THE AMERICAN CHAMBER OF COMMERCE IN HONG KONG

Submission on the Consultation Paper on the Review of the Patent System in Hong Kong

Executive Summary

The American Chamber of Commerce in Hong Kong is grateful for the opportunity to provide the comments of its members on the Consultation Paper on the Review of the Patent System in Hong Kong. We concur with the Government's position that an effective patent system helps nurture innovation in Hong Kong's industries and is one of the most effective ways to encourage advances in the scientific and technical fields.

Our responses to the Consultation Paper are as follows:

Standard patent system (Chapter 1): We doubt whether there is likely to be adequate demand for using an Original Grant Patent ("OGP") system in Hong Kong, especially considering the cost of establishing and operating such a system.

Even if an OGP system is introduced, it should only be operated in parallel with the current re-registration system because the current scheme already provides an inexpensive and effective method for patentees to obtain patent protection. An OGP system, if introduced, should not be at the short- or long-term expense of re-registration system users; neither should the cost of an OGP system be subsidised by the users of the re-registration system.

The current re-registration framework, however, could be improved. We suggest adding to the list of current designated patent offices those of the United States, Japan, Canada and/or Australia.

Short-term patent system (Chapter 2): The short-term patent system provides a relatively fast and useful method for protecting inventions with a relatively short commercial life. Although, there are risks in the short-term patent system where rights are granted without substantive examination – i.e. some invalid applications will be granted, potentially leading to abuse of the system, other measures in addition to the current injunctions and damages for groundless threats can be introduced to allow invalid short-term patents to be cancelled with more ease. We believe these changes would improve and encourage increased use of the system: (1) the term of protection should be extended to 10 years; and (2) the number of claims should be unlimited. We would also urge restraint in making any changes to the threshold for patentability for short-term patents.

Regulation of patent agency services in Hong Kong (Chapter 3): We believe that the Hong Kong government should encourage the development, and provide regulatory oversight of, a high-quality local patent agency profession. Having professionals knowledgeable and experienced in intellectual property matters will help Hong Kong become a hub for commercializing, financing and trading intellectual property.

Other suggestions:

- providing the opportunity to recover patent term for pharmaceutical products lost during extensive clinical trials and other regulatory approval procedures that are required before they receive pharmaceutical product licences and can be marketed;
- amending the Patents Ordinance (Cap. 514) to enable European and UK patents for second medical uses to continue to be validly registered in Hong Kong;
- expanding the defenses to groundless threats, to make it easier to send cease and desist letters to infringers;
- reviewing and updating the procedural rules for enforcing patents in courts and setting up an IP List;
- introducing procedural rules for amending patents;
- expanding the provisions in the Patents Ordinance dealing with biotechnological inventions; and
- introducing patent linkage to ensure that pharmaceutical product licences are not granted to products which infringe patents.

AmCham supports the Government's commitment to bettering Hong Kong's patent legislation and welcomes further discussions with the Government to formulate legislation and policies to make Hong Kong a world-class research, development and intellectual property trading centre.

Intellectual Property Committee
Pharmaceutical Committee

13 January 2012

Responses from AmCham to the Consultation Paper on the Review of the Patent System in Hong Kong – 31 December 2011

AmCham welcomes the opportunity to provide the comments of its members to the recently published Consultation Paper on the Review of the Patent System in Hong Kong. We wholeheartedly agree with the Government's statements that the effective protection of the fruits of creative ideas helps nurture innovation and that the patent system is one of the important tools in encouraging developments in different scientific and technical fields. However, establishing an OGP system in Hong Kong is not the answer to nurturing creativity or encouraging innovation and technological development.

Our comments below deal with the important issues discussed in the Consultation Paper. Some of the key principles upon which we base our comments are:

- Ensuring any changes to the current system for obtaining patents will be introduced only if they will be cost effective, sufficiently used by businesses seeking patents in Hong Kong and of direct benefit to innovator companies that use the system;
- Keeping the level of protection afforded to holders of Hong Kong patents in line with international standards of patent protection in developed markets;
- Taking into account the needs and special interests of SMEs, by improving the system for enforcing and defending patents, particularly in terms of simplifying procedures, improving speed and lowering costs;
- Improving the current system and where necessary, amending the Patents Ordinance to overcome areas of legal uncertainty or where changes have become necessary;
- Supporting Hong Kong to become an international centre for trading and monetizing intellectual property and encouraging the development of a patent agency profession.

