



The Hong Kong Association of the Pharmaceutical Industry

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Position Paper of The Hong Kong Association of The Pharmaceutical Industry on the Review of the Patent System in Hong Kong

INTRODUCTION

The Hong Kong Association of the Pharmaceutical Industry ("HKAPI") welcomes the opportunity to submit its comments to the Consultation Paper on the Review of the Patent System in Hong Kong published on 4 October 2011 by the Commerce and Economic Development Bureau and the Intellectual Property Department.

The HKAPI submission paper discusses:

- 1.) Implementing patent term extension for pharmaceuticals;
- 2.) Updating the Patents Ordinance along the lines of Section 4A of the UK Patents Act 1977 to accommodate second-medical use claims in Hong Kong;
- 3.) Setting up a patent linkage framework;
- 4.) A proposed Original Grant Patent system;
- 5.) A proposed regulatory regime for patent agents;
- 6.) Other general comments regarding the patent system.

BACKGROUND ON THE HONG KONG ASSOCIATION OF THE PHARMACUETICAL INDUSTRY

The HKAPI was formed in 1968 with the mission of ensuring that the people of Hong Kong would have access to innovative and effective drugs that would improve their health and quality of life. To do so, the HKAPI collaborates closely with all the key stakeholders in the healthcare sector including service providers, government bodies, patient groups and medical professionals to provide drug awareness education to the general public, and where appropriate, to support policies that would ultimately be beneficial to the people of Hong Kong, the healthcare sector and the local economy.

The HKAPI currently has 38 full members, all of which are global research and development oriented pharmaceutical companies, including the world's top-20. Our member companies supply over 70% of the prescription medicines in Hong Kong.

THE IMPORTANCE OF STRONG, COMPREHENSIVE INTELLECTUAL PROPERTY RIGHTS

Strong patent protection is needed to provide incentives to attract and retain investment in clinical trials and other research and development ("R&D") by local and multinational pharmaceutical companies ("PCs") in the dynamic knowledge economy. A study by Duke University in the United States has found that all countries that have developed innovative pharmaceutical sectors have strong protection for existing and new chemical entities ("NCEs") in terms of the scope and

length of patent coverage.¹ There is a strong positive relationship between the rigor of a country's intellectual property protection, and R&D investment spending.²

Hong Kong's patent rights, although comprehensive in comparison to most countries, actually lag behind many of the world's developed economies, specifically with regards to patent term extensions for pharmaceuticals. The United States and the European Union (E.U.) respectively implemented independent patent extension regimes for pharmaceuticals in 1984 and 1992. Regionally, South Korea, Taiwan, Singapore and Japan grant eligible pharmaceuticals periods of additional marketing exclusivity after expiry of the original patent.

Although the terms of these extensions vary from country to country, the shared intention behind these national schemes is to compensate for:

- 1.) patent erosion – i.e. the period of effective protection lost due to activities required to successfully seek product marketing approval; and
- 2.) the rising costs of bringing a new drug to market as pre-approval testing becomes increasingly more complicated and lengthy.

It is estimated that a drug entitled to 20 years of patent protection will in fact enjoy an effective patent life of only around 8-10 years, meaning half or more of a drug's patent protection has been subsumed by the regulatory approval process.

Increasingly complex NCEs that form the basis of innovative new drugs and treatments have significantly increased the time and cost of discovery and synthesis, placing a heavy burden on PCs. The vast majority of NCEs do not make it past the testing process; a variety of factors, including toxicity, carcinogenicity, manufacturing problems, inefficacy and economic concerns can conspire to block a drug candidate from reaching the market.

In the United States, generally less than one percent of NCEs studied in the pre-clinical stages make it to human testing; of these, only 22 percent continue onwards to gain FDA approval.³

Out-of-pocket costs for shepherding a new drug candidate from conception to marketing approval are over USD\$400 million, and where R&D costs are capitalized to the date of market launch at an 11 percent discount rate, the adjusted figure comes to USD\$802 million.⁴ The cost of R&D in the pharmaceutical industry has escalated at an annual rate of 7.4% over general inflation relative to 1980's drug launches⁵ and it is no surprise that it takes many years for PCs to recoup their investments.

Because of the rising expense of developing and bringing NCEs to market, PCs increasingly rely on the revenue generated by the infrequent blockbuster drug to cover the cost of R&D and the costs of past failed drug candidates. In large markets such as the United States and Europe, the understanding that: 1.) sales are highly skewed towards a limited number of blockbuster drugs and 2.) the attraction of additional revenues from an extended marketing exclusivity period

¹ Pg. 854, "Patents, Innovation and Access to New Pharmaceuticals", Henry Grabowski. *Journal of International Economic Law*. <http://fds.duke.edu/db/attachment/169>

² Pg. 855. Ibid.

