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USTR FOR CHRISTINA LUND AND JON ROSENBAUM

USDOC FOR 4330/IEP/WH/OSA/PETER FIELD

E.O. 12356: N/A  
TAGS: ETRD, EINV, BR, US  
SUBJECT: BRAZILIAN PHARMACEUTICALS: LATEST GOB THINKING  
ON PATENTS

1. INTRODUCTION AND SUMMARY. IN THE EXPECTATION THAT SUCH INFORMATION MAY BE USEFUL TO USG OFFICIALS IN THE UPCOMING WASHINGTON PHARMACEUTICALS ROUND, CONSULATE HAS COMPILED A LIST OF SOME OF THE MORE PROMINENT ARGUMENTS (TOGETHER WITH POSSIBLE REBUTTALS) AGAINST PHARMACEUTICALS PATENTS THAT WE HAVE EITHER READ OR HEARD FROM GOB OFFICIALS IN THE LAST TWO YEARS. INFORMAL TRANSLATIONS OF TWO RECENT NEWSPAPER ARTICLES THAT PURPORT TO OUTLINE RECENT GOB THINKING ON THE PATENTS QUESTION ARE ALSO INCLUDED, TOGETHER WITH CONSULATE'S

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COMMENTS. END INTRODUCTION AND SUMMARY.

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UNITED STATES DEPARTMENT OF STATE  
REVIEW AUTHORITY: NORMAN M. BOUTON  
DATE/CASE ID: 3 JAN 2002 200000143

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ARGUMENT A: BRAZIL HAS THE RIGHT TO ADOPT PATENTS AT THE APPROPRIATE TIME JUST LIKE EVERY OTHER COUNTRY

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2. AT THIS POINT IN BRAZIL'S HISTORY, THE COUNTRY'S LOCALLY OWNED PHARMACEUTICALS INDUSTRY IS SMALL AND GENERALLY UNDERDEVELOPED. HISTORY SHOWS THAT THE DEVELOPED COUNTRIES, E.G., JAPAN AND WEST GERMANY, ONLY EXTENDED PATENT PROTECTION WHEN THEIR NATIVE DRUG INDUSTRIES WERE STRONG AND HAD CAPTURED A SIGNIFICANT SHARE OF THE DOMESTIC MARKET. IT IS PERFECTLY REASONABLE FOR BRAZIL TO ADOPT THE SAME APPROACH AS THESE COUNTRIES: WHEN BRAZILIAN COMPANIES ACHIEVE A CERTAIN LEVEL OF DEVELOPMENT, THEN BRAZIL WILL ADOPT PATENT PROTECTION. APROPOS OF THIS, RELEVANT INTERNATIONAL TREATIES (SUCH AS THE PARIS CONVENTION) SPECIFY THAT RECOGNITION OF PATENTS IN PHARMACEUTICALS IS A MATTER FOR EACH NATION TO DECIDE FOR ITSELF.

3. COMMENTS: FIRST, THE HISTORY LESSON THAT IS SUPPOSEDLY SELF-EVIDENT IS DUBIOUS AT BEST. ONE OF THE MORE GLARING PROBLEMS WITH THIS ARGUMENT IS THAT THE BIGGEST, MOST DEVELOPED PHARMACEUTICAL INDUSTRY OF ALL, THAT OF THE UNITED STATES, GREW AND PROSPERED UNDER A REGIME OF PATENT RECOGNITION.

4. IN ADDITION, THE ARGUMENT IMPLIES THAT THE HISTORICAL DEVELOPMENT OF BRAZIL'S NATIVE DRUG INDUSTRY IS A LINEAR, INEVITABLE THING. HOWEVER, THE EVIDENCE SHOWS THAT, AS MEASURED IN TERMS OF MARKET SHARE, THE LOCAL INDUSTRY HAS ACTUALLY REGRESSED. IN THE EARLY 1960'S THE LOCAL COMPANIES ACTUALLY HAD A CONSIDERABLY LARGER SHARE (ABOUT

