R 281938Z MAY 87  
FM AMEMBASSY BRASILIA  
TO SECSTATE WASHDC 5744  

UNITED STATES DEPARTMENT OF STATE  
REVIEW AUTHORITY: NORMAN M. BOUTON  
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ACTION STR-17  

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EB-08 DINT-05 DOE-00 H-01 ARA-00 NSA-00 COM-00  
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USTR FOR JON ROSENBAUM  

E.O.12356: N/A  
TAGS: ETRD, EINV, BR  
SUBJECT: RECENT DEVELOPMENTS IN THE BRAZILIAN PHARMACEUTICALS SECTOR  

REF(S): (A) BRASILIA 05806; (B) RIO DE JANEIRO 02132  

THE FOLLOWING SAO PAULO 001361 SENT ACTION TO AMEMBASSY BRASILIA BEING REPEATED FOR YOUR INFO. QUOTE LIMITED OFFICIAL USE SAO PAULO 01361  

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1. ECONOFF RECENTLY SPOKE WITH VARIOUS INDIVIDUALS ACTIVE IN THE LOCAL PHARMACEUTICALS INDUSTRY/MARKET TO OBTAIN AN UPDATE ON THE SITUATION IN THAT SECTOR. PATENTS  

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2. THE THREATENED FILING OF A SECTION 301 PETITION BY
THE PMA HAS MOVED MEDIA REPORTS ON PHARMACEUTICALS FROM
THE BACK PAGES (IF SUCH REPORTS EXISTED AT ALL) TO PAGE
ONE OF THE MAJOR DAILIES HERE. MANY OF THESE ARTICLES
CHARACTERIZE THE 301 FILING THREAT AS THE OPENING OF A
"NEW FRONT" IN THE ONGOING SERIES OF TRADE DISPUTES
WITH THE U.S. EVERY GOB OFFICIAL QUOTED HAS EXPRESSED
OPPOSITION TO THE ADOPTION OF PHARMACEUTICALS PATENT
PROTECTION.

3. REASONS ADVANCED BY VARIOUS GOB OFFICIALS AS TO WHY
BRAZIL DOES NOT WANT TO RECOGNIZE PHARMACEUTICALS
PATENTS, HOWEVER, ARE VARIED AND NOT ENTIRELY COHERENT.
IN RECENT WEEKS, THE FOLLOWING OBJECTIONS TO DRUG
PATENTS HAVE BEEN RAISED: A) CITING UNNAMED "OFFICIAL"
SOURCES, THE DAILY "FOLHA DE TARDE" STATES THAT THE
PRIMARY REASON FOR GOB OPPOSITION IS THAT "THE EVENTUAL
PATENTING OF PHARMACEUTICAL PRODUCTS MAY BE EXTENDED TO
BIOTECHNOLOGY AS A WHOLE, WHERE BRAZIL'S TECHNOLOGICAL
BACKWARDNESS IN COMPARISON WITH THE U.S. IS TODAY MUCH
WIDER THAN IN THE TRADITIONAL PHARMACEUTICALS FIELD";
B) OFFICIALS AT THE NATIONAL INSTITUTE FOR INDUSTRIAL
PROPERTY PROTECTION HAVE BEEN QUOTED AS ARGUING THAT
THE TIME IS NOT RIPE FOR RECOGNITION OF PATENTS SINCE
LARGE, WELL CAPITALIZED NATIONAL PETROCHEMICAL
COMPANIES ARE ON THE VERGE OF MAKING INVESTMENTS IN THE
AREA, AND THESE PLANNED INITIATIVES WOULD BE PREEMPTED;
C) A SLIGHT VARIATION ON THE ABOVE THEME IS SEEN IN
VARIOUS NEWS REPORTS WHICH CITE THE "INFANT INDUSTRY"
STATUS OF BRAZIL'S LOCAL DRUG SECTOR; VARIOUS OFFICIALS
ARE QUOTED AS SAYING THAT THE INDUSTRY NEEDS THE
LIBERTY OF NON-RECOGNITION OF DRUG PATENTS IN ORDER TO

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MATURE; D) FREQUENTLY MENTIONED IS THE CLAIM THAT
MULTI-NATIONALS ALREADY CONTROL ABOUT 80 PERCENT OF THE
LOCAL DRUG MARKET (WE BELIEVE THIS FIGURE TO BE
INCORRECT; THE CORRECT FIGURE IS 72 PERCENT), SO IT
WOULD BE LUDICROUS TO CONCEDE TO THEM THE ADDITIONAL
ADVANTAGE OF PATENT PROTECTION; E) "FOLHA" RECENTLY
QUOTED UNNAMED OFFICIALS AS SAYING THAT SINCE
INVESTMENTS IN THE CHEMICALS SECTOR (WHICH PRESUMABLY
INCLUDES PHARMACEUTICALS) IS HIGH, THERE IS "NO NEED TO
CHANGE A WINNING TEAM." (COMMENT: THIS ARGUMENT, WHICH
WAS ALSO ADVANCED BY AN INPI OFFICIAL AT THE MARCH

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BILATERAL MEETING IN RIO DE JANEIRO, APPEARS TO CONTRADICT ARGUMENT "D" IF A "WINNING TEAM" IS INTERPRETED AS A STRONG LOCALLY-OWNED PHARMACEUTICALS INDUSTRY. END COMMENT).