³ Pg. 851. Ibid.

⁴ Pg. 852. Ibid.

⁵ Ibid.

derived from patent extensions, have acted as sufficient incentive for PCs to develop new drugs and treatments that would not otherwise have been investigated.

PATENT EXTENSIONS: SUPPLEMENTARY PROTECTION CERTIFICATES

Supplementary protection certificates ("**SPCs**") are the patent extension scheme covering medicinal products originally implemented by the E.U two decades ago. The HKAPI believes that Hong Kong should adopt the E.U. framework, or a similar one, in order to harmonize its patent protection scheme with, or improve over, those belonging to its trading partners and many competitors.

SPCs form part of the E.U.'s statutory regime and provide an additional period of marketing exclusivity for a novel pharmaceutical in respect of which a marketing authorization has been granted, with all the entitlements and limitations of the original (basic) patent. The SPC takes effect at the expiry of the basic patent for a period equal to the time which elapsed between the date on which the application for the basic patent was filed, and the date of the first authorization to put the product on the market, reduced by five years. The marketing exclusivity provided by the SPC may not exceed five years, though products eligible under a pediatric extension may be allowed an additional six months. The regulations administering SPCs are precisely defined and are non-discretionary. Each pharmaceutical is eligible for one SPC only, and applicants do not need to justify their application.

SPCs provide for a nuanced, sensitive approach to patent extension. Because of the way the time extension is calculated, every year over 10 years' development effectively means that enhanced effective patent life is decreased; this provides an incentive for PCs to expedite their R&D and to keep the process to 10 years.

NURTURING HONG KONG'S PHARMACEUTICAL INDUSTRY

Due to limitations in the size of its physical and human capital, Hong Kong cannot expect to have a domestic pharmaceutical industry matching the scale of a large market such as the United States, Japan or Europe (although Switzerland with a similar sized population has a well developed pharmaceutical industry). It is, however, appropriate to ask whether patent term extensions would:

- 1.) Encourage PCs to augment, or maintain their investments in Hong Kong;
- 2.) Contribute to the growth of a domestic pharmaceutical sector.

In regard to the first point, increasing patent terms in Hong Kong can affect where these companies spend their money. PCs have stated that a country's patent terms are taken into account when deciding where to invest. There is a strong and realistic risk that PCs may decide to focus their investments to countries that offer the additional bonus of greater return to R&D investment from increased patent terms. This could consequently harm the development of a local pharmaceutical industry, and also deprive Hong Kong of clinical trial opportunities (discussed below).

Concerning the second point, Hong Kong is home to some of the world's foremost research universities, including the University of Hong Kong, Chinese University of Hong Kong and Hong Kong University of Science and Technology, all of which rank highly in international academic standings. Moreover, the quality of research from Hong Kong universities has since the late-1990's been on competitive footing with many Northern European countries.⁶ Hong Kong also rates as one of the best and easiest places to do business in the world, with a highly educated and capable research and managerial workforce. In addition, its close cultural, political and commercial ties to China make it an ideal entre into the burgeoning mainland market, making Hong Kong an even more attractive location for PCs.

HONG KONG AS A PREFERRED DESTINATION FOR CLINICAL TRIALS THREATENED

Since the late-1990's, Hong Kong has rapidly filled a niche as a preferred site in Asia for clinical trials by leading PCs. The reasons that Hong Kong has become a site of choice for clinical trials are:

- 1.) Highly-educated and capable research, medical and investigative personnel experienced in conducting Phase I to IV clinical trials across a wide spectrum of therapeutic areas;
- 2.) The ease of recruiting appropriate numbers of suitable clinical research subjects. Ninety percent of medical services are provided through the 42 public hospitals, 47 specialist clinics and 13 general outpatient clinics operating under the Hospital Authority;
- 3.) An international and regional hub located a 5-hour flight from most Asian countries and linked to approximately 130 destinations around the world by more than 3,600 flights a week, coupled with a world-class communications network;
- 4.) A stable political environment with a well-administered and transparent legal system;
- 5.) Modern research and medical facilities that can support multinational trials, including those accredited by the U.S. Food and Drug Administration ("**FDA**") and the Chinese State Food and Drug Administration ("**SFDA**");
- 6.) The use of English as the lingua franca of medical research and testing, as well as business;
- 7.) Lower costs relative to North America and Europe; and
- 8.) Intellectual property rights broadly on par with international standards.