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40 PERCENT) OF THE MARKET THAN THEY HAVE TODAY (LESS THAN 20 PERCENT). THE WHOLE PHARMACEUTICALS SECTOR IS STAGNANT OWING TO THE FAILURE TO ATTRACT SIGNIFICANT NEW INVESTMENTS IN THE LAST 10 YEARS. IF LACK OF PATENT PROTECTION IS SUCH A DEVELOPMENT-STIMULATING CONDITION, THEN WHY, AFTER 18 YEARS OF THIS STIMULATION, HAS THE BRAZILIAN INDUSTRY ACTUALLY LOST GROUND TO THE MNC'S? WE THINK THAT DEVELOPMENT (OR LACK THEREOF) IN THE FIELD OF MEDICINES IS NEITHER NECESSARILY LINEAR NOR INEVITABLE, BUT RATHER IS HEAVILY INFLUENCED BY GOVERNMENT POLICIES. IN THIS REGARD, GOB POLICIES SPEAK FOR THEMSELVES. WE

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THINK THAT IN VIEW OF THE HISTORICAL RECORD THE NEW REPUBLIC WOULD BE WELL ADVISED TO REVIEW PAST GOB POLICIES THAT HAVE BEEN ANYTHING BUT WINNING. ONE OF THESE, OF COURSE, IS THE REFUSAL TO EXTEND PATENT PROTECTION TO PHARMACEUTICALS.

5. AS FAR AS INTERNATIONAL OBLIGATIONS GO, THE GOB POSITION IS IMPECCABLY CORRECT. STANDING ON LEGAL POINTS, HOWEVER, HARDLY ADDRESSES THE REAL ISSUE HERE. FOR US, WE THINK IT SHOULD BE THE FOLLOWING: WHAT POLICY IS IT THAT IS MOST EFFECTIVE AT IMPROVING THE MEDICINES SUPPLY SYSTEM? IF THE GOB IS REALLY HAPPY WITH THE CURRENT SYSTEM, THEN THERE IS NO REASON TO CHANGE POLICIES. IF IT ISN'T, THEN WHY BE SO INFLEXIBLE? WHY NOT EXPLORE SOME ALTERNATIVES?

ARGUMENT B: WHY CHANGE A WINNING TEAM?  
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4. INVESTMENT IN THE PHARMACEUTICALS SECTOR HAS BEEN VERY HIGH IN THE PAST TWO DECADES. THIS IS A VOTE OF CONFIDENCE IN THE GOB'S POLICIES IN THE SECTOR. WHY CHANGE A WINNING TEAM?

5. COMMENTS: WITH ALL DUE RESPECT, ANYONE WHO MAKES THIS

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USDOC FOR 4330/IEP/WH/OSA/PETER FIELD

E.O. 12356: N/A

TAGS: ETRD, EINV, BR, US

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ARGUMENT IS NOT WELL INFORMED ABOUT THE BRAZILIAN PHARMACEUTICALS INDUSTRY. ASK ANY GOB OFFICIAL WITH DIRECT EXPERIENCE IN THE HEALTH SECTOR AND HE WILL TELL YOU THAT THE NEW REPUBLIC IS WORKING VERY HARD TO CORRECT SERIOUS DEFICIENCIES IN BRAZIL'S TRADITIONAL HEALTH CARE SYSTEM, INCLUDING MEDICINES DEVELOPMENT/PRODUCTION.

6. THE PRESENT SITUATION IN THE PHARMACEUTICALS SECTOR IN PARTICULAR IS ANYTHING BUT A "WINNING TEAM". GOB ORGANS WITH RESPONSIBILITIES IN MEDICINES SUPPLY, SUCH AS DIMED, SUFFER FROM SERIOUS SHORTAGES OF BOTH HUMAN AND FINANCIAL  
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RESOURCES. IN PAST CONSULTATIONS, GOB OFFICIALS NOT DIRECTLY ASSOCIATED WITH THE HEALTH CARE SECTOR HAVE CITED HUGE INVESTMENTS IN THE "CHEMICALS" OR "FINE CHEMICALS" SECTOR. THESE NUMBERS MUST BE MEASURING SOMETHING, BUT THEY MOST ASSUREDLY ARE NOT MEASURING INVESTMENTS IN THE PRODUCTION OF HUMAN PRESCRIPTION MEDICINES. BY ALL ACCOUNTS THE U.S. IS THE BIGGEST PLAYER IN THE BRAZILIAN ETHICAL DRUGS MARKET. THE PRESIDENT OF THE LOCAL U.S. DRUG MANUFACTURERS ASSOCIATION REPORTS THAT INVESTMENTS IN THE PAST 5 YEARS BY U.S. FIRMS HAS BEEN "PRACTICALLY ZERO." THE ONLY MULTINATIONAL THAT HAS MADE SIGNIFICANT INVESTMENTS RECENTLY HAS BEEN RHODIA, WITH CAPITAL OUTLAYS OF ABOUT DOLS 20 MILLION, AND THIS IS MOSTLY FOR PRODUCTION DESTINED FOR EXPORT. DUE IN PART TO THIS LACK OF INVESTMENT, THE COUNTRY CONTINUES TO BE HIGHLY DEPENDENT ON IMPORTED RAW MATERIALS.

