

ROUTINE

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EXCISE

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PUBLIC COMMENT.

ACTION: PTO-01

INFO: 534-01 REVIEW COPY-01 3134-01 4322-01 4320-01 4110-01 104-01  
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FM AMEMBASSY SANTO DOMINGO

TO RUEHC/SECSTATE WASHDC 6776

RUCPDOC/USDOC WASHDC 0343

INFO RUEHLO/AMEMBASSY LONDON 0708

RUEHKG/AMEMBASSY KINGSTON 0350

RUEHGV/USMISSION GENEVA 0045

RUEHOL/AMEMBASSY BONN 0037

RUEHPU/AMEMBASSY PORT AU PRINCE 0391

BT

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USDOC FOR THE US PATENT AND TRADEMARK OFFICE

DEPARTMENT PASS USTR

US MISSION GENEVA FOR USTR

E.O. 12958: DECL: 01/01/10

TAGS: KIPR, ETRD, DR

SUBJECT: UPDATE ON PHARMACEUTICAL PATENT ISSUES

REF: A. STATE 133570 (NOTAL)

CLASSIFIED BY: DONNA J. HRINAK, AMBASSADOR, REASON FOR  
CLASSIFICATION: 1.5D

1. (U) THIS IS AN ACTION MESSAGE. SEE PARA. 9.

2. SUMMARY: THE AMBASSADOR MET AUGUST 26 WITH THE GERMAN AND UK AMBASSADORS AND MEMBERS OF THE TRADE ASSOCIATION REPRESENTING U.S. AND OTHER MULTINATIONAL PHARMACEUTICAL COMPANIES IN THE DOMINICAN REPUBLIC (EMPRESAS FARMACEUTICAS DE INVESTIGACION Y DESARROLLO OR EFID). EFID BRIEFED THE AMBASSADORS ON THE STATUS OF IPR LEGISLATION NOW UNDER CONSIDERATION BY THE GODR AND HIGHLIGHTED ITS DISCRIMINATORY AND GATT TRIPS-ILLEGAL PROVISIONS. EFID WILL PROVIDE A LIST OF PIRATED PRODUCTS NEXT WEEK WHICH THE AMBASSADORS WILL USE IN MAKING JOINT DEMARCHES ON THE SECRETARIES OF HEALTH AND INDUSTRY AND COMMERCE.

END SUMMARY.

BACKGROUND

3. THE STATUS OF PHARMACEUTICAL PATENTS IN THE DOMINICAN REPUBLIC DETERIORATED WITH THE ISSUANCE AT YEAR END 1996 AND EARLY 1997 OF TWO RESOLUTIONS WHICH ATTACK PHARMACEUTICAL FIRMS' EXCLUSIVE USE OF THEIR PATENTS THROUGH A SYSTEM WHICH ALLOWS THE SECRETARIAT OF HEALTH TO ISSUE "HEALTH REGISTRATIONS" ("REGISTRO SANITARIO" IN SPANISH) TO APPLICANTS REGARDLESS OF WHO HOLDS THE PRODUCT PATENT. THE AMBASSADOR, JOINTLY WITH THE UK AND GERMAN AMBASSADORS, VISITED THE SECRETARIES OF FOREIGN AFFAIRS AND HEALTH TO NOTE THAT THESE PROVISIONS VIOLATE OTHER PROVISIONS OF DOMINICAN LAW AND COULD DAMAGE THE DR'S INTERNATIONAL IMAGE. SINCE THEN, THE GODR HAS ISSUED DRAFT IPR LEGISLATION FOR

STATUS OF IPR LEGISLATION

4. EFID DELIVERED ITS COMMENTS ON THE DRAFT IPR LEGISLATION ON JULY 15. POST ALSO DELIVERED THE USG COMMENTS FORWARDED REFTEL. ACCORDING TO THE EFID REPRESENTATIVES, THE SECRETARIAT OF INDUSTRY AND COMMERCE BROUGHT IN ITS CONSULTANT, DR. CARLOS CORREA, SEVERAL WEEKS AGO AND GAVE HIM THE COMMENTS THAT HAD BEEN RECEIVED.

THE CONSULTANT IS BELIEVED TO HAVE TAKEN THE COMMENTS BACK TO ARGENTINA FOR FURTHER WORK BUT HE WAS QUOTED WHILE HE WAS IN THE DOMINICAN REPUBLIC AS SAYING HE THOUGHT THE DOMINICAN LAW IS WELL BALANCED. THE EFID REPRESENTATIVES NOTED THAT THIS IS NOT SURPRISING SINCE THE LAW IS ALMOST A COPY OF ARGENTINE LAW.

5. THE EFID REPRESENTATIVES BRIEFED THE AMBASSADORS ON THE PROVISIONS IN THE LAW WHICH DISCRIMINATE AGAINST THE OWNERS OF PATENTS. IN THE OPPOSITION PROCESS, FOR EXAMPLE, THOSE WHO WOULD OPPOSE A PATENT HAVE 120 DAYS TO ACT WHILE THE PATENT OWNER HAS ONLY 30 DAYS TO RESPOND. EFID'S LEGAL ADVISOR PROVIDED THE AMBASSADORS WITH A DOCUMENT WHICH HIGHLIGHTS BOTH THE DISCRIMINATORY PROVISIONS AND THOSE THAT VIOLATE GATT TRIPS. EFID BELIEVES YET ANOTHER DRAFT OF THE LEGISLATION -- REPORTEDLY THE EIGHTH -- HAS ALREADY BEEN PRODUCED. EFID'S LEGAL ADVISOR BELIEVES THE CURRENT TEXT HAS DROPPED SUGGESTIONS MADE EARLIER BY A WIPO CONSULTANT ALTHOUGH SHE BELIEVES THE GODR WILL CLAIM THE LEGISLATION HAS WIPO'S IMPRIMATUR.