The combination of these factors has made Hong Kong an ideal place in Asia for PCs to situate their clinical trials over the past decade: in 1999 there were only two clinical trials⁷; by 2010 that number had jumped to 206.⁸ In recognition of the city's first-class universities, research institutions, hospitals and their respective experience relating to clinical trials, the science journal *Nature* declared in 2006 that in the life sciences "Hong Kong provides a strong clinical research infrastructure" that could be used to effectively leverage Hong Kong's bicultural and commercial links between China and the rest of the world.⁹ In the medium-term, Hong Kong can market itself

⁶ Pg. 8. "Biotechnology in Hong Kong: Prospects and Challenges". Joseph Wong. *University of Toronto, Department of Political Science*. http://www.savantas.org/cmsimg/files/Research/HKIP/Report/9_JWong.pdf

⁷ Pg. 7. "Clinical Trials Centre – 2002 Annual Report". University of Hong Kong. http://www.hkuctc.com/documents/CTC_Annual_Report_2002.pdf

⁸ Pg. 7. "Clinical Trials Centre – 2010 Annual Report". University of Hong Kong. http://www.hkuctc.com/documents/CTC_Annual_Report_2010.pdf

⁹ Pg. 15. "Biotechnology in Hong Kong: Prospects and Challenges". Joseph Wong. *University of Toronto, Department of Political Science*. http://www.savantas.org/cmsimg/files/Research/HKIP/Report/9_JWong.pdf

as a chief clinical trial site for foreign PCs and Chinese firms, and as a regional hub for cross-collaboration and the transfer of research and know-how.

Furthermore, as Hong Kong's stature in the field of clinical research and data collection grows, the city may begin to realize more opportunities to capture the more lucrative Phase I and II trials. The majority of clinical trials in Hong Kong are Phase III trials, which are the least value-added.¹⁰ So far there has been little effort to bid for Phase I or II trials, but these would require more expertise in clinical research. A patent extension framework for pharmaceuticals could make Hong Kong more attractive to domestic and multinational PCs as an investment destination for clinical trials. At the same time, more experience conducting clinical trials would be a boon to the local healthcare research environment, and help build the requisite expertise and skill required to conduct the more lucrative and value-added Phase I and II trials.

Hong Kong captured a potentially lucrative distinction in the mid-2000's when the Mainland's SFDA and Hong Kong concluded an agreement that research derived from clinical trials at Hong Kong's university-hospitals would be recognized by the relevant Chinese regulatory bodies. This understanding between Hong Kong and the SFDA meant that Hong Kong is the only place in the world outside the Mainland whose clinical data would be accepted by the SFDA.¹¹ Hong Kong is therefore potentially able to position itself as the principal clinical testing site of choice for foreign PCs targeting entry into the expanding Chinese market, yet seeking the world-class clinical research and data collection methods honed over the past decade by Hong Kong institutions.

Despite this, Hong Kong is at risk of losing its status as a preferred clinical research site in Asia to its many regional competitors, including Beijing, Shanghai, Seoul and Taipei, all of whom have been aggressively upgrading their workforces, institutions and infrastructure to position themselves as viable alternatives to this city. By not implementing patent extensions, Hong Kong risks being perceived as out of sync with the economic realities of pharmaceutical development, and accordingly, diminishing Hong Kong's standing amongst local firms and multinational PCs engaged in clinical trials. It is thus imperative that the Hong Kong government implement patent extensions to maintain, and grow, Hong Kong's competitive edge in clinical trials and other research and development in the world's increasing fluid knowledge economy.

SECOND MEDICAL USES AND THE NEED TO UPDATE THE PATENTS ORDINANCE

In light of recent amendments to the European Patent Convention ("EPC") and the recent decision of the European Patent Office ("EPO") Enlarged Board of Appeal in *Kos Life Sciences (G02/08) ("Kos")* the EPO and United Kingdom Intellectual Property Office ("UKIPO") will no longer grant Swiss-type claims for patents covering second medical uses. Instead, patents will in the future be granted with more straightforward wording, namely for a pharmaceutical product with a specified (second or further) medical use.

Many patentees with UK or European (UK) patents for inventions relating to second medical uses will want to register these patents in Hong Kong.

This will be a problem in Hong Kong because the Hong Kong Patents Ordinance (Cap. 514) still contains provisions similar to the pre-amended EPC. Unless Hong Kong changes its law, patents

¹⁰ Pg. 16. Ibid.