With these principles in mind, we have also accepted the Government's request that we include other suggestions for improving the patent system. Our responses are as follows:

Standard patent system (Chapter 1)

(a) What benefits will an Original Grant Patent ("OGP") system bring to Hong Kong? Will an OGP system promote local innovation and enhance patent quality?

(b) Will there be sufficient demand to support an OGP system in Hong Kong? Will it be a cost-effective system?

(c) Should we introduce an OGP system in Hong Kong with substantive examination outsourced to other patent office(s) and, if so, which ones and why?

(d) Irrespective of the answers to (c) above, should the current "re-registration" system be maintained, and, if so, should the system be modified as appropriate, including expansion to recognize the patents granted by other jurisdiction(s), and, if so, which ones?

Responses

The main issue is whether or not there is likely to be a sufficient demand for using an OGP system in Hong Kong, bearing in mind the cost involved in setting up and operating such a system. At present, we do not believe that a strong enough case has been advanced for introducing an OGP system in Hong Kong.

The current re-registration system provides a cost-effective and efficient method for companies to obtain patents where they have already filed patent applications at one of the designated patent offices outside Hong Kong. If an OGP system were to be introduced, this should only be done in parallel with the current re-registration system. It should not be to the short- or long-term detriment of users of the re-registration system and neither should the cost of an OGP system be subsidised by the users of the re-registration system.

The current re-registration system, however, could be improved. We suggest adding to the list of designated patent offices, provided the law on patentability in those countries is sufficiently similar to Hong Kong law and the examination of patent applications by those patent offices is robust.

We suggest the Government should consider adding the United States Patent and Trademark Office as a designated office under the patent re-registration system. The reason is that this office is where most patent applications are filed, and the United States is well recognised as the country with the largest amount of R&D expenditure on the invention of new and technically advanced products. Other offices which might also be considered include the Japan Patent Office, the Canadian Intellectual Property Office and the Australian patent office (IP Australia).

Short-term patent system (Chapter 2)

(e) What benefits does the short-term patent system bring to Hong Kong? Does it promote local innovation?

(f) Should we retain the current short-term patent system in its existing form, or should we introduce changes to the system? If the latter, what sort of changes should be introduced?

(1) Should we introduce substantive examination? If so, when should it be carried out? Should it be a mandatory requirement or optional? Should it be a condition for commencement of infringement proceedings? Should the question of whether a substantive examination be carried out be left to the choice of the patent owner or a third-party, and who should bear the costs?

(2) Should we extend the current term of protection? If so, how long should the term of protection be?

(3) Should we relax the present restriction on the number of claims that may be included in each patent application? If so, how many claims should be allowed in each patent application or should there be no restriction at all?

(4) Should we lower the threshold for patentability for short-term patents? If so, what alternative threshold should be applied?

(5) What other changes are required?

(g) Should we discontinue the short-term patent system altogether?

Response

The short-term patent system provides a relatively fast and useful method for protecting inventions with a relatively short commercial life. This is important to SMEs in Hong Kong. There are, however, inherent risks in a system where patent rights are granted without substantive examination in that some invalid patents will be granted, which can lead to abuse. As it is

currently only the court that deals with validity issues affecting Hong Kong patents, we suggest the government, when reviewing litigation procedure (which we discuss in more detail below), considers introducing a simplified court procedure for defendants and third parties to challenge the validity of short-term patents.

We also believe the following changes would improve and encourage greater use of the system and bring it closer into line with utility models/"lesser patents" available in other countries:

- The term of protection should be extended to 10 years;
- The number of independent claims should be unlimited.

We would urge caution in making any changes to the threshold for patentability for short-term patents.

