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INFO RUEHDC/USDOC WASHDC
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LIMITED OFFICIAL USE SECTION 01 OF 05 SAO PAULO 01560

STATE PLEASE PASS USTR

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

BRASILIA PLEASE POUCH RECIFE AND SALVADOR DA BAHIA

E.O. 12356: N/A
TAGS: ETRD, EIND, EINV, BR
SUBJECT: IMPACT OF LACK OF PATENT PROTECTION: SURVEY OF
U.S. PHARMACEUTICAL FIRMS

REF: (A) STATE 102584; (B) BRASILIA 03902 (NOTAL)

1. SUMMARY: IN RESPONSE TO USG CONCERNS, THE ASSOCIATION OF 25 (MOSTLY) U.S. PHARMACEUTICAL FIRMS OPERATING IN BRAZIL (LAWG) CANVACED ITS MEMBERS ON THEIR LOSSES DUE TO PATENT PIRACY. THE SIXTEEN COMPANIES WHICH RESPONDED REPORTED THAT IN THE DECADE ENDING IN 1985 LACK OF PATENT PROTECTION COST THEM DOLS 402.6 MILLION. IF ONE WERE TO INCLUDE LOSSES FOR WHICH DATA IS UNAVAILABLE OR WHICH ARE INTANGIBLE, E.G., "OPPORTUNITY COSTS", THE GLOBAL FIGURE FOR ALL U.S. DRUG FIRMS PROBABLY WOULD APPROACH DOLS 1 BILLION. DESPITE THIS, ONLY ONE FIRM COUNTS PATENT PROTECTION AMONG ITS PRINCIPAL CONCERNS. WHILE OFTEN ADMITTING BIG LOSSES, MOST OF THE OTHERS SEEM TO REGARD PIRACY AS AN ACCEPTABLE PRICE FOR DOING BUSINESS IN BRAZIL. THEY FEEL THAT PUSHING FOR CHANGE MIGHT BRING THEM ONLY ADDITIONAL HEADACHES. END SUMMARY.
THE LAWG SURVEY

2. IN RESPONSE TO REF B, CONSULATE OFFICERS HAD EXTENSIVE DISCUSSIONS WITH MEMBERS OF THE LATIN AMERICAN WORKING GROUP (LAWG), A COALITION OF 25 (MOSTLY) U.S. DRUG COMPANIES OPERATING IN BRAZIL. IN ORDER TO COMPLY WITH OUR REQUEST FOR MORE PRECISE INFORMATION, A LAWG OFFICIAL SUBSEQUENTLY CANVACED ITS MEMBERSHIP ON WHAT IMPACT THE LACK OF PATENT PROTECTION HAS HAD ON THEIR OPERATIONS. THE CONSULATE FINALLY RECEIVED THE RESULTS IN JUNE. IN COMPILING AND ANALYZING THIS DATA, ECONOFF COUGHT ADDITIONAL INFORMATION AND CLARIFICATION FROM EXECs OF THOSE FIRMS MOST SERIOUSLY AFFECTED. IN PARTICULAR, HE ASKED THOSE FIRMS WHO CLAIMED MAJOR LOSSES FROM PIRATING WHERE -- AMONG THE VARIOUS PROBLEMS THEY ARE ENCOUNTERING IN THIS COUNTRY -- THEY RANK LACK OF PATENT PROTECTION.

METHODOLOGY

3. LAWG ASKED ITS MEMBER FIRMS TO ESTIMATE ON A YEARLY BASIS THE TOTAL DOMESTIC SALES THEY HAD LOST DUE TO LACK OF PHARMACEUTICAL PATENT PROTECTION OVER THE DECADE 1976-85. A "LOST SALE" WOULD BE CONSIDERED ANY SALE BY OTHER COMPANIES (EITHER NATIONAL OR FOREIGN) OF A DRUG CHEMICALLY IDENTICAL TO ONE THAT THE RESPONDENT MARKETS IN BRAZIL AND ON WHICH IT ENJOYS A CURRENT PATENT IN THE U.S. OF LAWG'S 25 MEMBER FIRMS, 16 RESPONDED TO THE SURVEY. BELOW ARE INDIVIDUAL COMPANY ESTIMATES OF TOTAL LOST SALES DURING THE 10-YEAR PERIOD, PLUS ADDITIONAL COMMENTS BASED ON FOLLOW-UPS BY ECONOFF.