¹¹ Ibid.

with claims drafted in this new form that are re-registered in Hong Kong are likely to be invalid for lack of novelty. In particular, section 94, which contains the novelty requirement, will require amendment along the lines of section 4A of the UK Patents Act 1977.

Hong Kong registers UK, European (UK) and Chinese State Intellectual Property Office ("**SIPO**") patents. Although in the future, patents in the UK and Europe will no longer contain Swiss-type claims, SIPO currently grants patents with Swiss-type claims for second medical uses (both for the treatment of a new disease or medical condition and for new dosage regimes). Amending the Hong Kong Patents Ordinance along the lines of section 4A of the UK Patents Act should not affect the ability to re-register Chinese patents with Swiss-type claims.

PATENT LINKAGE

Patent linkage refers to bringing about consistency between a state's drug regulator and its Patent Office to prevent generic drugs obtaining marketing authorization until after the expiration of patents protecting the original drug product or its patented use. Hong Kong does not currently have such a system in place meaning that infringing products can obtain government product marketing licences, though the United States, China, Japan, Canada and Singapore all have such systems.

In the United States, patent linkage is provided under the 1984 Hatch-Waxman Act. The FDA maintains in the Orange Book a list of drug products and uses currently protected by patents. Generic copies of existing medicinal substances currently under patent will not receive marketing approval from the FDA. In addition, producers of generics must certify that:

- 1.) the substance on which their imitative product is based has not already been patented;
- 2.) that the patent has expired;
- 3.) give the date on which the patent will expire and promise not to market the generic copy until that date;
- 4.) that the patent is either not infringed or invalid.

Patent linkage helps prevent unnecessary litigation, provides ready access to information about the scope and expiry of patents, and increases efficiency in the pharmaceutical industry by increasing predictability and transparency. The HKAPI believes that patent linkage would be beneficial to Hong Kong for these reasons and that such a system should be established in the near future.

STANDARD PATENTS AND AN ORIGINAL GRANT PATENT SYSTEM

With regards to the proposed implementation of an original grant patent ("**OGP**") system, the HKAPI is concerned that such a system will unnecessarily raise patenting costs, especially considering that it is unlikely that there will be significant demand for OGP patenting and because the current "re-registration" system more than adequately meet the needs of the pharmaceutical industry and other sectors in Hong Kong. Because the size of the local market is small, there is doubt about whether the OGP system will ever attract a sufficient critical mass of users who apply only for a domestic Hong Kong original patent, so as to adequately cover the scheme's operational costs without having to raise fees, or require subsidizing from the users of the re-registration system.

The current re-registration system is inexpensive (HK\$896) and quick (six months to register a standard patent in Hong Kong), and convenient for users. The HKAPI recommends that the proposed OGP system not be implemented, and that the present re-registration framework be kept intact. In the alternative, the OGP could be operated in parallel with the re-registration system, though the caveats discussed above should be kept in mind. The main point the HKAPI wants to emphasize is that the re-registration system should not be abolished, but instead maintained in its current form as it has, over the years, proved very capable of satisfactorily meeting the many needs and demands of HKAPI members in Hong Kong.

REGULATION OF PATENT AGENCY SERVICES IN HONG KONG

It would be beneficial to have a body of well trained local patent agents accredited and regulated by a government body to ensure the delivery of consistent and quality patent related services. Any government-run scheme should ensure that properly educated and accredited staff, equipped with the necessary technical training, are employed to uphold the general public and industry's confidence in the system. Such a system would also provide a further career path for graduates in science and technology from Hong Kong's universities and colleges.

OTHER ISSUES

There are other important improvements that need to be made to the Hong Kong patent system:

- 1.) Court rules regarding the procedure for enforcing patents (Rules of the High Court O.103) are in need of updating. RHC O.103 does not properly reflect the changes made to patent law with the 1997 enactment of the Patents Ordinance and the Rules need to be updated to reflect the present Patents Ordinance and global trends in patent litigation.
- 2.) There should be a less expensive procedure for litigating straightforward patent disputes. In a number of jurisdictions (particularly the UK) great efforts have been made to streamline patent litigation, to make cases faster and less expensive for litigants.
- 3.) Unlike other jurisdictions, there is no specialist court or division of a court dealing with patent and other intellectual property litigation in Hong Kong. Rather, patent infringement proceedings and intellectual property-related disputes are assigned to a general list in the Court of First Instance. Sometimes, the case may be allocated to a judge with more experience dealing with intellectual property matters. Costs in the Court of First Instance can run high, and there is need for a group of judges with greater experience dealing with intellectual property cases.