Taiwan
Biotech Take-Off Plan and new rules

Taiwan's Executive *Yuan* announced its Biotech Take-Off Diamond Plan in 2009. The strategic plan is designed to strengthen trust in the infrastructure of IP protection through world-class expertise in integrating electronics and semiconductors, and to transform Taiwan into a regional hub for biotech research and development (R&D), manufacturing and operations. This strategic plan aims to provide an efficient mechanism to ease the transition between research and pre-clinical development for new drugs and medical devices. Under the plan, a biotech venture capital fund of $1.76 billion, the so-called 'mega fund', has been established for start-ups. In addition, several changes have been made to IP regulations and infrastructures in Taiwan in order to ensure good IP practice in Taiwan, especially in the field of biotechnology.

The new Food and Drug Administration

Organisational integration

As part of the Biotech Take-Off Plan, the new Food and Drug Administration (FDA) officially became operational on January 1 2010. The new FDA integrates the previous functions of the Bureau of Food Safety, the Bureau of Pharmaceutical Affairs, the Bureau of Food and Drug Analysis and the National Bureau of Controlled Drugs. It will have a staff of 505, 100 of whom will be newly recruited exclusively to perform food safety inspections at points of entry into the country. The Bureau of Standards, Metrology and Inspection, under the Ministry of Economic Affairs, is currently responsible for inspecting the safety of imported food. However, in order to strengthen Taiwan's food safety control in response to the controversy over melamine-tainted dairy products from China in 2008, this function will transfer to the new FDA when its new staff are recruited in 2011.

It has also announced that the non-profit Department of Health-authorised Centre for Drug Evaluation (CDE), which provides support in screening applications for new drugs before they are approved for sale, will be merged into the new FDA, together with four other agencies. The CDE was established by the Department of Health on July 13 1998. Under the delegation and commission of the department, the CDE:

- evaluates new drugs and new medical devices for regulatory requirements;
- offers related consultation services; and
- makes timely recommendations to meet the needs of policy development.

Functional improvement through integration

By integrating the functions of different bureaus or institutes from the Department of Health and the Ministry of Economic Affairs, the government hopes that the new FDA will:

- strengthen control over consumer safety;
- provide speedier, more sophisticated and integrated services to drugs and medical devices manufacturer applicants; and
- help to develop Taiwan's bio-medical industry.

The IP Court

Taiwan's IP Court has been operational since July 1 2008. This specialised court hears civil, criminal and administrative cases involving IP disputes.

Solving the double-track system

Prior to the IP Court, patent infringement cases in Taiwan were determined under a 'double-track system'. This involved civil courts hearing patent infringement cases, yet having no authority to pronounce on invalidity defences; these were determined exclusively by administrative authorities, including the Taiwan IP Office, the IP Office's Administrative Appeal Commission, the Administrative High Court and the Administrative Supreme Court. Without the authority to determine whether the disputed patent was invalid, the civil courts often stayed infringement suits pending a final decision from the administrative authorities on the issue of invalidity. As a result, patent infringement

cases were often criticised for being too time-consuming and failing to result in damage payments.

In response to these problems, part of the 2008 reforms involved appointing examination officers to the IP Court. As experts in science and technology, these officers have the power and authority to:

- clarify the disputes in question;
- ask questions directly to witnesses or verification experts;
- state opinions on the case to the judge; and
- assist in gathering and preserving evidence.

The double-track system has also been revised so that the IP Court can rule on invalidity defences, if these are raised by the defendants, based on the merits of the case. Henceforth, the IP Court should not stay a case pending a final decision on validity issues from the administrative authorities. In cases where the alleged infringed patents or claims are found invalid by the IP Court, the patentees cannot use such patents or claims against the opposing party.