Regulation of patent agency services in Hong Kong (Chapter 3)

(h) Should Hong Kong have a regulatory regime for professionals providing patent agency services? Should the promulgation of a regulatory regime or otherwise be made dependant on whether an OGP system is to be implemented in Hong Kong?

(i) If a regulatory regime is to be introduced for providers of patent agency services:

(1) should we restrict the provision of such services to persons meeting certain qualifications or requirements only? Or should we limit the use of particular titles only but allow the provision of such services by any person?

(2) should the regulation apply to all types of patent agency services or only to certain services e.g. the drafting and amendment of patent specifications under an OGP system?

Response

We believe that the Hong Kong government should encourage the development of a high-quality local patent agency profession. Having professionals knowledgeable and experienced in dealing with intellectual property will help Hong Kong become a centre for commercializing, financing and trading intellectual property. In particular, in order to properly assess the value of patent rights, it is important that professionals with an understanding of patent law and technology are available to carry out due diligence on the scope of patent claims (to determine the breadth of the monopoly afforded by a patent) and the validity of patents. A patent profession will also provide another career path for Hong Kong graduates in science and engineering.

As is the case with solicitors and barristers, persons entering the patent agent profession should undergo proper training, examination and accreditation to ensure high-quality service. The patent agency profession should be properly regulated by a statutory body to maintain high standards and protect users across the full range of patent agency services. The government of Hong Kong should consider its role in not only setting standards for and regulating the profession, but in developing the institutions for training patent agent professionals and establishing accreditation that adheres to international standards.

Other suggestions

(j) How else should we position our system for the purposes of encouraging local innovation and attracting investors to use Hong Kong as a launching pad for their research and development operations?

Response

There are a number of other important areas which should be included in any review of the patent system in Hong Kong and in order to develop Hong Kong into a research and development hub or an intellectual property trading centre. These are discussed in more detail below and include the following:

- **Patent term recovery (Supplementary Protection Certificates).** To provide the opportunity to recover patent term for pharmaceutical products lost during the time taken to complete extensive clinical trials and other regulatory approval procedures before they receive pharmaceutical product licenses and can be marketed. This is discussed in more detail in Appendix A below;

- **Second medical use patents**. Amendments are needed to the Patents Ordinance (Cap. 514) to enable European and UK patents for second medical use inventions to continue to be validly registered in Hong Kong. This is discussed in more detail in **Appendix B** below;

- **"Groundless threats" and sending cease and desist letters**. Section 89 of the Patents Ordinance provides various remedies to persons aggrieved by an unjustified threat of patent litigation, subject to certain limited defenses. This section creates a significant risk to patent owners who send cease and desist letters to infringers prior to the commencement of litigation and in practice, patent owners are usually advised to start patent infringement proceedings before communicating with the infringer. This significantly adds to costs in matters where an infringer would have been willing to undertake to cease infringing the patent without the patentee having to start litigation.

  We suggest that the defenses to groundless threats be widened to allow parties to attempt to settle disputes before litigation is commenced without the risk of a groundless threats claim, particularly where the infringer is the manufacturer or importer of an infringing product. We suggest considering introducing the wider defenses available in the groundless threats provisions relating to trade marks, as well as the recently amended section 70 of the United Kingdom Patents Act 1977.

- **Procedural rules for litigating patents.** The current procedural rules for patent litigation in the Rules of the High Court ("RHC"), Order 103 relate to the pre-1997 Registration of Patents Ordinance (Cap 42). The ability to enforce a patent, at a reasonable cost and within a suitably short time-frame is as important as obtaining a patent. Patent litigation can be very expensive and in some cases, a simpler and quicker procedure would be more appropriate for all the parties. We suggest that Hong Kong examine the current procedures used in the English Patents Court and the English Patents County Court, which have been significantly reformed and improved over the last ten years to make patent litigation less costly and much quicker to resolve.

- **Introducing an IP List at the High Court**. We also suggest that serious consideration be given to appointing a panel or list of judges to deal with intellectual property cases, including patent cases (similar to the current position for company cases and construction cases). This would enable a number of judges to become more experienced in this specialist area of law and in dealing with cases concerning complex technology. Judges with specialist IP experience are becoming increasingly common in a number of Asian and European countries and are invariably preferred by litigants.

