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EXCISE

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SANTO DOMINGO 005268

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--DRAFT LEGISLATION AND POSSIBLE
REGULATORY CHANGES: THE GOOD AND THE BAD

1. (U) CLASSIFIED BY LINDA E. WATT, CHARGE D'AFFAIRES
A.I.: REASON: 1.5 (D)

2. (U) SUMMARY: SEVERAL LEGISLATIVE OR REGULATORY
PROPOSALS IMPACTING ON INTELLECTUAL PROPERTY RIGHTS AND
HEALTH CARE ARE NOW UNDER DISCUSSION IN THE DOMINICAN
REPUBLIC, INCLUDING LONG-AWAITED INDUSTRIAL PROPERTY
LEGISLATION. ONE SOURCE REPORTS THAT THE TREATMENT OF
COPYRIGHTS IN THE PROPOSED LEGISLATIVE PACKAGE IS
EXCELLENT WHILE THERE ARE SIGNIFICANT PROBLEMS WITH THE
TREATMENT OF TRADEMARKS AND PATENTS. THE LOCAL PIRATE
PHARMACEUTICAL INDUSTRY AND ITS SUPPORTERS IN
GOVERNMENT ARE PUSHING HARD TO KEEP THE GODR FROM
REGULATING QUALITY CONTROL OF PHARMACEUTICALS AS WELL.
END SUMMARY.

IPR LEGISLATION

3. LONG-AWAITED INDUSTRIAL PROPERTY LEGISLATION
WAS SUBMITTED TO THE DOMINICAN SENATE AS PART OF A
PROPOSED NEW COMMERCIAL CODE (CODIGO DE ORDENAMIENTO DE
MERCADOS) ON OCTOBER 2. MEMBERS OF THE COMMISSION
FORMED TO UPDATE THE CODE WERE GIVEN LESS THAN A WEEK
TO REVIEW THE INDUSTRIAL PROPERTY DRAFT PRODUCED BY THE
SECRETARIAT OF INDUSTRY AND COMMERCE AND SENT TO THE
PRESIDENT LAST YEAR AT THIS TIME. COMMISSION MEMBERS
RECEIVED COPIES OF THE FINAL LEGISLATION AFTER IT WAS
SUBMITTED TO THE CONGRESS BY THE FERNANDEZ
ADMINISTRATION. SEVERAL OF THEM ARE BELIEVED TO BE
PREPARING AN OPEN LETTER TO THE PRESS TO SAY THEY HAD
NOT OKED THE FINAL BILL. COMMISSION MEMBER

INFORMED ECONOFF THAT WHILE THE
TREATMENT OF COPYRIGHTS IN THE CODE IS EXCELLENT, THERE
ARE SIGNIFICANT PROBLEMS WITH THE TREATMENT OF
TRADEMARKS AND PATENTS.

HEALTH BILL

4. (U) HEALTH SECTOR LEGISLATION WHICH MAY YET IMPACT
ON PHARMACEUTICAL PATENTS IS ALSO UNDER CONSIDERATION

BY THE CONGRESS. MERCK SHARP & DOHME LEGAL
REPRESENTATIVE MARY FERNANDEZ INFORMED ECONOFF THAT ON
SEPTEMBER 9 SHE ATTENDED A PUBLIC DISCUSSION OF HEALTH
SECTOR LEGISLATION INTRODUCED IN THE SENATE. FERNANDEZ
REPORTED THAT ALL REFERENCES TO PATENTS HAVE BEEN
REMOVED FROM THE SENATE BILL. TIPPED OFF BY A
BYSTANDER WHO SAID HE WAS CONFUSED BECAUSE HE THOUGHT
THE MEETING WAS SUPPOSED TO BE TAKING PLACE ON THE
HOUSE SIDE OF THE LEGISLATURE, FERNANDEZ SENT A STAFFER
TO THE HOUSE WHO DISCOVERED THAT ANOTHER BILL,
REPLACING ALL THE REFERENCES TO PATENTS DELETED FROM
THE SENATE BILL, HAD BEEN INTRODUCED QUIETLY ON THE
HOUSE SIDE. THE HOUSE LEGISLATION WOULD PUT INTO LAW A
REQUIREMENT THAT PHARMACEUTICAL PATENTS COULD NOT BE
ISSUED WITHOUT REVIEW BY THE SECRETARIAT OF HEALTH
(SESPAS). TRADEMARKS AND TRADENAMES FOR MANY PRODUCTS
WOULD ALSO HAVE TO BE REVIEWED AND OKED BY SESPAS.
SESPAS WOULD ALSO HAVE TO APPROVE THE IMPORTATION OF
MEDICAL EQUIPMENT. FERNANDEZ AND OTHER ATTORNEYS ARE
WATCHING THIS LEGISLATION CAREFULLY.

