by applicable Law;

    c. to seek to change any cross-referencing by a customer of those NDC Numbers with a Retained Product (including the right to receive notification from the Respondents of any such cross-referencing that is discovered by a Respondent);

    d. to seek cross-referencing from a customer of the Respondent's NDC Numbers related to such Divestiture Product 0.004 Tw [(o)-4( )]TJ 5(e)-4(c)6(ew [-2(qu(e

FDA to facilitate the investigation of adverse effects related to the specified Divestiture P

Intellectual Property;

provided further, however, that in cases in which documents or other materials included in the assets to be divested contain information: (i) that relates both to the specified Divestiture Product and to Retained Products or Businesses of any Respondent and cannot be segregated in a manner that preserves the usefulness of the information as it relates to the specified Divestiture Product; or (ii) for which any Respondent has a legal obligation to retain the original copies, the specified Respondent shall be required to provide only copies or relevant excerpts of the documents a

U. "Closing Date" means, as to each Divestiture Product, the date on which a Respondent (or a Divestiture Trustee) consummates a transaction to assign, grant, license, divest,

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4. with universities or other research institutions for the use of the specified Divestiture Product in scientific research;

5. relating to the particularized marketing of the specified Divestiture Product or educational matters relating solely to the specified Divestiture Product(s);

6. pursuant to which a Third Party manufactures or plans to manufacture the specified Divestiture Product as a finished Product on behalf of the Respondent;

7. pursuant to which a Third Party provides or plans to provide any part of the manufacturing process including, without limitation, the finish, fill, and/or packaging of the specified Divestiture Product on behalf of Respondent;

8. pursuant to which a Third Party provides the Product Manufacturing Technology related to the specified Divestiture Product to the Respondent;

9. pursuant to which a Third Party is licensed f3a 0 -1.16 TD [(m)4(s)ithroccwTw [for tg prococct,)c

12. Product recall reports filed with the FDA related to the specified Divestiture Product, and all reports, studies and other documents related to such recalls;

13. investigation reports and other documents related to any out of specification results for any impurities found in the specified Divestiture Product;

14. reports related to the specified Divestiture Product from any consultant or outside contractor engaged to investigate or perform testing for the purposes of resolving any product or process issues, including without limitation, identification and sources of impurities;

15. reports of vendors of the active pharmaceutical ingredients, excipients, packaging components and detergents used to produce the specified Divestiture Product that relate to the specifications, degradation, chemical interactions, testing and historical trends of the production of the specified Divestiture Product;

16. analytical methods development records related to the specified Divestiture Product;

17. manufacturing batch records related to the specified Divestiture Product;

18. stability testing records related to the specified Divestiture Product;

19. change in control history related to the specified Divestiture Product; and

20. executed validation and qualification protocols and reports related to the specified Divestiture Product.

CCC. "Product Employee Information" means the following, for each Divestiture Product Core Employee, as and to the extent permitted by Law:

1. a complete and accurate list containing the name of each Divestiture Product Core Employee (including former employees who were employed by the specified Respondent within ninety (90) days of the execution date of any Remedial Agreement);

2. with respect to each such employee, the following information:

   a. the date of hire and effective service date;

   b. job title or position held;

   c. a specific description of the employee's responsibilities related to the relevant Divestiture Product; *provided, however*, in lieu of this description, the specified Respondent may provide the employee's most recent performance appraisal;

   d. the base salary or current wages;

   e. the most recent bonus paid, aggregate annual compensation for the relevant Respondent's last fiscal year and current target or guaranteed bonus, if any;

   f. employment status (*i.e.*, active or on leave or disability; full-time or part-time);

used, prior to the Acquisition Date, for any Retained Product that is the subject of an active (not discontinued) NDA or ANDA as of the Acquisition Date; and,

2. in those instances in which any Respondent (i) owns, licenses or controls the rights to the Drug Master File of a Product that is the subject of an NDA ("NDA Product") that is the therapeutic equivalent (as that term is defined by the FDA) of any Divestiture Product that is the subject of an ANDA and (ii) such NDA Product is a Retained Product, a full, complete and unlimited Right of Reference or Use to such Drug Master File to reference or use in any Application related to that Divestiture Product.

FFF. "Product Manufacturing Employees" means all salaried employees of a Respondent who have directly participated in the planning, design, implementation or operational management of the Product Manufacturing Technology of the specified Divestiture Product (irrespective of the portion of working time involved unless such participation consisted solely of oversight of legal, accounting, tax or financial compliance) within the eighteen (18) month period immediately prior to the Closing Date.