7. EVEN WITHIN THE PHARMACEUTICALS SECTOR, THERE HAS BEEN A FLIGHT AWAY FROM PRESCRIPTION LINES AND TOWARD SUCH

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BETTER MONEY EARNERS AS COUGH DROPS, MOUTHWASH, DANDRUFF SHAMPOO, OVER THE COUNTER COLD MEDICINES, AND OTHER SUCH PARAPHERNALIA THAT COULD ONLY BE VERY LOOSELY DESCRIBED AS MEDICINES. IN GENERAL, WHAT LITTLE INVESTMENT THAT HAS OCCURRED HAS BEEN CONCENTRATED IN THESE PRODUCT LINES.

ARGUMENT C: PHARMACEUTICALS IS A STRATEGIC INDUSTRY

8. NON-RECOGNITION OF PATENTS FOR DRUGS IS APPROPRIATE BECAUSE MEDICINES IS A STRATEGIC INDUSTRY. AS SUCH, THE GOVERNMENT CANNOT CEDE A MONOPOLY TO A FOREIGN ENTITY, SINCE DOING SO COULD LEAVE THE NATION VULNERABLE TO EMBARGOS OR OTHER SUPPLY DISRUPTIONS THAT WOULD BE

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DETRIMENTAL TO THE BRAZILIAN POPULATION.

9. COMMENTS: THIS ARGUMENT PAINTS A SCARY SCENARIO: IF THE GOB ADOPTED A PATENT REGIME FOR DRUGS, DUE TO ANY NUMBER OF SEEMINGLY UNRELATED EXTERNAL FACTORS A WIDE VARIETY OF COMMONLY USED AND IMPORTANT -- PERHAPS EVEN LIFE-SUSTAINING -- MEDICINES COULD SUDDENLY BECOME UNAVAILABLE. THE RESULT WOULD BE WIDESPREAD SUFFERING.

10. THE ONLY PROXEM WITH THIS SCENARIO IS THAT IT IS NOT A SCENARIO; IT IS THE REALITY OF BRAZIL THROUGHOUT THE LATTER HALF OF 1986 AND, TO A SOMEWHAT LESSER EXTENT, TODAY. WHEN DEMAND TOOK OFF IN MARCH OF 1986, BRAZIL'S AGING PHARMACEUTICALS PHYSICAL PLANT PROVED UNABLE TO KEEP UP. ACCORDING TO PEDRO ZIDO, PRESIDENT OF THE SAO PAULO STATE PHARMACEUTICAL PRODUCTS WHOLESALERS ASSOCIATION, ONLY ABOUT 20 PERCENT OF THE WIDE VARIETY OF MEDICINES THAT DISAPPEARED DURING THE CRUZADO PLAN HAVE NOW RETURNED TO NORMAL SUPPLY. THE PROBLEM, ACCORDING TO FAUSTO SPINA, PRESIDENT OF THE SAO PAULO PHARMACEUTICAL PRODUCTS ASSOCIATION, IS THAT BRAZIL HAS TO IMPORT 70 PERCENT OF THE RAW MATERIALS INDISPENSABLE FOR THE PRODUCTION OF MEDICINES. BRAZIL'S CURRENT FINANCIAL SITUATION HAS LED TO A TIGHTENING OF IMPORT QUOTAS FOR THESE RAW MATERIALS AS WELL AS PACKAGING.

