

► ENFORCEMENT RESULTS ◀

Taiwan Upgraded to “Watch List” Country According to the Announcement of the US Special 301 Out-Of-Cycle Review Results

The Office of the United States Trade Representative (the “USTR”) announced the annual special 301 “out-of-cycle review” results on January 19, 2005 (U.S. Eastern Time: January 18, 2005). According to these results, Taiwan is upgraded from a “Priority Watch List” country to a “Watch List” country¹. This indicates the USTR’s recognition of Taiwan’s active efforts in resolving the issues of piracy and counterfeiting, and the various measures for intellectual property rights protection, on which the U.S. has long expressed its concerns. On May 3, 2004, in announcing the Special 301 Lists for year 2004, the USTR listed Taiwan and fourteen other trading partners as “Priority Watch List” countries; of which Taiwan, Portland and Malaysia are listed as targets for out-of-cycle reviews, in order

¹ Note: The USTR classifies countries that provide insufficient protection in intellectual property rights into three different classes: “Priority Foreign Countries,” “Priority Watch List,” and “Watch List.” For “Priority Foreign Countries,” the U.S. will conduct negotiations with such countries within six months. If no agreements can be reached after the negotiations, the U.S. will adopt relevant trade sanction measures. For “Priority Watch List” or “Watch List” countries, there will be no instant encounters on any retaliatory measures or instant requests for counseling, unless any further serious violation against intellectual property rights is found. In addition, if the U.S. considers that certain countries in a given year require another review, such countries will be additionally listed as the “out-of-circle review” targets. As to the countries supervised under the “Section 306 Monitoring”, according to the Trade Act of the U.S., if any violation against the bilateral agreements on intellectual property rights protection entered into with the U.S. occurs, and no actions are carried out to improve the intellectual property rights protection environment pursuant to the commitments made, the U.S. may from time to time initiate a trade sanction without conducting a new investigation or counseling.

to assess their respective intellectual property protection status and progress in the fall season of 2004. The result of this out-of-cycle review marks the first time that Taiwan is upgraded to a “Watch List” country ever since Taiwan was listed as a “Priority Watch List” country for four consecutive years from 2001.

Since Taiwan’s accession to the World Trade Organization (the “WTO”) in 2002, Taiwan has performed most of its accession commitments, including abiding by various WTO agreements, regularly reviewing domestic laws, regulations and measures for compliance and making appropriate amendments. For the past year or so, the Taiwan government has expended substantial efforts on intellectual property rights protection. The Ministry of Economic Affairs (the “MOEA”) and each of its relevant agents and units continue to implement the action plans on intellectual property rights protection, and to combine the resources of the prosecutors, police, investigators and each of its departments for injecting them with full strength into various tasks on intellectual property rights protection, whether on legislation amendments, counterfeit and piracy crackdowns, border control enhancements and promotional and educational expansions, which are noticeable and concrete achievements. These achievements include the following: Taiwan completes a further amendment of its Copyright Law on August 24, 2004; the Intellectual Property Rights Protection Squad prepares to set up an intellectual property rights training school; and Judicial Yuan sets up an intellectual property rights professional court. The results of these endeavors have all received high recognition from the U.S. government, the rights groups and among the industries.

In 2005, Taiwan will continue to enhance each protection task in intellectual property rights and to further improve the following items that the U.S. have expressed concerns: preventing medicine testing material from unfair commercial use (Legislative Yuan passed the third reading on January 21, 2005 for the amendments to Article 40-1 and addition of Article 40-2 of Pharmaceutical Affairs Law), striking copyright infringement activities on the Internet, enhancing enforcements to effectively reduce piracy and counterfeit activities. These tasks are to implement in full scale Taiwan government’s determination to

protect intellectual property rights in order for the U.S. to remove Taiwan entirely from the Special 301 Lists when the Special 301 Report for 2005 is scheduled to announce in early May 2005.

Lastly, the MOEA emphasized that protecting intellectual property rights is not merely the international responsibility Taiwan should bear, at the same time, it also concerns the upgrading of Taiwan industries and increasing their global competitiveness. In addition, such is the foundation for Taiwan to continue its developments in the knowledge economy and information technology era. The MOEA will continue to coordinate with the relevant agencies and fully cooperate in the follow-up of the intellectual property rights protection tasks, so as to establish a sound intellectual property rights protection environment for Taiwan.

► ENFORCEMENT MEASURES ◀

The Intellectual Property Court will be Designed on a “Two-in-One by Physics Approach” basis, which Combines Administrative Litigation and Civil Litigation

According to a Commercial Times report on January 12, 2005, in order to accelerate the establishment of the “Intellectual Property Court,” the Judicial Yuan has recently prepared the “Draft Intellectual Property Court Act,” and will hold a counseling conference to solicit advices and comments to render the draft proposal more suitable.