EFID'S MUCH AWAITED CALL ON HEALTH SECRETARY

6. THE AMBASSADOR ASKED THE EFID REPRESENTATIVES IF THEY HAD RECEIVED THEIR APPOINTMENT WITH THE SECRETARY OF HEALTH. ERASMO VASQUEZ, THE FORMER SECRETARY OF HEALTH, HAD REFUSED TO MEET WITH THEM IN THE FACE OF URGING BY ALL THREE AMBASSADORS. ALTHOUGH HE WAS REPLACED AT THE END OF MAY BY DR. ALTAGRACIA GUZMAN, THE EFID REPRESENTATIVES SAID THEY STILL HAD HAD NO SUCCESS IN OBTAINING AN APPOINTMENT. THEY REPORTED SECRETARY GUZMAN HAD REPLACED THE SECRETARIAT'S LEGAL COUNSEL WITH AN APPOINTEE WHO, THOUGH LESS OBJECTIONABLE THAN THE PREVIOUS INCUMBENT, HAD STATED HE WOULD DO EVERYTHING TO COMPLY WITH THE LAW PROVIDED IT WAS "WITHIN HIS INSTRUCTIONS."

NEXT STEPS

7. THE AMBASSADOR, TOGETHER WITH THE GERMAN AND UK AMBASSADORS, WILL VISIT THE SECRETARIES OF HEALTH AND INDUSTRY AND COMMERCE TO UNDERLINE ONCE AGAIN THE DAMAGE THAT WILL BE DONE TO THE DR'S INTERNATIONAL IMAGE THROUGH LACK OF COMPLIANCE WITH ITS INTERNATIONAL OBLIGATIONS. THE AMBASSADOR ASKED EFID TO TRANSLATE ITS DOCUMENT HIGHLIGHTING THE DISCRIMINATORY PROVISIONS OF THE LEGISLATION AND THOSE THAT VIOLATE GATT TRIPS. THE AMBASSADORS WILL HAND THIS DOCUMENT TO THE SECRETARIES. EFID ALSO PROVIDED THE AMBASSADORS WITH A LIST OF RECORDED PHARMACEUTICAL PATENTS IN THE DOMINICAN REPUBLIC. THE AMBASSADORS ASKED EFID TO ANNOTATE THIS LIST TO SHOW THE SUBSTANCES THAT ARE CURRENTLY BEING PIRATED. EFID PROMISED TO PROVIDE THE REQUESTED LIST AND TRANSLATION THE WEEK OF SEPTEMBER 2.

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WE WILL FOLLOW THROUGH WITH THE APPOINTMENTS ONCE THESE DOCUMENTS ARE IN HAND.

✓ 8.

WHILE EFID HAS HAD A STRONG RELATIONSHIP WITH PHARMA IN THE U.S., IT HAS NOT HAD A SIMILAR RELATIONSHIP WITH EUROPEAN ASSOCIATIONS.

✓ THE EFID REPRESENTATIVES SAID THEY BELIEVED THE EU HAD RECENTLY MADE SUCH AN APPROACH TO ARGENTINA. THE AMBASSADORS AGREED IT WOULD BE HELPFUL IF THE ISSUE IN THE DR WERE RAISED BY OTHERS THAN THE U.S.

COMMENT AND ACTION REQUEST

9. THE EFID REPRESENTATIVES ASKED THE AMBASSADORS TO STUDY THE POSSIBILITY OF ACTION UNDER ARTICLE 65 OF GATT TRIPS, SAYING THEY BELIEVED THE U.S. HAD TAKEN SUCH ACTION AGAINST ECUADOR. WASHINGTON AGENCIES ARE REQUESTED TO COMMENT ON THIS PROPOSAL.

10. WHILE OTHER PARTS OF THE GODR (I.E. DIRECTORATE GENERAL OF TELECOMMUNICATIONS AND THE OFFICE OF AUTHORS' RIGHTS) ARE ACTIVELY WORKING TO IMPROVE OTHER VIOLATIONS OF INTELLECTUAL PROPERTY RIGHTS, THE TREATMENT OF PHARMACEUTICAL PATENTS IS WORSENING. FOR THE FIRST TIME AN EFID REPRESENTATIVE PUT AN APPROXIMATE DOLLAR FIGURE TO COMPANY LOSSES -- \$50 MILLION ANNUALLY. WHILE AT LEAST SOME GODR OFFICIALS RECOGNIZE THAT THIS SITUATION IS INCONSISTENT WITH CURRENT GODR INTERNATIONAL OBLIGATIONS, OTHERS LOOK TO THE YEAR 2000. THERE WILL BE NO CHANGE IN POLICY WITHOUT SUBSTANTIAL PRESSURE FROM THE U.S. AND OTHER GOVERNMENTS. HRINAK

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