THE RESULTS: INDIVIDUAL COMPANY LOSSES

4. A. SMITH KLINE FRENCH (SKF):

- TOTAL LOST SALES: DOLS 45.8 MILLION

- COMMENT: OF THE ABOVE TOTAL, DOLS 41.9 MILLION WERE LOST IN DRUGS INTENDED FOR HUMANS, WITH THE BALANCE (DOLS 3.9 MILLION) IN VETERINARY MEDICINES.

5. B. PFIZER:

- TOTAL LOST SALES: DOLS 42.7 MILLION

- COMMENT: A PFIZER EXEC TOLD ECONOFF THAT HIS FIRM HAS BEEN ABLE TO "MINIMIZE" ITS VULNERABILITY TO PIRACY BY BEING VERY SELECTIVE IN CHOOSING WHICH DRUGS TO INTRODUCE ON THE LOCAL MARKET. "THIS IS 'PATENT PROTECTION' IN BRAZIL", HE SAID. "IF THE COMPOUND IS VERY EASY TO COPY (AS IS THE CASE WITH SEVERAL OF THE COMPANY'S HEART MEDICINES), WE WON'T MARKET IT HERE." OF COURSE, THIS STRATEGY CARRIES WITH IT THE OPPORTUNITY COSTS OF SACRIFICING WHATEVER LOCAL SALES MIGHT BE REALIZED FROM THE PRODUCT. THUS THE LOSSES THE FIRM REPORTED TO LAWG ARE UNDER-

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

BRASILIA PLEASE POUCH RECIFE AND SALVADOR DA BAHIA

E.O. 12356: N/A

TAGS: ETRD, EIND, EINV, BR

SUBJECT: IMPACT OF LACK OF PATENT PROTECTION: SURVEY OF

- STATED TO THE EXTENT THAT THEY EXCLUDE SUCH LOSSES.

- C. ELI LILLY

- TOTAL LOST SALES: DOLS 79.6 MILLION

- COMMENT: THE MAJOR LOSS HAS BEEN DUE TO COPYING OF
- THE COMPANY'S DRUG ILOSONE (GENERIC NAME: ERITROMI-
- CINA). OTHER LILLY DRUGS HIT BY PIRATING ARE REFLEX
- (CEFALEXINA), KEFLIN (CEFALOTINA), KEFAZOL (CEFAZO-
- LINA), CEFALORIDINA (CEFALORIDINA), AND DOLOXENE
- (PROPOXIFENO).

- D. UPJOHN

- TOTAL LOST SALES: DOLS 12.4 MILLION

- COMMENT: VIRTUALLY ALL OF THE LOSSES OCCURRED WITH
- THE COMPANY'S DRUG FRADOMICINA, THE SUBJECT OF
- PREVIOUS CONSULATE REPORTING (SAO PAULO 01186).

- E. F. WYETH

- COMMENT: THE FIRM'S LOCAL REP RESPONDED THAT WYETH
- "WAS VERY LITTLE AFFECTED BY PIRATE PRODUCTS."

- F. ALCON

- COMMENT: ACCORDING TO THE COMPANY'S FINANCIAL
- MANAGER, ALCON DOES NOT "HAVE ANY SPECIAL CASE THAT
- SHOULD BE EMPHASIZED."

- G. SYNTEX

- COMMENT: ACCORDING TO SYNTEX'S LOCAL REP, THE FIRM
- "HAS NOT SUFFERED LOSS IN SALES DUE TO PIRATES OF
- OUR PRODUCTS."

- N. MERCK SHARP AND DOHME

- TOTAL LOST SALES: DOLS 36.1 MILLION

- I. BRISTOL-MYERS

- TOTAL LOST SALES: DOLS 3.2 MILLION

- J. LEPETIT-DOW

- TOTAL LOST SALES: DOLS 36.3 MILLION

- COMMENT: THE ABOVE FIGURE REPRESENTS ONLY LOSSES
- DURING 1982-1985. ACCORDING TO A COMPANY REP,
- DATA FOR EARLIER YEARS IS UNAVAILABLE.