- **Patent amendment rules and procedure.** Apart from cases where a Hong Kong patent is based on a European patent which is amended during an EPO Opposition, all applications to amend Hong Kong patents must be made to the Court under section 46 of the Patents Ordinance, or under section 102 of the Patents Ordinance where infringement or revocation proceedings are pending. The procedure for amending patents is, however, not clearly set out and parties wishing to amend their patents are left unsure of what procedure to use. We would ask that appropriate and clear rules are provided for patent amendment applications.

- **Biotechnological inventions.** Inventions in the field of biotechnology have, in recent years become increasingly important in a number of industries, including pharmaceuticals and agriculture. There is, however, very little in the Patents Ordinance concerning the patentability of biotechnological inventions (products consisting of, or containing biological materials and processes by which biotechnological material is produced, processed or used). We suggest that consideration be given to introducing provisions which deal specifically with the patentability of biotechnological inventions.

- **Patent linkage.** Patent linkage provides measures in the pharmaceutical approval process to prevent a person from obtaining a product licence from the government to enter the market with a generic version of a patented medicine before a patent covering that product has expired. This is designed to avoid the obvious inconsistency of one section of government (the Patent Registry) granting a patent to an innovator (which enables him to prevent others from marketing the same product), while another section of government (the pharmaceuticals regulator) grants to an infringer a pharmaceutical product marketing licence.

  Notable countries which practice patent linkage include the United States, China, Japan, Korea, Australia, Canada and Singapore.

AmCham supports the Government's commitment in improving the patent legislation in Hong Kong and welcomes further discussions with the Government in formulating legislation and policies in making Hong Kong a world-class research, development and intellectual property trading centre.

Intellectual Property Committee
Pharmaceutical Committee

13 January 2012

Enclosures

Appendix A – Patent term extensions for pharmaceuticals (Supplementary Protection Certificates).

Appendix B – Further comments on second medical use patents.

Appendix A

Patent term restoration (supplementary protection certificates) for pharmaceuticals and plant protection (agrochemical) products

The current review of the patent system is an opportune time for Hong Kong to align itself with other advanced countries' patent practice by adopting a patent term restoration system for pharmaceutical and plant protection products.

The justification for patent term restoration

The justification for patent term restoration for pharmaceuticals is well established and relates to their unique nature as both commercial products which are the result of enormous research and development efforts and expenditure, and items vital to public healthcare and welfare.

The life of a patent (20 years) is calculated as the length of time between the filing of the application for the patent and when the patent expires. However, the substantial work and investment needed to establish the three criteria of safety, efficacy and quality which all new products seeking product licences must fulfill means that a considerable amount of this protection period is lost even before the product makes it to market. The length of the approval process shortens the "effective life" of the patent (the period of time that a product is covered by a patent while it is on the market) to an average of less than eight years[1]. Patent term restoration compensates developers of new and innovative drugs for the erosion of their patent rights due to the time taken to carry out the work, such as the various phases of clinical trials and the regulatory evaluation process needed to obtain marketing approval (both overseas and locally) to sell the drug – and thus providing an adequate incentive for further research and development of new and better drugs.

[1] Example illustration:

The patent term is only 20 years from filing. But, taking into account the need for various phases of clinical trials, it takes an average of 9-12 years to get U.S. or European marketing approval.

Hong Kong requires that a product has already obtained a Certificate of Pharmaceutical Product (CPP) from certain overseas regulators in order to register a drug in Hong Kong. To obtain an overseas CPP, a pharmaceutical company will already have waited the time spent by an overseas regulatory authority in evaluating the patent and granting approval. After the CPP is obtained, the Hong Kong regulatory authority will review the application itself before approving it, which will typically take another 12-18 months. In the circumstances, regulatory approval time (both overseas and Hong Kong, inclusive) will result in a very substantial reduction in effective protection period to the innovator.

