

UNCLASSIFIED

Dept of State, RPS/IPS, Margaret P. Grafeld, Dir DEPARTMENT OF COMMERCE

( ) Release ( ) Excise ( ) Deny ( ) Declassify

Date 4/27/81 Page 01 of 02 Exemption

021142 DCA116

29/04342

29/04392

|      |         |         |         |         |         |         |         |
|------|---------|---------|---------|---------|---------|---------|---------|
| INFO | CCEN-01 | OPS-01  | J350-01 | CFCO-01 | 3010-01 | 6410-01 | 4120-01 |
|      | 4121-02 | 6240-01 | 6241-01 | 3130-01 | NTIS-01 | 4210-01 | 4211-01 |
|      | 4220-02 | 5100-01 | 4321-01 | 4322-01 | 4330-01 | AMAD-01 | 5120-01 |
|      | 6600-02 | 6310-01 | 4331-01 | PTO-01  | 4332-01 | 6710-01 | 6720-01 |
|      | 4400-02 | 5130-01 | 6910-01 | 6920-02 | 4410-02 | 4430-02 | 6420-01 |
|      | 6320-01 | 4530-02 | 4122-01 | 6810-01 | 6430-02 | 6200-01 | NBS-01  |
|      | 6440-01 | DSEC-01 | 4110-01 | PSP-01  | 5121-01 | 6330-01 | 6450-01 |
|      | OPTI-01 | 6331-01 | BES-01  | /061 AD | AMA     |         |         |

RR RUEHDC  
 DE RUEHC #2753 2712308  
 ZNR UUUUU ZZH  
 R 262305Z SEP 87  
 FM SECSTATE WASHDC  
 TO RUEBR/AMEMBASSY BRASILIA 0000  
 INFO RUENRI/AMCONSUL RIO DE JANEIRO 0000  
 RUENSO/AMCONSUL SAO PAULO 0000  
 RUEHBU/AMEMBASSY BUENOS AIRES 0000  
 RUENSG/AMEMBASSY SANTIAGO 0000  
 BT  
 UNCLAS STATE 302753

E.O. 12356: N/A  
 TAGS: ETRD, EINV, EINH, BR, US  
 SUBJECT: BRAZIL PHARMACEUTICALS 301 INVESTIGATION:  
 PUBLIC HEARINGS

1. SUMMARY: PUBLIC HEARINGS WERE HELD SEPTEMBER 14 IN WASHINGTON, D.C., AS PART OF THE SECTION 301 ACTION FILED BY THE PHARMACEUTICAL MANUFACTURERS ASSOCIATION (PMA) ALLEGING THAT BRAZIL'S DENIAL OF INTELLECTUAL PROPERTY RIGHTS (IPR) PROTECTION FOR PHARMACEUTICALS CONSTITUTES AN "UNREASONABLE ACTION WHICH BURDENS OR RESTRICTS U.S. COMMERCE." TESTIMONY SUPPORTING THE PMA PETITION WAS PRESENTED BY PMA PRESIDENT HOSSINGHOFF AND 5 EXECUTIVES OF PMA-AFFILIATED COMPANIES. WRITTEN TESTIMONY IN SUPPORT OF THE PMA PETITION WAS SUPPLIED BY EVERY EUROPEAN EUROPEAN PHARMACEUTICAL INDUSTRY ASSOCIATION. OVERALL THE HEARING PROVIDED A USEFUL OPPORTUNITY TO REVIEW BRAZIL'S LACK OF INTELLECTUAL PROPERTY RIGHTS PROTECTION FOR PHARMACEUTICALS AND HOW THIS IMPACTS NEGATIVELY NOT ONLY ON THE PMA COMPANIES STILL OPERATING IN BRAZIL BUT ON THE BRAZILIAN PHARMACEUTICAL INDUSTRY AND THE BRAZILIAN PUBLIC AS WELL. END SUMMARY

2. INTRODUCTION

USTR DIRECTOR FOR BRAZIL AND SOUTHERN CONE AFFAIRS CHRISTINA LUND, WHO CHAIRED THE PROCEEDINGS, OPENED THE HEARINGS BY REVIEWING THE 301 PROCESS. SHE NOTED THAT THESE PUBLIC HEARINGS WERE THE FIRST STEP IN INVESTIGATING THE 301 COMPLAINT, AND THAT THE USG WOULD NEXT BE REQUESTING CONSULTATIONS WITH THE GOB ON THIS ISSUE. SHE NOTED THAT THE USG HAD CONSULTED WITH THE GOB ON SEVERAL OCCASIONS PRIOR TO THE PMA'S FILING OF THE 301 PETITION.

