

ROUTINE

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DEPARTMENT OF COMMERCE

**EXCISE**

INCOMING

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FM AMEMBASSY SANTO DOMINGO  
TO RUEHC/SECSTATE WASHDC 2267  
INFO RUCPDOG/USDOC WASHDC  
RUEHLO/AMEMBASSY LONDON 0024  
RUEHKG/AMEMBASSY KINGSTON 0593  
RUEHOL/AMEMBASSY BONN 0071  
RUEHGV/USMISSION GENEVA 0062  
RUEHPU/AMEMBASSY PORT AU PRINCE 1113  
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SANTO DOMINGO 005269

USDOC FOR THE US PATENT AND TRADEMARK OFFICE  
DEPARTMENT PASS USTR  
US MISSION GENEVA FOR USTR

E.O. 12958: DECL: 9/10/2003  
TAGS: KIPR DR  
SUBJECT: IPR--BAYER WINS IN DR SUPREME COURT

REF: SANTO DOMINGO 4544

1. (U) CLASSIFIED BY PAUL LARSEN, ECO/POL COUNSELOR:  
REASON: 1.5 (D)

2. SUMMARY: GERMAN PHARMACEUTICAL COMPANY BAYER AG HAS WON A SUIT BROUGHT AGAINST DOMINICAN NATIONAL LABORATORY ETHICAL PHARMACEUTICAL FOR THE PIRACY OF THE SUBSTANCE "CIPROFLOXACINA." MERCK SHARP & DOHME HAD DECIDED BEFORE THE DECISION BY THE DOMINICAN SUPREME COURT BECAME PUBLIC TO JOIN BAYER IN THE COURTS. MERCK'S ATTORNEY EXPECTS TO SEND THE FIRST "CEASE & DESIST" LETTERS ON OCTOBER 22. LOCAL ATTORNEYS ARE ALSO PRESSING AHEAD WITH THEIR PLANS TO TAKE A SUIT BEFORE THE SUPREME COURT TO CONTEST THE GOOD RESOLUTIONS PASSED IN LATE 1996 AND EARLY 1997 THAT ALLOW THE COMMERCIALIZATION OF DRUGS IN THE DOMINICAN REPUBLIC BY COMPANIES THAT DO NOT HOLD PRODUCT PATENTS. END SUMMARY.

BAYER WINS IN DOMINICAN SUPREME COURT

3. (U) IN A RULING DATED JULY 16, 1998, BUT MADE PUBLIC FOR THE FIRST TIME THIS WEEK, THE DOMINICAN SUPREME COURT UPHOLD A SUIT BROUGHT BY BAYER AG AGAINST LOCAL LABORATORY ETHICAL PHARMACEUTICAL FOR VIOLATION OF THE BAYER PATENT FOR THE SUBSTANCE "CIPROFLOXACINA." BAYER FIRST FILED SUIT IN THE DOMINICAN COURTS IN 1991. THE SUPREME COURT'S RULING STATES IN PART, "IF BAYER AG REGISTERED AND PATENTED ITS FORMULA IN THE DOMINICAN REPUBLIC, ONLY IT AND THOSE IT AUTHORIZES CAN USE THE SAME IN THE COUNTRY."

MERCK ALSO TO SUE

4. MERCK SHARP & DOHME HAS NOW AUTHORIZED LOCAL ATTORNEY TO TAKE LEGAL ACTION IN THE DOMINICAN COURTS. WHILE THIS DECISION WAS MADE BEFORE THE SUPREME COURT RULING WAS RELEASED, IN AN OCTOBER 21 CONVERSATION WITH ECONOFF, [REDACTED] WAS MORE UPBEAT ABOUT THE PROSPECTS FOR THE MERCK LITIGATION.