Early results from the IP Court

There are 10 judges and 10 examination officers at the IP Court. The IP Court judges are well trained in IP law and practice, while the examination officers assist the court in understanding and clarifying the technical issues involved in IP cases. The examination officers' opinions cannot be adopted as evidence in the litigation unless they are reviewed by the IP Court under the principles and rules of evidence. However, the system of incorporating both examination officers and professional judges seems to be having positive effects on IP litigation with respect to both the quality and speed of adjudication.

Before the 2008 reforms, on average it took the High Court 684 days to close a civil patent suit. After the reform, this amount of time was reduced to 155 days at first instance and 149 days at second instance. According to the official reports, the average number of days to close a case in the IP Court from July 2008 to June 2009 is shown in Figure 1.

The state of filings and dispositions handled from July 2008 to June 2009 is shown in Figure 2.

The cases heard before the IP Court from July 1 2008 to April 30 2010 are shown in Figure 3.

Amendments to pharmaceutical and biotechnology patents

In order to improve Taiwan's patent practice and to facilitate future development in the biotech industry, the IP Office has been working on amendments to the Patent Act in order to provide an appropriate legal infrastructure and environment for industrial development. The last proposed bill of the Patent Act Amendment was passed by the Executive *Yuan* on December 3 2009.

Pre-trial exemption

The current Patent Act sets out certain exemptions from patent infringement for the purposes of non-profit research, education or experiment. In order to encourage

Figure 1: Number of days to close a case

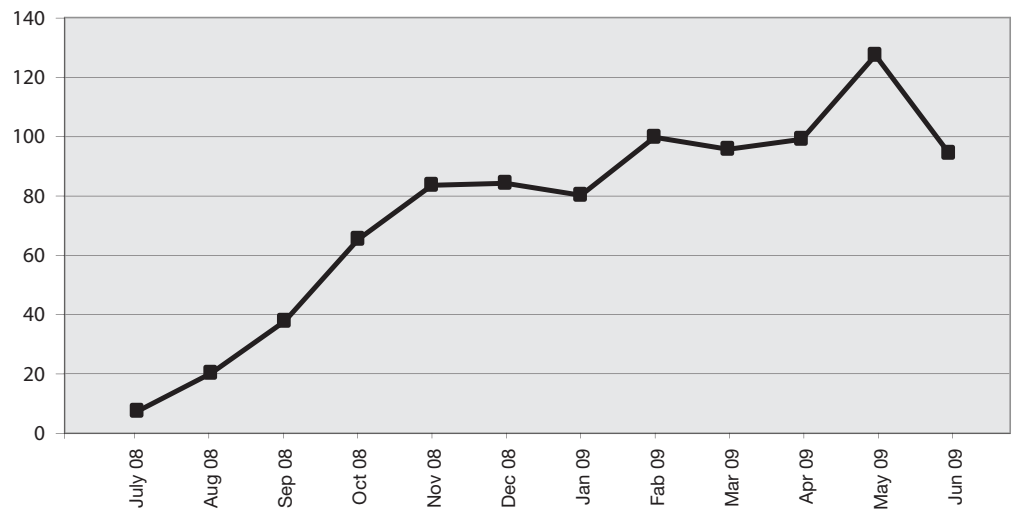
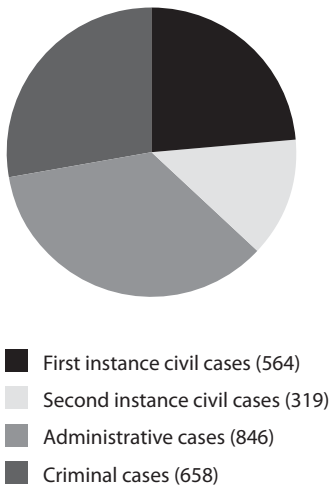


Figure 2: State of filings and dispositions handled

Case type	Cases lodged		Cases closed	Pending cases	Rate of closed cases (%)
	Total	Newly lodged			
Total	1,480	1,480	1,025	455	69.26
First instance civil cases	414	414	303	111	73.19
Second instance civil cases	233	233	150	83	64.38
Criminal cases	366	366	366	275	75.14
Administrative cases	467	467	297	170	63.60

Figure 3: Cases heard before the IP Court



the development of generic drugs and to promote public health, the draft act would extend the scope of such exemptions to cover research, experiment and any necessary behaviour designed to obtain a marketing registration in accordance with the Pharmaceutical Affairs Act. This is an effective response to the need for pre-approval trials of generic drugs before the patent expiration of brand name drugs and would address the difficulties in proving the non-profit nature of pre-approval trials. These exemptions will also apply to research and experimentation carried out to obtain marketing approvals in foreign countries.