4. A LIKELY EXPLANATION FOR THIS LACK OF COHERENCE IS THAT PHARMACEUTICALS PATENTS IS A NEW AND SOMEWHAT ARCANNE ISSUE TO THE MAJORITY OF GOB DECISION MAKERS. THIS ALSO HOLDS FOR THE LOCAL MEDIA. WE SUSPECT THAT MANY GOB OFFICIALS ARE FOR THE FIRST TIME FOCUSING ON THIS TOPIC AND FORMING THEIR OWN POSITIONS. NEWS REPORTS INDICATE THAT THERE HAVE BEEN TWO INTER-MINISTERIAL MEETINGS IN RECENT DAYS WHOSE TASK IS TO PREPARE THE GOB POSITION REGARDING PHARMACEUTICALS FOR REVIEW AND APPROVAL BY PRESIDENT SARNEY. AS A RESULT OF THESE MEETINGS, WE CAN EXPECT A MUCH MORE COHERENT PRESENTATION OF THE GOB POSITION ON JUNE 8.

5. MANY INDUSTRY LEADERS HERE ARE AWARE OF THE DRAFT
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ARTICLE RECENTLY PREPARED BY THE SUBCOMMITTEE ON
INDIVIDUAL RIGHTS OF THE CONSTITUENT ASSEMBLY REF B).
SEVERAL TOLD ECONOFF THAT THEY BELIEVE OFFICIALS OF THE
NATIONAL INSTITUTE FOR PROPERTY PROTECTION (INPI) HAVE
BEEN FOLLOWING THE MOVEMENT OF THE DRAFT ARTICLE
THROUGH THE SUBCOMMITTEE. THEY OPINE THAT, ALTHOUGH
THE CONSTITUTIONAL INITIATIVE IS WORTH PURSING, THE
SOLID OPPOSITION OF INPI, THE BRAZILIAN ASSOCIATION OF
CHEMICAL INDUSTRIES (ABIQUIM), AND OTHER ENTITIES MAKES
THE ADOPTION OF PATENT PROTECTION THROUGH THIS APPROACH
PROBLEMATIC. THEY FEEL THAT A POTENTIALLY MORE
FRUITFUL APPROACH WOULD BE FOR THE USG AND THE PMA TO
PAY MORE ATTENTION TO THE CARROT SIDE OF THE
CARROT-STICK DICHOTOMY THROUGH A STEPPED-UP EDUCATIONAL
EFFORT. IN PART, THIS COULD BE DONE BY RESPONDING TO
SOME OF THE MANY MISCONCEPTIONS CONCERNING A

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PHARMACEUTICALS PATENT REGIME THAT ARE PREVALENT HERE.
SOME OF THESE MISCONCEPTIONS, AND SUGGESTED RESPONSES
to them, will be the subject of Septel.

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6. ON FRIDAY, MAY 23, ALL PHARMACEUTICAL PRODUCTS
RECEIVED A 25.6 PERCENT PRICE INCREASE. THIS COMES ON
THE HEELS OF OTHER PRICE INCREASES GRANTED EARLIER IN
1987 THAT AMOUNTED TO A CUMULATIVE 111.7 PERCENT OR
143.7 PERCENT (DEPENDING ON THE TYPE OF DRUG) FROM

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MARCH 1, 1986 THROUGH APRIL 1, 1987. THUS, CUMULATIVE PRICE INCREASES SINCE MARCH 1 OF LAST YEAR NOW COME TO 140.3 PERCENT OR 180.5 PERCENT, WHICH COMPARE FAVORABLY WITH THE OFFICIAL INFLATION RATE FOR THE PERIOD OF APPROXIMATELY 107 PERCENT. PRICES ARE PRESENTLY STILL AT RELATIVELY HIGH LEVELS -- A DRUG THAT COST CRUZADOS 10 IN NOVEMBER OF LAST YEAR NOW COSTS AROUND CRUZADOS 28 -- AND MOST LABS ARE OPERATING AT A PROFIT. HOWEVER, INFLATION HAS BEEN RUNNING IN THE AREA OF 20 PERCENT PER MONTH (800 PERCENT ANNUALIZED) RECENTLY, SO THESE INCREASES ARE NOT AS GREAT IN REAL TERMS AS THEY MIGHT SEEM.