11. THE POINT IS THAT BRAZIL DIDN'T GO TO WAR WITH ANYONE, AND DIDN'T ADOPT PATENT PROTECTION, YET THE SCARY SCENARIO OF WIDESPREAD MEDICINES SHORTAGES HAS BECOME A

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REALITY ANYWAY. THIS SITUATION IS "MADE IN BRAZIL",  
I.E., IT HAS COME ABOUT SOLELY AS A RESULT OF THE GOB'S  
IT AND CURRENT POLICIES. BRUNO CARLOS DE ALMEIDA  
CUNHA, PROFESSOR OF PHARMACEUTICAL SCIENCES AT THE  
UNIVERSITY OF SAO PAULO, WAS QUOTED RECENTLY AS SAYING  
THAT THE CURRENT SHORTAGES OF MEDICINES SHOWS THAT THE

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USTR FOR CHRISTINA LUND AND JON ROSENBAUM

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EXCESSIVE DEPENDENCE ON IMPORTS MAKES BRAZIL EXTREMELY  
VULNERABLE. WE AGREE. WHY NOT ASK THE FOLLOWING  
QUESTION: HOW CAN THE GOB ENCOURAGE THE WORLD'S  
INNOVATORS IN THE MEDICINES FIELD TO INCREASE BRAZIL'S  
SELF-SUFFICIENCY? ONE OBVIOUS ELEMENT IN SUCH A STRATEGY  
WOULD BE TO RECOGNIZE THE VALUE OF INNOVATION THROUGH  
PATENT PROTECTION.

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ARGUMENT D: BIOTECHNOLOGY

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 12. CITING UNNAMED "OFFICIAL" SOURCES, THE SAO PAULO DAILY "FOLHA DE TARDE" STATES THAT THE PRIMARY REASON FOR ~~LIMITED OFFICIAL USE~~

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GOB OPPOSITION TO PHARMACEUTICALS PATENTS 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."

13. COMMENTS: THE LOGIC OF THIS ARGUMENT IS ELUSIVE. PART OF THE "BACKWARDNESS" ALLUDED TO IS THE RESULT OF THE CURRENT BRAZILIAN REGIME OF LACK OF PHARMACEUTICALS PATENT PROTECTION. THE U.S. IS THE ACKNOWLEDGED WORLD LEADER IN THE EMERGING FIELD OF BIOTECHNOLOGY. IMAGINE THE EFFECT ON THE U.S. INDUSTRY IF AN AMERICAN COURT RULED THAT BIOTECHNOLOGY-DEVELOPED PRODUCTS ARE NOT PATENTABLE. IN ALL LIKELIHOOD VIRTUALLY EVERY GENETIC ENGINEERING FIRM WOULD GO OUT OF BUSINESS, AND THE BIOTECHNOLOGY FIELD WOULD STAGNATE. THE POINT IS THAT THERE IS A CAUSAL LINK BETWEEN THE FACT THE U.S. IS NUMBER ONE IN BIOTECHNOLOGY AND THE FACT THAT THE U.S. RECOGNIZES BIOTECHNOLOGY PATENTS. LET US IMAGINE SOME BRILLIANT BRAZILIAN SCIENTIST THAT DISCOVERS THROUGH BIOTECHNOLOGY THE CURE FOR, SAY, AIDS. IF HE WANTED TO BE COMPENSATED FOR HIS EFFORTS (AND WHO DOESN'T?), HIS BEST BET WOULD BE TO TRAVEL TO THE U.S. OR EUROPE, PATENT THE MEDICINE, AND SELL IT TO SOME LARGE DRUG FIRM THERE. LACK OF PATENT PROTECTION ENCOURAGES THIS TYPE OF "BRAIN DRAIN."

14. THE ABOVE SCENARIO IS NOT SO FAR FETCHED. IN FACT, THERE IS A BRAZILIAN CITIZEN WHO HAS RECENTLY DEVELOPED A NEW TYPE OF ARTIFICIAL SKIN. IN A RECENT INTERVIEW, HE STATED THAT HE IS SEEKING PATENTS ON THE PRODUCT IN EUROPE AND THE U.S., AND IS INTERESTED IN WORKING OUT ~~LIMITED OFFICIAL USE~~

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LICENSING AGREEMENTS WITH DRUG FIRMS IN THOSE COUNTRIES.  
HE IS DOING WHAT ANYBODY WOULD DO.

