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TAGS: ETRD KIPR ECON UP
SUBJECT: UKRAINE CONTINUES DIALOGUE WITH PHARMACEUTICAL INDUSTRY ON IPR ISSUES

REFS: A) KYIV 456

B) KYIV 110
C) 2007 KYIV 2865
D) 2007 KYIV 1780
E) 2007 KYIV 1452

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1. (SBU) Summary: The GOU held a public roundtable on May 28 to discuss IPR enforcement issues of importance to the pharmaceutical industry. GOU reps said they were now implementing the data exclusivity provisions agreed to as part of Ukraine's accession to the WTO, but admitted that generic drugs were sometimes still able to improperly receive market approval. There was some dispute over the role that executive branch agencies should be playing in regulating pharmaceutical approvals as opposed to the judiciary, but the GOU committed to do what it could to bolster enforcement. End Summary.

2. (U) EconOff attended a May 28 roundtable entitled "Legal Enforcement and Protection of Medicines," hosted by the State Department of Intellectual Property (SDIP), Ukraine's lead agency for intellectual property rights (IPR) issues. The roundtable brought together officials from SDIP, the Ministry of Health, and the State Pharmacological Center -- responsible for registering new pharmaceutical drugs (i.e. granting market approval) -- with representatives of the pharmaceutical industry, mostly local patent lawyers employed by large international firms. The event was a follow-up to a November 2007 meeting of the U.S.-Ukraine Enforcement Cooperation Group (ECG) that focused on similar issues (ref C).

Enforcing WTO Rules...
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3. (U) Volodymyr Dmytryshyn, SDIP Deputy Chairman, emphasized the importance of improving IPR enforcement in the pharmaceutical sector in order to both protect the rights of companies operating in Ukraine and to ensure that Ukrainians have access to safe, quality medicines. Dmytryshyn and Olga Baula, 1st Deputy Chairperson of the State Pharmacological Center, noted Ukraine's accession to

the WTO on May 16 and said that the GOU was now enforcing the five-year data exclusivity provisions agreed to as part of WTO accession negotiations.

4. (SBU) Baula said that the State Pharmacological Center was doing its best to make its drug registration system as transparent as possible, noting that new applications were now publicly available on the internet. (Note: Poor access to applications had previously been a primary complaint of pharmaceutical companies. End note.) She added that the State Pharmacological Center was trying to develop a cadre of its own experts, recognizing that the current situation, with some of its staff working part-time in the private sector, created the potential for a conflict of interests.

... But a Data Exclusivity Loophole Remains
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5. (U) Baula admitted, however, that a problem remained in the enforcement of the data exclusivity provisions. She said that generic producers were occasionally beating the original manufacturer to the Ukrainian market with applications to register their drugs. In such cases, said Baula, with no application from the innovative drug producer on file, the generic would be registered even though its clinical test data would presumably come from a third party, and the five-year data exclusivity period could not be enforced. Michael Doubinsky, a well-respected patent attorney who often advises the GOU, noted that other countries, including Russia, had tackled such problems and argued that Ukraine needed to make systematic changes to ensure that a generic drug could not get registered by the State Pharmacological Center before the original.

Patent Linkage Also Needs Strengthening
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6. (U) Doubinsky added that, despite the improvements made as part of WTO accession, there was still a gap between

patent applications and pharmaceutical registration rules. Too often a generic drug was able to improperly receive market approval when the patent of the original producer was still valid, said Doubinsky. Baula responded that the State Pharmacological Center was not responsible for verifying the validity of patents, a task that fell to SDIP and the courts, before registering a drug.

Reliance on Courts?
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7. (U) Doubinsky argued that relying on court litigation was not an efficient strategy, as patent cases often lasted as long as three years, and companies were loath to file a case against the State Pharmacological Center for fear of upsetting the principal government regulator. Iryna Vasylenko, Head of SDIP's Legal Division, noted that courts

officially had up to 1,460 days to rule on a patent case and that some judges still lacked the necessary expertise.

8. (SBU) One local patent attorney criticized the USG for pressuring GOU agencies to defend the IP rights of U.S. pharmaceutical companies; such companies, he said, should use the Ukrainian court system. EconOff responded that, while the USG was calling on Ukraine to improve protection of IP rights, it was up to Ukraine to decide how best to do so. EconOff recognized that courts should play an important, although not solitary, role.

Comment: Signs of Progress
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9. (U) That the GOU is now initiating public discussions with industry to explore how to improve IPR enforcement testifies to Ukraine's real progress over the last few years. Ukraine's system of granting market access to pharmaceutical drugs remains imperfect, but the GOU appears serious about improving it. Dmytryshyn, for example, said in his closing statements that the GOU recognized "the gap" between patent approvals and pharmaceutical registration and would work to eliminate it.

10. (SBU) Contrary to the criticism directed at the USG, Post has long recognized the critical role of the courts in bolstering IPR enforcement and has targeted much of its IPR technical assistance on training Ukrainian judges (refs A-B, D-E). Unfortunately, however, defending IP rights in Ukrainian courts remains costly, lengthy, and risky, as many judges lack the expertise needed to properly adjudicate IPR cases, and as corruption in the courts is still widespread. Post believes that the path to enhanced IPR enforcement lies in improving the performance of both the relevant GOU agencies and the courts.

TAYLOR