- K. AYERST

- TOTAL LOST SALES: "ABOUT" DOLS 18 MILLION

- COMMENT: A COMPANY REP TOLD ECONOFF THAT LACK OF
- PATENT PROTECTION HAD BEEN THE PRIMARY CAUSE FOR
- CANCELLING A DOLS 2 MILLION EXPANSION WHICH WAS TO
- FOCUS ON CLINICAL TESTING OF DRUGS THE PARENT WAS
- DEVELOPING. "WE (I.E., AYERST BRAZIL) WERE COMPET-
- ING WITH OPERATING DIVISIONS IN OTHER COUNTRIES
- WHICH COULD OFFER PATENT PROTECTION. THE COMPANY
- FINALLY DECIDED THAT HAVING SUCH AN OPERATION IN
- BRAZIL WOULD BE TOO RISKY." ALONG WITH THE CANCEL-
- LED PROJECT WENT 40 PROJECTED ADDITIONAL JOBS.

- L. SCHERING

- TOTAL LOST SALES: DOLS 6.1 MILLION

- M. BEECHAM

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USDOC FOR 4338/IEP/WH/OSA/PETER FIELD

BRASILIA PLEASE POUCH RECIFE AND SALVADOR DA BAHIA

E.O. 12356: N/A

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TOTAL LOST SALES: DOLS 29.4 MILLION

M. JOHNSON AND JOHNSON

TOTAL LOST SALES: DOLS 101 MILLION

COMMENT: A J & J REP TOLD ECONOFF THAT MANY OF THE FIRM'S DRUGS WERE COPIED VERY SOON AFTER BEING INTRODUCED IN BRAZIL. APPROXIMATELY 86 PERCENT OF THE ABOVE LOSSES WAS CAUSED BY COPYING OF THE ANTI-WORM DRUG MEBENDAZOLE AND ITS "ASSOCIATIONS" (COMBINATIONS WITH OTHER ANTI-WORM MEDICINES). THIS DRUG WAS DEVELOPED AND PATENTED BY J & J AND MARKETED IN BRAZIL BY JANSSEN, A J & J SUBSIDIARY BASED IN BELGIUM. J AND J'S DRUG NOW HAS ONLY 23 PERCENT OF THE MARKET, WITH COPIES HOLDING THE REMAINDER. AN INTERESTING TWIST TO J & J'S OTHERWISE TYPICAL PROBLEMS IS THAT THE PRINCIPAL LOCAL PIRATE FIRM INVOLVED, ANDROMACO, WAS PURCHASED SEVERAL YEARS AGO -- PIRATED DRUG LINES AND ALL -- BY THE U.S.' G.D. SEARLE. ALONE AMONG THE COMPANIES WHICH ECONOFF CONTACTED, J & J REGARDS LACK OF PATENT PROTECTION AS ITS "SINGLE BIGGEST PROBLEM" IN BRAZIL.

O. SYDNEY ROSS

COMMENT: THE FIRM'S LOCAL GENERAL MANAGER TOLD ECONOFF THAT OVER THE LAST TEN YEARS IT HAD NOT LOST ANY SALES DUE TO PIRATE COMPETITORS. HE ADDED, HOWEVER, THAT AFTER THE 17-YEAR PATENT ON ONE OF ITS DRUGS HAD EXPIRED, A LOCAL COMPANY STARTED MANUFACTURING THE RAW MATERIAL AT A VERY HIGH PRICE -- AND FROM THAT POINT IMPORTATION OF THE MATERIAL WAS BANNED. "THUS", HE SAID, "WE HAVE PAID ABOUT DOLS 200,000 PER YEAR FOR ABOUT EIGHT YEARS OVER WHAT WOULD HAVE BEEN THE LANDED COST OF THAT RAW MATERIAL AT THE INTERNATIONAL PRICE." IN THIS AND MANY OTHER CASES WITH WHICH ECONOFFS ARE FAMILIAR, CIP HAS REFUSED TO ALLOW ANY PRICE ADJUSTMENT TO OFFSET THE HIGHER COST OF THE MANDATORY PURCHASE OF A LOCALLY PRODUCED

RAW MATERIAL.