GGG. "Product Manufacturing Technology" means all of the following related to a Divestiture Product:

1. all technology, trade secrets, know-how, formulas, and proprietary information (whether patented, patentable or otherwise) related to the manufacture of that Product, including, but not limited to, the following: all product specifications, processes, analytical methods, product designs, plans, trade secrets, ideas, concepts, manufacturing, engineering, and other manuals and drawings, standard operating procedures, flow diagrams, chemical, safety, quality assurance, quality control, research records, clinical data, compositions, annual product reviews, regulatory communications, control history, current and historical information associated with the FDA Application(s) conformance and cGMP compliance, and labeling and all other information related to the manufacturing process, and supplier lists;

2. all ingredients, materials, or components used in the manufacture of that Product including the active pharmaceutical ingredient, excipients or packaging materials; and,

3. for those instances in which the manufacturing equipment is not readily available from a Third Party, at the Acquirer's option, all such equipment used to manufacture that Product.

HHH. "Product Marketing Materials" means all marketing materials used specifically in the marketing or sale of the specified Divestiture Product in the Geographic Territory as of the Closing Date, including, without limitation, all advertising materials, training materials, product data, mailing lists, sales materials (*e.g.*, detailing reports, vendor lists, sales data), marketing information (*e.g.*, competitor information, research data, market intelligence reports, statistical programs (if any) used for marketing and sales research), customer information (including customer net purchase information to be provided on the

basis of either dollars and/or units for each month, quarter or year), sales forecasting models, educational materials, and advertising and display materials, speaker lists, promotional and marketing materials, Website content and advertising and display materials, artwork for the production of packaging components, television masters and other similar materials related to the specified Divestiture Product.

III. "Product Research and Development Employees" means all salaried employees of a Respondent who have directly participated in the research, Development, regulatory approval process, or clinical studies

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the Website(s), *except* to the extent that a Respondent can convey its rights, if any, therein; or (2) content unrelated to any of the Divestiture Products.

II.

IT IS FURTHER ORDERED that:

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relevant Acquirer for the Divestiture Product has executed all such agreements directly with each of the relevant Third Parties.

D. Respondents shall:

1. submit to each Acquirer, at Respondents' expense, all Confidential Business

E. For each Acquirer of a

7. in the event Respondents become (i) unable to supply or produce a Contract Manufacture Product from the facility or facilities originally contemplated under a Remedial Agreement with an Acquirer and (ii) that Product is the subject of an ANDA, then Respondents shall provide a therapeutically equivalent (as that term is defined by the FDA) Product from another of Respondents' facility or facilities in those instances where such facilities are being used or have previously been used, and are able to be used, by Respondents to manufacture such Product(s);

8. provide access to all information and facilities, and makture seui[R -10.47 -1.17,e2(t)-2(i)-22(i)-22e

information to all other employees, executives or other personnel of Respondents (other than as necessary to comply with the requirements of this Order).

H. Not later than thirty (30) days after the Closing Date, Respondents shall provide written notification of the restrictions on the use and disclosure of the Confidential Business Information related to the Divestiture Products by Respondents' personnel to all of their employees who (i) may be in possession of such Confidential Business Information or (ii) may have access to such Confidential Business Information. Respondents shall give the above-described notification by e-mail with return receipt requested or similar transmission, and keep a file of those receipts for one (1) year after the Closing Date. Respondents shall provide a copy of the notification to the relevant Acquirer. Respondents shall maintain complete records of all such notifications at Respondents' registered office within the United States and shall provide an officer's certification to the Commission stating that the acknowledgment program has been implemented and is being complied with. Respondents shall provide the relevant Acquirer with copies of all certifications, notifications and reminders sent to Respondents' personnel.

I. For each Acquirer of a Divestiture Product that is a Contract Manufacture Product, Respondents shall:

1. for a period of twelve (12) months from the Closing Date or until the hiring of u(s)1(imila)i

3. during the Divestiture Product Core Employee Access Period(s), not interfere with the hiring or employing by that Acquirer or its Manufacturing Designee of the Divestiture Product Core Employees related to the Divestiture Products and assets acquired by that Acquirer, and remove any impediments within the control of Respondents that may deter these employees from accepting employment with that Acquirer or its Manufacturing Designee, including, but not limited to, any noncompete or nondisclosure provision of employment with respect to a Divestiture Product or other contracts with Respondents that would affect the ability or incentive of those individuals to be employed by that Acquirer or its Manufacturing Designee. In addition, Respondents shall not make any counteroffer to such a Divestiture Product Core Employee who has received a written offer of employment from that Acquirer or its Manufacturing Designee;

provided, however, that, subject to the conditions of continued employment prescribed in this Order, this Paragraph shall not prohibit Respondents from continuing to employ any Divestiture Product Core Employee under the terms of that employee's employment with Respondents prior to the date of the written offer of employment from the Acquirer or its Manufacturing Designee to that employee;