ARGUMENT E: ADOPTION OF PATENTS WILL WIPE OUT THE LOCAL  
INDUSTRY

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15. COMMENTS: THIS IS ONE OF THE BIGGEST MISCONCEPTIONS  
AROUND. FIRST, NATIONAL FIRMS IN GENERAL ARE NOT  
SURVIVING FROM COPYING OF PATENTED DRUGS. WE ESTIMATE  
THAT LESS THAN 10 PERCENT OF THE NATIONAL FIRMS' CURRENT  
TOTAL SALES ARE OBTAINED FROM SALES OF ON-PATENT DRUGS.  
BESIDES, TAKE A LOOK AT THE U.S., JAPAN, OR WEST  
GERMANY. ALL OF THESE COUNTRIES HAVE A STRICTLY ENFORCED  
SYSTEM OF PATENT PROTECTION, AND ALL HAVE HUGE, DYNAMIC  
INDUSTRIES THAT DO NOTHING BUT MANUFACTURE OFF-PATENT  
"GENERIC" DRUGS. OF THE TOTAL THERAPY REGIME, A VERY  
SMALL PERCENTAGE IS CURRENTLY ON-PATENT. WE DON'T THINK  
THAT EXTENSION OF PATENT PROTECTION TO MEDICINES WILL BY  
ITSELF PUT A SINGLE NATIONAL COMPANY OUT OF BUSINESS.

16. GENERAL COMMENTS: GOB OFFICIALS IN THE HEALTH SECTOR  
ARE PROUD OF THE FACT THAT THE NEWOEFC HAS AFFORDED  
A VERY HIGH PRIORITY TO IMPROVING BRAZIL'S HEALTH CARE  
SYSTEM. AN IMPROVEMENT ON PAST PERFORMANCE WILL REQUIRE  
SUBSTANTIAL INCREASES IN FINANCIAL RESOURCES, HUMAN  
RESOURCES AND, PERHAPS MOST IMPORTANTLY, INNOVATIVE  
THINKING. STICKING TO THE OLD IDEAS WILL PROBABLY YIELD  
THE OLD RESULTS. IN THE DRIVE TO IMPROVE BRAZIL'S HEALTH  
CARE SYSTEM, NOTHING -- INCLUDING THE CURRENT PATENT  
REGIME -- SHOULD BE SACROSANCT.

17. THE U.S. IS VERY PROUD OF THE QUALITY OF ITS HEALTH  
CARE SYSTEM; THIS QUALITY IS RECOGNIZED WORLDWIDE. THE  
U.S. HEALTH CARE SYSTEM IS THE RESULT OF CERTAIN  
POLICIES AND PRIORITIES. WE'VE BEEN WELL SERVED, AND THE

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WORLD HAS BEEN WELL SERVED, BY THE PRODUCTS THAT HAVE  
COME OUT OF THAT SYSTEM. WE HAVE A WINNING TEAM, AND WE  
FEEL THAT PATENT PROTECTION HAS BEEN CRUCIAL TO OUR  
SUCCESS. WE URGE THE GOB TO HAVE AN OPEN MIND TOWARD  
THIS ISSUE, WHICH WE FEEL IS IN OUR MUTUAL INTEREST. END  
GENERAL COMMENTS.

18. TWO ARTICLES IN THE SAO PAULO BUSINESS DAILY "GAZETA  
MERCANTIL" OF MAY 22 OUTLINE WHAT APPEARS TO BE THE MOST  
RECENT THINKING WITHIN THE GOB TOWARD PHARMACEUTICALS  
PATENT PROTECTION AND THE JUNE 8 WASHINGTON

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CONSULTATIONS. INCLUDED HEREWITH IS CONSULATE'S INFORMAL  
TRANSLATION OF BOTH ARTICLES.