P. WARNER-LAMBERT

COMMENT: FOUR YEARS AGO WARNER-LAMBERT ABANDONED DIRECT MARKETING OF ITS DRUGS IN BRAZIL AND LICENSED TO A NATIONAL COMPANY (ACHE) ITS PARKE-DAVIS (P-D) AND WARNER CHILCOTT (WC) LINES OF ETHICAL DRUGS. THE COMPANY'S REMAINING BUSINESS IN BRAZIL FOCUSES ON CONSUMER PRODUCTS SUCH AS CHEWING GUM, CANDIES, RAZOR BLADES, AND TOOTHBRUSHES. ITS LOCAL PRESIDENT TOLD ECONOFF THAT "DUE TO THE ABSENCE OF A SPECIFIC PHARMACEUTICAL DEPARTMENT IT WOULD BE ALMOST IMPOSSIBLE TO RECONSTRUCT THE SALES LOST DUE TO LACK OF PATENT PROTECTION DURING THE PERIOD P-D AND WC WERE STILL OPERATING UNDER OUR OWN MANAGEMENT." HE ADDED THAT "DUE TO THE CONTINUOUSLY ASPHYXIATING PRICE CONTROL POLICY THAT THE GOVERNMENT HAS EXERTED OVER THE PHARMACEUTICAL INDUSTRY IN GENERAL, OUR LOCAL SUBSIDIARY WAS NOT ABLE TO CONTINUE ABSORBING SUCCESSIVELY DEFICITARY RESULTS FROM ITS PHARMACEUTICAL OPERATIONS. THUS WE WERE PRACTICALLY FORCED INTO LICENSING OFF THE P-D AND WC LINES (AT A FIRE-SALE PRICE) TO ACHE AS THE ONLY PRACTICAL WAY TO CONTINUE MAINTAINING OUR PRESENCE IN A PHARMACEUTICAL MARKET AS IMPORTANT AS BRAZIL."

TOTAL LOST SALES

5. THE 16 LANG MEMBERS WHICH RESPONDED TO THE SURVEY DOCUMENTED LOSSES TOTALLING DOLS 402.6 MILLION OVER THE TEN-YEAR PERIOD. SINCE SEVERAL OF THE RESPONDENTS DID NOT AVE COMPLETE DATA FOR THE DECADE, AND NINE COMPANIES

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

BRASILIA PLEASE POUCH RECIFE AND SALVADOR DA BAHIA

E.O. 12356: N/A

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(ABBOTT, ALLERGAN-LOK, CYANAMID, FARMITALIA, MILES, RORER, SEARLE, SQUIBB, AND STIEFEL) DIDN'T RESPOND AT ALL, THIS FIGURE SHOULD BE REGARDED AS A BARE MINIMUM. IT ALMOST CERTAINLY IS CONSIDERABLY LOWER THAN THE ACTUAL GLOBAL TOTAL. TO ARRIVE AT SUCH A TOTAL ONE WOULD HAVE TO FACTOR IN THE PROBABLE LOSSES IN YEARS NOT COVERED BY DATA OR SUFFERED BY COMPANIES WHICH NEVERTHELESS CHOICE NOT TO RESPOND TO THE SURVEY. MOREOVER, THE TOTAL WOULD HAVE TO INCLUDE THE CONSIDERABLE LOSSES OR "OPPORTUNITY COSTS" OF THE KIND DESCRIBED BY PFIZER IN PARA 3.