DOMINICANS BAIL OUT OF REGIONAL HARMONIZATION MEETING

5. (U) FOLLOWING UP ON EFFORTS BEGUN LAST YEAR TO
HARMONIZE HEALTH REGISTRATION REQUIREMENTS BETWEEN
CENTRAL AMERICA AND THE DOMINICAN REPUBLIC, THE
GUATEMALAN MINISTRY OF PUBLIC HEALTH ISSUED INVITATIONS
TO REGIONAL HEALTH AUTHORITIES TO ATTEND A MEETING
SEPTEMBER 17-19. THIS PROCESS WAS SUPPORTED
FINANCIALLY BY FEDEFARMA (FEDERACION CENTROAMERICANA DE
LABORATORIOS FARMACEUTICOS). UPON RECEIPT OF HIS
INVITATION, DR. EDUARDO HOWELLEMONT, SESPAS DIRECTOR OF
DRUGS AND PHARMACIES, PASSED IT TO INFADOMI, THE
ASSOCIATION REPRESENTING THE DOMINICAN NATIONAL (AND
FREQUENTLY PIRATE) LABORATORIES. INFADOMI HELD AN
EMOTIONAL PRESS CONFERENCE THE WEEK BEFORE THE
GUATEMALA MEETING CLAIMING THAT THE MULTINATIONAL
PHARMACEUTICAL COMPANIES (I.E. FEDEFARMA) WERE SEEKING
TO DISRUPT DOMINICAN DRUG SALES TO CENTRAL AMERICA. AS

A RESULT, THE GODR DID NOT SEND A REPRESENTATIVE TO A
MEETING WHICH WOULD SEEM TO HOLD INTEREST TO BOTH THE
HEALTH AUTHORITIES AND ALL SECTORS OF THE
PHARMACEUTICAL INDUSTRY.

INFADOMI ATTACKS NEWEST HEALTH CARE DECREE

6. INFADOMI HAS REPORTEDLY BEEN ACTIVE ON OTHER
FRONTS. ON APRIL 29, THE GODR ISSUED DECREE NO. 148-98
WHICH INTRODUCES SIGNIFICANT CHANGES IN THE PROCESS FOR
OBTAINING HEALTH REGISTRATIONS FOR PHARMACEUTICAL
PRODUCTS AS WELL AS ESTABLISHING NATIONAL STANDARDS FOR
THE MANUFACTURE AND IMPORTATION OF PHARMACEUTICAL
PRODUCTS. THE DECREE WAS WELL-RECEIVED BECAUSE OF
QUESTIONS RAISED ABOUT THE QUALITY OF CERTAIN DRUGS ON
THE DOMINICAN MARKET. INFORMED EMBOFFS.
HOWEVER, THAT INFADOMI SOUGHT THROUGH THE COMMISSION
FOR THE REFORM OF THE STATE TO MAKE UNILATERAL CHANGES
IN THE DECREE BEFORE IT WAS PUBLISHED IN THE OFFICIAL
GAZETTE, THE DOMINICAN EQUIVALENT TO THE FEDERAL
REGISTER. THE COMMISSION WAS REPORTEDLY SURPRISED TO
LEARN THERE WERE OTHER INTERESTS IN THE LOCAL
PHARMACEUTICAL INDUSTRY WHEN EFID (ASSOCIATION
REPRESENTING U.S. AND OTHER MULTINATIONAL
PHARMACEUTICAL COMPANIES IN THE DR) RAISED A BELATED
DISSSENT TO THE INFADOMI PROPOSAL.

7. (U) INFADOMI IS REPORTEDLY PRESSING THE COMMISSION
TO WEAKEN THE MANUFACTURING STANDARDS SET IN THE
DECREE. IT IS ALSO SEEKING TO ADD A REQUIREMENT THAT
IF A REQUEST FOR A HEALTH REGISTRATION IS NOT PROCESSED
BY SESPAS WITHIN 60 DAYS OF SUBMISSION, NATIONAL

Dept of State, RPS/IPS Margaret P. Garfield, Dir
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LABORATORIES WOULD BE AUTHORIZED TO SELL "SIMILAR" PRODUCTS.

8. [REDACTED] REPORTS THAT EFID HAS DECIDED TO PARTICIPATE IN THE PROCESS OF MODIFYING THE DECREE NOW ON-GOING BEFORE THE REFORM COMMISSION BECAUSE THE COMMISSION'S RECOMMENDATIONS WILL GO TO THE PRESIDENT WHETHER EFID PARTICIPATES OR NOT. [REDACTED] NOTES, "AT LEAST HE WILL RECEIVE A RECORD OF WHAT WE DIDN'T AGREE ON." THE PROCESS IS LIKELY TO BE A VERY SKEWED ONE HOWEVER, INFADOMI HAS RECRUITED SUPPORT FROM A NUMBER OF SMALL TRADE ASSOCIATIONS WHILE EFID IS LIKELY TO BE THE LONE VOICE ON THE OTHER SIDE BECAUSE OTHER IPR ASSOCIATIONS HAVE REFUSED TO PARTICIPATE IN A DEEPLY FLAWED PROCESS.

COMMENT

9. [REDACTED] THE EMBASSY PLANS TO INFORM INDIVIDUAL SENATORS ABOUT OUR CONCERNS ABOUT THE INTELLECTUAL PROPERTY LEGISLATION. WATT

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