7. THE HISTORICAL PROBLEM WITH THE INDUSTRY HAS BEEN THAT THE GOB PRICING AUTHORITIES HAVE REFUSED TO ACCEPT THE OFFICIAL INFLATION INDEX IN SETTING PHARMACEUTICALS PRICES. PRICES TYPICALLY WERE SET LOWER, AND THE CUMULATIVE "LAGGING" EFFECT HAS RESULTED IN NET LOSSES FOR THE INDUSTRY AS A WHOLE FOR 5 OF THE LAST 6 YEARS. THIS PROBLEM COULD SOON BE RESOLVED WITH THE SIGNING OF A PROTOCOL ESTABLISHING A SO-CALLED "TRIGGER MECHANISM" THAT, WHEN INFLATION ATTAINED A CERTAIN LEVEL, WOULD AUTOMATICALLY RAISE DRUG PRICES BY A CORRESPONDING AMOUNT.

8. ALTHOUGH OPINIONS DIFFER WITHIN THE INDUSTRY AS TO WHETHER SUCH A TRIGGER PROTOCOL WILL EVENTUALLY BE SIGNED, ON BALANCE PROSPECTS ARE PRESENTLY CONSIDERED NEGATIVE. RUMOR HAS IT THAT SOME OTHER PENDING TRIGGER PROTOCOLS WITH OTHER INDUSTRIAL SECTORS HAVE BEEN CANCELLED. SEVERAL LEADING OFFICIALS OF THE GOB'S PRICING AUTHORITY REPORTEDLY RESIGNED THIS WEEK OVER DIFFERENCES WITH THE GOB'S FINANCE MINISTER. ALSO, THERE IS NOW TALK OF BASING ANY TRIGGER FORMULA ON ONLY THE HIGHEST INFLATION INDEX FOR A SPECIFIED PERIOD.
80 PERCENT OF THE CONSUMER PRICE INDEX. WITH BRAZIL'S VERY HIGH INFLATION, SUCH A FORMULA WOULD LEAD TO RAPID
DETERIORATION IN MARGINS.
9. THE INDUSTRY FEARS THAT CONSUMER RESISTANCE -- AND
RESENTMENT -- TO THE HUGE INCREASES AT THE DRUGSTORE
THAT HAVE ALREADY BEEN GRANTED MIGHT COMPEL THE GOB TO
REVERT TO ITS OLD PRICE DEPRESSING POLICIES. THERE ARE
SIGNS SUGGESTING THAT SUCH A PUBLIC REACTION MAY
ALREADY BE OCCURRING. THE MAY 19 EDITION OF THE DAILY
"O ESTADO DE SAO PAULO" CARRIED AN ARTICLE HEADLINED
"MEDICINES, ONLY FOR THE PRIVILEGED." THROUGH
INTERVIEWS WITH MANAGERS OF PHARMACIES IN POORER SAO
PAULO NEIGHBORHOODS, THE AUTHOR MAKES THE POINT THAT IN
THE WAKE OF THE LATEST PRICE INCREASES MANY WORKING
CLASS INDIVIDUALS CAN NO LONGER AFFORD ESSENTIAL
MEDICINES.
10. ONE EXAMPLE CITED IN THIS ARTICLE SHOULD SUFFICE TO
GRASP ITS TONE: "IN SANTO AMARO, AT THE LARGO 13 DE
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MAIO, A SPOT THROUGH WHICH A LARGE PART OF SAO PAULO'S
LOWER INCOME POPULATION PASSES, THE NOSSA SENHORA
APARECIDA DRUGSTORE IS ALREADY FEELING THE EFFECTS OF
THE PRICE ADJUSTMENTS. GIROTTO, THE MANAGER OF THE
PHARMACY, REPORTS THAT HIS SALES HAVE FALLEN 30 PERCENT
IN VOLUME IN THE LAST MONTH. 'THE MIDDLE AND UPPER
MIDDLE LEVEL CLASSES CONTINUE TO BUY, BUT THE LOWER
INCOME GROUPS HAVE FEW ALTERNATIVES', HE SAID." SUCH
ARTICLES HAVE AN UDDENTIABLE EMOTIONAL IMPACT WHICH
COULD AFFECT FUTURE GOB PRICING DECISIONS.
11. PFIZER DIRECTOR RICHARD DOBE REPORTS THAT HIS
COMPANY HAS YET TO FEEL ANY FALL-OFF IN DEMAND. IN ANY
EVENT, HOWEVER, DUE TO THE NATURE OF THE MEDICINES
DISTRIBUTION SYSTEM HERE A DROP IN DEMAND AT THE RETAIL
LEVEL WOULD NOT BE FELT AT THE MANUFACTURER FOR AT
LEAST 2 MONTHS.