19. (BEGIN TRANSLATION OF FIRST ARTICLE)

(TITLE) PHARMACEUTICAL PATENTS -- BRAZIL-U.S. MEETING  
WILL ALSO DISCUSS PRICES AND INVESTMENTS

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ALMOST CERTAIN THAT BRAZIL WILL NOT MODIFY ITS INDUSTRIAL CODE TO PROTECT PHARMACEUTICALS PATENTS, THE U.S. GOVERNMENT IS EXPECTED TO PUT AN EMPHASIS DURING THE FORTHCOMING BILATERAL CONSULTATIONS ON JUNE 8 IN WASHINGTON ON THREE OTHER POINTS CONSIDERED FUNDAMENTAL: WHAT WILL BE THE PRICING POLICY FOR MEDICINES, FOR LAUNCHING NEW PRODUCTS, AND FOR FOREIGN INVESTMENTS IN BRAZIL.

WITH REFERENCE SPECIFICALLY TO PATENTS, UNDER PRESSURE FROM THE PHARMACEUTICAL MANUFACTURERS ASSOCIATION (PMA) TO WHICH ARE ASSOCIATED 18 COMPANIES THAT ARE INSTALLED HERE, WASHINGTON SHOULD PLACE ON THE TABLE SOME SUGGESTIONS THAT, WITHOUT QUESTIONING A CHANGE IN THE LAW, COULD SATISFY THE MANUFACTURERS' INTERESTS.

A WELL INFORMED SOURCE TOLD THIS NEWSPAPER THAT A WAY OUT WOULD BE FOR THE BRAZILIAN GOVERNMENT TO GUARANTEE THAT ANY NEW PRODUCT OF A NATIONAL LABORATORY SHOULD BE APPROVED BY THE HEALTH AUTHORITIES BEFORE IT IS PRODUCED IN COMMERCIAL SCALE, AS A WAY OF ASSURING PATENT PROTECTION.

FOREIGN LABORATORIES, WHICH ALLEGE EXCESSIVE EXPENSES IN THE DEVELOPMENT OF A NEW PRODUCT WITHOUT AN ADEQUATE  
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REMUNERATION IN THE MARKET, BECAUSE A NATIONAL COMPANY BY COPYING WITHOUT ANY INVESTMENT CAN SELL FOR LOWER PRICES COMPATIBLE WITH ITS LOWER PRODUCTION COSTS. "IRONICALLY, IT CAN EVEN HAPPEN THAT THE NATIONAL COMPANY THROWS OUT OF THE MARKET THE FOREIGN ONE, WHICH IN FACT WAS THE ONE THAT DID THE RESEARCH AND DEVELOPED THE MEDICINE," COMMENTS THE SOURCE.

A LACK OF PATENT PROTECTION IS A WAY, ACCORDING TO THIS SOURCE, OF ALLOWING THE EXISTENCE OF NATIONAL LABORATORIES WHICH TODAY ACCOUNT FOR ABOUT 20 PERCENT OF THE MARKET, BUT WERE RESPONSIBLE FOR OVER 40 PERCENT ABOUT 15 YEARS AGO. SLOWLY, DUE TO FINANCIAL DIFFICULTIES, THE NATIONAL FIRMS, WERE BOUGHT BY MULTINATIONALS.

THE BRAZILIAN GOVERNMENT, MEANWHILE, IS NOT READY TO MAKE

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CONCESSIONS TO THE U.S. BECAUSE IT FEELS BACKED BY THE PARIS CONVENTION, WHICH STATES THAT TO PROTECT PATENTS IS A NATIONAL DECISION. BRAZIL CONSIDERS THE PHARMACEUTICAL INDUSTRY OF VITAL (STRATEGIC) IMPORTANCE AND WANTS TO ALLOW THE NATIONAL COMPANIES FREE ACCESS TO INPUTS AND INTERMEDIATE AND FINAL PRODUCTS. THE CLIMATE TODAY, AMONG THE MULTINATIONAL LABORATORIES, PARTICULARLY THE U.S., IS OF AN AVERSION TO MARKET IN BRAZIL NEW PRODUCTS WHICH IN OTHER COUNTRIES ENJOY PROTECTION.

SOME OF THESE ITEMS ARE DIFFICULT TO BE COPIED AND, CERTAINLY, COMMENTS THE SOURCE, IT WOULD NOT BE INTERESTING TO THE NATIONAL LABORATORIES TO MANUFACTURE THEM BECAUSE THE INVESTMENT REQUIRED TO SET UP A UNIT FOR THIS PURPOSE WOULD NOT GUARANTEE ANY RETURN.