The draft Act is to combine the current administrative litigation and civil litigation in trademark and patent systems “two-in-one” for structuring the “Intellectual Property Court Act,” which tentatively excludes criminal litigation. In addition, the “Intellectual Property Court” hierarchy is set for first instance to be in high court and appeal will go to supreme court. During the initial stage, the “Intellectual Property Court” will only be set up in Taipei, and tentatively there are no plans to establish branch courts in the South.

As the “Intellectual Property Court” tries to incorporate both administrative litigation and civil litigation in its establishment, there are still different opinions on whether it should adopt a “Two-in-One by Physics Approach” or a “Two-in-One by Chemistry Approach.” Nevertheless, it is very likely that the Judicial Yuan will adopt the “Two-in-One by Physics Approach” first at the initial stage.

According to Chen Tson-Gen, Chief of Department of Administration, the Judicial Yuan, the so-called “Two-in One by Physics Approach” means that within the “Intellectual Property

Court,” administrative litigation and civil litigation are conducted separately. On formality, it appears no different from the current system. However, as it is under the jurisdiction of the same court, the process of litigation procedure may be designed as follows: prior to finalization of the patent administrative litigation, the civil litigation proceeding is automatically stayed until patent ownership is determined in the administrative litigation, and civil litigation may proceed immediately thereafter. In terms of litigation efficiency, this new approach will be more economical than the current system where two different courts exercise separate jurisdiction.

Materials from:

<http://news.chinatimes.com/Chinatimes/newslist/newslist-content/0,3546,120507+122005011200475,00.html>

► LAWS AND REGULATIONS ◀

New “Customs Anti-Smuggling Statute” Strengthens Intellectual Property Rights Protection

According to the newly added Article 39-1 of the Customs Anti-Smuggling Statute promulgated by the President on January 19, 2005, where imported/exported goods clearing customs, or imported/exported goods carried by the travelers or via postal services infringe patent, trademark or copyright (excluding parallel imports of genuine goods), a fine shall be imposed at one to three times the price of the goods, and such goods shall be confiscated.

In addition, in order to discourage the illegitimate dealers from evading the inspections conducted by the customs on the goods to be exported by ways of falsifying goods names, tariffs, non-reporting, concealment and submitting untrue certifying documents in order to export stolen vehicles and counterfeits, fraudulently filing for business tax return, passing-off waste disposals as textile materials exported for reprocessing, the amendments made this time increased the maximum fine for such illegal conducts from NT\$ 30,000 to NT\$1 million under Paragraph 2 of Article 37. The Directorate General of Customs (the “DGOC”) further emphasized the customs’ determination to combat illegal conducts. From now on, once an illegal export case is discovered, a fine up to a maximum of NT\$3 million may be imposed depending the circumstances of each case. Further, the goods involved may be confiscated.

The DGOC expressed that to fully implement the intellectual property rights protection is one of the government’s key policy implementation goals. In the mean time, as the USTR upgrades Taiwan from a 301 Priority Watch List country to a Watch List country, Taiwan customs will further strengthen

enforcing border control measures for intellectual property rights protection to deter major violations from occurring, so as to enhance Taiwan's international image overall.

For details of the above-mentioned amended articles (in Chinese), please go to:
<http://law.moj.gov.tw/fn/fn4.asp?id=26059>

The Amendments to the "Implementation Regulations for Suspension of Release of Goods Infringing on Copyright or Plate Right by Customs Authority" Promulgated

The MOEA and the Ministry of Finance (the "MOF") jointly announced on January 27, 2005 the amendments to Article 2, Article 3 and Article 5 of the "Implementation Regulations for Suspension of Release of Goods Infringing on Copyright or Plate Right by Customs Authority." These Implementations Regulations were first promulgated on June 8, 1998 and amended on March 20, 2002. The Copyright Law amended on September 1, 2004 added the provision of temporary suspension of release of goods by the customs authority. The Implementation Regulations are thus accordingly amended. A summary of the amendments is as follows:

1. Amending the basis for filing by copyright or plate right holders for suspension of release of imported or exported goods which infringe their copyright or plate right. Also added is the provision of other equivalent security when applying for suspension of release of good by customs.
2. Amending the review basis of applications for suspension of release of goods to be conducted by the customs.
3. Amending the basis of applications filed with the customs for inspecting the items suspended for release.

For the details of the above-mentioned amendments (in Chinese), please go to:
http://www.tipo.gov.tw/copyright/copyright_law/copyright_law_1_8.asp

After License for a New Drug of New Ingredients is Issued, a Five-Year Protection Period for Exclusive Data Right is Granted

In recent years, original drug developers in Europe and the U.S. have repeatedly appealed to the Department of Health (the "DOH") in the hope that Taiwan will soon implement the provisions of Article 39.3 under the Agreement on Trade-Related Aspects of Intellectual Property Rights (the "TRIPS") pursuant

to WTO spirits which is to provide a certain exclusive protection time period on the data of the new drug approved.