List of countries with patent term extensions

Below is a list of the 59 countries/regions that have patent term restoration for pharmaceutical products:

Albania	**El Salvador**	**Korea**	**Romania**
Armenia	**Estonia**	**Kyrgyz Rep.**	**Russian Federation**
Australia	**Finland**	**Latvia**	**Singapore**
Austria	**France**	**Lithuania**	**Slovak Rep.**
Azerbaijan	**Germany**	**Luxembourg**	**Slovenia**
Belarus	**Greece**	**Macao**	**Spain**
Belgium	**Guatemala**	**Macedonia**	**Sweden**
Bosnia & Herzegovina	**Honduras**	**Malta**	**Switzerland**
Bulgaria	**Hungary**	**Moldova**	**Taiwan**
Chile	**Iceland**	**Morocco**	**Turkmenistan**
Costa Rica	**Ireland**	**Netherlands**	**Ukraine**
Cyprus	**Israel**	**Nicaragua**	**UK**
Czech Rep.	**Italy**	**Norway**	**USA**
Denmark	**Japan**	**Poland**	**Uzbekistan**
Dominican Republic	**Kazakhstan**	**Portugal**	

We strongly believe that the introduction of patent term restoration for pharmaceuticals will position Hong Kong amongst the advanced markets that afford fair protection to innovators' rights. In the long run, this will be beneficial to an industry that is at the forefront of encouraging innovation and to the patients in Hong Kong who benefit from access to newly developed and better drugs.

Appendix B

Second medical use patents

As a result of recent changes in European and UK patent law, we believe that an amendment needs to be made to the Hong Kong Patents Ordinance to allow European and UK patents covering second (and further) medical use inventions to continue to be re-registered as valid Hong Kong patents.

Background

Second (and further) medical use inventions concern the novel and inventive use of a known drug either (1) for the treatment of a different disease; (2) having a new time, frequency or dosage of administration; or (3) having a new method of drug administration. Under current Hong Kong law, second and further medical use inventions can be patented, but only by using "Swiss-type claims"[2]. In the past, patents for second (and further) medical use inventions granted by the European Patent Office ("EPO") and the UK Intellectual Property Office ("UKIPO") had Swiss-type claims.

Changes to the European Patent Convention

However, following changes made to the European Patent Convention ("EPC") by the EPC 2000 amendments and the subsequent decision of the EPO Enlarged Board of Appeal in the *Kos Life Sciences* case (G02/08), patents will no longer be granted by the EPO and the UKIPO with Swiss-type claims. Instead, such patents will have claims drafted in a simpler form (for example, "product X for use in the treatment of disease B"). However, under current Hong Kong law, such patents, if re-registered in Hong Kong, are very likely to result in the Hong Kong patent making invalid claims for lack of novelty.

Suggested amendments to the Patents Ordinance

To avoid this unintended consequence arising from the EPC 2000 amendments on future second medical use patents in Hong Kong, an amendment should be made to section 94 (4) of the Hong Kong Patents Ordinance as shown below in A. This amendment is similar to the amendment made by section 4A (4) of the United Kingdom Patents Act 1977.

This proposed amendment would not prohibit Hong Kong patents having Swiss-type claims, which will continue to be necessary in the future in the case of patents based on Chinese patents having Swiss-type claims.

[2] Swiss-type claims are usually in the form "the use of substance or composition X for the manufacture of a medicament for therapeutic application Y".

Suggested amendments to the Patents Ordinance dealing with second medical use patent claims

Novelty

Section 94

(1) An invention shall be considered to be new if it does not form part of the state of the art.

(2) The state of the art shall be held to comprise everything made available to the public (whether in Hong Kong or elsewhere) by means of a written or oral description, by use, or in any other way-

(a) before the deemed date of filing of an application for a standard patent for the invention or, if priority was claimed, before the date of priority; or

(b) before the date of filing of an application for a short-term patent for the invention or, if priority was claimed, before the date of priority, whichever is the earlier.

…

(4) Subsections (1) to (3) shall not exclude the patentability of any substance or composition, comprised in the state of the art-

(a) for use in a method referred to in section 93(4) where its use for any method referred to in that subsection is not comprised in the state of the art; or
(b) for a specific use in a method referred to in section 93(4) where that specific use is not comprised in the state of the art.