5. [REDACTED] PROPOSED THAT MERCK PROCEED WITH LITIGATION ON FOUR SUBSTANCES:

ACTIVE INGREDIENT	TRADEMARK	PATENT EXPIRATION DATE
SIMVASTATIN	ZOCOR	2001
ALENDRONATE	FOSAMAX	2003
FINASTERIDE	PROSCAR	2006
LOSARTAN	COZAAR	2009

1. [REDACTED] HAS RECEIVED THE GO-AHEAD ON THE FIRST THREE. LOSARTAN IS COVERED BY A DUPONT PATENT LICENSED TO MERCK; MERCK IS PURSUING AUTHORIZATION FROM DUPONT TO PROCEED WITH THE PROPOSED LITIGATION. FERNANDEZ IS PARTICULARLY ANXIOUS TO INCLUDE THE LATTER TWO SUBSTANCES GIVEN THEIR LONGER TERM PATENT EXPIRATION DATES IN THE FACE OF THE AMOUNT OF TIME THE CASES MAY BE IN THE COURTS.

6. [REDACTED] INFORMED ECONOFF SHE EXPECTS TO ISSUE THE FIRST "CEASE & DESIST" LETTERS ON OCTOBER 22. LETTERS WILL BE SENT ASKING COMPANIES THAT HAVE APPLIED FOR HEALTH REGISTRATIONS FOR THE PATENTED SUBSTANCES TO RESCIND THEIR REQUESTS; ASKING COMPANIES THAT HAVE ALREADY RECEIVED HEALTH REGISTRATIONS BUT HAVE NOT YET STARTED MARKETING THE SUBSTANCES TO REFRAIN; AND, FINALLY, ASKING A COMPANY THAT IS NOW MARKETING A PIRATED SUBSTANCE TO TAKE IT OFF THE MARKET WITHIN 30 DAYS. [REDACTED] HAS DECIDED TO TAKE ON ROWE (CHARACTERIZED LOCALLY AS "THE DOMINICAN FACE OF ROEMMERS") IN THE LATTER ACTION.

OTHER LEGAL ACTIONS BY THE GOOD GUYS

7. [REDACTED] AS REPORTED REFTEL, LOCAL ATTORNEYS REPRESENTING PFIZER AND MERCK SHARP & DOHME ARE STILL MOVING AHEAD TO CONTEST BEFORE THE SUPREME COURT THE CONSTITUTIONALITY OF THE

REF: SANTO DOMINGO 4544

RESOLUTIONS ISSUED AT YEAR END 1996 AND EARLY 1997 WHICH ALLOW THE COMMERCIALIZATION OF DRUGS IN THE DOMINICAN REPUBLIC BY COMPANIES THAT DO NOT HOLD PRODUCT PATENTS. THE ATTORNEYS ARE ANXIOUS TO FILE THEIR SUIT BEFORE THE ADMINISTRATIVE COURT RULES IN A SIMILAR SUIT BROUGHT BEFORE IT IN 1997. [REDACTED] IN PARTICULAR, HAS EXPRESSED SOME CONCERN ABOUT THE COMPOSITION OF THE ADMINISTRATIVE COURT PANEL AND WISHES TO AVOID A SITUATION IN WHICH THE SUPREME COURT MIGHT REFUSE TO TAKE THE CASE FOLLOWING AN ADMINISTRATIVE COURT RULING.

COMMENT

8. [REDACTED] WHILE LOCAL INTELLECTUAL PROPERTY ATTORNEYS ARE HOPEFUL ABOUT THE BAYER SUPREME COURT VICTORY, THEY HAVE NOT YET HAD AN OPPORTUNITY TO REVIEW THE DECISION AND ITS LIKELY IMPACT ON THE PIRATE FIRMS AND FUTURE LITIGATION. THE EMBASSY HAS ASKED [REDACTED] REPRESENTATIVES OF EFID, THE ASSOCIATION REPRESENTING U.S. AND OTHER MULTINATIONAL PHARMACEUTICAL COMPANIES IN THE DR, TO TRY TO IDENTIFY WHAT PRODUCTS THE PIRATING COMPANIES ARE EXPORTING TO HAITI AND CENTRAL AMERICA.

WATT  
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#5269

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