NEW DRUG/PRESENTATION REGISTRATIONS
12. THE GOB’S TRADITIONAL DRUG/PRESENTATION
REGISTRATION ORGAN, THE MEDICALS DIRECTORATE (DIMED),
is reportedly in the process of reorganization under
new leadership. Industry officials report that the new
DIMED leadership is much more cooperative and is trying
to speed up new product registrations. Letters were
recently sent to all drug companies asking them to
prioritize their products awaiting registration.
Another example of the new attitude at DIMED is that
the long-standing requirement that all drugs be
re-registered annually was waived this year in order to
conserve DIMED staff time for more pressing priorities.
13. THE RECENTLY CREATED NATIONAL HEALTH COUNCIL (CNS),

14. THE SHORTAGES OF MANY DRUGS THAT HAVE PLAUGED
BRAZIL SINCE THE SECOND QUARTER OF 1986 CONTINUE,
ALBUT AT A SLIGHTLY LESS SEVERE LEVEL THAN THAT WHICH
OCCURRED IN THE FOURTH QUARTER OF 1986. THE PRESIDENT
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TAGS: ETRD, EINV, BR
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OF THE SAO PAULO STATE PHARMACEUTICALS PRODUCTS
WHOLESALE ASSOCIATION TOLD ECONOFF THAT ONLY ABOUT 20
PERCENT OF THE DRUGS THAT DISAPPEARED DURING THE LATTER

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HALF OF 1986 HAVE NOW RETURNED TO THE MARKET. THE
BIGGEST REASON FOR THESE CONTINUING SHORTAGES, HE
OPINES, IS THE TIGHT CONTROL OF IMPORT LICENSES FOR RAW
MATERIALS AND PACKAGING MAINTAINED BY THE FOREIGN TRADE
OFFICE OF THE BANK OF BRAZIL (CACEX). SUCH TIGHT
CONTROLS HAVE BEEN PROMPTED BY BRAZIL'S EXTERNAL
BALANCE OF PAYMENTS CRISIS WHICH SURFACED IN LATE
1986. IMPORT RESTRICTIONS ARE PARTICULARLY Crippling,
NOTES FAUSTO SPINA, PRESIDENT OF THE SAO PAULO
PHARMACEUTICALS PRODUCTS ASSOCIATION, DUE TO THE FACT
THAT "BRAZIL HAS TO IMPORT 70 PERCENT OF THE RAW
MATERIALS INDISPENSABLE FOR THE PRODUCTION OF
MEDICINES."

15. PFIZER'S DOBE REPORTS THAT HIS FIRM'S QUOTAS FOR
IMPORTS OF RAW MATERIALS HAVE BEEN REDUCED BY 20
PERCENT FROM ITS 1986 QUOTA, AND THAT SALES ARE STILL
LIMITED BY CAPACITY TO PRODUCE. FRANZ SCHONING,
MANAGER OF BAYER'S PHARMACEUTICALS DIVISION, CLAIMS
THAT HIS COMPANY'S IMPORT QUOTAS "ARE FAR BELOW THE
NEEDS OF THE MARKET." THIS YEAR BAYER WILL BE ALLOWED
TO IMPORT THE SAME QUANTITY OF RAW MATERIALS AS 1985.
SINCE BAYER'S PHARMACEUTICALS SALES EXPANDED BY 60
PERCENT IN 1986, SCHONING REASONS THAT 1987'S IMPORT
QUOTA WILL BE SUFFICIENT FOR ONLY ABOUT HALF OF BAYER'S
PRODUCTION NEEDS.

16. SHORTAGES OF PACKAGING MATERIALS SUCH AS SMALL
BOTTLES AND ALUMINUM TUBES ARE PERSISTING FOR THE SAME
REASON -- IMPORT RESTRICTIONS. BRAZIL IS CURRENTLY
IMPORTING THESE ITEMS FROM ARGENTINA, MEXICO, AND
WESTERN EUROPE, BUT IN INSUFFICIENT QUANTITIES.
OTHER ISSUES

17. THE ANGLO-U.S. PHARMACEUTICAL MANUFACTURERS
ASSOCIATION (CIFAB) HERE RECENTLY HIRED A LOBBYIST TO
WORK ON CONSTITUTIONAL ISSUES WITH THE FEDERAL CONGRESS
IN BRASILIA. CIFAB IS NOT PUBLICIZING THIS ACTION
OWING TO AN EARLIER PLEDGE MADE TO ABIFARMA THAT IT
WOULD KEEP INDEPENDENT LOBBYING EFFORTS TO A MINIMUM.
PRIORITY ITEMS ARE COMBATTING ANY WORDING IN THE NEW
CONSTITUTION THAT MANDATES NATIONALIZATION OF THE
PHARMACEUTICALS SECTOR AND/OR MARKET RESERVE, AND
WORKING FOR RECOGNITION OF PHARMACEUTICAL PATENTS.