

security system. It has performed an important social-policy function for the past 36 years. Investment-linked insurance products serve the same purposes as the traditional life products and have become an increasingly important component of Taiwanese retirement planning due to such products' ability to offer insurance coverage while allowing policyholders to determine their own investment portfolios. At a time when it is in the interest of society to encourage more citizens to engage in long-term saving for their old age, the TRC's proposal would have the contrary result of discouraging people from including investment-linked products in their retirement plans.

Most investment-linked products are linked to mutual funds. Since the capital gain from mutual funds and listed shares are currently not subject to income tax, there is no reason to give different treatment to investment-linked insurance products. Indeed, all life and annuity products, including investment-linked products, are already subject to Alternative Minimum Tax and should not be further subject to an extra income tax. Particularly when the market has been suffering from extreme volatility, it is unclear why the Executive Yuan would wish to support short-term mutual-fund trading over long-term mutual-fund investing.

In most international markets, in addition, unit-linked contracts that meet certain defined criteria are usually taxed as life insurance. The FSC has already required that investment-linked products provide at least a minimum level of insurance coverage; therefore such products are not purely for investment purposes and should be treated as life insurance.

Investment proceeds accrued in the investment account serve the purpose of funding the insurance protection and are an integral part of the life insurance payment. According to the current Income Tax Act, Estate and Gift Tax Act, and Insurance Act, insurance payments are exempted from income tax and estate tax. Imposing income tax on the investment account of investment-linked insurance products or estate tax on the death benefits thereof would therefore be contrary to existing law. Should the government decide to take a different approach towards insurance product taxation, it would need to go through the legislative process to revise the laws.

Finally, from a customer perspective, it is important that policyholders have the option of a separate account for investment-link products as it provides an added layer of financial security; otherwise customers could lose their savings to other general creditors if an insurer were to fail. Removing this option would deprive consumers of an important element of protection.

For all these reasons, we strongly encourage the TRC to reconsider its position and to support tax policy that will better meet the growing retirement needs of this aging society.

#### **Issue 4: Amend the Labor Pension Act allow more market-appropriate options for employees.**

The Committee appreciates the IB's coordination with

the Council of Labor Affairs (CLA) to seek removal of requirements in the Labor Pension Act that restrict life insurers from offering attractive annuity products to Taiwan's workforce. These requirements are: a) a threshold company size of 200 employees, b) the stipulation that at least 50% of employees give their consent, and c) a guaranteed minimum return set at the two-year time-deposit rate.

We commend the CLA for considering granting employees the option of investing some or all of the "voluntary" portion of their contributions in asset classes that would be expected to provide greater returns over the long run – and hope that this privilege could be extended to regular (non-voluntary contributions) for those with a longer-term investment horizon. It is well-accepted, sound advice that individuals with at least 10 years to go until retirement should consider investing in equities, fixed-income instruments, and other riskier assets that promise returns far above traditional bank-deposit rates. Other Asian countries adopted such an approach long ago. Despite the current economic situation, when markets around the world recover, they can be expected to once again provide opportunities for superior returns.

The committee urges the IB to continue to coordinate with the CLA to remove the above-mentioned barriers so as to allow Taiwan's workforce to benefit from annuity products.

## **INTELLECTUAL PROPERTY & LICENSING**

Intellectual property rights concerns have often been at or near the top of the advocacy agenda of AmCham Taipei. We have been sufficiently impressed with the progress over the past few years, and with the good will shown by the key agencies involved, that the Chamber endorsed Taiwan's removal from the Special 301 Watch List when USTR prepared its 2008 report. We expressed this strong support during both the annual review and the subsequent out-of-cycle review that finally resulted in Taiwan being removed from the Watch List earlier this year.

We have noted over the past year that Taiwan has continued to strengthen its IPR protection. In particular, establishment of the Intellectual Property Court in July 2008 marked a major milestone for Taiwan's IPR protection. Internet piracy was dealt a serious blow through the passage of the ISP (Internet Service Provider) bill by the Legislative Yuan in April, and the speedy promulgation of that bill by the President in May. We have also seen beneficial reviews of the Trademark, Copyright, Fair Trade, and Patent Laws, and of regulations pertaining to compulsory licensing, which will result in revisions of these laws and regulations.

The Intellectual Property Task Forces and the National Police Administration have maintained a high level of action to investigate and bring to justice those involved in the counterfeiting and piracy of goods. Previously AmCham had raised concerns about the growing use of the Internet

as a distribution platform for counterfeit and pirated goods, but over the past few years the Taiwan authorities have successfully taken action against hundreds of Internet sales and auctions sites that were in violation.