3. PMA PRESENTATION

GERALD J. HOSSINGHOFF, PRESIDENT OF THE PMA, LED OFF THE PRESENTATIONS, FOLLOWED BY FIVE EXECUTIVES OF PMA-AFFILIATED FIRMS. THESE INDIVIDUALS, EACH OF WHOM ALSO IS ACTIVE IN PMA IPR OR LATIN AMERICAN COMMITTEES, WERE RICHARD M. FURLAUD (SQUIBB), ROLF H. HENEL (LEBERLE), BROVER A. HERRIAM (PFIZER), DONALD E. BOULTBEE (SMITH KLINE & FRENCH), AND RICHARD G. WATERMAN (MERREL DOW).

4. THE MAJOR THEME OF THE SIX PRESENTATIONS WAS THAT

BRAZIL'S FAILURE TO PROVIDE ADEQUATE PATENT PROTECTION FOR PHARMACEUTICALS WAS UNREASONABLE, BURDENSOME ON THE U.S. PHARMACEUTICAL COMPANIES OPERATING IN BRAZIL, AND COUNTERPRODUCTIVE TO BRAZIL'S OWN DOMESTIC INTERESTS. BRAZIL HAS CONSCIOUSLY EXCLUDED PHARMACEUTICAL PRODUCTS AND PROCESSES FROM AN OTHERWISE ADEQUATE PATENT PROTECTION SCHEME. THIS HAS AFFECTED U.S. FIRMS NEGATIVELY THROUGH THE PIRATING OF PRODUCTS AND THEIR SALE IN BRAZIL IN COMPETITION WITH THE U.S. DEVELOPERS OF THE PRODUCTS. THE PMA VERY CONSERVATIVELY ESTIMATES THAT THIS PIRATING HAS COST THEIR MEMBERS 160 MILLION DOLLARS IN LOST SALES IN THE PERIOD 1979-86, AND MAY COST AS MUCH AS 1 BILLION DOLLARS 1987-2000. FINALLY, THE PMA SPEAKERS STRESSED THAT THE LACK OF PHARMACEUTICAL PATENT PROTECTION WAS NOT IN LINE WITH BRAZIL'S LONG-TERM INTERESTS. THEY POINTED OUT THAT BRAZIL WAS THE EIGHTH LARGEST FREE WORLD ECONOMY AND A MAJOR TRADING NATION. BRAZIL MUST PLAY A RESPONSIBLE ROLE IN TRADE AND INVESTMENT MATTERS COMMENSURATE WITH ITS STATUS. THEY NOTED THAT ONE OF BRAZIL'S ALLEGED PURPOSES OF DENYING PATENT PROTECTION FOR PHARMACEUTICALS WAS TO ENCOURAGE THE DOMESTIC PHARMACEUTICAL INDUSTRY. IN FACT, JUST THE OPPOSITE HAS HAPPENED: THE MARKET SHARE OF DOMESTIC PHARMACEUTICAL COMPANIES IN BRAZIL HAS DECLINED SINCE IPR PROTECTION WAS REMOVED IN 1969. FURTHERMORE, DOMESTIC

FIRMS ARE NOT ENGAGING IN ANY SIGNIFICANT R AND D. THREE U.S. FIRMS HAVE WITHDRAWN FROM BRAZIL, AND A NUMBER OF OTHERS ARE HOLDING BACK ON INVESTMENT PLANS.

5. QUESTIONS AND ANSWERS

THE THEMES INTRODUCED DURING THE PMA PRESENTATIONS WERE FURTHER DEVELOPED DURING THE QUESTION-AND-ANSWER PERIOD FOLLOWING THE PRESENTATIONS, AND SOME NEW ISSUES WERE ALSO RAISED. THE USG INTERAGENCY PANEL CONSISTED OF REPRESENTATIVES OF USTR, STATE, COMMERCE (INCLUDING PATENT AND TRADEMARK OFFICE) AND TREASURY. THE MOST SIGNIFICANT QUESTIONS DEALT WITH THE ISSUES OF EXACTLY WHY THE PMA IS PURSUING THIS ACTION AGAINST BRAZIL, WHAT THE PMA HOPES TO ACCOMPLISH THROUGH THE 301 CASE, WHETHER THE PMA WOULD ACCEPT A COMPROMISE OFFERED BY THE BRAZILIAN GOVERNMENT, AND WHETHER THE PMA WAS CONSIDERING FILING FURTHER 301 ACTIONS AGAINST OTHER COUNTRIES.

6. IN RESPONSE, PMA PANELISTS NOTED THAT BRAZIL WAS CHOSEN FOR TWO BASIC REASONS. FIRST, BRAZIL HAS NEITHER PRODUCT NOR PROCESS PATENT PROTECTION. THIS IS INEXCUSABLE FOR A COUNTRY WITH THE EIGHTH LARGEST FREE-WORLD ECONOMY. FURTHERMORE, BRAZIL IS SEEN AS A LEADER AMONG NEWLY-INDUSTRIALIZED COUNTRIES AND THE G-77 AND ACTION TAKEN BY OR AGAINST BRAZIL WOULD BE SEEN AS AN IMPORTANT PRECEDENT.