6. ONE FINAL POINT: THE ESTIMATED LOSSES WERE DERIVED FROM THE VALUE OF UNIT SALES, IN BRAZILIAN CURRENCY (CRUZADOS) CONVERTED TO DOLLARS. HOWEVER, PHARMACEUTICAL PRICES IN BRAZIL ARE MUCH LOWER THAN IN MOST OTHER MARKETS; REPORT-EDLY THEY ARE THE LOWEST IN LATIN AMERICA, AND IN THE WORLD ARE UNDERCUT ONLY IN INDIA AND PAKISTAN. THUS THE DOLLAR LOSS IS CORRESPONDINGLY LOWER THAN THAT WHICH WOULD HAVE RESULTED FROM A SIMILAR NUMBER OF "LOST" UNIT SALES IN THESE OTHER MARKETS.

7. WITH ALL OF THE ABOVE INTANGIBLES PUSHING UP THE TOTAL, A GLOBAL ESTIMATE OF PROBABLE LOSSES FOR THE TEN-YEAR PERIOD APPROACHING DOLS 1 BILLION DOES NOT SEEM UNREASON-ABLE. A LAWG REP RECENTLY TOLD ECONOFF THAT, IN PREPARING FOR A POSSIBLE 301 ACTION, THE U.S. PMA IS GATHERING FROM ITS MEMBERS WITH OPERATIONS IN BRAZIL COMPLETE DATA ON LOSSES FROM PATENT PROTECTION AS WELL AS OTHER PROBLEMS. BASED ON OUR PERUSAL OF THE PMA'S QUESTIONNAIRE AND OUR UNDERSTANDING THAT THE ASSOCIATION WOULD BE BETTER ABLE TO ELICIT COOPERATION, WE EXPECT ITS SURVEY TO PROVIDE MORE COMPLETE FIGURES THAN LAWG OBTAINED. OUR SOURCE PROMISED TO PROVIDE US A COPY OF THE PMA SURVEY WHEN COMPLETED.

LOCAL R & D: A NON-STARTER

8. SALES LOSSES OF SUCH MAGNITUDE, COUPLED WITH NO PROS-PECT OF CHANGE IN BRAZIL'S PATENT REGIME, APPEAR TO PRE-CLUDE ANY POSSIBILITY OF ITS DEVELOPING THE SLIGHTEST

DEGREE OF GENUINE SELF-SUFFICIENCY IN DRUG RESEARCH AND DEVELOPMENT. ALL OF OUR SOURCES REPORT LITTLE OR NO LOCAL BASIC RESEARCH UNDERWAY OR CONTEMPLATED. WHAT LITTLE "RESEARCH" EXISTS IS MAINLY DEVOTED TO CLINICAL TESTING OR TO PERFECTING THE SCIENCE OF PIRACY, I.E., "REVERSE ENGINEERING" DRUG COMPOUNDS. THE MOST FREQUENTLY CITED REASON FOR THE LACK OF SIGNIFICANT R & D: LACK OF PATENT PROTECTION. AS ONE EXEC PUT IT, "IT DOESN'T MAKE ANY SENSE FOR MNC'S OR EVEN LOCALS TO DO ANY RESEARCH GIVEN THE LAWLESS ENVIRONMENT THAT EXISTS HERE. IF THERE WERE SOME BRILLIANT BRAZILIAN SCIENTIST WHO DISCOVERED THE CURE FOR CANCER, THE SMARTEST THING HE COULD DO WOULD BE TO TRAVEL TO THE U.S. OR EUROPE AND SELL IT TO A MNC WHO COULD PATENT IT. THAT'S THE ONLY WAY HE COULD DEFEND HIMSELF AGAINST PIRACY AND BE COMPENSATED FOR HIS WORK. IN BRAZIL, THE ONLY LOCAL RESEARCH CONSISTS OF MASTERING THE TECHNOLOGY OF COPYING DRUGS."