THE LACK OF AN ECONOMY OF SCALE FOR CERTAIN FINE CHEMICAL

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AMEMBASSY BRASILIA IMMEDIATE  
USDOC WASHDC  
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E.O. 12356: N/A  
TAGS: ETRD, EINV, BR, US  
SUBJECT: BRAZILIAN PHARMACEUTICALS: LATEST GOB THINKING

PRODUCTS JUSTIFIES AN EXPECTATION BY WASHINGTON THAT BRAZIL WILL NOT ADOPT A MARKET RESERVE IN THIS AREA. THE BRAZILIAN GOVERNMENT IS THINKING OF INCREASING THE BRAZILIAN PARTICIPATION IN THE MANUFACTURE OF THESE PRODUCTS -- 22 PERCENT OF THE RAW MATERIALS TERMED AS FINE CHEMICALS ARE PRODUCED IN BRAZIL -- BUT IS NOT PLANNING TO IMPOSE A RESERVE BECAUSE THE ECONOMY OF SCALE IN THE PHARMACEUTICAL SECTOR IS EXTREMELY IMPORTANT DUE TO HIGH COSTS FOR RESEARCH, ARGUES THE SOURCE.

REGARDING NEW PRODUCTS -- ANOTHER ITEM FOR DISCUSSION ON

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JUNE 8 -- THE U.S. COMPLAINS THAT IT IS TAKING AT LEAST 2 YEARS TO REGISTER A PROJECT WITH THE INDUSTRIAL DEVELOPMENT COUNCIL (CDI). (COMMENT: THIS SHOULD READ DIMED. END COMMENT).

TO CIRCUMVENT THE DECLINE OF PROFITS, MANY LABORATORIES RESORTED TO METHODS WHICH INVOLVED THE LAUNCHING OF NEW PRODUCTS, BUT THIS PROCEDURE IS STUMBLING DUE TO THE DELAY IN HAVING PETITIONS APPROVED, COMPLAIN THE SECTOR REPRESENTATIVES.

THE WASHINGTON MEETING WILL BE ATTENDED BY MEMBERS OF BOTH GOVERNMENTS AND IT IS NOT INTERESTING, AND AN AGGRAVATION OF THE CONFLICT IS NOT IN U.S. INTERESTS, PARTICULARLY AT THIS TIME WHEN A NEW CONSTITUTION IS BEING DRAFTED IN BRAZIL. THEREFORE, THE PMA'S CLAIMS WILL BE PLACED ON THE TABLE, BUT SHOULD BE TREATED KEEPING IN VIEW THAT INTERESTS BETWEEN THE TWO COUNTRIES ARE ABOVE THE COMPLAINTS OF THE PRIVATE SECTOR. (END TRANSLATION OF FIRST ARTICLE)

20. (BEGIN TRANSLATION OF SECOND ARTICLE)

(TITLE) THE PRESIDENT WILL DECIDE  
IT WILL BE UP TO THE PRESIDENT TO DECIDE WHICH ATTITUDE BRAZIL WILL ADOPT IN RESPONSE TO U.S. REQUESTS TO CHANGE

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SOME ITEMS OF THE INDUSTRIAL PROPERTY CODE OF 1971, TO GUARANTEE A MORE SIGNIFICANT PROTECTION OF INDUSTRIAL PATENTS, PARTICULARLY OF PHARMACEUTICAL PRODUCTS DEVELOPED IN BRAZIL BY FOREIGN COMPANIES. THIS INFORMATION WAS GIVEN YESTERDAY BY A SOURCE AT THE MINSITRY OF COMMERCE AND INDUSTRY (MIC), WHO BELIEVES THAT THE PROBLEM IS MORE POLITICAL THAN TECHNICAL.

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THE MINISTRY OF SCIENCE AND TECHNOLOGY (MCT), WHICH MONITORS THE LAUNCHING OF NEW PHARMACEUTICAL PRODUCTS IN THE MARKET, FEELS THAT THE BRAZILIAN GOVERNMENT'S POSITION DURING THE MEETING IN WASHINGTON ON JUNE 8 WILL BE TO LISTEN TO WHAT THE U.S. HAS TO SAY REGARDING INDUSTRIAL PATENTS. THE MIC AS WELL AS THE MCT DISCARD THE POSSIBILITY OF BRAZIL MAKING CHANGES DIRECTLY IN THE LEGISLATION THAT REGULATES THE INDUSTRIAL REGISTRATION OF PATENTS AT THIS MOMENT WHEN NEGOTIATIONS ARE TAKING PLACE.