7. THE PMA REPLY TO THE QUESTION ABOUT TIMING COVERED SEVERAL POINTS. PMA PANELISTS NOTED THAT IN FACT THEIR MEMBERS HAD BEEN CONCERNED EVER SINCE BRAZIL DROPPED PATENT PROTECTION IN 1969. WHEN NEITHER PMA NOR USG CONSULTATIONS WITH THE GOB OVER THE YEARS PRODUCED POSITIVE CHANGES, THE PMA LOBBIED TO HAVE LACK OF IPR PROTECTION ADDED AS AN ACTIONABLE ISSUE IN THE 1984 REVISION OF SECTION 301, AND ALSO AS A CRITERION TO BE CONSIDERED DURING THE GSP GENERAL REVIEW. PMA PANELISTS ALSO STRESSED THAT THEIR 301 ACTION WAS FULLY CONSISTENT WITH THE U.S. IPR OBJECTIVES IN THE GATT NEW ROUND. FINALLY, PMA PANELISTS NOTED THAT A NUMBER OF IMPORTANT NEW DRUGS ARE BEING DEVELOPED BY PMA MEMBERS NOW THAT WILL REQUIRE PATENT PROTECTION IF THEY ARE TO BE MARKETED IN BRAZIL.

UNCLASSIFIED

C15 (KF)  
 INCOMING  
 TELEGRAM

021142 DCA116

UNCLASSIFIED  
DEPARTMENT OF COMMERCE

INCOMING  
TELEGRAM

PAGE 02 OF 02

021142 DCA116

8. ON THE QUESTION OF WHAT THE PMA HOPED TO ACCOMPLISH THROUGH THE 301 ACTION, THE PMA PANELISTS RESPONDED THAT GIVEN THE HISTORY OF THIS ISSUE WITH BRAZIL, IT APPEARED THAT THE ONLY WAY TO "BRING THE GOB TO THE TABLE" SERIOUSLY WAS TO FILE A 301 ACTION. IN REGARD TO THE

CHANGES THAT THE PMA WOULD LIKE TO SEE IN BRAZIL'S IPR PROTECTION FOR PHARMACEUTICALS, THE FOLLOWING SPECIFIC POINTS WERE MENTIONED: (A) PRODUCT PATENT PROTECTION FOR NEW ACTIVE INGREDIENTS, (B) PRODUCT BY PROCESS PROTECTION, (C) REVERSAL OF THE BURDEN OF PROOF IN PATENT INFRINGEMENT CASES, (D) NO COMPULSORY LICENSING, (E) LONGER PATENT VALIDITIES, AND (F) BETTER PATENT ENFORCEMENT. IN RESPONSE TO A QUESTION, PMA PRESIDENT MOSSINGHOFF CLEARLY INDICATED THAT THE PMA WOULD NOT ACCEPT AN INTERIM OR COMPROMISE SOLUTION TO THE 301 COMPLAINT.

9. THE PMA REPRESENTATIVES NOTED THAT A NUMBER OF OTHER COUNTRIES ALSO HAVE INADEQUATE PATENT PROTECTION FOR PHARMACEUTICALS, BUT WOULD NOT SPECIFICALLY DISCUSS PLANS TO FILE OTHER 301 PETITIONS. IN RESPONSE TO A RELATED QUESTION THE PMA SAID THAT IT HAD BEEN IN CONTACT WITH ITS EUROPEAN COUNTERPART ORGANIZATIONS, WHICH SHARE PMA CONCERNS AND SUPPORT ITS ACTION AGAINST BRAZIL. THE PMA WAS NOT AWARE, HOWEVER, WHETHER THE EC WAS CONSIDERING TAKING SIMILAR ACTION AGAINST BRAZIL.

10. ATTENDANCE AND INTEREST

THE HEARINGS WERE RELATIVELY WELL ATTENDED. AUDIENCE LARGELY CONSISTED OF PMA COMPANIES AND OTHERS WITH A PMA CONNECTION (HEARINGS COINCIDED WITH PMA BOARD MEETING) AND USG REPRESENTATIVES. APPROXIMATELY SIX BRAZILIAN MEDIA REPRESENTATIVES WERE PRESENT. DIPLOMATS FROM BRAZIL, ARGENTINA, CHILE, AND THE FRG ATTENDED. IN ADDITION, THE EUROPEAN FEDERATION OF PHARMACEUTICAL INDUSTRY ASSOCIATIONS, ALL OF ITS INDIVIDUAL MEMBERS, AND SEVERAL EUROPEAN NATIONAL INDUSTRY GROUPS SUBMITTED WRITTEN PRESENTATIONS IN SUPPORT OF THE PMA POSITION.

11. COPIES OF WRITTEN SUBMISSIONS ARE BEING POUCHED TO EMBASSY BRASILIA. COPY OF HEARINGS TRANSCRIPT WILL BE SENT AS SOON AS IT IS MADE AVAILABLE. WHITEHEAD

BT

#2753

UNCLASSIFIED