Extension of patent terms

The current Patent Act allows the patentee to apply for a two to five-year extension of the patent term in cases where the governmental approval process for their pharmaceuticals or agrichemicals (and related processes) would take over two years from the patent's publication. The draft act would eliminate the current minimum requirement of two-year governmental approval process time. Further, the extension term for which patentees could apply would be based only on the first government approval time. The extended patent scope would be limited to the effective ingredient plus its indication, as proposed at the first government approval.

The patentability of animals and plants

In order to promote the biotechnology industry, the draft act would allow animals and plants to be patented. It is believed that allowing a monopoly on technology for animals and plants would not adversely impact the development of traditional industries, because the patentability of animals and plants will be accompanied by existing regulations on the exhaustion of rights, compulsory licences, and exemptions for non-commercial private use, experimental conduct and farmers.

The Cross-Strait Agreement on IP Rights Protection

As trade across the Taiwan Strait increases, IP rights protection has become increasingly important. On June 29 2010 Taiwan and China, both members of the World Trade Organisation, signed the Economic Cooperation Framework Agreement. This is analogous to a free trade agreement but has been used for the special relationship

between Taiwan and China. On the same day, both countries signed the Cross-Strait Agreement on IP Rights Protection. The agreement is independent of the Economic Cooperation Framework Agreement, so it will continue to have effect even if the latter is terminated.

Coverage of the Cross-Strait Agreement on IP Rights Protection

The Cross-Strait Agreement on IP Rights Protection creates a mechanism for resolving IP disputes between both sides. Through it, both Taiwan and China have agreed to implement mechanisms for the competent authorities to strengthen exchanges in IP affairs, settle examination differences and handle IP-related problems effectively. Under this agreement, IP protection-related agencies on both sides of the strait will be in charge of the dispute resolution process. In Taiwan, the IP Office will supervise the cross-strait protection of trademarks, patents and copyrights, while the Council of Agriculture will be responsible for the protection of plant species.

The agreement's coverage includes protection and cooperation with regard to patent, trademark, copyright and plant variety rights. According to the agreement, Taiwan and China mutually recognise each other's priority right for patents, trademarks and plant varieties, and accept one another's plant variety right applications. That is, both sides will protect the priority rights of applicants from each terrirory based on the first filing application date of patents, trademarks and plant variety rights. Therefore, rights holders will no longer need to worry that a third party might take the advantage of the time gaps between applications. In addition, applications for plant variety rights from either side will be accepted by both Taiwan and China. As such, the agreement will go further in safeguarding R&D achievements.

With regard to the development of the cultural innovation industry, in this agreement China has agreed to provide copyright authentication services directly in Taiwan, in order to shorten the time it takes for the product to reach the Chinese market. It is believed that this agreement will help to solve cross-strait IP rights disputes and thus push forward cooperation, especially with regard to cultural products.

Conclusions

Taiwan has concentrated on its high-tech industries, focusing on the development and production of electronic, information technology and semiconductor products in the past 20 years, and has achieved remarkable success. Through the proposed amendment to the Patent Act, the new IP Court and the new FDA, Taiwan has shown its willingness and capability to cooperate and integrate itself into the worldwide system of IP economics and rights protection. Taiwan is regarded as a natural gateway for collaboration with China based on its geographic position and the common Chinese culture, so it is beneficial for foreign businesses looking to enter the Chinese market to set up their R&D, production and operation in Taiwan.

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