9. A LOCAL JOURNALIST WHO HAS WRITTEN EXTENSIVELY ABOUT THE PHARMACEUTICAL INDUSTRY, HOWEVER, RECENTLY COUNTERED TO ECONOFF THAT "MNC'S DON'T WANT TO CONDUCT RESEARCH IN BRAZIL" AND THAT PATENT PROTECTION HAS VERY LITTLE TO DO WITH THAT SENTIMENT. AS PROOF, HE CLAIMED THAT "EVEN BEFORE THE LOSS OF PATENT PROTECTION (IN 1969), MNC'S CONDUCTED NO DRUG RESEARCH IN BRAZIL." (COMMENT: WE FIND THIS CHARGE PLAUSIBLE; AFTER ALL, WITH THE POSSIBLE EXCEP-TION OF CERTAIN TROPICAL DISEASES BRAZIL APPEARS TO LACK ANY COMPARATIVE ADVANTAGE IN OR ATTRACTIVENESS FOR PHARMA-CEUTICAL RESEARCH. NEVERTHELESS, REGARDLESS OF WHAT WAS OR WAS NOT DONE BEFORE 1969 THE SUBSEQUENT LACK OF PATENT PROTECTION SEEMS TO GUARANTEE THAT BRAZIL WILL REMAIN A NON-STARTER IN THE IDENTIFICATION AND DEVELOPMENT OF NEW MEDICINES. END COMMENT).

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

BRASILIA PLEASE POUCH RECIFE AND SALVADOR DA BAHIA

E.O. 12356: N/A

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WHY SO LAID-BACK?

10. GIVEN LOSSES OF THE MAGNITUDE CITED ABOVE, ONE WOULD EXPECT PATENT PROTECTION TO BE AMONG U.S. PHARMACEUTICAL PRODUCERS' HIGHEST CONCERNS. HOWEVER, AS PREVIOUS REPORTING HAS INDICATED AND AS THE ABOVE CONFIRMS, FOR THESE COMPANIES (WITH THE NEWLY DISCOVERED PROMINENT EXCEPTION OF JOHNSON AND JOHNSON) THE PATENT PIRACY ISSUE TAKES A BACK SEAT TO OTHER PROBLEMS, PARTICULARLY PRICING.

11. IN THE FACE OF THE SEEMINGLY ENORMOUS LOSSES SUFFERED BY HIS FELLOW MEMBERS (IF NOT BY HIS OWN COMPANY), THE LAID-BACK ATTITUDE OF ABBOTT'S LOCAL TOP EXECUTIVE (THE CURRENT HEAD OF LAW) SEEMS SURPRISING. HIS EXPLANATION: "WITH THE PARTIAL EXCEPTION OF ACHE, THE LOCAL COMPANIES ARE SMALL, UNDERCAPITALIZED, HAVE NO TECHNOLOGY AND NEVER WILL HAVE ANY. THE ONLY WAY THEY CAN MAINTAIN THEIR 20 PERCENT SHARE OF THE MARKET AND EKE OUT AN EXISTENCE IS THROUGH COPYING. IF YOU LOOK AT LATIN AMERICA, YOU WILL FIND THAT BRAZIL HAS THE WEAKEST NATIONAL DRUG INDUSTRY, AND THE LOWEST DRUG PRICES. I THINK THOSE TWO FACTS ARE CAUSALLY RELATED. WITHOUT LOCAL COMPANIES TO LOBBY ON OUR COLLECTIVE BEHALF, THE GOB WOULD TREAT THE PHARMACEUTICAL INDUSTRY EVEN WORSE THAN IT DOES NOW. THIS IS THE PRICE WE PAY FOR DOING BUSINESS IN THIS COUNTRY. WE WOULD ALL BE BETTER OFF IF THE LOCAL COMPANIES WERE STRONGER, AND ONE WAY THE MNC'S CAN HELP THEM OUT IS TO TURN A BLIND EYE TO THEIR PIRATE ACTIVITIES."

12. OTHER COMPANY REPS VOICED SIMILAR SENTIMENTS. ONE SAID HE VIEWED PIRACY AS A SORT OF "LOCAL TAX" ON OPERATIONS WHICH HAD TO BE PAID. "SURE THE TAX IS HIGH," HE SAID, "BUT IT'S AFFORDABLE. BESIDES, IF WE WERE TO MAKE AN ISSUE OF PIRACY, WE WOULD PUSH THE LOCALS INTO A LIFE OR DEATH STRUGGLE AGAINST US. THEY WOULD INTRIGUE AGAINST US WITH THE GOVERNMENT AND IN GENERAL MAKE OUR LIVES MISERABLE." DACHI

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