Campus-related copyright infringement has been one of our main concerns for the past several years. Enforcement against piracy activity on the Ministry of Education (MOE)-sponsored Internet service provider TANet (for Taiwan Academic Network) has much improved, as has enforcement against the unauthorized use of copyrighted material on or near universities. The MOE has also organized a far-reaching awareness program for students and faculty.

Despite this progress, further improvement is still needed in certain areas. Last year's passage of a P2P Protection Act and this year's passage of the ISP bill promises to bring significant protection regarding the uploading and downloading of copyrighted works. The Committee looks forward to the implementation of the two bills, but hopes the government ensures that the administrative agency handling enforcement of the laws has the necessary mandate and resources to effectively monitor the industry and enforce regulations.

Internet piracy of optical media remains a problem. The software industry continues to suffer from "end-user piracy" – the unauthorized copying, distributing, or under-licensing of software by users in government and commercial settings. The software industry has found, for example, that while piracy levels dropped in 2008, monetary losses actually increased, evidencing the increased scope of the problem (as well as the increased size of the market, both legitimate and pirated). An International Data Corp. study in 2008 estimated that reducing software piracy in Taiwan by 10 percentage points would add US\$400 million to GDP and US\$40 million in tax revenue.

The Committee urges the Taiwan government to focus on the following areas in the coming year:

#### **Issue 1: Improve remedies for trade-dress violations.**

The Committee continues to call on the Taiwan government to find better remedies to the continued problems of passing-off or other trade-dress violations. The enforcement and judicial jurisdiction of these trademark abuses are not clearly established in Taiwan. As a result, trademark owners are left with few enforcement alternatives. While the Fair Trade Law does, in theory, cover these abuses, in reality it is rendered ineffective in this regard due to the lack of an enforcement mechanism, the absence of discovery through search and seizure, and the inadequate hearing process at the understaffed Fair Trade Commission. Attempts to use the judicial system to seek redress through existing trademark law often result in jurisdictional issues that complicate the cases for law-enforcement authorities and the courts. The reviews currently being undertaken of the Trademark Law and Fair Trade Law should provide an excellent opportunity to devise a solution to this problem.

#### **Issue 2: Improve judicial treatment of IP cases.**

The Committee reiterates the position taken in *White Paper* submissions over the last 10 years that Taiwan courts hamper enforcement of IP laws by letting off most convicted IP offenders with light, suspended sentences and low fines. With the current level of sentencing, counterfeiters have come to view being taken to court as merely a manageable cost of doing business. As matters now stand, the financial incentives to engage in counterfeiting far outweigh the risk of severe punishment. Counterfeiting can be deterred by removing the motivation for counterfeiting – profits. Once counterfeiting is unprofitable, it will diminish.

The Committee strongly urges the Ministry of Justice and the Judicial Yuan to continue IPR educational and training programs for prosecutors and judges, and to issue procedural and sentencing guidelines along the following lines:

- A. As allowed in the revised Trademark, Patent, Copyright, and Fair Trade Laws, impose steeper fines on convicted infringers than are currently the norm.
- B. Give stiffer sentencing in cases involving risk to public health, as with contraband or counterfeit pharmaceuticals and agro-chemicals. The Trademark Law, the 2004 revision of the Pharmaceutical Affairs Law, and the Pesticide Administrative Law provide tools for heavier punishment for those found guilty of the manufacture, import, or sale of these counterfeit and contraband products.
- C. Broaden the scope of seizures made in IPR crimes. Law-enforcement authorities should be instructed to seize a broader range of sales documentation during IPR raids, for later review, along with production, distribution, and sales equipment. Depriving offenders of the means of making, distributing, or selling counterfeit products will deter future counterfeiting and serve to increase the cost of criminal acts to levels that would-be infringers will find unacceptable.

The Committee also encourages changes in the Civil Code to allow for effective mechanisms for statutory damages and discovery in civil cases, and a recognition that IP rights-holders have a right to recover the costs of enforcement.

#### **Issue 3: Reconsider proposed amendments to the Copyright Act.**

The Committee is concerned about two proposed amendments to the Copyright Act that have been drafted by the Taiwan Intellectual Property Office (TIPO).