4. until the Closing Date, provide all Divestiture Product Core Employees with reasonable financial incentives to continue in their positions and to research, Develop, manufacture and/or market the Divestiture Product(s) consistent with past practices and/or as may be necessary to preserve the marketability, viability and competitiveness of the Divestiture Product(s) and to ensure successful execution of the pre-Acquisition plans for that Divestiture Product(s). Such incentives shall include a continuation of all employee compensation and benefits offered by Respondents until the Closing Date(s) for the divestiture of the assets related to the Divestiture Product has occurred, including regularly scheduled raises, bonuses, and vesting of pension benefits (as permitted by Law);

provided, however, that this Paragraph does not require nor shall be construed to require Respondents to terminate the employment of any employee or to prevent Respondents from continuing to employ the Divestiture Product Core Employees in connection with the Acquisition; and

5. for a period of one (1) year from the Closing Date, not, directly or indirectly, solicit or otherwise attempt to induce any employee of the Acquirer or its Manufacturing Designee with any amount of responsibility related to a Divestiture Product ("Divestiture Product Employee") to terminate his or her employment relationship with the Acquirer or its Manufacturing Designee; or hire any Divestiture Product Employee;

provided, however

acquired by that Acquirer. Each Respondent shall also covenant to that Acquirer that as a conditi

2.

1. The Interim Monitor shall have the power and authority to monitor Respondent's compliance with the divestiture and asset maintenance obligations and related requirements of the Order, and shall exercise such power and authority and carry

G. Respondents shall indemnify the Interim Monitor and hold the Interim Monitor harmless against any losses, claims, damages, liabilities, or expenses arising out of, or in connection with, the performance of the Interim Monitor's duties, including all reasonable fees of counsel and other reasonable expenses incurred in connection with the preparations for, or defense of, any claim, whether or not resulting in any liability, except to the extent that such losses, claims, damages, liabilities, or expenses result from gross negligence, willful or wanton acts, or bad faith by the Interim Monitor.

H. Respondents shall report to the Interim Monitor in accordance with the requirements of this Order and as otherwise provided in any agreement approved by the Commission. The Interim Monitor shall evaluate the reports submitted to the Interim Monitor by Respondents, and any reports submitted by each Acquirer with respect to the performance of Respondents' obligations under the Order or the Remedial Agreement(s). Within thirty (30) days from the date the Interim Monitor receives these reports, the Interim Monitor shall report in writing to the Commission concerning performance by Respondents of their obligations under the Order; *provided, however,* beginning ninety (90) days after Respondents have filed their final report pursuant to Paragraph VII.B., and ninety (90) days thereafter, the Interim Monitor shall report in writing to the Commission concerning progress by each Acquirer or the Acquirer's Manufacturing Designee toward obtaining FDA approval to manufacture each Divestiture Product and obtaining the ability to manufacture each Divestiture Product in commercial quantities, in a manner consistent with cGMP, independently of Respondents.

I. Respondents may require the Interim Monitor and each of the Interim Monitor's consultants, accountants, attorneys and other representatives and assistants to sign a customary confidentiality agreement; *provided, however,* that such agreement shall not restrict the Interim Monitor from providing any information to the Commission.

J. The Commission may, among other things, require the Interim Monitor and each of the Interim Monitor's consultants, accountants, attorneys and other representatives and assistants to sign an appropriate confidentiality agreement related to Commission materials and information received in connection with the performance of the Interim Monitor's duties.

K. If the Commission determines that the Interim Monitor has ceased to act or failed to act diligently, the Commission may appoint a substitute Interim Monitor in the same manner as provided in this Paragraph.

L. The Commission may on its own initiative, or at the request of the Interim Monitor, issue such additional orders or directions as may be necessary or appropriate to assure compliance with the requirements of the Order.

M. The Interim Monitor appointed pursuant to this Order may be the same Person appointed as a Divestiture Trustee pursuant to the relevant provisions of this Order.

IV.

IT IS FURTHER ORDERED that:

A. If Respondents have not fully complied with the obligations to assign, grant, license, divest, transfer, deliver or otherwise convey the Divestiture Product Assets as required by this Order, the Commission may appoint a trustee ("Divestiture Trustee") to assign, grant, license, divest, transfer, deliver or otherwise convey these assets in a manner that satisfies the requirements of this Order. In the event that the Commission or the Attorney General brings an action pursuant to § 5(*l*) of the Federal Trade Commission Act, 15 U.S.C. § 45(*l*), or any other statute enforced by the Commission, Respondents shall consent to the appointment of a Divestiture Trustee in such action to assign, grant, license, divest, transfer, deliver or otherwise convey these assets. Neither the appointment of a Divestiture Trustee nor a decision not to appoint a Divestiture Trustee under this Paragraph shall preclude the Commission or the Attorney General from seeking civil penalties or any other relief available to it, including a court-appointed Divestiture Trustee, pursuant to § 5(*l*) of the Federal Trade Commission Act, or any other statute enforced by the Commission, for any failure by Respondentsf i(o i)-2(t)-2(,.17 Td [(ai)-2(na)a-3(

the one (1) year period, the Divestiture Trustee has submitted a plan of divestiture or the Commission believes that the divestiture can be achieved within a reasonable time, the divestiture period may be extended by the Commission; *provided, however*, the Commission may extend the divestiture period only two (2) times.