A GOVERNMENT SOURCE ACCOMPANYING THE TALKS WITH THE U.S. ADMITTED THAT THE U.S. GOVERNMENT COULD EXERT PRESSURE FOR A SOLUTION TO THE PROBLEM OUTSIDE THE SCOPE OF THE INDUSTRIAL PROPERTY CODE. THIS COULD BE DONE, FOR EXAMPLE, THROUGH THE CREATION OF MECHANISMS FOR INSPECTION OR SURVEILLANCE OF PRODUCT FORMULAE BEFORE THEY REACH THE MARKET. IN THIS MANNER CONGRESSIONAL APPROVAL OF CURRENT LEGISLATION WOULD NOT BE NECESSARY. (END TRANSLATION OF SECOND ARTICLE).

21. COMMENT: IF THESE REPORTS ARE ACCURATE, IT LOOKS AS THOUGH THE GOB EXECUTIVE BRANCH IS MAKING A GOOD FAITH EFFORT TO MEET USG AND PMA CONCERNS WITHOUT PROVOKING A NATIONALIST BACKLASH IN THE CONGRESS AND THE CONSTITUTIONAL CONVENTION; SUCH A BACKLASH, WE FEEL, IS A REAL THREAT AND IT COULD HAVE NEGATIVE CONSEQUENCES FOR U.S. INVESTMENT HERE. SPECIFICALLY, THE GOB SEEMS TO BE THINKING ABOUT ESTABLISHING DE FACTO PATENT RECOGNITION THROUGH SOME SORT OF ADMINISTRATIVE REGULATION.

22. THERE MAY BE ANOTHER FRUITFUL NEGOTIATING PATH. ALL OF THE ARGUMENTS WE HAVE HEARD FROM THE GOB FOR NON-RECOGNITION OF DRUG PATENTS HAVE TO DO WITH INTERNAL DEVELOPMENT OR NATIONAL SOVEREIGNTY. ON THE OTHER HAND,

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TAGS: ETRD, EINV, BR, US  
SUBJECT: BRAZILIAN PHARMACEUTICALS: LATEST GOB THINKING

ONE OF THE MOST IMPORTANT DRIVING FORCES BEHIND THE PMA'S 301 THREAT IS THE FEAR THAT BRAZIL WILL BECOME "THE NEXT ITALY", I.E., THAT BRAZIL WILL SOON START TO EXPORT LARGE QUANTITIES OF PIRATED MEDICINES OR RAW MATERIALS. SINCE THE GOB (AT LEAST OSTENSIBLY IN THE SHORT RUN) IS PRIMARILY CONCERNED WITH INTERNAL DEVELOPMENT AND THE PMA IS PRIMARILY CONCERNED WITH EXPORTS, IT HAS OCCURRED TO US THAT THERE MAY EXIST GROUNDS FOR A COMPROMISE HERE. IF THE GOB COULD BE INDUCESSTO AGREE TO PROHIBIT THROUGH ADMINISTRATIVE REGULATION (PERHAPS THROUGH CACEX) THE EXPORT OF ON-PATENT DRUGS OR RAW MATERIALS, THE SPECTER

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OF BRAZIL BECOMING "THE NEXT ITALY" WOULD DISAPPEAR AND WITH IT A LOT OF THE STEAM BEHIND THE PMA'S 301 PETITION DRIVE. WE HAVE NO WAY OF KNOWING WHETHER SUCH AN ARRANGEMENT, TOGETHER WITH THE DE FACTO DOMESTIC PATENT PROTECTION AFFORDED BY ADMINISTRATIVE REGULATION, WOULD BE ACCEPTABLE TO ALL PARTIES CONCERNED, BUT IN THEORY AT LEAST THIS APPROACH SEEMS WORTH PURSUING. AT THE SAME TIME WE RECOGNIZE THAT BRAZILIAN PRIORITIES VIS A VIS EXPORTS/DOMESTIC NEEDS COULD CHANGE. DACHI

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