1. Article 37bis. According to the draft, both domestic and foreign rights-holders of sounds, music, videos, films, etc. will be required to join a copyright collection society in order to collect royalties from those who publicly rebroadcast, perform, or present their works. Participation in such societies, for which TIPO is authorized to set the licensing fee structure, is currently voluntary. In proposing the amendment, TIPO appears to be responding to complaints from restaurants, retail

stores, coffee shops, hotels, and other establishments regarding licensing conditions for the rebroadcast or public performance and presentation of music and images. TIPO cites several foreign laws and treaties as the precedent for the proposed revision, but we believe its draft is based on an inaccurate interpretation of those sources. Should the amendment be enacted, the result would be to unreasonably restrict rights-holders in the execution of their copyrights, a clear violation of the doctrine of fair treatment stipulated in the WTO's TRIPS agreement (Trade-Related Aspects of Intellectual Property Rights). For that reason, we strongly oppose this draft amendment and ask TIPO not to seek its passage.

2. Article 71bis. This amendment would simplify the licensing process and require rights-holders to exercise their rights through copyright collection societies in the case of use of their copyrighted works by radio and TV stations. The amendment would give TIPO the right to intervene in the negotiation of a copyright license and even to decide the amount of the license fee/compensation. It appears to re-introduce – this time in the context of radio and TV broadcasting and simulcasting – the concept of compulsory licensing that was the subject of considerable controversy several years ago.

If the amendment is passed, radio and TV stations would no longer need to bargain seriously with rights-holders, but rather would be inclined to wait for negotiations to fail and then apply for a compulsory license. This would severely jeopardize the interests of copyright owners who prefer to collect fees directly rather than join a collection society. The result would be a significant step backward in the development of copyright licensing in Taiwan. Compulsory licensing, which inevitably undermines rights-holders basic interests, should be an exceptional practice reserved for extraordinary circumstances; its scope should be as narrow as possible. Extending that scope to radio and TV broadcasting and simulcasting would potentially constitute a serious violation of the TRIPS principle of fair treatment. We vigorously oppose this draft amendment.

#### **Issue 4: Tighten Customs procedures against counterfeit goods.**

As Taiwan seeks to further open up cross-Strait travel and transportation, it is increasingly important for the Customs Administration to serve as an effective gatekeeper to keep out counterfeit and/or contraband goods. Procedures for customs inspection and seizures need to be broadened, simplified, and streamlined.

Under current Customs procedures, little or no information about infringers is made available to rights-holders when seizures take place. By not sharing information and developing cooperation with rights-holders, Customs and other law-enforcement bodies are losing an opportunity to gain better knowledge of infringer networks, and thereby to improve deterrence.

In addition, a significant amount of trade in counterfeit and pirated goods is carried out daily through the mails. The Taiwan postal service's inspection system of packages for counterfeit goods is ineffectual, a deficiency that is being exploited by those who trade in counterfeited and pirated goods.

Customs should make better use of databases of suspected infringers as a weapon in fighting the trade in counterfeit and pirated goods. Senders and receivers of all counterfeit goods found during customs and postal inspections should be entered into this database and actively monitored. Coordination should be better established with the Judicial Yuan, TIPO, Ministry of Justice, Ministry of Interior, and Ministry of Finance (which has departments dealing with tobacco and spirits) so that the names of fined or convicted smugglers and those trading in counterfeit and pirated goods can be systematically added to the Customs database for future monitoring.

#### **Issue 5: Tackle the problem of end-user piracy.**

The software industry continues to suffer the most in Taiwan from “end-user piracy” – the unauthorized copying, distributing, or under-licensing of software by users in both private and public institutions. Indeed, while piracy levels dropped in 2008, losses actually increased, evidencing the increased scope of the problem (but also the increase in the overall size of the market – legitimate and pirate). Taiwan needs to take the following actions to decrease end-user piracy:

- A. Continued government programs to raise public awareness by pointing out the risks associated with using pirated software and encouraging the use of legitimate products. As reducing software piracy requires a fundamental shift in the public's attitude, public education is critical to achieving success. We commend the Taiwan government for its past efforts in this regard, and note that some of the most successful activity to reduce software piracy in Taiwan has involved comprehensive public education campaigns launched jointly by government and industry.
- B. Targeted actions, with follow-up prosecutions in appropriate cases to send a deterrent message and foster the use of legitimate software by businesses in Taiwan.
- C. Greater attention to the problem by government agencies, which are among the biggest users of business software. While governments generally have procurement policies in place for physical property, some government agencies, government contractors, and government employees do not always pay proper attention to software procurement procedures. As a result, the unauthorized use of business software in the public sector has become an endemic problem in Taiwan. We encourage the government to review current legislation, policies, and practices with an eye to promoting the use of legal software. Among those steps should be adding the use of proper software asset management (SAM) among the audit requirements for both public and private sector entities. We further

encourage an increased IT budget for purchasing legitimate software so that government units can set an example for the private sector in terms of IPR protection and the promotion of proper business practices.