3. Subject to any demonstrated legally recognized privilege, the Divestiture Trustee shall have full and complete access to the personnel, books, records and facilities related to the relevant assets that are required to be assigned, granted, licensed, divested, delivered or otherwise conveyed by this Order and to any other relevant information, as the Divestiture Trustee may request. Respondents shall develop such financial or other information as the Divestiture Trustee may request and shall cooperate with the Divestiture Trustee. Respondents shall take no action to interfere with or impede the Divestiture Trustee's accomplishment of the divestiture. Any delays in divestiture caused by Respondents shall extend the time for divestiture under this Paragraph in an amount equal to the delay, as determined by the Commission or, for a court-appointed Divestiture Trustee, by the court.

4. The Divestiture Trustee shall use commercially reasonable efforts to negotiate the most favorable price and terms available in each contract that is submitted to the Commission, subject to Respondent's absolute and unconditional obligation to divest expeditiously and at no minimum price. The divestiture shall be made in the manner and to an Acquirer as required by this Order; *provided, however*, if the Divestiture Trustee receives bona fide offers from more than one acquiring Person, and if the Commission determines to approve more than one such acquiring Person, the Divestiture Trustee shall divest to the acquiring Person selected by Respondents [(t)-2(he)42(m)-2(e)4(u)1(r)ho stn-eeRs 001 [(th)2(e10 Tda)4(bs)-(s0.00429.06 0 Td-a)4om a

purposes:

A. To assure such Respondent’s compliance with any Remedial Agreement, this Order, any Law (including,

E. No Respondent shall seek, directly or indirectly, pursuant to any dispute resolution mechanism incorporated in any Remedial Agreement, or in any agreement related to any of the Divestiture Products a decision the result of which would be inconsistent with the terms of this Order or the remedial purposes thereof.

F. No Respondent shall modify or amend any of the terms of any Remedial Agreement without the prior approval of the Commission, except as otherwise provided in Rule 2.41(f)(5) of the Commission's Rules of Practice and Procedure, 16 C.F.R. § 2.41(f)(5). Notwithstanding any term of the Remedial Agreement(s), any modification or amendment of any Remedial Agreement made without the prior approval of the Commission, or as otherwise provided in Rule 2.41(f)(5), shall constitute a failure to comply with this Order.

VII.

IT IS FURTHER ORDERED that:

A. Within five (5) days of the Acquisition, Respondents shall submit to the Commission a letter certifying the date on which the Acquisition occurred.

B. Within thirty (30) days after the Order Date, and every sixty (60) days thereafter until Respondents have fully complied with Paragraphs II.A., II.B., II.C., II.D.1, II.D.2., II.D.3, II.E., II.F., II.G., II.H., II.I., and II.J., Respondents shall submit to the Commission a verified written report setting forth in detail the manner and form in which it intends to comply, is complying, and has complied with this Order. Respondents shall submit at the same time a copy of its report concerning compliance with this Order to the Interim Monitor, if any Interim Monitor has been appointed. Respondents shall include in their reports, among other things that are required from time to time, a full description of the efforts being made to comply with the relevant paragraphs of the Order, including:

1. a detailed description of all substantive contacts, negotiations, or recommendations related to (i) the divestiture and transfer of all relevant assets and rights, (ii) transitional services being provided by the Respondents to the relevant Acquirer, and (iii) the agreement(s) to Contract Manufacture; and
2. a detailed description of the timing for the completion of such obligations.

C. One (1) year after the Order Date, annually for the next nine years on the anniversary of the Order Date, and at other times as the Commission may require, Respondents shall file a verified written report with the Commission setting forth in detail the manner and form in which it has complied and is complying with the Order.

VIII.

IT IS FURTHER ORDERED that Respondents shall notify the Commission at least thirty (30) days prior to:

A. any proposed dissolution of a Respondent;

B. any proposed acquisition, merger or consolidation of a Respondent; or

C. any other change in a Respondent including, but not limited to, assignment and the creation or dissolution of subsidiaries, if such change might affect compliance obligations arising out of this Order.

IX.

IT IS FURTHER ORDERED that, for purposes of determining or securing compliance w gpD /iite-te-teIhe

NON-PUBLIC APPENDIX I
AGREEMENTS RELATED TO THE DIVESTITURES

[Redacted From the Public Record Version, But Incorporated By Reference]