According to the partial amendments to the Pharmaceutical Affairs Law promulgated by the President on February 5, 2005 (see notes below), after license for a new drug of new ingredients is issued, a five-year protection period for exclusive data right is granted. Without the consent of the license holder, other drug manufacturers shall not refer to or quote the original drug's filing information in order to apply for registration. However, manufacturers of generic drugs (where patent terms expired or unprotected by patents) may commence submitting the application for registration from the third year, without waiting until the fifth year when the exclusive data protection term expires. Therefore, generic drug manufacturers may file the applications first, and the drugs may be marketed upon expiration of the five-year protection period.

In addition, in order for international new drugs of new ingredients to be introduced in Taiwan for use by Taiwan nationals, this new law also prescribes that an application for registration must be filed with DOH within three (3) years upon receiving marketing approval in a foreign country in order to be eligible for the foregoing exclusive protection.

After the said amendments are passed, the DOH has initiated the relevant peripheral measures to conduct communications, negotiations with industries in the hope to minimize the impacts from the high drug prices during data protection period and the postponed marketing schedules for generic drugs, so as to safeguard the development of domestic drug manufacturing industries and to promote national health.

Notes:

Article 40-1 of the Pharmaceutical Affairs Law (Amended)

For the purpose of protecting public interests, where necessary, the central competent health authority may disclose information owned or deposited with regarding drug ingredients, usage instructions, or other related information as stated on applications for drug manufacture or importation by the pharmaceutical dealers. However, trade secrets as stated in the pharmaceutical dealers' applications for registration of new drugs shall be kept confidential.

Regulations regarding the scope and method of disclosure referred to in the preceding Paragraph shall be established by the central competent health authority.

Article 40-2 of the Pharmaceutical Affairs Law (Amended)

Regarding the issues of new drug license, the central competent health authority shall disclose the patent numbers or application numbers which are already disclosed and provided by the applicants.

Within five (5) years upon the issuance of a license for new drug of new ingredients, other drugs manufacturers shall not refer to or quote the said filing information to apply for registration without consent of the license owners.

After three (3) years upon the issuance of a license for new drug of new ingredients, other drug manufacturers may apply for registration of drugs of identical ingredients, identical dosage types, identical dosage volumes and identical units pursuant to the provisions of this Act and the relevant regulations regarding review on new drug registrations. If the relevant laws and regulations are complied with, a drug license may be issued on the date after five years from the issuance of license to a new drug of new ingredients.

Within three (3) years after a new drug of new ingredients receives marketing approval in a foreign country, an application for registration must be filed with the central competent health authority, in order for Paragraph 2 to apply *mutatis mutandis*.

The scope of new drug patents do not include the research, teaching or experiments carried on prior to the application for registration is filed by the drug manufacturer.

Amendments to “Science and Technology Basic Law” Promulgated on January 19, 2005

The Legislative Yuan passed the amendments to Article 5, Article 6 and Article 13 of “Science and Technology Basic Law” on December 24, 2004. Such Articles were further promulgated by the President on January 19, 2005. In the future, for research and development in science and technology conducted by public schools, public research units (institutions), juristic persons (corporations/foundations) or groups with government subsidies, irrespective of the amounts involved

thereof, unless treaties or agreements entered into by Taiwan provide otherwise, the Government Procurement Law shall not apply.

The above-mentioned amendments, in relation to intellectual property rights, will broaden the promotion and implementation of research and development results in science and technology with government subsidies. In addition, such amendments will make research and development cases in science and technology with government subsidies more flexible, which would help upgrade Taiwan’s international competitiveness in science and technology development.

For the amendments please refer to:

<http://law.moj.gov.tw/fn/fn4.asp?id=26090>

Taiwan Protects Aborigines Traditional Intellectual Creation by Law

The President announced the “Aborigines Basic Law” on February 5, 2005 which was promulgated on the same date. Taiwan hopes to “safeguard the aborigines basic rights, promote aborigines survival and development, and establish a co-existing ethnic group relationship” by this Law.

Article 12 of the above-mentioned law which concerns intellectual property rights states that “The government shall protect and promote the development on bio-diversified knowledge and intellectual creation of the aboriginal tradition. The relevant matters shall be enacted by other laws.” Such legislation signifies that Taiwan officially commits itself in protecting, by law, the aborigines traditional intellectual creation. In addition, the “Aborigines Traditional Intellectual Creation Protection Code” and other relevant legislative tasks have also been actively pursued.

For details of the “Aborigines Traditional Intellectual Creation Protection Code” (in Chinese), please go to:

<http://law.moj.gov.tw/fn/fn4.asp?id=26441>

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