#### **Issue 6: Step up enforcement against smuggled and counterfeit goods.**

A position stated annually in this *White Paper* is that the Department of Health and the Council of Agriculture need to establish more effective monitoring and enforcement of pharmacies and agro-chemical vendors, respectively, to better protect against smuggled and counterfeit goods. There should be an aggressive suspension of relevant licenses of those vendors found trading in contraband or counterfeit product.

The Committee also applauds actions taken by the Spirits and Tobacco Sections of the Treasury Bureau, Ministry of Finance, in targeting tobacco and spirits smuggling and counterfeiting at the local and distribution level. Their actions, however, are not enough. Millions of dollars in government and tax revenue is lost each year through sales of potentially unsafe products by these spirits and tobacco smugglers and counterfeiters.

In addition, we applaud the efforts, especially over the past few years, of the Intellectual Property Task Force and the National Police Agency on counterfeit and pirated goods. These organizations have, usually independently, taken hundreds of actions in the last year against on-line sales of counterfeit products. We are concerned that there appears to be less focus in the last three years, and far fewer actions, on shops, markets and street vendors of counterfeit and pirated products. We hope that these enforcements bodies will in the coming year orient more of their activities to the neglected areas.

#### **Issue 7: Continue to improve campus IPR protection.**

The Committee welcomes the efforts of the MOE and TIPO in jointly addressing concerns about campus IPR protection by holding publicity events and seminars at colleges and universities throughout 2008. We have been encouraged by the progress regarding two types of violations – the illegal copying of textbooks on campus and the illegal downloading of copyrighted material using the MOE-sponsored Internet service provider TANet – although further actions need to be taken to maintain the momentum.

We are encouraged by the MOE policy announced on November 25, 2008 that forbids (with certain exceptions subject to approval) the use of P2P file-sharing software on the TANet that could be used to download pirated software. A recent survey, however, indicated that more than 20 colleges and universities also subscribe to ADSL access services from private ISP providers for their faculty members and for students in dormitories. These ADSL users may not be covered by the MOE's monitoring of the use of illicit P2P software. The Committee therefore urges the MOE take all necessary steps to ensure that the abovementioned policy is also fully applied to ADSL users.

## **MEDICAL DEVICES**

The Committee is delighted that the relevant governmental agencies have responded positively to several of the issues we raised in the 2008 *Taiwan White Paper* and have taken appropriate action to improve the business environment in this industry. For example, the medical device section of the Bureau of National Health Insurance (BNHI) has worked closely with industry concerning the reclassification of special medical devices and on the price-cut issue. The Bureau of Pharmaceutical Affairs (BOPA) of the Department of Health (DOH) has provided us with needed assistance in developing registration guidelines for In Vitro Diagnostic Devices, specifying expiration dating on medical devices, and clarifying regulations and laws where necessary. We appreciate their efforts in making these needed changes. In addition, after several discussions with the Bureau of Foreign Trade and the Industrial Development Bureau, both under the Ministry of Economic Affairs, selected medical devices manufactured by international companies in China are now allowed to be imported. This regulatory revision helps to align Taiwan with the global market.

Nevertheless, as several other issues still remain unresolved, it is important that this kind of positive collaboration between government and industry continue. The outstanding issues include the need for an independent regulatory agency with specific sets of regulations governing medical devices, establishment of guidelines for the review and management of direct-to-consumer advertising, greater openness and communication with industry in setting reimbursement procedures, and permission to import additional medical devices made by multinational firms in China.

Below, we present detailed recommendations concerning these issues.

#### **Issue 1: Create an independent regulatory body and regulations for medical devices.**

While specific regulatory agencies and laws are in place for medical devices in the United States and the European Union, in Taiwan the review and regulation of medical devices comes under the jurisdiction of BOPA and the governing statute is the Pharmaceutical Law. The need for a separate law and oversight unit for medical devices is clear. The medical device industry is fundamentally different from drug manufacturing, and cannot be effectively managed by an agency whose expertise is in drug regulation and by a law borrowed from another industry and then modified.

For the sake of the medical device industry's growth and development, the Committee welcomes the plan to establish a new agency under the DOH, the Taiwan Food and Drug Administration (TFDA), as an opportunity to place the regulation of medical devices on a more specialized and rational basis. In this regard, we hope that the TFDA will follow the organizational model of the U.S. FDA so as to ensure effective management. Along with this change,